



**National Accreditation Board for Testing
and Calibration Laboratories (NABL)**

NABL 163



Policy for Participation in Proficiency Testing Activities

**ISSUE NO. : 08
ISSUE DATE : 07-Mar-2019**

**AMENDMENT NO. : --
AMENDMENT DATE :--**

AMENDMENT SHEET

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1. INTRODUCTION

Proficiency Testing is one of the important tools to determine the technical competence of the testing / medical / calibration laboratories.

According to ISO/IEC 17025:2017, a laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in inter-laboratory comparisons or proficiency testing programs. Other means may include the regular use of reference materials, or replicate tests or calibrations using the same or different methods. By these mechanisms a laboratory can provide evidence of its competence to its clients, interested parties and the accreditation body.

According to ISO 15189:2012, medical laboratories seek confirmation for confidence in their results through participation in suitable inter-laboratory comparisons.

This document derives NABL policy on participation in Proficiency testing activities to conform to the requirements of ILAC-P9:06/2014, ILAC Policy for Participation in Proficiency Testing activities.

2. SCOPE

This document stipulates the minimum requirements of PT participation during accreditation process of testing, calibration and medical laboratories (Conformity Assessment Bodies - CABs).

This also gives information about the measures against poor performance of CABs as defined in Proficiency Testing program.

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3. NABL POLICY

3.1. Applicant CAB shall successfully participate in at least one PT program prior to gaining accreditation in each discipline applied.

3.2. For applicable tests and calibrations in the CAB's scope of accreditation, the CAB shall seek participation in one or more of the following PT activity options. They are listed in descending order of preference, with the most desirable at the top of the list:

- I. Scheme delivered by an Accredited PT provider
- II. Scheme delivered by PTP which is accepted by NABL by other means like approval, funded, policies or guidance document;
- III. Scheme delivered by an Applicant PT provider;

However, where above formal PT Programs are not available / scheduled or not appropriate, alternatively:

- a. The applicant testing/ medical laboratory shall participate in suitable inter-laboratory comparisons with sufficient number of accredited laboratories, as per ISO/IEC 17043:2010 'Conformity assessment – General requirements for proficiency testing'.
- b. The applicant calibration laboratory shall participate in suitable inter- laboratory comparisons, as per NABL 164 'Guidelines for Inter-laboratory Comparison for Calibration Laboratories where formal PT Programs are not available'.

Note: There are areas of testing and calibration for which suitable PT / ILC is not practical. In such cases, NABL and the laboratory shall discuss and agree on suitable alternative means by which performance can be assessed and monitored. This would need to be considered as part of the planned PT and/or related activities.

3.3. Accredited CAB shall have 4-year plan for Proficiency Testing participation which shall cover all the accredited groups as practicable (e.g. Food & agriculture, pressure & vacuum, high voltage, building material, etc.) under each discipline of accreditation. In Medical testing, accredited laboratories shall participate in at least one Proficiency Testing / External Quality Assurance Scheme in a year per discipline, as appropriate. This plan shall be applicable strictly considering the above options for PT given under section 3.2 of this document.

3.4. Successful participation in PT is necessary for significant enhancement of scope such as addition of discipline

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- 3.5. CAB shall take appropriate corrective actions in case of poor performance in PT programs within one month period. In two consecutive events of poor performance in PT participation/unsatisfactory corrective actions leads to the scope reduction as per NABL 216.
- 3.6. Apart from the above defined minimum requirements, CAB shall also abide by the PT participation required by the respective Regulators, NABL & regional bodies like APAC.
- 3.7. Accredited CAB shall submit 4 year PT plan as per Form 18 (Annexure A) which will be reviewed by NABL for its suitability in relation to the scope of accreditation. In case of non-suitability of the PT plan submitted by the CAB, NABL may guide in identifying the required PT coverage.
- 3.8. NABL provides guidance to the CABs regarding the proficiency testing programs through its website, by giving the list of NABL accredited / applicant PT Providers with their accredited PT scheme details. NABL has also given reference to some international organization providing PT program. This helps the CABs in participating in other programs, in case where no national programs are available.
- 3.9. The PT program should be conducted in accordance with ISO/ IEC 17043:2010. All techniques covered in ISO/IEC 17043:2010 shall be acceptable for the purpose of Proficiency Testing.
- 3.10. Successful participation in national / international PT programs enhances the confidence in the competence of CABs.
- 3.11. At the time of on-site assessment, assessment team shall verify whether the CABs have participated in recognized Proficiency Testing Program as per the PT plans (Form 18) and whether the necessary corrective action were taken, if in terms of z-Score, En values etc. the CAB performance has not been satisfactory.

Note: For calibration laboratories, measurement audits will be considered to be a complimentary effort to Inter-Laboratory Proficiency Testing. The calibration laboratories will be provided with artifacts with their characterization by National Physical Laboratory, New Delhi or nodal laboratories appointed by NABL for the same objective or any other NMI's who are signatory to BIPM.

- 3.12 NABL shall nominate its accredited/applicant CABs for participation in APAC and other international Proficiency Testing program, as and when they are available. Following sequential preference shall be given to the laboratories:

- ✓ Accredited CABs not having participated in any other APAC PT program.
- ✓ CABs having unsatisfactory performance in a past PT program.

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- ✓ CAB with long period of accreditation
- ✓ Applicant CAB

NABL shall co-ordinate all activities related to PT program with APAC and the participating CAB.

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Annexure A

Form 18

Proficiency Testing Plan							
CAB ID							
CAB Name							
Field of Accreditation	Testing / Calibration / Medical						
4 - Year Period of Participation							
Accredited Discipline(s)	Group(s) under Discipline	Proficiency Testing Participation Plans (Year wise)				Results	Remarks (for NABL use only)
<i>Note: CAB should ensure that PT plan covers the major parameters in each group under the relevant discipline</i>							
For NABL use only							
<div style="border: 1px solid black; padding: 5px; min-height: 80px;"> <p>Reviewed and Approved by:</p> </div>							

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