

Policy**PL-07****SNAS POLICY ON ACCREDITATION OF LABORATORIES**

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PURPOSE: This document determines SNAS policy on accreditation of laboratories.

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1 SNAS POLICY ON ACCREDITATION OF LABORATORIES

- 1.1 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.
- 1.2 Laboratories providing services in the field of clinical (medical) examinations (to determine the diagnosis, monitoring, management, prevention and treatment of disease, or to evaluate health status - more detail see art. 3.20 of ISO 15 189), 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.
- 1.3 Accreditation Certificate number (X-xxx) form letter abbreviations X expressing scope of accreditation and a three-digit number xxx.
- 1.4 If the calibration laboratory granted accreditation to ISO/IEC 17025, issued accreditation certificate has identified scope of accreditation by the letter K. In the list of accredited CAB in AIS, it will be referred to as calibration laboratory.
- 1.5 If accreditation according to ISO/IEC 17025 is granted for testing laboratory, certificate has identified scope of accreditation by the letter S. In the list of accredited CAB in AIS, it will be referred to as testing laboratory.
- 1.6 If accreditation according to ISO 15189 is granted for medical laboratory, certificate has identified scope of accreditation by the letter M. In the list of accredited CAB in AIS, it will be referred to as medical laboratory.
- 1.7 SNAS accredits also laboratories which develop and validate or modify and validate methods for testing, calibration and medical examination (accreditation of flexible scope) and doing this is governed by provisions of the Standard ISO/IEC 17025 or ISO 15189 and Policy PL-21.
- 1.8 In all relevant schemes of testing, calibration or medical examination shall be fulfilled the requirements of the ISO/IEC 17025 or ISO 15189 standards according to specification in ILAC (The International Laboratory Accreditation Cooperation), EA (The European Co-operarion for accreditation) and/or application documents for ISO/IEC 17025 and/or ISO 15189 issued as international standards or documents issued by recognized international organizations.
- 1.9 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). Otherwise, the assessment of notification / authorization criteria is not performed and the notification /

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authorization is performed by the regulatory authority.

- 1.10** SNAS consistently pays attention to the applicant/accredited laboratory competency in the field of testing, examination and calibration and keeping principles of impartiality, objectivity and non-discrimination. Policy and procedures of the applicant/accredited laboratory 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.).
- 1.11** 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 when assessing participation of laboratories on PT.
- 1.12** Applicants for accreditation in the field of testing, medical examination and calibrations can be:
- a.** laboratories performing testing and/or examination and/or calibration activities, being independent legal or physical persons;
 - b.** physical or legal person which besides other activities deals also with testing and/or examination and/or calibration,
 - c.** persons or organizations seeking authorization or notification related to testing and/or examination and/or calibrations condition of which is accreditation granting.
- 1.13** Laboratories which are part of organization performing also other activities than testing and/or examination and/or calibrations have to demonstrate fulfilling conditions of impartiality, it means to demonstrate that other performed activities do not compromise tests, examinations or calibrations results.
- 1.14** 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 accredits also laboratories which intend to perform sampling only (MSA-L/01).
- 1.15** 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.
- 1.16** SNAS accredits laboratories (CABs) for expressing opinions and interpretations only if they ask for it and are performing corresponding testing and/or examination and/or calibrations as accredited activity. Laboratory staff members expressing

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opinions and interpretations shall demonstrate competence for performing this activity.

- 1.17** 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, complaints, also personnel, traceability, measures for risk and opportunities, assuring the quality of examination results, test and/or calibration results, test reports and calibration certificates are verified assessed as minimum. 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 schemes (e. g. calibration and test laboratory, test laboratory and inspection body etc.) SNAS tries to perform surveillance in all "Accreditation schemes" within given year.
- 1.18** In the case of re-accreditation and surveillance of a laboratory that has several workplaces / places of activity performing accredited activities that perform accreditation activities according to the same procedure, a witness assessment of all principles of accredited activities at all workplaces need not be performed, but sampling of accredited activities may be used.
- 1.19** For re-accreditation are applied all mentioned principles related to accreditation however information concerning CAB from previous assessments during accreditation cycle shall be taken into account.
- 1.20** The extension of scope of an accreditation is principally similar to accreditation. Extension can be related e. g. to new activities within already accredited scope of accreditation or to new locations (besides samples and on site measurements in already accredited activities schemes) or extension for specific activities – for example modification and validation of methods, development of new methods and expression of opinions and interpretations (more details in MSA-04). Extension of accreditation can be done together with a planned service if it is requested by an CAB. Extension of accreditation of an accredited laboratory to a new accreditation scheme is not considered as an extension of accreditation but as a new accreditation and is managed by the same principles as accreditation.

2 RELATED DOCUMENTS

ISO/IEC 17011	Conformity assessment. 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
MSA-04	Procedure for accreditation.
MSA-06	Responsibility of SNAS and CAB

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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 range and frequency of proficiency testing participation

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