SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

MSA - 04

ACCREDITATION PROCEDURE

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MSA available on: https://www.snas.sk

Content

1 INTRODUCTION

This Methodological Guideline for Accreditation (MSA) regulates the basic principles that apply to applicants for accreditation services (the preliminary assessment, the accreditation, reassessment, the change of accreditation, the surveillance, the witness assessment, the extraordinary assessment, the accreditation for the notification/authorization purposes, the assessments associated with various types of attestations).

The principles for granting a certificate of compliance with the principles of Good Laboratory Practice (GLP) are governed by special regulations stated in the National GLP Compliance Program of the Slovak Republic
(see https://www.snas.sk/slp/dokumenty#narodny_program_dodrziavania_zasad_slp).
MSA applies binding international documents. The following formulations are used in the guideline:
- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "can" indicates permission, possibility or ability.

2 ABBREVIATIONS AND TERMS

2.1 ABBREVIATIONS

AK	Acceptance Commission
AIS	Accreditation Information System
AO	Accredited body
CAB	Conformity Assessment Body, the concept includes the accredited body and
the	applicant for an accreditation service
DI	Documented Information
E	Professional expert
EA MLA	EA Multilateral Agreement
EA BLA	EA Bilateral Agreement
EMAS	EU Eco-Management and Audit Scheme
ES	European Community
G	Case officer
HK	Evaluation Commission
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Co-operation
ILC	Inter-Laboratory Comparison
IO	Inspection Body
KL	Calibration Laboratory
ML	Medical Laboratory
MLA	Multilateral Agreement
MRA	Mutual Recognition Arrangement
MSA	Methodical Guideline for Accreditation
NBÚ	National Security Authority

OA	Annex of Application for Accreditation Service which states the "Specification of Activities" of a CAB for the relevant scope.
OG	Guarantor
OZ	Organizational Unit
P	Assessor
PK	Quality Manual
PS	Assessment Group
PT	Proficiency Testing
RA	Scope of accreditation
SL	Testing Laboratory
GLP	Good Laboratory Practice
VO	Head of department
VP	Lead Assessor
ÚPVS	Central Government Portal

2.2 TERMS

Accreditation – the third-party attestation related to a CAB providing formal demonstration of the competence to perform specific conformity assessment tasks

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

Accreditation activities - individual tasks in the accreditation process.

Accredited body (AO) – a CAB which was granted accreditation upon the demonstration of the compliance with the accreditation requirements.

Accreditation requirements – a set of requirements resulting from: the harmonized technical standard published in the Official Journal of the European Union, the technical standard, the technical regulation concerning the area of the conformity assessment or any other generally binding legal regulations and normative documents determining the conditions of the CAB's activities.

Accreditation process - the activities carried out from the moment of receiving an application through granting and maintaining of accreditation, as defined by the accreditation scheme.

Decision on accreditation – the decision on granting, not granting, maintaining, extending, reducing, suspending and withdrawing of accreditation.

Accreditation scheme – the rules and procedures related to the accreditation of conformity assessment bodies, to which the same requirements apply.

Accreditation symbol – a symbol issued by SNAS to be used by CABs so as to prove their accreditation

Conformity assessment activity – the activity performed by CAB when assessing conformity

Flexible scope of accreditation– the scope of accreditation expressed in such a way as to allow the CAB to amend the methodology and other parameters within the CAB's competence, and confirmed by SNAS

Impartiality – the presence of objectivity

Accreditation area – a general definition of the accredited CAB's activities or those, for which the accreditation is sought

Expert – an external collaborator of SNAS at all levels – a lead assessor, an assessor, a professional expert

Professional expert – a person appointed by the accreditation body to provide specific knowledge or expertise in the assessed area of accreditation. The professional expert can be an external or internal SNAS employee.

Note 1: The professional expert works under the supervision of the VP/P and provides him expert opinions on the assessed professional activity, either before the assessment, during it (see note 2) or after the assessment (before taking a decision on the granting or continuation of accreditation).

Note 2: Within the framework of the PS, the professional expert cannot act independently as an assessor (e.g. formulate identified nonconformities).

Note 3: Within the Accreditation Information System (AIS), the designation "expert" is used for a professional expert.

Appeal – a request by a Conformity Assessment Body to reconsider an adverse decision on accreditation related to its requested accreditation status

Authorized person – a person entered by the CAB into the AIS system as a person authorized to act on behalf of the applicant / accredited person within the scope of the provided accreditation services

Conformity Assessment Body (CAB) – the body providing conformity assessment services which may be or is subject to accreditation. In this regulation, CAB means an accredited body or applicant. It may be the CAB directly or an organization/person of which the conformity assessment body is a part

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

Assessment program – a set of planned assessments, in accordance with a specific accreditation scheme to be carried out by SNAS in a particular CAB during an accreditation cycle

Guidance – the participation in any of the CAB's activities which is subject to accreditation

Assessor – a person appointed by SNAS to perform an assessment of a CAB, either individually or as an assessment group member

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

Assessment plan – a description of activities and a preparation of a specific assessment

Assessment – a process assessing the compliance with the accreditation requirements to determine the competence of a CAB within the defined scope of accreditation based on the standard(s) and/or other normative documents, and to be performed by SNAS

Suspending of accreditation – the temporary restriction of the whole scope of accreditation or a part thereof

Workplace – all the locations where one or more key activities are performed; or a determined space where the employee regularly performs work on the permanent premises within the organizational structure of the employer. If the organizational structure includes multiple permanent spaces at one address (e.g. laboratories, separate departments, divisions), it is one workplace.

Place of activity – a specific area where the employee performs work outside the permanent premises specified in the organizational structure of the employer (e.g. on the customer's premises)

Reaccreditation – the assessment performed in order to renew the accreditation cycle

Scope of accreditation – the specific conformity assessment activities for which an accreditation is requested by the CAB or was granted

Extending of accreditation – the addition of conformity assessment activities to the scope of accreditation

Complaint – an expression of dissatisfaction by any person or organization, other than an appeal, to SNAS relating to the activities of SNAS or the accredited CAB, and where a response is expected

Witness assessment – the observing of the performance of the CAB conformity assessment activities within the scope of its accreditation by SNAS

Specification of activities – the scope of activities for which the CAB seeks accreditation, which is identical in form to the "Scope of Accreditation", however may differ from each other in content

Technical area /sector certification scheme/conformity assessment scheme – the rules and procedures related to accreditation of the relevant conformity assessment bodies to which the specific requirements apply.

Assessment technique – the method used by SNAS to perform an assessment

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

Maintaining of accreditation – confirming the continuation of accreditation within the defined scope

Virtual site – the virtual site where the CAB performs its work or provides services by means of an on-line environment that allows individuals to perform processes regardless of physical locations. Where processes shall be performed in a physical environment, the virtual site cannot be used e. g. in testing, calibration, medical examinations, warehousing, production, installation or repairing of physical products

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

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

Change in accreditation of a formal nature – a specific form of the change in accreditation in accordance with the § 29(1)(a) and (b) of the Act, which is not considered an extension of accreditation pursuant to the Chapter 7.10 of ISO/IEC 17011 (e.g. a formal amendment in the area or scope of accreditation, the change in the normative documents according to 7.1.11.1, the change to a standard that does not affect the method, an incorporation of reported changes to the flexible scope of accreditation, the modification of the scope of accreditation resulting from the regulator's requirements, the modification of the scope of accreditation resulting from the requirements of mandatory EA, ILAC, IAF documents, other modifications that do not affect the relevant determinant)

Change in accreditation based on assessment – the change in accreditation resulting from the assessment outcomes (the change in accreditation of a formal nature or reducing of accreditation). The due time for the SNAS decision-making under the § 25 of the Act shall begin to apply after completing the relevant service.

List of accredited activities (List) – based on the 'Scope of Accreditation', and includes the activities covered by the flexible scope along with information regarding the limits of flexibility. List is managed by the accredited CAB independently

Withdrawal of accreditation – the termination of accreditation to the full extent

Reduction of accreditation – the withdrawal of a part of the scope of accreditation

Applicant - a legal/physical entity that files an application for granting of accreditation for the CAB

Note:
Unless otherwise specified or explained in the text, the requirements related to the performance of accreditation services in the certification bodies also apply to the validation and verification bodies and environmental verifiers.

3 RELATED DOCUMENTS

ISO/IEC 17011	Conformity Assessment - Requirements on the accreditation bodies accrediting the conformity assessment bodies
Act No. 53/2023 Coll.	Act on accreditation of conformity assessment bodies (hereinafter referred to as „the Act ")
Act No. 71/1967 Coll.	Act on Administrative Proceedings (administrative order), as amended
SNAS Policies	see https://www.snas.sk/akreditacia/hlavne-znaky-akreditacie#metodicke_smernice_a_politiky_snas
RR-02	Price list of SNAS services see: https://www.snas.sk/akreditacia/cennik-sluzieb-snas
MSA SNAS	see https://www.snas.sk/akreditacia/hlavne-znaky-akreditacie#metodicke_smernice_a_politiky_snas

ST-05	SNAS Evaluation Committees, see: https://www.snas.sk/o-nas/identifikacia-snas#poradne_organy_snas

4 PRELIMINARY ASSESSMENT

4.1 INFORMATION ON PRELIMINARY ASSESSMENT

4.1.1 The CAB is an applicant for a preliminary assessment requesting that SNAS conduct a preliminary assessment.

4.1.2 The preliminary assessment is an accreditation service that may be requested by the CAB at its own discretion or upon the recommendation of SNAS.

4.1.3 The objective of the preliminary assessment is to assess the compliance with the accreditation requirements in general terms according to the relevant standards and regulations in a given area and the accreditation scheme and related methodological guidelines for accreditation, and to examine the readiness of the applicant for accreditation.

4.1.4 The filing of an application for the preliminary assessment is a fundamental condition to conduct a preliminary assessment (see Chapter 5).

4.1.5 The applicant for whom a preliminary assessment will be performed shall provide SNAS with the required documents necessary for the assessment.

4.1.6 SNAS shall electronically provide the CAB with the following: the PS draft and the fee calculation for the service according to the applicable price list. The CAB shall then electronically provide its opinion on the PS draft by analogy as with other accreditation services.

4.1.7 During the preliminary assessment, SNAS shall not provide any advice or guidance on how to address and eliminate any identified findings.

4.1.8 The PS shall prepare a "Record of the Preliminary Assessment" on the preliminary assessment outcomes which shall state the identified findings related to the compliance of the accreditation requirements. The findings shall be used to enable the CAB to eliminate any issues that would prevent the CAB from being granted accreditation. The record of the preliminary assessment is not binding for the CAB.

4.1.9 Following the completion of the preliminary assessment the CAB may decide whether or not to apply for accreditation. The record of the preliminary assessment is not binding for SNAS when making a decision on accreditation.

4.1.10 The preliminary assessment does not constitute a condition for granting of accreditation.

5 ACCREDITATION

5.1 INFORMATION ON ACCREDITATION PROCEDURE

5.1.1 SNAS shall perform an assessment of the compliance with the accreditation requirements during the accreditation, the reaccreditation, the change of accreditation, the suspension of accreditation, the withdrawal of accreditation. The suspension and the withdrawal of accreditation are the exception, should the accredited body request so.

5.1.2 The information on the accreditation process, the procedure of filing an application and determining an approximate fee amount for the accreditation service, and the necessary forms are available on the SNAS website www.snas.sk, or in the AIS.

5.1.3 The additional information related to the accreditation process shall be provided to the applicant upon request by the SNAS Secretariat and a relevant SNAS department. The accreditation body personnel shall not provide information that could be considered as consultation or other advisory services that could cast doubt on the objectivity of the accreditation process and decision-making.

5.1.4 All processes, including the application for accreditation services, their course, the processing of the assessment outputs and handling of the entire service shall be performed electronically - directly in the Accreditation Information System (AIS).

5.1.5 SNAS shall issue the decision on accreditation and the certificate of accreditation based on the CAB's application for accreditation after assessing and confirming the compliance with the accreditation requirements.

5.1.6 The CAB that is issued the decision on accreditation and the certificate of accreditation upon demonstration of the compliance with of the accreditation requirements also becomes an AO.

5.1.7 Acting as an AO and exercising the rights under the § 36(1) of the Act without a valid decision on accreditation or exercising the rights under the § 36(1) of the Act in an area or scope that are not subject to a valid decision on accreditation shall be prohibited.

5.2 APPLICATION FOR ACCREDITATION SERVICE

5.2.1 SNAS shall decide on accreditation, reaccreditation, the change in accreditation, the suspension of accreditation or the withdrawal of accreditation on the basis of an application. The CAB that is not an AO in the relevant accreditation area and applies for accreditation, or an AO that applies for reaccreditation, the change of accreditation, the suspension of accreditation or the withdrawal of accreditation is an applicant for an accreditation service.

5.2.2 The applicant for an accreditation service shall file an application through the AIS in the national language or in the language determined by SNAS in the information system.

5.2.3 Prior to filing an application, a new legal entity wishing to apply for accreditation shall first register on https://ais.snas.sk. The Accredited Bodies (AOs) shall be no longer required to register.

The CAB wishing to apply for an accreditation service shall first complete/check the correctness of the data in the Card of the Body in the AIS specifically in the Basic Data (including the details of the statutory representatives), Related Relationships, Users and Conformity Assessment Bodies sections (where, amongst others, it shall assign the head managers and quality managers to the CAB and the workplaces/organizational units). Only then can the organization proceed to the completion of the Application for Accreditation Service - Transfer of Accreditation'. Only then can the CAB proceed to the completion of the "Application for Accreditation Service" (hereinafter referred to as the Application). The applicant shall complete a separate Application for Accreditation Service for every single area of accreditation.

5.2.4 The application for an accreditation service shall include

- the business name and place of business of the applicant for the accreditation service, if it be a physical entity – entrepreneur, or the business name and registered office of the applicant for the accreditation service, if it be a legal entity;
- the identification number of the organization;
- the identification of the organizational unit which is to perform the activities of the accredited body;
- the place of the activity performance which is subject to the application;
- the designation of the relevant accreditation service;
- the identification of the area of accreditation and the scope of accreditation which is subject to the application;
- the commitment to comply with the accreditation requirements and other requirements under the Act during the validity of the decision on accreditation;
- the name, surname and status of the authorized person;
- the signature of the authorized person and the date.

5.2.5 The written documents necessary to verify and regularly monitor the compliance with the relevant accreditation requirements shall be attached to the application. When filing an application, all prescribed documents as per the Act and the SNAS regulations shall be uploaded in electronic form. These are:

- the evidence of the organizational structure of the legal/physical entity, showing the integration of the CAB in a larger organizational unit, if any;
- the addresses of all sites and the information on the activities in all workplaces, including the virtual site, for which the accreditation is requested;
- the PK/DI according to the accreditation scheme in question (e. g. Quality Manual with annexes, documented procedures);
- the OA annexes (both parts) according to the applied for accreditation scheme. The relevant OA Annex Part 1 shall be drawn up according to the relevant MSA-X/01, the OA Annex Part 2 shall be elaborated according to the CAB documentation structure;
- the human resources (a list of the CAB's personnel, including the employees performing relevant expert activities), if not included in the PK/DI;
- if applicable, technical resources (a list of technical equipment, if not part of the PK/DI);
- in the case of applicants for accreditation or reaccreditation of the calibration and testing laboratories (of the inspection bodies only if applicable), the TL 606 form

'Questions on the information systems used' shall be attached to the application. The filled in form shall be uploaded in the section 'Other documents' of the Application;

- in the case of the calibration, testing and medical laboratories (of the inspection bodies only if applicable) and also in the case of the use of 'IN-HOUSE/IN-HOME' calibration:
  - the PT participation strategy for the next accreditation cycle developed in accordance with the PL-23 and MSA-L/14;
  - the KL, SL - evidence (e. g. reports) of successful participation in the PT/ILC for each sub-area (the first granting of accreditation and the extension of accreditation);
  - the ML - evidence (e. g. reports) of successful participation in the ILC for each sub-area (the first granting of accreditation and the extension of accreditation). In the case of the ML participation in the PTs at the official proficiency test organizers accredited according to ISO/IEC 17043, no evidence is required (PTs have multiple cycles, the number of which shall be specified in the PT participation strategy);
  - the "IN-HOUSE/IN-HOME" calibration - evidence (e.g. reports) of successful participation in the PT/ILC for each sub-area (the first granting of accreditation and the extension of accreditation) to be uploaded in the "Other Documents" section of the Application;
  - the KL - in the case of an application for the first granting of accreditation and the extension of accreditation for the calibration of recording equipment in road transport, an application for the PT from a competent PT provider is sufficient;
  - the completed Annex 1 to the Strategy of participation in the interlaboratory comparisons (proficiency testing, interlaboratory comparative measurements, etc.), the plan for the next accreditation cycle (accreditation/reaccreditation/extension of accreditation) to be uploaded in the "Other documents" section of the Application;
  - in the case of accreditation/extension of accreditation, the completed Annex 1 to the Interlaboratory Comparison Participation Strategy on participation in the interlaboratory comparisons for the areas/sub-areas for which accreditation is requested, to be uploaded in the 'Other documents' section of the Application;
  - in the case of reaccreditation, the completed Annex 1 to the Interlaboratory Comparison Participation Strategy on participation in the interlaboratory comparisons for the whole of the last accreditation cycle to be uploaded in the 'Other documents' section of the Application;
- for the applicants for accreditation or the extension of accreditation for the calibration of recording equipment in road transport in the case of an application for the initial accreditation and the extension of accreditation for calibration of recording equipment in road transport, an application for the PT by a competent PT provider shall be required. The SNAS professional expert shall attend the PT during the witness assessment;
- in the case of applicants for accreditation or reaccreditation of the inspection bodies, all inspection procedures shall be entered in the 'Other documents' section of the Application.

- in the case of applicants for attestation / re-attestation of compliance with notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll. is inserted in the Application in the section "other documents", completed form TL 257 - Control questions for subjects fulfilling individual notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll.

5.2.6 If the expert activities are performed in several workplaces or locations (e. g. on the customer's rented premises, another laboratory) or any branches, the annex to the application for accreditation (the relevant OA form) shall state clearly where the activities in question are performed (applies to all types of CABs). In the case of laboratories performing expert activities outside the permanent premises (on-site, on the customer's premises, in mobile facilities, etc.), this shall also be indicated in the annex to the application for accreditation. Should the laboratory apply for an accreditation service for the authorization/notification purposes, the name of the regulator shall be included on page 9 of the Application for Accreditation Service (Applicant's Note to the Application).

5.2.7 Upon completion of the application in the AIS, a payment receipt documenting the filing, registration and evaluating the application for accreditation shall also be included. The fee shall be charged only for the initial accreditation and paid for each area of accreditation (e.g. in the case of the AOs management systems, the fee shall be charged for each certification standard as well as in the case of the extension) The fee to be paid upon applying shall be non-refundable. For a foreign entity, in which case a contract on the services is concluded, the fee may be included in the final calculation and settled at once together with the service fee. The CABs shall settle the payment to the SNAS account held at the State Treasury, Radlinského 32, 810 05 Bratislava, IBAN: SK02 8180 0000 0070 0036 9571. The CAB's ID number serves as the Variable Symbol. The Specific Symbol is not required. The invoice shall be sent to the CAB after settling the payment.

5.2.8 Besides the required annexes, the applicant shall be bound to provide other documented information relevant to the assessment of the compliance with the accreditation requirements at the PS's or case officer's request.

5.2.9 The DI shall contain references to the relevant part of the standard in order to easily identify the documented implementation of the relevant standard requirement. The PK/DI shall document the implementation of the relevant accreditation scheme requirements.
The PK/DI shall also contain (or refer to) information such as:

- the area and scope of accreditation;
- the templates of completed certificates, inspection reports, protocols and other outputs of the accredited activity with an estimated placement of the relevant SNAS accreditation symbol, SNAS notification symbol, combined MRA/MLA symbol of the accredited body or reference to the accreditation statute;
- the lists of personnel indicating their status and the performed accreditation-related activities;
- the specified non-accredited activities in order to identify any potential conflicts of interest.

5.2.10 After completing the application electronically, the CAB shall send the application via the AIS (page11), If you do not sign the application directly in AIS (page

11), then it is necessary to deliver the otherwise signed application to SNAS. Signing outside of AIS and delivering the application can be done using one of the following options:

1. electronically - to the SNAS e-box via the ÚPVS website,
2. in paper form - print and, after signing it by an authorized person of the organization, deliver/send by mail to the SNAS address...

The administrative procedure in the matter of accreditation will only begin with the delivery of the signed SNAS application (forms of delivery: AIS - page 11; ÚPVS e-box; by mail, in person)

5.2.11 SNAS shall reject an application or terminate the accreditation process at any point within the application process or at the beginning of the assessment process should evidence of fraudulent behavior occur, the conformity assessment body deliberately provide false information or the conformity assessment body withhold any information.

5.3 REVIEW AND ACCEPTANCE OF APPLICATION

5.3.1 The SNAS Secretariat shall review the formalities of the application, including the completeness of the mandatory annexes attached to the application (see also Annex 1).

5.3.2 Should the SNAS Secretariat detect absence of the prescribed formalities in the application, it shall, within 5 working days after receiving the application, invite the applicant for an accreditation service to remove the deficiencies within a specified period of time, which shall not be shorter than 15 days. Should a compelling reason occur for doing so, SNAS may on the CAB's proposal, extend the due time. SNAS may also proceed according to the first and the second sentence repeatedly.

5.3.3 If the application meets the requirements, it shall be submitted to the relevant SNAS department.

5.3.4 The head of the relevant SNAS department shall assign a case officer to review the application received. If necessary, the case officer shall request its further completion based on § 22(10) of the Act and SNAS may suspend the administrative proceedings for granting of accreditation pursuant to the § 23 of the Act. If the application complies with the requirements, the case officer shall submit it to the AK. The AK shall evaluate the application in terms of facts and the content, its completeness, adequacy, sufficiency of resources and the feasibility of performing the accreditation service within the period of time set out by law or within a reasonable time, which shall be recorded in the AIS by the chair/vice-chair/secretary of the AK. Should SNAS be unable to provide for the assessment in a timely manner, the CAB shall be notified.

5.3.5 The AK may, where appropriate, propose that the applicant execute a preliminary assessment.

5.3.6 In case of minor deficiencies, based on the recommendation of the relevant technical guarantor, it is possible to forward the application with corrections entered in AIS - section "Documentation" - "Supporting documentation" or "Subject documentation" to the acceptance committee and accept

5.3.7 Should the AK discover that the application does not contain all the relevant documents, the AK may return the application to the AIS for further elaboration and completion of those documents pursuant to the § 22(10). SNAS may, in such a case, suspend the administrative proceedings aiming to grant accreditation pursuant the § 23(1)(b) of the Act. After the completion of the required documents, the application shall be resubmitted to the AK for acceptance.

5.3.8 An application for an accreditation service shall not be accepted by the AK should:

- after being called upon by the AK pursuant the § 22(10) of the Act, the CAB fail to submit the required documents within the period of time pursuant to the § 23(1)(b) and;
- there be a conflict of interest in the CAB upon the performance of the activities for which the accreditation is requested, and this conflict fail to be eliminated;
- the CAB and the OZ for which the accreditation is sought not be clearly defined;
- the area and the scope of accreditation be not clearly defined;
- SNAS be unable to provide for the accreditation service to the extent required;
- the applicant be a foreign entity from the territory in which their local accreditation body is located, which is a signatory of the EA MLA/BLA, ILAC MRA, IAF MLA in the area for which the body seeks accreditation, unless otherwise agreed with the local accreditation body in advance.

5.3.9 Should the application be not accepted, SNAS shall issue a decision to suspend the proceedings. When seeking accreditation again, the applicant shall be bound to repeat the entire application process, including settling the application fee.

5.3.10 Should the application have only formal shortcomings that can be corrected by filing in a new application, no additional fee shall be required.

5.3.11 As for minor shortcomings, the application may be accepted with corrections entered in the 'Documentation', 'Supporting documentation' or 'Entity documentation' sections of the AIS, upon a competent expert guarantor's recommendation.

5.4 FEE AMOUNT CALCULATION

5.4.1 After accepting an application, SNAS shall determine the accreditation service fee according to the valid "Price list of SNAS Services " published on the SNAS website (www.snas.sk). The applicant shall be informed about the fee amount via the AIS.

5.4.2 The specified fee shall be invoiced to the applicant upon the completion of the accreditation service; for foreign CABs, usually in advance.

5.4.3 As far as a transition to the current version of the international standards used for the accreditation/accredited activities performance during scheduled assessments or unplanned services is concerned, an hourly rate shall be added to the assessment fee for the time needed to assess the compliance with all the requirements of the current version of the international standards used for accreditation/certification.

5.5 THE ASSESSMENT GROUP DRAFT

5.5.1 SNAS shall appoint an assessment group composed of the SNAS employees and/or experts.

5.5.2 The members of the PS shall normally be as follows: a Lead Assessor (VP) and/or an Assessor(s) (P) and/or professional expert(s) (E), the number of which shall be determined in order to expertly assess the activities listed in the application. In addition to those appointed, the members of the PS may also be an observer of the VP/P, an assistant to the VP/P, a SNAS employee in charge of monitoring or internal audit, an interpreter or other persons (e. g. an EA evaluation group member, etc.).

5.5.3 Where the CAB applies for accreditation for the notification/authorization purposes, the case officer shall address the relevant regulator to determine whether the nominated/approved technical experts will participate in the assessment, unless other arrangements were agreed upon in advance.

Note: The assessment of the requirements with the view of notification/authorization shall be conducted in accordance with the MSA-N/01, Accreditation for the notification purposes.

5.5.4 The CAB shall be entitled to comment on the bias and impartiality of the PS members. Upon the acceptance of the application, the CAB shall receive a notification disclosing the "Assessment Group Draft"(hereinafter referred to as the "Draft") in the AIS and requesting the CAB's opinion on the PS composition within a specified period of time.

5.5.5 The CAB shall express its position on each PS member directly in the AIS and send it back to SNAS by clicking on the "Send Opinion" button. In response to the notification mail, the CAB is required to electronically send an opinion on the PS composition to SNAS within seven days at the latest.

5.5.6 Any legitimate objections to the PS members (e. g. conflict of interest of a PS member with the entity under consideration) shall be expressed by the CAB in the electronic form. In the case of justified objections, the SNAS shall take this opinion into account and make a new draft (see MSA-06).

5.5.7 Pending the receipt of the consent regarding the PS composition, SNAS may suspend the administrative proceedings for granting of accreditation pursuant to the § 23of the Act.

5.5.8 Once the approval of the draft has been recorded in the AIS, the PS shall be appointed.

5.6 ASSESSMENT PROCEDURE– GENERAL PRINCIPLES

5.6.1 The purpose of the assessment is to assess the CAB's compliance with the accreditation requirements and to confirm its competence to perform the activities for which the accreditation is sought and/or which are the subject of the assessment.

5.6.2 The accreditation requirements apply equally to all CABs regardless of their size and the scope of activities.

5.6.3 The requirements to be assessed are set out in the current accreditation schemes, namely:

- for the testing and calibration laboratories in ISO/IEC 17025;
- for the medical laboratories in ISO 15189;
- for the proficiency test organizers in ISO/IEC 17043;
- for the certification bodies certifying managements systems in ISO/IEC 17021-1, which is for the certification bodies certifying quality management systems supplemented by ISO/IEC 17021-3, for the certification bodies certifying the environmental management systems supplemented by ISO/IEC 17021-2, for the certification bodies certifying the occupational health and safety management systems supplemented by ISO/IEC TS 17021-10, for the certification bodies certifying the sustainable forest management systems supplemented by TD SFCS 1005, for the certification bodies certifying the energy management systems supplemented by ISO 50003, for the certification bodies certifying the food safety management systems supplemented by ISO 22003-1 (ISO/TS 22003), for the certification bodies certifying the quality management systems in welding supplemented by EA-6/02, for the certification bodies certifying the information security management systems supplemented by ISO/IEC 27006, for the certification bodies certifying the anti-bribery management systems supplemented by ISO/IEC TS 17021-9, for the certification bodies certifying the IT service management systems supplemented by ISO/IEC 20000-6 and for the certification bodies certifying the business continuity management systems supplemented by ISO/IEC TS 17021-6;
- for the certification bodies certifying products in ISO/IEC 17065, which is for the certification bodies certifying the products according to the sector specific schemes supplemented by: EA-3/02 for protected designations of origin, protected geographical indications and traditional specialties guaranteed , EA-3/12 for organic production, EA-6/02 for welding processes, TD SFCS 1006 for the customer chain of forestry products, the eIDAS Regulation and ETSI EN 319 403-1 standard for the provision of trusted services, TD MNB-Assessment scheme 000MRA1044 for the interoperability of railway systems, the ECM Regulation and the ERA accreditation scheme ERA 1172/002 for the maintenance of rolling stock;
- for the certification bodies certifying persons in ISO/IEC 17024;
- for the inspection bodies in ISO/IEC 17020;
- for the environmental verifiers in the European Parliament and Council (ES) regulation No. 1221/2009, Commission Regulation (EU) No. 2017/1505 and No. 2018/2026 and in ISO/IEC 17021-1;
- for the validation and verification bodies in EN ISO/IEC 17029, EN ISO 14065 and in regulated area in Commission Implementing Regulation (EU) 2018/2067 as amended by Commission Implementing Regulation (EU) 2020/2084; and in non-regulated area (sector specific schemes) in ISO 14066, EN ISO 14064-3.

5.6.4 Accreditation for the notification/authorization purposes or the attestation of the compliance with the notification/authorization requirements shall be conducted in accordance with this MSA, MSA-N/01 and the agreements between SNAS and the relevant regulator.

5.6.5 The assessment also requires compliance with the requirements set out by SNAS, and which are a clarification of the requirements specified in the basic standards or resulting from the EA, IAF, ILAC mandatory application documents... In the case of accreditation for the notification/authorization purposes, the compliance with the requirements specified by the regulators shall also be taken into account.
5.6.6 When selecting the activities to be assessed, SNAS shall also take into account the risks relating to the scope of accreditation and arising from the CAB's activities, locations and personnel.

5.6.7 The PS members shall assess the competence of the CAB to perform the required activities in terms of the above stated requirements in the documentation and records submitted (PK, DI and procedures, etc.), by various assessment techniques such as: the review of documentation and files, the on-site assessment, the interview, the witness assessment (the assessment of practical performance of activities, the assessment of competence to perform the activities and the compliance with the documented policies and procedures, the witness assessment on the premises of the applicant's client), the remote assessment, the measurement audits, the unannounced visits and the performance examination in the proficiency testing and other inter-laboratory comparisons, where relevant. When not appropriate or feasible to conduct the witness assessment, this shall be justified. On-site assessments shall be carried out both, directly at the CAB as well as on the operation sites outside the permanent premises of the CAB.

5.6.8 All the information obtained in the assessment process shall be deemed confidential. All the participants in the accreditation process shall commit to confidentiality by signing a Statutory Declaration.

5.6.9 The PS members shall not provide any consultation or advice during the assessment process to address potential issues in the area under consideration, even if this would make the assessment more efficient and expeditious.

5.6.10 At the request of SNAS, the CAB shall be obliged to submit the documents necessary for the assessment of the compliance with the accreditation requirements at any stage of the assessment, within a specified period of time, which shall not be less than 15 days. SNAS may extend the due time at the request of the applicant or the AO. SNAS may suspend the proceedings if it invited the applicant/AO to submit the documents, under the § 23(1)(b) of the Act.

5.7 DOCUMENTATION REVIEW

5.7.1 The assessment begins with a documentation review. The documentation to be reviewed generally consists of the PK/DI and the procedures, or DI for the performance of expert activities.

5.7.2 Furthermore, for laboratories, they are also the results of proficiency testing or interlaboratory comparisons in which the laboratory participated, the records of the development/validation of new methods (if relevant), the procedures and, where applicable, the examples of the opinions and interpretations expressed, the use of the

decision rule, the strategy for the participation in the PT/ILCs, the "IN-HOUSE/IN-HOME" calibration procedures, and others, as appropriate. If the laboratory is accredited/reaccredited as a laboratory with the flexible scope, the procedure for the flexible scope management, including the management of the "List of Accredited Activities" and the performance of the modifications and validations of the relevant test methods or calibrations, the verifications of additional, newly introduced methods and the development of new methods shall also be assessed. Where appropriate, the PS members may ask the CAB for the additional documentation necessary for the assessment, e. g. the calculations of uncertainties for a given range of activities with the appropriate examples of the identification of uncertainties.

5.7.3 The CAB is to submit the documents necessary for the assessment of the compliance with the accreditation requirements upon request of SNAS within a specified period of time, which shall not be shorter than 15 days. SNAS may extend the due time on the CAB's request. SNAS may, pursuant to the § 23(1)(b) of the Act, suspend the proceedings once it has invited the CAB to submit the documents.

5.7.4 The documentation requested by SNAS and the PS from the CAB during the accreditation service shall be uploaded by the CAB to the relevant service in the "CAB Documentation" section of the AIS.

5.7.5 Should the CAB fail to file the necessary documents (e. g. for the know-how protection reasons or to maintain confidentiality, etc.) even after being requested to do so, and these will need to be reviewed during the on-site assessment, the CAB shall immediately inform the case officer of this fact and the reasons causing thereof. Based on this information, the case officer shall, together with the OG, reassess the number of assessment days required for each PS member and take this into account when recomposing the PS, reassessing the fee amount, and shall also change the VP in the On-Site Assessment Plan, provided one has already been drawn up. The CAB shall be immediately informed about the changes made by the case officer.

5.7.6 The documentation review shall be carried out by the VP and all P's who shall send their sub-reports on the documentation assessment to the VP. The final report from the documentation review shall be completed by the VP.

5.7.7 The purpose of the documentation review is to evaluate how the individual accreditation requirements are documented in the PK, DI or other supporting or complementary documents they refer to. A "Report of documentation review" shall be elaborated based on the documentation review and then uploaded by the VP into the AIS. Where nonconformities are identified against the documentation of the requirements of the relevant standard or regulation, the VP shall record those directly in the AIS data fields and a notification stating these nonconformities along with the Documentation Assessment Report shall be sent to the CAB.

5.7.8 If the PS identifies any findings of a more serious nature in the compliance of the accreditation requirements, SNAS shall invite the CAB to remove the nonconformities related the compliance of the accreditation requirements within a specified period of time, which shall not be less than 15 days. Should a compelling reason occur for doing so, SNAS may extend the due time on the CAB's request. The CAB must remove the identified nonconformities and inform SNAS thereof. Only then can the on-site assessment be

conducted. SNAS may, pursuant to the § 23(1)(a) of the Act, suspend the proceedings if it has invited the applicant for accreditation, the applicant for reaccreditation or the applicant for the change in accreditation to eliminate the noncompliance with the accreditation requirements.

5.7.9 Where minor nonconformities are identified, SNAS shall not suspend the proceedings and the assessment of the CAB may continue without suspending the proceedings.

5.8 ASSESSMENT PLAN

5.8.1 Prior to the assessment, the G/VP shall agree an assessment date with the PS and the CAB and provide the CAB with an access the 'Assessment Plan' in the AIS, which will be commented on by a responsible CAB officer directly in the AIS.

5.8.2 The Assessment Plan shall be made available in advance to allow the CAB to prepare for the assessment, to resolve any ambiguities or, where applicable, any issues in advance and to ensure that all relevant CAB's employees are present at the assessment.

5.8.3 The assessment plan shall define the assignment of the tasks to the PS and shall include the time and the content allocation of particular activities in order to create a sufficient time to assess the compliance with all relevant requirements and monitor the performance of the activities for which the accreditation is sought. Where applicable, the assessment plan may, upon an agreement with the CAB, be updated during the course of the assessment.

5.9 ASSESSMENT TECHNIQUES

5.9.1 The objective of the assessments is to examine the fulfillment of documented information and procedures of the CAB in practice and the CAB's competence to perform specific expert activities.

5.9.2 The assessment of the compliance with the accreditation requirements is conducted according to the documents pursuant to the § 3(8) of the Act (Regulation (ES) No 765/2008, ISO/IEC 17011, the documents issued by SNAS - policies, methodological guidelines and decisions of the Director, which govern its activities in the preliminary assessment, accreditation, reaccreditation, the change of accreditation, the suspension of accreditation, the withdrawal of accreditation, extraordinary assessment and surveillance, and the implementation of the accreditation requirements published on the website of SNAS, and other internal regulations of SNAS).

5.9.3 The assessments shall be conducted directly on the CAB's premises, as well as in all other location where the CAB performs one or more activities (see MSA-06) covered by the scope of accreditation, or in other workplaces based on the risk analysis respectively. The assessment shall be performed in the presence of the CAB's representatives, namely at least the head of the department, the quality manager and the personnel performing the expert activities.

5.9.4 The assessment of the compliance with the accreditation requirements shall be conducted by the PS, which is upon conducting the assessment of the compliance with the accreditation requirements authorized to:

– in cooperation with the CAB enter the premises, facilities and installations, land and other premises of the CAB for the necessary time, should they be associated with the subject of the assessment of the compliance with the accreditation requirements;
– require that the CAB and its employees provide the PS with documents, other papers, statements, information, including technical data carriers necessary for conducting the assessment of the compliance with the accreditation requirements within a specified period of time, and other cooperation.

5.9.5 SNAS mainly uses the following assessment techniques:

– on-site assessments;
– remote assessments;
– combined assessments;
– witness assessments;
– document reviews;
– reviews of the files containing information, documentation and explanations that relate to the performed activities under the granted accreditation;
– measurement audits and validation audits;
– assessments of performance in the proficiency testing and other interlaboratory comparisons;
– unannounced visits, should SNAS reasonably suspect a breach of an accreditation requirement or violation of the accredited body's obligations under the § 36(2) of the Act;
– interviews with an employee or contractor of an applicant for accreditation service or an employee or contractor of an accredited body, during which the employee's or contractor's expertise and experience in the area of accreditation and the scope of accreditation which is subject to the application or the activities of the accredited body are examined.

5.9.6 Remote assessment shall be conducted by means of electronic means in accordance with the IAF Mandatory Document (IAF MD 4) on the use of the information and communication technology (ICT) for the audit/assessment purposes (MSA-08).

5.9.7 When assessing the accreditation requirements, SNAS shall also conduct a witness assessment which assesses the compliance of the performed activity with the documented procedure and evaluates the accuracy of achieved results by CAB.

5.9.8 The CAB shall ensure that the witness assessments is be performed and, if necessary, enable access to the premises where the product is being designed, to the production premises, the premises where the conformity assessment is to be conducted, the premises to perform tests and the storage space of the producer/operator.

5.9.9 Both online witness assessments and offline recordings shall be accepted. In the case of the certification bodies providing the CAB clients with remote assessment of the performance of the certification processes, the CAB must provide for a real-time auditor-

directed online video from the production and the job sites or the auditor review of the recorded offline videos in the areas without a direct connection, with a possible requirement to provide for a specific new partial online video, if relevant. Dated photographs with the time indication constitute acceptable evidence.

5.9.10 A variety of techniques is used to perform an assessment, such as witness assessment (observation) of expert activities (where justified), a form of simulated/model performance assessment shall be accepted as well (e. g. MSA-I/03, MSA-CP/03, MSA-CS/15), interviews with the CAB technical and administrative personnel, file reviews (by means of vertical audits) and a combination of these techniques.

5.9.11 In the professional area, when assessing laboratories and, where applicable, also inspection bodies, the emphasis shall be inter alia, on how the measurement traceability is ensured (see PL-13), on the calculation of uncertainties in test results and calibrations (MSA-L/12), on the PT/ILC results and the strategy for participation in the PT/ILC (PL-07, PL-23, MSA-L/14), and on the expression of compliance (MSA-L/04).

5.9.12 Following the assessment, a final meeting with the CAB management shall be held during which the PS shall present the assessment outcomes and provide information on the further procedure.

5.9.13 Should the PS identify a nonconformity in the fulfilment of the accreditation requirements, SNAS shall invite the CAB to remove the nonconformity in the compliance of the accreditation requirements within a specified period of time, which shall not be less than 15 days. Should a compelling reason occur for doing so, SNAS may, upon the CAB's request, extend the due time.

5.9.14 After the assessment, the VP shall complete the Record(s) of Nonconformity(ies) in the AIS, set a deadline for sending the cause analysis and the extent of the nonconforming work and a proposal of the corrective measures (usually within 10 working days), as well as the deadline for the nonconformities found during the assessment and the documentation review to be removed, and shall submit them electronically to the applicant.

5.9.15 Pursuant to the § 23(1)(a) of the Act, SNAS may suspend the proceedings if it has invited the CAB to eliminate the nonconformity related to the compliance with the accreditation requirements.

5.9.16 The VP shall elaborate a 'SNAS Report of Findings' signed by the VP and a CAB representative in 2 copies, in which case one copy shall be retained by the CAB immediately after the assessment/witness assessment, and shall also be disclosed via the AIS. In the case of the remote assessment, the 'SNAS Report of Findings' does not need to be signed by the VP and a CAB representative and shall also be disclosed via the AIS. Once the report is disclosed in the AIS, the CAB shall confirm a receipt thereof.

5.9.17 The VP shall then elaborate a 'Summary Report' containing detailed information. The Summary Report shall be disclosed to the CAB upon the completion of the assessment

processes. Should the information stated in the "SNAS Report of Findings" differ from the relevant information given in the "Summary Report," the CAB shall be informed thereof in the: "Other Relevant Information" section.

5.9.18 Upon the receipt of the notification of nonconformity, the CAB representative shall electronically via the AIS confirm that he/she has been notified of the nonconformity, understands it and shall express his/her position on it. Should the CAB representative refuse to accept the nonconformity, the procedure in the article o. 5.10.2.5 of this MSA shall apply.

Note: Should for valid reasons be not possible to complete the Nonconformity Record and its acceptance in the AIS on the spot, it is desirable to complete a paper record and to record and accept the nonconformity in the AIS after the assessment as soon as possible.

5.9.19 Should a nonconformity be identified, the CAB shall be bound to:
– enter the root cause, the scope analysis and the proposed corrective measures specified in the Nonconformity Record into the AIS within a specified timeframe and submit thereof to SNAS via the AIS;
– enter the information on how the nonconformity was removed into the AIS (under the Description of the nonconformity removal) and attach the evidence of the removal no later than the date set out by the VP and send it to SNAS via the AIS.

5.9.20 Should the removal of the nonconformities fail to be accepted by the PS members, the VP shall again request that the CAB remove the nonconformities and provide further evidence of such removal within a specified period of time, which shall not be less than 15 days. Should the CAB be, for serious reasons, incapable of removing the nonconformities within the specified period of time, SNAS may, upon the CAB's request, extend the period of due time. SNAS may suspend the proceedings pursuant to the § 23(1)(a) of the Act should the CAB be asked to eliminate the nonconformities related to the compliance with the accreditation requirements within accreditation, reaccreditation, the change of accreditation.

5.9.21 Pursuant to the § 30(1)(a) of the Act, SNAS shall decide on suspension of accreditation to the extent of granted accreditation or part thereof for a period not exceeding 180 days, provided that the period shall not exceed the validity period of the decision on accreditation, should the CAB fail to remove the nonconformity related to the accreditation requirements within the specified period of time. In the decision, SNAS shall impose an obligation on the CAB to remove the identified deficiencies within a specified period of time, which shall not be less than 15 days and not more than 120 days. SNAS may perform an extraordinary assessment to verify that the identified deficiencies were removed.

5.9.22 In the cases where the assessment demonstrates the CAB's incompetency to perform the activity in a part of the required scope, the assessment will conclude with a proposal to grant accreditation in an appropriately reduced scope. Should the CAB fail to demonstrate the competence to the perform expert activities in the full required scope

and/or is not able to demonstrate the compliance with the system requirements to the full extent, the assessment will conclude with a proposal not to grant accreditation.

5.10 EVALUATION AND CLASSIFICATION OF FINDINGS

5.10.1 The PS shall classify individual findings according to the following classification scale:

- **Conformity** – full compliance with the relevant accreditation requirements.
- **Nonconformity** – non-compliance with or deviation from the accreditation requirements.
- **Risk** – the area of potential non-compliance with the accreditation requirements.

5.10.2 Finding of the "Nonconformity" type

5.10.2.1 Each nonconformity shall be clearly associated with a specific standard requirement or another document containing the accreditation requirements against which the nonconformity is identified.

5.10.2.2 Should SNAS identify a nonconformity in the compliance with the accreditation requirements, the CAB shall be asked to remove the nonconformity in the compliance of the accreditation requirements within a specified period of time, which shall not be less than 15 days. For accredited CABs, the due time for the reasonable removal of the non-conformity shall be 2 months, for the CABs applicant for granting accreditation, the maximum due time for removal of the nonconformity shall be 12 months. Should a compelling reason occur for doing so, SNAS may, upon the CAB's request, extend the period of time. SNAS may, pursuant to the § 23(1)(a) of the Act, suspend the procedure should the CAB be asked to remove the nonconformity related to the compliance with the accreditation requirements.

5.10.2.3 Provided that the CAB is incapable of removing the nonconformity, the accreditation cannot be granted.

5.10.2.4 If the accreditation was already granted and the CAB fails to remove the non-conformity within the specified period of time, SNAS shall, pursuant to the § 30(1)(a) of the Act decide to suspend the accreditation to the extent of the granted accreditation or part thereof for the period of not more than 180 days, and the period is not to exceed the validity of the decision on accreditation, unless the CAB removes the non-conformity with the accreditation requirements within the specified period of time. In its decision, SNAS shall impose an obligation on the accredited body to remove the identified deficiencies within a specified period, which shall not be less than 15 days and not more than 120 days. SNAS may perform an extraordinary assessment to verify that the identified deficiencies have been removed.

5.10.2.5 Should the CAB fail to accept an identified nonconformity, this fact shall be indicated in the AIS and a complaint justifying not accepting the nonconformity shall be

promptly sent to SNAS. The SNAS Director will decide on the appointment of a commission to investigate the complaint. The commission shall be composed of at least three members, including the head of a relevant department, a relevant technical guarantor and another member who shall be a member of the relevant Evaluation Commission. If the assessment is performed by the Head of Department or by a technical guarantor, the group shall be appointed from among the other members of the relevant Evaluation Commission. The due time for removing the nonconformity shall be suspended and shall commence on the date of the decision on the complaint. SNAS may suspend the proceedings for the period lasting from the receipt of the complaint reasoning not accepting the nonconformity through the decision on the complaint.

5.10.3 Finding of "the Risk" type

5.10.3.1 A risk constitutes an area of the potential incompliance with the accreditation requirements, e. g. from the assessment of the negative trends in the HR field, from the low number of the CAB's outputs, etc.

5.10.3.2 The risks shall be recorded in the 'SNAS Report of Findings' and the 'Summary Report'.

5.10.3.3 The CAB is not expected to respond directly to the identified risks, but to evaluate them and take measures to ensure the compliance with the accreditation requirements in future work. The VP appointed for the next assessment shall take the identified risks into account when planning and conducting the assessment.

6 REACCREDITATION

6.1 INFORMATION ON REACCREDITATION

6.1.1 The AO may apply for reaccreditation based on an application filed no later than four months prior to the expiry of accreditation.

6.1.2 The reaccreditation process itself is the same as for accreditation, except that the results from the previous assessments during the last accreditation cycle may be taken into account.

6.1.3 An application for reaccreditation shall be filed in accordance with the § 20 of the Act and articles No. 5.2 and 5.3 of this MSA. During the validity of accreditation, an application for reaccreditation solely may be filed in the relevant field of accreditation.

6.1.4 Should the AO also wish to change accreditation as part of reaccreditation, two separate applications shall be filed - one for reaccreditation and one for the change of accreditation.

6.1.5 For the calibration, testing and medical laboratories (for the inspection bodies only if applicable), the participation in the PT/ILC for the previous period is examined as a part of reaccreditation. If a laboratory participates in the PT/ILC for a specific accreditation cycle and the results are known until after reaccreditation, these results shall be considered as the participation in the PT/ILC for that specific accreditation cycle.

6.1.6 SNAS shall issue a decision on accreditation upon a request for reaccreditation should the AO demonstrate the compliance with the accreditation requirements. If the applicant for a reaccreditation fails to comply with the accreditation requirements, SNAS shall issue a decision not to grant accreditation, and the applicant for reaccreditation shall be bound to settle the costs for the assessment of the compliance with the accreditation requirements, if performed. The decision pursuant to the first sentence shall replace and withdraw the decision on accreditation pursuant to the § 26 of the Act in extenso.

7 CHANGE OF ACCREDITATION

7.1 BASIC INFORMATION

7.1.1 SNAS shall issue a decision on accreditation amending the accreditation granted by the decision pursuant to the § 26 of the Act and withdraw the decision on accreditation, should the AO requests that SNAS:

- extend the area of accreditation or the scope of accreditation;
- reduce the area of accreditation or the scope of accreditation;
- change the data pursuant to the § 26(3) (b) through (e) of the Act:
  - the business name and place of business of the accredited body, if it be a physical entity – entrepreneur, or the business name and registered office of the accredited body, if it be a legal entity;
  - the identification number of the organization;
  - the organizational unit which is to perform the activities of the accredited body;
  - the place of the activity performance of the accredited body.

7.1.2 As for the area of accreditation or the scope of accreditation SNAS shall make a decision upon examining the compliance with the accreditation requirements only within the scope of the requested change of accreditation.

7.1.3 The original scope of accreditation granted by the decision on accreditation pursuant to the § 26, 28 and 30 of the Act shall remain unchanged and be deemed to have been assessed except the part that is amended by the decision pursuant to the § 29(1) of the Act (see also article No. 7.1.1 of this MSA). The period of validity of the accreditation under the original decision on accreditation shall not be extended by the decision under the § 29(1) of the Act (see also article No. 7.1.1 of this MSA).

7.1.4 SNAS shall issue a decision on accreditation reducing the area of accreditation or the scope of accreditation granted by the decision pursuant to the § 26 of the Act and shall also terminate the decision on accreditation should SNAS during the assessment discover that the AO failed to comply with the accreditation requirements stipulated by the Act in its activities, which only relate to a part of the specified area of accreditation or a part of the scope of accreditation, and the AO demonstrates the competence to perform the activities of the AO on the basis of the decision amended so.

7.1.5 SNAS shall, even without a proposal, issue a decision on accreditation pursuant to the § 29(1) of the Act (see also article No. 7.1.1 of this MSA) reducing the granted accreditation, should it discover a reason for the withdrawal of accreditation pursuant to the § 31 of the Act, which only concerns a part of the specified area of accreditation or a part of the scope of accreditation pursuant to the § 20(3)(c) of the Act, and the AO demonstrates the competence to perform the activities of the AO on the basis of the decision amended so.

7.1.6 SNAS shall issue a decision on accreditation, in which the changes pursuant to the § 29(1)(c) of the Act shall be taken into account should the accredited body inform SNAS about these changes or SNAS discover them itself, and the AO comply with the accreditation requirements. If demonstrated that the changes pursuant to the § 29(1)(c) of the Act have an impact on the compliance with the accreditation requirements, SNAS may perform an extraordinary assessment.

7.1.7 SNAS shall issue a decision on accreditation, in which the changes pursuant to the § 29(1)(a) and (b) of the Act shall be taken into account, also in the event of other changes that may affect the AO's ability to comply with the accreditation requirements. In the context of such changes SNAS shall make a decision by examining the compliance with the accreditation requirements only to the extent of the requested change of accreditation.
These changes are divided in terms of the complexity of examining the compliance with the accreditation requirements to the extent of the required change into:

- the changes of a formal nature to accreditation (e.g. a formal amendment in the area or the scope of accreditation, the amendments of the normative documents according to 7.1.11.1, an amendment to a standard that does not affect the method, the incorporation of the reported changes to the flexible RA, a modification to the RA resulting from regulator's requirements, a modification to an RA resulting from the requirements of mandatory EA, ILAC, IAF documents, other amendments that do not affect the respective determinant, etc.). The AO shall file an application using the TL 607 Request for Change of Accreditation of a formal nature, which is available on the SNAS website;
- the changes to accreditation, the examination of which is identical to an extension of the area of accreditation or the scope of accreditation, and shall be assessed in accordance with the procedures for the extension or the extraordinary assessment, as appropriate, as set out in the article No. 7.2 of this MSA. The AO shall file an application using the TL 05 Request for Accreditation Service, which is available in the AIS.

7.1.8 In the event that a formal change to accreditation results from the assessment results, the following procedure shall follow:

- the VP shall record a recommendation to make changes in accreditation in the SNAS Report of Findings (TL 229);
- the AO shall add an Application for Change of Accreditation of a formal nature (TL 607) to the relevant service;
- the VP shall state relevant facts in the VP's Recommendations;

- SNAS shall terminate the service and, in accordance with the decision on the service termination, implement the approved changes within the timeframes set out in the § 25 of the Act.

7.1.9 Should the assessment results indicate the need to reduce accreditation, the following procedure shall apply:

- the VP shall record a recommendation to reduce of accreditation in the SNAS Report of Findings (TL 229);
- the VP shall state the relevant facts in the VP's Recommendations;
- SNAS shall terminate the service and, in accordance with the decision on the service termination, implement the approved reduction of accreditation within the timeframes set out in the § 25 of the Act.

7.1.10 The AO is to promptly inform SNAS of any change(s) in:

- the data pursuant to the § 26 (3) (b) and (c) of the Act, should the accredited body not be a legal entity whose data are entered in the Register of Legal Entities, Entrepreneurs and Public Authorities;
- the data pursuant to the § 26(3)(d) and (e) of the Act:
  - the organizational unit, which is to perform the activities of the accredited body;
  - the place of the activity performance of the accredited body
- the organization, management and expertise of employees;
- the basic policy;
- the area and the scope of accreditation;
- other factors, that may affect the ability of the accredited body to comly with the accreditation requirements.

7.1.11 The AO shall detail what the change and its scope is in the notification on the change in order for SNAS to be able to assess whether there has been a modification in the area of accreditation or the scope of accreditation.

7.1.12 Any change in the AO from the originally existing assessed state of the conditions under which accreditation was granted shall be assessed for the compliance with the accreditation requirements. The AO shall reflect any changes in the relevant documentation to be sent to SNAS. SNAS controls neither the Quality Manual nor the documented information of the AO. The AO is to upload the up-to-date PK or DI, as appropriate, to the AIS prior to the assessment.

7.1.13 The changes to normative documents can be divided into three levels from which further procedures relating to the scope of accreditation are derived.

7.1.13.1 The changes to the title or the reference of the standard and minor changes to the normative procedure:

- the AOs shall notify (in writing, electronically) SNAS of this fact clearly indicating the formal nature of the change in the title or the reference of the standard, or a minor change in the procedure. Following such notification, assessment, approval and/or issuance of a new scope of accreditation, the AOs may indicate the

reference of the new standard in the certificates, the inspection reports, the test reports or the calibration certificates followed by the word 'replaces' and the reference of the original standard for the laboratories with the fixed scope. Where protocols and certificates refer to the internal regulations based on the superseded standard, this change shall be clearly documented in the AO's relevant internal regulation.

7.1.13.2 The changes related to the modification of the original normative laboratory procedure:

- in this case, the CABs with the fixed scope of accreditation or the CABs with laboratories of this type shall apply for an extension of accreditation at SNAS requesting that the new method be included and, if necessary, apply for the reduction of accreditation requesting that the old method, which shall no longer be used, be excluded;
- the CAB with the flexible scope must notify (in writing, electronically) SNAS of the changes to the used standard, specifying exactly the modification against the original normative procedure in question. The further procedure is similar to that for the changes concerning the title or the reference of the standard, except that the facts concerning the modification of the original procedure shall be inspected during the scheduled surveillance. The procedure for the laboratories with the flexible scope follows PL-21 and MSA-07.

7.1.13.3 Significant changes to the CAB's procedure:

- The significant changes to the CAB's procedures constitute an extension of accreditation and shall be assessed in accordance with the procedures for extending of accreditation or for extraordinary assessment, as appropriate.

7.1.14 The procedure and principles used upon conducting the assessments of the changes are analogous to the procedures and principles used during accreditation outlined in the Act and this MSA, emphasizing the stated changes of accreditation.

7.1.15 Should the reported changes be only of a formal nature, an administrative review of the changes shall be conducted merely, and the changes shall only be inspected during the next planned service.

7.1.16 Until an issuance of a new decision on accreditation, the AO shall not be entitled to refer to the accreditation for which the extension, reduction or change is requested.

7.2 SCOPE OF ACCREDITATION OR AREA EXTENSION

7.2.1 The procedure and principles used upon conducting an assessment for the purpose of extending the area of accreditation or the scope of accreditation are analogous to the procedures and the principles for accreditation set forth in the Act and this MSA, with emphasis on the required extension of the scope of accreditation.

7.2.2 The CAB shall file an application for extending of accreditation together with relevant annexes (the items that the CAB seeks to extend must be color coded in the

relevant Annex (OA) to the application for an accreditation service specifying the areas of accreditation and the type of activities within the CAB's current scope of accreditation).

7.2.3 In the case of laboratories, the CAB shall submit a success rate in the PTs with an application requesting extension (as defined in PL 23), including the relevant proof of success in those PTs. The extension of accreditation may relate to a new scope of the activities within the already accredited area or to the new locations of the activities.

7.2.4 For SL, KL, ML, IO and PTP, the extension of the AO's activities by a new area of accreditation (e. g. the AO has a testing area accredited and wants to obtain accreditation for calibration, certification, inspection, ...) shall not be considered an extension of accreditation, but a new accreditation instead and shall be governed by the procedure for granting of accreditation.

7.2.5 The following shall be considered an extension of accreditation in particular:

- the new site for the performance of activities (applicable to all CABs) and new geographical locations for the performance of activities if limited in the original scope of accreditation;
- the change of the fixed scope to the flexible scope and vice versa;
- in the SL with the fixed scope, a new matrix, a property, a new method principle, a new method, a method modification that needs to be validated/verified, the expression of opinions and interpretations;
- a new method or standard reference and an insignificant extension of the scope of accreditation with uncertainty shall not be considered to be extension of accreditation;
- in the SL with the flexible scope, a new method principle, a new workplace, a place of performance;
- in the KL, a new type of gauge, measurement device, extension of measuring range, an improvement of the calibration uncertainty, the change of the calibration method, the change of the calibration performance location (e. g. KL performs calibrations in the laboratory and asks for an 'on-site calibration performance' to be added);
    - a new numerical marking of the method or an amendment of the standard that do not affect the calibration method shall not be considered an extension of accreditation.
    - the change in the formularization of a calibration uncertainty (the change in the way of recording) where this change does not result in an improvement of the uncertainty value shall not be considered an extension of accreditation and shall be assessed during the next possible assessment (the change shall be reported prior to the preparation of the assessment). Should there be many significant changes in the formularization of calibration uncertainties in the scope of accreditation or the body require their assessment prior to the next scheduled assessment, the changes applying to the formularization of calibration uncertainties shall be assessed by means of an extraordinary assessment;

Note: The changes in the expression of an uncertainty (the change in the management of records) can only be applied by the KL in its output documents after granting of the modified scope of accreditation.

- in the ML with the fixed scope: a new matrix, a new principle, a new analyte, a modification of the method which changes the essential characteristics of the original method and shall therefore be subject to validation/verification;
- the insignificant changes in the analyte name, in the name of the method introduced, in other specifications shall not be considered as an extension of accreditation.
- in the ML with the flexible scope a new method principle, a new workplace, a performance site;
- for the IO, an extension are new areas/sub-areas of inspection or areas and sub-areas of inspection, scope of requirements, scope of inspection, methods and procedures of inspection within the already accredited area of accreditation, or new workplaces/places of performance of activities;;
- for the proficiency test organizers, an extension is considered to be e. g. an introduction of a new area of testing, a new subject that has not been included in the scope of the activity yet, not a change in a parameter;
- for the certification bodies certifying management systems: the EA code, the technical area, a category, the main technical area and an additional management system;
- for the certification bodies certifying products: a product group, an item within the product group, the certification scheme/module/system/specific standard;
- for the certification bodies certifying persons: the type/category of activities, the certification scheme;
- for the validation and verification bodies: group of activities in regulated area, in non-regulated area sector specific schema, sector;
- for the environmental verifiers: the EA code/NACE code.

7.2.6 When extending the accreditation, SNAS may require an assessment of the documentation, e. g. where the extension relates to the locations of the accredited activities performance, or where the extension has a significant impact on the AO's approved documentation.

7.2.7 In the event of a positive decision on the accreditation extension, SNAS shall issue a new decision on accreditation and a new accreditation certificate amending the accreditation granted by the original decision on accreditation pursuant to the § 26 and withdrawing this original decision on accreditation. The scope of accreditation granted by the original decision on accreditation pursuant to the Act shall remain unchanged and shall be deemed to have been assessed except for the part that is amended by the decision pursuant to the § 29(1) of the Act (see also article 7.1.1 of this MSA). The validity of accreditation under the original decision on accreditation shall not be extended by the decision under the § 29(1) of the Act (see also article 7.1.1 of this MSA).

8 ASSESSMENT AFTER ACCREDITATION / REACCREDITATION (SURVEILLANCE)

8.1 BASIC SURVEILLANCE PROCEDURE

8.1.1 SNAS shall perform a surveillance to assess whether the AO continues to comply with the accreditation requirements during the validity of the decision on accreditation. The surveillance shall be carried out at least twice during the validity of the decision on accreditation, unless otherwise specified in the accreditation requirements. The assessments of the compliance with the accreditation requirements during the surveillances shall be divided in such a way so as to assess all the accreditation requirements during the validity of the decision on accreditation.

8.1.2 The surveillance shall be performed in accordance with the § 22 of the Act and the provisions and requirements set out in the Chapter 5 of this MSA shall apply accordingly.

8.1.3 The surveillance shall be performed in accordance with the documents pursuant to the § 3(8) of the Act (No.765/2008 (EC) Regulation, ISO/IEC 17011, the documents issued by SNAS - policies, methodological guidelines and decisions of the Director governing its activities in the preliminary assessment, accreditation, reaccreditation, the change of accreditation, the suspension of accreditation, the withdrawal of accreditation, extraordinary assessment and surveillance, and the application of the accreditation requirements published on the SNAS website, and other internal regulations of SNAS).

8.1.4 The service begins at the initiative of SNAS and is commenced on the date when SNAS takes the first action against the AO.

8.1.5 The surveillance shall be planned and performed on the basis of the assessment program which consists of individual surveillances and reaccreditations (KD - Service Planning) and takes into account the risks identified at the AO.

8.1.6 After being granted accreditation, the CAB shall be subject to the ongoing surveillance for the duration of accreditation. The purpose of the surveillance is to assess whether the AO continues to comply with the accreditation requirements and to confirm the continuation of accreditation or decide on the renewal of accreditation.

8.1.7 SNAS shall set up a service in the AIS - surveillance. The AO shall receive a notification on the disclosure of the surveillance fee amount as well as a notification on the PS draft via the AIS. The AO shall send an opinion on the proposed composition of the PS to SNAS much like during accreditation.

8.1.8 The AO shall be bound to send an opinion on the PS composition to SNAS electronically in response to the notification email within 7 days at the latest. SNAS may suspend the administrative proceedings for granting accreditation in accordance with the § 22 (10) of the Act until the AO's consent with the PS composition is received. Should the AO fail to meet the deadline, SNAS may suspend accreditation.

8.1.9 The AO shall enter the current PK with attachments or a relevant DI and, where relevant, the list of the AO's personnel, including those performing the relevant expert activities, into the "CAB Documentation" section of the AIS following the SNAS service set up. Upon the VP's or the case officer's request, the AO shall also provide other documents (working procedures, internal directives, management review report, etc.) relevant to the assessment. - in the case of applicants for attestation / re-attestation of compliance with notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll. is inserted in the Application in the section "other documents", completed form TL 257 - Control questions for subjects fulfilling individual notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll.

8.1.10 At the request of SNAS at any stage of the assessment, the AO shall submit the documents necessary for the assessment of the compliance with the accreditation requirements within a specified period of time, which shall not be less than 15 days. SNAS may extend the due time upon the AO's request. SNAS may suspend the proceedings pursuant to the § 23(1)(b) of the Act once requested that the AO submit documents.

8.1.11 The assessment procedure during the surveillance is similar to that for accreditation (the procedure outlined in the Chapter 5 of this MSA), except that the compliance with the accreditation requirements is generally examined to the extent set out in the KD – Planning services. The following is reviewed during each surveillance - the compliance with the internal audit requirements, the management review, the complaints and appeals, the use of the accreditation symbol and the references to accreditation, the application of the SNAS policies, as well as other relevant facts or risks of which SNAS is notified prior to or during the surveillance.

8.1.12 As during the accreditation, the surveillance involves a witness assessment of the expert activities performance so as to examine a representative selection covering all these activities during a single accreditation cycle. The assessment procedure for the witness assessments is similar to that outlined in the Chapter 9 of this MSA.

8.1.13 During the validity of accreditation, the surveillance shall cover the examination of the compliance with any accreditation requirements and any accredited activities at all sites where one or more activities are performed in accordance with the sampling policy.

8.1.14 Should the AO have multiple sites or places of activities, the assessment is required to be conducted at each site/place during the accreditation cycle. The sites are considered to be any locations where one or more activities are performed. The surveillance shall consider any relevant requirements of the standard and any expert activities performed at a specific site(s) or place(s) of activities.

8.1.15 Where the AO was granted a notification/authorization by the Regulator, the case officer shall approach the Regulator to ask whether the technical experts nominated/approved by the Regulator will take part in the assessment, unless in advance agreed on the conditions excluding the Regulator's representatives from the assessment.

Note: The assessment of the requirements for the purpose of notification/authorization shall be conducted in accordance with MSA-N/01: Accreditation for the Notification purposes.

8.1.16 Should the PS identify a nonconformity in the compliance of the accreditation requirements, SNAS shall request that the AO remove the nonconformity related to the compliance with the accreditation requirements within a specified period of time, which shall not be less than 15 days. Should a compelling reason occur for doing so, SNAS may extend the due time upon the AO's request.

8.1.17 SNAS may suspend the proceedings, should it request that the AO remove the nonconformity related to the accreditation requirements.

8.1.18 After reviewing the OG service during surveillances, the VO shall assess the conducted accreditation service and adopt a standpoint in which he/she shall decide on maintaining the accreditation in force or recommend that the SNAS Director make appropriate changes.

8.1.19 The accreditation service shall be deemed delivered without a change in the scope of accreditation by the decision of the Head of Department. Should the VO recommend that the SNAS Director make appropriate changes, the accreditation service shall be deemed delivered upon a decision of the SNAS Director.

8.1.20 Should the AO refuse to allow SNAS to conduct a surveillance, SNAS shall decide on the suspension of accreditation to the extent of the accreditation granted or a part thereof, for a maximum period of 180 days, however, the period not exceeding the period of validity of the decision on accreditation.

8.1.21 In the decision on the suspension of accreditation, SNAS shall impose an obligation on the AO to remove the identified deficiencies within a specified period of time, which shall not be less than 15 days and not more than 120 days. SNAS may conduct an extraordinary assessment to verify the removal of the detected deficiencies. Should the AO fail to eliminate the identified deficiencies, SNAS shall decide on the withdrawal of accreditation,

8.2 SURVEILLANCE IN LABORATORIES

8.2.1 The surveillance conducted in laboratories shall also examine the test/calibration methods, the medical procedures, the quality assurance of the test/calibration results, the test/calibration result reporting, the monitoring of the performance of selected representative tests/calibrations, the participation in the PT or ILC programs and the results thereof. In the event of an unsatisfactory result, the PS shall investigate whether the laboratory made an analysis of its nonconforming work, whether appropriate corrective actions were taken and whether their fulfilment resulted in correction. If the subsequent participation in the PT/ILC fails to confirm that the issue was tackled, SNAS shall consider the suspension of accreditation for the relevant item within the accreditation scope or the general suspension of accreditation, as appropriate. In such a

case, the full complexity of the quality assurance of the test and/or calibrations results and other factors affecting the laboratory's performance shall be taken into account.

8.2.2 After granting accreditation, all types of laboratories and, where applicable, inspection bodies, shall, within a single accreditation cycle, participate in the PTs in terms of the PL-23 or other appropriate ILCs and achieve satisfactory results in each sub-area of the activity as defined in the participation strategy elaborated on the basis of their scope of accreditation, where such comparisons are organized, available and applicable.

8.2.3 For the laboratories with the flexible scope, the implementation of the flexible scope into the practice is also subject to surveillance, including the assessment of the reported changes to validations and/or verifications performed after the last on-site assessment at the site in question.

8.3 SURVEILLANCE OF THE PROFICIENCY TESTS PROVIDERS

8.3.1 During the validity of accreditation, the provider shall be bound to conduct a minimum of 2 PTs for one subject (1 item of the scope of accreditation) for a specific subject of the proficiency testing during a single accreditation cycle.

8.3.2 During the validity of accreditation, the provider shall be bound to conduct for multiple subjects (two and more items of the scope of accreditation) a minimum 1 PT for a specific subject of the proficiency testing during a single accreditation cycle.

8.4 SURVEILLANCE OF CERTIFICATION BODIES, VALIDAION AND VERIFICATION BODIES AND ENVIRONMENTAL VERIFIERS

8.4.1 The surveillance plan for the certification bodies and validation and verification bodies and environmental verifiers shall ensure that assessment of the planning, the management and the performance of certification/ validation and verification/ environmental verifiers, and confirm a permanent confidence in the certification body/validation and verification body/ environmental verifiers competence. The scope of surveillance depends on the scope of accreditation taking into account the findings from the conducted accreditation/reaccreditation assessments and surveillances, possible changes in the body or other relevant data.

8.4.2 The surveillance shall include a witness assessment at client of the certification body/validation and verification body/, environmental verifier which need not be conducted at the same time as the surveillance. The witness assessment does not replace the surveillance.

8.4.3 During the surveillance, the on-site assessments involve interviews with the personnel performing certifications/validations and verifications/ environmental verifications and file reviews of the certifications/validations and verifications/ environmental verifications performed within the planned scope of surveillance.

8.5 SURVEILLANCE OF INSPECTION BODIES

8.5.1 The surveillance scope depends on the scope of the accredited subjects/areas/sub-areas of inspection, taking into account the findings of previous assessments, any potential changes in the AO and other relevant data. The objective of the surveillance is to confirm the compliance with the accreditation requirements so as to ensure the permanent confidence in the inspection body competence.
8.5.2 The surveillance includes witness assessments, expert interviews with the personnel, the review of closed case files and inspection of the effectiveness of corrective actions arisen from previous assessments. The witness assessments may also be conducted out of the on-site assessment dates of the surveillance. The witness assessment alone does not replace surveillance.
8.5.3 Where applicable, appropriate and available, the results of the IO participation in the PT for expert activities related to measurement and testing shall be reviewed.

9 WITNESS ASSESSMENT

9.1 WITNESS ASSESSMENT PRINCIPLES

9.1.1 When assessing the accreditation requirements, the Slovak National Accreditation Service shall also conduct a witness assessment assessing the compliance of the performed activity with the documented procedure and evaluates the correctness of the results achieved by the accredited body.

9.1.2 The CAB shall ensure that the witness assessment be feasible and, if necessary, ensure an access to the facilities where the product is designed, the production sites, the facilities designated for the conformity assessment, the testing facilities and the manufacturer/operator's storage facilities.

9.1.3 Where activities are performed outside the permanent premises (sampling, measurements on the customer's site, mobile laboratory, audits on the customer's site, inspections, etc.), the demonstration shall be conducted at the places where these activities are performed.
Note: When accrediting the bodies certifying persons, products and management systems, the witness assessment shall be conducted according to MSA-CO/03, MSA-CP/03, MSA-CS/15, for accreditation of the inspection bodies according to MSA-I/03, for accreditation of the environmental verifiers according to MSA-E/05 and for accreditation of the validation and verification bodies according to MSA-V/03.

9.1.4 The witness assessment may be conducted at the same time as the on-site assessment, or separately.

9.1.5 The scope and nature of the witness assessment shall be based on the scope of the accreditation service, the number and complexity of the groups of accredited areas, taking

into account the volume, organizational changes and other relevant factors.

9.1.6 The whole scope of accreditation shall be subject to the witness assessment. The witness assessment of the full scope of accreditation should, where relevant, be conducted as part of the accreditation cycle. Should the scope of activities be too broad, a so-called sampling (selection) of activities shall be performed.

10 ASSESSMENT PROGRAM FOR ACCREDITATION CYCLE

10.1 PRINCIPLES TO DEFINE THE ASSESSMENT PROGRAM FOR ACCREDITATION CYCLE

10.1.1 The number of surveillances within an accreditation cycle shall be determined upon the accreditation requirements set out in the documents pursuant to the § 3(8) of the Act. Unless otherwise specified, there shall be at least three surveillances within the first accreditation cycle and at least two surveillances in each subsequent accreditation cycle.

10.1.2 In addition to assessing the conformity assessment activities given by the scope of accreditation, the assessment plan shall also take into account other factors, such as the knowledge acquired by SNAS about the management system and the AO's activities and operations.

10.1.3 During the accreditation cycle, the given requirements and the scope of accreditation taking into account the risk shall be assessed.

10.1.4 The time period between two assessments shall not exceed 24 months.

10.1.5 The surveillances shall, within a single accreditation cycle, be generally carried out in accordance with their scheduling in the Surveillance Card (KD - Planning services).

10.1.6 Scheduling also takes due account of whether it is the first surveillance after obtaining the initial accreditation, which shall generally be conducted within 12 months after granting of the initial accreditation.

10.1.7 In areas of accreditation where the interval of surveillances is stipulated by specific regulations, the procedure shall be followed accordingly.

10.1.8 The accreditation cycle also takes into account the number of workplaces, for a high number of workplaces has an impact on the number of planned services within an accreditation cycle.

11 EXTRAORDINARY ASSESSMENT

11.1 PRINCIPLES TO PERFORM EXTRAORDINARY ASSESSMENT

11.1.1 SNAS may conduct an extraordinary assessment upon:

- the AO's application;
- a complaint or other filings against the AO;
- the need to assess whether a nonconformity in the compliance with the accreditation requirements under the § 22(9) of the Act was removed;
- the need to assess whether a deficiency under the § 30(2) of the Act was eliminated;
- the need to assess the transition of the accredited body to a new or amended document pursuant to the § 21 of the Act;
- the fact found during the process of deciding on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation or the withdrawal of accreditation;
- the discovery of other facts that may affect the AO's ability to meet the accreditation requirements;
- the declaration of bankruptcy over the AO's assets.

11.1.2 When conducting an extraordinary assessment, the procedure under the § 22 of the Act shall be followed and the provisions and requirements set out in Chapter 5 of this MSA shall apply accordingly.

11.1.3 The extraordinary assessment shall be carried out in accordance with the documents pursuant to the § 3(8) of the Act (No.765/2008 (EC) Regulation, ISO/IEC 17011, the documents issued by SNAS - policies, methodological guidelines and decisions of the Director which govern its activities during the preliminary assessment, accreditation, reaccreditation, the change of accreditation, the suspension of accreditation, the withdrawal of accreditation, extraordinary assessment and surveillance and the application of the accreditation requirements published on the SNAS website, and other internal regulations of SNAS).

11.1.4 The party that made a complaint or another filing against the AO shall bear the costs of an extraordinary assessment arising upon the complaint review or review of another filing against the AO, if proven that the complaint or other filing against the AO was unjustified. In other cases, the costs of the extraordinary assessment shall be borne by the AO. The costs of the extraordinary assessment shall be determined according to the SNAS price list in force.

11.1.5 The extraordinary assessments shall always be conducted upon an agreement with the CAB.

11.1.6 SNAS shall set up a service for the extraordinary assessment performance in the AIS. The CAB shall receive a notification on the disclosure of the extraordinary assessment fee amount as well as a notification on the proposed PS composition via the AIS. The opinion on the proposed PS composition shall be sent to SNAS as in accreditation. The CAB shall send an opinion on the PS composition in response to the notification email to SNAS via the AIS within 7 days at the latest. Should the CAB fail to meet the deadline, SNAS may suspend accreditation.

12 BEGINNING AND TERMINATION OF ACCREDITATION SERVICES

12.1 DECISION OF SNAS

12.1.1 SNAS shall make a decision within:
- four months for accreditation, reaccreditation and the change of accreditation pursuant to the § 29(1)(a) of the Act,
- 30 working days for the change of accreditation pursuant to the § 29(1)(b) or (c) of the Act, for the suspension of accreditation pursuant to the § 30(1)(d) of the Act and the withdrawal of accreditation pursuant to the § 31(d) of the Act.

12.1.2 The due time pursuant to the article 12.1.1 of this MSA shall commence upon the receipt of an application for accreditation, an application for reaccreditation, an application for the change of accreditation, an application for the suspension of accreditation, or an application for the withdrawal of accreditation, which complies with the requirements under the § 20(2) to (4) of the Act or upon the removal of any deficiencies in the application pursuant to the § 20(5) of the Act. The due time shall not run during the period of the suspension of proceedings.

12.1.3 SNAS shall decide within:
- 30 working days on the change of accreditation pursuant to the § 29(3) or (4) of the Act, the suspension of accreditation pursuant to the § 30(1)(a) to (c) of the Act and the withdrawal of accreditation pursuant to the § 31(a) to (c) of the Act.

12.1.4 The due time under the article 12.1.3 of this MSA shall commence from the time SNAS learns about the fact that is the reason for the change of accreditation, the suspension of accreditation or the withdrawal of accreditation. The due time referred to in the paragraph 1 shall not run during the period of the suspension of proceedings.

12.1.5 SNAS shall decide on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation and the withdrawal of accreditation upon the Evaluation Commission's recommendation, which shall be composed of the Slovak National Accreditation Service employees or other profesionals who work in the field that is subject to evaluation, as defined in ST-05.

12.1.6 Upon the guarantor's and the VO's opinion in the case of accreditation, reaccreditation, the change of accreditation, the suspension of accreditation and the withdrawal of accreditation, the SNAS Evaluation Commission (HK) shall assess the accreditation service performed, take an expert opinion and record it in the AIS, in which it shall recommend that the SNAS Director grant/not grant accreditation or return the case for further elaboration. Once elaborated, the case will be reassessed by the HK (see also ST-05).
Note: In the transition to the current version of the international standards used for accreditation, the HK shall also assess another performed accreditation service (surveillance, extraordinary assessment).

12.1.7 The status, competence and work principles of the Evaluation Commission are governed by the Statute and internal Rules of Procedure of SNAS (ST-05) published on the SNAS website.

12.1.8 The recommendation of the Evaluation Commission is based on the results submitted by the PS. For the services where PS is not appointed, the HK shall be irrelevant. The PS members are not members of the Evaluation Commission concerning the same matter.

12.1.9 Following a decision on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation and the withdrawal of accreditation, SNAS shall send a notification to the CAB allowing the CAB to access information containing: the HK's conclusions, the Summary Report and the VP's Recommendations, and should the accreditation be still in force, the KD - Planning services, which is prepared by SNAS for the entire period of accreditation validity.

12.1.10 For surveillance and extraordinary assessments, the VO shall assess the performed accreditation service after reviewing the OG service and take a stand on the decision whether the accreditation should remain unchanged or recommend that the SNAS Director make appropriate changes.

12.1.11 The accreditation service shall be deemed delivered by the decision of the SNAS Director, or in the case of the surveillance/extraordinary assessment without a change in the granted accreditation, by the decision of the Head of Department.

12.1.12 In the case of the preliminary assessment, the service shall be deemed completed on the date of sending/handing/disclosing the 'Report of Preliminary Assessment' to the applicant via the AIS.

12.1.13 Before issuing output documents, SNAS will ensure a multi-stage control of the data contained in them. This control within AIS is carried out by professional guarantors and the director, and subsequently by the SNAS lawyer.

12.1.14 Following the decision and depending on the type of accreditation service SNAS shall send the CAB:

- the decision on accreditation;
- the certificate of accreditation and/or the certificate of the compliance with the notification requirements;
- the model of the SNAS accreditation symbol, the SNAS notification symbol or the combined ILAC MRA/IAF MLA symbol of the accredited body;
- the agreement on granting a license for the use of the combined ILAC MRA/IAF MLA symbol by the accredited body (for the new applicants of the accreditation service).

12.1.15 Upon signing of the agreement on granting a license for the use of the ILAC MRA/IAF MLA combined symbol of the accredited body by the statutory representative, SNAS shall electronically send the CAB the appropriate combined symbol with a

registration number and request a template showing the symbol placement in protocols, certificates or other documents on which the CAB may, subject to the terms and conditions set forth in the Licensing Agreement and in MSA-02, use the combined symbol.

12.1.16 The AO shall be responsible for the results reported.

12.2 SUSPENSION OF PROCEEDINGS

12.2.1 SNAS may suspend the proceedings provided that SNAS:

- invited the applicant for accreditation, the applicant for reaccreditation or the applicant for the change of accreditation to eliminate the nonconformity concerning the compliance with the accreditation requirements pursuant to the § 22(9) of the Act,
- invited the applicant for the accreditation service or the accredited body to submit the documents pursuant to the § 22(10) of the Act,
- found it impossible to conduct the assessment of the compliance with the accreditation requirements due to a crisis situation (§ 2(a) of Act No 387/2002 Coll. on the Management of the State in Crisis Situations Outside the Time of War and the State of War).

12.2.2 SNAS may also suspend the proceedings, should, for serious reasons, the party to the proceedings propose so, however, only for a maximum period of 90 days.

12.2.3 SNAS shall resume the proceedings as soon as the reasons for the proceeding's suspension passed. Should the proceedings related to the change of accreditation, the suspension of accreditation or the withdrawal of accreditation which commenced on the initiative of SNAS, be suspended pursuant to paragraph 1(b) of the Act (requested that the CAB submit the documents pursuant to the § 22(10) of the Act) and should the CAB fail to submit the documents pursuant to the § 22(10) of the Act, SNAS shall resume the proceedings on the day following the expiry of the specified due time.

12.3 TERMINATION OF PROCEEDINGS

12.3.1 SNAS shall terminate the proceedings withing the whole or a part of the application scope, should the CAB:

- fail to eliminate the deficiencies in the application within the due time specified in the call pursuant to the § 20(5) of the Act, and was informed on the possible suspension of the proceedings;
- fail to remove the nonconformity regarding the compliance with the accreditation requirements within the due time specified in the call pursuant to the § 22(9) of the Act, and was informed on the possible suspension of the proceedings;
- fail to submit the required documents within the due time specified in the call pursuant to the § 22(10) of the Act to SNAS, and was informed on the possible suspension of the proceedings;

– fail to ensure the possibility to conduct the assessment or witness assessment.

12.4 DECISION ON ACCREDITATION

12.4.1 The Conformity Assessment Body which is not an AO in the relevant area of accreditation and applies for accreditation is an applicant for accreditation. If the applicant for accreditation complies with the accreditation requirements, SNAS shall issue a decision on accreditation.

12.4.2 Should the applicant for accreditation fail to comply with the accreditation requirements, SNAS shall issue a decision not to grant accreditation and the applicant for accreditation shall be liable for the costs of the assessment of the compliance with the accreditation requirements, if any. The applicant for accreditation may file a new application for accreditation after the expiry of the date on which the decision to terminate the proceedings becomes definitive or after the date on which the decision not to grant accreditation becomes definite, at the earliest.

12.4.3 The decision on accreditation shall include in particular:

- the name and registered office of SNAS;
- the business name and place of business of the accredited body, should it be a physical entity - entrepreneur, or the business name and registered office of the accredited body, should it be a legal entity;
- the identification number of the organization;
- the organizational unit which is to perform the activities of the accredited body;
- any locations where the accredited body performs its activities;
- the identification number of the accredited body assigned by the Slovak National Accreditation Service;
- the area of accreditation and the statement of the conformity of the accredited body's activity with a document which specifies the accreditation requirements pursuant to the § 21 of the Act, in relation to which the assessment of the compliance with the accreditation requirements pursuant to the § 22 of the Act is conducted;
- a brief description of the scope of accreditation;
- the period of the decision on accreditation validity;
- the reference number and the date of issue of the decision on accreditation.

12.4.4 The scope of accreditation is set out in the Annex to the decision on accreditation. The Annex shall be considered the integrant of the operative part of the decision on accreditation.

12.4.5 The decision on accreditation shall be valid for five years starting on the date of the decision on accreditation entry into force. A shorter period of validity may be specified in the decision on accreditation, should it be stated in the document specifying the accreditation requirements according to the § 21 of the Act or in the rules of European organizations and international organizations associating the accreditation bodies in the field of accreditation of the conformity assessment bodies.

12.5 CERTIFICATE OF ACCREDITATION

12.5.1 Based on a valid decision on accreditation, SNAS shall issue a Certificate of Accreditation to the accredited body.

12.5.2 The Certificate of Accreditation is a public document that certifies the granting of accreditation in a specified area and in a specified scope.

12.5.3 The Certificate of Accreditation shall, in particular, include:

- the name and registered office of SNAS;
- the business name and place of business of the accredited body, should it be a physical entity - entrepreneur, or the business name and registered office of the accredited body, should it be a legal entity;
- the identification number of the organization;
- the organizational unit which is to perform the activities of the accredited body;
- all locations where the accredited body performs its activities;
- the identification number of the accredited body assigned by the Slovak National Accreditation Service;
- the area of accreditation and the statement of the conformity of the accredited body's activity with a document which specifies with the accreditation requirements pursuant to the § 21 of the Act, in relation to which the assessment of the compliance with the accreditation requirements pursuant to the § 22 of the Act is conducted;
- a brief description of the scope of accreditation;
- the period of validity of the decision on accreditation;
- the number and the date of issue of the decision on accreditation;
- the stamp of SNAS and the signature of the person authorized to act on behalf of SNAS, indicating his/her name, surname and post;
- the reference number and the date of issue of the certificate of accreditation.

12.5.4 The scope of accreditation is stated in the Annex to the Certificate of Accreditation.

12.5.5 The validity of the Certificate of Accreditation shall expire upon termination of the relevant decision on accreditation or the withdrawal of accreditation pursuant to the § 32 of the Act.

12.6 DECISION ON SUSPENSION OF ACCREDITATION

12.6.1 SNAS shall decide on the suspension of accreditation within the scope of the granted accreditation or a part thereof, for a maximum period of 180 days, where the due time may not exceed the period of validity of the decision on accreditation, should the accredited body:

- fail to remove the nonconformity with the accreditation requirements pursuant to the § 22(9) of the Act within the specified due time;

- fail to fulfil the obligations of the accredited body under the § 36(2)(b), (c), (e) or (g):
  - fail to provide the cooperation during the assessment of the accreditation requirements, and in particular, fail to provide the necessary documents, information and explanations;
  - fail to allow persons authorized by SNAS to enter the premises/facilities, to access the technical equipment and to inspect the documentation;
  - fail to abide by the principles of impartiality, independence, reliability and integrity,
  - fail to enable SNAS to conduct surveillance;
- not be able to perform the activities which are the subject of the accreditation;
- request so.

12.6.2 In the decision on the suspension of accreditation, SNAS shall oblige the AO to remove the identified deficiencies within a specified period of time, which may not be shorter than 15 days and longer than 120 days. SNAS may conduct an extraordinary assessment to verify the removal of the identified deficiencies.

12.6.3 During the validity of the decision on the suspension of accreditation, the accredited body shall be prohibited from:

- acting as an accredited body and exercising the rights under the § 36(1) of the Act in the area of accreditation or the scope of accreditation specified in the decision on the suspension of accreditation;
- accepting new applications to act as an accredited body in the area of accreditation or the scope of accreditation specified in the decision on the suspension of accreditation.

12.6.4 SNAS shall withdraw the decision on the suspension of accreditation immediately after the reason for its issuance passed.

12.7 DECISION ON WITHDRAWAL OF ACCREDITATION

12.7.1 SNAS shall decide on the withdrawal of accreditation, should:

- the AO fail to eliminate detected deficiencies pursuant to the § 30(2) of the Act;
- the AO repeatedly, during the validity of the decision on accreditation, violate the obligation under the § 36(2)(b) or (c) of the Act:
  - fail to provide the cooperation during the assessment of the accreditation requirements, and in particular, fail to provide the necessary documents, information and explanations;
  - fail to allow persons authorized by SNAS to enter the premises/facilities, to access the technical equipment and to inspect the documentation;
- SNAS be proven fraudulent behavior of the AO, or the AO deliberately provide false information or fail to provide all the information with an impact on the compliance with the accreditation requirements;
- the AO request so.

12.8 TERMINATION OF ACCREDITATION

12.8.1 Accreditation shall terminate upon:
- the termination of the AO without a legal successor,
- the withdrawal of accreditation
- the expiry of the decision on accreditation, or
- entering of the accredited body into liquidation.

12.9 APPEAL AGAINST THE DECISION OF THE SLOVAK NATIONAL ACCREDITATION SERVICE

12.9.1 Based on a proposal of the Board of Appeal the Director shall decide on the appeal against the decision made by SNAS.

12.9.2 The members of the Board of Appeal shall be appointed and removed by the Director. No Board of Appeal member may be a member of the Assessment Commission or the Assessment Group regarding the same case, nor the person whose impartiality and freedom from bias may be doubted with regard to his/her relationship to the case, to the parties or to their representatives.

12.9.3 An appeal against the decision on accreditation pursuant to the § 29(3) of the Act, an appeal against the decision on the suspension of accreditation pursuant to the § 30(1) of the Act and an appeal against the decision on the withdrawal of accreditation pursuant to the § 31 of the Act shall not have suspensory effect.

12.9.4 A decision to lift the suspension of accreditation under the § 30(4) of the Act shall not be subject to appeal.

13 TRANSFER OF ACCREDITATION

13.1 ACCREDITATION TRANSFER PROCEDURE

13.1.1 In the event of a change that could affect the conditions under which the accreditation was granted (e. g. the change in the legal status of the AO or the organization of which the AO is an organizational part, the merger of the AO with another AO, the reassignment of the workplace performing the accredited activities to another legal entity, etc.), the AO wishing to carry on performing the accredited activities shall notify SNAS in writing of the aforementioned facts.

13.1.2 The written notification shall be submitted by the AO without any due delay, but no later than by the date on which the legal status or organizational change takes place.

13.1.3 The successor organization shall file an application for the transfer of accreditation via the AIS. The successor organization, if not yet registered, shall register via the AIS on https://ais.snas.sk. It also shall complete/check the correctness of the data on the Card of the Body in the AIS, specifically in the Basic information (including details of the statutory

representatives), Related Relationships, Users and Conformity Assessment Bodies sections (where, amongst others, it shall assign the head managers and quality managers to the CABs and the sites). Only then shall the organization proceed to the completion of the Application for Accreditation Service - Transfer of Accreditation'.

13.1.4 The application for the transfer of accreditation shall include the following information and documents, as applicable:

- the evidence that the successor organization which the accredited body is a part of may be regarded legally liable;
- the document by which the change was decided on (e.g. the legal entity cancellation and the merger with another legal entity, ...) or a reference to this document;
- the declaration of the successor organization top management on the commitment to create the conditions suitable for the accredited activity performance in a manner that complies with the relevant accreditation standard requirements and on the assumption of all obligations of the accredited body;
- the current organizational structure of the successor organization, including the location of performing the accredited activities;
- the updated PK or DI letters incorporating the changes resulting from the change;
- the confirmation that the current technical management of the conformity assessment body and its expert staff shall remain unchanged;
- the confirmation that the activities will be performed in unaltered facilities and with the same equipment;
- any changes to the management system;
- the completed OA form (both parts).

13.1.5 Following a request for the transfer of accreditation, SNAS shall promptly arrange for the assessment of the required changes and make a decision based on the outcome of the assessment.

13.1.6 Should the changes announced by the successor organization or the AO prove not to affect the compliance with the accreditation requirements and the conditions under which the accreditation was granted continue to be fulfilled, SNAS shall withdraw the original decision and issue a new decision on accreditation. Conversely, SNAS shall send a notification informing about the commencement of the administrative proceedings to suspend accreditation. The notification in question shall also be sent, should the successor organization or the AO fail to support the announced changes with the necessary documents or should the compliance with the accreditation requirements require to be verified during an extraordinary surveillance.

13.1.7 The successor organization shall not be entitled to refer to the accreditation granted to the original AO until a new decision on accreditation is issued.

14 ANNEXES

Annex 1: Documents to be uploaded to the AIS when filing an application in the electronic form in accordance with the Chapter 5.

14.1 ANNEX 1: DOCUMENTS ENTERED TO AIS WHEN FILING AN APPLICATION IN ELECTRONIC FORM AS REFERRED TO IN CHAP. 5

Table 1: Testing, calibration and medical laboratories

Application documents:	Granting of accreditation	Reaccreditation	Accreditation change (extension)
Evidence of the organizational structure of the legal entity/physical person, showing the integration of the CAB and the addresses and activities of all sites for which accreditation is sought, including the virtual site	x	x	x
Documented information according to the relevant accreditation scheme (e. g. Quality Manual with annexes, documented information),	x	x	x
Annex to the OA according to the accreditation scheme (both parts)	x	x	x
Human Resources (List of employees, unless included in the PK/DI)	x	x	x
Technical Resources (List of technical equipment, unless included in the PK/DI)	x	x	x
Filled in the TL 606 form - „Questions on the information systems used “	x [1)]	x [1)]	
Participation strategy in PT/ILC elaborated pursuant to PL-23 and MSA-L/14	x	x	x
Receipt of the application fee payment	x		
KL, SL – evidence (e. g. reports) of successful participation in PT/ILC for each sub-area	x		x
IN-HOUSE / IN-HOME calibration – evidence (e. g. reports) about a successful participation in the PT/ILC for each sub-area	x		x
ML – evidence (e. g. reports) of successful participation in ILC for each sub-area.	x		x

Application documents:	Granting of accreditation	Reaccreditation	Accreditation change (extension)
In case of the participation of ML in PT at official proficiency test organizers accredited pursuant to ISO/IEC 17043, no evidence shall be required (PT consist of multiple cycles with the number stated in the participation strategy).			
KL – Calibration of recording equipment in road transport (initial granting of accreditation, granting of accreditation, extension of accreditation): application for PT at a competent PT provider (no evidence required)	x		x
Annex no. 1 to Participation Strategy in PT – plan for the next accreditation cycle (5 years)	x	x	x
Annex no. 1 to the Participation Strategy in the PT – participation for the areas/sub-areas to which the accreditation is applied for	x		x
Annex no. 1 to the Participation Strategy in the PT – participation for the entire current accreditation cycle		x	
Completed form TL 257 - Control questions for subjects fulfilling individual notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll.	x[4)]	x[4)]	x[4)]

Table 2: Inspection bodies, proficiency tests organizers and certification bodies

Application documents:	Granting of accreditation	Reaccreditation	Accreditation change (extension)
Documents confirming the legal format of the applicant	x		
Evidence of the organizational structure of the legal entity/physical person, showing the integration of the CAB and the addresses and activities of all sites for which accreditation is sought, 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 of the OA according to the accreditation scheme (both parts)	x	x	x
Human Resources (List of employees, unless included in the PK/DI)	x	x	x
Technical Resources (List of technical equipment, unless included in the PK/DI) (where applicable)	x	x	x
Filled in the TL 606 form - „Questions on the information systems used“	x [2)]	x [2)]	
Receipt of the application fee payment	x		x [3)]
Completed form TL 257 - Control questions for subjects fulfilling individual notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll.	x[4)]	x[4)]	x[4)]
Inspection procedures for all assessed areas/ sub-areas	x[5)]	x[5]	x[5]

1) Only for testing and calibration laboratories
2) Only for inspection bodies, where applicable
3) Only in case of extension by another management system or sector-specific scheme

[4] Only in case of applicants for attestation / re-attestation of compliance with notification requirements according to Act no. 146/2023 Coll. on air protection and Decree no. 299/2023 Coll.

[5] Only for inspection body