АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PA02

RULES FOR THE PARTICIPATION IN INTER-LABORATORY COMPARISONS AND PROFICIENCY TESTING SCHEMES

Reviewed by: Radivoje Nikoličić Quality Manager (QM)	Approved by: Prof. Aco Janićijević, PhD Acting Director

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

Table of Contents: Page:

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 (ILC) and proficiency testing (PT) schemes, and the ATS activities related thereto, as well as ATS procedure regarding the adopted policy. Inspection bodies and certification bodies certifying products that perform analytical tests itself 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 for the Participation in Inter-laboratory Comparisons and Proficiency Testing Schemes.

Pursuant to the requirements of SRPS ISO/IEC 17025, laboratories shall put in place a procedure to monitor the quality of test/calibration results obtained when performing internal quality control (use of certified reference materials, replicate tests or calibrations using the same or different methods, etc.) and external quality control (participation in proficiency testing schemes or other inter-laboratory comparisons).

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

2. REFERENCE DOCUMENTS AND DEFINITIONS

2.1 Reference Documents

- SRPS ISO/IEC 17025:2006 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 17011:2007, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies;
- SRPS ISO/IEC 17043:2011 Conformity assessment - General requirements for proficiency testing;
- EA-03/04 G, Use Proficiency Testing as a Tool for Accreditation in Testing;
- EA-04/18 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	evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons
Inter-laboratory comparison -ILC	organisation, performance and evaluation of testing/calibration on the same or similar items performed by two or more laboratories in accordance with predetermined conditions
PT activity	participation in proficiency testing or other inter-laboratory comparisons
Property	The quantity being measured (e.g. sulphur concentration, fat content, length, hardness)
Product	The item that the measurement technique is being applied to (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 organisation identifies within its scope, and therefore the number of specific proficiency tests that should be conducted
Frequency of participation	This is how often a laboratory determines that it needs to participate in PT activities for a given sub-discipline

3. ATS POLICY

Laboratories that are accredited or seeking accreditation are expected to participate in available and adequate PT activities.

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 PT activities – proficiency testing are organised 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 standard.

ATS shall regularly inform laboratories about PT activities – proficiency testing that are organised within the EA and within APLAC (Asia Pacific Laboratory Accreditation Cooperation) if it receives information thereof. *Furthermore, laboratories can use EPTIS (European Proficiency Testing Information System) database of PT activities. A link to the EPTIS database (www.eptis.bam.de) was published on the ATS website (www.ats.rs).*

Laboratories seeking accreditation are obliged to successfully participate at least once in appropriate and available PT activities prior to applying for accreditation. ATS shall not grant accreditation to testing laboratories if they have not successfully participated at least once in appropriate and available PT activities.

If there are no available PT activities – proficiency testing for a specific field of calibration, 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 a CMC (Calibration and Measurement Capabilities) published in the BIPM key comparison database *(www.kcdb.bipm.org/bipm-kcdb/appendixC)* for the said field of calibration shall be considered acceptable.

Accredited laboratories should participate at least once in available PT activities – proficiency testing for every bigger sub-discipline within a field of accreditation scope during the accreditation validity period (4 years).

Before being granted accreditation or before reassessment or surveillance assessment and after the final report has been sent by the organiser of the scheme, 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.

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

Laboratories participating in ILCs shall adhere to the instructions and deadlines defined by the organiser. 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.

For those testing and calibration areas where there are no available PT activities laboratories must prove their competence in a different way (e.g. by using certified reference materials, replicate tests or calibrations using the same or different methods, etc.) or internal quality control.

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 undertake corrective and/or preventive actions where necessary.

Where a calibration laboratory obtains results that are considered to be outside the acceptable range (|En| > 1), the laboratory is obliged to undertake adequate actions that shall be preceded by a root cause analysis. It is the responsibility of ATS to assess the undertaken documented corrective actions ensuring elimination of the cause of results that are outside the acceptable range.

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's participation 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. suspend or reduce accreditation scope or withdraw accreditation in full).

Furthermore, mandatory participation in PT activities can be stipulated by 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 TA and APLAC PT 006.

ATS shall evaluate 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 schemes for organisational and economic reasons, as well as due to unavailability of adequate PT activities – 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, it is mandatory for laboratories to identify groups of sets of measurement techniques, properties and products where the proficiency testing - PT outcome for one of those sets can be directly correlated to the other sets of measurement techniques, properties and products contained

within the group. These groups of sets of measurement techniques, properties and products are termed a *sub-discipline*.

A sub-discipline, as defined above, 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 different 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. This is 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 – proficiency testing 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 uncertainties of measurement;
- significance and final use of testing/calibration data (e.g. forensic tests involve a high level of risk).

Level and frequency of participation in PT activities can be stipulated by law and in that case laboratories are under obligation to implement the said level and frequency requirements.

5. ANNEXES

- Annex 1**:** Form entitled Report on Participation in PT Activities

REPORT ON PARTICIPATION IN PT ACTIVITIES

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

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

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