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PROCEDURE

FOR

FLEXIBLE ACCREDITATION SCOPE

List of amendments

№	Date	Version, revision	Reason for amendment	Effective of/ Entry in to force:
1	*20.07.2021*	*Version 1, Revision 1*	*Amendment and suplementation in regard to the findings of the EA Team conducted the first part of the peer-evaluation*	*15.09.2021*
2.	*13.09.2021*	*Version 1, Revision 1*	*Modification of the date of entry into force of the document in connection with a report by the quality manager Ent. № 20-02 / 005 / B / 13.09.2021*	*15.10.2021*

CONTENTS

1. PURPOSE

The purpose of the procedure is to determine the policy and process of EA BAS for assessment and accreditation of CABs that wish to implement and maintain a management system capable of controlling the flexible scope of accreditation.
The procedure contains the general set of criteria that allow the CAB to take responsibility for the management of the entire scope of accreditation or part of it without prior assessment by EA BAS for each new activity. It is intended for accredited CABs and assessors of EA BAS, participating in the assessment process for providing accreditation for flexible scope.

2. TERMS, DEFINITIONS AND ABBREVIATIONS

2.1. Terms, definitions

For the purposes of this procedure, the relevant terms and definitions given in ISO EC 17011 and ISO/IEC 17000 shall be used.

2.2. Abbreviations

EA BAS - Executive Agency "Bulgarian Accreditation Service"
CAB - Conformity Assessment Body
BAS QR 2 - Accreditation procedure of EA BAS

3. FORMULATION OF THE SCOPE OF ACCREDITATION

3.1. Fixed scope of accreditation

The fixed scope of accreditation describes in detail the activities that have been assessed and accredited by EA BAS and ensures that the competence of the CAB for each activity that is added/extended to the scope has been assessed.

3.2. Flexible scope of accreditation

Flexible scope, as defined in ISO / IEC 17011, is the scope of accreditation, expressed in such a way as to allow conformity assessment bodies to make changes in methodology and other parameters that fall within the competence of the conformity assessment body, as well as has been confirmed by the accreditation body.

The introduction of new methods, products, processes, services or parameters / characteristics and schemes is carried out according to the procedure and requirements for extension of the scope of accreditation, described in the Accreditation Procedure of EA BAS, BAS QR 2.

Flexible scope can refer to the whole scope or a certain part of it. The flexible scope may be a combination of fixed and flexible parts of the scope or may be a substantially fixed scope comprising, for example, one or two flexible activities.

4. EA BAS ACCEDITATION POLICY FOR FLEXIBLE SCOPE.

Conformity assessment bodies may be accredited for flexible coverage, subject to the following conditions:

- The introduction of new updated versions of the standards or other documents, in which the methods are described, must be performed in shorter terms, in comparison with the planned on-site assessments by EA BAS;

- When there is a customer requirement.

EA BAS provides accreditation of flexible scope, when the modifications of the accredited scope do not include new methods, not covered by an accredited scope.

Flexibility can cover the whole scope of accredited activities or only part of them. This means that part of the accredited activities may have a fixed scope and another part a flexible scope. The flexible scope defined in the certificate and the order to it should not require a change in the process of its application by the CAB. If such a change is necessary, it is considered an extension.

For certification bodies of management systems, bodies for certification of persons, bodies for validation and verification and *Certification Bodies for purposes of notification* - provides only a fixed scope of accreditation

4.1. EA BAS provides flexible scope with the following degree of flexibility:

4.1.1. Application of new (updated) versions (editions) of documents defining the methods or criteria for conformity assessment used by the CAB (standards or other documents) or the documents that replace them.

It applies to inspection bodies, product certification bodies, test laboratories, calibration laboratories, test and calibration laboratories and medical laboratories *for conformity assessment activities in the voluntary field. It does not apply to accredited CABs and candidates for accreditation for the purposes of notification.*

4.1.2. Flexible scope based on common flexibility test methods for:

– Products, groups/subgroups of products (according to a given description);
– Type of test/characteristic;
– and/or a combination of them,
if this does not alter the applicability of those test methods.

Applies to testing laboratories for *activities in the voluntary field.* medical laboratories and PT Providers for.

Laboratories must maintain a detailed, dated list of Products, product groups/subgroups and characteristics belonging to those mentioned in the flexible scope of accreditation.

Within the framework of the granted accreditation, it is necessary for the CAB to maintain records for all performed verifications / validations and to be able to constantly demonstrate its competence in full.

In general, it is considered that the standardized test methods describe the product / performance / method requirements sufficiently and are therefore not suitable for providing a flexible scope within the meaning of paragraph 4.1.2.

The policy of EA BAS is not to provide accreditation for a flexible scope of calibration laboratories and testing and calibration laboratories in the calibration part within the meaning of item 4.1.2.

5. REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

5.1. General applications

It is the responsibility of the CAB to demonstrate and provide evidence of competence and compliance with the accreditation requirements.
Flexibility is a reflection of the CAB's competence not only to technically carry out the activities covered by the accreditation, but also its ability to manage the process of implementing the flexible scope and its commitment to offer accredited activities within that scope.
The CAB must describe and announce to its potential customers the limits of its accredited flexible scope.
CABs, as well as EA BAS, should in no way suggest that CABs with flexible scope are more competent than those with fixed scope.

5.2. Criteria for flexibility scope assessment

5.2.1. The CAB have to documented the process for analysis, development and implementation of a flexible scope, indicating the following:

- How to determine the input requirements
- How conformity assessment services are developed
- How to validate, that the requirements are met
- How is it verified, that the CAB has met the requirements
- Responsibilities for flexible management and for each area of activity;
- The contract review process confirms and informs the client/contracting authority that the application falls within its flexible scope
- Information on what is covered by the accreditation is transparent and accurate

5.2.2. CABs have to shall maintain a List of dated versions of the standards, technical specifications and normative documents against which they carry out their conformity assessment activities within the accredited flexible scope.

5.2.3 The list must be kept up to date and made publicly available.

5.2.4 The contract review procedure should describe in detail the actions of the CAB, when requesting a service that is within the accredited flexibility, but has not been performed before. In this case, the CAB must:

- to inform the client about his inability to issue a report/certificate under accreditation until the documented process of CAB for development and approval of the service / activity within the flexible scope is completed
- to inform the client about the relevant consequences (eg change of terms and price)
- to have all the necessary resources and other means necessary for the completion of the specific requested service;
- to have staff with appropriate qualifications for the implementation of the specific service and its validation or verification;
- validate or verify the method described in the new standard
- update the List only after performing all necessary technical activities, according to the documented CAB process for development, implementation and validation of activities within the flexible scope.
- to use premises in connection with the flexible scope, which have been declared in advance and assessed by EA BAS. Otherwise, the activity cannot be included in the List of flexible scope of CABs.

If the process of validation of an activity leads to the conclusion that the CAB is not able to issue valid reports / certificates, the CAB must ensure that an analysis of the cause is performed and adequate corrective action is taken. Such actions by the CAB must include:

- Informing the client that while the analysis and all subsequent actions are performed, the CAB will not be able to issue accredited reports / certificates and the reasons for this
- Review the relevant procedures or methods to address the identified problem and ensure that it does not recur in the future
- Redefining the boundaries within which the scope is flexible. In this case, the CAB must inform EA BAS in order to check whether the way in which the scope of accreditation is described should be changed.

6. APPLICATION FOR FLEXIBLE SCOPE

CABs may apply for flexible scope in initial accreditation and in case of extension of the scope of accreditation for degree of flexibility in the sense of item 4.1.1

For the degree of flexibility in the sense of item 4.1.2 CABs can apply after the first cycle of accreditation (after initial accreditation), when the stability of the management system is confirmed by EA BAS.

CABs with a fixed scope of accreditation can apply for flexible scope by submitting an application for extension of the scope of accreditation.

CABs submit to EA BAS the following documents, in addition to the documents required when applying for re-accreditation and extension of the scope:

- Scope of accreditation, with a specified degree of flexibility - for all or part of the scope;
- Procedure for application of flexible scope, according to item 5.2;
- List of staff responsible for flexible coverage.

7. FLEXIBILITY ASSESSMENT AND ACCREDITATION

7.1. EA BAS considers applications for flexible scope, assessing the risks associated with each specific activity and CAB.

7.2. In determining the level of risks associated with the activities and the possibility of CABs to be accredited with flexible scope, EA BAS considers in the accreditation process the following aspects in the activities of CABs:

a) The degree of understanding of the CAB of the rules and procedures for the implementation and management of flexible scope;

b) Efficiency and stability of the CAB management system;

c) The complexity of conformity assessment activities;

d) Degree of flexibility requested by the CAB;

e) The risks for the reputation of EA BAS, CAB and for the market;

f) Ensuring constant technical competence of the CAB staff responsible for the activities related to the flexible scope;

g) Knowledge and compliance of CABs with relevant standards and activities;

h) The expectations of stakeholders and regulators;

i) The planned frequency of use of the flexible range;

j) The degree and scope of controls proposed by the CAB for the management of flexible scope;

k) Risks from locations and geographical features.

A risk assessment shall be performed by a scheme manager for the relevant accreditation scheme when reviewing an application for a flexible scope for the aspects referred to in points (c), d), e), h), I), k) and by a lead assessor in the evaluation and reporting process for the aspects referred to in points (a), (b), (f), (g), (j). The risk assessment shall be documented in the application review form and in the lead assessor's report.

The CAB assessment program is prepared in accordance with BAS QR 2 and BAS QI 2, and when assessing the risks, the aspects described in item 7.2 are also considered. The plans for the specific assessments shall also include an assessment of the flexible scope, adding additional time, depending on the degree of flexibility (for all or part of the scope), the frequency of application of the flexible scope of the CAB and the degree of assessed risk.

During the on-site assessment of flexible scope, the teams of EA BAS assess the compliance of the CAB with the requirements specified in item 5.2 and monitor the activity in which the change has occurred and the CAB has applied its procedure for flexible scope or sample from it.

The on-site assessment includes:

(a) an assessment of the competence and ability of the CAB to carry out any activity covered by the flexible scope of accreditation;

b) assessment of the management and control system applied by the CAB in order to maintain a flexible scope of accreditation;

c) assessment of the process of reviewing, validating, approving and authorizing modified activities for use within the flexible scope of accreditation, including risk assessment;

7.3. To assess the competence of the CAB to manage a flexible scope of accreditation, EA BAS will use the following methods and techniques for assessment:

a) assessment of CAB documentation for flexible scope management;
b) assessment of the effective implementation of CAB procedures;
c) assessment of the adequacy of the CAB competence criteria for all key personnel;
d) verification of the adequacy of the existing mechanisms for determining and monitoring the competence of CSO staff;
e) interviews with key staff designated by the CAB to assess the competence of the staff responsible for implementing the flexible scope;
f) evaluation of CAB records to justify the development and implementation of a flexible scope.
The sample for monitoring the activity is determined so as to confirm the current control and effective implementation by the CAB of:

- all changed activities;
- validation of the changed activities;
- metrological assessment, where applicable / quality assurance mechanism;
- competence and training of the staff involved in the changed activities;
- provided access of the staff to the necessary working procedures / instructions, regulatory requirements, standard, etc .;
- comparisons with other activities;
- -Risk Assessment.

Information about the assessed flexible scope is documented by the team of EA BAS, clearly indicating the scope proposed for accreditation as flexible.
When it is established that the applicant for flexible scope does not meet the requirements specified in item 5.2, EA BAS refuses to provide flexible scope to the CAB.
When it is established for a CAB with granted flexible scope that it has issued reports / certificates under accreditation, without fulfilling the requirements specified in item 5.2, the teams of EA BAS will find a discrepancy related to the application of flexible scope.

Depending on the nature of the non-compliance, the severity and its consequences, EA BAS provides an opportunity for the CAB to carry out corrective actions in order to eliminate the non-compliance, to limit the flexibility for part or all of the accredited scope. Carrying out corrective actions is in accordance with BAS QR 2.

8. PRESENTATION OF FLEXIBLE ACCREDITATION SCOPE

8.1. For inspection bodies and product certification bodies:

In cases where the whole scope is flexible, the standards / documents are not dated. In the accreditation order before the table is written Type of scope: "flexible scope *", and below the table are added a note with the following text:

"The introduction of a new version of the standards or standards that replace them is allowed. An up-to-date list of the standards with their dated versions is provided by the CAB. "

When the scope is a combination of fixed and flexible, the order to the accreditation certificate before the table shall state "fixed and flexible scope" and the standards / documents in the part of the flexible scope shall be marked with the sign "*" and a note below the table indicating that the marked range is flexible:

*"For areas / standards marked with an" * ", the introduction of a new version or a standard that replaces them is permitted. An up-to-date list of the standards with their dated versions is provided by the CAB."*

8.2. For testing laboratories, calibration laboratories, medical laboratories, suitability test organizers.

8.2.1.In the cases when a flexible scope is provided in the sense of item 4.1.1 In the accreditation order before the table is written Type of scope: "flexible scope *", and under the table a note with the following text is added:

"The introduction of a new version of the standards or standards that replace them is allowed. The laboratory maintains an up-to-date list of standards with their dated versions. "

8.2.2 In the cases when a flexible scope is provided in the sense of item 4.1.2 In the accreditation order before the table is written Type of scope: "flexible scope *", and under the table a note with the following text is added:

** Within its competence, the laboratory is authorized to determine all the characteristics (column 3) according to the marked test methods (column 4) belonging to the product group (column 2) after verification, verification with CPM / PM and calibrated technical resources. The laboratory maintains a detailed, dated list of products and characteristics belonging to the products mentioned in the scope of accreditation.*

When the scope is a combination of fixed and flexible, the order to the accreditation certificate before the table shall state "fixed and flexible scope" and the standards / documents in the part of the flexible scope shall be marked with the sign "*" and a note below the table indicating that the marked range is flexible.

9. APPLICABLE DOCUMENTS

EA-2/15 M	"EA Requirement for the Accreditation of Flexible Scopes"
BAS QR 2	Accreditation procedure of EA BAS

BAS QI 2 Instructions for determining the duration of the on-site assessment. Influencing factors

BAS QA 2.X.1 Applications for accreditation

Application 1

EXAMPLES OF GRANTING FLEXIBLE ACCREDITATION SCOPE

1. Products Certification Body

To perform certification of products (processes) according to the following scope:

Scope type: flexible *			
№	**PRODUCTS**	**CERTIFICATION SCHEME**	**STANDARD / REGULATORY DOCUMENT**
1	2	3	4
1	Quality in fusion welding of metallic materials	ПК 7.1 Procedure "Scheme 6" ПК 7.2	БДС EN ISO 3834-1 БДС EN ISO 3834-2 БДС EN ISO 3834-3 БДС EN ISO 3834-4

** The introduction of a new version of the standards or standards that replace them is permitted. An up-to-date list of standards with their dated versions is provided by the CAB.*

To perform product certification according to the following scope:

Scope type: flexible *for part of the* scope			
№	**PRODUCTS**	**CERTIFICATION SCHEME**	**STANDARD / REGULATORY DOCUMENT**
1	2	3	4
1.	Safes *	Scheme A Scheme B Scheme C	БДС EN 1143-1 БДС EN 15659 БДС EN 14450 ТС
2.	Vaults	Scheme A Scheme B Scheme D	БДС EN 1143-1 ТС
5.	Doors, windows, shutters and grilles	Scheme A Scheme B Scheme C	БДС EN 1627* БДС EN 1522 ТС

For areas / standards marked with an "", the introduction of a new version or a standard that replaces them is allowed. An up-to-date list of standards with their dated versions is provided by the CAB*

2. Inspection bodies within the meaning of item 4.1.1

To performs control:

Scope type: flexible					
№	Area of control	Type of control	Controlled parameter / characteristic	Test methods / measurement used in control	Normative acts, standards, specifications, schemes
1	2	3	4	5	6

1.	Products made of metallic materials and their alloys	On new and / or in use / operation sites / facilities / products	Type and size of imperfections / imperfections	РП 7.1 БДС EN ISO 17636-1 БДС EN 12681-1 БДС EN ISO 10893-6	БДС EN ISO 5817; БДС EN ISO 6520-1; БДС EN ISO 17635; БДС EN ISO 10675-1; БДС 13060; БДС EN 12681-1; БДС EN ISO 10893-6;

The introduction of a new version of standards / documents or standards / documents that replace them is allowed. An up-to-date list of standards / documents with their dated versions is provided by the CAB.

To performs control:

Scope type: flexible *for part of the* scope					
№	Area of control	Type of control	Controlled parameter / characteristic	Test methods / measurement used in control	Normative acts, standards, specifications, schemes
1	2	3	4	5	6
1.	Noise in the working environment	Initial / periodic of new and / or in operation sites and facilities	- Daily noise exposure level - Average weekly noise exposure level - Peak sound pressure level - Noise level - Equivalent noise level	РПК 7.1-10 * БДС EN ISO 9612* (БДС ISO 1999:2014) БДС 15471:1982	Ordinance №6, (SG, issue 70/2005) Ordinance №7 (SG No. 88/1999) Ordinance №9 (SG No. 46/1994)
2.	Electrical installations and equipment for voltages up to and above 1000 V	Initial / periodic of new and / or in operation sites and facilities	Insulation resistance	BDS 1986: 1982, v.3.3 a), b), e) and f) PKK 7.1-05 Version 01 / revision 01 / 01.02.2020	Ordinance №16-116 (SG No. 26/2008) Ordinance №3 (SG No. 90 and 91/2004)

For areas / standards marked with "", the introduction of a new version of standards / documents or standards / documents that replace them is allowed. An up-to-date list of standards / documents with their dated versions is provided by the CAB.*

3. Testing laboratories

To performs control:

Scope type: flexible			
№	**Name of the products tested**	**Type of test/characteristic**	**Test methods (standardized / validated)**
1	2	3	4
x	Concrete	Density	БДС EN 12390-7 БДС EN 992
		Compressive strength	БДС EN 12390-3; БДС EN 1354
		Tensile strength in splitting	БДС EN 12390-6
		Bending strength	БДС EN 12390-5

"The introduction of a new version of the standards or standards that replace them is allowed. The laboratory maintains an up-to-date list of standards with their dated versions. "

To performs control:

Scope type: flexible *for part of the* scope			
№	**Name of the products tested**	**Type of test/characteristic**	**Test methods (standardized / validated)**
1	2	3	4
x.	Суровини и продукти от растителен произход, фураж и фуражни добавки	x.1 Влага/сухо вещество	ВЛМ-37
		x.2. Пестициди	ВЛМ-17*

** Within its competence, the laboratory is authorized to determine all the characteristics (column 3) according to the marked test methods (column 4) belonging to the product group (column 2) after verification / validation, CPM / PM security and calibrated technical funds. The laboratory maintains a detailed, dated list of products and characteristics belonging to the products and characteristics mentioned in the scope of accreditation.*

4. Medical laboratories

To performs control:

Scope type: flexible			
№	**Name of the products tested**	**Type of test/characteristic**	**Test methods (standardized / validated)**
1	2	3	4
1.	Тъкан	Хистология	ПК 5.5-2 *
		Имунохистохимия	ПК 5.5-3 *
		Флуоресцентна in situ хибридизация (FISH)	ПК 5.5-4 *
		Мултигенен експресионен анализ	ПК 5.5-5 *

Позовавания:

ПК 5.5-2 Хистология

ПК 5.5-3 Имунохистохимия

ПК 5.5-4 Флуоресцентна in situ хибридизация (FISH)

ПК 5.5-5 Мултигенен експресионен анализ

[b1]

* Within its competence, the laboratory is authorized to determine all the characteristics (column 3) according to the marked test methods (column 4) belonging to the product group (column 2) after verification / validation, CPM / PM security and calibrated technical funds. The laboratory maintains a detailed, dated list of products and characteristics belonging to the products and characteristics mentioned in the scope of accreditation..

To performs control:

Scope type: flexible *for part of the* scope			
№	**Name of the products tested**	**Type of test/characteristic**	**Test methods (standardized / validated)**
1	*2*	*3*	*4*
x.	Кръвен серум/плазма	x.1 Количествено определяне на HBV DNA	ПК-5.5.3-04
		x.2 Количествено определяне на HCV RNA	ПК-5.5.3-03
		x.3 Определяне на генотип на HCV	ПК-5.5.3-03
		x.4 Молекулярно-генетичен анализ на прогностични и предиктивни маркери	ПК 5.5-6 *
		x.5 Мултигенен молекулярно-генетичен анализ на прогностични и предиктивни маркери	ПК 5.5-7 *

Позовавания:

ПК-5.5.3-04	Процедура за количествено измерване на HBV DNA
ПК-5.5.3-03	Процедура за количествено измерване на HCV RNA + генотипиране
ПК 5.5-6	Молекулярно-генетичен анализ на прогностични и предиктивни маркери
ПК 5.5-7	Мултигенен молекулярно-генетичен анализ на прогностични и предиктивни маркери

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* Within its competence, the laboratory is authorized to determine all the characteristics (column 3) according to the marked test methods (column 4) belonging to the product group (column 2) after verification / validation, CPM / PM security and calibrated technical funds. The laboratory maintains a detailed, dated list of products and characteristics belonging to the products and characteristics mentioned in the scope of accreditation.

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