



**Accreditation Education Research & Scientific Service Center,  
Nepal**

**Policy for Participation in Proficiency Testing  
Activity / Interlaboratory Comparison**

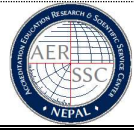
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## 1. Introduction

Proficiency Testing is one of the important tools to determine the technical competence of the Testing, Calibration and Medical Testing laboratories.

According to ISO/IEC 17025, a laboratory shall have quality control procedures for monitoring the validity of tests undertaken. This monitoring may include participation in interlaboratory comparisons or proficiency testing programs. Other means may include the regular use of reference materials, or replicate tests 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.

ISO 15189 also requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons.

This document derives AERSSC policy on participation in Proficiency testing activities to conform to the requirements of ILAC-P9:01/2024 ‘ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing’.

The minimum PT activity according to a laboratory’s scope is:

- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan

Satisfactory participation in National / International PT programs enhances the confidence in the competence of the laboratory.

It is recognized that there are areas of Testing and Medical Testing for which suitable PT does not exist or is not practical. In such cases, the laboratory should follow this document.

The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

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## 2. Scope

This document stipulates the AERSSC policy on PT Participation (minimum PT participation requirements and frequency of PT participation) during the accreditation process of Testing, Calibration and Medical Testing Laboratory.

This document also describes the requirements for reviewing PT participation and performance (in particular consistently poor performance) according to the PT Plan submitted by the laboratory.

**Interlaboratory Comparison** is organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

**Proficiency testing** means evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

**Outlier** is observation in a set of data that appears to be inconsistent with the remainder of that set.

### References

- ILAC-P9:01/2024- ILAC Policy for Participation in Proficiency Testing activities.
- ISO/IEC 17025: 2017- General requirements for the competence of testing and calibration laboratories
- ISO 15189: 2022- Medical laboratories — Requirements for quality and competence
- ISO/IEC 17043: 2023- Conformity assessment — General requirements for proficiency testing

## 3. Policy

3.1 Applicant laboratory shall satisfactorily participate in at least one PT program/ EQA prior to gaining accreditation in each discipline applied.

- AERSSC 33: Application Form for Medical Laboratories
- AERSSC 34: Application Form for Testing Laboratories

**Note 3:** Participation in PT program with Z score less than 2 or En value less than 1 will be considered as satisfactory participation.

Participation in PT program with Z score  $\geq 2$  or En value  $\geq 1$  (question / outliers results) will also be acceptable, if the laboratory has taken necessary corrective actions based on root cause analysis.

3.2 For applicable tests and calibrations in the laboratory's scope of accreditation, the laboratory is required to participate in one or more of the following PT activity options.

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They are listed in descending order of preference, with the most desirable at the top of the list:

- i. PT program/ EQA delivered by an Accredited PT provider

**Note:** PT provider should be accredited by an Accreditation Body covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC e.g. by APAC, IAAC & EA whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate PT items/ parameters)

- ii. PT program/ EQA delivered by reputed institute
- iii. PT program delivered by an Applicant PT provider

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

- The Testing/ Medical Testing laboratory shall participate in suitable interlaboratory comparisons with a sufficient number of accredited laboratories.

**Note:** There are areas of testing and calibration for which suitable PT/ ILC is not practical. In such cases, the laboratory is encouraged to

- Participate in another similar product/ parameter related to the scope of accreditation
- Participate in other QC measures as mentioned in relevant standards (ISO/IEC 17025/ ISO 15189) The above are acceptable as 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 laboratory shall have 3-year plan for Proficiency Testing participation which shall cover all the accredited groups as practicable under each discipline of accreditation. In Medical testing, accredited laboratories shall participate in at least one Proficiency Testing/ EQA 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 The laboratory shall take appropriate corrective actions based on root cause analysis in case of poor performance in PT programs within one month. In two consecutive events of poor performance in PT participation/ unsatisfactory corrective actions led to the scope reduction as per AERSSC 30.

3.5 PT Plan

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- a) The accredited laboratory shall submit a 3-year PT plan as per F 38 which will be reviewed by AERSSC for its suitability in relation to the scope of accreditation.
- b) Continued compliance with the PT plan submitted by the laboratory will be verified during the assessment. Appropriateness of root cause analysis and corrective actions undertaken by the laboratory for poor performance will also be verified during the assessment.



Form - F38

Laboratory Name:

\_\_\_\_\_

Field of Accreditation:

\_\_\_\_\_

Accreditation Certificate Number (Testing/Calibration/Medical):

\_\_\_\_\_

Period of Participation:

Accredited discipline(s)	Group(s) under discipline	PT activities Plan (year wise) 1 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> year	Status and Result of PT activities 1 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> year

Note: CAB shall ensure that the PT plan covers the groups/analyte/parameter under each discipline.

Reviewed and approved by