

BSCA POLICY FOR TRANSITION TO ISO/IEC 17025:2017

The document defines the Policy of the Republican Unitary Enterprise "Belarusian State Center for Accreditation" (hereinafter - BSCA), aimed at introducing a new version of ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories", published on 30/11/2017, as a criterion for accreditation of testing and calibration laboratories.

1. The policy was developed pursuant to Resolution No.15 of the General Assembly of the International Laboratory Accreditation Cooperation (ILAC) of 2016, which established a 3-year transition period to ISO/IEC 17025:2017 (until 30.11.2020).

2. During the transition period, accreditation certificates for versions of the STB ISO/IEC 17025-2007 standards and GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) are equally valid.

3. The policy applies to the BSCA, accredited testing and calibration laboratories and applicants for accreditation (hereinafter - the applicants for accreditation).

4. For the successful implementation of ISO/IEC 17025:2017, BSCA, guided by PL SM 8.2.4-2013 "Policy on the transition to new standards and new versions of standards", establishes the procedure for the accreditation body, applicants for accreditation and accredited CABs to transfer to a new version of the standard, including but not limited to the following:

4.1 The procedure for the State Enterprise "BSCA":

From 2018:

- initiates the development and adoption in the Republic of Belarus of an interstate standard identical to ISO/IEC 17025:2017;
- analyzes the availability of resources necessary for the preparation and implementation of assessments, plans to conduct assessments according to the new version of the standard;
- provides training for assessors, technical experts, trainings for employees of accredited CABs and applicants for accreditation on the new requirements in the field of accreditation of testing and calibration laboratories;
- informs stakeholders about the implementation of new accreditation criteria for testing and calibration laboratories established by PL SM 4.6.1 "Policy regarding the scope of the BSCA activity and accreditation criteria";
- initiates the development and independently develops methodological materials on new accreditation requirements for applicants for accreditation and accredited CABs (handouts for training, a form for assessing the willingness of laboratories to transfer to GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017,

IDT), hereinafter referred to as “self-assessment form” in the Appendix to the Policy);

From 2019:

– conducts work on the assessment of competence for the purpose of accreditation, planned work on the assessment of competence for the purpose of re-accreditation and surveillance, extending accreditation for compliance with the requirements of STB ISO/IEC 17025-2007;

– prior to the official entry into force of GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT), at the request of the accredited CAB or applicant for accreditation, assesses compliance with the requirements of ISO/IEC 17025:2017. (In this case, the accreditation certificate according to GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) will be issued after the official publication in the Republic of Belarus of GOST ISO/IEC 17025-2019 (ISO / IEC 17025:2017, IDT);

– conducts work on the assessment of competency for the purpose of re-accreditation, surveillance, extending of accreditation for compliance with the requirements of GOST ISO/ IEC 17025-2019 (ISO/IEC 17025: 2017, IDT) from the date of publication of the official version of GOST ISO/IEC 17025-2019 (ISO / IEC 17025: 2017, IDT);

– does not accept applications for accreditation for compliance with the requirements of STB ISO/IEC 17025-2007 from the date of publication of the official version of the interstate standard GOST ISO/IEC 17025-2019 (ISO/IEC 17025: 2017. IDT).

From 2020:

– carries out work at the request of accredited CABs with the type of work "Transition to a new version of the fundamental standard" whose planned work (re-accreditation and surveillance) falls on 2021-2024;

– cancels the accreditation certificates valid for the period 01.12.2020-31.12.2024, in case of accredited CABs evading the assessment of competency for the purpose of re-accreditation and surveillance in accordance with GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) and applying for accreditation indicating the type of work "Transition to a new version of the fundamental standard."

4.2 The procedure for the accredited CAB to transfer to a new version of the standard:

– acquires the official version of GOST ISO/IEC 17025-2019 (ISO/IEC 17025: 2017, IDT), after its publication and adoption in the Republic of Belarus;

– develops a Plan for the transition to a new version of the fundamental standard;

- conducts a self-assessment of the laboratory management system for compliance with criteria established in GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) (Self-assessment form in the Appendix);
- conducts an analysis of the conformity of the competence of laboratory personnel to perform work in accordance with the requirements of GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT);
- conducts external training for laboratory personnel on the requirements of GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT);
- teaches laboratory personnel the requirements of GOST ISO/IEC 17025-2019 (ISO / IEC 17025:2017, IDT);
- informs customers about changes in new requirements;
- liaises with the accreditation body on the implementation of the transition plan and compliance with the established transition dates;
- submits an application for conducting work on competency assessment for the purpose of re-accreditation (the period from 01/01/2019 to 25/07/2020), extending of accreditation and updating the accreditation scope with an additional indication of the type of work “Transition to a new version of the fundamental standard”;
- provides a completed self-assessment form, a set of documents for the management system with amendments, a plan for the transition to a new version of the fundamental standard with an application for conducting work on competency assessment with a view to re-accrediting, extending of accreditation and updating the area of accreditation;
- provides an application for accreditation with an indication of the type of work “Transition to a new version of a fundamental standard”, a set of management system documents with a passport for carrying out planned work on surveillance during the transition period, but no later than September 30, 2020, in addition to changes, the Plan of measures for the transition to a new version of the fundamental standard and the completed self-assessment form;
- accredited CABs whose re-accreditation or surveillance falls on the period from 01/12/2020-31/12/2024, and they did not plan other accreditation activities during the transition period (until 30/11/2020), as they are ready, but not later than September 25, 2020, must submit an application for accreditation with an indication of the type of work “Transition to a new version of a fundamental standard” with a set of management system documents with amendments, an Action Plan for the transition to a new version of the standard and filled form for self-assessment.

4.3 Procedure for applicants for accreditation:

- as an accreditation criterion apply the interstate standard GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) after its publication and adoption in the Republic of Belarus;
- when applying for accreditation during the transition period before the adoption in the Republic of Belarus of GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT), applicants for accreditation should use STB ISO/IEC 17025-2007 as a criterion for accreditation;
- laboratories that have confirmed their competence in the transition period for compliance with the requirements of STB ISO/IEC 17025-2007, must comply with the requirements of this Policy (clause 4.2) and, by the deadlines, no later than September 25, 2020, make the transition to GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT).

5. When implementing the requirements of this Policy, laboratories are advised to use the original edition and the official translation of ISO/IEC 17025:2017, materials prepared before publication and adoption in the Republic of Belarus of GOST ISO/IEC 17025-2019 (ISO/IEC 17025:2017, IDT) by ISO and BSCA.

6. Amendments to the accreditation certificate (administrative procedure) when confirming the competence of an accredited entity in accordance with GOST ISO / IEC 17025-2019 (ISO / IEC 17025: 2017, IDT) will be carried out (before the expiration date) without changing the validity and number of the accreditation certificate.

7. From December 1, 2020, accreditation certificates for compliance with STB ISO / IEC 17025-2007 are considered invalid.

**Form “Results of assessing the readiness of the laboratory for the transition to GOST ISO/IEC 17025-2019”
(instructions for filling)**

In the form “Results of assessing the readiness of the laboratory for the transition to GOST ISO/IEC 17025-2019”, the provisions of GOST ISO/IEC 17025-2019 are defined and the degree of change in the requirements of STB ISO/IEC 17025-2007 is presented. Detailed information on the actual changes in STB ISO/IEC 17025-2007 is not given, only the degree of change is given * and therefore the laboratory must use this form in combination with GOST ISO/IEC 17025-2019 and STB ISO/IEC 17025-2007.

The laboratory is responsible for the complete identification of changes between the standards, determining the degree of their impact on the management system and technical activities and making the necessary changes. Detailed information on the changes should be indicated in this form and submitted to the State Enterprise “BSCA” (in the form of a document in Word format) at least 2 months before the State Enterprise “BSCA” assesses the laboratory’s transition to the new version of the standard. The form is sent with documents / documented procedures * demonstrating the fulfillment of new or changed requirements. The implementation result is verified by the assessment team. If the laboratory believes that at present it meets new or changed requirements and does not need to be amended, it should reflect this in this form. The information provided to the State Enterprise “BSCA” should include not only a link to the document/documentated procedure, but also should contain explanations as to what has been changed and what actions have been taken by the laboratory (see the example).

For experts on accreditation of the State Enterprise "BSCA":

After reviewing the information (documents / documented procedures) provided by the laboratory and completing the assessment in order to confirm the implementation of the requirements of GOST ISO/IEC 17025-2019, assessors should reflect the fulfillment of the requirements of GOST ISO/IEC 17025-2019 in this form, thus generating a report on the transition from STB ISO/IEC 17025-2007 to GOST ISO/IEC 17025-2019. If any conclusions were made regarding new or amended requirements, they should be indicated in the final competency assessment report and cross-referenced in this form. Conclusions and recommendations on the transition to accreditation in accordance with GOST ISO / IEC 17025-2019 should be given at the end of this form.

Notes:

***The degree of changes:**

- Structural - the requirement remains unchanged, but with a new number
- Minor - the wording of the requirement has changed, but overall the requirements have the same meaning
- Major - changes will require the laboratory to introduce new or change existing practices
- New requirement – there were no such requirements/provisions in the previous version of the standard

** Standard GOST ISO/IEC 17025:2019 (ISO/IEC 17025:2017, IDT) does not contain mandatory requirements for the development of a Laboratory Quality Manual. Accreditation Rules, approved by the Resolution of the State Committee for Standardization of the Republic of Belarus

dated May 31, 2011 No. 27 (as amended by Gosstandart dated June 19, 2017 No. 49) also did not oblige laboratories to have a Quality Manual as the main document of the management system. Therefore, BSCA does not establish mandatory requirements for the presence in the laboratory of the document SM - Quality Manual.

An example of designing an assessment of the readiness of a laboratory for transferring to GOST ISO/IEC 17025-2019

COMPLETED BY A CALIBRATION/TESTING LABORATORY	
Full name of the legal entity:	Limited Liability Company “Rhythm”
Full name of the branch of the legal entity (if any):	-
Full name of the laboratory:	Testing laboratory
Accreditation Certificate Number:	BY/112 X.XXXX
Position, Full Name of laboratory personnel responsible for filling out the form:	Sergeenko Irina Vasilievna
Date of completion:	18.12.2018

COMPLETED BY ASSESSORS OF THE STATE ENTERPRISE “BSCA”	
FULL NAME of an assessor(s):	
Date of the review:	

GOST ISO / IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor
clause	clause	clause	clause		Changes made	Documents submitted	Fulfillment of the requirement, reference to the findings
6.	Resource requirements	-	-	-	No changes required		No changes required
6.2.3	Personnel	5.2.1	Personnel	Structural	The policy and procedure describing the increased requirement for evidence of	- Provisions on the testing laboratory dated 01.06.2018 No. 3/98 (case 24-	<i>Fulfillment of the requirement:</i>

GOST ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause	clause	Changes made	Documents submitted		Fulfillment of the requirement, reference to the findings			
					personnel competency required a change to the SM documents. In fact, personnel will have to	2018) - Job descriptions, approved by the Director of the enterprise. (Case OK 21-2018) - STP 6.2-2017 "Personnel Management"	Yes	No
							Reference to the finding	
							NC	Concern
6.2.5	Personnel	5.2.5	Personnel	Structural	<p>demonstrate competence in the conduct of internal laboratory control (analysis of samples with known values, etc.), monitoring the testing as a part of an internal audit conducted by a competent employee.</p> <p>All employees were familiarized with the changes (see the sheet of familiarization XYZ-001 attached).</p> <p>Passport of the laboratory (case 12-99), table 6</p>	<p>- Organizational and administrative documents (case 2-33)</p> <p>Training Programs for Interns (Case 3-12)</p> <p>Minutes of Attestation for 2018, (case OK 22-2017).</p> <p>Personnel Registration Journal (Case 11-19),</p> <p>02.RK IL.3.05-2017 p.5.2.2 sheet of familiarization XYZ-001</p>	Fulfillment of the requirement:	
							Yes	No
							Reference to the finding	
							NC	Concern

					Keeping records on the selection and training of personnel, monitoring their activities and authorizing and monitoring of competence were fully implemented; only structural changes were required with regard to the numbering of the QM. All employees were familiarized with the changes (see sheet of familiarization XYZ-001)	for those involved (case 13-15) Provisions on the testing laboratory dated 01.06.2018 No. 3/98 (case 24-2018) - STP 4.2.4-2018							
GOST ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor						
clause		clause			Changes made	Documents submitted	Fulfillment of the requirement, reference to the findings						
6.3.1	Facilities and environmental conditions	5.3.1	Production and environmental conditions	Structural	The requirements for the facilities and environmental conditions necessary for the implementation of laboratory activities were properly documented earlier, the procedure required structural changes in terms of the numbering of points of the	- 01.RK IL.3.05-2018 p. 6.3.3 - IL passport, table 7 Instructions for the validation of industrial facilities IV 01-2018 - Report on the validation of industrial facilities from 22/04/2018	<p><i>Fulfillment of the requirement:</i></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td></td> <td></td> </tr> </table> <p><i>Reference to the finding</i></p> <table border="1"> <tr> <td>NC</td> <td>Concern</td> </tr> </table>	Yes	No			NC	Concern
Yes	No												
NC	Concern												

					<p>QM. Additionally, instructions have been developed for the validation of rooms in which the emission of harmful substances is possible. Validation of the facilities of the laboratory of chemical toxicological tests.</p> <p>All employees were familiarized with the changes (see fact sheet XYZ-001)</p>	<p>-Cause IL 25-2017 “Test reports of harmful production factors”</p>		
--	--	--	--	--	---	---	--	--

The results of the assessment of the readiness of the laboratory for the transition to GOST ISO/IEC 17025-2019

GOST ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made	Documents submitted	Fulfillment of the requirements, reference to the findings	
	Foreword		Foreword	New	Does not contain mandatory requirements, but should be reviewed by the laboratory when reviewing the management system.			
	Introduction		Introduction	New				
1.	Scope	1.	Scope	Minor				
2.	Normative references	2.	Normative references	Minor				
3.	Terms and definitions	3.	Terms and definitions	New				
4.	General requirements	4.	-	-	No changes required		No changes required	
4.1	Impartiality	4.1	Management requirements	Major			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
4.2	Confidentiality	4.1	Management requirements	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
5.	Structural requirements	4.1	Organizational structure	Major			Fulfillment of the requirement:	
							Yes	No

						<i>Reference to the finding:</i>		
						NC	Concern	
GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
6.	Resource requirements	-	-	-	No changes required		No changes required	
6.1	General requirements	4.1	Organizational structure	Minor			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
6.2	Personnel	5.2	Personnel	Structural			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
6.3	Laboratory facilities and environmental conditions	5.3	Production and environmental conditions	Structural			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
6.4	Equipment	5.5	Equipment	Minor			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern

GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
6.5	Metrological traceability	5.6	Measurement traceability	Structural			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
6.6	Externally provided products and services	4.6	Purchasing services and supplies	Minor			Fulfillment of the requirement:	
							Yes	No
							NC	Concern
7.	Process requirements	-	-	-	No changes required		No changes required	
7.1.	Review of requests, tenders and contracts	5.10 4.4	Reporting of Results Review of requests, tenders and contracts	Major			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
7.2.	Selection, verification and validation of methods	5.4	Test and calibration methods and method validation	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
7.3.	Sampling	5.7	Sampling	Minor			Fulfillment of the requirement:	
							Yes	No

GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
7.4.	Handling of test or calibration items	5.8	Handling of tests and calibration items	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
7.5.	Technical records	4.13	Control of records	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
7.6.	Evaluation of measurement uncertainty	5.4	Test and calibration methods and method validation	Structural			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
7.7.	Ensuring the validity of results	5.9	Assuring the quality of test and calibration results	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern

7.8.	Reporting of results	5.10	Reporting the results	Major			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
7.9.	Complaints	4.8	Complaints	Major			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
7.10.	Nonconforming work	4.9	Control of nonconforming testing and/or calibration work	Minor			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
7.11.	Control of data and information management	5.4	Test and calibration methods and method validation	Minor			<i>Fulfillment of the requirement:</i>	
							Yes	No
							<i>Reference to the findings:</i>	
							NC	Concern
8.	Management system requirements	4.0	Management requirements	-	No changes required		No changes required	

8.1.	Options	-	-	New			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.2.	Management system documentation (Option A)	4.2	Management system	Structural			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
8.3.	Control of management system documents (Option A)	4.3	Document control	Structural			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.4.	Control of records (Option A)	4.13	Control of records	Structural			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.5.	Actions to address risks and opportunities (Option A)	4.10 4.2 4.1	Improvements Management system Organizational structure	New			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern

GOCT ISO/IEC 17025-2019		STB ISO/IEC 17025-2007		Degree of change	To be completed by a laboratory		To be completed by an assessor	
clause		clause			Changes made and documents submitted		Fulfillment of the requirements, reference to the findings	
8.6.	Improvement (Option A)	4.10 4.7	Improvement Service to the customer	Minor			Reference to the findings:	
							NC	Concern
							Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.7.	Corrective actions (Option A)	4.11	Corrective actions	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.8.	Internal audits (Option A)	4.14	Internal audits	Minor			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern
8.9.	Management review (Option A)	4.15 4.2	Management review Management system	Major			Fulfillment of the requirement:	
							Yes	No
							Reference to the findings:	
							NC	Concern

Annex A	Metrological traceability	-	-	New	Does not contain mandatory requirements, but should be reviewed by the laboratory when reviewing the management system
Annex B	Management system options	-	-	New	
Bibliography	-	-	Bibliography	Structural	

Conclusions: