

Policy**PL - 58****THE POLICY AND PROCEDURE OF SNAS FOR THE
ASSESSMENT OF LABORATORIES ACCORDING TO THE
REQUIREMENTS OF THE STANDARD ISO 15189: 2022****Approved by: Ing. Štefan Král, PhD.
 Director SNAS**

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SCOPE: This regulation determines the policy and procedure of SNAS in the transition to the accreditation of laboratories according to the requirements of the reviewed standard ISO 15189: 2022 published in December 2022.

Update of the document with regard to the information published in the Official Journal of the European Union 2024/581 20.02.2024.

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Date of elaboration: 02.05.2024

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By coming into force of this PL expired the validity of PL-58 from 28.02.2023.

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1 POLICY

SNAS assesses the competence of medicine (ML) laboratories according to the standard ISO 15189, provided they ask for.

A reviewed version was published in December 2022 of the standard ISO 15189: 2022, that, compared to the previous version ISO 15189: 2012 brought a more comprehensive revision. This standard applies to all types of medical laboratories.

In accordance with the resolution adopted at the General Assembly of ILAC: „Resolution GA 26.08“from 15.11.2022 concerning the implementation of this new standard and assessment of the fulfilment of its requirements in the accredited laboratories SNAS provided allowed three-year transitory period for the implementation of this reviewed standard since it was issued. This way the termination of the transitory period is set to **31.12.2025**.

Commission implementing decision (EU) 2024/581 of 16 February 2024, published on February 20, 2024, on the harmonized standard for accreditation of medical laboratories drafted in support of Regulation (EC) No. 765/2008 of the European Parliament and of the Council, the transition period was shortened to **20 August 2025**.

Article 1 of the aforementioned decision refers to the harmonization of standard EN ISO 15189: 2022 as amended by standard EN ISO 15189: 2022/A11: 2023 Medical laboratories. Quality and competence requirements (ISO 15189: 2022) starting from the date of publication of the above decision.

In Article 2, information is also published about withdraw of the harmonized standard EN ISO 15189: 2012 Medical laboratories- Requirements for quality and competence from the Official Journal of the European Union as from 20 August 2025

Until this deadline all accredited ML shall meet the requirements of the standard ISO 15189: 2022 and requirements of the standard ISO 15189: 2022 as amended by standard EN ISO 15189: 2022/A11: 2023. This will be checked up by SNAS whether during the planned or unplanned assessments and in the case, they are met, it will award the accreditation with the reference to the fulfilment of the new version of this standard. In the case of the change by ILAC of the deadline for the transitory period, SNAS reserves the right to modify the deadlines set by this policy.

2 ASSESSMENT PROCEDURE AND DEADLINES

SNAS will accept the applications for accreditation, reaccreditation and extension according to the standard ISO/IEC 15189: 2012 **until 30.09.2023, at the latest**. (From 01.10.2023, SNAS only accepts applications for accreditation, reaccreditation and extension according to ISO 15189: 2022).

SNAS will accept the applications for accreditation, reaccreditation and extension from ML according to the standard ISO 15189:2022 **since 01.09.2023, at the earliest**.

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At the latest by 31.12.2023 the accredited ML meeting the requirements of the standard ISO/IEC 15189: 2012 shall notify SNAS in writing whether they have realized in their management system the requirements of the standard ISO 15189: 2022 or within what date they will realize them; however, such deadline **must not be later than 31.12.2024**. During the assessment planned, SNAS will verify the meeting of the requirements of the standard. ML can apply for the assessment of meeting of the ISO 15189: 2022 requirements also out of the planned assessments, what SNAS will realize in the form of extraordinary assessment. All on-site assessments for the purpose of examination of the meeting of requirements will be carried out **by 20.05.2025, at the latest**.

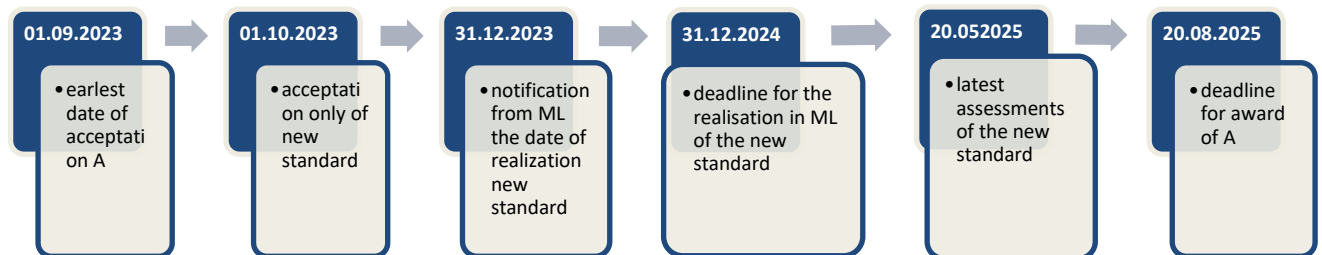
ML accredited according to the standard ISO/IEC 15189:2012 shall demonstrate the meeting of all requirements of the standard ISO 15189:2022 **by 20.07.2025** and SNAS **by 20.08.2025 at the latest** will award the ML the accreditation along with the decision and certificate of accreditation in which the reference will be made to the meeting of the requirements of the standard ISO 15189: 2022 (the accreditation validity period will remain unchanged).

A sufficiently long time period is given for the implementation of the requirements of the updated version of ISO 15189: 2022. The nonconformities shall be resolved within the time, specified in the MSA-04

ISO/IEC 15189: 2012



ISO 15189: 2022



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3 RELATED DOCUMENTATIONS

- ISO 15189: 2022 Medical laboratories – Requirements for quality and competence
- ISO/IEC 17011 Conformity assessment – Requirements for accreditation bodies
accrediting conformity assessment bodies
- MSA-04 Accreditation procedure
- ADOPTED RESOLUTIONS OF THE TWENTY-SIXTH ILAC GENERAL ASSEMBLY VIRTUAL
MEETING, 15 November 2022
- Commission implementing decision (EU) 2024/581

4 ANNEXES

- Annex 1 Plan of the implementation of the Standard ISO 15189: 2022 in the practice of
assessments carried out by SNAS in the laboratories.

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ANNEX 1

**PLAN OF THE IMPLEMENTATION OF THE STANDARD ISO/IEC IN THE PRACTICE OF ASSESSMENTS
CARRIED OUT BY SNAS IN THE LABORATORIES.**

Ord. No	Phase	Deadline
1	Analysis of the requirements of the Standard ISO 15189: 2022	January, February 2023
2	Discussion within SNAS on the interpretation of the requirements of the standard ISO 15189: 2022	February 2023
3	Harmonised Standard	EK
4	Information in HAV about the implementation of the requirements of the standard ISO 15189: 2022	April 2023
5	EA training in relation to the requirements of the standard ISO 15189: 2022	June 2023 (deadline set by EA)
6	Setting up of the working group for the implementation in the practice of SNAS of ISO 15189: 2022 SNAS; Training for the employees of SNAS	July, August 2023
7	Updating of SNAS documentation including the check list for the assessment of the meeting of the requirements of ISO 15189: 2022	August – November 2023
8	Advanced training for VP and P of SNAS aimed at the interpretation of the requisites of ISO 15189: 2022 and of the updated SNAS documentation, informing of VP and P about the training outputs (in the case of necessity)	September – October 2023 – 2 trainings
9	Information in HAV about the provision of services according to the requisites of the standard ISO 15189: 2022	September, October 2023
10	Informative seminar for the laboratories accredited by SNAS	September 2023
11	Beginning of acceptance of applications for the accreditation according to the standard ISO 15189: 2022	October 2023

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