1. PURPOSE

The purpose of this procedure is to define the requirements for proficiency testing (PT) and interlaboratory comparisons (ILC) other than PT that laboratories and, when necessary, inspection bodies wishing to be accredited by NAC or maintain their accreditation status must participate in.

2. SCOPE

This procedure covers the work of testing/calibration laboratories and, when necessary, inspection bodies wishing to be accredited and maintain their accreditation regarding PT and ILC other than PT, and the evaluation by the assessment team and NAC.

3. DEFINITIONS

Definitions related to this procedure are provided in INST.001-NAC Definitions and Abbreviations Used in NAC Documentation Instruction.

Accredited CAB: Refers to all CABs that conduct testing or calibration activities (testing, sampling, calibration, and medical laboratories, inspection bodies, biobanks, PT providers, and reference material producers).
External quality assessment (EQA): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO 15189:2022, 3.10).
Interlaboratory 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 (ISO/IEC 17043:2023, 3.4).
Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023, 3.7).
Note: Further information on the design of various proficiency testing schemes is given in ISO/IEC 17043:2023 Annex A (Informative).

4. RELATED DOCUMENTS

ISO/IEC 17043:2010 (ISO/IEC 17043:2023) Conformity assessment — General requirements for proficiency testing
ISO/IEC 17011:2017 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
ILAC P9/01:2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing
EA 4/18: Guidance on the Level and Frequency of Proficiency Testing Participation
EA 4/21: Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation
FR.024-NAC.TCL Participation List for Proficiency Testing and Comparison Measurements

5. IMPLEMENTATION

5.1. NAC Policies for PT and ILC Programs other than PT

Testing, calibration, and medical laboratories, as well as inspection bodies when necessary, that wish to be accredited by NAC and to maintain their granted accreditation are responsible for conducting the necessary activities to demonstrate and monitor their technical competence. One way for CABs to demonstrate their technical competence is to participate in valid and appropriate proficiency testing and achieve successful results. Additionally, participation in PT is not only required for laboratories but also for other CABs accredited according to different standards that conduct testing and/or calibration activities within the scope of accredited conformity assessment activities (such as biobanks, PT providers, and reference material producers).

Technical competence can also be demonstrated by participating in interlaboratory comparison programs other than proficiency testing and obtaining successful results. Examples of these programs include:
• Evaluation of the performance characteristics of a method, determination of the properties of a reference material,
• Comparison of results between two or more laboratories at their own request,
• Demonstration of equivalence of measurements by National Metrology Institutes.

PT and ILC programs other than PT should meet the requirements of ISO/IEC 17043:2010 (ISO/IEC 17043:2023) standard.
If these cannot be done, it can be achieved through regular use of reference materials and repetition of tests or calibrations using the same or different methods.

5.2. NAC Criteria for PT and ILC Programs other than PT

Proficiency testing/Interlaboratory comparison tests are an important tool in evaluating the technical competence of laboratories and ensuring the quality of test results. Laboratories can also use proficiency testing or interlaboratory comparisons as a training and risk management tool. NAC requires laboratories applying for accreditation to carry out activities according to the criteria specified below regarding proficiency testing or interlaboratory comparisons.

5.2.1. Accreditation Process

CABs should primarily consider their accreditation scopes and accredited testing, calibration, and sampling activities when determining the level and frequency of participation. Ideally, participation in proficiency testing (PT) should be provided separately for each test or measurement technique used and for each characteristic (component, parameter) of each product. However, this may not always be possible in terms of logistics and cost.

In this case, CABs are expected to group the technical competence areas within their accreditation scopes. This grouping can be defined and relevant with at least one test or measurement technique, characteristic, and product. The performance demonstrated in PT for a

specified combination within a technical competence area can be directly related to other test or measurement techniques, characteristics, and product combinations in the same technical competence area.

A technical competence area may include multiple test or measurement techniques, characteristics, or products, provided that equivalence and comparability are ensured. However, the most important point to consider when defining an area is that it should not generally include different technical competencies. Because different technical competencies generally require different qualifications, training, and the use of different equipment, knowledge, or experience.

The minimum activities related to proficiency testing or interlaboratory comparisons that laboratories or CABs conducting testing or calibration activities as part of conformity assessment activities must meet during their accreditation application to NAC are as follows.

1. Proficiency testing or interlaboratory comparison programs related to the scope of accreditation should be identified. When available and appropriate, the results obtained before the accreditation is granted and a participation plan for an accreditation cycle, including other activities not participated in, should be filled out in the FR.024-NAC.TCL Proficiency Testing and Comparison Measurements Participation Form and records of the activities carried out should be submitted with evidence.

2. To be granted accreditation, test laboratories must achieve at least one successful result from each of the technical competence areas grouped as described above. Calibration laboratories must achieve at least one successful PT/ILC result for at least one of the disciplines within their scope. These results should be submitted to NAC along with the participation plan.

The guidelines for participation in PT and ILC to meet the above-mentioned requirements are explained in the GL.057-NAC.TCL Guideline for Participation in PT and ILC Programs.

NAC reviews the suitability of the submitted proficiency testing or interlaboratory comparison programs participation plans to the accreditation scopes. In cases where they are not found suitable, the CAB is requested to update its participation plan, add programs suitable for the scope, and ensure participation.

The PTs participated in should be conducted by an accredited PT provider according to ISO/IEC 17043:2010, and the documents in the process should be prepared in the main language or a language that the CAB will understand. The results of these programs should be provided in a timely manner to meet the needs of the CABs. A PT and/or ILC offering a scope similar to the scope for which the CAB is accredited can be considered technically appropriate. If a regular PT and/or ILC is not available for a particular test or measurement technique, a PT and/or ILC with a scope similar to the scope of the CAB or covering a significant portion of the activity may be preferred.

In cases where PT or ILC programs are not available or participation is not possible, NAC and the laboratory should discuss the matter and agree on appropriate alternative ways in which competence can be assessed and monitored. In addition, in cases where participation in PT may

be difficult due to the technical characteristics of the test or measurement, lack of PT programs, the low number of existing CABs in the sector, etc., the areas where participation in PT is provided from the testing/calibration sections will be accepted, and necessary measures will be ensured for other areas. Alternative measures that can be taken may include, but are not limited to:

• Participating in an interlaboratory comparison (ILC) with the participation of at least two or more laboratories,
• Use of certified reference materials (when practicable, the conformity of the procedures of the reference material to ISO 17034 requirements should be established),
• Evaluation of RPD (relative percent difference) using repeatability and/or reproducibility.

In participation in proficiency testing, laboratories are expected to participate in proficiency testing not continuously at the same and similar measurement ranges, but to the extent possible, covering the measurement value range they have. Throughout the period they maintain their accreditation, laboratories should report to NAC all the results they obtain from the proficiency testing or interlaboratory comparisons they specify in the participation plan, the activities they carry out regarding unsuccessful results, the records related to this activity, and their updated participation plans.

5.2.2. Participation Plan for Proficiency Testing and Interlaboratory Comparison Programs

The participation list for proficiency testing and interlaboratory comparison programs allows laboratories to analyze their own needs and determine the appropriate level and frequency of participation. Laboratories should prepare a "Proficiency Testing and Comparison Measurements Participation Plan" consistent with their accreditation scopes, covering the sub-disciplines within the scope, and including the level and frequency of participation, and update this plan according to the conditions affecting competence.

The document "EA-4/18: Guidance on the Level and Frequency of Proficiency Testing Participation" should be used to determine the sub-areas. The level and frequency of participation in proficiency testing or interlaboratory comparisons are determined by evaluating the testing or calibration activities of the laboratory on a risk basis (including legislation and additional requirements from the customer, if any). Sub-areas should be determined and established by laboratories to represent all methods and matrices within the accreditation scope, and participation should be provided at different parameters in the established sub-areas. The compatibility of the sample type provided in the participation plan with the sample type mostly used by the laboratory in its daily activities should be considered. In this context, the participation plan is reviewed and updated as needed according to:

a) Number and frequency of tests/calibrations/sampling/measurements
b) Turnover rate of technical personnel
c) Experience and knowledge of technical personnel
d) Source of metrological traceability
e) Known stability/instability of the test or measurement technique
f) Stability of analyte and matrix
g) Importance and end-use of test/calibration/sampling data
h) Risk level associated with the use of pt items posing biological hazards

i) Number of different calibration ranges
j) Complexity and robustness of the methodology
k) Conformity statements and changes in relevant requirements
l) Risks and opportunities related to laboratory activities
m) Scope of verification and/or validation

For each identified sub-area, participation in proficiency testing should be provided at least once in 48 months, and successful results should be obtained. The suitability of the participation plans prepared by the laboratories should be evaluated by the assessment teams during the assessments.

5.3. Evaluation of Results

The NAC assessment team evaluates the results obtained by the laboratories from their participation plans and participations related to their own scopes before, during, or after the assessment within the framework of the aforementioned criteria and reaches a conclusion about the technical competence of the laboratory. In case of unsuccessful results, it examines the effectiveness of the corrective actions carried out and may request additional corrective actions if necessary. Z, z', and zeta scores outside the | z, z' and zeta | ≤ 2.0 limit and En scores outside the |En| ≤ 1 limit are considered unsuccessful results, and it is expected to open corrective actions and/or demonstrate that the situation is under control. In cases where the assessment team cannot be sure of the technical competence of the laboratory, it may request the laboratory to participate in a proficiency test or interlaboratory comparison again in the relevant area.

When necessary, NAC evaluates the effectiveness of the corrective actions carried out by the laboratories regarding the unsuccessful results (proficiency testing or interlaboratory comparisons) they report to NAC, with the support of an expert on the subject, and updates the accreditation decision of the laboratory according to the new situation, if necessary. In the accreditation decision process, the proficiency testing and interlaboratory comparison participation plans, participations, and results obtained by the laboratories are examined and evaluated. If the laboratory has unsuccessful results, the corrective actions it has carried out are examined and evaluated. In case the laboratory continuously obtains successful results, options such as applying different surveillance intervals can be implemented.

5.4. Types of Interlaboratory Comparisons and Proficiency Testing

NAC provides guidance through various methods for access to proficiency testing and interlaboratory comparison programs or databases related to these programs. In some cases, regulatory authorities, industrial or professional sectors, regional cooperation organizations may request or mandate participation in proficiency testing or interlaboratory comparison programs related to their fields. In these cases, NAC provides guidance to the laboratories it accredits, when appropriate. NAC does not organize interlaboratory comparisons or proficiency testing.

Interlaboratory comparisons or proficiency testing can be organized by independent organizations, regional and international associations, or in the form of programs conducted by laboratories among themselves.

If requested by NAC, participation in proficiency testing/interlaboratory comparison programs organized by APAC/ILAC/IAAC or other programs determined by NAC is mandatory.
Laboratories should primarily select programs of proficiency testing providers operating at the national and/or international level, accredited according to ISO/IEC 17043. In the absence of such programs, interlaboratory comparison tests organized by organizations that organize ILCs other than PT or arranged by laboratories among themselves, meeting the requirements of ISO/IEC 17043 standard, should be preferred. (EA-4/21 INF; this can be used to assess the validity of these ILCs in accordance with the requirements of ISO/IEC 17043:2010 (ISO/IEC 17043:2023).)
Laboratories should provide evidence to the NAC assessment team that the proficiency testing programs they participate in meet the requirements of ISO/IEC 17043 standard. If it is evaluated by the assessment team that this evidence does not meet the requirements of ISO/IEC 17043 standard, the laboratory needs to participate in a new proficiency test or interlaboratory comparison program.

5.4.1. Programs Organized by Independent Organizations

The participating laboratory is responsible for ensuring that the proficiency testing and comparison program offered by the organizer complies with the ISO/IEC 17043 standard. Laboratories should follow the relevant organizations.

5.4.2. Programs Organized by APAC

In such organizations, NAC provides guidance for the coordination between the organizer and the participating laboratory. For the organizations that APAC notifies to NAC, the relevant laboratories are informed via e-mail, telephone, or official letter. In cases of limited participation, priority is given to accredited laboratories.

5.4.3. Programs Arranged by Laboratories Among Themselves

Different types of ILCs that NAC accepts as alternatives to PTs and can be used by accredited CABs include:
- ILC organized by a sufficient number of laboratories as a one-time or continuous study;
- Organization of interlaboratory comparisons with a limited number of participating laboratories. (It should be done in accordance with EA 4/21 and ISO/IEC 17043:2010 (2023).)

In such comparison programs, the statistical evaluation performed may not be sufficient due to the limited number of participants. In cases where the above-mentioned programs are not available and it is not possible to apply alternative quality control methods, such programs can be accepted as a requirement of the relevant policy.

6. AUTHORITIES AND RESPONSIBILITIES

The accreditation officer, program manager, assessment team members, and management of the laboratory wishing to be accredited are responsible for the implementation of the

requirements of this procedure.

7. REVISION TABLE

Date	Section	Amendment
19.03.2020	Header	Logo has been changed.
11.07.2023	5.2.1	"At least one successful result is required in the main test/calibration category (microbiology, chemistry, temperature, pressure, etc.) for the granting of accreditation." has been added.
22.03.2024	All	The entire text has been revised according to the rules in the revised ILAC P9:2024.

8. APPENDICES