 **APPROVED**

**Director of "National Accreditation Body” SNCO**

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 ***April 20, 2023***

**POLICY ON PARTICIPATION**

**IN PROFICIENCY TESTING (PT) AND**

**INTERLABORATORY COMPARISONS (ILC)**

**PL-05**

**DEVELOPED BY:**

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 **“*The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Armenian version will prevail*”**

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# Introduction

This document describes how the results of proficiency testing (hereinafter: PT) and interlaboratory comparison (hereinafter: ILC) are managed and used by «National Accreditation Body» SNCO (hereinafter: ARMNAB) for the purpose of assessing the technical skills of the testing, calibration, medical laboratories (hereinafter: laboratories), and where relevant, inspection bodies accredited and in the process of being accredited.

***Note: PT and ILC may be used in some types of inspection (for example, verification of measuring instruments) where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or by regulators.***

ARMNAB demands that the accredited laboratories, inspection bodies (if applicable) participate in PT, ILC or other comparisons. In the course of assessments and accreditation decision-making, the NAB shall take into account the laboratory’s participation in PT, ILC or other comparisons and the results obtained as those results serve as an important tool to assess the competence of the laboratory.

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# 2. Normative references

Only the latest publications of the documents cited without a date shall be applicable. The following documents are referred to in this document:

[1] GOST ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

[2] GOST ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

[3] GOST ISO/IEC 17043, Conformity assessment. General requirements for proficiency testing

[4] AST ISO/IEC 15189 Medical laboratories - Requirements for quality and competence

[5] GOST ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

[6] ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities

[7] EA-4/18 Guidance on the level and frequency of proficiency testing participation

[8] EA-4/21 INF:2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

[9] ‘‘Procedure on organizing interlaboratory comparative tests (interlaboratory comparisons)’’ EEC (Eurasian Economic Commission) Board decision N 12 of 26.01.2016.

# 3. Terms and definitions

The following terms and definitions are used in this document:

**proficiency testing (PT) -** evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

*NOTE - Proficiency testing is organized through PT providers.*

**proficiency testing scheme –** a proficiency test developed and implemented in one or several stages in a certain scope of testing, measurement, calibration, or inspection

**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

**level of participation -** the number of sub-disciplines that an organisation identifies within its scope, and therefore, the number of specific proficiency tests that should be considered for participation

**frequency of participation -** a frequency stipulated by the laboratory, specifying how often a laboratory shall participate in PT for the stipulated subdisciplines.

**subdiscipline (area of technical competence) -** field of expertise defined by a minimum of one measurement process, characteristic and product, for calibration laboratories – metrological sector, which are related.

***Example: testing of microbiological properties***

*Accredited testing activities performed by the laboratory:*

* *Enumeration of Escherichia coli in meat*
* *Enumeration of Salmonella in meat*
* *Enumeration of Escherichia coli in vegetables*
* *Enumeration of Salmonella in vegetables*
* *Enumeration of Escherichia coli in dairy products*
* *Enumeration of Escherichia coli in drinking water*
* *Enumeration of Escherichia coli in swimming pool water*

***Considerations for determinations of subdisciplines***

*For the enumeration of Escherichia coli, the laboratory identifies that it uses the same method for the testing of meat and vegetable samples. This method has been validated for the matrices of the two types of samples which the laboratory identifies as one subdiscipline.If that method is not applicable to dairy products, the laboratory uses a different method for those samples identifies one more subdiscipline.*

*For the enumeration of Salmonella, the laboratory uses a method different from the one used for the enumeration of Escherichia coli. The laboratory decided to identify one subdiscipline for the meat and vegetable matrices.*

*Although sampling and pre-treatment techniques are different for the enumeration of Escherichia coli in water, , the mentioned method (which is different to the method used for the food products) is used for both drinking water and swimming pool water, so the laboratory identifies these as one more subdiscipline.*

***Resulting subdisciplines from this exercise***

* *Enumeration of Escherichia coli in meat and vegetables*
* *Enumeration of Escherichia coli in dairy products*
* *Enumeration of Salmonella in meat and vegetables*
* *Enumeration of Escherichia coli in drinking water and swimming pool water*

The identification of the spheres of technical competence (subdiscipline), along with examples, is described in detail in the EA-4/18 document.

# 4. General rules

4.1 The NAB requires laboratories to have a documented procedure on the participation in PT schemes, ILC or other comparisons appropriate to the scope of accreditation, including the analysis of the obtained results, implementation of monitoring and taking relevant actions (e.g. corrective, improvement) as required.

4.2 The NAB requires laboratories to identify the subdisciplines within the scope of accreditation and the level and frequency of participation in PT, taking into account the risk-based approach (see EA-4/18), e.g.:

▪ the number of the performed measurements/tests/verifications

▪ the frequency of tests with different concentrations

▪ different calibration/verification interval numbers

▪ changes in the technical personnel

▪ the technical personnel’s experience and knowledge

▪ source of metrological traceability (availability of reference materials, samples, etc.)

▪ use of standard/non-standard methods

▪ method complexity and stability

▪ risks and opportunities associated with laboratory activities, particularly those which will prevent or reduce undesirable impacts and potential failures in the laboratory activities and will result in improvement

▪ method validation and/or verification scope etc.

4.3 The NAB stipulates the following minimum requirements for participation in PT (testing, medical lab.) / ILC (calibration, verification lab.):

a) before the accreditation or accreditation extension, the laboratory shall present evidence of participation in PT/ILC for at least one subdiscipline specified in the accreditation scope (guided by the risk-based approach), as well as evidence of its positive results, achieved within 3 years before submitting the application for accreditation, and shall prepare its plan (according to the form developed by the NAB) of PT/ILC participation during the accreditation cycle for all the subdisciplines specified in the accreditation scope,

b) or a contract, the provisions of which have not yet been implemented, but which has been concluded with the PT provider/ILC executer (in case of the first accreditation, extension of the scope of accreditation), according to which a PT/ILC shall be implemented by the end of the accreditation process (by the time a supplementary onsite assessment report is presented by the NAB),

c) once accredited, the laboratory shall participate in PTs at least once for each subdiscipline before the end of the accreditation cycle, and in case it is impossible to participate in it (due to a timeframe change by the provider or absence of the PT scheme), it shall participate in interlaboratory comparisons (ILC) and/or take other types of measures within the period stipulated by the plan (see point 4.9, EA-4/18, ILAC P9, EA-4/21),

d) when submitting an application for reaccreditation, the laboratory shall provide the results of the PT, ILC and/or other types of measures implemented for each subdiscipline based on the requirement of subpoint c) of point 4.3 and shall prepare the plan of PT participation for the next accreditation cycle.

4.4 There are some testing/calibration/verification scopes (e.g. periodic certification of gas cylinders, etc.) for which the PTs organized by the providers are missing, or there are few laboratories for the given scope, or there are impediments to the relocation of the samples (reference materials), etc. In those cases, the laboratory can demonstrate its technical competence by successfully completing interlaboratory comparisons with two or more laboratories (in accordance with the document EA-4/21). It is preferable to do it with the involvement of more than two laboratories to obtain accurate results.

4.5 If there is a reference laboratory for the given scope in the Republic of Armenia, the interlaboratory comparisons shall be performed/organized with/by that laboratory.

4.6 ARMNAB accepts the results of the following PT/ILC organizers:

- PT providers accredited or authorized by the Eurasian Economic Union (EAEU) member states. Laboratories performing activities within the frames of the technical regulation of the EAEU shall first participate in the PT schemes organized in the framework of the EAEU member states, and in their absence – in those by third countries;

- providers accredited or recognized (e.g., state-authorized) in line with the requirements of GOST ISO/IEC 17043-2013 [3] standard;

- national metrology institutes;

- independent organizations, associations that prove that they meet the requirements of the GOST ISO/IEC 17043 standard;

- organizations included on the EPTIS website https://www.eptis.bam.de/en/index.htm.

4.7 In case of any questionable or unsatisfactory results, the laboratory shall analyze them immediately, find the root causes and take relevant corrective/improvement actions, including the withdrawal of the implementation of the given test/calibration in the scope of accreditation until the elimination of the root causes and the completion of the required actions. The effectiveness of the actions taken shall be verified through another participation in the PT. The accredited laboratory shall immediately notify the NAB of the unsatisfactory results, actions taken and level of effectiveness.

4.8 Prior to planning participation in PT, ILC or other comparisons, the laboratory shall take into account the technical regulations, rules, and other documents relevant to its scope of activities for the entire accreditation cycle. The plan of participation in PT, ILC or other comparisons shall be updated regularly by the laboratory, especially in case of any change in personnel, methods, equipment. The plan, its compliance with the scope of accreditation and its implementation shall be assessed by the NAB during the first accreditation and each surveillance.

4.9 Laboratories should maintain records of analyzes performed to demonstrate unavailability of PT and/or ILC providers.

5. This policy shall be revised upon necessity.

**HISTORY OF REVISIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Edition** | **Amendment**  | **Amended points/word** | **Amended (previous) version** | **Signature of the person making the amendments**  |
| **No** | **Approval date** | **No** | **Approval date** |
| 1 | 01.01.2017 | 1 | 03.04.2018 | Add EA-4/21 INF:2018 document in points 1, 2, 4.4, 4.5  |  |  |
| 2 | 04.04.2022 |  |  | The entire text |  |  |
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