АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PA02

RULES FOR PARTICIPATION IN PROFICIENCY TESTING PROGRAMS AND INTER-LABORATORY COMPARISONS

Any differences between the Serbian and English versions of this document are not intended, but if in doubt, the Serbian version should be consulted.

1. SCOPE

These Rules shall stipulate the policy of the Accreditation Body of Serbia (ATS) as regards the participation of testing/calibration laboratories and medical laboratories in inter-laboratory comparisons (*interlaboratory comparison-ILC*) and programs for proficiency testing (*proficiency testing-PT*), as well as the ATS procedure regarding the adopted policy. Inspection bodies and certification bodies certifying products that perform analytical tests themselves as part of the process of inspection activities or certification of products and that influence the results of the inspection or certification, shall also fully adhere to the Rules, as well as proficiency testing providers where applicable.

According to the requirements of SRPS ISO/IEC 17025 conformity assessment bodies (CAB) shall put in place a procedure to monitor the quality of test/calibration results by using appropriate methods established by the standard.

Participation in proficiency testing schemes or inter-laboratory comparisons other than proficiency testing enables a laboratory to prove its technical competence to its clients, ATS, and other interested parties.

2. REFERENCE DOCUMENTS AND DEFINITIONS

2.1 Reference Documents

- SRPS ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories;

- SRPS EN ISO 15189:2014, Medical laboratories – Requirements for quality and competence;

- SRPS ISO/IEC 17020:2012, Conformity assessment – Requirements for the operation of various types of bodies performing inspection;

- SRPS EN ISO/IEC 17065:2016, Conformity assessment – Requirements for bodies certifying products, processes and services;

- SRPS ISO/IEC 17011:2018, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies;

- SRPS ISO/IEC 17043:2011, Conformity assessment – General requirements for proficiency testing;

- EA-4/21 INF:2018, Guidelines for the assessment of the appropriateness of small inter-laboratory comparison within the process of laboratory accreditation

- EA-4/18 INF:2010, Guidance on the level and frequency of proficiency testing participation;

- ILAC-P9:06/2014, ILAC Policy for Participation in Proficiency Testing Activities.

2.2 Definitions

For the purposes of this document, the following terms shall have the following meanings:

Proficiency testing - PT (*proficiency testing*-PT)	evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.
Inter-laboratory comparison	organization, performance and evaluation of testing/calibration on the same or similar items

(*interlaboratory comparision*-ILC)	performed by two or more laboratories in accordance with predetermined conditions.
PT activity	participation in proficiency testing or other inter-laboratory comparisons other than proficiency testing.
Property	the quantity being measured (e.g. sulfur concentration, fat content, length, hardness).
Product	the sample being tested/calibrated (e.g. soil, water, concrete, vegetables, serum, thermometer, manometer).
Sub-discipline	an area of technical competence defined by a minimum of one measurement technique, property and product.
Level of participation	the number of sub-disciplines that an organization identifies within its scope, and therefore the number of specific proficiency tests that should be conducted.
Frequency of participation	the number of participation in PT activities for a particular sub-discipline in a given time period.

3. ATS POLICY

All laboratories that applied for accreditation and laboratories that are accredited (term "laboratories“ refer to all CAB specified in the first paragraph of art. 1 of these Rules) have to participate in available and adequate PT activities necessarily before applying for initial assessment, reassessment and extension of the scope of accreditation, if the existing participation results are not applicable to the required extension of the accreditation scope.

Laboratories are obliged to investigate **by themselves** whether certain PT activities are available and therefore appropriate. *When planning participation in PT activities, laboratories shall check whether they are organized in accordance with ISO/IEC 17043. ATS recommends that they use services of accredited PT providers that, by means of their accreditation status, prove that proficiency testing activities are organised and implemented in accordance with ISO/IEC 17043 standard.*

Notice: laboratories can use EPTIS (European Proficiency Testing Information System) database of PT activities. On the ATS website (www.ats.rs) a link to the EPTIS database is established - (www.eptis.bam.de).

Laboratories seeking accreditation are obliged to successfully participate at least once in appropriate and available PT activities prior to applying for accreditation.

Laboratory is obliged to participate in available and appropriate proficiency testing schemes (organized by a domestic/foreign provider). If it is confirmed that they are not available or appropriate, participation in inter-laboratory comparisons other than proficiency testing is accepted. Additionally, if it is confirmed that there are no available and appropriate proficiency testing schemes, the satisfactory result of laboratory participation in bilateral comparison with the national metrology institute (Directorate of measures and precious metals – DMDM or NMI of other

country) if it has CMC (Calibration and Measurement Capabilities) for the said field of calibration in BIPM key comparison database *(www.kcdb.bipm.org/bipm-kcdb/appendixC)* shall be considered acceptable.

Comparison with NMI that successfully participated in a key or supplementary comparison for the relevant calibration area in the BIPM database of key and supplementary comparisons (*https://kcdb.bipm.org/AppendixB/KCDB*) is considered acceptable.

Notice: Comparison with a designate institute (Designated Institutes (DI)) that has a published CMC a given area of calibration in the BIPM database of key comparisons or successful participation in a key or supplimentary comparison for the corresponding area of calibration in the BIPM database of key and supplementary comparisons is also considered acceptable.

The minimum participation of accredited laboratories in the available proficiency testing is once for each major sub-discipline within the scope of accreditation for the period of validity of the accreditation (4 years), except in cases when it is regulated by law or other relevant regulations (e.g. for medical laboratories).

Before being granted accreditation or before reassessment or surveillance, as well as the requested extension of the scope of accreditation and after the report has been sent by the organiser of the program, laboratories are obliged to submit to ATS the information about their participation in PT schemes by using the model Report on Participation in PT Activities that is attached as Annex 1 (the data is submitted in the form of an excel file).

In case of unsatisfactory results, it will also be necessary to submit relevant records of the root cause analysis and undertaken actions relating to it.

Laboratories participating in PT activities shall adhere to the instructions and deadlines defined by the organizer. Uncertainty of measurement must be calculated and presented in line with the guidelines provided in EA-4/02 M, Expression of the Uncertainty of Measurements in Calibration.

Laboratories shall provide records of its rationale for not participating in available PT activities.

Laboratory policy of participation in PT activities must be adequately described in internal laboratory documents.

Laboratories must evaluate PT results, keep adequate records, and undertakeactions where necessary.

Where a calibration laboratory obtains results that are considered to be outside the acceptable range (in relation 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 is obliged to undertake adequate actions that shall be preceded by a root cause analysis. ATS shall assess the appropriateness and documentation of the measures taken to eliminate the causes of the deviation of the measurement results.

In case of significant changes in the laboratory (new equipment, turnover of key technical staff, etc.), ATS can, where necessary, require a new proof of technical capacity which will entail laboratory participating in PT activities.

When a laboratory fails to participate in available and adequate PT activities in line with the requirements of these Rules or if adequate actions were not undertaken in case of unsatisfactory results, ATS shall undertake appropriate actions (e.g. will not grant accreditation, suspend or reduce accreditation scope or withdraw accreditation in full).

Furthermore, mandatory participation in PT activities can be stipulated by the law.

4. DETERMINATION OF SUB-DISCIPLINES, LEVEL, AND FREQUENCY OF PARTICIPATION IN PT SCHEMES

Laboratories should depending on the scope of accreditation, identify sub-disciplines, level and frequency of participation in PT activities as part of their PT Programme. This Programme shall be reviewed on an annual basis as part of management review activities. Guidelines to be used to determine sub-disciplines, level and frequency of participation in PT schemes can be found in EA-04/18 INF: 2010 and APLAC PT 006.

ATS shall evaluate the adequacy of identified sub-disciplines, level and frequency of participation in PT activities.

4.1 Criteria for determining sub-disciplines

It is a known fact that it is not feasible for laboratories to participate in PT activities for organisational and economic reasons, as well as due to unavailability of adequate PT schemes – proficiency testing, in case of each testing/calibration method (i.e. for each measurement technique and each property for each test/calibration product) from their scope of accreditation.

Therefore, laboratories must identify groups of sets of measurement techniques, properties and products where the PT outcome for one of those sets can be directly correlated to other sets of measurement techniques, properties and products contained within the group. These groups of sets of measurement techniques, properties and products are termed sub-disciplines.

A sub-discipline may contain more than one measurement technique, property or test/calibration product as long as equivalence and comparability can be demonstrated.

The first consideration for a laboratory, when determining a sub-discipline, is that it should generally not contain measurement techniques, properties, or test/calibration products from different areas of testing/calibration.

When determining a sub-discipline, it may be helpful to consider a stepwise approach working up from measurement technique through properties to products because it is more likely that there will be several products or properties associated with one measurement technique.

4.2 Criteria for determining level and frequency of participation in PT activities

After a careful analysis of the use of other ways ensuring trust in the quality of testing/calibration results, laboratories shall define the level and frequency of participation in PT activities including, although not limited to the following:

- use of certified reference materials;

- comparison of analysis results by independent techniques;

- participation in method development/validation;

- use of control charts;

- other comparisons (e.g. analysis on blind samples within the laboratory).

Furthermore, when determining the level and frequency, laboratories shall take into consideration the level of risk for the area of testing/calibration by considering:

- number of tests/calibrations performed;

- turnover of technical staff;

- experience and knowledge of technical staff;

- source of traceability (e.g. availability of reference materials, national standards);

- known uncertainities of measurement;

- significance and final use of testing/calibration data (e.g. forensic test involve a high level of risk).

The level and dynamics of participation in proficiency testing schemes, i.e. PT activities shall be regularly reviewed and adjusted in relation to the scope of accreditation (including legislation, identified and evaluated risks, and other parameters that may affect the level and dynamics of participation, about which appropriate records are kept), in order to maintain confidence in the validity of the results.

5. ANNEXES

Annex 1**:** form entitled Report on Participation in PT activities – *it is filled in the form of an excel table with the content as given in the above form*

REPORT ON PARTICIPATION IN PT ACTIVITIES

Name of the CAB		Accreditation number *(where applicable)*	
Address			

Year *(start of activities)*	Област ПТ активности			PT/ILC/EQA provider	Name of the PT/ILC/EQA	Final PT/ILC/EQA Report (date)	No of participants	Results (e.g. z-score, En-number)	Actions undertaken *(link to the ref. no. of internal document)*
	Test/calibration item Product	Testing/ Calibration area	Property (parameter)						

Acronyms:
PT - proficiency testing
ILC - interlaboratory comparison
EQA - external quality assessment