

Policy

PL - 10

SNAS POLICY ON ACCREDITATION FOR AUTHORIZATION/ NOTIFICATION PURPOSES

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PURPOSE: This document delineates the SNAS policy on CAB accreditation for the authorization/ notification purposes.

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1 SNAS POLICY ON ACCREDITATION FOR AUTHORIZATION/NOTIFICATION PURPOSES

The requirements of the Regulation of European Parliament and Council No. 765/2008 and the Decision of the European Parliament and the Council No. 768/2008 extended the accreditation in the European region into a regulated sphere.

SNAS policy on and approach to accreditation of conformity assessment bodies (CAB) for authorization/notification purposes are based on:

- Regulation (EC) No. 765/2008 which set out the requirements for accreditation and market surveillance relating to the marketing of products and Decision of EP and Council 768/2008 where the duties of EA members are formalized and where it is stressed the need for close cooperation between EA, European Commission, accreditation bodies and national regulators;
- horizontal requirements for accreditation of conformity assessment bodies for the notification purposes defined in the document EA-2/17 which is applies by accreditation bodies for assessment of notified bodies or conformity assessment bodies seeking notification if their accreditation scope is an object of notification;
- requirements specified in the relevant harmonisation international legislation and requirements set on national level;
- relevant technical regulations for conformity assessment bodies and related documents issued by EA, ILAC and IAF.

The aim of this activity is to unify requirements for accreditation of CAB which has or will have in the scope of its accreditation also an activity necessitating, according to a technical regulation, authorization/notification. For CAB itself, it means ridding of multiple assessments carried out within the process of accreditation for the notification purposes.

2 COOPERATION WITH NATIONAL REGULATORS

Communication, cooperation and strengthening of the linkages between SNAS and national regulators are important prerequisites for an accreditation in the regulated field, the aim of this is carrying out the process in the most effective way.

As for this, SNAS has a documented and implemented structure enabling effective involving national regulators in accreditation in the regulated fields:

- Accreditation Board, whose task is to supervise the impartiality and objectivity of SNAS's performances, to conceptually participate in the development and maintenance of the principles and main policies of the accreditation system in the Slovak Republic. It is also a coordination forum between national regulators and SNAS in exchanging accreditation experiences for authorization/notification purposes;

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- SNAS Technical Committees, which are established to confirm the professional competence of assessors and experts in the field of accreditation and to address technical and methodological issues in the areas of SNAS accreditation to ensure that all professional and technical issues and relevant documents are discussed and resolved in SNAS at required professional level, including accreditation for authorization/notification purposes;
- direct participation of the regulator in the assessment, by including its expert in the SNAS assessment group;
- indirect participation of the regulator in the assessment, through the transfer assessment outputs by SNAS to the regulator.

3 ACCREDITATION OF CALIBRATION AND TESTING LABORATORIES FOR THE AUTHORIZATION PURPOSES TO CARRY OUT THE VERIFICATION OF LEGALLY CONTROLLED MEASURING INSTRUMENT IN ACCORDANCE WITH ACT NO. 157/2018 COLL. ON METROLOGY AND ON THE AMENDMENT OF CERTAIN LAWS AS AMENDED

According to § 33 par. 2 of Act no. 157/2018 Coll. on metrology and on the amendment of certain laws as amended (hereinafter referred to as the "Metrology Act"), the applicant for authorization can demonstrate the fulfilment of the authorization requirements according to the paragraph 1 letter a) to o) by the accreditation according to a special regulation in the field and scope that is the subject of the application for authorization to perform the verification of the legally controlled measuring instrument, while the accreditation must be valid during the validity of the decision on authorization¹.

According to § 34 par. 2 of the Act on Metrology, the Slovak Office of Standards, Metrology and Testing (thereinafter as "Office") will carry out an on-site inspection of fulfilment of authorization requirements at the site of the applicant for authorization, if at the time of submission of the authorization application the authorization applicant has accreditation according to the special regulation in the field and scope that is the subject of the authorization application. At least two employees of the Office shall participate in the performance of the control of the fulfilment of authorization requirements.

¹ Note 1) : accreditation according to STN EN ISO/IEC 17025 in the field and scope that is the subject of the request for authorization (Appendix 1 of Methodological procedure No. 52 on authorization for the performance of verification of legally controlled measuring instruments and the performance of official measurement as amended by Addendum No. 01 effective from 01.04.2020, Addendum No. 02 effective from 01.04.2022 and Addendum No. 03 effective from 01.04.2023 – hereinafter referred to as "Methodological procedure").

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According to § 34 par. 5 of the Act on Metrology, the verification of the fulfilment of the authorization requirements according to paragraph 2 is an assessment of the applicant's application for authorization and the on-site inspection of the authorization applicant by the Office; when performing the assessment of the fulfilment of the authorization requirements according to § 33, the results of the assessment within the framework of the granted accreditation according to a special regulation will be used. The verification of the legally controlled measuring instrument or conducting a specific measurement by the applicant for authorization are the part of the on-site inspection of the applicant for authorization.

Pursuant to MP 52: 2019 Methodological procedure, if the applicant for authorization applies for authorization with the accreditation, the accreditation is required for the type of specified legally controlled measuring instrument according to Annex no. 1 of the Decree to the scope that is the subject of the request for applicant authorization (Article 5.1.4).

According to the Art. 5.4.10 Methodological procedure, SNAS in accordance with § 3 par. 7 letters p) of the Act on Accreditation shall send a summary report on the assessment of the fulfilment of the accreditation requirements according to § 22 of the Act on Accreditation and the decision on accreditation, suspension of accreditation or cancellation of accreditation, if it has been issued to the Office, after the assessment of the accredited body, which is accredited for the purposes of authorization according to of the Act on Metrology, within five working days from the summary report issuance or from the issuance of the decision on accreditation, suspension of accreditation or cancellation of accreditation, if issued.

SNAS accredits bodies, especially calibration laboratories according to STN EN ISO/IEC 17025 in the field and scope that is the subject of the application for authorization for the purposes of authorization for the verification of the legally controlled measuring instrument according to the Act on Metrology.

The granted accreditation for calibration laboratories according to STN EN ISO/IEC 17025 solely applies to calibration performance of the measuring instrument, not to the verification performance², which is not covered by the accreditation. Within the scope of the accreditation of the accreditation certificate, the type of measuring instrument and the measuring range are specified according to the Decree of the Office No. 161/2019 Coll. on measuring instruments and metrological control as amended by Decree no. 346/2022 Coll.

² Note 2): SNAS, within the accreditation of calibration laboratories, assesses only the activities related to the calibration of the measuring instrument.

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The activities required for the verification of the measuring instrument in accordance with § 25 par. 6, 7 and 8 of the Act on Metrology are not accredited in the case of accredited calibration laboratory, and the Office shall perform a verification of their execution according to § 34 par. 5 of the Metrology Act.

Accredited calibration laboratory issues a report (usually a calibration certificate) from the carried out calibration, which shall meet the requirements of the Art. 7.8 ISO/IEC 17025. However, this report shall not be mistaken for the verification document issued in accordance with § 25 par. 8 and 10 of the Act on Metrology for the purpose of verifying the legally controlled measuring instrument.

Should the authorized body issue a verification certificate of the legally controlled measuring instrument in accordance with § 25 par. 8 and 10 of the Metrology Act, such a document shall not bear the SNAS accreditation mark, as this activity is not accredited.

Should the calibration laboratory issue a report that also contains non-accredited activities (e.g., verification activities of the legally controlled measuring instrument), such a report shall clearly state which of the activities and calibration results (or which part of the report) are covered by the accreditation of the calibration laboratory and which are not. In such a case, the report issued by the accredited calibration laboratory may bear the SNAS accreditation mark, as long as the report with the accredited results meets the requirements of Art. 7.8 ISO/IEC 17025.

4 RELATED DOCUMENTS

ISO/IEC 17011: 2017	Conformity Assessment. Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
Regulation EP and C 765/2008	setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Decision EP and C 768/2008	on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
MSA-04	Procedure for the Accreditation
MSA-06	Responsibility of SNAS and CABs
MSA-N/01	Accreditation for Notification Purposes
ST-06	SNAS Technical Committees
ST-11	Accreditation Board

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