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Policy

PL - 23

SNAS POLICY ON PARTICIPATION IN PROFICIENCY TESTING

Approved by: **Mgr. Martin Senčák**
Director

PURPOSE:

This document defines the SNAS policy on participation of laboratories, and where relevant, also of inspection bodies in the proficiency testing.

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By coming into force of this PL expired the validity of PL-23 from **01.07.2021.**

1 POLICY

1. SNAS assesses the fulfillment of requirements of the standards ISO/IEC 17025 for testing and calibration laboratories, ISO 15189 for medical laboratories and if it is relevant ISO/IEC 17020 for inspection bodies and these standards require that laboratories, and if appropriate inspection bodies, have to have a system for assurance of quality of test and/or calibration results and within this system they participate in proficiency testing (external quality assessment) or in other inter-laboratory comparisons. SNAS requires laboratories to participate in regular proficiency testing (PT) / interlaboratory comparisons (ILC) before and after accreditation .

2. Where it is available, SNAS requires for the specific areas of technical activities of inspection bodies the participation in proficiency testing or in other appropriate mutual comparisons. It is mainly for the activities related to measurement, testing and/or calibration.

   Note:
   Proficiency testing (PT = accredited MLPM, EHK, MPS)
   evaluation of partícipant performance against pre-astablished crítería by means of interlaborJory comparísons (ISO / IEC 17043: 2010, 3.7). PT is organized by a competent PT provider accredited to the requirements of the ISO / IEC 17043 standard

   Interlaboratory comparison (ILC = non accredited MLPM, MP, EHK)
   Organízation, performanoe and evaluaUon of measurernents or tests on the same or similar items by two or more laboratories in accordance with predeterrnined conditions (ISO / IEC 17043: 2010, 3.4). ILC is organized by an not accredited provider which meets the relevant requirements of ISO / IEC 17043.

3. Laboratories and, where relevant, IO shall participate in PT programs organized by accredited (competent) PT provider, if they are organized in a given sub-area. This also needs to be taken into account in the strategies of participation in the PT and to harmonize its participation with the plan submitted by the PT provider.

4. SNAS supports the active participation of laboratories in regional PT / ILC organized by EA, BIPM, ILAC, APLAC, or AB of other countries in accordance with EA regulations

5. If the accredited PT organizer does not organize the required PTs in the area, or if the PTs are not available, the CAB shall participate in the ILC. ILCs are considered acceptable if they meet the essential requirements regarding the impartiality and confidentiality of the laboratory performance assessment as well as relevant requirements of ISO / IEC 17043. The CAB is required to document that the PT provider did not organize PT or these were not available in the subarea. The same requirements apply to the PT provider who has not demonstrated competence by a third party

6. PT are considered as an important tool to demonstrate the competence and keeping the

quality of technical activities of laboratories (where relevant also for inspection bodies). For this reason, laboratories and, where relevant, also inspection bodies, which are in the accreditation process or have already been accredited, have to have developed the strategy of participation in appropriate PT, which takes into account the risks and opportunities of activities of CAB and other processes for quality control and quality assurance of technical activities. Strategy of participation in PT is elaborated for one accreditation cycle and has to be reviewed and updated. The strategy of participation in PT is reviewing by SNAS during each assessment.

7. Submission of plans for participation in PT is required by SNAS from accredited laboratories and, where relevant, from accredited inspection bodies. An overview of the results of participation with the evaluation from the for the previous period is also required.

8. The PT / ILC results of a participant who is a program provider or reference laboratory in a given PT program cannot be used as evidence of PT performance. If the independent coding results is secured, laboratory that is linked with the organizers can participate at this comparative program and laboratories send to organizers encrypted results to evaluate

9. SNAS in case the relevant PT program is not organized by accredited PT accepts the results of participation also in other types of ILC, which primary purposes are different from those of PT, such as:

   - determination of the characteristics of reference materials,
   - comparison of small amounts of laboratories/inspection bodies based on their own initiative,
   - supporting the declaration of equivalence of measurements of national metrology institutes, etc.

   In such cases it is needed to have clearly pre-defined criteria and procedures, based on which the results of ILC will be evaluated in order to be acceptable for PT/ILC purposes. All such organized ILCs which will also be used for purposes of PT/ILC, have to meet relevant requirements of standard ISO/IEC 17043.

10. Witnessing of a test or measurement by members of an assessment team during an assessment is not considered to be a form of PT / ILC aimed at monitoring of laboratory performance and does not replace PT / ILC performed by a provider accredited to ISO / IEC 17043.

11. Calibration and testing laboratories, before granting the accreditation and extension of accreditation have to participate in external quality assessment (proficiency testing, inter-laboratory comparison) in each sub areas of specification of their activities that they are applying for accreditation and achieve satisfactory results.

12. Before granting the accreditation and extension of accreditation, the medical (clinical) laboratories have to participate in external quality assessment (proficiency testing, inter-laboratory comparison) in each sub areas of specification of their activities that they are applying for accreditation and achieve satisfactory results.

13. Before granting the accreditation and extension of accreditation, the inspection bodies, where relevant, laboratories have to participate in external quality assessment (proficiency testing, inter-laboratory comparison) in each sub areas of specification of their activities that they are applying for accreditation and achieve satisfactory results

14. After granting the accreditation, all types of laboratories and, where relevant also inspection bodies, during one accreditation cycle, have to participate PT/ILC and achieve satisfactory results in each sub-activity which is defined in their "Scope of accreditation".

    Note: the general guideline for defining the sub-fields of scope of accreditation can be found in MSA-L/14.

15. When SNAS is assessing of competence of laboratories or, where relevant, also inspection bodies, it takes into account the results of participation in an appropriate PT. If appropriate PTs are not available, it takes into account participation in suitable ILC organized by accredited providers of proficiency testing and also the results of PT/ILC organized by non-accredited providers. In this case it has to be demonstrable that by planning, preparation, execution and evaluation of PT/ILC the relevant requirements of ISO/IEC 17043 were fulfilled.

16. During every on-site assessment SNAS verifies the results of participation of laboratories PT/ILC in terms of covering the whole scope of accreditation. If accredited laboratory or inspection body (where relevant) does not participate PT/ILC for some of identified sub-fields in one accreditation cycle and these PT/ILC were available a, SNAS suspend the accreditation for given technical activity from the scope of accreditation of CAB.

17. If PTs are not available, the CAB shall participate in an ILC. These include e.g. interlaboratory comparison (also bilateral comparison) by the competent provider PT (accredited), by the organizer ILC (non-accredited).

18. If PTs / ILCs are not available (feasible), the laboratory shall ensure quality control by other appropriate procedures.

19. In the case the regulator in the regulated area orders participation in the ILC with an unaccredited organizer, SNAS will take into account whether an accredited organizer was available in the given area. If it is not available, SNAS will verify that the organizer meets all the requirements set out in point 20 of this policy.

20. The laboratory shall notify SNAS in advance of its participation in the ILC, at the same

time it send the following documented information:

a. ILC program
b. The ILC provider
c. Purpose of ILC (eg methods and procedures)
d. detailed description of statistical analysis of results (in case of several participants)
e. Procedure used to determine reference values (in case of several participants)
f. Instruction for participants
g. Criterion of acceptability of results.
h. Number of participants
i. the term of ILC realization
j. Reference laboratory, if any
k. Person / CAB responsible for evaluation
l. Method of evaluation

After ILC completion, the laboratory shall send SNAS results of participants, statistical data, range of acceptable results and Report of the ILC evaluation

21. In the case of unsatisfactory participation in PT/ILC for all or some fields of the scope of accreditation, SNAS checks whether the laboratory (inspection body, where relevant) analyzed the causes, range of unsatisfactory participation, took appropriate and effective corrective actions In the case of recurrent unsatisfactory participation in PT/ILC for an appropriate parameter/characteristic, in accordance with the situation SNAS suspend of validity of accreditation in corresponding scope..

22. SNAS requires the participation of laboratories and inspection bodies in the relevant PT/ILC, where it is required by regulators and stakeholders/interested parties.

23. SNAS publishes the available PT/ILC on its website (www.snas.sk) and, where it is possible, available and appropriate, invites, eventually nominates laboratories and inspection bodies (where relevant) to participate in PT organized by EA, ILAC, APLAC and in other PT/ILC organized at national and international level.

2 RELATED DOCUMENTS

ISO/IEC 17011	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories.
ISO 15189	Medical laboratories - Requirements for quality and competence.
ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection.
ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing.
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities
MSA-04	Procedure for accreditation.
MSA-06	Responsibilities of SNAS and conformity assessment body.

MSA-L/14	Guideline for determination of the level and frequency of participation in PT.