**PL SM 4.6.2-12-2023**

**POLICY**

**ON TRANSITION TO ISO 15189:2022**

**MEDICAL LABORATORIES.**

**REQUIREMENTS FOR QUALITY AND COMPETENCE.**

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| Developed by | Accreditation Department No. 1 |
| Responsible for revision | Accreditation Department No. 1 |
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*This document defines the policy of the Republican Unitary Enterprise “The Belarusian State Centre for Accreditation” (hereinafter referred to as BSCA, the accreditation body) which aims at introduction as a criterion for accreditation of medical laboratories of a new version of* *ISO 15189:2022 Medical laboratories*  *— Requirements for quality and competence, published on 06.12.2022.*

**1** This policy is developed in pursuance of the Resolution of the General Assembly of the International Laboratory Accreditation Cooperation dated August 26, 2022, which established a 3-year transition period to the new version of ISO 15189:2022 *Medical laboratories* **—** Requirements for quality and competence(**until 06.12.2025**).

**2** During the transition period, accreditation certificates according to versions of standards STB ISO 15189-2015 (ISO 15189:2012, IDT) and the new version of STB ISO 15189 (ISO 15189:2022, IDT) have the same legal force.

**3** The policy applies to BSCA, accredited medical laboratories and applicants for accreditation.

**4** To implement ISO 15189:2022, BSCA, guided by PL SM 4.6.2 *Policy on transition to new standard or new version of the standard*, establishes the procedure for the accreditation body, applicants for accreditation and accredited CABs for the transition to a new version of the standard, which includes , but not limited to the following:

**4.1 Procedure of the State Enterprise BSCA:**

**Since 2023 year:**

– conducts a comparative analysis of the previous and new versions of the standard;

– analyzes the provision of resources necessary for the preparation and implementation of competence assessments, plans to conduct assessments according to the new version of the standard;

– conducts training for assessors, technical assessors, trainings for employees of accredited CABs and applicants for accreditation on new accreditation requirements for medical laboratories;

– informs interested parties about the implementation of new accreditation criteria for medical laboratories established by PL SM 4.6.1 Policy on scope of BSCA activity and accreditation schemes;

– initiates the development and develops methodological materials on new accreditation requirements for applicants for accreditation and accredited CABs (handouts for trainings, form for assessing the readiness of laboratories for the transition to STB ISO 15189 (ISO 15189:2022, IDT), hereinafter referred to as “form for self-assessment" (Annex to the Policy).

**Since 2024 year:**

– initiates the development and adoption in the Republic of Belarus in 2024 of STB ISO 15189, identical to ISO 15189:2022;

– before the official entry into force of STB ISO 15189, identical to ISO 15189:2022, at the request of accredited CABs and applicants for accreditation conducts an assessment of compliance with the requirements of ISO 15189:2022.

An accreditation certificate for compliance with the requirements of the new version of the state standard will be issued after the official publication in the Republic of Belarus of the state standard STB ISO 15189, identical to ISO 15189:2022.

**Since 2025 year:**

– carries out work to assess the competence of applicants for accreditation for the purpose of accreditation, assess the competence of accredited CABs for the purpose of reaccreditation, extending the scope of accreditation, periodical assessment of competence for compliance with the requirements of STB ISO 15189 (ISO 15189:2022);

– carries out work on requests from accredited CABs with the type of work “Transition to a new version of the basic standard” whose planned work (reaccreditation, periodic assessment of competence) falls on 2026-2029;

– cancels accreditation certificates valid from 07.12.2025 to 31.12.2029, in case of evasion of accredited CABs from undergoing assessment of competence for the purpose of reaccreditation, periodic assessment of competence for compliance with the requirements of STB ISO 15189 (ISO 15189:2022) and filing an application for accreditation indicating the type of work “Transition to a new version of the basic standard.”

**4.2 The procedure for an accredited CAB for transition to a new version of the standard:**

– acquires the official version of STB ISO 15189 (ISO 15189:2022), after its publication and adoption in the Republic of Belarus;

– develops a Transition Plan to a new version of the basic standard;

– conducts self-assessment of the laboratory management system for compliance with its requirements established in STB ISO 15189 (ISO 15189:2022) (self-assessment form in the Annex);

– conducts an analysis of the competence of laboratory personnel for compliance with the requirements of STB ISO 15189 (ISO 15189:2022);

– conducts external training of laboratory personnel regarding the requirements of STB ISO 15189 (ISO 15189:2022);

– trains laboratory personnel regarding the requirements of STB ISO 15189 (ISO 15189:2022);

– informs customers about changes in new accreditation requirements;

– submits an application to carry out assessment of competence for the purpose of reaccreditation (period from 01.01.2025 to 06.07.2025), extending the scope of accreditation with an additional indication in the application form of the type of work “Transition to a new version of the basic standard”;

– provides with an application for assessment of competence for the purpose of reaccreditation, extending the scope of accreditation, a completed self-assessment form, a set of management system documents with changes, a plan for transition to a new version of the basic standard;

– provides, for carrying out planned work on periodic assessment of competence during the transition period, but no later than **06.10.2025**, in addition to the Technical Competence Certificate, an application for accreditation indicating the type of work “Transition to a new version of the basic standard”, a set of management system documents with changes, an action plan for transition to a new version of the basic standard and a completed self-assessment form;

– accredited CABs whose reaccreditation or periodic assessment of competence falls on the period from 07.12.2025 to 31.12.2029; they did not plan other accreditation work during the transition period (until 07.12.2025), as soon as they were ready, but no later than **06.09.2025**, must submit an application for accreditation indicating the type of work “Transition to a new version of the basic standard” with a set of management system documents with changes, an action plan for the transition to a new version of the standard and a completed self-assessment form.

**4.3 Procedure for applicants for accreditation:**

– apply STB ISO 15189 (ISO 15189:2022) as an accreditation criterion after its publication and adoption in the Republic of Belarus;

– when submitting an application for accreditation during the transition period before the adoption of STB ISO 15189 (ISO 15189:2022) in the Republic of Belarus as an accreditation criterion, applicants for accreditation must apply STB ISO 15189-2015 (ISO 15189:2012, IDT);

– laboratories that have confirmed their competence to comply with the requirements of STB ISO 15189-2015 (ISO 15189:2012, IDT) during the transition period, must fulfil the requirements of this Policy (clause 4.2) and, within the established time frame, no later than **06.09.2025**, make the transition to STB ISO 15189 (ISO 15189:2022).

**5** When implementing the requirements of this Policy, laboratories are recommended, before the publication and adoption of STB ISO 15189 (ISO 15189:2022) in the Republic of Belarus, to use the original edition and official translation of ISO 15189:2022, materials prepared by ISO and BSCA.

**6** Amendments to the accreditation certificate when confirming the competence of the accredited CABs according to STB ISO 15189 (ISO 15189:2022) will be carried out (until the expiration of their validity period) without changing the validity period and number of the accreditation certificate.

**7** From **07.12.2025**, accreditation certificates for compliance with the requirements of STB ISO 15189-2015 (ISO 15189:2012, IDT) are considered invalid.