

NABL 181(A)



National Accreditation Board for Testing and Calibration Laboratories (NABL)

SPECIFIC CRITERIA FOR PT PROVIDER ACCREDITATION (AS PER ISO/IEC 17043:2023)

ISSUE NO.: 01

ISSUE DATE: 13-02-2024

AMENDMENT NO.: --

AMENDMENT DATE: --



Documents

Document Sharing Hub

AMENDMENT SHEET

S. No.	Amendment no.	Page No.	Clause No.	Date of Amendment	Amendment made	Reasons	Signature QA Team	Signature Competent Authority
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	References	4
3.	Specific Policy of NABL for PT Providers	5
4.	General requirements	7
5.	Structural requirements	7
6.	Resource requirements	8
7.	Process requirements	12
8.	Management system requirements	21

1. Introduction

All PT Providers are required to comply with all the requirements listed in the International Standard ISO/IEC 17043: 2023 'Conformity Assessment – General Requirement for the Competence of Proficiency Testing Providers' for all types of proficiency testing schemes. ISO 13528:2022 provides support for the implementation of ISO/IEC 17043:2023 particularly, on the requirements for the statistical design, validation assigned value of proficiency test items, ensuring reasonableness of Standard deviation for proficiency assessment (SDPA), identification of possible blunders (outliers) in case of consensus value approach, review of results, and reporting summary statistics. This document specifies NABL requirements for provider of proficiency testing to comply along with ISO/IEC 17043: 2023. It contains requirements for PT providers to enable them to demonstrate that they operate competently and can generate valid evaluations of participant performance.

PT involves the use of interlaboratory comparisons for the evaluation of laboratory performance. PT can provide evidence of competence and it can be an indicator of an underlying or emerging problem. The need for ongoing confidence in laboratory performance is essential not only for laboratories and their customers but also for other interested parties, such as regulators, accreditation bodies and other organizations that specify requirements for laboratories.

There are many different purposes for interlaboratory comparisons, which can be addressed by PT schemes, including but not limited to:

- a) evaluation of the performance of laboratories for specific measurements, tests, calibrations, examinations, inspections or sampling;
- b) identification of problems in laboratories that, for example, can be related to measurement or test methods, effectiveness of training and supervision of personnel, or calibration of equipment;
- c) establishment of the effectiveness of measurement or test methods and the comparability of measurement and test results;
- d) provision of additional confidence to users of measurement and test results;
- e) identification of differences in measurement and test results;
- f) education of participating laboratories based on the outcomes of such comparisons;
- g) validation of measurement uncertainty claims.

For the following types of interlaboratory comparisons, the term PT does not usually apply because laboratory competence must be established in advance, in order to ensure the validity of measurements or tests, as well as the metrological traceability of assigned values:

Doc. No.: NABL 181(A)	Specific Criteria for PT Provider Accreditation (as per ISO/IEC 17043:2023)		
Issue No.: 01	Issue Date: 13-02-2024	Amend. No: --	Amend. Date: --

- h) evaluation of the performance characteristics of a measurement or test method (often described as collaborative trials);
- i) assignment of values to reference materials;
- j) support for statements of the equivalence of measurements of National Metrology Institutes (NMIs), or their Designated Institutes (DIs) through “key and supplementary comparisons”, conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated Regional Metrology Organizations (RMOs).

It is recognized that interlaboratory comparisons for purposes h), i) and j) can contribute to independent demonstrations of laboratory competence. The requirements of this document can be applied to many of the technical planning and operational activities for these interlaboratory comparisons.

Types of PT schemes – PT schemes vary according to the needs of the sector in which they are used, the nature of the PT items, the measurement and test methods in use and the number of participants. In their simplest form, most PT schemes feature a comparison of results obtained by one laboratory with those obtained by one or more other laboratories. For more details about types of PT schemes refer Annex A – ISO/IEC 17043: 2023.

2. References

- 2.1. ISO/IEC 17043: 2023, Conformity assessment – General requirements for proficiency testing,
- 2.2. ISO 13528: 2022 Statistical methods for use in proficiency testing by interlaboratory comparison

Doc. No.: NABL 181(A)	Specific Criteria for PT Provider Accreditation (as per ISO/IEC 17043:2023)		
Issue No.: 01	Issue Date: 13-02-2024	Amend. No: --	Amend. Date: --

3. Specific policy of NABL for PT providers

3.1. The PT provider shall have conducted at least one PT program in same / similar Matrix (PT item) in accordance with ISO/IEC 17043:2023 for the applied scope of accreditation.

Example -In a group (e.g. building materials, metals and alloys, food and agricultural products etc.) with at least some of the critical parameters.

If PT program not conducted or not completed for any part of scope of accreditation, the PT provider shall at least provide PT design document (detailed document as how the program will be conducted) and identify the PT item/artifact and if possible conduct the homogeneity assessment of the PT items prepared.

Note – The intention of the policy is to ensure competency in preparation of all type of PT items covering appropriate discipline/ group/sub-group etc. pertaining to the scope applied.

3.2. The PT provider shall have completed at-least one Internal Audit and one Management review before applying for accreditation and it shall be conducted after completion of PT program(s).

3.3. For calibration PT programs, 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 (say National Physical Laboratory NPL, India).

3.4. For Calibration PT programs, where PT artifact is not owned by PT provider (applicable only for the artifacts where site calibration is done), the following conditions shall be fulfilled:

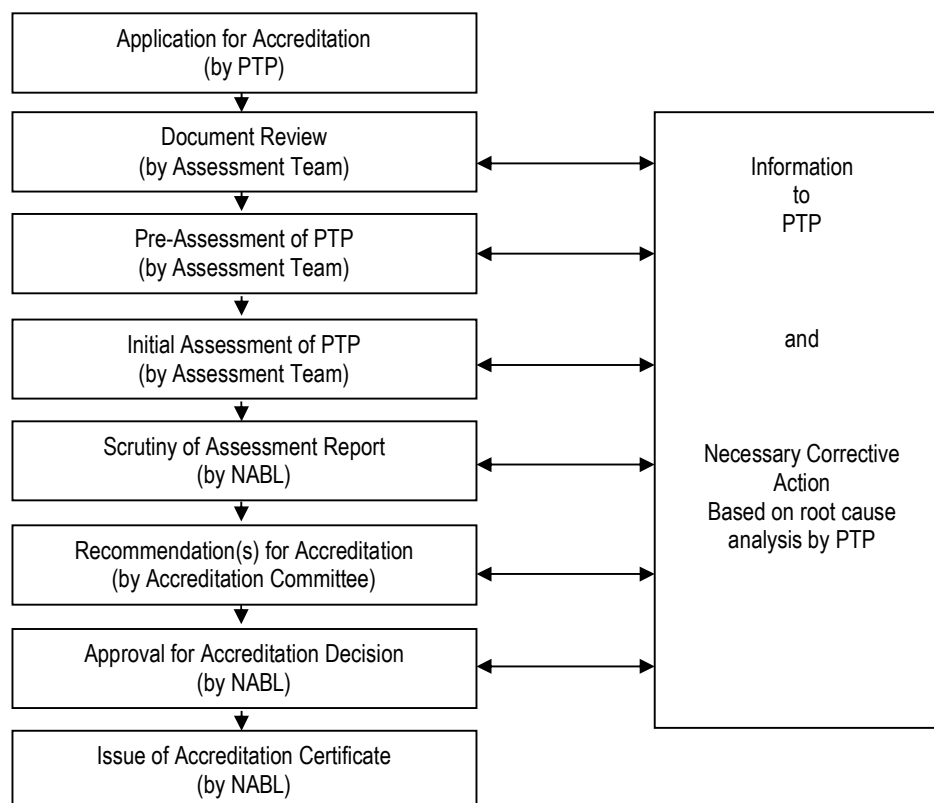
- There shall be a contract between the PT provider and the owner of the artifact. Duration of the contract shall be minimum two years. It shall also describe the conditions for maintenance, servicing, storage, etc., for maintaining integrity of the artifact. It shall also include the condition that during the period of conduct of PT, the artifact shall not be used for any other purpose. The contract shall include among others, requirements for the duration shall not be less than two years.
- The PT provider shall document administrative as well as technical procedure for use of such artifacts, including the system for calibration of the artifact before use/ commencement of PT scheme.
- The PT program shall be completed by PT provider covering all the PT artifacts/ analytes/parameters applied.

3.5. PT provider shall not enroll (or) accept participation from following but not limited to:

- laboratory(ies) used for testing or calibration/ involved in assessing homogeneity and stability of PT item
- organization(s) used for preparation/production of PT item

Note: Checking the competency through this PT is not applicable for these laboratory(ies) / organization(s) as they are already involved / competent in one (or) other activity of PT item.

PTP Accreditation Process Flow Chart



4. General requirements

The roles of key personnel shall be clearly defined identifying any potential conflict of interest. The PT provider shall have declaration of independence in case of identified conflict of interest. In addition, the organization chart shall clearly define the position and relationship of PT provider with other activities. PT provider to demonstrate impartiality where conflict of interest is identified and records to be retained.

5. Structural requirements

The applicant/accredited PT provider shall have legal entity as mentioned in NABL 180.

Any changes (e.g. Key Personnel including the members of advisory group/ technical experts, External service providers used for critical PT activities etc.) are to be informed to NABL within the prescribed timeline (refer NABL 131).

Doc. No.: NABL 181(A)	Specific Criteria for PT Provider Accreditation (as per ISO/IEC 17043:2023)			 Documents Page No.: 7 of 50
Issue No.: 01	Issue Date: 13-02-2024	Amend. No: --	Amend. Date: --	

6. Resource requirements

a. General

Measurements or tests related to PT item characterization or for assessing homogeneity and stability shall be conducted under the responsibility of the PT provider. All the tests shall be conducted in accordance with the relevant requirements of ISO/IEC 17025 or ISO 15189. Following can be used:

- An accredited laboratory whose service is suitable for the intended use (i.e. the scope of accreditation specifically covers the appropriate measurements or tests) and the Accreditation Body is covered by the ILAC arrangements or by Regional Arrangements recognized by ILAC (e.g. NABL).
- National Physical Laboratory (NPL, NMI of India) or any other NMI whose service is suitable for the intended use and is covered by the CIPM MRA.

Where the PT item is a material that meets the definition of “reference material”, it shall be produced by reference material producer accredited in accordance with ISO 17034 or ISO 15194 or by National Physical Laboratory (NPL, NMI of India) or any other NMI whose service is suitable for the intended use and is covered by the CIPM MRA.

- An accredited reference material producer whose service is suitable for the intended use (i.e. the scope of accreditation specifically covers the appropriate reference material) and the Accreditation Body is covered by the ILAC arrangements or by Regional Arrangements recognized by ILAC (e.g. NABL).

b. Personnel

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.

PT provider shall have competent person to review and authorize the PT reports issued by PT provider under NABL accreditation.

The qualification and experience criteria of relevant field (Testing / Calibration / Medical) shall apply. The relevant academic qualifications, experience and demonstration of technical competence to the assessment team shall be the basis for acceptance of person to review and authorize the report.

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.

The availability of personnel performing key activities to be ensured by PT provider during assessment for demonstration of their competence before assessment team.

If technical experts / advisory or steering group are used then following information to be available:

- Biodata/CV of individuals,
- Purpose for which the expert is to be used,
- Contractual agreement and expert's concurrence to be part of PT provider, (contractual agreement to define the scope of activity which PTP avails from technical experts/ advisory or steering group)
- Confidentiality,
- Minutes of advisory committee and/or records of communications through e-mail or letter. In case, where the activity is critical for performance of PT scheme at-least following shall be available with PT provider.
 - Records of activities monitored and controlled as well as inputs given by them (pertaining to PT item preparation, quality control mechanism and/ or homogeneity assessment results).
 - Record of communication when making comments on participants results.
 - Records of communication when making comments or recommendations based on the outcomes of the PT round.

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

S. No.	Items / Particular	Competence requirements	Name of the Person	Remarks/ Comments
1.	For Planning of proficiency testing schemes			
2.	To assess data/information to determine stability and homogeneity, as well as assigned values and associated uncertainties of the properties or characteristics of the PT item			
3.	To evaluate the performance of PT participants			
4.	To give opinions and interpretations as well as advice to the participants			
5.	To review and authorize PT reports			

The person responsible for quality management system / quality manager should be fully aware of the requirements of ISO/IEC 17043:2023, and principles applicable to the organization's field of accreditation / compliance.

Note - The PT provider to ensure availability of documented information demonstrating competence of personnel for authorized PT activities.

c. Facilities and environmental conditions

PT provider to ensure availability of appropriate facilities for the different operations while conducting PT programs including but not limited to the following:

- i. Production
- ii. Packaging
- iii. Handling
- iv. Storage

In case of incompatible PT activities, the PT provider shall take measures such as appropriate separation between neighboring areas to prevent cross-contamination or interference. The PT provider shall also control the activities which can adversely influence the PT scheme. Records of such measures and controls shall be maintained by the PT provider.

d. External service provider

The PT provider may use external services for activities permitted by the standard. When using external services, the PT provider must be able to demonstrate to NABL that each external service provider complies with the relevant standard requirements. The external service provider providing critical activities shall be informed that they may be subjected to an assessment by NABL.

The information that shall be made available to NABL about external service provider(s) includes but not limited to:

- Name and address of the external service provider(s);
- Key activities performed by the external service provider(s); and
- Information about how the PTP assesses the competence (e.g. copy of accreditation certificate, audit reports) of each external service provider.
- The assessment shall ensure compliance to the relevant requirements of ISO/IEC 17043 and other related standards like ISO/IEC 17025, ISO 17034, ISO 15189, ISO/IEC 17020 and ISO 15194 etc.

The following information shall be readily available with PT provider for the test or measurement carried out by either in-house or external service provider:

- Test report / calibration certificate along with original observation data generated while performing testing/calibration for the purpose of assigning value and/or homogeneity and/or stability testing.
- Method adopted for assigning values and ensuring homogeneity & stability of PT items.

7. Process requirements

7.1. Establishing, contracting and communicating the PT scheme objectives

- The participants should be suitably informed that the records of PT scheme participation shall be accessible to NABL.
- Records of relevant communication shall be maintained and retained by the PT provider for a minimum period of 2 years.

7.2. Design and Planning of a PT scheme

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

S. No.	Title	Particulars	Comments / Remarks
a)	the personnel involved in the design and operation of the PT scheme		
b)	the activities to be undertaken by external providers of products and services and their contact details		
c)	criteria to be met for participation in the PT scheme		
d)	the number and type of expected participants in the PT scheme		
e)	description of activities to be performed and results to be reported by participants		
f)	a description of the range of values or characteristics, or both, to be expected for the PT items		
g)	the potential major sources of errors involved in the area of PT offered		
h)	requirements for the production, quality control, storage and distribution of PT items		
i)	arrangements to prevent collusion between participants or falsification of results and procedures to be employed if collusion or falsification of results is suspected		
j)	a description of the information which will be supplied to participants and the time schedule for the various phases of the PT scheme		

S. No.	Title	Particulars	Comments / Remarks
k)	for continuous PT schemes, the frequency or dates upon which PT items will be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which measurements or tests will be carried out by participants		
l)	any information on methods or procedures which participants must use to store, handle, prepare, ship or dispose of the PT item and perform the measurements or tests		
m)	procedures for the measurement or test methods to be used for the homogeneity and stability testing of PT items and, where applicable, to determine their biological viability		
n)	preparation of any standardized reporting formats to be used by participants		
o)	a detailed description of the statistical analysis to be used		
p)	the origin, metrological traceability and uncertainty of any assigned values; <i>NOTE: Assigned values can have uncertainty contributions from sources in addition to the uncertainty of measurement results used for characterization, such as inhomogeneity and instability, and interlaboratory differences if more than one laboratory is used for characterization</i>		
q)	the treatment of results from different measurement or test methods, where permitted by the PT scheme		
r)	criteria for the evaluation of the performance of participants		
s)	a description of the data, interim reports or information to be returned to participants		
t)	a description of the extent to which participant results, and the conclusions that will be based on the outcome of the PT scheme, will be made public or shared		

S. No.	Title	Particulars	Comments / Remarks
u)	actions to be taken in the case of lost, delayed or damaged PT items		

Note:

- It is expected that PT provider incorporates sufficient information in PT plan document for all the requirements given in clause 7.2.1.3 (a to u) of ISO/IEC 17043: 2023.
- When assigned value (AV) is determined independent of participants, the uncertainty of AV should be calculated considering, uncertainty due to inhomogeneity and instability of the PT items. While following consensus value approach uncertainty need not include components due to inhomogeneity and instability but should include uncertainty due to interlaboratory differences.
- Uncertainty due to interlaboratory differences to be included when AV determined from consensus approach from expert laboratories.

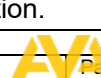
Collusion may take place either amongst the participants or between the PT provider and participants. Few suggested means that will provide guidance to the PT provider and assessor to prevent collusion and falsification are as follows:

- PT provider should provide adequate justification for the method adopted for assigning value to PT items.
- The size/amount of PT item sent to participants should not be too large. The design of the PT scheme should ensure that the time gap between receipt of the sample, date of testing and date of reporting should be minimum. Adequate justification should be provided in case of longer time gap.
- Distributing PT items to participants for a particular property or characteristics with slightly varying property values instead of sending same PT items to all the participants, without prior intimation to participants.
- When a PT scheme requires testing on a particular date and time, PT provider should obtain the results from the participants within the specified time.

PT provider shall identify, analyze and document risks to impartiality, integrity and objectivity and also collusion and falsification. The threats to the above could arise from following but not limited to:

- PT provider being part/related to another body such as testing/ calibration laboratory (under same ownership, common management, same personnel, coercion openly or secretly, etc.)
- Participation from competitor laboratories in PT program.
- Collusion among participants such as discussion among participants, testing/calibration of PT item in another laboratory (better equipped, specialized).
- Request from participants for duplicate PT items with false justification.

Doc. No.: NABL 181(A)	Specific Criteria for PT Provider Accreditation (as per ISO/IEC 17043:2023)		
Issue No.: 01	Issue Date: 13-02-2024	Amend. No: --	Amend. Date: --



Documents

Document Sharing Hub

PT provider shall document and implement a procedure for identifying risks and mitigation measures, where applicable.

When a relationship poses unacceptable threat to impartiality, PT services shall not be provided to the related participant.

It should be ensured that PT items are prepared, handled and distributed by authorized person / agencies. The access to the records of codification and distribution of PT items shall be controlled.

If there is provision for witnessing on line testing, this should be resorted to. In this case the different participant laboratories may be asked to carry out testing on different days at different times to enable the PT Provider to monitor testing activities.

Similarly, in case studies as for sampling, PT provider may video-graph the conduct of case study if practically possible or get witnessed the case study from independent experts in its advisory group.

The PT provider should have provision to get participants original observation data of test or measurement conducted on PT item, when collusion or falsification of results are suspected.

The case studies in sampling should be well documented, approved by independent experts and objective evaluation should be possible.

Doc. No.: NABL 181(A)	Specific Criteria for PT Provider Accreditation (as per ISO/IEC 17043:2023)		
Issue No.: 01	Issue Date: 13-02-2024	Amend. No: --	Amend. Date: --