REPUBLICAN UNITARY ENTERPRISE
"BELARUSIAN STATE CENTRE FOR ACCREDITATION"

RI SM 7.8-02-2014

SCOPE OF ACCREDITATION. REQUIREMENTS TO DESCRIPTION. INTRODUCTION OF CHANGES TO SCOPE OF ACCREDITATION

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1 SCOPE

1.1 This work instruction is a management system document of Republican Unitary Enterprise "Belarusian State Centre for Accreditation" (hereinafter – BSCA) developed to further clause 7.8 of BSCA Quality Manual, DP SM 7 with account of clause 7.8 of GOST ISO/IEC 17011 and lays down requirements to the contents, description, issue, storage, changing, withdrawal of scope of accreditation.

1.2 The instruction shall be applied by BSCA personnel involved in accreditation process.

2 REFERENCES

This instruction references the following documents:

Resolution of the State Committee on Standardization of May 31, 2011 No. 27 “On Approval of Accreditation Rules” (hereinafter referred to as the Accreditation Rules);

TP 2007/003/BY Measurement units approved for application in the Republic of Belarus;

STB ISO 9000 (ISO 9000, IDT) Quality management systems. Fundamentals and vocabulary;

STB ISO 15189 (ISO 15189, IDT) Medical laboratories. Requirements for quality and competence

GOST ISO/IEC 17021-1 (ISO/IEC 17021-1, IDT) Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements;

STB ISO/IEC 17025 (ISO/IEC 17025, IDT) General requirements for the competence of testing and calibration laboratories;

GOST ISO/IEC 17000 (ISO/IEC 17000, IDT) Conformity assessment. Vocabulary and general principles;

GOST ISO/IEC 17011 (ISO/IEC 17011, IDT) Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies;

GOST ISO/IEC 17020 (ISO/IEC 17020, IDT) Conformity assessment. Requirements for the operation of various types of bodies performing inspection;

GOST ISO/IEC 17024 (ISO/IEC 17024, IDT) Conformity assessment. General requirements for bodies operating certification of persons;

GOST ISO/IEC 17025 (ISO/IEC 17025, IDT) General requirements for the competence of testing and calibration laboratories;

GOST ISO/IEC 17043 (ISO/IEC 17043, IDT) Conformity assessment. General requirements for proficiency testing;

GOST ISO/IEC 17065 (ISO/IEC 17065, IDT) Conformity assessment. Requirements for bodies certifying products, processes and services;

RK SM BSCA Quality Manual;

DP SM 4.3 Rules for application accreditation symbol, combined ILAC MRA and IAF MLA mark, text reference to accreditation and signatory status of EA BLA, ILAC MRA, IAF MLA

DP SM 7 Accreditation process;

DP SM 7.6 Assessment;

DP SM 7.7-01 Preparation of materials to consideration at the meeting of Technical commission for accreditation

RI SM 7-05 Classifier of the scope of activity in the field of conformity assessment (laboratories/inspection bodies);

RI SM 7-07-2017 Classifier of scope of activities in the field of conformity assessment (certification bodies);

RI SM 7.4 Management of contracts;

RI SM 7.8-01 Accreditation certificate. Requirements to contents and design. Introduction of changes to the accreditation certificate;

RI SM 9.3-01 Management of records and organizational and administrative documentation;

ILAC G18:04 Guideline for the Formulation of Scopes of Accreditation for Laboratories;

EA-4/17 M EA position paper on the description of scopes of accreditation of medical laboratories;

IAF ID 1 IAF Informative document for QMS and EMS scopes of accreditation.

IAF/ILAC-A5/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):Application of ISO/IEC 17011:2004

Note: When using this procedure the current versions of the referenced documents shall be used. If the reference documents are replaced (modified), then the modified documents should be used. If reference documents are cancelled without replacement, the provisions of the procedure in which references are given to them are applied in the part that does not affect these references.

3 TERMS AND DEFINITIONS

Terms and definitions used in this procedure are those of STB ISO 9000, GOST ISO/IEC 17000, GOST ISO/IEC 17011.

4 DENOTATIONS AND ABBREVIATIONS

Denotations and abbreviations used in this Provision are as follows:

NPA	– normative legal act
OORA	– Department of accreditation activity management
CAB	– conformity assessment body
Register	– Register of the National accreditation system of the Republic of Belarus
TKA	– Technical Accreditation Commission
TKP	– Technical code of good practice
TNPA	– Technical normative legal act in the field of technical regulation and standardization
IDT	– indication of the level of identity with the international standard (identity in technical content and structure)

5 RESPONSIBILITY

5.1 Responsibilities of personnel for the activity described in this instruction are reflected in Annex 1.

6 GENERAL

6.1 Grounds for issuing scope of accreditation

6.1.1 Scope of accreditation of an accredited CAB is prepared by lead assessor in the form of an Annex to the certificate of accreditation, taking into account the requirements of clause 7.8.3 of GOST ISO/IEC 17011, based on the claimed scope of accreditation submitted by the applicant/accredited body, and with account of the results of document review and assessment.

6.1.2 BSCA issues scope of accreditation to accredited body after a positive decision of Technical Commission for Accreditation (hereinafter - TKA) on confirmation of competence and accreditation, extending of accreditation, reaccreditation, actualization of scope of accreditation, introduction of changes to the certificate of accreditation.

6.2 Requirements to description of scope of accreditation of an accredited body

6.2.1 Scope of accreditation of an accredited CAB is executed using a personal computer on A4 white paper on one side vertically according to the form given in Annex 4 to the Accreditation Rules.

To draw up scope of accreditation a template is used in electronic form placed at BSCA website www.bsca.by.

6.2.2 Scope of accreditation includes:

6.2.2.1 the first sheet where the following details are indicated:

- ✓ Annex to certificate of accreditation, or annexes to certificate of accreditation with assigned number;
- ✓ registration number of the certificate of accreditation of an accredited body according to the Register of the National Accreditation System of the Republic of Belarus (hereinafter - the Register);
- ✓ the date of registration of the certificate of accreditation, corresponding to the date the information was entered in the Register;
- ✓ form number of the certificate of accreditation;
- ✓ total number of sheets of the scope of accreditation;
- ✓ issue number (indicated at reissue of the accreditation scope during the accreditation cycle);
- ✓ the heading "SCOPE OF ACCREDITATION" or "SUPPLEMENT TO SCOPE OF ACCREDITATION";
- ✓ date of issue of the scope of accreditation, which corresponds to:
  - the date the information was entered in the Register (in case of accreditation);
  - date of the new term of the validity of certificate of accreditation, adopted in accordance with TCA decision on re-accreditation (in case of reaccreditation);
  - when making changes to the certificate of accreditation (for example, in connection with actualization, extending of accreditation, reducing of accreditation) - the date the information was entered in the Register;
- ✓ full name of accredited body;
- ✓ full name of the legal entity, if the accredited body is its unit;
- ✓ codes for each type of accredited body in accordance with RI SM 7-05, RI SM 7-07;
- ✓ information about the place of activity of the accredited body and, if applicable, conformity assessment activities carried out at each place of activity covered by the accreditation scope.

  This information is placed under the accreditation scope table in the form of a notice according to the following options for carrying out activities:
  - Laboratory activities are carried out directly in the laboratory;
  - Laboratory activities are carried out directly in and outside the laboratory;
  - Laboratory activities are carried out outside the laboratory.

6.2.2.2 Subsequent sheets of scope of accreditation are issued in the form of a table in which only the column numbers of the table are indicated. When transferring the scope of accreditation data to the next sheet, all the scope of accreditation columns shall be filled out.

6.2.3 All accreditation scope sheets have headers and footers.

On the first sheet, the header includes BSCA logo and the heading "National Accreditation System of the Republic of Belarus. Republican Unitary Enterprise "Belarusian State Center for Accreditation".

On the following pages of scope of accreditation, the header includes BSCA logo and the heading "Annex No. ___ to certificate of accreditation BY/112 X.XXXX or BY/112 XXX.YY" (for laboratories and certification bodies, respectively). Other information may be indicated here according to clause 6.12 of this procedure.

The footer on all pages includes lead assessor's signature, stamp, decision date (day, month, year), sheet number and total number of sheets.

6.2.4 The scope of accreditation and header text is in the font Times New Roman N 14, the table in the scope of accreditation and footer text is in the font Times New Roman N 11 - 12.

6.2.5 Requirements for the design of tables of scope of accreditation for each type of accredited body are given in this instruction.

6.2.6 Scope of accreditation is prepared in 2 copies. The first copy of scope of accreditation is issued to the accredited body, the second copy is kept at BSCA.

At the written request of the accredited body, the number of copies of scope of accreditation can be increased, the decision in this case is made by the head of the accreditation department.

6.2.7 Signatures on the scope of accreditation are executed in blue.

6.2.8 All accreditation scope sheets are signed by lead assessor and attested by a stamp with the State Enterprise "BSCA" logo. The last sheet of scope of accreditation is signed by BSCA Director or its deputy with indication of the full name and confirmed with a blue round seal "State Enterprise "BSCA", first line: Head of accreditation, second line: body of the Republic of Belarus, third line: director of State, fourth line: enterprise "BSCA". This attribute is placed under the text/table with a distance of not more than one single line spacing.

6.2.9 Corrections in scope of accreditation are not allowed. Changes to the scope of accreditation are made in accordance with section 6.12 of this instruction.

6.2.10 Scope of accreditation on paper is kept in the accredited body file.

6.2.11 Scope of accreditation in electronic form, a file and a brief description of the scope of accreditation is entered by the case officer of OORA into the Register, the entered information is displayed on the BSCA website www.bsca.by.

6.2.12 A brief description of the scope of accreditation contains information on objects and their codes according to RI SM 7-05, RI SM 7-07.

6.2.13 Responsibility and authority on description of scope of accreditation is established in Annex 1 to this instruction.

6.3 Additional requirements to scope of accreditation of a testing laboratory

6.3.1 Scope of accreditation testing laboratory s determined by:

- ✓ the name of test object (nomenclature of products);
- ✓ characteristics of the test object (nomenclature of indicators);
- ✓ object code and type of test;
- ✓ documents laying down:
  - o requirements to test objects;
  - o test methods (techniques) as applied to each defined characteristic (indicator).

6.3.2 The form of scope of accreditation of a testing laboratory is set in Annex 4 of the Accreditation Rules.

6.3.3 The requirements for filling out the scope of accreditation of a testing laboratory table are given in table 1.

Table 1

Column N	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	**2**	**3**
1	Item number	Consecutive numbering of the item/sub-item of the test objects and determined characteristics (indicators) of the test object (product) is indicated. Object of testing and defined characteristic (indicator) are assigned item number/sub-item for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new defined characteristics (indicators) are added to the scope of accreditation, numbering continues within the numbering of this object. When an object is added, it is assigned a new ordinal item number/subitem.
2	Name of object of testing	Full name of the test object (test product) is indicated in full accordance with its name mentioned in the documents laying down the requirements for the test object. If there are different names, the highest level document prevail.
3	Code/Commodity nomenclature of Eurasian Economic Union	The code of the test object/type of test is indicated in accordance with RI SM 7-05 or Commodity nomenclature of Eurasian Economic Union (corresponding to Annex 1 or 2)

Column N	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	2	3
4	Characteristics of object of testing	1 The full name of the parameter(s) of the measured value of the test object (product) is indicated. If necessary (according to the recommendation of the technical committee), indicators of the accuracy of the method (test procedure), measurement error or uncertainty, measurement range with units are indicated. 2 The full name of the parameter of the measured value is indicated in full accordance with its name established in NPA including TNPA which set technical requirements for the product (test object). If the name of the characteristics of the object in NPA, including TNPA laying down the technical requirements for the product (test object) differ from the name of determined parameters according to the test procedure, then the name used in NPA including TNPA, shall be used
5	Indication of NPA, including TNPA laying down the technical requirements for the product (test object)	Index, serial registration digital number, year of approval of the document is indicated. The full name of the document is given only in the absence of an index, serial registration digital number, year of approval of the document. When mentioned the second time the full title of the document may not be given, but a link shall be used to the note placed on the last sheet of scope of accreditation under the table.
6	Indication of NPA, including TNPA laying down requirements to test methods	Index, serial registration digital number, year of approval of the document laying down the methodology/method of testing of the object (product) is indicated. In addition, references to the numbers of sections and paragraphs of the document laying down the methodology/method of testing of the object (product) shall be indicated if the testing laboratory uses only one methodology/one method from among several provided by mentioned documents. The full name of the document is given only in the absence of an index, serial registration digital number, year of approval of the document. The full name of the document may not be repeated in, in this case a link shall be given to the note in the form of an asterisk * and number 1-XX, which is placed on the last sheet of scope of accreditation under the table. When performing tests in the framework of a contract with customers from other states, NPA, including TNPA, which lay down requirements for objects and/or test methods of other states may be indicated after confirmation of competence in accordance with the established procedure. In this case, scope of accreditation provides a link in the form of an asterisk* and number 1-XX to the note placed on the last sheet of scope of accreditation under the table, with the following content: “the use of NPA and TNPA of other countries are used only for performing tests in the framework of a contract with these countries”.

6.3.4 If there is no serial number of the document laying down the test method(s), the scope of accreditation shall indicate the full name of the document, the name of the organization that approved and/or agreed the document, the date of approval and/or agreeing.

6.4 Additional requirements to scope of accreditation of a calibration laboratory

6.4.1 Scope of accreditation of a calibration laboratory is determined by calibration and measuring capabilities (CMC), expressed as:

- ✓ measured value;
- ✓ calibration method(s);
- ✓ calibration object;
- ✓ measuring range;
- ✓ extended measurement uncertainty;
- ✓ code according to RI SM 7-05.

6.4.2 The scope of accreditation of calibration laboratory form is set in Annex 4 of the Accreditation Rules.

6.4.3 The requirements for filling out the scope of accreditation of a calibration laboratory table

are given in table 2.

Table 2

Column N	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	**2**	**3**
1	Item number	Indicated in accordance with the code of the measurement field (for example, the code of the measurement field 26.51/99.013 corresponds to the item 13 of the accreditation scope). The consecutive numbering of the sub-item of the units under calibration and the measurands (indicators) of this unit under calibration is indicated within one code of the measurement field (for example, if there are several units under calibration having the same code of the measurement field, items/sub-items numbers of the accreditation scope are indicated as follows: 13.1, 13.2, 13.3 and etc.). The item number is assigned to the object for the entire accreditation cycle. The item number/subclause are assigned to object and measurands (indicator) for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new measurands (indicators) are added to the scope of accreditation, numbering continues within the numbering of this object. When an object is added, it is assigned a new ordinal item number/subitem.
2	Code of measurement field	Indicated in accordance with RI SM 7-05
3	Name of measurands	The full name of a measurand is indicated
4	Objects of calibration	The name of the calibrated measuring instrument (groups of measuring instruments) is indicated
5	Calibration and measuring capabilities (range/extended uncertainty U (k, P)	The measurement range(s) of the measured quantity or parameter of the measured quantity shall be indicated with the indication of units of quantities in accordance with TR 2007/003/BY. The numerical value of the expanded uncertainty is indicated for a specific measurement range with a probability of coverage of approximately 95%. Units of measurement of uncertainty shall correspond to units of the measured size or be relative to the measured value
6	Indication of documents laying down calibration methods (techniques).	Calibration methods are indicated which are used for calibration of measuring instruments.

6.4.4 The values indicated in columns 5 and 6 of table 2 are determined by the calibration and measuring capabilities of the laboratory.

6.4.5 In the absence of the serial number of the document laying down calibration method(s), the scope of accreditation shall indicate the full name of the document, the name of the organization that approved and agreed the document, the date of approval and agreeing.

6.5 Additional requirements to scope of accreditation of a verification laboratory

6.5.1 Scope of accreditation of a verification laboratory is determined by:

- ✓ nomenclature of measurement instruments for verification (name, type of measurement instrument);
- ✓ metrological characteristics: limits/range of measurements, class, rank, division value, error;
- ✓ code according to RI SM 7-05.

6.5.2 Form of scope of accreditation of a verification laboratory is set in Annex 4 to Accreditation Rules.

6.5.3 Requirements to filling in scope of accreditation of a verification laboratory are provided

in table 3.

Table 3

Column N	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	**2**	**3**
1	Item number	Consecutive numbering of objects of calibration. Object of calibration is assigned an item number for the entire accreditation cycle. Item number/subclause are assigned to object and determined characteristics (indicator) for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new defined characteristics (indicators) are added to the scope of accreditation, numbering continues within the numbering of this object. When an object is added, it is assigned a new ordinal item number/subitem.
2	Code/Title of work type	The code and the type of work are indicated in accordance with clauses 4.4; 4.5 of TKP 8.003-2011: 1 – initial verification; 2 – последующая поверка
3	Code of measurement field	Indicated in accordance with RI SM 7-05
4	Name (type of measuring instrument)	The name, type (if necessary) of measuring instruments (the name of the group of measuring instruments) subject to verification shall be indicated
5	Metrological characteristics limits of measurements, class, category, division value, error	The limits of measurement of the measured value, in which the verification of measuring instruments is allowed, indicating the units of quantities in accordance with TR 2007/003/BY Accuracy characteristics of verified measuring instruments: class, category, division value, error

6.5.4 In absence of serial number of the document laying down the verification method(s), the scope of accreditation shall indicate the full name of the document, the name of the organization that approved and agreed the document, the date of approval and agreeing.

6.6 Additional requirements to scope of accreditation of a medical laboratory

6.6.1 Scope of accreditation of a medical laboratory is determined by:

- ✓ object of examination (body system, biological material);
- ✓ characteristic of examination object (parameter, marker, test);
- ✓ documents laying down examination methods/techniques for each indicator;
- ✓ examination object code/examination type.

6.6.2 Form of scope of accreditation of a medical laboratory is set in Annex 4 of the Accreditation Rules.

6.6.3 Requirements to filling in tables of scope of accreditation of a medical laboratory are set in table 4.

Table 4

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	**2**	**3**
1	Item number	Consecutive numbering of objects of examinations and defined characteristics of this object. Item number/subclause are assigned to object and determined characteristics (indicator) for the entire accreditation cycle.

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	2	3
		When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new defined characteristics (indicators) are added to the scope of accreditation, numbering continues within the numbering of this object. When an object is added, it is assigned a new ordinal item number/subitem.
2	Name of the object of examinations	The name of the object of examinations is indicated (body system, biological material)
3	Indication and/or name of documents laying down requirements for examination methods	Indicate denotation and name of documents laying down requirements for examination methods
4	Characteristics of object of examinations	Indicate characteristics of object of examinations (type, principle of examinations method)
5	Code	The code of the object examinations/type of examinations is indicated in accordance with RI SM 7-05

6.6.4 In absence of serial number of the document laying down the examination method(s), the scope of accreditation shall indicate the full name of the document, the name of the organization that approved and agreed the document, the date of approval and agreeing.

6.7 Additional requirements to scope of accreditation of an inspection body

6.7.1 Scope of accreditation an inspection body is determined by:

- ✓ object of inspection;
- ✓ type of inspection;
- ✓ documents laying down methods (techniques) and inspection procedures;
- ✓ code.

6.7.2 Form of scope of accreditation of an inspection body is set in Annex 4 of the Accreditation Rules.

6.7.3 Requirements to filling in tables of scope of accreditation of an inspection body are set in table 5.

Table 5

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	2	3
1	Item number	Consecutive numbering of objects of inspection shall be used tem number/subclause are assigned to object and determined characteristics (indicator) for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new defined characteristics (indicators) are added to the scope of accreditation, numbering continues within the numbering of this object. When an object is added, it is assigned a new ordinal item number/subitem.
2	Name of the inspection object	Indicate the name of the inspection object

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	2	3
3	Type of inspection	Indicate type of inspection (or its separate part)
4	Indication of NPA, including TNPA laying down requirements for inspection objects/inspection methods and procedures	Indicate denotation and name of methods and procedures of inspection
5	Code/Commodity nomenclature of Eurasian Economic Union	The code of the test object/type of test is indicated in accordance with RI SM 7-05 or Commodity nomenclature of Eurasian Economic Union (corresponding to Annex 1 or 2)

6.7.4 In absence of serial number of the document laying down inspection method(s), the scope of accreditation shall indicate the full name of the document, the name of the organization that approved and agreed the document, the date of approval and agreeing.

6.8 Additional requirements to scope of accreditation of a proficiency testing provider

6.8.1 Scope of accreditation of a proficiency testing provider is determined by:

- ✓ proficiency testing scheme;
- ✓ technical field and proficiency testing object;
- ✓ characteristics of proficiency testing object;
- ✓ code.

6.8.2 Form of scope of accreditation of a proficiency testing provider is set in Annex 4 of the Accreditation Rules.

6.8.3 Requirements to filling in tables of scope of accreditation of a proficiency testing provider are set in table 6.

Table 6

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	Item number	Consecutive numbering of a clause/subclause of the type of proficiency testing program, a sample for the program (products, material), determined parameter (value), and the characteristic shall be used. Number of the item/subclause is assigned to the type of proficiency testing program, a sample for the program (products, material), determined parameter (value), and the characteristic for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another parameter (value) or another characteristic. This item is not displayed in the next edition in the new edition of the current cycle. When new defined characteristics (indicators) are added to the scope of accreditation, numbering continues within the numbering of this programme. When an programme is added to the scope of accreditation, it is assigned a new ordinal item number/subitem.
2	Type of proficiency testing programme	Indicate type of proficiency testing programme
3	Name of the sample of the programme (product, material)	Indicate technical field
4	Determined parameters (values), characteristics	Indicate full name of parameter(s) of the value of the proficiency test item
5	Statistical processing methods	Indicate NPA including TNPA laying down statistical processing methods

6.9 Additional requirements to scope of accreditation of a certification body of products,

services, processes

6.9.1 Scope of accreditation of a certification body of products, services, processes is determined by:

- ✓ object (products, services, work);
- ✓ documents laying down the requirements to object (products, services, work) and the procedure for confirmation of compliance;
- ✓ object code.

6.9.2 Form of scope of accreditation of a certification body of products, services, processes is set in Annex 4 of the Accreditation Rules.

6.9.3 Requirements to filling in tables of scope of accreditation of a certification body of products, services, processes are set in table 7.

Table 7

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	Item number	Consecutive numbering of the item/sub-item of the object (products, services, work) shall be used. Item number/sub-item is assigned to the object for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new objects are added to the scope of accreditation, numbering continues.
2	Name of conformity assessment object	Indicate name of the object (products, services, work)
3	Code of conformity assessment object	Indicate object code according to OKRB 007, OKRB 015
4	Designation of NPA including TNPA laying down requirements for object	Indicate denotation and name of TNPA laying down requirements for object (products, services, work)
5	Designation of NPA including TNPA laying down requirements for procedure of confirmation of compliance	Indicate denotation and name of TNPA laying down requirements for procedure of confirmation of compliance

6.10 Additional requirements to scope of accreditation of a management system certification body

6.10.1 Scope of accreditation a management system certification body is determined by:

- ✓ object of conformity assessment (type of economic activity);
- ✓ documents laying down management system type;
- ✓ object code and EA;
- ✓ TNPA laying down requirements to order of confirmation of compliance.

6.10.2 Form of scope of accreditation of a management system certification body is set in Annex 4 of the Accreditation Rules.

6.10.3 Requirements to filling in tables of scope of a management system certification body are set in table 8.

Table 8

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	Item number	Indicate consecutive numbering of objects (type of economic activity) Item number is assigned to the object for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator,

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
		the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new objects are added to the scope of accreditation, numbering continues.
2	EA code	Indicate EA code
3	Name of conformity assessment object scope	Indicate name of the object (type of economic activity)
4	Object code according to OKRB 005-2011	Indicate code of object according to OKRB 005-2011
5	Designation of NPA including TNPA laying down requirements for conformity assessment object	Indicate denotation and name of TNPA laying down management system type
6	Designation of NPA including TNPA laying down requirements for certification procedure	Indicate denotation and name of TNPA laying down requirements for procedure of confirmation of compliance

6.11 Additional requirements to scope of accreditation of a personnel certification body

6.11.1 Scope of accreditation of a personnel certification body is determined by:

- ✓ object (method of control);
- ✓ qualification level;
- ✓ product and manufacturing sectors;
- ✓ documents establishing the management system type;
- ✓ code.

6.11.2 Form of scope of accreditation of a personnel certification body is set in Annex 4 of the Accreditation Rules.

6.11.3 Requirements to filling in tables of scope of accreditation of a personnel certification body are set in table 9.

Table 9

№ column	Column title	Content of record and requirements to filling in tables of scope of accreditation
1	**2**	**3**
1	Item number	Indicate consecutive numbering of objects. Item number/sub-item is assigned to the object for the entire accreditation cycle. When accreditation is partially withdrawn, the number of the withdrawn clause/subclause is not assigned to another indicator, the item is excluded from scope of accreditation and is not displayed in the next edition in the new edition of the current cycle. When new objects are added to the scope of accreditation, numbering continues.
2	Name of conformity assessment object scope	Indicate denotation and name of object
3	Code of conformity assessment object scope	A code according to RI SM 7-07 is indicated
4	Designation of NPA including TNPA laying down requirements for conformity assessment object	A designation and a name of TNLA laying down requirements for conformity assessment object is indicated
5	Designation of NPA including TNPA laying down requirements for certification procedure	A designation and a name of TNLA laying down requirements for procedure of confirmation of compliance is indicated

6.12 Introducing changes to the scope of accreditation

6.12.1 Scope of accreditation is changed in the following cases:

- ✓ extending accreditation;
- ✓ actualization of scope of accreditation;

- ✓ partial withdrawal of scope of accreditation;
- ✓ introducing changes to the certificate of accreditation.

6.12.2 Extending accreditation is carried out in accordance with the procedure DP SM 7, preparation of materials for consideration at TKA is carried out in accordance with DP SM 7.7.

After assessment of competence of the accredited body and TKA positive decision on extending accreditation, the scope of accreditation can be issued in a new edition, or issued as a separate Annex.

When scope of accreditation is published as a separate annex the first sheet of the scope of accreditation shall provide the following details are included (see clause 6.2.2.1 of this instruction): the heading "ANNEX No. XX from DD.MM.YYYY TO ACCREDITATION SCOPE of DD.MM.YYYY ", Revision number of the current scope of accreditation. Identification of the edition of “ADDITIONS TO THE ACCREDITATION SCOPE” is the date of TKA indicated n the footer of the sheet.

When reissuing the scope of accreditation in a new edition, the revision number and the date of issue of the new edition of the scope of accreditation are indicated.

The procedure for preparing and signing of additions to the scope of accreditation is performed in accordance with section 6.2 of this instruction.

6.12.3 Actualization of scope of accreditation is carried out in the following cases:

- ✓ change of details, name of legal entity and (or) accredited body;
- ✓ cancellation, reissue, replacement of TNPA, implementation of TNPA, identical to the current version in terms of the application of methods (methods);
- ✓ expanding the range of objects (which do not require on-site assessment) within methods (techniques) and procedures included in the current scope of accreditation;
- ✓ reducing scope of accreditation (initiated by accredited body).

Scope of accreditation of an accredited CAB can be updated by publishing a new edition or partially (in separate sheets). Lead assessor makes a decision whether to issue a new edition of the scope of accreditation as a whole or as separate sheets taking into account the rationality of preparing draft of scope of accreditation.

For the purposes of actualization of the scope of accreditation, the accredited body submits an application to the State Enterprise “BSCA” in the form specified in Annex 3 of the Accreditation Rules. The application shall be supported by:

- ✓ results of a comparative analysis of documents according to the form of Annex 6 of the Accreditation Rules;
- ✓ separate scope of accreditation sheets that need to be updated, or a draft of a new edition of the updated scope of accreditation taking into account previously issued additions to the scope of accreditation (if any);
- ✓ tables of the Passport of technical competence (if necessary), which provide information on the updated scope of accreditation.

Consideration of applications for actualization is carried out in accordance with DP SM 7.

Lead assessor conducts a review of documents submitted by the accredited body, and prepares a Report on document and records review (Annex 2). The report is submitted to the head of the department for signing.

Preparation of materials for consideration at TKA is carried out in the manner prescribed in DP SM 7.7-01. Analysis of materials on the actualization of CAB’s scope of accreditation by a technical guarantor is not carried out.

If a single legal entity has several separate structural units accredited for identical scope of accreditation and having one certificate of accreditation, a single scope of accreditation is issued, which sets forth the scope of accreditation for each separate structural unit.

When actualizing individual sheets of scope of accreditation, date of TKA decision is indicated in the footer next to the lead assessor signature. This date shall correspond to the date the information was entered in the Register.

The procedure for preparing and signing updated scope of accreditation is performed in accordance with section 6.2 of this instruction.

A case officer affixes a mark about a change in the scope of accreditation on the back side of the certificate of accreditation in accordance with RI SM 7.8-01. This requires agreeing signature of the head of accreditation body, BSCA director (or the authorized person substituting director). The signature is decrypted and confirmed with the blue accreditation body stamp. A case officer enters information on changes in the scope of accreditation into the amendments registration sheet according to RI SM 7.8-01.

When extending accreditation is performed simultaneously with amending the previously issued scope of accreditation, then the scope of accreditation can be issued in a new edition.

The previously issued scope of accreditation is stored in the accredited body for at least two accreditation cycles.

Previously issued individual sheets are not removed from the scope of accreditation, THEY ARE stored in the file of the accredited body for at least two accreditation cycles.

6.12.4 When part of the scope of accreditation is withdrawn, the scope of accreditation is issued in a new edition or a new edition of individual sheets is published, relevant item(s) are excluded from the scope of accreditation.

6.13 Issue of scope of accreditation

6.13.1 BSCA front office issues accreditation documents (certifiacate of accreditation, scope of accreditation) personally to the head of the accredited body or its authorized representative who has the appropriate permission (power of attorney), within the timeframe prescribed by Accreditation Rules. Information on issued of accreditation documents is entered in “The registration book on issue of accreditation documents” (Annex 3). The issuance of scope of accreditation is confirmed by the recipient's signature in this registration book.

7 MANAGEMENT OF RECORDS

Management of records laid down by this procedure is provided in Table 1.

Table 1 Management of records

Name and type* of record	Location of the record storage	Person responsible for record maintenance	Location of record form	Storage period of the record
Report on review of documents and records with the purpose of actualization of scope of accreditation (kept in paper)	File of accredited CAB	Quality manager/ lead assessor	IPS Standart / Our documents/ RI SM 7.8-02/Annex 2	
Registration book of issue of accreditation documents	Front office	Quality manager/ Front office Head	IPS Standart / Our documents/ RI SM 7.8-02/Annex 3	

Annex 1

I Matrix of responsibility and authority on description of scope of accreditation

Note:
О – responsible for the implementation of the function;
У – participates in the implementation of the function;
И – notified of function implementation.

№	Stage of preparation of accreditation scope	RESPONSIBLE							
		Director	**Deputy director**	**Secretary of front office**	**Head of accreditation department**	**Case officer of OORA**	**Lead assessor**	**ssessment team members**	**Head of OORA**
1	Preparing scope of accreditation						**О**		
2	Preparation and transfer of documents for signing (certificate of accreditation, scope of accreditation)					**О**	**У**		***И***
3	Agreeing of scope of accreditation		**У**		**У**		**О**		
4	Signing documents (certificate of accreditation, scope of accreditation)	**О**							
5	Entering information on accredited body into the Register					**О**			***И***
6	Issuance of documents to accredited body (certificate of accreditation, scope of accreditation)			**О**		**У**			
7	Filing a complete set of materials					**О**			***И***

II Matrix of allocation of responsibility and authority on actualization of scope of accreditation

Note:
О – responsible for the implementation of the function;
У – participates in the implementation of the function;
И – notified of function implementation.

No	Stage of actualization of accreditation scope	RESPONSIBLE									
		Director	Deputy Direcor	Front office staff	Head of accreditation departments	case officer	Lead assessor	Assessment team members	TKA members	Head of OORA	Economist of OORA
1	**Receipt and consideration of application for actualization of accreditation scope**										
1.1	Receipt and registration of an application			**О**							
1.2	Appointment of a case officer									**О**	
1.3	transfer of application to OORA case officer			**О**		**И**					
1.4	Checking the correctness of the application and completeness of documents					**О**				**И**	
1.5	making decision on application				**И**	**О**				**У**	
2	**Preparation for actualization**										
2.1	Appointment of a lead assessor				**О**	**И**					
2.2	Drawing up man-hour expenditure of the work					**И**	**О**				
2.3	Agreeing man-hour expenditure of the work				**У**		**О**			**У**	
2.4	Calculation of the contract price and preparation of the draft contract, pricing, act of acceptance of work					**О**					**У**
2.5	Agreeing and signing of the contract				**О**	**И**				**И**	**О**
2.6	Entering the contract into the information database and registration, transfer of act of acceptance, man-hour expenditure and pricing to a case officer, sending contract to an accredited body			**О**		**О**				**И**	
2.7	Control of contract payment and informing a lead assessor on this					**О**	**И**				
3	**Document and records review**										
3.1	Document review						**О**	**У**			
3.2	Drawing up a report on the analysis of documents						**О**	**У**			
3.3	Control of implementation of corrective actions based on the results of the assessment of documents (if necessary)						**О**	**У**			
4	Preparation of materials for consideration and decision making at TKA										
4.1	Preparing scope of accreditation or individual sheets of scope of accreditation					**И**	**О**				
4.2	control of quality of work on assessment of an accredited body and control of readiness of assessment materials for TKA				**О**		**И**		**О**		
4.3	Submission of assessment results to TKA				**И**	**О**	**У**				
4.4	Making decision on actualization	**И**	**И**		**И**	**И**	**И**		**О**		
4.5	Preparation and sending extract from the			**У**		**О**					

No	Stage of actualization of accreditation scope	RESPONSIBLE									
		Director	Deputy Direcor	Front office staff	Head of accreditation departments	case officer	Lead assessor	Assessment team members	TKA members	Head of OORA	Economist of OORA
	minutes of the TKA meeting to the accredited body										
4.6	Preparation and submitting documents on actualization for signing (certificate of accreditation, scope of accreditation)					**О**	**У**				
4.7	Agreeing of scope of accreditation						**О**				
4.8	Signing documents on changing scope of accreditation	**О**									
4.9	Entering information about the accredited body in the Register					**О**					
5	**Issue of documents on actualization**										
5.1	Issuing documents on actualization to accredited body			**О**		**У**					
6	**Submission of case files to archive and reporting on the results of accreditation**										
6.1	Filing of materials					**О**					
6.2	Reporting on the results of work on actualization	**И**	**И**		**О**	**У**	**У**				
6.3	Control of implementation of the actualization procedure		**О**		**У**	**И**	**И**	**И**	**И**		

Annex 2
Form of report on document review for actualization of accreditation scope

	REPORT **on document and records review for the purpose of actualization of accreditation scope**	Registration number of the certificate of accreditation BY/112

Full name of a legal entity	
Full name of CAB including full name of a branch of the legal entity (if any)	
Reason for document review:	
Document review date	
Reason for actualization of scope of accreditation	
☐	changes in details: names of the legal entity and (or) CAB
☐	cancellation, revision, replacement of TNLA, including cases when not the whole document is canceled and replaced; introduction of changes (amendments) to the existing TNLA; the introduction of TNLA identical to those in force with regard to application of test/examination/verification /calibration methods
☐	extending the range of test/research/verification/calibration/certification objects (not requiring on-site assessment) according to the methods (techniques) and procedures included in the current scope of accreditation
☐	reducing scope of accreditation (on CAB initiative)
Document review conducted by: *Surname, initials of the person*	
List of documents submitted for review:	1. Comparative document review for the purpose of actualization of scope of accreditation on paper and in electronic form - 1 copy. 2. A draft of the claimed scope of accreditation in the new edition or separate sheets of the scope of accreditation on paper and in electronic form - 1 copy.
Annex:	

Conclusion:

1.1 In the submitted documentation nonconformities are not raised. CAB documents (name of CAB; legal entity) can be submitted to TKA meeting to consider actualization:

☐ scope of accreditation and its issue in new edition

☐ pages of scope of accreditation: №_____ and their issue in new edition
(indication of clauses of scope of accreditation, subject to change)

1.2 In the submitted documentation, nonconformities are raised according to a comparative analysis. Identified nonconformities require closing. The deadline for closing nonconformities and submitting revised documents is _____.
Note: Actualization work is suspended for the period during which the CAB is closing nonconformities specified in the comparative analysis and in this report.

Report is prepared by:

_____	_____	_____	_____
(position)	*(signature)*	*(initials, surname)*	*(date)*

Report is checked by:

Head of department	_____	_____	_____
	(signature)	*(initials, surname)*	*(date)*

Annex 3
Form of registration book on issue of accreditation documents

Date of TKAmeeting	No. of extract	Name of organization	No. of the certificate of accreditation	No. of letter of attorney
1	2	3	4	5

Name of documents issued to the CAB	Number of copies	Number of sheets	Signature on receipt	Full name of the person who received documents	Date of receipt of documents
6	7	8	9	10	11

Amendments registration sheet

N	Date of introduction of the amendment	N of notification of change, date of approval	Paragraph changed	Signature of the person who introduced the change	Full name of the person who introduced the change
1	2	3	4	5	6
1					Demidov I. V.
2					Kondratovich A. N.
3					Misevich M. A.
4			Clause 6.2.2.1, Clause 6.4.3 table 2, Clause 1		Mamai S. P.