



National Accreditation Board for Testing and Calibration Laboratories (NABL)

SPECIFIC CRITERIA FOR PT PROVIDER ACCREDITATION

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AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment made	Reasons	Signature QA Team	Signature CEO
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7							
8							
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10							

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Scope	4
3.	References	4
4.	Specific Policy of NABL for PT Providers	5
5.	Requirements	6
5.1	Personnel	6
5.2	Typical format for Design Document	8
5.3	Homogeneity and Stability	10
5.4	Statistical Design	24
5.5	Assigned Value	26
5.6	Operation of Proficiency Testing Schemes	28
5.7	Reports	28
5.8	Sampling Program	29
5.9	Qualitative PT Schemes	29
5.10	Communication with Participants	37
5.11	Organization	37
5.12	Subcontracting Services	39
5.13	Complaints and Appeals	40
5.14	Records	40
5.15	Internal Audits	40
5.16	Management Reviews	42

1. INTRODUCTION

All PT Providers are required to comply with all the requirements listed in the International Standard ISO/IEC 17043: 2010 'Conformity assessment – General requirement for proficiency testing' for all types of proficiency testing schemes. ISO 13528 provides support for the implementation of ISO/IEC 17043 particularly, on the requirements for the statistical design, validation of proficiency test items, review of results, and reporting summary statistics.

Proficiency testing is the evaluation of participant's performance against pre-established criteria by means of interlaboratory comparisons. Proficiency testing schemes vary according to the needs of the sector in which they are used, the nature of the proficiency test items, the methods in use and the number of participants.

The term "proficiency testing" is taken in its widest sense and includes, but is not limited to:

- a) quantitative scheme — where the objective is to quantify one or more measurands of the proficiency test item;
- b) qualitative scheme — where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;
- d) simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- e) single occasion exercise — where proficiency test items are provided on a single occasion;
- f) continuous scheme — where proficiency test items are provided at regular intervals;
- g) sampling — where samples are taken for subsequent analysis; and
- h) data transformation and interpretation — where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Note:

- Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programmes, or both.
- Actually “quantitative” and “qualitative” are not schemes in pure terms this is only the way statistics of a scheme will be handled. All schemes i.e. sequential, simultaneous, single occasion, continuous, sampling, data transformation and interpretation can be quantitative or qualitative.

2. SCOPE

This document specifies additional requirements for provider of proficiency testing to comply along with ISO/IEC 17043: 2010.

3. REFERENCES

- 3.1** ISO/ IEC 17043: 2010, Conformity assessment – General requirements for proficiency testing,
- 3.2** ISO 13528: 2015 Statistical methods for use in proficiency testing by interlaboratory comparisons

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 181	Specific Criteria for Proficiency Testing Provider			
Issue No.: 03	Issue Date: 16-May-2020	Amend. No.: --	Amend. Date: --	Page No. 4 of 43

4. Specific Policy of NABL for PT Providers

4.1 The PT Provider shall have conducted at least one PT program in same / similar Matrix (PT item) in a group (e.g. building materials, metals and alloys, food and agricultural products etc.) with at least some of the critical parameters in accordance with ISO/IEC 17043:2010 for the applied scope of accreditation.

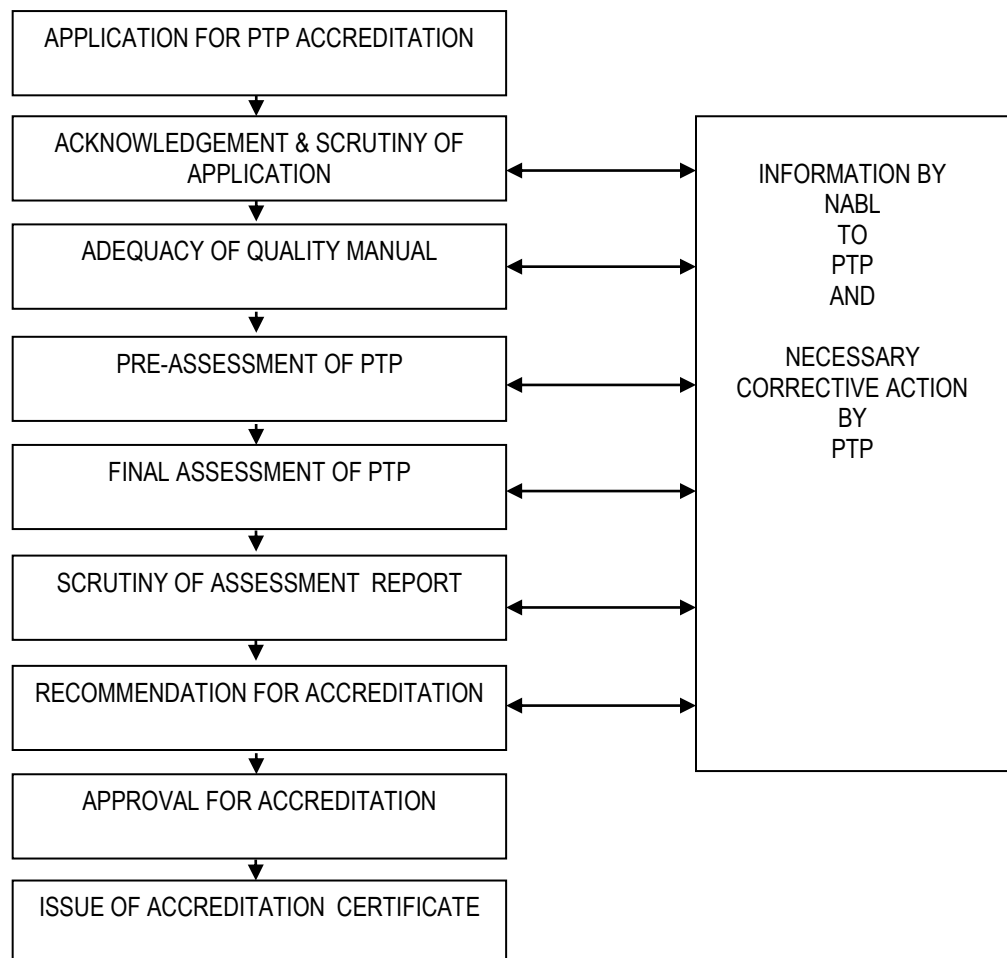
Note – For PT Program not conducted / not completed, at least PT design document (detailed document as how the program will be conducted) shall have been prepared for entire scope of accreditation.

4.2 The PT Provider shall have completed an Internal Audit and Management review before applying and it shall be conducted after completion of PT scheme.

4.3 In case of PT programs for calibration laboratory, the Reference standard used for assigning the value of artifact (PT item) shall be calibrated against a standard which is directly traceable to National Metrological Institute (NMI).

Note- NABL documents NABL 100, NABL 131, NABL 132, NABL 133, NABL 134 and NABL 216 are applicable for PT Providers also.

4.2 PTP Accreditation Process Flow Chart



5. Requirements

5.1 Personnel

- 5.1.1 PT Provider should have personnel who are fully conversant with the product behavior during storage, retention and transport. These personnel should have good knowledge of manufacturing or processing of the product.
- 5.1.2 PTP should have competent person to review, report and authorize the reports issued by PT provider under NABL accreditation.
- 5.1.3 For a person to be accepted for this purpose, personal evaluation shall be done during assessment. The Qualification and experience criteria of relevant field (testing / Calibration / Medical) shall apply. In case of medical field, persons are required to be postgraduate in relevant medical field or Ph.D. in relevant scientific fields with work experience of ten years in clinical laboratories out of which 5 years at supervisory level and above. The relevant academic qualifications, experience and demonstration of technical competence to the assessment team shall be the basis for acceptance of person to review, report and authorize the report.
- 5.1.4 In the event of non availability of personnel within the PT Provider organization, the PT Provider should have access to such expertise (Personnel with comprehensive knowledge of testing / measurement of the product for required parameters in the scope of accreditation) in the Advisory/ Steering Committee formed.
- 5.1.5 The interview of such personnel (telephonically or directly) during the assessment shall be arranged if required to ensure access of PT Provider to technical experts having knowledge of PT items.
- 5.1.6 Person having the responsibility of statistical analysis shall be familiar with specific methods used in the evaluation of PT results such as z-score, En ratio or other methods used in the specific PT program and with use of software for the evaluation of PT results.
- 5.1.7 If technical experts / advisory or steering group are used then following information to be available:
- 5.1.7.1 CV of individuals,
- 5.1.7.2 Purpose for which the expert is to be used,
- 5.1.7.3 Contractual agreement and expert's concurrence to be part of PT Provider,
- 5.1.7.4 Confidentiality,
- 5.1.7.5 Minutes of advisory committee and/or records of communications through e-mail or letter

5.1.8 The proficiency testing provider shall authorize personnel for all the key activities and records shall be available with PTP. **Typical format for maintaining records for personnel is as follows:**

S. No.	Items / Particular	Name of the Person	Remarks/ Comments
1.	For Selection of appropriate proficiency test items		
2.	For Planning of proficiency testing schemes		
3.	To perform particular types of sampling		
4.	To operate specific equipment		
5.	To conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the proficiency test item		
6.	To prepare, handle and distribute proficiency test items		
7.	To operate the data processing system		
8.	For conducting statistical analysis		
9.	To evaluate the performance of proficiency testing participants		
10.	To give opinions and interpretations		
11.	To authorize the issue of proficiency testing reports		

5.2

Typical format for Design document:

Typical format for design document to include at least the following information:

S. No.	Title	Particulars	Comments / Remarks
1.	Unique identity of the PT Scheme		
2.	Type of Scheme		
3.	Objective, purpose and basic design of the PT scheme		
4.	The name of the Proficiency testing provider.		
5.	Address of the Proficiency testing provider		
6.	The name, address and affiliation of the coordinator and other personnel involved in the operation of the proficiency testing scheme.		
7.	The activities to be subcontracted and the names and addresses of subcontractors to be involved in the operation of the proficiency testing scheme.		
8.	Criteria to be met for participation.		
9.	The number and type of expected participants in the proficiency testing scheme		
10.	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 specific proficiency testing round		
11.	A description of the range of values or characteristics, or both, to be expected for the proficiency test items.		
12.	The potential major sources of errors involved in the area of proficiency testing offered		
13.	Requirements for the production, quality control, storage and distribution of proficiency test items.		
14.	Reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected		

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 181	Specific Criteria for Proficiency Testing Provider			
Issue No.: 03	Issue Date: 16-May-2020	Amend. No.: --	Amend. Date: --	Page No. 8 of 43

S. No.	Title	Particulars	Comments / Remarks
15.	A description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme.		
16.	For continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of the results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants.		
17.	Expected initial and target dates or deadlines of the scheme,		
18.	Any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements.		
19.	Procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability.		
20.	Preparation of any standardized reporting formats to be used by participants		
21.	A detailed description of the statistical analysis to be used		
22.	The origin, metrological traceability and measurement uncertainty of assigned values		
23.	Criteria for the evaluation of performance of participants		
24.	A description of the data, interim reports or information to be returned to participants		
25.	A description of the extent to which participants' results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public		
26.	Actions to be taken in the case of lost or damaged proficiency test items.		

Note-

- The participants should be suitably informed that the records of PT scheme participation shall be accessible to NABL, if so desired by it
- Laboratory (subcontractor/ in-house) involved in assessing homogeneity, stability and / or preparation of PT items in PT scheme shall not be participant in that particular PT scheme.

5.3 Homogeneity and Stability

Extract from ISO 13528: 2015 (E) Cl 6.1, 6.1.1, 6.1.2, Annex B, Annex E.2

- 5.3.1 The proficiency testing provider shall ensure that batches of proficiency test items are sufficiently homogeneous and stable for the purposes of the proficiency testing scheme. The provider shall assess homogeneity and stability using criteria that ensure that inhomogeneity and instability of proficiency test items do not adversely affect the evaluation of performance. The assessment of homogeneity and stability should use one or more of the following approaches:
- 5.3.1.1 experimental studies as described in Section III. D or alternative experimental methods that provide equivalent or greater assurance of homogeneity and stability;
- 5.3.1.2 experience with the behaviour of closely similar proficiency test items in previous rounds of the proficiency testing scheme, verified as necessary for the current round;
- 5.3.1.3 assessment of participant data in the current round of the proficiency testing scheme for evidence of consistency with previous rounds, for evidence of change with reporting time or production order, or any unexpected dispersion attributable to inhomogeneity or instability.

Note 1- These approaches can be adopted on a case-by-case basis, using appropriate statistical techniques and technical justification. The approach will often change during the lifetime of a proficiency testing scheme, for example as accumulated experience reduces the initial requirement for experimental study.

Note 2- Relying on experience (as in above) is only reasonable so long as:

- The process for producing batches of the proficiency test item(s) does not change in any way that may impact homogeneity;
- The materials used in production of the proficiency test item(s) do not change in any way that may impact homogeneity;
- There is not a “failure” in homogeneity identified via either homogeneity testing or participant responses; and,
- The homogeneity requirements for the material are reviewed regularly, taking account of the intended use of the material at the time of the review, to ensure that the homogeneity achieved by the production process remains fit for purpose.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 181	Specific Criteria for Proficiency Testing Provider			
Issue No.: 03	Issue Date: 16-May-2020	Amend. No.: --	Amend. Date: --	Page No. 10 of 43

EXAMPLE- If previous rounds of a proficiency testing scheme used proficiency test items that were tested and demonstrated to be sufficiently homogeneous and stable, and with the same participants as in previous rounds, then if an interlaboratory standard deviation in the current round is not greater than the standard deviation in previous rounds, there is evidence of sufficient homogeneity and stability in the current round.

5.3.2 For calibration proficiency testing schemes where the same artefact is used by multiple participants, the proficiency testing provider shall assure stability throughout the round, or have procedures to identify and account for instability through the progression of a round of the proficiency testing scheme. This should include consideration of tendencies for particular proficiency test items and measurands, such as drift. Where appropriate, the assurance of stability should consider the effects of multiple shipments of the same artefact.

5.3.3 All measurands (or properties) should normally be checked for homogeneity and stability. However, where the behaviour of a subset of properties can be shown to provide a good indication of stability and/or homogeneity for all properties reported on in a round, the assessment described in section III A may be limited to that subset of properties. The measurands that are checked should be sensitive to sources of inhomogeneity or instability in the processing of the proficiency test item. Some important cases are:

5.3.3.1 When the measurement is a proportion, a characteristic that is a small proportion can be more difficult to homogenize and so be more sensitive in a homogeneity check;

5.3.3.2 If a proficiency test item is heated during processing, then choose a measurand that is sensitive to uneven heating;

5.3.3.3 If a measured property can be affected by settling, precipitation, or other time-dependent effects during the preparation of proficiency test items, then this property should be checked across filling order.

EXAMPLE- In a proficiency testing scheme for the toxic metal content of soils, measured metal content is primarily affected by moisture content. A check for consistent moisture content may then be considered sufficient to ensure adequate stability of toxic metals.

Note- An example of homogeneity and stability checks is provided in Section III E, using statistical methods recommended in Section III. D.

A. Statistical Method recommended for Homogeneity and Stability Check

D.1 General Procedure for a homogeneity check

D.1.1 To conduct an assessment for homogeneity for a bulk preparation of proficiency test items, follow the procedure given below:

Choose a property (or properties) or measurand(s) to assess with the homogeneity check.

Choose a laboratory to carry out the homogeneity check and a measurement method to use. The method should have a sufficiently small repeatability standard deviation (s_r) so that any significant inhomogeneity can be detected. The ratio of the repeatability standard deviation for the method to the standard deviation for proficiency assessment should be less than 0,5, as recommended in the IUPAC Harmonized Protocol (or $1/6$ of δ_E). It is recognized that this is not always possible, so in that case the proficiency testing provider should use more replicates.

Prepare and package the proficiency test items for a round of the proficiency testing scheme, ensuring that there are sufficient proficiency test items for the participants in the proficiency testing scheme and for the homogeneity check.

Select a number g of the proficiency test items in their final packaged form using a suitable random selection process, where $g \geq 10$. The number of proficiency test items included in the homogeneity check may be reduced if suitable data are available from previous homogeneity checks on similar proficiency test items prepared by the same procedures.

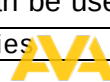
Prepare $m \geq 2$ test portions from each proficiency test item using techniques appropriate to the proficiency test item to minimize between-test-portion differences.

Taking the $g \times m$ test portions in a random order, obtain a measurement result on each, completing the whole series of measurements under repeatability conditions.

Calculate the general average $\bar{x}$, within-samples standard deviation s_w , and between-samples standard deviation s_s , as shown in D.3.

D.1.2 When it is not possible to conduct replicate measurements, for example with destructive tests, then the standard deviation of the results can be used as s_s . In this

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 181	Specific Criteria for Proficiency Testing Provider			
Issue No.: 03	Issue Date: 16-May-2020	Amend. No.: --	Amend. Date: --	Page No. 12 of 43



situation it is important to have a method with a sufficiently low repeatability standard deviation s_r .

D.2 Assessment criteria for a homogeneity check

D.2.1 The following three checks should be used to assure that the homogeneity test data are valid for analysis:

- a) Examine the results for each test portion in order of measurement to look for a trend (or drift) in analysis; if there is an apparent trend, take appropriate corrective action regarding the measurement method, or use caution in the interpretation of the results.
- b) Examine the results for proficiency test item averages by production order; if there is a serious trend that causes the proficiency test item to exceed the criterion at D.2.2 or otherwise prevents use of the proficiency test item, then (i) either assign individual values to each proficiency test item; or (ii) discard a subset of proficiency test items significantly affected and retest the remainder for sufficient homogeneity; or (iii) if the trend affects all proficiency test items, follow the provisions at D.2.4.
- c) Compare the difference between replicates (or range, if more than 2 replicates) and, if necessary, test for a statistically significant difference between replicates, using Cochran's test (ISO 5725-2). If the difference between replicates is large for any pair, review a technical explanation for the difference and if appropriate, remove the outlying group from the analysis or, if $m > 2$ and the high variance is caused by a single outlier, remove the outlying point.

Note- If $m > 2$ and a single observation is removed, subsequent calculation of s_w and s_s will need to take the resulting imbalance into account.

D.2.2 Compare the between-samples standard deviation s_s with the standard deviation for proficiency assessment σ_{pt} . The proficiency test items may be considered to be adequately homogeneous if:

$$s_s \leq 0,3 \sigma_{pt} \quad (D.1)$$

Note 1- The justification for the factor of 0,3 is that when this criterion is met the between-samples standard deviation contributes less than 10 % of the variance for evaluation of performance, so the performance evaluation is unlikely to be affected.