DOCUMENTED PROCEDURE

SAMPLING FOR ASSESSMENT OF LABORATORIES, INSPECTION BODIES AND PROFICIENCY TESTING PROVIDERS

DP SM 7.4-01-2015

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CONTENTS

1 SCOPE

1.1 This documented procedure (hereinafter the procedure) is the management system document of the Republican Unitary Enterprise "Belarusian State Center for Accreditation" (hereinafter BSCA) and is developed to implement Clause 7.4 of the RK SM as well as the requirements of Section 7 of GOST ISO/IEC 17011 and IAF/ILAC-A5. The procedure establishes the order for sampling during the process of accreditation laboratories, inspection bodies and proficiency testing providers.

1.2 The requirements of this documented procedure are mandatory for application by the BSCA involved in accreditation process.

2 REFERENCES

This documented procedure contains references to the next documents:

STB ISO 9000 (ISO 9001, IDT) Quality Management System. General provisions and vocabulary;

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 to accreditation bodies accrediting conformity assessment bodies;

RK SM BSCA Quality manual;

PL SM 7.15 Policy on participation of accredited laboratories in proficiency testing;

DP SM 7 Accreditation process

DP SM 7.6 Assessment;

DP SM 7.7-01 Preparing documentation for consideration at the meeting of the Technical commission on accreditation;

EA-4/18 Guidance on the level and frequency of proficiency testing participation

IAF/ILAC-A5 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 should be used. If the reference documents are replaced (modified), then the modified documents should be used. If reference documents are canceled 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 DEFENITIONS

In the documented procedure terms and definitions in accordance with STB ISO 9000, GOST ISO/IEC 17000, GOST ISO/IEC 17011 are used, including:

3.1 representative sampling — sampling made according to the rules, so that it reflects the specificity of the total population by composition, and by the individual characteristics of representative objects included in the sampling;

3.2 measurement - the process of experimental production of one or more values of the quantity that can reasonably be attributed to the value;

3.3 measurement principle - phenomenon underlying measurement;

EXAMPLE 1 Thermoelectric effect, which is used to measure temperature.

EXAMPLE 2 The energy of absorption, which serves to measure molar concentrations

3.4 measurement procedure - a detailed description of the measurement in accordance with one or more measurement principles and a given measurement method that is based on a measurement model and includes the calculations necessary to obtain a measurement result;

3.5 reassessment – assessment carried out by BSCA for maintaining accreditation;

3.6 extending accreditation – extending accreditation scope including arrangement of new premises for testing/calibration activities;

3.7 representative – giving an objective idea of something; being a typical representative of a large number, the totality of something.

4 NOTATIONS AND ABBREVIATIONS

In the documented procedure the following notations and abbreviations are used:

BSCA, accreditation body, enterprise – Republican Unitary Enterprise «Belarusian State Centre for Accreditation»;

DP – documented procedure;

OA No 1, No **2** – Accreditation department No 1, No 2;

OAOS – Department for certification body accreditation;

OORA – Department of accreditation activities management;

CAB – Conformity Assessment Body;

SM – management system;

TKA – Technical Commission on Accreditation;

OAL – Department for Laboratories Accreditation;

EA – European co-operation for Accreditation

IAF – International Accreditation Forum

ILAC – International Laboratory Accreditation Cooperation

IDT - Identified degree of compliance with the international standard (identity of the technical content and structure)

5 RESPONSIBILITY

The matrix of responsibility and authority on the documented procedure are defined in Annex 1 of DP SM 7.

6 SAMPLING

6.1 General

6.1.1 Sampling of the assessment objects is carried out in preparation for the assessment during:

- initial accreditation;
- re-accreditation;
- extending accreditation;
- surveillance and monitoring.

During the preparation for each assessment of the CAB, the following assessment objects are subject to sampling:

- elements of the CAB's management system;
- technical aspects (representative methods of testing, calibrations, inspections, proficiency testing according to the scope of accreditation of the CAB, the location of the assessment, personnel to be assessed). Recommendations for the sampling of assessment objects are given in Annex 1

6.1.2 During the sampling of assessment objects the location of the CAB is taken into account, in which at least one of the key activities of the CAB included in the scope of accreditation are conducted and the number of personnel involved in the implementation of the scope of accreditation applied by the CAB.

The sampling of assessment objects is carried out taking into account the analysis of the information submitted by the CAB in the passport of technical competence prior to the assessment by BSCA.

6.1.3 During any assessment the sampling is carried out in a such way as to ensure that the assessment team will witness a representative number of samples of the CAB's activities (methods according to the accreditation area and elements of the management system) to ensure a proper assessment of the competence of the CAB.

6.1.4 During initial accreditation the assessment of the CAB is carried out for all elements of the management system and for the entire the scope of accreditation applied by the CAB (all areas of the testing/calibration/inspection/proficiency testing, all personnel performing the tests/calibrations/inspections/proficiency testing, all sites of activities in accordance with the scope of accreditation).

During extending accreditation the assessment of the CAB is carried out for those elements of the management system of the CAB that have been modified as a result of the extending and all the additional

scope of accreditation (all areas of the additional scope of testing/calibration/inspection proficiency testing, all personnel conducting testing/calibration/inspection/proficiency testing according to the additional scope applied, all sites of implementation of activities according to the additional scope of accreditation).

6.1.5 During surveillance and re-assessment the selection of the sampling is carried out in such a way as to ensure that the BSCA will assess the representative number of samples of the CAB's activities (methods according to the scope of accreditation and elements of the management system) for the validity period of the accreditation certificate (accreditation cycle).

6.1.6 The assessments after the initial accreditation are carried out according to the program of surveillance and re-accreditation for the accreditation cycle (hereinafter the program), which is compiled for 5 years by the lead assessor conducted the initial evaluation.

The program includes surveillance of the CAB for the accreditation cycle and assessment for the purpose of re-accreditation. The program contains tabular data with information on the timing of assessments, on the elements of the CAB's management system being checked and on technical aspects (representative test/calibration/inspection/proficiency testing methods/programs according to the scope of accreditation of the CAB and the location of the assessment).

6.1.7 The surveillance and re-accreditation program for the accreditation cycle is drawn up taking into account the following:

- For each surveillance it is necessary to assessment the functioning of the following elements of the management system:
  - complaint (claims),
  - internal audits,
  - control of nonconformity in operations;
  - corrective actions,
  - management review (using a combination of assessment techniques, analysis of documents and interviewing a representative of the senior management of the conformity assessment body),
  - technical records and results assurance (for laboratories), personnel monitoring (for inspection bodies)
  - metrological traceability.
- For re-accreditation all elements of the management system are subject to the assessment.
- The sampling of the object is carried out in such a way that for the accreditation cycle all the activities of the CAB are assessed according to the scope of accreditation, all locations and all key CAB's staff (using any of the assessment techniques) at least once.

6.1.8 For the sampling of the objects for a specific assessment, the results of the previous assessment are taken into account. The elements of the management system for which nonconformities were established as a result of the previous assessment are necessarily planned for assessment and the results of the analysis of the information submitted by the CAB about activities in the scope of accreditation and changes from the moment last assessment.

6.1.9 Also during the preparation of plan for each subsequent assessment after initial accreditation, it is necessary to assess factors that may influence the change in the assessment plan planned for the surveillance and the re-accreditation program for the accreditation cycle. To do this, it is necessary to analyze the information provided by the CAB on its activities within the scope of accreditation and all changes that have taken place in the CAB since the last assessment and assess the impact of the changes that have occurred on the possibility of the CAB to carry out activities in accordance with the scope of accreditation.

These factors can be defined as follows:

- the number of tests/calibrations/inspections/proficiency testing conducted;
- changes in personnel;
- experience and knowledge of the personnel;
- universally recognized stability/instability of the measurement method;
- changes in the technical facilities of the laboratory/inspections/proficiency testing provider;

- the significance and end-use of tests/calibrations/inspections/proficiency testing data (for example, forensic medicine is an area with a high level of data reliability);
- the results of the participation of the laboratory in proficiency testing programs;
- changes that have occurred in the structure of the CAB since the last assessment;
- significant changes in the management system.

6.1.10 During the planning of witnessing in the preparation of a specific assessment plan, the lead assessor is guided by a surveillance and re-accreditation program for the accreditation cycle and by the results of the analysis of the information submitted by the CAB.

6.1.11 Witnessing of tests/calibrations/inspections/proficiency testing is recommended to plan for those methods/programs according to the scope of accreditation for which there were no or very few (less than 5) CAB's activities, as well as for changes in personnel since the last assessment in specific test/calibrations/inspections/proficiency testing methods according to the scope of accreditation.

6.1.12 The analysis of the case is effectively used during the assessment of test/calibration/inspection/proficiency testing methods for which the CAB has carried out a large number of works since the last assessment.

6.1.13 Also it is necessary during each assessment to assessment the effectiveness of the corrective actions taken and the implementation of the improvement recommendations that were received by the CAB as a result of the previous assessment, and the use of accreditation symbols and text links to accreditation by the CAB (assessment of the CAB's compliance with of the scope of accreditation).

6.1.14 During developing a plan for a specific assessment of the CAB, the assessment team is guided by the surveillance and re-accreditation program for the accreditation cycle, as well as the results of the analysis of the information submitted by the CAB, and determines assessment techniques in accordance with clause 6.5:

6.1.15 The surveillance and re-accreditation program for the accreditation cycle is periodically reviewed taking into account the results of the previous assessment and, if necessary, updated (re-written).

6.2 Sampling for witnessing

6.2.1 Selection of representative methods for laboratory witnessing

6.2.1.1 The criteria for selecting of representative methods for witnessing of laboratories are:

- principle of the test method/measurement principle and the properties of the tested object (for testing laboratories);
- measured value/measurement principle (for calibration laboratories);

also take into account:

- complexity of the test/calibrations method (technical equipment, labor input),
- risks of consequences in the adoption of the CAB of an incorrect decision based on the results of tests/calibrations (the number of works carried out in the scope of accreditation).

Note 1: In cases where the CAB tests/calibrates various objects for which similar test/calibration methods are used, the same measurement equipment is used and the same persons are conducted tests/calibrations, it is sufficient to assess one at a time more complex test calibration objects.

Note 2: The determination of the minimum number of representative test/calibration methods during initial accreditation or extending of accreditation is carried out depending on the total number of test/calibration methods applied for accreditation.

6.2.1.2 It is necessary to witness a certain number of methods. The number of methods for witnessing for laboratories is determined according to Table 1.

Table 1

The number of test/calibration methods applied in the scope of accreditation (having a different principle of the method or intended for measuring various measured values)	The minimum number of representative sample methods in each test calibration filed
from 1 till 6	100%
more than 6	one representative method from a representative sample of methods in each direction in the scope of accreditation * ** Note: in each accreditation cycle it is necessary to change representative methods from a representative sample taking into account witnessing made in the previous cycle.*

6.2.1.3 Because of the specifics of the calibration processes, the technical assessors can request in advance from the calibration laboratory (during preparation for the assessment) detailed information about the calibration methods, including information on the calculation of the uncertainty.

6.2.2 Selection of representative methods for inspection witnessing

In the case of initial accreditation, whenever possible, all representative inspection objects are subject to witness.

The number of witnessing depends on the number of inspection objects or processes included in the scope of accreditation.

All representative objects of inspection activity shall witness at least once for the accreditation cycle.

During surveillance BSCA, at any time, witness at least one inspection process carried out by the inspection body at the location of the inspected object.

The results of previous witnessing are taken into account.

6.2.3 Selection of proficiency testing programs for witnessing of proficiency testing providers

The criteria for selecting of proficiency testing programs for witnessing of proficiency testing providers are

- principle of the method of preparation of samples for proficiency testing;
- the procedure for determining the attributed value;
- the value that is applied to be determined during the proficiency testing;

also take into account:

- complexity of the preparation of samples for proficiency testing, determination of attributed values that are attributed for proficiency testing (technical equipment, labor input);
- risks of consequences in the adoption of the CAB of an incorrect decision based on the results of proficiency testing (the number of works carried out in the scope of accreditation).

Note 1: In cases where the CAB conducts proficiency testing on the testing/calibration цm epy various objects for which similar test/calibration methods of preparation of samples are used, the same measurement equipment is used and the same persons are conducted preparation of samples, it is sufficient to assess one at a time more complex proficiency testing objects.

Note 2: The determination of the minimum number of representative proficiency testing methods during initial accreditation or extending of accreditation is carried out depending on the total number of proficiency testing methods applied for accreditation.

6.2.4 Sampling for witnessing for calibration laboratories

During initial accreditation, whenever possible, all representative calibration methods are subject to assessment.

The number of witnessings depends on the number of calibration areas included in the scope of accreditation. At least one representative method is selected for each calibration area. In cases where the CAB carries out calibrations of various items for which similar calibration methods are used, and the same persons perform calibrations, it is sufficient to assess the most complex calibration item.

All representative calibration methods must be assessed at least once per accreditation cycle.

When conducting a surveillance competency assessment, each time BSCA conducts a witnessing of at least one calibration method. In this case, the results of previous assessments are taken into account.

The selection of representative methods, calibration objects, and the implementation of the planned assessment volume are controlled by the head of the department for laboratories accreditation No. 2 and the organizer of the accreditation work. Special control along with registration in the IS "Accreditation" is carried out over the work on the assessment of conformity assessment bodies, the area of accreditation of which contains a large number of methods.

6.3 Selecting a location for assessment

6.3.1 The main locations of the CABs activities in the scope applied for accreditation are:

- CAB's office premises in which key activities are carried out;
- production facilities, as well as the CAB's sites where test/calibration/inspection/proficiency testing activities are carried out directly, including maintenance of work records relating to the process and test/calibration/inspection/proficiency testing results.

Note 1: The places of direct implementation of the testing/calibration/inspection/proficiency testing activity of the CAB in the scope applied for accreditation also include the locations of the actual sites of the test/calibration/inspection/proficiency testing object, including mobile (mobile) locations.

6.3.2 During initial accreditation and extending accreditation, the assessment is conducted at all sites of the CAB's activities in the scope applied for accreditation.

During the preparation for surveillance and re-accreditation, in the presence of several locations of the CAB, the assessment team selects the sites for the assessment, taking into account selected representative test/calibrations/inspections/proficiency testing methods/subjects/programs.

During surveillance and re-accreditation, the assessment is carried out in the main office of the CAB, as well as in the production facilities of the CAB, where test/calibration/inspection/proficiency testing activities are carried out for selected representative test/calibration/inspections/proficiency testing methods/subjects/programs.

6.3.3 During initial accreditation, in addition to visiting the main (head) office, in the assessment plan must be included a visit to all other sites of the CAB in which at least one of the key activities (IAF/ILAC-A5, M.7.5.7.1 -M.7.5.7.4), is performed by the CAB.

6.3.4 Key activities include:

- preparation and approval of policies;
- development and approval of processes and procedures;
- review of application and contractual obligations related to testing/calibration/inspection/proficiency testing;
- conducting tests/calibrations/inspections/proficiency testing;
- storage of reagents and testing/proficiency testing materials, management of standards for calibrations/proficiency testing;
- planning of proficiency testing program, evaluation of functioning characteristics, approval of the final report on proficiency testing;
- development and approval of policies, processes and procedures for appeal and complaint review which is received from clients and other parties regarding the activities of accredited CAB;
- the final decision on appeals and complaint.

6.3.5 During selecting of the assessment locations, the results of previous assessments are taken into account so that during the accreditation cycle all sites of the CAB's activities in the scope applied for accreditation were assessed at least once.

6.4 Selection of CAB's personnel to be assessed

6.4.1 Criteria for the selection of the CAB's personnel to be assessed during testing/calibrations/inspections/proficiency testing for selected representative test/calibrations/inspections /proficiency testing methods are:

- the number of tests/calibrations/inspections/proficiency testing carried out for selected representative methods by each of the CAB specialist individually for a certain period (during accreditation and extending accreditation - within a year prior to applying for accreditation, during surveillance and re-accreditation - since the last assessment);
- education, qualifications, experience in testing/calibration/inspection/proficiency testing activities;
- results of participation in proficiency testing and Interlaboratory Comparisons;
- results of previous assessments,
- changes that have occurred in the personnel of the CAB since the last assessment.

6.4.2 The assessment team determines from personnel of the CAB conducting tests/calibrations/inspections/proficiency testing for selected representative methods, personnel to be assessed: minimally one CAB for each selected representative test/calibration/inspection/proficiency testing method/program for a specific assessment.

6.4.3 During selecting the personnel of the CAB to be assessed, the results of previous assessments are taken into account so that during the accreditation cycle all the CAB's personnel carrying out activities throughout the scope of accreditation were assessed at least once with application one of the technique of the CAB's assessment specified in clause 6.5.

6.5 Selection of techniques for assessment

6.5.1 General provision

Techniques of the assessment of CAB include:

- on-site assessment;
- remote assessment;
- witnessing;
- document review;
- file review;
- measurement audits;
- review of performance in proficiency testing and other interlaboratory comparisons;
- validation audits;
- unannounced visits;
- interviewing.

In order to cover the areas of CAB activities (field of technical competence) according to the scope of accreditation, BSCA uses a balanced combination of various access assessment techniques, including:

- assessment of the functioning of the management system (mandatory) is conducted by the method of document review and interview;
- assessment of the competence of the CAB to conduct tests/calibrations/inspection/proficiency testing according to the scope of accreditation can be carried out using techniques, but not limited to the following combinations:
  - witnessing of tests/calibrations/inspections/proficiency testing (can be carried out in combination with interview and document review);
  - case review, including the results of participation in proficiency testing and other interlaboratory comparisons;
  - interview of the CAB's personnel (can be carried out in combination with the document review).

Depending on the duration of the testing/calibrations/inspections/proficiency testing, the availability of samples of the testing/calibration/inspection/proficiency testing object, the financial costs of testing/calibration/inspection/proficiency testing, etc. one of the techniques or a combination thereof may be

used.

6.5.2 Document review

Document review (horizontal assessment) is an assessment of one process from its beginning to its completion (for example, conducting an internal audit according to the internal procedures adopted by the CABs developed according to the requirements of the basic standard). During document review assessors assess in detail how each of procedure is conducted, without being distracted by interrelated processes. The advantage of this assessment is the ability to assess in detail all the actions of one process, all accompanying documentation on this process, all the personnel involved in this process.

The document review is used to assess the effectiveness of the functioning of individual elements of the CAB's management system.

During initial accreditation and re-accreditation, a document review of all elements of the CAB's management system is carried out.

During planning of surveillance the lead assessor taking into account the results of previous assessments of the CAB that have occurred since the previous assessment of the change, and, guided by the requirements of p.6.1 of this procedure, determines the need for a document review for each element of the management system.

A document review of the elements of the CAB's management system is recommended to be planned in the presence of nonconformities in these elements established during the period of the previous assessment and in the presence of significant changes that occurred in the CAB's management system.

6.5.3 Case review

Case review is a complete assessment of all aspects of testing/calibrations/inspections/proficiency testing for the selected representative test/calibration/inspection/proficiency testing method/program.

Case review is used to assess the technical competence of the CAB in carrying out the test/calibrations/inspections/proficiency testing for the selected representative test/calibration/inspection/proficiency testing method/program and assessment of the performance of the CAB's management system regarding the selected representative method.

Case review includes competency assessment of the CAB in carrying out tests/calibrations/inspections/proficiency testing for a selected representative method/program or process in practice using various combinations of assessment techniques (interview, record review, analysis of participation in proficiency testing programs and interlaboratory comparisons).

During case review, the assessment team carries out a record review of the CAB regarding the testing/calibration/inspection/proficiency testing of the selected representative method/program.

6.5.4 Witnessing

6.5.4.1 Witnessing of tests/calibrations/inspections/proficiency testing can be carried out using:

- real samples of testing/calibrations when performing the current activities of the CAB;
- product specimen (for testing) sampled in the presence of a technical assessor or provided by assessment team
- standards (for calibration laboratories)

6.5.4.1.1 This technique can be used in combination with measurement audit technique (see 6.5.8). In this case, the witnessing of testing/calibrations/inspections/proficiency testing can be carried out using:

- test items (test data) for the calculation of indicators of proficiency testing (for proficiency testing providers)
- certified reference material with known values
- samples with specified parameters/characteristics (encrypted samples) provided by the assessment team, while the person to be assessed does not know the parameters/characteristics specified (mutual application of measurement audit techniques)

6.5.4.2 Modeling of testing/calibration/inspection/proficiency testing

In justified cases (duration of the tests/calibrations/inspections/proficiency testing, significant financial costs of the CAB for organizing and conducting real tests/calibrations/inspections/proficiency testing and etc.), it is allowed to assess the competence of the CAB in carrying out the test/calibrations/inspections/proficiency testing for the selected representative test method/program, modeling the entire test/calibration/inspection/proficiency testing process or its individual stages, provided that the CAB during assessment will confirm documented all the prescribed actions. In this case, an additional interview is conducted with the CAB personnel who directly carried out such activities.

6.5.5 Analysis of participation in proficiency testing programs and interlaboratory comparisons (ILC)

During the assessment of the competence of laboratories for the representative method selected for assessment, BSCA takes into account the results of participation in the PT and ILC taking into account EA 3/04 and EA 4/18 as follows.

During sampling for witnessing, it is possible to credit the results of participation in the PT and ILC, provided that the laboratory provides documentary evidences:

- obtaining positive results of participation in the PT by a representative method;
- participation in the PT and ILC (taking into account the BSCA Policy on the frequency of participation in the PTs) on a representative method on an ongoing basisC
- participation in this PT or ILC of all personnel responsible for carrying out tests/calibrations by a representative method.

6.5.6 Remote assessment

Remote assessment is the assessment of the physical location or virtual site of the CAB and conducting activities of the CAB using electronic means, such as online video conferencing applications (e. g. Skype).

Remote assessment can be carried out in the following cases:

- when on-site assessment is not possible due to unforeseen, force majeure situations related to the current inability to physically visit the CAB (due to a threat to the safety of members of the assessment team, travel restrictions);
- CAB carries out systematic implementation of its management system in which records, data, etc. can be reviewed on any platform, regardless of where the work is conducted;
- when OOS is traceable and verifiable records of compliance in place of the remote assessment;
- if it is necessary to conduct additional assessments, but there is difficulties to implement trips in a short time.

Remote evaluation is not carried out in the following cases:

- when assessed CAB had identified a significant number of nonconformities in the location that needs to be assessed during the previous assessments;
- during the initial assessment of a new site of the CAB, new scope of accreditation or when there are significant changes;
- if the on-site assessment has not been carried out for a long period of time.

6.5.7 Unannounced visit

Unannounced visit is the assessment conducted without prior planning and informing the CAB. This assessment is usually carried out when BSCA receives information (e.g. complaints about the CAB activities or information from public authorities) that poses a risk to the BSCA reputation and accreditation provided by the BSCA.

Unannounced visits, at a minimum, include an assessment of compliance by the CAB with the requirements as specified in the information received by the BSCA.

6.5.8 Measurement audit

A measurement audit is the assessment carried out by comparing the results obtained during testing/calibration/inspection of the assessed CAB with the results of the reference CAB taking into account

the measurement uncertainties assigned to the reference value and the measurement uncertainty reported by the assessed CAB.

Samples in this case can be used as described in 6.5.4.1.1

6.5.9 Interviewing

Interviewing is the competency assessment of the CAB personnel, the assessment of their knowledge and skills, carried out by direct oral communication of the assessor with the CAB personnel.

When applying the interviewing technique, a situational interview can be used in which the CAB personnel is asked to solve a typical situation, and he must state the sequence of his actions and explain the feasibility of his decisions. At the same time clarifying questions are asked to find out how the CAB employee will behave if events develop in one way or another. This method allows a comprehensive assessment of the competence of CAB employees and its theoretical knowledge.

As a rule, this technique is combined with other assessment techniques in order to obtain more complete information about the experience, skills and knowledge of the assessed personnel.

6.5.10 Validation audits

Assessment, during which the validation processes carried out in the CAB are evaluated, as well as reports published as a result of validation, and decisions made.

This assessment technique can be carried out both in the examination of documents and in the on-site assessment.

7 RECORDS CONTROL

As a result of this procedure, no records are to be stored.

Annex 1
Recommendation for sampling

Table 1

Responsibility for sampling

Name of activity and stages		Initial accreditation	Extending of accreditation	Re-accreditation	Surveillance
1	2	3	4	5	6
Stage of activities with applicant (accredited CAB)	resource review	(director and heads of OA No.1, No.2, OAOS) Lead assessor - analysis of the spheres of the CAB's activities in the scope applied for accreditation, i.e. selection of technical assessors	Lead assessor - analysis of the spheres of the CAB's activities in the scope applied for accreditation, i.e. selection of technical assessors	Lead assessor - analysis of the directions in the scope of accreditation (taking into account the results of previous assessments)	-
	Preparation for assessment	Leading assessor - selecting of the elements of the management system to be assessed	Leading assessor - selecting of the elements of the management system to be assessed	Leading assessor (during drawing up the surveillance and re-accreditation program for the accreditation cycle) - selecting of the elements of the management system to be assessed	Leading assessor (during drawing up the surveillance and re-accreditation program for the accreditation cycle) - selecting of the elements of the management system to be assessed; selecting of locations in the assessment of activities (taking into account the results of previous assessments)
		Lead assessor and technical assessor - definition of groups of representative methods from the scope applied for accreditation and selection of a representative method from the group (taking into account the location and CAB personnel)	Lead assessor and technical assessor - definition of groups of representative methods from the scope applied for accreditation and selection of a representative method from the group (taking into account the location and CAB personnel)	Lead assessor (during drawing up the surveillance and re-accreditation program for the accreditation cycle) - selecting of methods for assessment, taking into account the coverage of the entire scope of accreditation for the accreditation cycle Lead assessor and technical assessor (during drawing up the assessment plan) selection of representative methods from the scope of accreditation (taking into account the location, CAB personnel, the results of previous assessments and analysis of the information submitted by the CAB)	Lead assessor - (during drawing up the surveillance and re-accreditation program for the accreditation cycle) - selecting of methods for assessment, taking into account the scope of the entire scope of accreditation for the accreditation cycle. Lead assessor and technical assessor (during drawing up the assessment plan) - selection of a representative method from the scope of accreditation (taking into account the location, CAB personnel, the results of previous assessments and analysis of the information submitted by the CAB)

1	2	3	4	5	6
Stage of activities with applicant (accredited CAB)	Assessment	Technical assessor - personnel selection for selected representative methods according to the scope of accreditation	Technical assessor - personnel selection for selected representative methods according to the scope of accreditation	Technical assessor - personnel selection for selected representative methods according to the scope of accreditation (taking into account the results of previous assessments)	Technical assessor - personnel selection for selected representative methods according to the scope of accreditation (taking into account the results of previous assessments)

Table 2

Scope of assessment

Name of activity and stages		**Initial accreditation**	**Extending of accreditation**	**Re-accreditation**	**Surveillance**
1	**2**	**3**	**4**	**5**	**6**
Assessment	Scope of accreditation	100% of the spheres (directions) of activity applied for accreditation	100% of the spheres (directions) of activity applied for accreditation	taking into account the results of the previous assessment with a view to surveillance and analyzing the information submitted by the CAB in such a way that during the accreditation cycle all the activities of the CAB according to the object and test codes and the type of testing/calibration/inspection/ proficiency testing and all areas (directions) of the accredited CAB's activities were covered by the assessment for the accreditation cycle	taking into account the results of the previous assessment with a view to surveillance and analyzing the information submitted by the CAB in such a way that during the accreditation cycle all the activities of the CAB according to the object and test codes and the type of testing/calibration/inspection/proficiency testing and all areas (directions) of the accredited CAB's activities were covered by the assessment for the accreditation cycle
	Management system	100% of the elements of the management system using the technique of document review and interviewing	100% of the elements of the management system using the technique of document review and interviewing, which are amended and/or added related to extending of accreditation	100% of the elements of the management system using the technique of document review and interviewing	Selection of elements of the management system, taking into account the requirements of p. 6.2 and the results of the previous assessment, as well as changes in the management system that have occurred in the CAB so that all elements of the management system undergo a assessment for the accreditation cycle

1	2	3	4	5	6
Assess-ment	Pesonnel	All the CAB's personnel performing activities for the selected representative methods/program of testing/calibration/inspection/ proficiency testing: at least 1 for each representative method/program of testing/calibration/ inspection/ proficiency testing from the group of methods according to the scope of accreditation by the witnessing method, the rest with application of the interview method and record review. *Note: in the case of a large number of personnel, it is recommended to assess the witnessing of at least 1/4 of the number of the CAB's personnel performing activities for a particular selected representative method from the group of methods*	All the CAB's personnel performing activities for the selected representative methods/program of testing/calibration/ inspection/proficiency testing: at least 1 for each representative method/program of testing/calibration/ inspection/ proficiency testing from the group of methods according to the extending of scope of accreditation by the witnessing method, the rest with application of the interview method and record review. *Note: in the case of a large number of personnel, it is recommended to assess the witnessing of at least 1/4 of the number of the CAB's staff performing activities for a particular selected representative method from the group of methods*	Selectively from the number of personnel performing the activity for selected representative methods/program of testing/calibration/ inspection/proficiency testing: at least 1 for each representative method/program of testing/calibration/ inspection/proficiency testing the group of methods planned for reassessment by the witnessing method (taking into account the changes in the CAB's staff, as well as the results of previous assessments), the rest using method of interview and record review *Note 1: If it is not possible to witness all the CAB's staff, it is recommended that the accreditation cycle be assessed at least 1/4 of the number of the CAB's staff performing activities for a particular selected representative method from the group of methods,* *Note 2: When planning the assessments in the next accreditation cycle, it is necessary to select personnel for the assessment by the witnessing method, which was not witnessed in the previous cycle*	Selectively from the number of personnel performing the activity for selected representative methods/program of testing/calibration/ inspection/proficiency testing: at least 1 for each representative method/program of testing/calibration/ inspection/proficiency testing from the group of methods planned for surveillance by the witnessing method (taking into account the changes in the CAB's staff, as well as the results of previous assessments), the rest using method of interview and record review *Note 1: If it is not possible to witness all the CAB's staff, it is recommended that the accreditation cycle be assessed at least 1/4 of the number of the CAB's staff performing activities for a particular selected representative method from the group of methods,* *Note 2: When planning the assessments in the next accreditation cycle, it is necessary to select personnel for the assessment by the witnessing method, which was not witnessed in the previous cycle*

	Locations	Office premises of the CAB, in which key activities are carried out and 100% of the production facilities of the CAB, where activities are carried out directly according to the scope of accreditation	100% of the production facilities of the CAB, where activities are carried out directly according to the scope of accreditation	Office premises of the CAB, as well as 100% of locations and activities for selected representative methods in accordance with the scope of accreditation, taking into account the analysis of the information provided by the CAB	Office premises of the CAB, as well as 100% of locations and activities for selected representative methods in accordance with the surveillance and reassessment program for accreditation cycle, taking into account the results of the previous assessments and analysis of the information provided by the CAB in such a way that during the accreditation period all the sites of the CAB's activities in the scope of accreditation were assessed at least once

Annex 2

Recommendations for determination of the number of witnessing of testing/calibrations/inspections/proficiency testing and required number of technical assessors for preparation of surveillance and reassessment program for accreditation cycle

(an example for testing physical and chemical laboratories)

Input data:

Staff:

- the number of personnel involved in the trials of 8 people

Scope of accreditation:

- number of objects in the scope of accreditation 3 (drinking water, sewage water, soil)
- number of test methods in the scope of accreditation 23

1. To select objects for witnessing you need:

1.1 to divide the scope of accreditation according to the areas of activity declared in the scopeof accreditation in the areas: physical and chemical methods, organoleptic methods, microbiological methods, methods for determining properties, etc.

1.2 divide the directions into groups of methods according to the measurement principle (where necessary)

1.3 determine in respect of which test objects which test methods included in the scope of accreditation are implemented

1.4 to calculate the number of indicators to be determined for each test object

1.5 to identify employees of the CAB, which are assigned certain methods

1.6 Calculate the number of witnessing that need to be carried out to cover the entire scope of accreditation

1.7 Plan the number of witnessing for each assessment, taking into account the assessment of all the CAB's specialists

1.8 In view of the assigned codes of competence, select technical assessor and determine their number for each assessment

Activities	**Groups of methods**	**Tested objects**	**Number of indicators**	**Number of methods in a scope**	**Staff No**	**Number of witnessing per cycle (taking into account the influence of the matrix of the objects being tested and all the personnel of the CAB)**	**Witnessing plan (in parentheses the numbers of employees of the CAB are indicated)**	**Maintenance number**
Physico-chemical	Chromatography	water sewage	5	1	1,2	2	1 PK (1) PO (2)	TO 1
		drinking-water	4					
		soil	2			1	1 PK (1)	
	Atomic absorption	soil	4	1	3,4	2	2 PK (3) PO (4)	TO 2

	Photometry	water sewage	3	3	1,3	2	1 PK (3) PO (1)	TO 1
		drinking-water	3					
	Wet chemistry	water sewage	3	3	1,3,4	3	1 PK (3) 2 PK (4) PO (1)	TO 2
		drinking-water	3	3				
Organoleptic	Taste	drinking-water	1	1	1,3,4	1	1 PK (1, 2, 3)	TO 1 TO 2
	Colour	drinking-water	1	1		1		
	Smel	drinking-water	1	1		1		
Microbiological	-	drinking-water	3	3	5,6	2	2 PK (5) PO (6)	TO 3
Radiation monitoring	-	water sewage	1	1	7,8	2	2 PK (7) PO (8)	TO 4
		drinking-water	1					
Determination of properties (pH, dry matter, etc.)	PH measurement	drinking-water	1	1	2,3	1	1 PK (2)	TO 1 TO 2
		soil	1					
	weight method (dry, suspended)	water sewage	2	2	2,3	1	1 PK (3)	
		drinking-water	2	2		1	1 PK (2)	

	The number of witnessing planned for the accreditation cycle	Number of maintenance	CAB's personnel
1 PK	8	2	1, 2, 3
2 PK	5	3	3, 4, 5, 7
PO	6	4	1, 2, 4, 6, 8

Amendments registration sheet

No	Date of introduction of the amendment	No of notification of the amendment, date of approval	Paragraph amended	Signature of the person who introduced the amendment	Full name of the person who introduced the amendment
1	2	3	4	5	6