



General Criteria for Accreditation
Technical Policy No.2
Participation in Proficiency Testing Activities



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Technical Policy No.2: Participation in Proficiency Testing Activities

AS TP 2

Fourth Edition July 2020

Published by:

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Edition Statement

Edition	Amendment	Date of Issue	ISBN No.
1	Initial issue as an AS TP	October 2014	n/a
2	Clarification on what constitutes unsatisfactory performance in PT.	July 2015	n/a
3	Remove reference to APLAC PT programmes.	March 2019	n/a
4	Rebrand document.	July 2020	978-1-877531-76-7

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0 Preamble

IANZ typically published its technical criteria for accreditation in the Specific or Supplementary Criteria for Accreditation publications relevant to each accreditation programme or field. To ensure consistency of application of common policies, IANZ also publishes generic Technical Policy publications that apply to all fields within the scope of the publication.

This Technical Policy document sets out the IANZ policy in regard to participation in proficiency testing activities. Specific or Supplementary Criteria for Accreditation may also provide programme or field specific guidance on how this policy is to be implemented.

1 Scope

- 1.1 This policy applies to all applicant and accredited laboratories in the IANZ Laboratory Accreditation Programmes. It includes both calibration laboratories and testing laboratories.
- 1.2 The policy also applies to applicant and accredited inspection bodies where the concept is relevant i.e. particularly where the inspection undertakes testing activities as part of its inspection process. In these cases the term “laboratory(ies)” in the following text can be replaced by “inspection body(ies)” and the policy applied.
- 1.3 The policy also applies as appropriate to applicant and accredited reference material producers and proficiency testing providers where the concept is relevant i.e. where testing activities such as homogeneity testing, stability testing and/or determination of assigned values are undertaken in a laboratory.

2 Introduction

ISO/IEC 17025⁽¹⁾ requires laboratories to have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include participation in inter-laboratory comparisons or proficiency testing programmes, and must be planned and reviewed. Similarly, ISO 15189⁽²⁾ for medical laboratories requires participation in inter-laboratory comparisons such as those organised by external quality assessment schemes.

ISO/IEC 17043⁽³⁾ defines proficiency testing (PT) as the determination a laboratory’s testing or calibration performance against pre-established criteria by means of inter-laboratory comparison. Inter-laboratory comparison (ILC) is the organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with pre-determined conditions. ILCs can be organised for purposes other than PT (e.g. to evaluate the performance characteristics of a method, to characterise a reference material, or to compare results of two or more laboratories on their own initiative) but collectively they effectively constitute PT activity.

Laboratories may also demonstrate their technical competence through other means such as regular and planned use of (certified) reference materials, intra-laboratory comparisons, or by replicate tests or calibrations using the same or different methods. However, the international laboratory accreditation community has increasingly placed greater emphasis on participation in PT activities as one of the fundamental mechanisms for accredited laboratories to demonstrate their technical competence. Participation in PT activities is accepted as being the preferred tool in a laboratory’s quality control programme to demonstrate the on-going validity and comparability of results. As a result, IANZ, as a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), is required to have a policy regarding the participation of its accredited laboratories in PT activities.⁽⁴⁾

3 IANZ Policy on Participation in PT Activities

3.1 In accordance with accepted international norms, it is IANZ policy that applicant and accredited laboratories shall:

- (a) Demonstrate their technical competence by the satisfactory participation in proficiency testing activity where such activity is available and appropriate, and that;
- (b) The minimum amount of PT activity required per laboratory is one or more activities (to cover the proposed scope of accreditation) prior to gaining accreditation, followed by:
 - (i) Participation in as many PT activities (where available and appropriate) as required to cover the scope of accreditation, and;
 - (ii) For the activities / programme(s) selected, to participate in all relevant rounds that are available. Where multiple programmes/rounds exist covering the same methodologies on similar sample types, participation in all rounds may be relaxed. This would need to be justified on a performance-based criteria and each case will be treated on its merits. The overall frequency must still be such as to demonstrate on-going proficiency.

3.2 Aside from the issues of coverage and frequency, laboratories are expected to select PT activities according to the following criteria (in a generally decreasing order of preference):

- (a) Mandated proficiency testing programmes. In some areas of testing, participation in a particular programme is mandated by other stakeholders in the accreditation process or by other laboratory approval bodies.
- (b) Proficiency testing programmes operated by accredited (to ISO/IEC 17043⁽³⁾) proficiency testing providers within the scope of their accreditation.
- (c) International PT/ILC programmes (preferably from accredited providers and/or operated in accordance with ISO/IEC 17043).
- (d) National PT/ILC programmes (preferably from accredited providers and/or operated in accordance with ISO/IEC 17043).
- (e) Multi-laboratory PT/ILC programmes operated generally in accordance with ISO/IEC 17043 (but not necessarily accredited).
- (f) Formal inter-laboratory comparison programmes involving several independent laboratories.
- (g) Less formal inter-laboratory comparison programmes between two or more laboratories.

3.3 Where none of the above types of PT activities are available or appropriate, applicant and accredited laboratories must have formalised plans for the regular demonstration of their technical competence by alternative means (see 2 above).

4 Administration of the Policy

4.1 ISO/IEC 17025 and ISO 15189 require a laboratory's quality control programme (including the participation in PT activities) to be planned and reviewed. As part of the Accreditation Questionnaire submitted to IANZ with each Application for Accreditation or Application for Reassessment, IANZ will require each laboratory to submit a PT Participation Plan. This Plan will be in the form of a matrix detailing:

- (a) How the plan covers the major elements of the laboratory's (proposed/existing) scope of accreditation.
- (b) The type of PT activities planned for each element over the coming accreditation cycle (typically 4 years). The detail required to be included, as appropriate, will be:
 - The names of any formal PT programmes that the laboratory will participate in and the dates/frequency, and/or;
 - Any other ILC activities the laboratory plans to undertake, including dates / frequency, and/or;

- Where no PT activities are available or appropriate, what other activities the laboratory plans to undertake (e.g. intra-laboratory comparisons, certified reference materials, etc.) to demonstrate their technical competence, including dates / frequency.

The purpose of the Plan is to ensure all activities covered by the scope of accreditation is covered by appropriate PT activity. It is intended to be a living document, reviewed and updated regularly by the laboratory.

4.2 On receipt, the PT Participation Plan will be reviewed by IANZ assessment teams and discussed with the laboratory during next on-site assessment to ensure all activities of the scope of accreditation are covered and to assist laboratories in sourcing or developing appropriate PT activity. It will be further reviewed at each on-site assessment throughout the accreditation cycle to verify planned activities have been undertaken and to review future planned activities.

4.3 The participation in PT activities is of little value without the combined results being analysed to determine the nature of any discrepancies and the effect of this on any routine test or measurement results. Discrepancies may be in the order of expected uncertainty or they may indicate a serious shortcoming in a laboratory's procedure. It is important for laboratories to have undertaken this analysis and to have adequately determined and implemented appropriate corrective action.

Records of the above analysis and any action taken on all PT activity results are required, including those for which no further action is considered appropriate i.e. satisfactory results.

Along with the PT Participation Plan, the results from PT activities and their analyses will be viewed by IANZ at each assessment. Accredited organisations are required to maintain on-going satisfactory performance in proficiency testing activities. Failure to demonstrate satisfactory performance may result in accreditation of the affected activity(ies) being revoked until such time as satisfactory performance can again be demonstrated. Unsatisfactory performance (usually defined by the provider for formal proficiency testing activities) may constitute unexplained discrepancies outside prescribed limits for two or more consecutive comparisons and for which corrective actions has not been demonstrated to be effective.

5 **References**

1. ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories
2. ISO 15189 – Medical laboratories – Particular requirements for quality and competence
3. ISO/IEC 17043 – Conformity assessment – General requirements for proficiency testing
4. ILAC-P9:06/2014 – ILAC Policy for Participation in Proficiency Testing Activities