



PL 009-03

PROFICIENCY TESTING REQUIREMENTS

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1. Purpose and Scope

The purpose of this document is to define NiNAS policy and specific requirements for participation in Proficiency Testing activities by accredited and applicant laboratories (including testing, calibration and medical laboratories). This document also applies to applicant and accredited inspection bodies where the concept is relevant, i.e. particularly where the inspection body undertakes testing activities as part of its inspection process. In these cases the term “laboratory” in the rest of this document can be replaced by “inspection body” and the policy applied.

2. References/Definitions

- 2.1 **Inter-laboratory Comparison (ILC):** Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
- 2.2 **Proficiency Testing (PT):** The determination of the calibration or testing performance of a laboratory, or the testing performance of an inspection body against pre-established criteria by means of inter-laboratory comparison. Note: In Medical Laboratories, PT is often referred to as EQA (External Quality Assurance)
- 2.3 **Proficiency Testing Scheme:** Proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration or inspection. Where reference to PT/ILC is made in this document, it will also include alternatives to PT/ILC, as agreed on by NiNAS.

ILAC-P9/06 - ILAC Policy for Participation in Proficiency Testing Activities.

ISO/IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

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3. Background

NiNAS shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate. NiNAS will agree with



the laboratories on the minimum amount and frequency of proficiency testing participation according to the criticality of their scope. It is recognised that there may be areas where PT schemes are not available or are not practical, in such cases a suitable alternative shall be proposed by the laboratory and agreed to by NiNAS. This agreement shall be documented using F 060-02. Accredited laboratories shall ensure, where necessary, that appropriate root cause analysis, corrective actions and preventative actions are carried out.

4. General Requirements

- 4.1 On Application for Accreditation all applicant laboratories are required to participate in appropriate proficiency testing or inter-laboratory comparisons for the scope of accreditation required and provide NiNAS with the relevant proof of participation and satisfactory performance during the submission of the application form. ‘Appropriate’ participation can be described as that level of participation which will result in an acceptable level of risk, i.e. risk that the laboratory may issue reports with results falling outside of the specified measurement uncertainty stated on the report.
- 4.2 The NiNAS policy requires that laboratories undertake PT or ILC’s for all items or parameters listed on their proposed schedule of accreditation, at an acceptable level of uncertainty.
- 4.3 Whilst this policy accepts that there may be areas where PT is not commercially available, in cases where there is increased risk, then the lack of commercially available PT is not considered a valid reason for non- participation. Other alternatives shall be considered and agreed by NiNAS.
- 4.4 Proficiency Testing activities may include:
 - i. an external proficiency testing scheme, preferably operated in accordance with ISO/IEC 17043;
 - ii. an Inter-laboratory comparison scheme (where two or more laboratories are used);
 - iii. suitable alternative to PT/ILC, as agreed to by NiNAS, where PT schemes are not available or are not practical.

5. Maintenance of Accreditation

- 5.1 All accredited testing laboratories must preferably participate in proficiency testing schemes that have been independently shown to comply with the requirements of ISO/IEC 17043.
- 5.2 Participation in other unaccredited schemes is acceptable until such time that there are sufficient accredited schemes in the various disciplines. The laboratory



shall satisfy itself on the competence of the PT providers whose schemes it voluntarily participates in.

- 5.3 Accredited Proficiency Scheme Providers are available from NiNAS. A register of non- accredited proficiency scheme providers and specific inter-comparison schemes can also be obtained from NiNAS for information purposes, this implies that it is acceptable by NiNAS, but will not imply that these schemes meet accreditation criteria.
- 5.4 Where appropriate, all accredited Laboratories shall participate in PT / ILC for items on their schedule of accreditation including specific tests or methods where these have been separately listed. These shall be addressed in the PT activity plan. However, for example, items under ICP analysis including Fe, Mn, Zn may cover for each other for the sake of initial accreditation, but the Lab should try to participate for as much as it can of these items on other participations.
- 5.5 Laboratories can from time to time be invited to participate in international proficiency testing schemes. Such participation is usually above and beyond that as required by NiNAS and is at the discretion of the Testing Laboratory and / or NiNAS.
- 5.6 The laboratory shall review their own performance and investigate all measurement results that fail to meet the minimum acceptance criteria, including where there is evidence of consistent poor performance, and record the root cause analysis conducted and all corrective and preventative action(s) taken.

6. PT/ILC Activity Plan

- 6.1.1 All accredited laboratories shall have available PT / ILC plans for at least 2 accreditation cycles, i.e. the activity schedule for the past accreditation cycle (where possible) and the plan for the subsequent accreditation cycle.
- 6.1.2 The plan shall cover all activities as specified above and shall be accomplished in a period not exceeding 2 accreditation cycles. Note: The frequency and extent of participation shall be justified by the laboratory and agreed on by NiNAS for each accredited method and shall be included in the plan.
- 6.1.3 The PT / ILC plan shall be addressed in the laboratory's documented management system, and the plan shall be subject to review in response to changes in staff, methodology or instrumentation, revision and approval as described.



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- 6.1.4 The laboratory may incorporate in the plan participation in any other organised PT or other comparison programmes organised nationally, regionally or internationally.
 - 6.1.5 Where no formal PT is practical or available, the laboratory shall indicate suitable alternative means by which performance will be assessed and monitored. These may include activities such as the use of reference materials or other comparisons.
 - 6.1.6 NiNAS will consider these alternative arrangements as part of the laboratory's planned activities. The onus is on the laboratory to provide the details of the plan and its justification thereof and obtain approval from NiNAS. Such alternatives must still comply with the reporting requirements in 9.
 - 6.1.7 The laboratory's PT activity plan shall be available for evaluation during the assessment of the laboratory; additionally NiNAS may request that a copy of the plan be submitted for evaluation at any time. The laboratory shall ensure that the plan is maintained and kept current.
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- 6.2 The PT activity plan should address:
 - 6.2.1 A breakdown of the parameters for which PT is conducted;
 - 6.2.2 Proficiency testing type (Inter-laboratory comparison; Use of a Reference material, PT scheme);
 - 6.2.3 The name/s and or identification of the PT schemes which the laboratory intends to participate;
 - 6.2.4 The measurement parameters;
 - 6.2.5 Any issues experienced with participating in PT;
 - 6.2.6 Frequency of participation per time period justified by the laboratory.
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- 6.3 Evaluation of PT activities During an Assessment
 - 6.3.1 The laboratory's participation in PT / ILC activities or suitable alternatives to PT, as agreed by NiNAS, will be evaluated against their plan. Failure of laboratories to show effective participation, or that the use of alternatives to PT has been agreed on by NiNAS, could result in suspension of the tests/calibration concerned.
 - 6.3.2 The laboratory shall make available to the assessment team all proficiency testing scheme and ILC reports.



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- 6.4 Proficiency testing / ILC reports shall be clear and comprehensive and include at least the following minimum information:
- i. Identification of the participants;
 - ii. Measurement protocol;
 - iii. Identification of the measurement standard or Artefact;
 - iv. Measurement results;
 - v. The reference value/s and how these were established;
 - vi. Evaluation of the measurement results;
 - vii. An indication of the performance of individual participants;
 - viii. Minimum acceptance criteria;
 - ix. Conclusion.
- 6.5 The effectiveness of corrective and preventative action taken will be evaluated during the assessment, and taken into consideration during the decision making process.

7.0 Forms

Table: 9-1 Forms in use with Policy 9	
Form Number	Title
F-062-02	PT Requirements for Laboratories



8.0 Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification
01/04/2023	Quality Manager	Page 3	Removal of dates of publication of the standards
		Header and footer	Updated to the standard format for NiNAS procedures