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Policy

PL - 23

SNAS POLICY ON PARTICIPATION IN PROFICIENCY TESTING

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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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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 should participate in proficiency testing (external quality assessment) or in other appropriate inter-laboratory comparisons. Where it is possible, accessible and appropriate, SNAS requires, that laboratories before and after granting the accreditation regularly participate in such testing/comparisons.

2. Where it is possible, available and appropriate, 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: For the purposes of this document, the term proficiency testing (PT) means also external quality assessment programs (medical laboratories) and the other appropriate inter-laboratory comparisons (MP), which results can be used for the evaluation of the competence of the laboratory technical activities and, where relevant also of the inspection body technical activities.

3. PT are considered as an important tool to demonstrate the competence and keeping the quality of technical activities of laboratories and inspection bodies (where relevant). 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 of activities of conformity assessment bodies and other processes for quality control and quality assurance of technical activities. This strategy is elaborated for one accreditation cycle and has to be reviewed and if it is necessary it should be updated at least once a year. The strategy of participation in PT is reviewing by SNAS.

   Note: the general guidelines for drawing up the strategy of participation in PT can be found in MSA-L/14.

4. Submission of annual plans for participation in PT in the corresponding calendar year 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 previous calendar year is also required.

5. SNAS accepts the results of participation also in other types of comparison, which primary purposes are different from those of PT, such as:

   - comparisons conducted to evaluate the performance characteristics of measuring/testing/calibration methods,
   - determination of the characteristics of reference materials,

- comparison of two or more 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 MP will be evaluated in order to be acceptable for PT purposes. All such organized MPs which will also be used for purposes of PT, have to meet relevant requirements of standard ISO/IEC 17043.

6. Calibration laboratories, before granting the accreditation have to demonstrate the competence by acceptable results of proficiency testing or by comparison measurement in each field of quantities specified in implemented strategy of participation in PT or by the results of a measurement audit during the assessment or by the results of indirect comparison measurements determined by SNAS.

7. Before granting the accreditation, the testing laboratories have to participate in proficiency testing or an appropriate inter-laboratory comparison in one of the fields of specification of their activities that they are applying for accreditation and achieve satisfactory results, if such comparisons are organized, available and appropriate.

8. Before granting the accreditation, the medical (clinical) laboratories have to participate in external quality assessment (proficiency testing, inter-laboratory comparison) in each of the fields of specification of their activities that they are applying for accreditation and achieve satisfactory results, if such comparisons are organized, available and appropriate.

9. Inspection bodies, where relevant, have to participate in proficiency testing or an appropriate comparison, in one of the fields of specification of activities, that they are applying for accreditation and achieve, if such comparisons are organized, available and appropriate.

10. After granting the accreditation, all types of laboratories and, where relevant also inspection bodies, during one accreditation cycle, have to participate in proficiency testing or in other appropriate comparisons and achieve satisfactory results in each sub-activity which is defined in their "Scope of accreditation", if such comparisons are organized, available and appropriate.

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

11. 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 or MP which are organized by accredited providers of proficiency testing and also the results of PT/MP organized by non-accredited providers. In this case it has to be demonstrable that by planning, preparation, execution and evaluation of PT/MP the relevant requirements of ISO/IEC 17043 were fulfilled.

12. During every on-site assessment SNAS verifies the results of participation of laboratories in proficiency testing or other inter-laboratory comparisons in terms of covering the whole scope of accreditation. If accredited laboratory or inspection body (where relevant) does not participate PT/MP for some of identified sub-fields in one accreditation cycle and these PT/MP were available and appropriate, SNAS can suspend the accreditation for given technical activity from the scope of accreditation of the body. In the case of unsatisfactory participation in PT/MP for all or some parameters/characteristics of the scope of accreditation, SNAS checks whether the laboratory (inspection body, where relevant) analyzed the causes of such a situation, took appropriate and effective corrective actions and did activities, which removed the problem. If this was not carried out and there are no relevant reasons for that, SNAS will suspend the validity of accreditation in corresponding scope. In the case of recurrent unsatisfactory participation in PT/MP for an appropriate parameter/characteristic, in accordance with the situation SNAS will consider the suspension of validity of accreditation in corresponding scope. Various factors are taken into account, such as other outputs from quality assurance and quality control system, the way of organization and evaluation of PT/MP, the total results of PT/MP, the results achieved in the related parameters/characteristics, etc.

13. SNAS requires the participation of laboratories and inspection bodies in the relevant PT/MP, where it is required by regulators, the representatives of appropriate industrial and technical sectors, regional organizations/associations and stakeholders/interested parties.

14. SNAS publishes the available PT/MP 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/MP 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.