SNAS SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

PROCEDURE FOR THE ACCREDITATION

MSA–04

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BRATISLAVA

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MSA accessible at: http:// www.snas.sk

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1 INTRODUCTION

This Methodical Guideline for Accreditation (MSA) regulates the basic principles relating to the applicants for accreditation service (preliminary assessment, accreditation, reassessment procedure of accreditation, surveillance, witness assessment, extraordinary assessment, assessment associated with different types of attestations, accreditation for purposes of notification/authorization).

The principles of granting of a certificate of compliance with the principles of Good Laboratory Practice (GLP) are governed by specific rules set out in the National GLP Compliance Program in Slovak Republic. (see http://www.snas.sk/index.php?l=sk&p=19).
MSA applies the binding international documents. The following formulations are used in the guideline:

- „shall“ indicates requirement,
- „should“ indicates recommendation
- „can“ indicates permission, possibility or ability

2 ABBREVIATIONS USED

AK	Acceptance Commission
AIS	Accreditation Information System
AO	Accredited Body
CAB	Conformity Assessment Body
DI	Documented Information
E	Expert
EA MLA	EA Multilateral Agreement
EA BLA	EA Bilateral Agreement
EMAS	EU Eco-Management and Audit Scheme
ES	European Community
G	Gestor
HK	Evaluation Commission
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Co-operation
ILC	Inter-Laboratory Comparison
IO	Inspection Body
KL	Calibration Laboratory
MLA	Multilateral Agreement
MRA	Mutual Recognition Arrangement)
MSA	Methodical Guideline for Accreditation
NBÚ	National Security Authority
OA	Annex of Application for Accreditation Service form where is stated „Specification of Activities“ of CAB for relevant scope
OG	Technical guarantee
OZ	Organizational Unit
OEP	Department for Economy and Operation

P	Assessor
PK	Quality Manual
PS	Assessment Group
PT	Proficiency Testing
SL	Testing Laboratory
SLP	Good laboratory Practice
VP	Lead Assessor

Terms

Accreditation – third party attestation related to a CAB providing formal demonstration of its competence to carry out specific conformity assessment tasks

Accreditation cycle – a cycle that begins on the date or after the date of granting of first accreditation or decision after reaccreditation decision and it shall not be longer than 5 years. The accreditation cycle consists of assessment after accreditation/reaccreditation (survailance) and reaccreditation.

Accreditation activities - individual work tasks of the accreditation process.

Accredited person (AO) - CAB, the accreditation was granted to on the basis of proving of compliance with accreditation requirements.

Accreditation process - activities from the receipt of application through to granting and maintaining of accreditation as defined by the accreditation scheme.

Accreditation decision – decision of granting, maintaining, extending, reducing, suspending and withdrawing of accreditation.

Accreditation scheme – rules and processes relating to accreditation of conformity assessment bodies to which the same requirements apply

Accreditation symbol - symbol issued by SNAS, the CABs shall use to prove they are accredited

Conformity assessment body – activity conducted by CAB when assessing conformity

Flexible scope of accreditation – scope of accreditation expressed to allow CABs to make changes in methodology and other parameters that are within CAB's competence confirmed by SNAS.

Impartiality - presence of objectivity.

Field of accreditation – is a general definition of CAB activities that are accredited or the accreditation of which is applied for.

Technical expert (expert) – person assigned by the accreditation body (3.2), who does not assess independently, works under the responsibility of an assessor (3.30), who provides specific knowledge or expertise with respect to the scope of accreditation (3.6) to be assessed.

Appeal – request by the conformity assessment body (3.4) for reconsideration of any adverse accreditation decision (3.13) related to its required accreditation status

Conformity assessment body (CAB) – a body providing conformity assessment services who can be or is an object of accreditation. As CAB for the purpose of this regulation we

understand the accredited person of applicant. It can be the conformity assessment body or organization/person the conformity assessment body is a part of.

Organizational unit – a workplace or other organizational unit of the conformity assessment body.

Assessment plan – a set of planned assessments, an accordance with the specific accreditation scheme, SNAS carries out in a particular CAB during accreditation cycle.

Guidance – participation at any of CAB activity that is subject to accreditation.

Assessor - person assigned by SNAS to carry out the CAB's assessment, whether independently or as an assessment group member.

SNAS personnel – internal or external individuals carrying out activities on behalf of SNAS.

Assessment programm – description of specific activities and preparation of the assessment.

Assessment – process undertaken by SNAS to determine the CAB's competence in defined scope of accreditation, based on standard(s) and/or other normative documents.

Remote assessment – assessment of the physical location or virtual site of CAB using the electronic means.

Suspending of accreditation – temporary restriction of the whole scope of accreditation or of its part.

Workplace – all locations where one or more of the key activities are performed; a certain area where the employee regularly performs work in permanent premises in the organizational structure of the employer

Place of activity – a certain area where the employee performs work outside the permanent premises specified in the employer's organizational structure (eg at the customer's premises)

Reaccreditation – assessment carried out to renew the accreditation cycle.

Scope of accreditation – specific conformity assessment activities the accreditation has been granted or CAB asks the accreditation for.

Extending of accreditation – completing conformity assessment activities within the scope of accreditation.

Complaint – expressing to SNAS of dissatisfaction, other than appeal, by any person or organization, relating to the activities of SNAS or accredited body, with the expectation of response.

Witness assessment – observing by SNAS of performing of conformity assessment activities by CAB within its scope of accreditation.

Specification of activities – it is a range of activities the accreditation of which the CAB is applying for and the form of which is identical with the „Scope of Accreditation"; however they can differ from each other from content point of view.

Technical area /sector certification scheme/conformity assessment scheme – rules and procedures relating to accreditation of relevant conformity assessment bodies, the specific requirements are applied to.

Assessment technique – method used by SNAS to carry out assessment.

Granting of accreditation – granting of accreditation for the defined scope of accreditation.

Maintaining of accreditation – confirming the continuation of accreditation in the defined scope.

Virtual site – Virtual site where CAB carries its work of provides services by means of on-line environment that enables people to carry out processes regardless to physical location. I tis not possible to use virtual sites there where the processes shall be carried out in physical environment, e.g. in testing, calibration, medical examinations, warehousing, production, installation of repairs of physical products.

Interested party – person or organization with a direct or indirect interest in accreditation.

List of accredited activities – it is the „Scope of Accreditation“ which involves the activities covered by the flexible scope, managed independently by the accredited CAB.

Withdrawing of accreditation – cancellation of accreditation in the full scope

Reduction of accreditation – cancellation of the part of the scope of accreditation.

Applicant – legal/physical entity submitting the Application for granting of accreditation for CAB.

Note:
Unless otherwise specified or explained in the text, the requirements in relation to the performance of accreditation services in the certification bodies also apply to environmental verifiers and greenhouse gas emission verifiers.

3 RELATED DOCUMENTS

ISO/IEC 17011	Conformity Assessment - Requirements on the accreditation bodies accrediting the conformity assessment bodies
Act No.505/2009 Coll.	On the accreditation of conformity assessment bodies and on the amendment of certain Acts in the wording of later regulations (hereinafter only „the Act“)
Act No.71/1967 Coll.	Act on Administrative Proceedings (administrative order) in the wording of later regulations
Policies of SNAS	see www.snas.sk
RR-02	Price list of services SNAS (see www.snas.sk)
MSA SNAS	see www.snas.sk

4 PRELIMINARY ASSESSMENT

Preliminary assessment is an accreditation service the applicant can ask for either at its sole discretion or based on SNAS recommendation.

The objective of this preliminary assessment is to assess in general terms the fulfilment of accreditation requirements according to relevant standards and regulations in the given area and accreditation scheme and to related methodical guidelines for accreditation and to check the state of readiness of the applicant for accreditation.

The basic condition for carrying out the preliminary assessment is to submit the Application for preliminary assessment (see chapter 5).

The applicant the preliminary assessment will be carried out at will provide SNAS with the documents necessary for assessment.

SNAS will make accessible to the applicant in electronic format the PS Proposal and calculation of service charges according to the price list. Subsequently the applicant gives his opinion on assessment group in electronic format, by analogy with other accreditation services.

During the assessment the PS doesn't provide consulting and instructions on how to resolve and remove the eventual deficiencies identified.

The PS identifies its findings in the "Record of the Preliminary Assessment". The findings serve to the client to be able to remove the eventual issues that could prevent him from obtaining the accreditation; they are not binding for the applicant.

After having finished the preliminary assessment, the applicant can decide whether to continue or not the process of granting of accreditation.

5 ACCREDITATION

5.1 INFORMATION ON THE ACCREDITATION PROCESS

5.1.1 Information on the accreditation process, procedure for submitting application and fixing of an approximate fee amount for the accreditation service and the necessary forms can be found on the SNAS website www.snas.sk, evtl. in AIS.

5.1.2 The additional accreditation process related information is provided to the applicant upon his request by SNAS secretariat and relevant SNAS department. The accreditation body personnel don't provide the information that could be considered as consultation or other advisory services that could cast doubt on the objectivity of accreditation process and decision making.

5.1.3 All processes, including the submitting of applications for accreditation services, their course, processing of outputs from the assessment and dealing with the entire service are carried out electronically, directly in the **Accreditation Information System (AIS)**.

5.2 APPLICATION FOR ACCREDITATION SERVICE

5.2.1 Before submitting the application, the new legal entity wishing to apply for granting of accreditation shall register at https://ais.snas.sk. The accredited persons (AO) no longer ned to register.
The applicant/AO wishing to apply for accreditation service shall first fill/check the accuracy of data in the Client Card - the sections of Basic Data (including the information on the statutory representatives), Related Relations, Users and Conformity Assessment Bodies (where he e.g. assigns to CABs and sites the managers and quality managers). Only then he can proceed to the completion of "Application for Accreditation Service" (hereinafter only Application). When submitting the Application, it is necessary to input electronically all prescribed documents according to Law and SNAS regulations. These are::

- document on the organizational structure of legal/physical entity which makes clear the incorporation of CAB in bigger organizational unit, if any,
- addresses of all sites and information on the activities, including the virtual site, the application is asked for,
- PK/DI of the particular accreditation scheme (e.g. Quality Manual with annexes, documented procedures),
- OA annex (both parts) according to the accreditation scheme which is asked for. The relevant OA Annex 1 shall be elaborated according to the relevant MSA-X/01, OA annex 2 based on structure of CAB
- human resources (list of employees of CAB, including employes performing relevant professional activities) if it is not part of PK/DI
- technical resources (list of technical equipment, provided it is not part of PK/DI,
- in the case of calibration, testing and medical laboratories (for inspection bodies only if applicable):
    - Strategy of participation in PT for the following accreditation cycle elaborated in accordance with PL-23 and MSA-L/14,
    - filled in Annex No. 1 to the Strategy of participation in interlaboratory comparisons (proficiency testing, interlaboratory comparative measurements, etc.), programm for the following accreditation cycle (accreditation/ reaccreditation, extension of accreditation) is to be inserted into the part „PT",
    - In the case of accreditation/extension of accreditation, the filled in Annex No. 1 to the Strategy of participation in the interlaboratory comparisons about the participation in the interlaboratory comparisons for the fields/sub-fields the accreditation is asked for is to be inserted in the part „PT",
    - in the case of reaccreditation, the filled in Annex No. 1 to the Strategy of participation in interlaboratory comparisons about the participation in the interlaboratory comparisons for the entire last accreditation cycle is to be inserted in the part „PT",
    - answered control questions (applies to laboratories, accreditation scheme: ISO/IEC 17025:2017).

If the professional activities are carried out in various workplaces or places of activities (e.g. rented premises at the customer, other laboratory), respecivelly workplace branches, from the Annexes to the Application for Accreditation Services (OA) shall make it clear, where the activities in question are carried out (all types of CABs). In the case of laboratories performing professional activities outside the permanent equipment (on site, at the customer, mobile device, etc.), this fact shall also be indicated in the annex to the application for accreditation. If laboratory applied an accreditation service for authorization / notification

purposes, it shall provide the name of the regulator in the Application for Accreditation Service on page 9 (Applicant's note to the application).

When filling in the application in AIS, it's necessary to attach the proof of payment of the fee associated with its submission, registering and assessment of the Application for Accreditation. The fee is paid only at the first accreditation and is paid for each field of accreditation (e.g. in the case of AO for management systems the fee is paid foe each certification standard and also in the case of extension). The fee to be paid when submitting the Application is irreversible. In the case of application submitted by a foreign subject where the service contract is concluded, the fee may be included in the total calculation and paid together with the payment for the service. The CABs pay the fee to the SNAS account maintained by the State Treasury, Radlinského 32, 810 05 Bratislava, IBAN: SK02 8180 0000 0070 0036 9571. The CAB Identification Number is indicated as the Variable Symbol, the specific symbol is not specified. CAB invoice will be delivered after payment.

5.2.2 Upon PS or case officer request, the applicant is obliged to provide, besides the annexes required, also other documented information in relation to the assessment.

5.2.3 DI shall contain references to the relevant part of the standard to make it easy to easily identify the documented implementation of the relevant requirement of the standard. PK/DI shall document the implementation of the requirements of the relevant accreditation scheme. PK/DI shall contain also the information (or refer to them), such as:

- field and scope of accreditation,
- samples of filled in certificates, inspection reports, protocols and other outcomes from accredited activity with estimated location of the relevant SNAS accreditation symbol, notification symbol of SNAS, combined symbol of MRA/MLA accredited body or reference to the accreditation statute,
- lists of personnel, showing their functions and carried out activities associated with the accreditation,
- defined non-accredited activities, in order to make it possible to identify the potential conflict of interests.

5.2.4 After having filled in the application in electronic format, the applicant/AO sends it to AIS and subsequently generates in PDF format. The form „Application for Accreditation Service" shall be signed by the statutory representative and delivered to SNAS. For signed is considered the form, signed with own hand or by means of „guaranteed electronic signature". The form is considered delivered, when signed with own hand and delivered to SNAS by mail, signed with guaranteed electronic signature and delivered into e-mail box of SNAS, or signed by guaranteed electronic signature and inputted into AIS.

5.2.5 SNAS refuses the application of terminates the accreditation process in any moment of the application submission process or at the beginning of assessment, if there is a prove of fraudulent behaviour, if the conformity assessment body deliberately provides false information or if the conformity assessment body concealed information.

5.3 REVIEW AND ACCEPTANCE OF APPLICATION

5.3.1 The proceedings according to the Law begin on the proposal from the proceedings participant by submitting of the relevant Application. The proceedings start from the day when the Application signed by the statutory representative was delivered to SNAS. If the service start at the instigation of SNAS, it starts on the day when SNAS made the first action towards the Applicant/AO.

5.3.2 SNAS Secretariat checks the formalities of the Application including the completeness of the mandatory annexes to the Application (See also Annex 3). In the case of incomplete materials, SNAS can suspend the proceedings and invites the applicant to complete them. If the Application meets the requirements, it is forwarded to the relevant SNAS department..

5.3.3 Head of the relevant department assigns a case officer to review the Application delivered. If necessary, the case officer will ask to complete it or, in collaboration with the professional guarantee will propose a preliminary assessment and SNAS suspends the proceedings. If the Application meets the requirements, gestor submits it to AK. AK assesses the Application from factual and content point of view, its completeness, adequacy, sufficiency of resources and possibility to realize the accreditation services within the statutory time limit or within acceptable time frame. This is recorded in AIS by the president/vice-president/secretary of AK. If SNAS is not able to provide the assessment on time, it notifies CAB about this fact.

5.3.4 If necessary, AK can propose to the applicant to carry out a preliminary assessment.

5.3.5 The Application for Accreditation Services will not be accepted when:

- the applicant/AO doesn't remove the deficiencies identified,
- there is a conflict of interests at the applicant/AO in the performance of activities the accreditation is requested for and this conflict was not removed,
- CAB and OZ the accreditation of which is asked for are not clearly defined,
- there is no clear definition of the field and scope of accreditation,
- SNAS is not able to provide the accreditation service in the extent requested,
- the applicant is a foreign body on the territory of which there is a local accreditation body which is a signatory of EA MLA/BLA, ILAC MRA, IAF MLA in the field the accreditation of which is the subject applying for, unless otherwise agreed with the local accreditation body in advance.

5.3.6 If the Application is not accepted, SNAS issues a decision on the suspension of proceedings. In the case of repeated interest in accreditation, the applicant is obliged to complete the entire process of submission of Application, including the payment of the fee for Application again.

5.3.7 In the case when the Application has only some formal insufficiencies, these can be corrected by submitting of the new application; repeated payment of the fee is not necessary. On the basis of the recommendation of the competent expert guarantor, in case of minor defects, it is possible to accept the application with corrections inserted into the AIS - section "Dokumentácia" - "podporná dokumentácia" or "Dokumentácia subjektu".

5.4 FEE AMOUNT CALCULATION

After having accepted the Application, SNAS determines the accreditation service fee according to the valid "Price list of SNAS services", published at the SNAS web site (www.snas.sk). The applicant is informed about the fee amount by means of AIS. The determined amount will be invoiced to the Applicant upon completion of the accreditation service, in the foreign subject case usually in advance. As far as the transition to the current text of international standards used for accreditation/certification during planned assessments or unplanned services is concerned, an hourly rate is added to the assessment sum for the time needed to assess all requirements of the current version of international standards used for accreditation/certification.

5.5 PROPOSAL OF THE COMPOSITION OF THE ASSESSMENT GROUP

5.5.1 After the Application was accepted, the Applicant/AO will get a notification which enable the access in AIS to the "Proposal of the Composition of the Assessment Group" (hereinafter only "Proposal") and will ask for the applicant's opinion on the PS composition within the determined period of time. The PS members usually are: lead assessor (VP) and/or assessor(s) (P) and/or expert(s) (E) whereby their number is proposed in such a way that will enable them to assess professionally all the activities specified in the Application. In addition to the above, other PS members may be the VO/P observer, VP/P assistant, SNAS employee charged with monitoring or internal audit, interpreter, evtl. other persons (e.g. EA evaluation team member, etc.).

5.5.2 The Applicant/AO shall express its opinion on each PS member directly in AIS and clicking on „Send opinion" send it back to SNAS. In the sense of notification mail, the Applicant/AO is obliged to send to SNAS the opinion on PS composition in electronic format within 7 days.
The eventual justified objections to any of PS members (i.e. conflict of interest of PS member with the assessed body) are to be submitted in the electronic form. In the case of justified objections SNAS shall take this opinion into consideration and prepare a new proposal (see MSA-06).

5.5.3 Until the acceptance of PS composition is delivered, SNAS can suspend the proceedings for granting accreditation in accordance with § 3 art. 6 of the Act.

5.5.4 After recording a favourable opinion on the Proposal in AIS, SNAS director appoints the PS to carry out the assessment.

5.6 ASSESSMENT PROCEDURE – GENERAL PRINCIPLES

5.6.1 The purpose of the assessment is to assess the fulfilment by applicant/AO of the accreditation requirements and to confirm the applicant's competence to perform the activities the accreditation is asked for and/or are subject of the assessment.

5.6.2 Accreditation requirements apply equally to all applicants/AO regardless of their size and scope of activities.

5.6.3 The requirements the fulfilment of which is to be assessed, are set out in the current accreditation schemes as follows:

- for testing and calibration laboratories in ISO/IEC 17025, supplemented by the standard CEN/TS 15675 for testing laboratories performing the measuring of emissions from stationary sources and their subcontractors,
- for medical laboratories in ISO 15189,
- for proficiency testing organizers in ISO/IEC 17043,
- for certification bodies certifying management systems in ISO/IEC 17021-1, complemented for the certification bodies certifying quality management systems with ISO/IEC 17021-3, for certification bodies certifying the environmental management systems with ISO/IEC 17021-2, for certification bodies certifying occupational health and safety management systems by ISO/IEC TS 17021-10, for certification bodies certifying sustainable forest management systems by TD SFCS 1005, for certification bodies certifying energy management systems with ISO 50003, for certification bodies certifying food safety management systems with ISO/TS 22003, for certification bodies certifying quality management systems in welding by the EA-6/02, for certification bodies certifying information safety management systems with ISO/IEC 27006 and for the certification bodies certifying anti-bribery management systems with ISO/IEC TS 17021-9,
- for certification bodies certifying products according to ISO/IEC 17065, which is, for the certification bodies certifying products according to sector specific schemes, complemented by: GLOBALG.A.P. General Regulations for good agricultural practice, EA-3/12 for organic production, EA-6/02 for welding processes, TD SFCS 1006 for consumer chain of forestry products and regulation eIDAS and accordingly ETSI EN 319 403 for the provision of reliable services
- for certification bodies certifying persons in ISO/IEC 17024,
- for inspection bodies in ISO/IEC 17020,
- for environmental verifiers in the European Parliament and Council (EC) regulation No.. 1221/2009, Commission Regulation (EU) No. 2017/1505 and no. 2018/20 and in ISO/IEC 17021-1,
- for GHG emissions verifiers in EN ISO 14065 and Regulation of the Commission (EU) No. 600/2012, 601/2012.

5.6.4 Accreditation for the purpose of notification/authorization or attestation of fulfilment of notification/authorization requirements is carried out in accordance with this MSA and the agreements between SNAS and the relevant regulator.

5.6.5 The fulfilment is required also into account during the assessment, of the requirements set by SNAS and precising the requirements specified in the basic standards, evtl. resulting from mandatory application documents EA, IAF, ILAC…. In the case of accreditation for notification/authorization purposes, the fulfilment of requirements set by regulatory bodies is taken into account too.

5.6.6 In choosing the activities to be assessed SNAS will take into account the risks related to the scope of accreditation and resulting from CAB activities, locations and personnel.

5.6.7 The PS members assess the CAB’s competence to carry out the required activities in accordance with the above requirements based on the documentation and records (PK, DI and procedures, etc) submitted, using various assessment techniques, such as review of documentation and files, on site assessment, witness assessment (assessment of the practical

performance of activities, assessment of the competence to perform activities and compliance with documented policies and procedures, witness assessment in the premises of the applicant's client), remote assessment, measurement audits, validation audits, unannounced visits and review of performance in the proficiency testing and other inter-laboratory comparisons, where appropriate. I fit is not suitable or possible to use the witness assessment, this fact shall be justified. The on site assessment is carried out directly in the CAB, as well as in the places of performing of activities out of the permanent premises of the CAB.

5.6.8 All information obtained in the assessment process is considered to be confidential. All participants in the accreditation process commit to preserve the confidentiality by signing the Statutory Declaration.

5.6.9 During the assessment process the PS members do not provide any advice or consultancy to solve the eventual issues in the field assessed, even if it would render more effective and accelerate the assessment.

5.7 DOCUMENTATION REVIEW

5.7.1 The assessment begins with documentation review. The reviewed documentation usually consists of PK/DI and procedures, evtl. DI for performing of the professional activities. In the case of laboratories, they are further calculations of uncertainties for a given range of activities with relevant examples of identification of uncertainties, results of proficiency testing, evtl. inter-laboratory comparisons the laboratory participated at, records of development/validation of new methods (if relevant), procedures, and, where possible, also the examples of opinions and interpretations expressed, strategy of participation in PT/ILC, „in-home" calibration procedures, eventually others. If the laboratory gets accredited as the laboratory with flexible scope, the procedures are to be assessed for flexible scope management, including the management of the „List of accredited activities" and of the performing of modifications and validations of relevant methods of testing or calibrations, verifications on newly introduced methods and development of new ones. If necessary, the PS members can ask the Applicant/AO for further documentation necessary for the assessment.

The applicant/AO shall input the documentation required by SNAS and PS during the accreditation into the AIS of the relevant service, part of Documentation of the subject.

If the CAB doesn't input the necessary documents even upon request (e.g. due to „know-how" protection or confidentiality reasons, etc.) and these will have to be assessed during the on-site assessment, it has to inform the case officer without any delay. Based on this fact the case officer together with the OG shall reassess the number of days of assessment of individual PS members and take this into account in the PS reestablishment and reassessment of the fee amount and VP in the On-site assessment plan. The case officer informs CAB about these changes without any delay.

5.7.2 The documentation assessment is carried out by VP and all Ps who send their sub-reports on the documentation assessment to VP. VP completes the final report from the documentation assessment.

5.7.3 During the documentation assessment i tis evaluated how the individual accreditation requirements are documented in PK, DI or other supporting, evtl. complementary documents

to which they refer to. A Report on documentation assessment is elaborated from the assessment of documentation, which is then inputted into AIS by VP. If nonconformities are identified against documenting of the requirements of the relevant standard or regulation, VP records those directly in the AIS data fields and a notification is delivered to the applicant about these findings along with the Report on the documentation assessment..

5.7.4 If the findings are of serious character and shall be removed prior to on-site, SNAS invites the applicant to remove them within the specified time and if the deficiencies are not removed in the specified period of time, it can suspend the proceedings in accordance with § 3 art. 5 of the Act. The applicant shall remove them and inform SNAS about it..

5.8 ON SITE ASSESSMENT PLAN

Prior to the on site assessment VP agrees with PS and CAB the assessment date and makes accessible for CAB in AIS the „On site assessment plan“ to which, once being made accessible, the responsible CAB expresses the opinion directly in AIS. The assessment plan is made accessible in advance in order to make it possible to CAB to prepare for the assessment, address in advance the unclarities, eventual issues and ensure the presence of all relevant CAB personnel at the assessment. The assessment programme defines the tasks PS is charged with and contains such time and factual breakdown of the individual activities that a sufficient space is available for the verification of the fulfilment of all relevant requirements and monitoring of the performance of activities the accreditation is asked for.

5.9 ON SITE ASSESSMENT, REMOTE ASSESSMENT

5.9.1 The objective of the assessment is to verify the fulfilment of documented CAB information and procedures in practice and the competence to carry out specific professional activities.

5.9.2 Onsite assessment is carried out directly in CAB’s premises as well as in all other locations where one or more key activities (see MSA-06) within the accreditation field are performed, in other workplaces based on risk analysis respectively.. The assessment is carried out in the presence of CAB’s representatives and that at least the head of department, quality manager and personnel carrying out professional activities.

5.9.3 The assessment can be carried out remotely, for instance when it comes to the surveillance during which the assessment is not carried out of testing or calibration or if it comes to virtual CAB site. Remote assessment is carried out using the electronic means and the relevant articles of MSA-04 are used to carry out the assessment.

5.9.4 A variety of techniques is used to carry out assessment, such as witness assessment (observing) of carrying out of professional activities (where justified), accepted is also the form of simulated/model performance of activities (e.g. MSA-I/03, MSA-CP/03, MSA-CS/15), interviews with CAB technical and administrative personnel, review of files (in the form of vertical audit) and combination of these techniques.

5.9.5 In the professional area, when assessing laboratories and where applicable also inspection bodies, the emphasis is, among others, put on the verification of how the follow up (traceability) is ensured of measurements (see PL-13), calculation of uncertainty of results of

testing and calibrations (MSA-L/11, MSA-L/12), results PT/ILC and strategy of participation in PT/ILC (PL-07, PL-23, MSA-L/08, MSA-L/14).

5.9.6 After the assessment, a final negotiation with the management of the AO/CAB takes place, in which PS presents the results of the assessment and informs about the next steps. After having carried out the assessment, VP fills in in the AIS the Record(s) on nonconformity(ies), specifies the date of submission of the analysis and range of causes of nonconform work and proposal of corrective actions, as well as the date for removal of nonconformities from the assessment and documentation assessment and passes them to the applicant electronically. If nonconformities are identified, date of their removal fixed and nonconformities are accepted by CAB, in the case when the nonconformities are not removed within the defined time, SNAS can suspend the proceedings in accordance with § 3 art. 5 Coll. VP elaborates the „Report of SNAS in findings " which is signed by VP and CAB representative in two copies, one copy to stay with CAB immediately after the assessment or, in the case of remote assessment, to be sent electronically. In such case CAB signs the „Report of SNAS on the findings after assessment or whiteness assessment and available in AIS. Subsequently, the VP will prepare the „Summary Report" which contains detailed information. In the case of remote assessment, it shall be made available through the AIS. In this case of AIS access, the CAB confirms familiarization with this report. The Summary report is made accessible to subject when the assessment processes are finished. Should the information in the „Report of SNAS of the findings from " differ from relevant information in the „Summary report", CAB will be informed about this fact by means of the section „Other relevant information, proposals for improvement, etc.".

After the notification delivery, the CAB's representative confirms electronically in AIS environment that he was made acquainted with the nonconformity, understood it and expresses his/her opinion towards it. In the case when the applicant´s/CAB's representative doesn´t accept the nonconformity, the process is managed by 5.10.2 of this MSA .

Note: If, because of justified reasons, it is not possible to fill the Report on nonconformities and acceptance thereof in AIS directly on site, it is desirable to elaborate the Report on nonconformities and acceptance thereof in paper form and to record and accept the nonconformities in AIS in the shortest possible time after the onsite assessment.

5.9.7 In the case of identified nonconformity is CAB obliged to:

- input into AIS within 10 working days the analysis of causes and rang and proposal of corrective actions documented in the Record on nonconformity and send them to SNAS through AIS,
- input into AIS the information about how the nonconformities were removed (in the part Description of nonconformity removal) and attach the evidences or their removal within the specified time set by VP and send them to SNAS through AIS.

5.9.8 If the nonconformity removal was not accepted by all PS members, the VP will once more ask the CAB to remove them and attach further evidences of removal. If CAB is not able to remove the nonconformities within the date set, he can ask for the extension of the time to remove the nonconformities according to the § 3 art. 5 of the Law.

5.9.9 If the nonconformities identified were not removed within the due time, SNAS either suspends the proceedings (according to § 3 Art. 5 of the Law) or, in the case of already

accredited body, suspends the validity of accreditation (according to § 7 Art. 6 letter b) of the Law).

5.9.10 In the cases when the assessment proves the inability of the CAB to carry out the activities within a part of the scope required, the conclusion from the assessment will be to grant the accreditation in the reduced scope. If the CAB doesn´t prove his competence to carry out the professional activities in the entire scope required and/or is not able to prove the fulfilment to full extent of system requirements, the conclusion from the assessment will be to propose the non-granting of the accreditation.

5.10 EVALUATION AND CLASSIFICATION OF FINDINGS

5.10.1 Individual findings are classified by PS according to the following classification scale.

- **Conformity** - full compliance with the relevant accreditation requirement.
- **Non conformity** - non-compliance or deviation from compliance with accreditation requirements.
- **Risk** - area of potential non-compliance with accreditation requirement

5.10.2. Finding of type “Non conformity”

Each non-conformity shall be clearly associated with a specific requirement of the standard or other document containing the accreditation requirements against which the non-conformity is identified.
In the case of accredited CABs, the maximum period for acceptable non-conformity removal is 2 months, in the case of CAB - an applicant for accreditation - the maximum period for non-conformity removal is 12 months. If the applicant has a non conformity deadline of more than 2 months, the applicant shall also request for service interrupting., Based on the request of the CAB, SNAS can extend the maximum period. There is no legal entitlement to extend the time limit.

If the CAB is unable to eliminate the nonconformity, it cannot be granted accreditation.

In the case that accreditation has already been granted and CAB does not remove the non-conformity within the deadline, SNAS will subsequently activate process of the accreditation suspension in its entirety or in its relevant part.

If the CAB does not accept the identified nonconformity, it is obliged to indicate this fact in the AIS and promptly deliver a complaint to SNAS, stating the nonconformity. The SNAS Director will decide to appoint a commission to investigate this complaint. The committee shall consist of at least three members, composed of the head of the relevant department, the competent professional technical guarantees and another member who must be a member of the relevant evaluation committee. In the case of an assessment by the Head of Department or a professional guarantee, the Group is appointed from the other members of the relevant Evaluation Committee. The time limit for the nonconformity removal shall be interrupted and shall commence on the date of the decision on the complaint.

5.10.3. Finding of type “Risk”

Risk is the area of potential nonconformity with accreditation requirements, e.g. from the assessment of negative trends in the personnel area, from the low number of CAB outputs, etc. The risks are recorded in the “SNAS Report on Findings” and in the “Summary Report”. CAB is not expected to respond directly to the identified risks, but CAB evaluate them and apply measures to ensure that accreditation requirements are met in next work. The VP appointed for further assessment shall take into account the identified risks when planning and conducting the assessment

6 REACCREDITATION

6.1 The actual process for reaccreditation is the same as for accreditation with the difference that it can take into consideration the results from previous assessments.

6.2 The application form for reaccreditation shall be submitted in accordance with Section 7, paragraph (4) of Act 505/2009 on accreditation of conformity assessment bodies and on amendments to acts, as amended.

6.3 During the granting of the accreditation in the relevant area, only application form for reaccreditation may be submitted 18eaccreditation.

6.4 If, within reaccreditation, AO has an interest to extend the scope of accreditation, it submits two independent applications - one Application for accreditation renewal and other Application for accreditation extension.

6.5 In the case of calibration, testing and medical laboratories (at inspection bodies, only where applicable), the re-accreditation shall assess participation in PT / ILC for the previous period. If a laboratory participates in a PT / ILC within a particular accreditation cycle and the results are known only after re-accreditation, these results shall be considered as participation in the PT / ILC for that particular accreditation cycle.

7 ACCREDITATION EXTENSION

7.1 The procedures and principles of performing of the assessment for the purpose of accreditation extension are analogous to the procedures and principles of accreditation focusing on the requested extension of accreditation scope. The AO elaborates the Application for accreditation extension with relevant Annexes. (Items that CAB applied extension of accreditation by shall be in the relevant Annex (OA) to the application for accreditation service with the specification of accreditation scope and type of activities marked in colour within the valid scope of CAB accreditation of CAB). In the case of laboratories, along with the application for extension CAB has to submit the success rate in PT (for KL for all field, SL at least in one field). The extension of accreditation can relate to

a new scope of activities within the already accredited field, or new location where the activities are carried out.

7.2 For SL, KL, ML, IO and PTP, the extension of AO activities by a new field of accreditation (e.g. AO has accredited the field of testing and it wants to get the accreditation for calibration, certification, inspection,...) is not considered as the extension of accreditation but as a new accreditation and it shall follow the procedure for granting of the accreditation.

7.3 As extension of accreditation is considered:

a) New workplace for the performance of activities (valid for all CAB) and new geographic locations for the performance of activities if they are restricted in the original scope of accreditation.

as well as:

b) in SL with fixed scope the new matrix, new principle of the method, method modification that shall be validated/verified, reporting of opinions and interpretations
New marking of the method, evtl. of the standard and insignificant extension of accreditation scope with uncertainty are not considered as accreditation extension.
In SL with flexible scope the principle of the method, new workplace, place of activities.

c) in KL the extension of measurement range, improvement of the uncertainty of calibration, change of the calibration method, change of the place where calibration is performed (e.g. KL carries out calibrations in the laboratory and asks to add the „performing of calibration on site“). The new numerical marking of the method or adding of the standard that have no impact on the calibration method are not considered to be accreditation extension. The change in the formularization of uncertainty of calibration (change in the way of recording) in the case, when such change does not cause an improvement of the value of uncertainty, is not considered as extension of accreditation and will be assessed in the course of the nearest assessment (the change has to be reported prior to the preparation of the assessment). If there are many significant changes in the formularization of the uncertainties of calibration in the scope of calibration or the subject requires the assessment thereof sooner than planned, the changes in relation to the formularization of uncertainties of calibration will be assessed in the form of extraordinary assessment. Note: KL can apply the changes in the formularization of uncertainty (change in the way of recording) in its output documents only after being granted the modified scope of accreditation.

d) In the ML with fixed scope: new matrix, new principle, new analyte, modification of the method that changes the essential characteristics of the original method and therefor it must be subject to the validation/verification.
The insignificant changes in the analyte’s name, name of the method introduced, in other specifications are not considered to be the extension of accreditation.
In ML with flexible scope new principle of method, new workplace, place of activity, new persons able to validate and modify methods.

e) in IO extension of the area and subarea of inspection.

f) For proficiency testing organizers, as extension is considered for instance the introduction of a new area of tests that has not yet been in the range of activities, not the change of particular parameter.

g) For certification bodies certifying management systems: EA code, technical field, category, main technical field and other management system.

h) For certification bodies certifying products: group of products, item within the group of products, certification scheme/module/system/particular standard.

i) For certification bodies certifying persons: type/category of activities, certification scheme.

j) For GHG emissions verifiers: group of activities.

k) For environmental verifiers: EA code/NACE code.

7.4 The complete assessment of documentation is not required for the extension with the exception of cases when the extension is related to the sites of carrying out of accredited activities or if the extension has a substantial impact on the management system documentation of the accredited body.

7.5 In the case of a positive decision on accreditation extension SNAS issues a new Accreditation certificate.

8 ASSESSMENT AFTER ACCREDITATION/REACREDITATION (SURVEILLANCE)

8.1 The surveillance is either planned is carried mainly on the basis of the assessment programm which consists of the individual surveillances and reaccreditation (KD – Planning of services), which takes into consideration the risks identified in CAB.

8.2 After being granted an accreditation, the CAB is constantly subject to surveillance during the whole time of accreditation validity. The purpose of surveillance is to assess whether the CAB continues to fulfil the accreditation requirements and confirm the continuation of accreditation or decide to renew the accreditation.

8.3 SNAS sets up a service in the AIS – surveillance. CAB gets the notification that the amount of payment for the surveillance has been made accessible as well as the notification from the AIS about the PS composition proposal. CAB sends its opinion on the proposed PS composition analogously to accreditation. CAB, in line with the notification email, is obliged

to send to SNAS the opinion on PS composition electronically within seven days. If CAB fails to meet this deadline, SNAS can suspend the accreditation.

8.4 Immediately after having approved all PS members, CAB shall input into „Subject‘s documentation“ part of AIS the current QM with annexes or relevant DI, list of CAB personnel, including personnel carrying out the relevant professional activities . Upon the request of the VP or case officer the CAB is obliged to deliver also other documents (working procedures, internal guidelines, report on the management review, etc.) relating to the assessment.

The assessment procedure for surveillance is similar to that of accreditation except that the fulfilment of accreditation requirements is examined generally in the extent set in the Card of surveillances. At every surveillance the fulfilment is checked of the requirements on internal audits, management review, complaints, use of accreditation mark and references to accreditation, application of SNAS policies and also further relevant facts evtl. risks, SNAS is informed about before or during the surveillance. Similar to accreditation, a part of surveillances is also the witness assessment of performing of professional activities in a way to assess within one accreditation cycle the representative selection covering all these activities (for certification see chapter 9). During the accreditation validity, the surveillances shall cover the verification of fulfilment of all accreditation requirements and all accredited activities in all sites one or several key activities are carried out in in accordance with the rules of sampling.

8.5 If CAB has several work places or places of activities, during the accreditation validity it is necessary to carry out the assessment on each site/working place. A location where one or more key activities are performed is considered the site. All relevant requirements of the standard and all technical activities performed on particular work place or place of activity are assessed during the assessment.

8.6 In the case of the assessment of fulfilment of notification/authorization requirements where it is agreed with the relevant regulator (for example in the field of subcontracting/externally provided technical activities associated with the evaluation of emissions from stationary sources) the surveillance is performed on the date set in the Programme of assessment. If the planned surveillance at subcontractor/external provider of technical activities related to the evaluation of emissions from stationary sources is not performed in the relevant year, in such case the outputs of subcontractor’s/external provider’s activities are examined during the planned assessments at accredited customers of this subcontractor.

8.7 In the case when the notification/authorization was granted to CAB by regulator, the case officer approaches the regulator to ask whether the by him determined/approved exerts will take part in the assessment provided no other conditions are agreed upon in anticipation that the regulator’s representatives will not participate at the given assessment.

Note: When assessing the requirements for the purpose of the verification of requirements on notification/authorization, it is to use the MSA-N/01 Accreditation for the purpose of notification.

8.8 Surveillance in the Laboratories

8.8.1 Reviewed during the surveillance in the laboratories, is also: testing/calibration methods, medical procedures, quality assurance of the results of testing/calibration, notifying of testing/calibrations results, monitoring of the performance of selected representative tests/calibrations, participation in PT programs or in ILC and their results. If the result was unsatisfactory, PS examines whether the laboratory performed the analysis of its nonconformity work, whether relevant corrective actions were performed and whether improvement was achieved based on these actions. When the follow up participation in PT/ILC does not prove the problem elimination, SNAS will, depending on circumstances, consider the suspension of accreditation for the particular item of the accreditation scope or general suspension of accreditation. In such a case the whole complex of quality assurance of results of tests and/or calibrations is taken into consideration as well as other factors that influence the laboratory activities.

8.8.2 After granting of accreditation, all laboratory types and where applicable also inspection bodies shall participate in proficiency testing or other appropriate inter-laboratory comparisons within one accreditation cycle in accordance with PL 23 PT or other relevant ILC and shall achieve satisfactory results in them, in each subfield of activity defined in the strategy of participation elaborated on the basis of their scope of accreditation, provided such comparisons are organized, available and applipable.

8.8.3 In the case of laboratories with flexible scope the implementation of flexible scope in practice including the assessment of reported changes of validations and/or verifications carried out since the last onsite assessment is also the subject of surveillance.

8.9 Surveillance at Proficiency Testing Providers

In the case of proficiency testing providers, during the accreditation validity in one accreditation cycle, the provider has to accomplish at least 2 PTs and in the case of several fields of activities (items of accreditation scope) at least 1 PT in each of the particular field of performance of proficiency testing (in each item of the scope of accreditation).

8.10 Surveillance at Certification Bodies and Verifiers

8.10.1 The plan of surveillance at certification bodies and verifiers shall ensure the assessment of planning, management and implementation of certification/verification and to confirm the permanent trust in the certification body/verifier's capability. The scope of surveillance depends on the scope of accreditation, taking into account the findings of the carried out accreditation/accreditation renewal assessment and surveillances, possible changes in the body or other relevant data.

8.10.2 Part of the surveillance is the witness assessment at the customer of the certification body/verifier that doesn't need to be carried out in the time, identical with the time of surveillance. The witness assessment doesn't replace the surveillance.

8.10.3 During the surveillance, the interviews are carried out at onsite assessment with the employees carrying out the certification/verification and review of files of the certifications/verifications performed within the planned scope of surveillance.

8.11 **Surveillance in the Inspection Bodies**

8.11.1 The scope of surveillance depends on the scope of accredited subjects / sub area of inspection, while the findings are taken into consideration from previous assessments, eventual changes in the CAB and other relevant data. The aim of surveillance is to confirm the fulfilment of accreditation requirements in a way to secure the permanent confidence in the competence of the inspection body.

8.11.2 Witness assessments, professional interviews with staff, reviews of files of closed cases and the check of effectiveness of the corrective actions from the previous assessment are part of the surveillance. The witness assessments can be performed also outside of the date of onsite assessment during surveillance. The witness assessment as such does not replace the surveillance.

8.11.3 Where applicable, appropriate and accessible, the results are checked of the participation of IO in PT for professional activities associated with the measurements and testing.

9 ASSESSMENT PROGRAMME OF ASSESSMENT FOR ACCREDITATION CYCLE

9.1 The assessment programme within the accreditation cycle usually consists of two surveillances and subsequent accreditation renewal - reaccreditation.

9.2 Besides the assessment of the conformity assessment activities given by the scope of accreditation the assessment programme takes into consideration also further factors, such as knowledge acquired by SNAS about the management system and CAB activities.

9.3 During the accreditation cycle, the specified requirements are assessed as well the scope of accreditation taking into account the risk.

9.4 The interval between two assessments shall not exceed 24 months.

9.5 The surveillances within the accreditation cycle are usually carried out in accordance with how they are planned in the Card of surveillances (KD – Planning of services). Planning also takes into account whether i tis the first surveillance after granting of accreditation which is generally carried out within 12 months from granting of the first accreditation. In the fields of accreditation, where the surveillance interval is determined by special regulations, i tis to be proceeded according to them.

9.6 In the case when SNAS can’t carry out the surveillance in the planned date due to CAB, SNAS will suspend the accreditation validity (for a maximum of 6 months) until the surveillance is carried out. Even if after that date surveillance is not performed, the accreditation will cease.

10 WITNESS ASSESSMENT

10.1 During the witness assessment, the compliance is assessed of the performed activity with documented procedure, the workmanship is observed of the performance of activity and if possible, the rightness is evaluated of the results achieved. If the activities are performed outside of permanent premises (sampling, measurement at customer, mobile laboratory, audits at customer, inspections, etc.), the demonstration of the performance of activity is carried out on places where these activities are performed.

Note: For the accreditation of bodies certifying persons, products and management systems the witness assessment is performed according to MSA-CO/03, MSA-CP/03, MSA-CS/15 (evtl. In the transitory period also MSA-CS/03), for the accreditation of inspection bodies according to MSA-I/03, for the accreditation of environmental verifiers according to MSA - E/05 and for the accreditation of verifiers of greenhouse gas emissions according to MSA-V/03.

10.2 Witness assessment can be performed either simultaneously with on site assessment or separately.

10.3 The scope and character of the witness assessment are carried out according to the scope of accreditation service, number and complexity of the groups of accredited fields, taking into consideration the volume, organizational changes and other relevant factors.

10.4 The whole scope of accreditation is subject to witness assessment. The witness assessment of the entire scope of accreditation should, if possible, be carried out within the accreditation cycle. If the scope of activity is too wide, the activities are selected by so called sampling.

10.5 CAB is obliged to ensure to SNAS assessors the entry into its customer's organization where the witness assessment should be carried out of its personnel activities.

11 EXTRAORDINARY ASSESSMENT

11.1 The extraordinary assessment is carried out as accreditation service in the cases such as:

a) need to assess the removal of the recorded nonconformities find during the assessment,
b) need for the on-site assessment due to the facts identified in the process of accreditation decision,
c) need for other extraordinary witness assessments as the result of the already carried out onsite assessment,
d) need to assess the CAB's transition to new, updated standards, regulations, etc.
e) SNAS suggestions,
f) complaints/other plaints of third party,
g) when significant changes took place in CAB,
h) when the accreditation was suspended.
i) CAB requierements

11.2 The extraordinary assessment is carried out always in agreement with CAB

11.3 SNAS sets up in AIS the service for the execution of the extraordinary assessment. CAB gets the notification that the amount of payment for the surveillance has been made accessible as well as the notification from the AIS about the PS composition proposal. CAB sends its opinion on the proposed PS composition analogously to accreditation. CAB, within the meaning of the notification email, is obliged to send to SNAS the opinion on PS composition electronically through AIS within seven days. If the accredited person fails to meet this deadline, SNAS can suspend the accreditation.

11.4 In case (f), the extraordinary assessment shall be carried out operationally, if justified, as soon as possible after the delivery of the complaint / other submission in the relevant area and scope to which the complaint / other submission was made. Extraordinary assessment in case (g), the assessment shall primarily focused on the area of occurred changes and may affect the fulfillment of the accreditation requirements. If necessary, SNAS may extend the scope of the assessment operatively.

The costs of extraordinary assessment support by the CAB and are determined according to SNAS price list. In cases (e) and (f), the costs of the extraordinary CAB assessment shall be support only in the case of a substantiated complaint / complaint.

12 BEGINNING AND TERMINATION OF ACCREDITATION SERVICES

12.1 The accreditation service proceedings begin from the day of delivery of the Application signed by statutory representative. SNAS is obliged to decide on accreditation proceedings within six months from the beginning of proceedings.

Note: The period of proceedings doesn't include the time during which the proceedings were suspended.

12.2 In the case of accreditation, reaccreditation and extension of accreditation, after the opinion of the professional guarantee and VO the SNAS Evaluation Commission (HK) evaluates the accreditation service provided and takes a standpoint and records in AIS, in which it recommends to SNAS director to grant/not to grant the accreditation or gives the case back for revision. After the revision HK assesses the case again.

Note: During the transition to the current wording of the international standards used for accreditation, HK assesses also accreditation service (surveillance, extraordinary assessment) carried out.

12.3 After having taken the decision on the accreditation, reaccreditation and extension of accreditation case, SNAS sends a notification to CAB in which he will get access in AIS to the information in relation to the HK conclusions, Summary report and VP recommendations, KD -Planning of services, elaborated by SNAS for the whole period of accreditation validity.

In the case of changes, if relevant (e.g. extension of accreditation, transfer of accreditation to other legal entity, etc.) the Card of surveillances can me updated in AIS as necessary.

12.4 In the case of surveillance/extraordinary assessment after the service review by OG, the VO assesses the carried out accreditation service and takes the standpoint in which it is decided whether keep the accreditation or recommends to SNAS director to carry out relevant changes.

12.5 The accreditation service is considered to be delivered by the decision of SNAS director, or, in the case of surveillance/extraordinary assessment without changes of the scope of accreditation by the decision of the head of department.

12.6 In the preliminary assessment, the service is considered to be completed on the day of sending/handing over/making accessible to the applicant in AIS the "Record on the preliminary assessment" in AIS.

12.7 When the decision on granting of accreditation is made, depending on the accreditation service type, SNAS sends to CAB:

- decision on granting of accreditation with the annex consisting of the certificate of accreditation and/or certificate of the fulfilment of notification requirements and the scope of accreditation,
- a pattern of SNAS accreditation symbol, notification symbol of SNAS or combined ILAC MRA/IAF MLA symbol of accredited person*,
- agreement on granting of a license to use the combined ILAC MRA/IAF MLA symbol af the accredited body (in the case of new applicants for accreditation service).

After the decision of not granting of the accreditation, SNAS will send to the applicant the decision on not granting of accreditation with relevant justification.

12.8 After signing of the agreement on granting of license to use the combined ILAC MRA/IAF MLA symbol of the accredited body by the CAB statutory representative, SNAS will send to CAB electronically the combined symbol along with the registration number and an application for sending of the sample location of this symbol on protocols, certificates and other documents the accredited body is authorized to place this symbol on, under the conditions set out in the license agreement and MSA-02.
CAB may start to use the combined ILAC MRA/IAF MLA symbol of accredited person only after a written approval by SNAS regarding the use of symbol on the specimens provided.

12.9 The accreditation validity time is 5 years.
After being granted the accreditation, CAB is responsible for the reported results.

13 NOTIFICATION AND ASSESSMENT OF CHANGES

13.1 After having been granted the accreditation, CAB is obliged to notify SNAS (in writing, in electronic format) on all the changes, having impact on:

- accredited activities,
- legal subjectivity, commercial or organizational position of the accredited body,

- organization and management (e.g. change of staff in key positions and activities),
- policy or procedures,
- resources and premises,
- equipment, work environment,
- bank mandate or other facts that can influence the accredited person's competence,
- specification and scope of activities,
- other facts influencing the competence to carry out of accredited activities.

13.2 In the notification of change CAB specifies in detail the change and its extent in order to make it possible to assess whether there was no change in the scope of accreditation.

13.3 Any change by CAB of the originally assessed existing conditions under which the accreditation was granted is to be assessed from the point of view of fulfilling of accreditation requirements. CAB shall consider all the changes in the relevant documentation to be sent to SNAS.

13.4 Assessment of Changes in General
SNAS provides for the operative assessment of notified changes and, based on the result, takes decision on the given issue.

13.5 Changes in the Quality Manual, Documented Information of the Accredited Body
SNAS doesn't manage the CAB's quality manual, documented information.
Prior to any relevant assessment, CAB is obliged to input the updated QM , evtl. DI into AIS

13.6 Changes in the Normative Documents
Changes in the normative documents can be divided into three levels the further procedures in relation to accreditation scope depend on. The levels of change and relevant procedures are as follows:

- <u>Changes in relation to the name or denomination of the standard and minor changes in the normative procedure.</u>
  The CAB shall notify SNAS abut this change (in writing, in electronic format) stating clearly that it is a formal change of the name or denomination of the standard, or a minor change in the procedure. After such notification, assessment, approval and/or issue of a new scope of accreditation the CAB can indicate in its certificates, inspection reports, protocols of testing or calibration certificates the denomination of the new standard, stating in the case of fixed scope laboratories the word "replaces" followed by the denomination of the original standard. If the references are indicated in the protocols and certificates to the internal regulations stemming from the replaced standard, this change is to be clearly documented in the relevant internal CAB regulation.

- <u>Changes in relation to the modification of original standard procedure in the laboratory.</u>

a) CAB with fixed scope of accreditation or CABs, the laboratories of this type are a part of, shall in such case ask SNAS for the extension of accreditation by a new method and in the same time, when necessary, ask for reduction of the accreditation by the method they will not use any more.

b) CAB with flexible scope has to notify SNAS (in writing, in electronic format) about the changes in the standard used, specifying precisely the modification towards the original normative procedures. The further procedure is similar to one concerning the name or denomination of the standard and during the planned surveillance the fact will be checked relating to the original procedure modification. The procedure for flexible scope laboratories is managed by the PL-21 and MSA-07.

- Significant changes concerning the CAB procedure.

  The significant changes in CAB procedures are assessed in accordance with the procedures for extension or reduction of accreditation, or, eventually for extraordinary assessment.

13.7 Assessment of Change
SNAS will assess the new situation and if the delivered documentation doesn't prove the fulfilment of accreditation requirements, SNAS will invite CAB to complete the documentation. If the CAB even after this call does not submit the required documentation SNAS will send to the AO a notification on the beginning of proceedings on the suspension of the accreditation. If it proves during the proceedings on the suspension of accreditation, that the CAB doesn't fulfil the accreditation requirements, SNAS will issue a decision on the suspension of accreditation. In the case of changes that can seriously influence the fulfilment of accreditation requirements, SNAS will secure the immediate control of the carried out changes and fulfilment of the accreditation requirements on site by means of the extraordinary assessment (see chapter 8). The extraordinary assessment will be carried out also in the case when it is impossible to assess administratively the impact of the changes on the fulfilment of accreditation requirements on the basis of data reported, or when there is a reasonable suspicion that the accreditation requirements are not fulfilled. SNAS notifies (in writing, in electronic format) the accredited body about the extraordinary assessment performance.
Until the new decision is issued, the AO has no right to refer to the accreditation.

13.8 In the case when only formal changes are reported and they don't affect the fulfilment of accreditation requirements, only an administrative assessment will be carried out and the control thereoff will be performed only during the next planned service.

14 REDUCTION OF ACCREDITATION

14.1 SNAS will reduce the accreditation, if AO
- in its activities fails to meet the requirements laid down by the Law or relevant mandatory accreditation requirements for the particular item from the scope of accreditation,
- based on CAB's request

14.2 Accredited person is informed about the reduction of accreditation in the form of decision.

15 SUSPENSION OF ACCREDITATION

15.1 SNAS will suspend the accreditation if AO:

- temporarily does not fulfil the requirements set by the Law or the relevant mandatory accreditation requirements,
- despite of the written appeal with the notice that shall not be longer than two months, the accredited body didn't remove the nonconformities in meeting of the accreditation requirements or the adopted actions are not sufficient to the full removal of deficiencies in the fulfilment of accreditation requirements,
- its quality management system temporarily doesn't provide the requested level of control,
- doesn't fulfil duly the accreditation requirements due to the changes regarding the accreditation granted, applicable to the legal form or trade activities, organization, management and expertise of the staff, basic policy, field and scope of accreditation,
- didn't provide collaboration during the assessment of the fulfilment of the requirements set by Law and of accreditation requirements, especially providing of necessary documents, information and explanations,
- does not allowed witness assessment,
- did not enable the SNAS entrusted persons to enter the premises, access the technical equipment and look into the documentation.

15.2 The maximum suspension period is 6 months whereby this period cannot exceed the period of accreditation validity.

15.3 SNAS may also decide on the suspension of accreditation also upon the request of the accredited body.

16 CANCELLATION OF SUSPENSION OF ACCREDITATION

16.1 After reviewing the deficiencies that led to the suspension of accreditation, e.g. in the form of extraordinary assessment the accredited body shall apply for in AIS). When, during the extraordinary surveillance, the fulfilment is identified again of the accreditation requirements for the given field, SNAS will decide on the cancellation of the suspension of accreditation. The accredited body will be informed in writing about this decision.

16.2 Any non compliance with the deadline given for the elimination of stated deficiencies or their non elimination is a reason for SNAS to decide according to the gravity of findings, on a reduction of the scope of accreditation or on withdrawal of accreditation. SNAS shall first inform the accredited body in writing of the initiation of proceedings leading to the reduction of accreditation/withdrawal of accreditation and subsequently it will decide on its reduction/withdrawal.

17 WITHDRAWAL AND TERMINATION OF ACCREDITATION

17.1 SNAS will decide on accreditation withdrawal if AO:

- In its activities doesn't fulfil the requirements set by the Law or accreditation requirements, the quality management system of the accredited body permanently does not secure the required quality level,

- doesn't fulfil the accreditation requirements due to the changes regarding the accreditation granted that relate to the legal form or trade activity, organization, management and expertise of the staff, basic policy, field and scope of accreditation,
- repeatedly violated its obligation to provide collaboration in the verification of the fulfilment of the requirements set by Law and of accreditation requirements, relevant mainly to the provision of necessary documents, information and explanations,
- repeatedly violated its obligation to enable the SNAS entrusted persons to enter the premises, access the technical equipment look into the documentation,
- violated its obligation to inform SNAS without any delay about the changes regarding the accreditation granted that relate to the legal form or trade activity, organization, management and expertise of the staff, basic policy, field and scope of accreditation and other facts that can influence the ability of the accredited person to fulfil the accreditation requirements,
- member of the top management of the GHG emissions verifier was convicted of fraud.
- if there is a proof of CAB's fraudulent behaviour or CAB deliberately provided false information or deliberately conceals or intentionally violated the accreditation requirements.

17.2 SNAS may also decide on the withdrawal of accreditation upon the request of AO.

17.3 The accredited person is informed about the accreditation withdrawal in the form of a decision.

17.4 Accreditation is terminated when:

- time expires of the accreditation validity
- the activity of the accredited body has been suspended for a period of six consecutive calendar months and a decision has not been made rightfully regarding the cancellation of accreditation suspension
- the accredited body enters into liquidation
- a bankruptcy was declared on the accredited body's property
- AO dies or is pronounced dead or becomes extinguished without legal successor

18 TRANSFER OF ACCREDITATION

18.1 In case of change that might affect the conditions under which the accreditation was granted (e.g. change of the legal status of AO or of the organization AO is an organizational part of, merger of the accredited body with another accredited body, transfer of the site performing the accredited activities into another legal entity, etc.) the AO who wants to continue to perform the accredited activities shall notify SNAS in writing on the above facts.

18.2 The AO submits the written notification without any delay, however at latest on the day when the change of legal status or organizational change will take place.

18.3 The request for transfer of accreditation is submitted into AIS by the successor organization. The successor organization, if not yet registered, is obliged to register in the AIS

at https://ais.snas.sk. It is also obliged to fill-in/check the rightness of data in the Card of the body - section of Basic Data (including the data of the statutory representatives), Related relationships, Users and Conformity assessment bodies (where it among others assigns to CABs and sites the managers and quality managers). Only than it can proceed to the completion of the "Application for accreditation service - accreditation transfer".

As a part of the Application for transfer of accreditation there must be relevant from the following:

- evidence that the successor organization, of which the accredited body is a part, is body that may be regarded as legally responsible,
- document by which the change was decided (e.g. legal entity winding-up and merger with another legal entity, ...) or a reference to this document,
- declaration of top management of successor organization about the commitment to create the conditions for performance of accredited activity in a manner which fulfils the requirements of the corresponding accreditation standard and about the transposition of all accredited body obligations,
- current organizational structure of successor organization with the inclusion of the site performing the accredited activities,
- updated pages of PK or DI with incorporated changes, resulting from the change,
- confirmation that the operations will be carried out in unchanged premises and with the same equipment,
- confirmation that the current technical management of the conformity assessment body and its specialized staff will remain unchanged ,
- any changes relating to the management system.
- filled in OA form (both parts).

18.4 The assessment of required changes is ensured operatively by SNAS based on the request of the transfer of accreditation and based on the result of assessment SNAS will make the decision.

18.5 If it is proven that the changes announced by the successor organization or accredited body do not affect the fulfillment of accreditation requirements and they continue to fulfil the conditions under which the accreditation was granted, SNAS will withdraw the original decision and issue a new decision on accreditation granting. Otherwise, SNAS will send a notification of the commencement of administration proceedings to suspend the accreditation. This notification is sent also in the case when the successor organization or accredited body accredited person does not document the notified changes with the necessary documents or in the case when the fulfilment of accredited requirements needs to be verified by extraordinary surveillance.

18.6 Until the decision is issued, the successor organization has no right to refer to the accreditation.

19 ANNEXES

Annex 1: Documents inputted into AIS when submitting the Application in electronic format in accordance with chapter 4.

ANNEX 1:
DOCUMENTS INPUTTED INTO AIS AT THE ELECTRONIC SUBMISSION OF APPLICATION ACCORDING TO CHAPT. 4

Testing, calibration and medicine laboratories

Documents to the application:	**Granting of accreditation**	**Reaccreditation**	**Accreditation extension**
Proof of organizational structure of legal/physical entity which clearly shows the CAB integration and address of all sites the granting of accreditation is asked for, including the virtual site,	x	x	x
Documented information according to the given accreditation scheme (e.g. quality manual with annexes, documented information),	x	x	x
Annex to AO according to accreditation scheme (both parts)	x	x	x
Human resources (list of personnel, if it is not part of PK/DI)	x	x	x
Technical resources (list of technical equipment if it's not part of PK/DI)	x	x	x
Strategy of participation at PT/ILC elaborated according to PL-23 and MSA-L/14	x	x	x
Confirmation of payment of the fee for application	x		
Elaborated check list (valid for ISO/IEC 17025:2017)	x	x	x
Card of the subject / PT (TL 71_X_PT_XX):			
Annex No. 1to the Strategy of participation in PT/ILC – plan for the following accreditation cycle (5 years)	x	x	x
Annex No. 1 to the Strategy of participation in PT/ILC – participation in the field/subfield the accreditation of which is asked for	x		x
Annex No. 1 to the Strategy of participation in PT/ILC – participation for the entire accreditation cycle		x	

Inspection bodies, certification bodies, GLP

Documents to the application:	Granting of accreditation	Reaccreditation	Accreditation extension
Documents proving the legal subjectivity of the applicant	x		
Proof of organizational structure of legal/physical entity which clearly shows the CAB integration and address of all sites the granting of accreditation is asked for, including the virtual site	x	x	x
Documented information according to the given accreditation scheme (e.g. quality manual with annexes, documented information)	x	x	x
Annex OA according to accreditation scheme (both parts)	x	x	x
Human resources (list of personnel, if it is not part of PK/DI)	x	x	x
Technical resources (list of technical equipment if it's not part of PK/DI) (if applicable)	x	x	x
Confirmation of payment of the fee for application	x		

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