

	<p align="center">PNAC POLICY FOR PARTICIPATION IN PROFICIENCY TESTING</p>	<p>G-02/13 Issue Date: 24/05/2021 Rev No: 05</p>
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1. Purpose

To meet the requirement of ISO/IEC 17025 & ISO 15189 of quality control procedures, this policy outlines the requirements of PNAC for participation in Interlaboratory comparisons (ILC) or proficiency testing (PT) programs.

2. Policy

- a. All applicant laboratories shall successfully participate in PT / ILC before getting accredited. In case where PT/ILC is not available/feasible, the lab shall prove its competence through other means.
- b. PNAC accepts all proficiency testing/ inter-laboratory comparisons recognized (ISO/IEC 17043) by the national, regional and international bodies i.e., APAC, ILAC, EA etc.
- c. In case where the PT on the same or similar type of sample is not available, the labs shall participate in PT/ILC, where competence on the specific techniques/equipment shall be confirmed (such as pharmaceuticals, or other similar fields).
- d. If the PT is not available anywhere in the world, then other measures like Internal Quality Assurance (Clause 7.7.1 of ISO/IEC 17025:2017) should be agreed and conformed by PNAC.

3. Scope


This policy is applicable to all testing and calibration labs seeking accreditation from PNAC.

4 Terminology

- a. *Proficiency testing (PT)* is the determination of the calibration or testing performance of a laboratory or the testing performance by means of interlaboratory comparison with the proficiency testing provider.
- b. *Inter-Laboratory Comparison (ILC)* is the organization, performance and evaluation of calibrations/tests on the same or similar calibrations/tests items by two or more laboratories in accordance with predetermined conditions.
- c. The ILAC requirements document specifying PT participation is entitled ILAC Policy for Participation in Proficiency Testing Activities (ILAC-P9). ILAC P9 requires that “*Accreditation bodies (ABs) seeking to sign or seeking to maintain their status as a signatory to the ILAC Multilateral Recognition Arrangement (MRA) shall demonstrate the technical competence of their accredited calibration and testing laboratories. One of the elements by which accredited laboratories can demonstrate technical competence is by satisfactory participation in PT activities where such activities are available and appropriate.*”
- d. *Laboratory (ies) mean testing, calibration and medical labs*

5. PNAC’s requirements on participation in PT

- a. Accredited laboratories are required to participate and achieve satisfactory performance on an annual basis for each round in an appropriate proficiency testing scheme or inter-laboratory comparison where such schemes are available and relevant to their scope of accreditation. Accredited laboratories must participate in, at a minimum, at least one

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activity for each sub discipline (note 1) within the laboratory's scope of accreditation, between periods of re-assessment.

- b. Applicant/Accredited laboratories must participate in each testing technique on annual basis.
- c. Laboratories preparing for accreditation are required to participate and achieve satisfactory performance in a proficiency testing or inter-laboratory comparison where such schemes are available and relevant to their scope of accreditation before a recommendation for accreditation can be considered.
- d. The PNAC assessment team will review at each surveillance visit the laboratory's performance in proficiency testing / inter-laboratory comparisons.
- e. Laboratories are required to have appropriate acceptance criteria and a procedure for investigating the cause of problems and for implementing corrective actions when these acceptance criteria are not met. A written record of these activities must be maintained. The laboratory must ensure that it does not claim accreditation for any tests that could be affected by the events that caused "out of specification" proficiency testing / inter-laboratory comparison results until it is satisfied that the investigation into the anomalous result has fully resolved the issue.
- f. If at any time the laboratory's performance in proficiency testing / inter-laboratory comparisons in the opinion of PNAC, casts doubt on the integrity of test results, PNAC may suspend the relevant tests from the laboratory's scope of accreditation. The laboratory will be required to provide PNAC with written evidence that the problem has been identified and satisfactorily rectified (which may include demonstrated satisfactory performance in subsequent proficiency testing/ inter-laboratory comparisons) before re-instatement of accreditation can be considered.
- g. Laboratories shall conduct proficiency tests in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.
- h. Laboratories shall also ensure that proficiency testing samples are equally distributed among trained and qualified personnel for the relevant tests.
- i. Laboratories shall have a documented plan of how they intend to cover the applicable program requirements or the major sub-disciplines and materials/matrices/product types on their scope of accreditation over a three-year period. The plan should be submitted on PNAC form F-02/33. The laboratories must also submit proficiency testing results and related corrective action responses to PNAC on F-02/31. Detailed corrective action responses, including root cause analysis, for any outlying or unacceptable final results related to testing/calibration on their Scope of Accreditation must also be submitted to PNAC not later than 45 days after receiving the PT results from PT providers.

Note 1: Examples of major sub disciplines are given below:

- environmental analysis: soil (including solid waste, sludge, compost);
- environmental analysis: water (waste water, ground water, drinking water);
- environmental analysis: air (emission);
- materials testing: chemical parameters;
- materials testing: physical quantities;
- materials testing: non destructive testing;

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- microbiology.
- food testing

References:

- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.
- ISO 15189:2012 Medical laboratories - Requirements for quality and competence
- ISO/IEC 17043:2010 General requirements for proficiency testing
- ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories, A2LA, USA