

**DP SM 7.4-02-2020****SAMPLING FOR ASSESSMENT OF CERTIFICATION BODIES**

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## 1 SCOPE

1.1 This documented procedure (hereinafter – the procedure) is a management system document of Republican Unitary Enterprise "Belarusian State Centre for Accreditation" (hereinafter – BSCA) developed to further clause 7.4 of BSCA Quality Manual with account of chapter 7 of GOST ISO/IEC 17011 and lays down the procedure for sampling for the accreditation process of certification bodies (hereinafter CB).

1.2 The requirements of this procedure are mandatory for personnel involved in accreditation process of CB.

## 2 REFERENCES

This procedure contains references to the following documents:

Accreditation Rules as approved by the Resolution of the State Committee on Standardization of May 31, 2011 No. 27

Order of the State Committee for Standardization of the Republic of Belarus dated May 22, 2018 No. 82 "On approval of classifiers of fields of competence of expert-auditors on confirmation of conformity of conformity assessment objects"

STB 1470 Food Safety Management Systems. Food safety management based on hazard analysis and critical control points. General requirements

STB 18001 OSH management systems. Requirements

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

STB ISO 9001 (ISO 9001, IDT) Quality management systems. Requirements

STB ISO 14001 (ISO 14001, IDT) Environmental management systems. Requirements with guidance for use

STB 16949 Quality management systems. Specific requirements for the application of STB ISO 9001-2015 for organizations involved in the supply chains of automotive, agricultural, material handling, mining and special machine engineering

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

STB ISO 22000 (ISO 22000, IDT) Food safety management systems. Requirements for any organization in the food chain

STB ISO/TS 22003 (ISO/TS 22003, IDT) Food safety management systems. Requirements for bodies providing audit and certification of food safety management systems

STB ISO/IEC 27001 (ISO/IEC 27001, IDT) information technology. Security techniques. Information security management systems. Requirements

STB ISO 50001 (ISO 50001, IDT) Energy management systems. Requirements with guidance for use

STB ISO 50003 (ISO 50003, IDT) Energy management systems. Requirements for bodies providing audit and certification of energy management systems

GOST ISO 13485 (ISO 13485, IDT) Medical devices. Quality management systems. Requirements for regulatory purposes

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

ISO 45001 Occupational health and safety management systems — Requirements with guidance for use

TKP 030 Good manufacturing practice

OK RB 005 Types of economic activities

OK RB 007 Classifier of products by type of economic activities

RK SM BSCA Quality Manual

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

IAF MD 4 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

IAF MD 8 Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)

IAF MD 9 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

IAF MD 16 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

IAF MD 17 Witnessing Activities for the Accreditation of Management Systems Certification Bodies

IAF MD 22 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

IAF ID 12 Principles on Remote Assessment

IAF ID 1 IAF Informative Document for QMS and EMS Scopes of Accreditation

UAE.S 2055-2 Halal products - Part 2: General Requirements for Halal Certification Bodies

EA-3/12 M EA Policy for Accreditation of Organic Production Certification

*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 ACRONYMS AND ABBREVIATIONS

Denotations and abbreviations used in this procedure are as follows:

BSCA, accreditation body	- Republican Unitary Enterprise «Belarusian State Centre for Accreditation»;
LA	- Lead assessor
DP	- documented procedure;
OA №1, №2	- Department of accreditation No. 1, No. 2;
OAOS	- Department for certification bodies accreditation;
CB	- certification body;
CB SM 9001	- quality management system certification body;
CB SM 1470, 22000	- certification body for food safety management systems;
CB SM 13485	- certification body for medical device quality management systems;
CB SM 14001	- certification body for environment management systems;
CB SM 18001	- certification body for occupation health and safety;
CB SM 27001	- certification body for information security management systems;
CB SM 45001	- certification body for management systems for the impact of professional activities on health and safety;
CB SM 50001	- certification body for energy management systems;
CB SM 030	- certification body for production sites for compliance

CB SM 16949	with the rules of GMP; - certification body for management systems for organizations involved in the supply chains of automotive, agricultural, material handling, mining and special machine engineering;
Accreditation extension CU TR (EAEU)	- accreditation in an additional scope of accreditation; - Technical Regulation of the Customs Union (Eurasian Economic Union);
MS	- management system;
TA	- technical assessor;
EA	- European co-operation for Accreditation;
GMP	- Good Manufacturing Practice;
IAF	- International Accreditation Forum;
IDT	- abbreviation of an identical degree of compliance with an International Standard (identity in technical content and structure)

## 5 RESPONSIBILITY AND AUTHORITY

Responsibilities of personnel for the activity described in this instruction are reflected in Annex 1 of documented procedure DP SM 7.

## 6 SAMPLING

### 6.1 General

6.1.1 When preparing for the assessment of competence of a certification body (hereinafter – assessment) the following objects are to be sampled for the purposes of the assessment:

- elements of management system of the CB;
- representative samples of scope of accreditation;
- personnel;
- locations of CB.

6.1.2 The sampling for assessment is carried out by team leader on the basis of analysis of information provided by CB before the assessment, including passport of technical competence in accordance with Appendix 5 of the Accreditation Rules.

6.1.3 The sampling for assessment is carried out so that to assess all elements of fundamental standard, all CB activities (codes/clusters/technical areas), all locations and personnel in accreditation cycle.

*Note 1: accreditation cycle starts from the date Technical commission for accreditation (TKA) made decision on accreditation or re-accreditation.*

*Note 2: for CB SM 9001, 14001, EA codes correspond to those in IAF ID 1, for CB SM 18001 EA codes correspond to those in IAF MD 22, for CB SM 1470, 22000 clusters and categories correspond to those in STB ISO 22003, for CB SM 13485 technical fields correspond to those in IAF MD 8, for CB SM 50001 technical areas correspond to those in STB ISO 50003, for CB SM 27001 EA codes correspond to those in IAF ID 1, for organic products CB products categories correspond to those in EA-3/12, for Halal CB products categories correspond to those in UAE.S 2055-2.*

Clustering of EA codes/categories is provided in IAF MD 17 (for CB SM 9001, 14001/45001/18001), IAF MD 22 (for CB SM 18001), IAF MD 16 (for CB SM 1470, 22000), technical areas to main technical areas in IAF MD 8 (for CB SM 13485).

The combination of codes for product/service/personnel is given in the Classifiers of fields of activity, approved by the order of the State Committee for Standardization of the Republic of Belarus of May 22, 2018 No. 82 (for CB of products, service, personnel).

*Note 3: assessment of CB activities and personnel is possible through application of any assessment techniques (at least once).*

*Note 4: When conducting witnessing the same client organization should be avoided during the cycle.*

6.1.4 In accordance with clause 16 of Accreditation Rules, when developing a CB assessment plan (Annex 10 to DP SM 7) team leader in agreement with assessment team members plans to conduct assessment using various assessment techniques (Annex 1).

## **6.2 Responsibility of the assessment team**

Before each assessment, BSCA appoints an assessment team competent in specific field of accreditation. To increase efficiency, the members of the assessment team work independently (except for the assessor who works together with team leader) according to technical assignment developed by team leader in accordance with the assessment plan.

Team leader assesses the CB management system (quality manual and other documents), including through interviewing the person in charge of the management system and other employees of the certification body.

Technical experts assess certification processes in the fields in which they are competent. A technical expert shall be competent and able to prove from a technical point of view representative objects selected from all groups of certification processes for the purposes of the assessment.

## **6.3 Mechanisms of implementation**

In order to ensure the assessment of a CB for all objects (paragraph 6.1.1), BSCA applies a balanced combination of various techniques (Annex 1).

## **6.4 Sampling of fundamental standard elements**

6.4.1 When selecting objects for the assessment the team leader takes into account the results of the previous assessment: those elements of the standard for which nonconformities were identified and concerns from the previous assessment are to be assessed mandatorily. In addition, the results of analysis of passport of technical competence submitted by the CB are taken into account in terms of changes since previous assessment, information on activities in the field of accreditation, etc.

### **6.4.2 Document review**

During accreditation and re-accreditation, all elements of the CB management system are assessed.

During surveillance of competency the following elements of the CB management system are included in the assessment plan: impartiality requirements, resource requirements, complaints and appeals, management reviews, internal audits, nonconformities, and corrective actions.

When extending accreditation the CB assessment is carried out for those elements of the management system that have been amended as a result of the expansion of accreditation and for the entire additionally declared area of accreditation.

In case of an unscheduled assessment of competence, the assessment plan shall include those elements of the CB management system which are affected by the appeal which requires unscheduled assessment.

In case of follow-up assessment, the assessment plan includes those elements of the CB management system which were not assessed (if the assessment plan was not fulfilled for reasons depending on the conformity assessment body) and/or for which nonconformities were identified and it is impossible to assess their elimination through documentary evidence.

During the preliminary assessment of competency, the following elements of the CB management system are included in the assessment plan: impartiality requirements, resource requirements, organizational structure, complaints and appeals, management review, internal audits, nonconformities and corrective actions, document control.

### **6.4.3 File review**

When applying the technique of a file review the assessment team assessed CB compliance with the CB management system requirements: resource requirements, process requirements.

## **6.5 Sampling of accreditation scope**

### **6.5.1 Witnessing**

#### **6.5.1.1 For management system certification bodies**

During accreditation, surveillance, extending of accreditation, re-accreditation, witnessing is carried out according to technical clusters taking into account the rules established in IAF MD 17 (for CB SM 9001, 14001, 45001/18001), IAF MD 16 (for CB SM 22000, 1470) , IAF MD 8 (for CB SM 13485), to technical areas (for CB SM 50001), to groups (for CB SM 030).

When conducting accreditation or extending accreditation, witnessing of the CB is carried out in each scheme of the management system by key code (for CB SM 9001, 14001, 45001/18001)/cluster (for CB SM 1470, 22000)/main technical area (for CB SM 13485)/technical area (for CB SM 50001)/in each group (for CB SM 030). In absence of a CB application for certification modeling of a process is allowed for the purposes of the assessment (for example, audit process, etc.).

The CB shall provide witnessing for each management system scheme for each key code (for CB SM 9001, 14001, 18001/45001)/cluster (for CB SM 1470, 22000)/main technical area (for CB SM 13485)/ technical area (for CB SM 50001)/in each group (for CB SM 030) during the cycle accreditation.

In accordance with the documented procedure DP SM 7 a program of surveillances and re-accreditation for the accreditation cycle and a program for covering accreditation scope in accreditation cycle are developed.

For CB SM 9001, 14001, 18001: program for coverage of accreditation scope shall ensure that in accreditation cycle all EA codes are covered through witnessing or file review in each management system scheme. If CB seeks accreditation or extension of existing accreditation only in non-key EA codes, then witnessing is carried out at least in each management system scheme in each cluster using one of the non-key EA codes. For the purposes of extending accreditation in the existing cluster, assessment of CB is possible through a document review technique which shall confirm the competence of CB personnel in non-key EA codes.

The possibility of granting accreditation in any EA code in full (taking into account the OK RB 005) depends on the ability of CB to demonstrate competence in the declared codes OK RB 005.

For CB SM 1470, 22000: witnessing in cluster “Food and feed processing” is carried out annually, for other clusters – at least once during the accreditation cycle. For the purposes of extending accreditation witnessing of the CB is required in additional category of the new cluster. For the purposes of extending accreditation within the existing category, assessment of CB is possible through a document review technique which shall confirm the competence of CB personnel in the existing category.

For CB SM 13485, witnessing is conducted for each main technical area.

For CB SM 27001, witness is conducted once during the accreditation cycle.

For CB SM 50001: witnessing is conducted for each technical area.

#### **6.5.1.2 For CB for products, services, personnel**

When conducting accreditation, surveillance of competence, expanding accreditation, re-accreditation, the choice of assessment technique depends on the nature of the conformity assessment (mandatory and voluntary forms).

If the products are subject to the mandatory conformity assessment in the form of certification, the CB competency assessment is carried out in each code (section (two-digit code) of OK RB 007)/CU (EAEU) TR using the following techniques: witnessing, interviewing, file and records review.

If the products are subject to the mandatory conformity assessment in the form of a declaration, the CB competency assessment is carried out in each code (section (two-digit code) of OK RB 007)/CU (EAEU) TR using the following techniques: interviewing, file and records review.

If the products are not subject to the mandatory conformity assessment (are voluntary), the CB competency assessment is carried out in each code (section (two-digit code) of OK RB 007) using the following techniques: interviewing, file and records review.

The program for covering the accreditation scope should provide the assessment of the CB in each code (section OK RB 007)/ CU (EAEU) TR) (for CB products)/in each code (for CB services, personnel) for an accreditation cycle.

In accordance with DP SM 7, a program of surveillances of competence and re-accreditation for the accreditation cycle and a program for covering the accreditation scope are being developed.

#### **6.5.1.3 For Halal CB**

When conducting accreditation, expanding accreditation, witnessing of the CB is carried out for each category established by UAE.S 2055-2.

In accordance with DP SM 7, a program of surveillances of competence and re-accreditation for the accreditation cycle and a program for covering the accreditation scope are being developed.

The program for covering the accreditation scope should provide coverage for all categories during the accreditation cycle through witnessing and file review.

#### **6.5.1.4 For CB for organic products and their production processes**

When conducting accreditation, expanding accreditation, witnessing of the CB is carried out for each category.

In the case of conducting a witnessing by modeling, the CB must ensure that the witnessing is conducted for each category after receiving accreditation upon receipt of the first certification application.



In accordance with DP SM 7, a program of surveillances of competence and re-accreditation for the accreditation cycle and a program for covering the accreditation scope are being developed.

The surveillance of the CB competence is carried out annually.

The program for covering the accreditation scope should provide coverage for all categories during the accreditation cycle through witnessing and file review.

### **6.5.2 Assessment using the technique of document review**

When conducting accreditation or extending accreditation assessment of a CB through document review is not allowed.

The file review technique is used when conducting the CB surveillance.

The total number of certification files subject to document review is calculated according to the formula:

$$X = \sqrt{n/5}, \text{ where}$$

X - the number of certification files to be assessed

n - the total number of certificates of conformity issued by the CB in the areas under assessment

The number of files to be assessed is calculated separately for certificates of conformity and declarations of conformity.

*Note 1: in case of nonconformities raised during document review, the assessment team may request additional certification cases to identify repeated nonconformities.*

With extending accreditation of personnel CB within a single certification scheme, CB assessment is done through document review.

### **6.5.3 Assessment using the technique of interviewing**

During accreditation, periodic assessment of competence, extending accreditation, re-accreditation, assessment of a CB by applying interviewing technique is usually carried out in combination with other techniques: witnessing and (or) file review.

## **6.6 Sampling of personnel**

6.6.1 The criteria for selecting CB personnel to be assessed are as follows:

- the number of certification work performed (since previous assessment);
- results of previous assessment;
- changes that have occurred in CB personnel (since personnel);
- responsibility assigned to personnel according to the elements of the fundamental standard.

6.6.2 The assessment team determines CB personnel to be assessed: at least one CB expert for each selected representative assessment object.

6.6.3 When selecting CB personnel to be assessed, the results of previous assessments are taken into account so that during the accreditation cycle all key personnel of the CB (full-time and external) operating within the accreditation scope are assessed at least once by one of the techniques referred to in Annex 1.

*Note 1: It is preferable to conduct witnessing of personnel who have not previously been observed.*

## 6.7 Sampling of locations

6.7.1 For accreditation and extending accreditation, assessments of a CB is carried out at all locations in the declared accreditation scope. In justified cases, a remote assessment is possible.

6.7.2 For a surveillance and re-accreditation, if there are several locations for the activity to be assessed, then the assessment team selects locations for the assessment taking into account representative samples of locations.

6.7.3 When choosing an assessment venue, the results of previous assessments are taken into account so that all CB locations in the declared scope of accreditation are assessed at least once (the main location is assessed at each assessment, additional locations at least once during the accreditation cycle).

*Note 1: The main location of CB includes the office premises where key activities are carried out including maintenance of working records related to the process and results of certification, and the workplaces of experts.*

*Note 2: Additional CB locations are premises in a location other than the main location (may be in another city) and where no key activities take place.*

*Note 3: Key Activities include:*

- *formulation and approval of policies;*
- *development and approval of processes and procedures;*
- *review of applications and contractual obligations related to certification work;*
- *analysis of certification results and making decisions on certification;*
- *storage of records;*
- *consideration of appeals and complaints and making decisions.*

## 6.8 Cross-border accreditation

If a certification body certifies activities outside the Republic of Belarus, BSCA conducts witnessing at least once in the accreditation cycle in each country where the certification body conducts its activities.

## 7. MANAGEMENT OF RECORDS

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

## Selection of assessment techniques

### 1. General

CB assessment techniques include:

- on-site assessment;
- remote assessment;
- witnessing;
- document review;
- file review;
- interviewing.

In order to cover all objects of assessment (clause 6.1.1), the accreditation body uses a balanced combination of various assessment techniques, including:

- assessment of management system elements (mandatory) is performed through techniques:
  - interviewing,
  - document review,
- assessment of representative objects of assessment according to the accreditation scope of the CB, personnel, which is carried out through techniques:
  - interviewing;
  - witnessing;
  - file review;
  - document review (when assessing personnel competence).

#### 1.1 Document review

Document review is an assessment of one process from its beginning to its completion (for example, conducting an internal audit according to internal procedures adopted by CB and developed according to the requirements of a fundamental standard).

In a document review, an assessor checks operations one after another, verifying in detail how each of them is performed, without being distracted by interconnected processes.

The advantage of this technique is the ability to verify in detail all the actions of one process, all the supporting documentation for this process, all the personnel involved in this process.

Document review is used to assess performance of individual elements of a fundamental standard.

It is recommended to plan a document review for those elements against which nonconformities were raised during previous assessment and if there are significant changes that have occurred in the CB management system.

#### 1.2 File review

File review is a complete assessment of all aspects of certification work for a selected representative object of assessment.

File review includes assessment of the CB competence in carrying out certification work on a selected representative object of assessment in practice. When applying the file review technique in the accreditation scope, the assessment team reviews the CB records related to the work on conformity assessment according to the selected representative object of assessment.

During each assessment, at least one file review shall be performed in each representative object of assessment.

When conducting accreditation and expanding accreditation the file review technique is not applied.

#### 1.3 Witnessing

Witnessing is a type of activity in which a technical expert observes the performance of a CB without interfering or influencing the process.

The purpose of the witnessing is to gain confidence in the competence of the certification body within the scope of accreditation.

Depending on the purpose, the witnessing can be carried out for the work in full or in part, for the stages of interest. The witnessing is carried out on the premises of the CB client or by conducting a witnessing on a remote access using electronic means (subject to the provisions of IAF ID 12 and the requirements of IAF MD 4).

During accreditation, expansion of accreditation in justified cases, to assess the CB competence in the certification work for the selected representative object of assessment, modeling is allowed, for example, the development of a program and an audit plan, work records, provided that the CB will inform the accreditation body in advance and provide an opportunity for monitoring upon receipt of the first application for certification work within the framework of the accreditation received. At the same time, additional interviewing is carried out for personnel directly involved in this activity.

В ходе свидетельской оценки член(ы) группы по оценке БГЦА:

During the witnessing, the member(s) of the BSCA assessment team:

- has (have) the right to ask questions for further clarification on completion of the assessment;
- does (do) not express own opinion about the assessed certification body or the applicant of the certification body, in the presence of a representative of the applicant of the certification body.

In such a situation, all discussions between the member(s) of the BSCA assessment team and the staff of the certification body being assessed must to be conducted privately in order to maintain the confidentiality of the assessment results.

*Note: if it is not possible to witness selected representative object of assessment during the assessment (for example: duration of the process, etc.) the assessment team may agree to witness this activity either 3 months before or after the planned assessment. If the CB does not provide the opportunity to conduct an assessment in the indicated time without a justified reason, the assessment team is obliged to recommend Technical Commission for Accreditation to consider suspension of accreditation of this CB.*

*Note: an example of achieving the goal of a certain activity through partial witnessing is absence of nonconformities raised during witnessing of one and the same CB auditor during two previous accreditation cycles in the same codes/clusters/technical areas at least twice.*

#### **1.4 Interviewing**

Interviewing is an assessment of CB personnel's competence, knowledge and skills, carried out through direct oral communication between an assessor and CB personnel.

When applying the interviewing technique, a situational interview can be used in which CB staff is asked to solve a typical situation, and he/she must state the sequence of his/her actions and explain the appropriateness of his/her decisions. At the same time, clarifying questions are asked in order to find out how a CB employee will behave if events develop in one way or another. This method allows comprehensively assess the competence of CB employees and their theoretical knowledge.

As a rule, this technique is combined with other assessment techniques to obtain more comprehensive information about experience, skills and knowledge of the staff under assessment.

#### **1.5 Remote assessment**

Remote assessment is an assessment of physical or virtual location of the CB and of the implementation of CB activities using electronic means such as online video conferencing applications (e.g. Skype).

Remote assessment can be carried out in the following cases:

- when an on-site assessment is not possible due to unforeseen force majeure situations related to current inability to physically visit CB (due to a threat to safety of assessment team members, travel restrictions);
- if a CB demonstrates consistent implementation of its management system, in which records, data, etc. can be traced on any site, regardless of where the work is performed;
- when a CB has traceable and record-based compliance at the location of the remote assessment;
- if follow-up assessment is needed but there are difficulties in taking a trip in a short time.

Remote assessment is not allowed in the following cases:

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

When expanding accreditation, a remote assessment by an LA is allowed if the CB is able to demonstrate the availability of personnel, to adequately perform all the functions of conformity assessment.

**Revision record sheet**

<b>No</b>	<b>№ of order on modification/ enter into force</b>	<b>Date of approval/ enter into force</b>	<b>Paragraph changed</b>	<b>Signature of the person who introduced the change</b>	<b>Print name of the person who introduced the change</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>