RULES ON PARTICIPATION IN PROFICIENCY TESTING AND/OR INTERLABORATORY COMPARISONS OTHER THAN PROFICIENCY TESTING

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1. SUBJECT MATTER AND SCOPE

The subject of this document is to define the ATCG policy regarding the participation of testing/calibration laboratories, medical laboratories, as well as inspection bodies and certification bodies for certification of products that perform tests as part of inspection or product certification procedures in proficiency testing (PT) and interlaboratory comparisons (ILCs) other than PT.

This document is intended for use by the abovementioned conformity assessment bodies (CABs) and for ATCG's staff, assessors and experts and decision makers.

The standards MEST EN ISO/IEC 17011, MEST EN ISO/IEC 17025 and MEST EN ISO/IEC 15189 prescribe the requirements for ensuring the validity of test results. They relate to procedures that can be carried out at the internal level in CABs (use of reference materials or quality control materials, functional checks of measuring and testing equipment, intermediate checks of equipment, repetition of testing/calibration using the same or different methods, etc.) as well as to external context through participation of CABs in PT/ILC schemes.

Participation in PT/ILC schemes is considered to be one of the most effective tool for monitoring the validity of test/calibration/measurement results as well as for confirming the competence of conformity assessment bodies (CABs). In that sense, this document defines the general policy, requirements and guidelines for participation in PT/ILC schemes applcable to both - accredited CABs and applicants for accreditation.

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

ATCG - Accreditation Body of Montenegro
EA - European co-operation for Accreditation
ILAC - International Laboratory Accreditation Cooperation EPTIS - European Proficiency Testing Information System
IRMM - Institute for Reference Materials and Measurements
CAB – Conformity assessment body

2.2. Definitions

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" (MEST ISO/IEC 17043)

Proficiency testing (PT) - "Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons" (MEST ISO/IEC 17043)
Note: Further information regarding the design of various proficiency testing schemes is provided in Annex A (Informative) of ISO/IEC 17043.

Laboratory - "A body that performs one or more of the following activities: testing, calibration, sampling, associated with subsequent testing or calibration that follows" (MEST ISO/ IEC 17025)

Medical laboratory – „Entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health“ (MEST ISO 15189)

PT/ILC item – „Sample, product, artefact, reference material, piece of equipment, measurement standard, object, image, data set or other information used for proficiency testing” (MEST ISO/IEC 17043 and EA-4/21 INF)

PT provider - „Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme" (MEST ISO/IEC 17043)

Participant – „Person or organization that undertakes activities related to proficiency testing and submits their results for performance evaluation by the proficiency testing provider" (MEST ISO/IEC 17043)

PT scheme – „Proficiency testing designed and operated in one or more proficiency testing rounds for a specified area of measurement, testing, calibration, examination, sampling or inspection" (MEST ISO/IEC 17043)

Small interlaboratory comparison (small ILC) – „An interlaboratory comparison organised by, and among seven or less laboratories" (EA-4/21 INF)

PT/ILC activity - Participation in proficiency testing or interlaboratory comparison other than proficiency testing

Sub-discipline - An area of technical competence defined by a minimum of one measurement technique, property and product, which are related

Level of participation - „The number of sub-disciplines that an organisation identifies within scope, and therefore the number of specific proficiency tests that should be considered for participation" (EA 4/18)

Frequency of participation - „The number of proficiency tests per unit of time, in which a laboratory participates for an activity as specified in their scope of accreditation" (EA 4/18)

External quality assessment (EQA) - „Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons" (MEST ISO 15189)

3. RELATIONSHIPS WITH OTHER DOCUMENTS

MEST EN ISO/IEC 17011:2018 - Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
MEST EN ISO/IEC 17025:2018 - General requirements for the competence of laboratories for testing/calibration.
MEST EN ISO 15189:2023 - Medical laboratories - Requirements for quality and competence
MEST EN ISO/IEC 17020:2013 - Conformity assessment - Requirements for the work of different types of inspection bodies
MEST EN ISO/IEC 17065:2020 - Conformity assessment - Requirements for bodies certifying products, processes and services
ISO/IEC 17043:2023 - Conformity assessment - General requirements for proficiency testing
EA 4/02 M:2022 - Evaluation of the Uncertainty of Measurement in Calibration
EA-4/21 INF:2019 - Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation
EA 4/18 G:2021 - Guidance on the level and frequency of proficiency testing participation
ILAC P9:01/2024 ILAC Policy for Proficiency Testing andor Interlaboratory comparisons other than Proficiency Testing

4. DESCRIPTION OF THE RULES

4.1 ATCG Policy

One of the elements by which CABs have to demonstrate the validity of their results is by comparison with results of other CABs, where such activities are available and appropriate. Participation in PT and/or ILCs other than PT, organised by competent providers is, for an accredited CAB, an integral part of the monitoring of the validity of its results.

Participation is applicable not only to laboratories, but also to CABs accredited to other standards performing testing and/or calibration activities as part of their accredited conformity assessment activities.

Note1: In this document, common term „laboratory“ will be used for testing laboratories, callibration laboratories, medical laboratories and other CABs performing testing and/or calibration activities as part of their accredited conformity assessment activities.

Note2: For medical laboratories term „EQA“ is used instead of „PT“

Note3: Examples of ILCs other than PT are given in:

- ISO/IEC 17043:2023 (Introduction points h), i), j), three types of ILCs are considered as ILCs other than PT as they consider in advance that the laboratories are competent and the purpose of the ILCs is not to assess the performance of the laboratory.
- ISO 15189:2022 (clause 7.3.7.3, point f)), ILCs other than PT are for example “participation in sample exchanges with other laboratories” or “ILCs of the results of the examination of identical IQC (internal quality control) materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material”

All accredited laboratories and applicants for accreditation shall participate in PT and/or ILC activities when available, appropriate and deemed necessary.

Participation in ILCs other than PT should only be envisaged when PTs are not available, and/or appropriate.

Laboratories shall investigate the availability of appropriate PT activities themselves, taking into account their suitability. When planning participation in PT activities, laboratories shall check that they are organized in accordance with the standard ISO/IEC 17043. ATCG's recommendation is to use the services of accredited PT providers who, by means of accreditation, have demonstrated that the proficiency testing is organized and conducted in competent manner. Laboratory shall have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT (see ILAC P9:01, Appendix A).

Note4: For information on available PT schemes, laboratories may use the EPTIS (European Proficiency Testing Information System) database as well as others databases within regional and international associations such as EA, ILAC, IRMM. On the ATCG website (www.akreditacija.me) links have been provided: www.eptis.bam.de; www.intercomparison.org; www.irmm.jrc.be.

Taking into consideration the outcome of the CAB’s risk assessment, applicants for accreditation and accredited CABs shall develop a participation plan in PT and/or ILCs other than PT (programme of PT/ILC activities) regarding their accreditation scope. The ATCG shall assess the PT/ILC participation programme to ensure that there is a representative and satisfactory participation in PT/ILC activities in respect to applicant scope before granting accreditation.

The ATCG shall also assess the justifications of the CAB’s alternative approaches when there are no available and appropriate PT and/or ILC’s other than PT to cover the applicant or accredited scope. The ATCG shall verify that the alternative approach implemented by the laboratory ensures the validity of the results.

Laboratories applying for accreditation, before submitting the application, shall at least once satisfactorily participate in appropriate and available PT and/or ILCs other than PT activity.

The recommended minimum participation of accredited laboratories in PT or ILCs other than PT is once for each major sub-discipline within the scope of accreditation during each accreditation cycle (4 years).

When applying for accreditation and before each surveillance assessment or reassessment, laboratories shall submit to ATCG the information end evidence on their participation in PT activities and/or ILCs other than PT by using the form *ZPA.04.01-1 Report on Participation in ILC/PT/EQA activities*. In case of unsatisfactory results, it shall also be necessary to submit to ATCG relevant records of the root cause analysis and undertaken corrective/preventive actions. Information provided to ATCG shall be considered as a risk factor, and may have an influence on ATCG assessment program.

Laboratories participating in PT sctivities and/or ILCs other than PT shall adhere to the instructions and deadlines defined by the provider. When relevant and applicable, uncertainty of measurement shall be calculated and presented in accordance with the guidelines provided in EA-4/02 M, Expression of the Uncertainty of Measurements in Calibration.

In case of small interlaboratory comparisons (at least three participants), as one of the alternatives to PT and/or ILC, the laboratories-organizers and the participant laboratories should perform their activities in accordance with the document EA 4/21 INF.

If there have been significant changes in the laboratory (change of equipment, key technical personnel, etc.), ATCG may request, when it deems necessary, re-confirmation of the technical competence of the laboratory by participation in relevant PT/ILC activities.

When a laboratory does not participate in available and appropriate PT or ILCs other than PT activities in accordance with the requirements of this document, or if appropriate actions have not been undertaken in case of unsatisfactory results, ATCG shall take appropriate actions (e.g. not grant accreditation, suspend or reduce accreditation, etc.).

Laboratories shall provide a written justification for not participating in available PT/ILC activities.

Laboratories shall evaluate the results of PT/ILC activities, make appropriate records, and take appropriate actions, when necessary. Specifically, in case when results are outside the limits of acceptability (with regards to the selected criteria depending on the nature of the work performed by the calibration/testing laboratory, e.g. En number, Z score), the laboratory shall take appropriate actions after carrying out root cause and extent analysis. ATCG shall assess the appropriateness and records on corrections/corrective actions.

4.2 Laboratory policies and procedures regarding PT/ILC activities

The laboratory shall have a policy and procedure for its PT/ILC enrollment.
Note: Besides harmonized standards, the obligation to participate in PT activities may also arise from regulatory requirements.

Laboratory shall develop the programme of PT/ILC activities for duration of accreditation cycle (period between two consecutive accreditation reassessments).

Laboratories should, based on the requested or granted scope of accreditation, determine the sub-disciplines, level and frequency of participation in PT/ILC activities consistant to its policy and procedure for PT/ILC enrollment.

When defining the programme of PT/ILC activities, laboratory should take into account factors such as:

- the degree to which other means are used to ensure the validity of the results;
- level of potential risks;
- specifics of requested or accredited technical areas and used methods/measurement techniques.

4.2.1 Criteria for determining sub-disciplines

It is recommended to use the guidelines given in EA-4/18 INF (Chapters 3, 4 and 5) bearing in mind that the cases listed in Chapter 5 are only examples of how a laboratory can approach the determination of sub-disciplines and should therefore not be considered as stringent and definite rules. When determining sub-disciplines, it is not recommended that different technical competencies be included in one sub-discipline (different qualifications, different training, use of different equipment, different knowledge and experience).

ATCG will assess the adequacy of identified sub-disciplines, levels and frequencies of participation in PT activities, for each laboratory individually.

The fact is that laboratories are not able to participate in PT/ILC activities for each testing/calibration method (i.e. for each each measurement technique and each property for each test/calibration item) within the scope of accreditation due to organizational and economic reasons, as well as due to unavailability of appropriate PT/ILC activities. Therefore, it is necessary for the laboratory to identify groups of sets of measurement techniques, properties and products in which the outcome of PT/ILC for one of these sets will be in direct correlation with other sets of measurement techniques, properties and products within the group. These groups of sets of measurement techniques, properties and products represent a sub-discipline.

When defining sub-disciplines, it is necessary to take into account that in one sub-discipline there are no measuring techniques, properties or testing/calibration items from different areas of testing/calibration.

When determining sub-disciplines, a stepwise approach can be used, starting from the measurement technique, through the property to the test item, because it is more likely that there will be several items or properties associated with one measurement technique.

Therefore, sub-disciplines can be determined according to:

a) measurement technique: it is possible (but not usual) to include different measurement techniques in the same sub-discipline;
b) property that is measured, determined or identified: it is possible to include more than one property (characteristic) in the same sub-discipline;
c) test items: it is possible to include different items in the same sub-discipline provided that matrices, subjects or materials included are of equivalent nature.

4.2.2 Criteria for determining the level and frequency of participation in PT/ILC activities

Laboratory should determine the level and frequency of participation in PT/ILC activities, after careful analysis of the use of other means of quality assurance of validity of test/calibration results, which include, but are not limited to:

- use of certified reference materials;
- comparison of analysis by independent techniques;
- participation in method development/validation;
- use of internal quality control measures
- use of control charts;
- other comparisons (eg laboratory analysis).

Also, when determining the level and frequency of participation in PT/ILC activities, laboratory must take into account the level of risk for the field of testing / calibration / medical testing, which includes:

- number of tests/calibrations undertaken;
- changes in the composition of technical staff;
- experience and education of technical staff;
- source of traceability (e.g. availability of reference materials, national standards, etc.)
- known uncertainty of measurement;
- significance and use of testing/calibration results (e.g. forensic science represents an area requiring a high level of assurance);
- if statements of conformity are required and changes in related specifications are made;
- risks and opportunities associated with the laboratory activities, in particular those that will prevent, or reduce, undesired impacts;
- extent of validation and/or verification of methods.

It should be noted that the level and frequency of participation in PT/ILC activities may be also prescribed by legislation and in that case the laboratory shall adhere to it.

5. FORMS

Ord. No.	Title	Reference	Issue/date	Storage medium	Retention period
1.	Report on ILC/PT/EQA activities	ZPA.04.01-1	18.04.2022.	Register-paper form	regularly updated