SNAS SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA
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**Policy**

**PL–07**

# SNAS POLICY ON ACCREDITATION OF LABORATORIES

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

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**PURPOSE:**

**This document determines SNAS policy on accreditation of laboratories.**

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Date of elaboration: **31.07.2018**

Verified by: **Ing. Ľudmila Bittnerová**

By coming into force of this PL expired the validity of **PL-07** from 10.05.2018.

# 1 SNAS POLICY ON ACCREDITATION OF LABORATORIES

1. At the assessment of the competency of laboratories to perform testing and/or calibration SNAS in general assesses meeting of the ISO/IEC 17025 Standard provisions and is governed by relevant politics and Methodical Guidelines for accreditation issued by SNAS.

2. Laboratories providing services in the field of clinical (medical) examinations (for the purpose of providing information for the diagnosis, management, prevention and treatment of disease - more detail see cl. 3.11 of ISO 15 189: 2012), SNAS generally assesses conformity with the requirements of the current version of ISO 15189 and is guided by relevant policies and methodological guidelines for accreditation issued by SNAS.

3. Accreditation Certificate number (X-xxx) form letter abbreviations X expressing scope of accreditation and a three-digit number xxx.

4. If the calibration laboratory granted accreditation to ISO/IEC 17025, issued accreditation certificate has identified scope of accreditation by the letter K. In the SNAS list of accredited CAB, it will be referred to as calibration laboratory.

5. If accreditation according to ISO/IEC 17025 is granted for testing laboratory, certificate has identified scope of accreditation by the letter S. In the SNAS list of accredited CAB, it will be referred to as testing laboratory.

6. If accreditation according to ISO 15189 is granted for medical laboratory, certificate has identified scope of accreditation by the letter M. In the SNAS list of accredited CAB, it will be referred to as medical laboratory.

7. Laboratories providing services in the field of medical examinations that do not comply with the definition in cl. 3.11. ISO 15 189: 2012 and whose competence is assessed according to ISO / IEC 17025: 2005 shall proceed in accordance with PL-46.

8. Laboratories providing services in the field of medical investigations, which meet the definition in Art. 3.11. ISO 15 189: 2012 and whose competence is currently assessed according to ISO / IEC 17025: 2005 shall notify SNAS in writing by 31.12.2018 within what date they submit application for accreditation according to ISO 15 189: 2012. Such deadline must not be later than 30.06.2019.

9. SNAS accredits also laboratories which develop or modify and validate methods for testing and calibration and doing this is governed by provisions of the Standard ISO/IEC 17025 or ISO 15189 and Policy PL-21.

10. Testing laboratories providing emissions from stationary sources measurement shall fulfill requirements of ISO/IEC 17025 as well as current version of CEN/TS 15675.

11. In all relevant sectors of testing, calibration or examination and it is recommended to fulfil the requirements of the ISO/IEC 17025 or ISO 15189 standards according to specification in ILAC, EA and/or application documents for ISO/IEC 17025 and/or ISO 15189 issued as international standards or documents issued by recognized international organizations.

12. Persons applying for accreditation in the field of testing or calibration and simultaneously seeking for notification or authorization and a condition to reach them is accreditation, shall meet the requirements for notified or authorized persons (PL-10). The assessment of both systems (accreditation and notification/authorization) is performed in one common process if it is agreed with the relevant authority (notification/authorization).

13. SNAS consistently pays attention to the applicant competency in the field of testing, examination and calibration and keeping principles of impartiality, openness, objectivity and non-discrimination. Policy and procedures of the applicant shall take into account all factors which could affect his competency, impartiality and integrity (ownership relations and interests, organizational aspects, decision procedures, financial matters, staff etc.).

14. All types of laboratories prior to granting accreditation and during the validity of accreditation shall participate on proficiency testing schemes to have possibility to evaluate the competence of laboratory to perform its technical activities, if such comparisons are organized and are accessible. SNAS is following its policy PL-23 for evaluation of the participation of laboratories on PT.

15. As an applicants for accreditation can appear:
    a) laboratories performing testing, examination or calibration activities, being independent legal or physical persons;

    b) physical or legal person which besides other activities deals also with testing, examination or calibration,

    c) persons or organizations seeking authorization or notification related to testing, examination or calibrations condition of which is accreditation granting.

16. Laboratories which are part of organization performing also other activities than testing or calibrations have to demonstrate fulfilling conditions of impartiality and objectivity; it means to demonstrate that other performed activities do not compromise tests, examinations or calibrations results.

17. CABs applying for multidisciplinary accreditation within which is also testing, examination or calibration performed, shall meet, requirements specified in relevant standards and documents (for example for persons performing certification or inspection), as well as requirements which are specific for ISO/IEC 17025:2005 and/or ISO 15189.

18. CABs/laboratories applying for accreditation in the testing field are assessed in the scope which according to their specification involves or does not involve sampling. SNAS assesses and accredits also laboratories which intend to perform sampling only (MSA-L/01).

19. For the purpose of assessing the performance of professional activities in testing and medical laboratories, it is possible to carry out professional activities on test items brought by assessors / experts, if appropriate. Test items can be, for example, CRM, RM matrix type with declared content / value of tested property, or test specimens that are validated within the relevant PT, provided that in the conditions of the pre-analytical phase (transport, storage prior to analysis) are met and the material is not after expiry. The test articles can be either native or preserved samples, or, identified microorganisms for biological analyzes, provided that the conditions of the pre-analytical phase (collection, transport, storage prior to analysis) are respected.

20. SNAS accredits laboratories (CABs) for expressing opinions and interpretations only if they ask for it and are performing corresponding testing and/or calibrations as accredited activity. Laboratory staff members expressing opinions and interpretations shall demonstrate competence for performing this activity.

21. After accreditation granting SNAS performs regular planned surveillances; during accreditation certificate validity, verifies whether the laboratory permanently meets all accreditation requirements related to its accredited activities. At each surveillance internal audits, management reviews, tests and/or calibration methods, assuring the quality of test and calibration results, test reports and calibration certificates are verified assessed. If an CAB/laboratory has several geographically remote locations, SNAS performs surveillance on all locations in one accreditation cycle. If an CAB has confirmed proficiency/competence in several accreditation fields (e. g. calibration and test laboratory, test laboratory and inspection body etc.) SNAS tries to perform surveillance in all "Accreditation Fields" within given year.

22. For reassessment are applied all mentioned principles related to accreditation however information concerning accredited laboratory from previous accreditation cycle and last assessment shall be taken into account.

23. The extension of scope of an accreditation is principally similar to accreditation. Extension can be related to new activities within already accredited scope of accreditation or to new locations (besides samples and on site measurements in already accredited activities fields) or extension for specific activities – for example modification and validation of methods, development of new methods and expression of opinions and interpretations. Extension of accreditation can be done together with a planned surveillance if it is requested by an CAB. Extension of accreditation of an accredited laboratory to a new accreditation field is not considered as an extension of accreditation but as a new accreditation and is managed by the same principles as accreditation.

24. Extraordinary surveillance is performed flexibly, in the shortest possible time after incentive was given, at the date determined by a client if the incentive originates from the client or determined by SNAS if the surveillance is performed as SNAS activity or on the base of the third party incentive. If it is needed SNAS which initiated the surveillance can the incentive scope flexibly extend.

## 2 RELATED DOCUMENTS

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| ISO/IEC 17011: | General Requirements for Accreditation Bodies accrediting CABs |
| PL-10: | Policy SNAS on accreditation for notification/authorization purposes |
| PL-21: | Policy SNAS on accreditation of flexible scope |
| PL-23: | Policy SNAS on participation in PT |
| PL-46: | The Policy and Procedure of SNAS for the Assessment of Laboratories According to the Requirements of the Standard ISO/IEC 17025:2017 |
| MSA-04: | Procedure for accreditation. |
| MSA-06: | Responsibility of SNAS and CAB |
| MSA-07: | EA requirements on the flexible scope accreditation |
| MSA-L/01: | Field and scope of accreditation of laboratories |
| MSA-L/14: | Determination of the level and frequency of proficiency testing participation |