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## METHODICAL GUIDELINE FOR ACCREDITATION

# SNAS AND CONFORMITY ASSESSMENT BODIES RESPONSIBILITIES

**MSA-06** 

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## **1 INTRODUCTION**

This methodological guideline for accreditation stipulates the rights, obligations and responsibilities of the Slovak National Accreditation Service and accredited Conformity Assessment Bodies. MSA applies binding international documents.

## **2 ABBREVIATIONS AND TERMS**

AO	Accredited Body	
AK	Acceptance Commission	
CAB	Conformity Assessment Body, the concept includes the accredited body and the	
	applicant for an accreditation service	
СО	Certification Body	
DPH	Value added tax	
Ε	Proffesional 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)	
EA	European co-operation for Accreditation	
EA MLA	EA Multilateral Agreement	
EA BLA	EA Bilateral Agreement	
EMAS	EU Eco-Management and Audit Scheme	
EMS	Environment Management System	
ERA	European Union Agency for Railways	
ES	European Community	
Expert	An external collaborator of SNAS at all levels – a Lead Assessor, an Assessor,	
	a Proffesional Expert level	
FALB	Forum of Accreditation and Licensing Bodies	
НК	SNAS Evaluation Commission	
IAF	International Accreditation Forum	
ILAC	International Laboratory Accreditation Cooperation	
MLA/MRA	Multilateral Agreement/ Mutual Recognition Arrangement	
MSA	Methodical Guideline for Accreditation	
OECD	Organization for Economic Cooperation and Development	
QMS	Quality Management System	
РТ	Proficiency Testing	
GLP	Good Laboratory Practice	
SNAS	Slovak National Accreditation Service	
TL	Form	
ÚNMS SR	Slovak Office of Standards, Metrology and Testing	
Act	Act No. 53/2023 Coll. on Accreditation of Conformity Assessment Bodies, as amended	



## **3 RELATED DOCUMENTS**

**External related documents -** Annex 1

National program for compliance with the GLP principles in Slovakia

**SNAS Policies** (see <u>www.snas.sk</u>)

MSA-02 Logo and SNAS symbols

MSA-04 Accreditation Procedure

MSA-07 EA requirements for accreditation of flexibles scopes

## 4 **RIGHTS OF SNAS**

#### SNAS shall be **entitled to**:

- 1. Apply assessment techniques, which are, in particular:
  - on-site assessment;
  - remote assessment;
  - combined assessment;
  - witness assessment under the § 22(5) of the Act;
  - document review;
  - examination of files that contain the information, documentation and interpretations related to the performed activities under the granted accreditation;
  - measurement audit and validation audit;
  - examination of the performance in the proficiency testing and other inter-laboratory comparisons;
  - unannounced visit, should SNAS reasonably suspect a breach of an accreditation requirement or violation of the accredited body's obligations under the § 22(3) of the Act;
  - an interview with an employee or contractor of an applicant for the accreditation services 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 as the subject of the accredited body's application or activity are examined;
- 2. Upon assessment of the compliance with the accreditation requirements:
  - 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 assessment subject of the compliance with the accreditation requirements;
  - require that the CAB and its employees provide its 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 support.
- 3. Within 5 working days from the application receipt, request that the CAB remove the deficiencies in the application 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 request, extend the due time. SNAS is entitled to proceed according to the first and the second sentence repeatedly.
- 4. Request that the CAB remove detected nonconformity in the compliance with the accreditation requirements within a specified period of time, which shall not be shorter than



15 days. Should a compelling reason occur for doing so, SNAS is entitled, on the CAB's request, to extend the due time.

- 5. Within a specified period of time, which shall not be shorter than 15 days, request that the CAB submit the documents necessary to assess the compliance with the accreditation requirements. SNAS is entitled to extend the due time, on the CAB's request.
- 6. Suspend the proceedings should:
  - SNAS requested that the applicant for an accreditation service remove the nonconformity related to the compliance with the accreditation requirements pursuant to the  $\S$  22 (9) of the Act,
  - SNAS requested that the CAB submit the documents pursuant to the § 22 (10) of the Act,
  - the assessment of the compliance with the accreditation requirements cannot be conducted due to a crisis situation.
- 7. Suspend the proceedings, should a party to the proceedings request so due to serious reasons, however, for a maximum period of 90 days.
- 8. Conduct an extraordinary assessment, should the changes pursuant to the § 29 (1) (c) of the Act prove to have an impact on the compliance with the accreditation requirements.
- 9. Conduct an extraordinary assessment on the basis of:
  - the accredited body's application pursuant to the § 20 of the Act;
  - a complaint or other filings against the accredited body;
  - 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 accreditation requirements pursuant to the § 21 of the Act;
  - a fact found during the process of deciding on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation or the withdrawal of accreditation;
  - the identification of other facts that may affect the accredited body's capacity to comply with the accreditation requirements;
  - the declaration of bankruptcy over the accredited body's assets.
- 10. Require the correct use of the accreditation symbol, references to accreditation and references to accreditation by the MLA/MRA signatories in accordance with the EA, ILAC, IAF international regulations, licensing agreements and the MSA-02 methodological guideline.
- 11. Terminate the licensing agreement for the use of the combined MLA/MRA accreditation symbol given to the accredited body, should the licensee fail to comply with the terms of this agreement.
- 12. Use the abbreviation "SNAS" for the purpose of representing the Slovak Republic in a European organization or an international organization associating the accreditation bodies.



## **5 SNAS RESPONSIBILITIES**

The responsibilities of SNAS derive from the regulations set out in the Annex No.1.

SNAS shall be **required** to:

- 1. Upon the performance of its activities, use the official stamp, the specimen of which is depicted in the Annex No. 1 of the Act and which contains:
  - the "Slovak National Accreditation Service" designation;
  - the abbreviation "SNAS";
  - the national emblem of the Slovak Republic.
- 2. Upon the performance of its activities, use:
  - the SNAS logo, a specimen of which is depicted in the Annex No. 2 of the Act;
  - a combined symbol consisting of the SNAS logo and a symbol of the relevant European organization or international organization associating the accreditation bodies which granted SNAS the permission to use its symbol; the combined symbol specimen is depicted in the documents pursuant to the § 2(7)(n) of the Act.
- 3. Appoint an assessment group composed of the SNAS personnel or experts for the assessment of the compliance with the accreditation requirements.
- 4. During the assessment of the accreditation requirements, conduct a witness assessment as well, which assesses the compliance of the performed activity with the documented procedure and evaluates the correctness of the achieved results of the CAB.
- 5. Based on the request for a preliminary assessment, assess the compliance with the accreditation requirements in outline pursuant to the § 18 of the Act.
- 6. Prepare a record of the preliminary assessment outcome, which shall indicate the identified deficiencies in the compliance with the accreditation requirements.
- 7. Not provide consultancy and advisory services during the preliminary assessment on how the applicant for the preliminary assessment is to demonstrate the compliance with the accreditation requirements.
- 8. Specify the details related to the assessment techniques pursuant to the § 22(3) of the Act in the documents pursuant to the § 3(8).
- 9. Assess the compliance with the accreditation requirements according to the documents pursuant to the  $\S$  3(8) of the Act.
- 10. Conduct an assessment of the compliance with the accreditation requirements pursuant to the  $\S$  22(1) to (8) of the Act.
- 11. Resume the proceedings as soon as the reasons for the suspension of the proceedings ceased. Should the proceedings for the change of accreditation, the suspension of accreditation or the withdrawal of accreditation, which commenced on the initiative of SNAS be suspended pursuant to the § 23 1(b) of the Act and the accredited body 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. Decide on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation or the withdrawal of accreditation following the application, unless stated in the § 29 (3) or (4), § 30 or § 31 of the Act otherwise.



- 13. Issue a decision on accreditation once the applicant for accreditation complies with the accreditation requirements; issue a certificate of accreditation to the accredited body on the basis of the final decision on accreditation
- 14. Terminate the proceedings within the entire scope of application or a part thereof, should the applicant for an accreditation service be informed about the possibility of the suspension of the proceedings and:
  - fail to remove the deficiencies in the application within the due time specified in the call pursuant to the § 20(5) of the Act;
  - fail to remove the non-compliance with the accreditation requirements within the due time specified in the call pursuant to the § 22(9) of the Act;
  - fail to submit the required documents to SNAS within the due time specified in the call pursuant to the § 22(10) of the Act;
  - fail to enable the performance of the witness assessment.
- 15. Decide within:
  - 4 months on accreditation, reaccreditation and the change of accreditation pursuant to the § 29(1) of the Act;
  - 30 working days on the change of accreditation pursuant to the § 29(1)(b) or (c) of the Act, 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;
  - 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;
- 16. Decide on accreditation, reaccreditation, the change of accreditation, the suspension of accreditation and the withdrawal of accreditation based on the evaluation commission's recommendation, which is composed of SNAS employees or other professionals active in the field that is the evaluation subject. The recommendation of the evaluation commission shall be based on the results presented by the assessment group. The assessment group members shall not be the evaluation commission members in the same matter.
- 17. Issue a decision not to grant accreditation, should the applicant for accreditation fail to comply with the accreditation requirements.
- 18. Based on the application for reaccreditation, issue a decision on accreditation, should the accredited body demonstrate the compliance with the accreditation requirements. Should the applicant for reaccreditation fail to comply with the accreditation requirements, SNAS shall issue a decision on not granting accreditation.
- 19. Issue a decision on accreditation, which shall change the accreditation granted by a decision pursuant to the § 26 of the Act and revoke this decision on accreditation, if the accredited body applies for
  - extension of the area or the scope of accreditation;
  - reduction of the area or the scope of accreditation;
  - a change of the data pursuant the  $\S 26(3)$  (b) to (e) of the Act.
- 20. Decide under the \$ 29(1)(a) by verifying the compliance with the accreditation requirements only to the extent of the requested change of accreditation.
- 21. Issue a decision on accreditation pursuant to the § 29(1) of the Act, even of its own motion, by which it shall reduce the granted accreditation, should it find a reason for the withdrawal



of accreditation pursuant to the § 31 of the Act, which, however, relates merely to a part of the determined area or scope of accreditation pursuant to the § 20(3)(c) of the Act, and provided the accredited body is competent to perform the activities of an accredited body on the basis of the decision changed so.

- 22. Issue a decision on accreditation, in which it shall take into account the changes pursuant to the \$ 29(1)(c) of the Act, should it become aware of them on the basis of its own findings, and the accredited body complies with the accreditation requirements.
- 23. Decide on the suspension of accreditation within the scope of the granted accreditation or a part thereof, for a period not exceeding 180 days, and the period shall not exceed the validity of the decision on accreditation, should the accredited body:
  - fail to remove the non-compliance with the accreditation requirements within the specified period of time pursuant to the § 22(9) of the Act;
  - fail to comply with the accredited body's obligations under the § 36(2)(b), (c), (e) or (g) of the Act;
  - be unable to perform the activity subject to accreditation;
  - request so.
- 24. In the decision pursuant to the § 30(1) of the Act, impose an obligation onto the accredited body to remove the findings within a specified period of time, which shall not be shorter than 15 days and longer than 120 days. SNAS shall be entitled to carry out an extraordinary assessment to verify the removal of the identified deficiencies.
- 25. Revoke the decision on the suspension of accreditation after the reason for the issuance ceased without any due delay.
- 26. Decide on the withdrawal of accreditation should:
  - the accredited body fail to remove the identified deficiencies pursuant to the § 30(2) of the Act;
  - the accredited body repeatedly violate the obligations stipulated pursuant the § 36(2)(b) or (c) of the Act during the validity of the decision on accreditation;
  - SNAS be proven fraudulent behavior of the accredited body or the accredited body deliberately provide false information or fail to provide all the information which have an impact on the compliance with the accreditation requirements;
  - the accredited body request so.
- 27. Proceed in accordance with the § 22 of the Act when conducting an extraordinary assessment.
- 28. Conduct an extraordinary assessment according to the documents pursuant to the 3(8) of the Act.
- 29. Conduct a surveillance to assess the ongoing compliance with the accreditation requirements by the accredited body during the validity of the decision on accreditation. The number of surveillances within accreditation cycle shall be specified according to the accreditation requirements set out in the documents pursuant to the § 3(8) of the Act. Unless specified otherwise, at least three surveillances shall be conducted in the first accreditation cycle and at least two surveillances in every subsequent accreditation cycle.
- 30. Divide the assessment of the compliance with the accreditation requirements during the surveillances in such a manner so as to assess all the accreditation requirements during the validity of the decision on accreditation.



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- 31. When conducting the surveillance, proceed pursuant to the § 22 of the Act.
- 32. Conduct the surveillance according to the documents pursuant to the § 3(8) of the Act.
- 33. Provide the accreditation services such as accreditation, reaccreditation, the change of accreditation, the suspension of accreditation and the withdrawal of accreditation.
- 34. Provide other services such as the preliminary assessment, the extraordinary assessment and the surveillance.
- 35. Comply with the requirements under the specific regulation (Articles 3 to 12 of the Regulation (EC) No 765/2008, as amended).
- 36. Determine the criteria for the selection, appointment, training and monitoring of the assessment group members, the evaluation commission and the Board of Appeal.
- 37. Determine the fee for the provided services, the method of calculation and publish this information on its website.
- 38. Provide information and expert opinions in the area of accreditation of the Conformity Assessment Bodies upon request.
- 39. Organize courses, trainings and further trainings for the personnel, experts, the Conformity Assessment Bodies which applied for a preliminary assessment or accreditation, and the accredited bodies.
- 40. Ensure the experience exchange among the accredited bodies.
- 41. Conduct the accredited body satisfaction survey regarding the accreditation services provided by SNAS.
- 42. Perform the accrediting body activities pursuant to the Act No. 67/2010 Coll. on Conditions for Launch of Chemicals and Chemical Substances and on amendment and supplement to certain acts (Chemical Act).
- 43. Publish the application templates and information about issued decisions on accreditation, decisions on the suspension of accreditation and decisions on the withdrawal of accreditation on its website.
- 44. Represent the Slovak Republic in the European organizations and international organizations associating the accreditation bodies in the area of accreditation of the Conformity Assessment Bodies, of which it is a member, and cover the tasks owed by the Slovak Republic by this membership.
- 45. Perform the activities according to specific regulations (the § 20 of the Act No. 137/2010 Coll. on Air, as amended, the § 3 of Act No. 351/2012 Coll. on Environmental Verification and Registration of Organizations in the European Union Scheme for Environmental Management and Audit and on amendment and supplement to certain acts, the § 24 of Act No. 414/2012 Coll. on Emission Trading and on amendment and supplement to certain acts, as amended).
- 46. Issue policies, methodological guidelines and decisions of the Director that regulate its activities in the preliminary assessment, accreditation, reaccreditation, the change of accreditation, the suspension of accreditation, the withdrawal of accreditation, the extraordinary assessment, the surveillance and the application of the accreditation requirements, which are published on the SNAS website, and other internal regulations of the Slovak National Accreditation Service.



- 47. Establish and operate an information system that enables communication between SNAS and the CAB that shall register in the information system and the accredited body, and which contains conformity assessment body data that shall register in the information system, the accredited body data, the data of the evaluation commission members, the data of the assessment group members, the data of the experts and the data of the other persons involved in the accreditation process, as well as the information concerning the accreditation services; the data can be used for statistical purposes and planning of SNAS activities.
- 48. Send a summary report from the assessment of the compliance with the accreditation requirements pursuant to the § 22 of the Act and the decision on accreditation, the suspension of accreditation or the withdrawal of accreditation, if issued, to UNMS after an assessment of an accredited body that is accredited for the authorization purpose pursuant to specific regulations (e.g. Act No. 56/2018 Coll. on Conformity Assessment of the Product and making a determined Product available on the Market and on amendment and supplement to certain acts, as amended by the Act No. 259/2021 Coll., the § 31 of the Act No. 157/2018 Coll. on Metrology and on amendment and supplement to certain acts, as amended by the summary report issuance or from the issuance of the decision on accreditation, the suspension of accreditation or the withdrawal of accreditation, if issued.
- 49. Prepare the SNAS activity plan, the quality policy and the quality objectives related to the SNAS activity in accordance with the state policy concept in the area of accreditation (§ 30(2) of the Act No.575/2001 Coll. on Organization of Government Activities and the Central State Administration, as amended) elaborated by the Office.
- 50. Participate in peer-evaluation (Article 2(16) of the Regulation (EC) No 765/2008, as amended) pursuant to a specific regulation (Article 10 of the Regulation (EC) No 765/2008, as amended.), in which it demonstrates the compliance with the requirements pursuant to a specific regulation (Article 11 of the Regulation (EC) No 765/2008, as amended.) and the relevant harmonized technical standard (ISO/IEC 17011 Conformity assessment. Requirements for accreditation bodies accrediting Conformity Assessment Bodies) published in the Official Journal of the European Union. The documents referred to in the Article 3(7)(n) of the Act, which demonstrate the compliance with the requirements under the first sentence, shall also be subject to assessment during the peer-evaluation.
- 51. Perform its activities for a fee in accordance with a specific regulation (Article 4(7) of the Regulation (EC) No 765/2008, as amended).
- 52. Comply with the obligations as signatories to the MLA/MRA Mutual Recognition Agreements and the agreements for the use of the combined ILAC MRA and IAF MLA symbols, including promptly notifying of any significant change that could affect the competence, impartiality, legal status or operational capability of SNAS and providing an impact analysis to the EA Secretariat.
- 53. Inform other EA MLA signatories in writing about any voluntary termination or reduction of its scope of the signatory status at least three months in advance.
- 54. Upon request, declare that the conformity assessment results (e. g. reports or certificates) issued by the Conformity Assessment Bodies accredited by the accreditation bodies that are signatories to the relevant EA MLA and/or ILAC MRA and/or IAF MLA scope are as reliable as those issued by the CABs accredited by SNAS.



- 55. Make its services available to all applicants whose accreditation requirements fall within the activities and limitations defined in the SNAS policies and rules.
- 56. Conduct an accreditation of technical activities according to the general criteria specified in the relevant international standards and directives and according to the other requirements published in the relevant EA, ILAC, IAF, FALB and OECD mandatory application documents.
- 57. Encourage and check the correct use of the accreditation symbols and the references to the accreditation status by the accredited Conformity Assessment Bodies and take appropriate measures in case of their misuse or abuse.
- 58. Provide the accreditation and attestation services in a non-discriminatory and impartial manner.
- 59. Ensure that all the personnel involved in the accreditation process act objectively and are free from undue commercial, financial or other influences compromising impartiality.
- 60. ensure that any decision-making in the matter of accreditation shall be made by a panel of impartial competent experts.
- 61. Not offer or perform the services compromising its impartiality, such as consultancy or the conformity assessment services, which are provided by the accredited Conformity Assessment Bodies.
- 62. Maintain discreetness and confidentiality of all the information provided by the conformity assessment body or obtained in the course of performing the services, except the cases stipulated by a specific regulation.
- 63. Appoint competent members of the assessment group.
- 64. Maintain records of the Conformity Assessment Bodies to demonstrate the effective compliance with the accreditation and competence requirements.
- 65. Suspend, reduce or withdraw accreditation, as appropriate, where non-compliance with accreditation requirements is demonstrated for validation and verification bodies in the regulated area, in accordance with the Article 54 of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084.
- 66. Record, maintain and securely retain the documentation related to the accreditation case of the conformity assessment body concerned in accordance with the applicable legislation.
- 67. Provide the public with the information on:
  - the assessment and accreditation processes,
  - the accreditation requirements,
  - the determination of the fee for the provided services,
  - the registration procedures and handling complaints and appeals.

(Note 1: SNAS provides the information on the website)

- 68. Provide the public with the information on the accreditation status granted by SNAS to the Conformity Assessment Bodies. The information on accredited bodies is published and kept updated on the SNAS website and shall include:
  - the name and address of the accredited conformity assessment body,
  - the date of granting accreditation and the date of its validity expiry,



- the area of accreditation,
- the scope of accreditation,

(Note 2: On its website, SNAS also provides information regarding the decisions on the suspension and the withdrawal of accreditation)

- 69. Provide the conformity assessment body with the information on an appropriate way of obtaining the traceability of measurement results in the area of granted accreditation and the information on the conditions and possibilities concerning the participation of laboratories or inspection bodies in the proficiency testing programs and interlaboratory comparisons. SNAS shall provide the information on its website.
- 70. Inform the accredited bodies about the international conventions in which SNAS was involved, its activities and the imposed restriction concerning its work. SNAS shall provide the information on its website, at seminars and trainings organized by SNAS.
- 71. Notify any change to its accreditation requirements (on the website, electronically, at SNAS seminars, in SNAS publications, etc.) and verify the implementation of the necessary modifications by the Conformity Assessment Bodies after taking the decision and publishing the modified requirements.
- 72. Indicate which activities are/are not covered by EA MLA, ILAC MRA, IAF MLA in the accreditation certificate.
- 73. Explain to the sector scheme owner, the CAB and the market the reasons, should the sector scheme in which SNAS participates fail to comply with the requirements set out in PL-18: EA Policy on Conformity Assessment Schemes.
- 74. Conduct the cross-frontier accreditation strictly in accordance with Regulation (EC) No 765/2008 and the EA, ILAC and IAF policies in the given area.
- 75. Be responsible for the content of all assessment reports.
- 76. Comply with the obligations deriving from the Articles 71, 72, 73, 74, 75 and 76 of the chapter VI of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084.
- 77. Compile, revise and update the list of environmental verifiers as well as the scope of their accreditation in the database on the relevant (EU) Commission website in accordance with the requirements of the Regulation (EC) No. 1221/2009 of the European Parliament and of the Council.
- 78. Elaborate a report on the surveillance results should it, after the consultation with a relevant environmental verifier, reach a decision that the activities of the environmental verifier failed to be performed adequately enough to ensure the compliance with the requirements of the Regulation (EC) No. 1221/2009 by the organization or the environmental verifier violated one or more requirements of this Regulation when conducting verification and validation; submit the report to the competent body in the Member State where the organization is registered or to which it applies for registration and, where appropriate, to the accreditation body that granted accreditation.

## 6 **RIGHTS OF THE AO AND THE CAB**

The accredited body shall **be entitled** to:





- 1. Use the references to the granted accreditation.
- 2. Use the SNAS accreditation symbol, the specimen of which is depicted in the Annex 3 of the Act, unless the accreditation requirement stipulates otherwise.
- 3. Have an accredited body identification number assigned by SNAS.
- 4. Participate in the activities organized by SNAS.
- 5. Use the references to the granted accreditation and to the accreditation granted by SNAS, which is a signatory of the MLA/MRA.
- 6. Apply for reaccreditation based on an application filed no later than four months prior to the expiry of accreditation
- 7. Receive information on the appropriate means of obtaining the traceability of measurement results in the area of granted accreditation and information on the terms and possibilities for laboratories or inspection bodies to participate in the proficiency testing programs and interlaboratory comparisons.
- 8. Evaluate the SNAS activities in the framework of regular surveys.
- 9. In the case of the validation and verification bodies in the regulated area, submit their comments related to the complaint pursuant to the Article 62(b) of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084.

#### CAB shall **be entitled** to:

- 1. Comment on the impartiality and objectivity of the assessment group members.
- 2. Respond to the submitted reports and raise questions on the SNAS findings.
- 3. Obtain free of charge information on the SNAS documents pursuant to the § 3(8) of the Act and European organizations and international organizations associating accreditation bodies in the area of accreditation of the Conformity Assessment Bodies, according to which the assessment of the compliance with the accreditation requirements is conducted.
- 4. File a new application for accreditation following the date the decision on the termination of the proceedings enters into force at the earliest or the date the decision not to grant accreditation enters into force.
- 5. File a complaint or an appeal against the SNAS decision or other filings (see chap. 9).

## 7 **RESPONSIBILITIES OF THE AO AND THE CAB**

The accredited body shall be **obliged** to:

- 1. Act as an accredited body and exercise the rights under the § 36(1) of the Act only in the case of the final decision on accreditation or exercise the rights under the § 36(1) of the Act only in the area or the scope which are covered by the final decision on accreditation.
- 2. Comply with the accreditation requirements in accordance with the decision on accreditation and the requirements stipulated by the Act.



- 3. Exercise the rights arising from accreditation only in the area and within the scope of the final decision on accreditation.
- 4. Without any due delay, inform SNAS of any changes related to:
  - the data pursuant to the § 26(3) (b) and (c) of the Act, should the accredited body be not the legal person whose data are entered in the Register of Legal Entities, Entrepreneurs and Public Authorities;
  - the data pursuant to the  $\S 26(3)(d)$  and (e) of the Act;
  - the organization, management and competence of the personnel;
  - the basic policy;
  - the area of accreditation and the scope of accreditation;
  - other facts which may affect the accredited body capacity to comply with the accreditation requirements.
- 5. Allow SNAS to conduct a surveillance.
- 6. Use the references to the granted accreditation, unless the accreditation requirements state otherwise.
- 7. Use the SNAS accreditation symbol, a specimen of which is depicted in the Annex 3 of the Act, unless the accreditation requirement stipulates otherwise.
- 8. Begin complying with the accreditation requirements by the deadline set by SNAS, should the CAB be notified of the changes to the accreditation requirements.
- 9. During the validity of the decision on the suspension of accreditation:
  - not act as an accredited body and exercise the rights under the § 36(1) of the Act in the area of accreditation or within the scope of accreditation covered by the decision on the suspension of accreditation;
  - not accept new applications to act as an accredited body in the area of accreditation or within the scope of accreditation specified in the decision on the suspension of accreditation.
- 10. Settle the costs for the assessment of the compliance with the accreditation requirements within reaccreditation, if conducted.
- 11. Not use their accreditation in a manner that would damage the reputation of SNAS.
- 12. Fully comply with the SNAS requirements related to applying the accreditation status when referring to their accreditation on the Internet, in documents, and refer to accreditation only for the activities and within the scopes specified in the accreditation certificate (see MSA-02).
- 13. Consistently comply with the requirements of the licensing agreement for the use of the combined ILAC MRA and/or IAF MLA symbols of the accredited body.
- 14. Use the SNAS accreditation symbol in the output documents concerning the area and the scope of the granted accreditation only during the validity of accreditation in accordance with MSA-02.
- 15. In the event of the withdrawal or the suspension of accreditation, cease using the SNAS accreditation symbol, the ILAC MRA and/or IAF MLA combined symbols of the accredited body (if assigned), the documents containing information on granting of accreditation and the references to the accreditation status without any due delay.



- 16. Not make any statement about their accreditation that could be considered misleading or unwarranted.
- 17. Not use its accreditation to imply that SNAS approves of the laboratory results, reports, products, processes, systems or personnel of the accredited organization.
- 18. Clearly distinguish between the activities covered and not covered by accreditation in its certificates or protocols/reports.
- 19. As for the calibration, testing and medical laboratories, upload an updated result summary from the participation in the PT for the past period into the AIS (PT card/Annual Analysis), always prior to the planned assessment using the TL 71 form (found on <u>www.snas.sk</u>) at the same time when the assessment group is approved at the latest.
- 20. As for the inspection bodies, where possible and appropriate, upload an updated result summary from the participation in the PT for the past period into the AIS (PT card/Annual Analysis), always prior to the planned assessment using the TL 71 form (found on www.snas.sk) at the same time when the assessment group is approved at the latest.
- 21. As for the certification bodies certifying persons, products, management systems, submit to SNAS via the AIS (PT card/Annual Analysis):
  - a current list of the valid and suspended certificates uploaded annually, the dates of their audits/tests/conformity assessments planned for the current year and a description of all its critical sites no later than by 31<sup>st</sup> January of the current year using the Excel forms TL 73/S (for the COs certifying management systems), TL 73/P (for the COs certifying products), TL 73/O (for the COs certifying persons) found on www.snas.sk;
  - an update of the current list of the valid and suspended certificates, the dates of their audits/tests/conformity assessments planned for the current year and a description of all its critical sites, should the change occur, no later than one month prior to a scheduled assessment, or if necessary, or anytime upon a call made by SNAS, using the Excel forms TL 73/S (for the COs certifying management systems), TL 73/P (for the COs certifying persons) found on www.snas.sk;

#### Note:

A critical site is defined as a site of the certification body, either in the Slovak Republic or abroad (see IAF/ILAC A5), at which key activities are performed and which include:

- *1.* For the certification bodies certifying products:
- policy formulation and approval;
- process and/or procedure development and approval thereof;
- *initial assessment of the competence and approval of the professional personnel and subcontractors;*
- management of the process monitoring the competence of personnel and subcontractors and its outputs;
- contract review, including an expert review of applications and identification of the technical requirements for the certification activities in new areas or the areas where the certification activities occur sporadically;
- decision on certification, including the expert review of the evaluation tasks.
- 2. For the certification bodies certifying management systems:
- *policy formulation;*



- process and/or procedure development;
- initial approval of the auditors and management of their trainings;
- ongoing monitoring of auditors;
- *the application review;*
- assignment of auditors;
- surveillance management or re-certification audits;
- review of the final report or the decision on certification or approval.
- 3. For the certification bodies certifying persons:
- policy formulation and approval;
- process and/or procedure development and approval necessary for the operation of the certification of persons systems, including the requirements for the selection and appointment of examiners;
- review of applications and contractual arrangements associated with the assessment and certification of persons;
- development, evaluation and maintenance of examinations and re-certifications;
- decision on the certification of persons including signing or authorization of the certificates;
- development and approval of policies, processes and procedures to handle complaints and appeals to the certification process, and criteria filed by applicants, candidates, certified persons and their employers, and third parties;
- final decision about the complaints and appeals.

If the processes, procedures and practices are developed and defined at a site, and these are, reviewed and approved of at the CO's headquarters, the site shall not be considered critical, nevertheless, the CO must provide for an appropriate surveillance of the site's activity and maintain appropriate records thereof.

The sites subject to the review/audit shall be considered other selected sites.

- 22. As for the EMAS environmental verifiers submit to SNAS via the AIS (PT card/Annual Analysis):
  - a current list of the effective validated and suspended environmental statements annually, the dates of their verifications planned for the current year and a description of all its critical sites no later than by 31<sup>st</sup> January of the current year (TL 73/E can be found on <u>www.snas.sk</u>);
  - an update of the list of the effective validated and suspended environmental statements, the dates of their verifications planned for the current year and a description of all its critical sites should a change occur, no later than one month prior to the scheduled assessment, or if required, or anytime upon an call made by SNAS (TL 73/E can be found on <u>www.snas.sk</u>);
- 23. As for the validation and verification bodies in the regulated area, submit the information to SNAS in accordance with the Article 77(1) of the Chapter VI of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084 (The template for the notification made by the verifier of the GHG emission reports can be found on www.snas.sk). Provided the information changes, the verifier of GHG emission reports shall always communicate these changes to SNAS on



the last day of the month. In an non-regulated area (sector-specific schemes), submit the prescribed information on TL 73/VV (published at www.snas.sk) annually, no later than January 31 of the current year. The information and its updates listed on the template and TL are entered into the AIS (PT card/Annual analyses).

- 24. Comply with other requirements specified by an accreditation body (communicated electronically via info@snas.sk, on the SNAS website and published in the relevant SNAS policies and MSA).
- 25. Inform the clients in question of the suspension, reduction or withdrawal of their accreditation and related consequences without any due delay.

#### CAB is **obliged** to:

- 1. Liaise during the assessment of the compliance with the accreditation requirements and in particular, provide all necessary documents, information and explanations.
- 2. Allow persons authorized by SNAS to enter the premises, access the technical equipment, inspect the documentation and carry out witness assessments.
- 3. Adhere to the principles of impartiality, independence, reliability and integrity.
- 4. File an application via the information system pursuant to the § 3(7)(o) of the Act in the state language or in the language specified in the information system by the Slovak National Accreditation Service.
- 5. Specify the area and the activities for which the accreditation is sought.
- 6. Upon request, provide the assistance and cooperation of all personnel so as to enable SNAS to verify the compliance with the accreditation requirements at all locations where the conformity assessment services are provided with all the personnel and at all the facilities/equipment.
- 7. Enable to perform a required or additional assessment, scheduled, regular or extraordinary assessment (e. g. due to a complaint, appeal, ...) by the SNAS personnel, as well as the monitoring/auditing of the activities of the SNAS personnel, and provide them with all necessary information, documents and records, and cooperation to perform the aforementioned activities.
- 8. Adhere to the principles of impartiality and independence, and provide access to the documents relevant to the compliance with these principles.
- 9. Ensure that the witness assessments 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's storage facilities. Where the conformity assessment activities are performed on-site, on the client's premises it shall, by means of a legally enforceable agreement, allow the SNAS assessment groups to assess the performance of those activities. Should the witness assessments be conducted outside the territory of the Slovak Republic, it may not refuse the performance of a witness assessment subcontracted by a competent local accreditation body.
- 10. Settle the costs for the assessment of the compliance with the accreditation requirements, if conducted, and if SNAS issued a decision not to grant accreditation.



- 11. As for the preliminary assessment, settle payment dully and in a timely manner pursuant to the \$12(2) of the Act.
- 12. In the case of the preliminary assessment, settle a late-payment interest to SNAS should it fail to pay the fee under the terms and conditions determined by SNAS in a due course and a timely manner.
- 13. Settle the payments for the provided services in a timely manner and agreed level.
- 14. Take corrective actions and remove any identified nonconformities within the timeframe specified by relevant regulations.
- 15. Remove any nonconformities within the required timeframe (see MSA-04).
- 16. Assist in the investigation and handling of any related complaints referred to it by SNAS.

## 8 ACCREDITATION STATUS MISUSE

Under PL-16, SNAS shall monitor the correct use of accreditation symbols and references to the accreditation status granted by the accredited Conformity Assessment Bodies and take appropriate measures in case of their misuse (intentional or unintentional) or abuse.

#### 8.1 ACCREDITATION STATUS MISUSE IDENTIFICATION

SNAS shall periodically assess the accredited body's compliance with MSA-02 and the licensing agreement requirements regarding the use of the ILAC MRA and/or IAF MLA combined symbol within the accreditation cycle. All types of protocols, certificates, reports, calibration letters, draft contracts and other documents, promotional materials are subject to verification or assessment. Documents bearing the accreditation symbols and/or references to the accreditation status shall be consistent with the scope of the granted accreditation (see MSA-02, chapter 7 below).

SNAS may also detect cases of the accreditation status misuse or abuse in other ways, such as:

- through complaints from the customers of the accredited bodies addressed to SNAS,
- by notifying SNAS by other body,
- through the state administration authorities, authorizing bodies,
- through the specialized press, the Internet and the mass media,
- at conferences, appointments and dealings where the personnel of the accredited bodies make presentations and distribute their promotional materials, etc.

#### 8.2 ASSESSMENT AND SANCTIONS

SNAS shall assess all cases of the self-identified accreditation status misuse or abuse, as well as all third-party notifications/alerts received in terms of accreditation requirements. In the case of a third-party notification, SNAS shall review the credibility and legitimacy of such notification.

Depending on the accreditation status misuse severity and extent and considering whether intentional (e. g. aiming to obtain a certain advantageous status) or due to an accident, misunderstanding or misinterpretation of the provisions of the accreditation requirements, SNAS shall take appropriate measures or impose sanctions.



Upon the accreditation status proof of misuse or abuse, SNAS shall:

- notify the accredited body of the findings in writing, request prompt corrections and the evidence of such corrections to be later reviewed; or
- withdraw the accredited body's authority to use the ILAC MRA and/or IAF MLA combined symbol; or
- suspend accreditation and perform an assessment of accreditation requirements during an extraordinary surveillance if the grounds well founded,
- in the event of repeated breaches of the accreditation symbol and/or references to accreditation correct use principles, or failure to take corrective actions by the CAB as requested by SNAS, SNAS may withdraw the accreditation of the body in question,
- take legal action in the event of serious intentional and substantial damage to the national accreditation body.

When identifying a suspicion of an administrative offense according to § 37 of Act no. 53/2023 Coll. as part of the assessment, SNAS will ensure that:

- the leading assessor insert evidence of suspicion into the AIS supporting documentation and immediately informed the head of the relevant department and the lawyer about these facts;
- the head of the department and the lawyer decided on the relevance of the suspicion;
- in the case of the relevance of the suspicion, the SNAS lawyer sent the ÚNMS SR an initiative on the suspicion of a violation of Act no. 53/2023 Coll.

When identifying a suspicion of an administrative offense according to § 37 of Act no. 53/2023 Coll. from sources other than assessment, SNAS will ensure that:

- the head of the department and the lawyer decided on the relevance of the suspicion;
- in the case of the relevance of the suspicion, the SNAS lawyer sent the ÚNMS SR an initiative on the suspicion of a violation of Act no. 53/2023 Coll.

## 9 COMPLAINTS, APPEALS AND OTHER FILINGS

#### **Principles**:

- 1. The Director of SNAS shall be responsible for handling complaints and appeals.
- 2. In addition to the complaints and appeals, other filings may be sent to SNAS as well (e. g. objection to the assessment group proposed composition, ...).
- 3. SNAS shall act objectively, impartially and independently upon handling any complaint/appeal/other filing and commit to observe confidentiality of any classified information.
- 4. The filing of a complaint under the Act on Reporting of Anti-Social Activities shall not prompt or give rise to draw the consequences that would cause any harm to the complainant.

#### 9.1 COMPLAINTS

#### 9.1.1 General

Given the legal status of SNAS, the complaint concept needs to be defined in relation to a series of documents.



#### According to ISO/IEC 17011

A complaint according to clause 3.20 of ISO/IEC 17011 is a person' or an organization's expression of dissatisfaction, other than an appeal, to an accreditation body concerning the activities of the accreditation body or an accredited conformity assessment body, and where a response is expected.

## Pursuant to the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084

A complaint under the Article 62 of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084 is a complaint against a validation and verification bodies in the regulated area filed by a competent authority, an operator or an aircraft operator or other interested parties.

Pursuant to the § 3 of Act No. 9/2010 Coll. on Complaints, as amended

A complaint is a filing of a physical person or a legal entity (hereinafter referred to as " the complainant"), by which the complainant:

- a) seeks protection of his/her rights or legally protected interests which he/she considers to have been violated by the action or inactivity (hereinafter referred to as "the action") of a public administration body;
- b) points to specific deficiencies, breaches of the regulations in particular, the elimination of which is within the public authority competence.

A complaint pursuant to the § 4 of Act No. 9/2010 Coll. on Complaints, as amended is not a filing that:

- a) is in the nature of an enquiry, statement, opinion, request, initiative or proposal;
- b) points to specific deficiencies in public administration body activities, the removal or handling of which is regulated by a special regulation;
- c) is a complaint under a special regulation;
- d) is directed against a public authority decision issued in the proceedings under a special regulation;
- e) is directed against the control, audit, surveillance or inspection conclusions pursuant to a special regulation;
- f) contains classified information or it is apparent from the content that its handling as a complaint under this Act would compromise classified information under a special regulation.

A complaint pursuant to the § 4 of Act No. 9/2010 Coll. on Complaints, as amended is not a filing by:

- a) a public administration body, in which it draws attention to shortcomings in the activities of another public administration body;
- b) a person authorized by a court to perform the exercise of official authority.

#### 9.1.2 Complaint handling

When dealing with complaints, SNAS proceeds in accordance with ISO/IEC 17011 and the Act No. 9/2010 Coll. on Complaints, as amended.



Complaints shall be made in writing, orally or electronically:

- in writing to Slovenská národná akreditačná služba, Karloveská 63, P. O. Box 74, 840 00 Bratislava 4;
- electronically to the following address: <u>snas@snas.sk;</u>
- by phone on working days between 9 a.m. 3 p.m. at +421 948 349 517;
- in person on working days from 9 a.m. 3 p.m. at the SNAS headquarters.

Should SNAS not be competent to handle a received complaint, it shall forward the complaint to the competent body without any due delay.

The complaint shall include:

- a) the name, surname, permanent or temporary residency address of the complainant, if a physical person;
- b) the name and registered office and the name and surname of the person authorized to act on behalf of the legal person, if a legal person;
- c) an indication of the person against whom the complaint is lodged, the deficiencies complained about, the complainant's claims (hereinafter referred to as "the complaint subject") and a signature.

Should a complaint lodged electronically not be signed and the complainant fail to confirm it by a handwritten signature **within 5 working** days of its lodging, the complaint shall be shelved.

Unless the complaint falls within the aforementioned requirements (e. g. lodged electronically without a signature, or is anonymous), however, provides relevant information in relation to the compliance with the accreditation requirements, SNAS may, at the Director's discretion, continue its investigation in order to confirm the legitimacy, with subsequent remedy or its unfoundedness.

The filing specified as a complaint although not a complaint shall be returned to the complainant by the Secretariat stating the reason without any due delay, however, no later than **30 working days** from the date of receipt. SNAS shall not return such a filing should it be competent to deal with it otherwise than by way of a complaint.

The Director shall appoint a Complaint Investigation Commission to investigate the complaint (see paragraph 9.3).

The response time for handling a complaint at SNAS is **60 working days**. In justified cases, the Director may extend this time by 30 working days before its expiry. The complainant shall be informed of the response time extension and the reasons for the extension without any due delay.

The response time limit for handling a complaint pursuant to the Article 62 of the Commission Implementing Regulation (EU) 2018/2067, as amended by the Commission Implementing Regulation (EU) 2020/2084, shall be 3 months from the complaint receipt. The validation and verification bodies in the regulated area concerned shall have the opportunity to comment on the complaint. In relation to the complaints against the SNAS accredited validation and verification bodies in the regulated area, SNAS is obliged to notify the Ministry of Environment of the Slovak Republic and the competent authority of the Member State in which the validation



and verification bodies in the regulated area performs the verification.

The final decision concerning the complaint shall be taken by the Director based on the Complaint Investigation Commission's recommendation.

The complaint is deemed closed upon sending a written notice of the investigation outcome to the complainant.

## 9.2 APPEALS

## 9.2.1 General

An appeal according to the clause 3.21 of ISO/IEC 17011 is a conformity assessment request body that an adverse decision on the requested accreditation status made by an accreditation body be reconsidered.

An appeal is an ordinary appeal against an illegitimate first instance decision.

## 9.2.2 Appeals handling

SNAS shall comply with ISO/IEC 17011 and the Act when handling appeals.

An appeal filed against a SNAS decision on accreditation shall be sent in writing to the SNAS address within **15 days** from the date of the decision receipt.

No appeals against the internationally recognized accreditation criteria set out by the applicable international standards and mandatory application EA, ILAC, IAF documents in the accreditation matter shall be possible.

The filed appeal shall clearly indicate who lodges it, against what decision and what is being requested.

The Director shall make a decision about the appeal against the decision on the basis of the Appeal Investigation Commission's recommendation.

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

The decision to lift the suspension of accreditation pursuant to the § 30(4) of the Act shall not be subject to appeal.

SNAS shall notify the appellant about the investigation status of his/her appeal **within 30 days** from the date of the appeal receipt by SNAS.

The appeal proceedings shall be concluded upon a Decision issuance and notifying the appellant about the conclusions resulting from the investigation.

#### 9.3 INVESTIGATION OF COMPLAINTS AND APPEALS

The members of the Complaint Investigation Commission or Board of Appeal (hereinafter referred to as "the Commission/the Board") shall be appointed and removed by the Director. A member of the Complaint Investigation Commission or Board of Appeal may not be a member of the Evaluation Commission or the Assessment Group on the same matter and the one who may be doubted as to his/her impartiality and objectivity having regard to his/her relationship



to the case, to the parties or to their representatives.

Where the complaint relates to an unaccepted nonconformity, the Commission/the Board shall be appointed in accordance with MSA-04. When warranted by the complaint seriousness, the Commission/the Board shall recommend an extraordinary assessment, and the CAB shall be notified thereof in advance.

Another complaint and another repeat complaint shall be deemed a complaint lodged by the same complainant on the same matter unless new facts are alleged. In order to deal with a repeat complaint, the Director shall appoint a new composition of the Commission/the Board. Upon dealing with the complaint, the handling of the previous complaint shall be checked and a report drawn up. A further repeat complaint shall be shelved.

If the previous complaint was dealt with correctly, SNAS shall notify the complainant, providing the statement of grounds thereof and instruction that any other repeat complaint shall be shelved. Should SNAS find that the previous complaint failed to be closed properly, it shall reinvestigate and handle the complaint. A complaint lodged by another complainant in an already handled matter shall not be investigated again. The complainant shall be informed about the conclusions of the complaint investigation.

#### 9.4 **OTHER FILINGS**

#### 9.4.1 General

In addition to complaints and appeals, the conformity assessment body is entitled to make other filings to SNAS.

Another filing means any filing, other than a complaint/appeal, in respect of which SNAS is expected to cooperate/resolve/review, such as

- an objection raised by a Conformity Assessment Body to the assessment group proposed composition,
- an objection raised by a Conformity Assessment Body to the assessment findings,
- a filing reacting to the SNAS activity or a SNAS employee activity or to an accredited Conformity Assessment Body activity and is not a complaint,
- a filing under the Act on Notification of Anti-social Activities, which is a notification under the § 2(1)(b) of the Act on Notification of Anti-social Activities, including an anonymous letter or a non-anonymous filing by a physical person of an anti-social activity other than a material anti-social activity of which he/she learned within the context of his/her work, profession performance, position or post.

## 9.4.2 Handling other filings

Filing, registration, investigation, examination of filings shall be carried out in accordance with the Act No. 9/2010 Coll. on Complaints, as amended or the Act No. 54/2019 Coll. on Protection of Whistleblowers of Anti-Social Activity and on amendment and supplement to certain acts.

Should the person filing a complaint request confidential treatment of his/her identity, any SNAS employee who knows the complainant's identity shall be obliged to maintain confidentiality on the complainant's identity and comply with the § 8 of Act No. 9/2010 Coll. on Complaints, as amended.

The CAB may file a written objection to SNAS against the assessment group proposed



composition. SNAS shall accept a legitimate objection, which is (e. g. a conflict of interest) and put forward a new composition of the assessment group to the CAB.

SNAS shall accept legitimate objections and reply to the complainant regarding the filed complaint.

The motions under the Act on Notification of Anti-Social Activity may be submitted to SNAS in person, by phone or electronically to the following address: <u>korupcia@snas.sk</u>. The motion must be examined by a responsible person **within 90 days** from the date of the receipt thereof. The response time may be extended by 30 days, of which the non-anonymous notifier must be informed. When acquainting himself/herself with the motion content, the responsible person shall enforce the confidentiality on the notifier's identity and protect personal data in accordance with the Act No 18/2018 Coll. on Protection of Personal Data and on amendment and supplement to certain acts, as amended. The notifier of the non-anonymous motion shall be informed of the result within ten days of completing the investigation. If the investigation reveals a commission of a crime, the person responsible shall be obliged to report thereof to the law enforcement authorities.

## **10 ANNEXES**

Annex No. 1: External related documents - Tables No.1 to 10



## ANNEX No. 1

## Table 1 GENERAL BASIC AND RELATED DOCUMENTS FOR ACCREDITATION BODY

International documents and laws	Document title
ISO/IEC 17011	Conformity Assessment. Requirements for Accreditation Bodies accrediting Conformity Assessment Bodies
IAF/ILAC A3	IAF/ILAC MLA/MRA – Narrative Framework for Reporting on the Performance of an AB - A Tool for the Evaluation Process
ILAC-P4	ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement
ILAC-P5	ILAC Mutual Recognition Arrangement (Arrangement)
ILAC-P8	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
IAF PL 1	Code of Conduct for Members of the IAF
IAF PL 6	Memorandum of Understanding
IAF PL 8	Rules for the Use of the IAF logo
IAF PL 9	General Principles for the Use of the IAF CERTSEARCH Mark
ILAC-G3	Guidelines for Training Courses for Assessors used by ABs



International documents and laws	Document title
ILAC-G21	Cross Frontier Accreditation — Principles for Cooperation
ILAC-R4	Use of the ILAC logo and Tagline
ILAC-R7	Rules for the Use of the ILAC MRA Mark
IAF ML 1	Guidance for the Exchange of Documentation among MLA Signatories for the Assessment of Conformity Assessment Bodies
IAF ML 2	General Principles on the Use of the IAF MLA Mark
IAF ML 3	Guidance for responding to Inquiries on Multilateral Recognition Arrangement (MLA) Signatory Equivalence and on the acceptance of certification documents
IAF ML 4	Policies and Procedures for a MLA on the Level of Single Accreditation Bodies and on the Level of Regional Accreditation Groups
IAF MD 7	Harmonization of Sanctions
IAF MD 12	Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries
IAF MD 14	Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)
IAF MD 20	Generic Competence for AB Assessors: Application to ISO/IEC 17011
IAF MD 28	Upload and Maintenance of Data on IAF Database
Regulation (EC) No 765/2008 of the European Parliament and of the Council	Setting out the requirements for Accreditation and Market Surveillance relating to the Marketing of Products
Decision No. 768/2008/EC of the European Parliament and of the Council	On a common framework for the marketing of products
EA-1/06	EA multilateral agreement - Criteria for signing - Policy and procedures for development
EA-1/17	EA Rules of Procedures
EA-1/17 S1	Supplement 1 to EA-1/17 Criteria for Membership
EA-1/17 S5	EA supplement 5 to EA-1/17, EA rules of procedure - levying of membership fees
EA-1/19	Rules for the use of EA logo and Graphic Specification
EA-1/20 S1	Supplement 1 to EA-1/20, Terms and Conditions for Financial Compensation from the Operating Grant to an EA Member Accreditation Body



International documents and laws	Document title
EA-1/21	EA Internal procedure for liaison activities
EA-1/22	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
EA-1/23	EA Policy to speak with "One Voice"
EA-2/02	EA Procedure for the evaluation of a National Accreditation Body
EA-2/13	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members.
EA-2/15	EA Requirements for the Accreditation of Flexible Scopes
EA-2/17	EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes
EA-3/01	EA Conditions for the use of accreditation symbols, text reference to accreditation and MLA signatory status
Act No. 9/2010 Coll.	On Complaints, as amended by later regulations
Act No. 67/2010 Coll.	On Chemical Substances and Chemical Preparations (Chemical Law)
Act No. 71/1967 Coll.	On Administrative Proceedings (Administrative Procedure Code), as amended by later regulations
Act No. 18/2018 Coll.	On Protection of personal data and amending and supplementing certain acts
Act No. 211/2000 Coll.	On Free Access to Information and on amendment and supplement to certain acts (Freedom of Information Act)
Act No. 53/2023 Coll.	On Accreditation of Conformity Assessment Bodies

#### BASIC AND RELATED DOCUMENTS FOR TESTING, CALIBRATION AND EXAMINATION

International documents and laws	Document title
ISO/IEC 17025	General requirements for the Competence of Testing and Calibration Laboratories
ISO 15189	Medical Laboratories – Particular requirements for Quality and Competence
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities
ILAC-P10	ILAC Policy on Traceability of Measurement Results
ILAC P14	ILAC Policy for Uncertainty in Calibration



ILAC-G18	Guideline for the Formulation of Scopes of Accreditation for Laboratories
EA-4/02	Expressions of the Uncertainty of Measurements in Calibration
EA-4/17	Description of Scopes of Accreditation of Medical Laboratories

#### **BASIC AND RELATED DOCUMENTS FOR PROVIDERS OF PT**

International documents and laws	Document title
ISO/IEC 17043	Requirements for the Competence of Providers of Proficiency Testing Schemes



## BASIC AND RELATED DOCUMENTS FOR INSPECTION

International documents and laws	Document title
ISO/IEC 17020	General criteria for the operation of various types of bodies performing inspection
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities
ILAC-P10	ILAC Policy on Traceability of Measurement Results
ILAC-P15	Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
ILAC-G27	Guidance on Measurements performed as part of an inspection process
ILAC-G28	Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies

#### Table No. 5

## BASIC AND RELATED DOCUMENTS FOR CERTIFICATION OF MANAGEMENT SYSTEMS

International documents and laws	Document title
ISO/IEC 17021-1	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 1: Requirements
ISO/IEC 17021-2	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 2: Competence requirements for Auditing and Certification of Environmental Management Systems
ISO/IEC 17021-3	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 3: Competence requirements for Auditing and Certification of Quality Management Systems
ISO 50003	Energy Management Systems. Requirements for Bodies providing Audit and Certification of Energy Management Systems
ISO/IEC 27006	Information Technology - Security techniques - Requirements for Bodies providing Audit and Certification of Information Security Management Systems
ISO/TS 22003	Food Safety Management Systems. Requirements for Bodies providing Audit and Certification of Safety Management Systems
ISO/IEC 20000-6	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems Part 6: Information Technologies – Service Management
ISO/IEC TS 17021-6	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems Part 6: Competence requirements for Auditing and Certification of Business Continuity Management Systems



ISO/IEC TS 17021-9	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 9: - Competence requirements for Auditing and Certification of Anti-bribery Management Systems
ISO/IEC TS 17021-10	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 10: Competence requirements for Auditing and Certification of Occupational Health and Safety Management Systems
IAF MD 1	Certification of Multiple Sites Based on Sampling
IAF MD 2	Transfer of Accredited Certification of Management Systems
IAF MD 4	Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems
IAF MD 5	Duration of QMS and EMS Audits
IAF MD 8	Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)
IAF MD 9	Application of ISO/IEC 17021 in Medical Devices QMS (ISO 13485)
IAF MD 11	IAF Mandatory Document for the Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)
IAF MD 13	Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)
IAF MD 15	IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance
IAF MD 16	Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
IAF MD 17	Witnessing Activities for the Accreditation of Management Systems Certification Bodies
IAF MD 21	Requirements for transition to ISO 45001: 2018 from OHSAS 18001:2007
IAF MD 22	Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)
IAF MD 23	Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies
IAF MD 24	Requirements for transition to ISO 50003: 2021
IAF MD 25	Criteria for Evaluation of Conformity Assessment Schemes
IAF MD 26	Requirements for transition to ISO/IEC 27001:2022
EA-6/02	EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834
EA-7/04	Legal Compliance as a part of accredited ISO 14001 certification
TD SFCS 1005	Requirements for Certification Bodies conducting Certification of Forest Management



#### Table No. 6 BASIC AND RELATED DOCUMENTS FOR CERTIFICATION OF PRODUCTS

International documents and laws	Document title
ISO/IEC 17065	Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services
EA-3/02	EA Policy for the accreditation of Certification Bodies conducting Certification of PDO, PGI and TSG
EA-3/12	EA Policy for Accreditation of Organic Production Certification
EA-6/02	EA Guidelines on the Use of ISO/IEC 17065and ISO/IEC 17021 for Certification to EN ISO 3834
EA-6/04	EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites
TD SFCS 1006	Requirements for Certification Bodies conducting Certification against the PEFC International Chain of Custody Standard
TD SFCS 1007	PEFC Trademarks Rules - Requirements
ERA_MNB- Assessment scheme 000MRA1044	Technical document ERA. Requirements for Conformity Assessment Bodies seeking Notification
ERA 1172/002 V3.1	Sectorial Scheme for Accreditation and Recognition of ECM certification Bodies under Regulation (EU) 2019/779
ETSI EN 319 403-1 V2.3.1	Electronic Signatures and Infrastructures; Trust Service Provider Conformity Assessment; Part 1: Requirements for conformity assessment bodies assessing Trust Service Providers

#### Table No. 7

#### BASIC AND RELATED DOCUMENTS FOR CERTIFICATION OF PERSONS

International documents and laws	Document title	
ISO/IEC 17024 Conformity Assessment - General requirements for Bodies conductin Certification of Persons		



#### Table No. 8 BASIC AND RELATED DOCUMENTS FOR ACCREDITATION OF ENVIRONMENTAL VERIFICATORS

International documents and laws	Document title	
ISO/IEC 17021-1	Conformity Assessment - Requirements for Bodies providing Audit and Certification of Management Systems - Part 1: Requirements	
Regulation (EC) No. 1221/2009 of the European Parliament	On the voluntary participation by Organizations in a Community Eco- anagement and Audit Scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC	
and of the Council Commission Regulation (EU) 2017/1505	Amending Annexes I, II and III to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS)	
Commission Regulation (EU) 2018/2026	Amending Annex IV to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organizations in a community eco-management and audit scheme (EMAS)	
Act No. 351/2012 Coll.	On Environmental Verification and Registration of Organizations within the Scheme of the European Community for Environmental Management and Audit and on change and amendment of some acts	

#### Table No. 9

#### BASIC AND RELATED DOCUMENTS FOR ACCREDITATION OF VALIDATION AND VERIFICATION BODIES

International documents and laws	Document title	
EN ISO/IEC 17029	Conformity assessment – General principles and requirements for validation and verification bodies	
EN ISO 14065	General principles and requirements for bodies validating and verifying environmental information	
ISO 14066	Environmental information – Competence requirements for teams validating and verifying environmental information	
EN ISO 14064-3	Greenhouse gases. Part 3: Specification with guidance for the verification and validation of greenhouse gas statements	
IAF MD 6	IAF Mandatory Document for the Application of ISO 14065: 2013	
Commission Implementing Regulation (EU) 2018/2067	On the Verification of Data and on the Accreditation of Verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council	
Commission Implementing	Amending and correcting Implementing Regulation (EU) 2018/2067 on the Data Verification and on the Accreditation of Verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council	



<b>Regulation (EU)</b> 2020/2084		
Commission Guidance and Templates to Regulations		
EA-6/03	EA document for Accreditation of Verification Bodies for the purpose of EU ETS Directive	
Act No. 414/2012 coll.	On Emission Allowance Trading	

## BASIC AND RELATED DOCUMENTS FOR ACCREDITATION IN REGULATED AREA

Title of European directive/regulation		
Personal Protective Equipment		
Active Implantable Medical Devices		
Hot Water Boilers		
Explosives for Civil Use		
Medical Devices		
Equipment and Protective Systems intended for Use in potentially explosive atmospheres		
Lifts		
Pressure Equipment		
In vitro Diagnostic Medical Devices		
Radio and Telecommunication Terminal Equipment		
Cableway Installations		
Noise Emissions		
Measuring Instruments		
Electromagnetic Compatibility		
Machinery		



Equipment used within a certain voltage range		
Pyrotechnic Articles		
Interoperability of the Rail Systems		
Non-automatic Weighing Instruments		
Toys		
Simple Pressure Vessels		
Appliances Burning Gaseous Fuels		
Transportable Pressure Equipment		
Construction Products		
Trust Services Providing (eIDAS)		
Rolling Stock Maintenance (ECM)		

Act	Title *)
Act No. 56/2018 Coll.	on the assessment of product conformity, making the specified product available on the market and on the amendment of certain laws
Act No. 157/2018 Coll.	on metrology and on the amendment of some laws
Act No. 106/2018 Coll.	on the operation of vehicles in road traffic and on the amendment of some laws
Act No. 124/2006 Coll.	on safety and health protection at work and on amendments to certain laws
Act No. 355/2007 Coll.	on the protection, support and development of public health and on the amendment of certain laws
Act No.282/2020 Coll.	on ecological agricultural production
Act No. 146/2023 Coll.	on air protection and amendments to some laws



Act No. 362/2011 Coll.	on medicines and medical devices and on the amendment of certain laws
Act No. 513/2009 Coll.	on railways and on amendments to certain laws
*) all laws as amended	

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