ACCREDITATION PROCEDURE

List of amendments

№	Date	Version, revision	Reason for amendment	Effective of/ Entry in to force:
1	09.09.2013 and 27.01.2014, voted on 14.11.2013 and 05.02.2014 by Accreditation Council		Corrective action in relation to the EA peer evaluation (June 2013), preventive actions, recommendations of the internal audit by the Ministry of Economy, Inspectorate of the Ministry of Economy	
2	05.11.2014, voted on 12.11.14 by Accreditation Council	Version 7, revision 1	Corrective action in relation to the FALB peer evaluation (September 2014), Improvement in the Management System	01.12.2014
3	16.03.2015, voted on 06.04.2015 by Accreditation Council	Version 7, revision 2	Corrective action in relation to non-compliance of internal audit (December 2014)	20.04.2015
4	08.02.2016, voted on 15.02.2016 by Accreditation Council	Version 7, revision 3	Update regarding to extention and improvement of the management system	01.03.2016
5	09.02.2017, voted on 16.02.2017 by Accreditation Council	Version 7, revision 4	Update regarding to extention and improvement of the management system and membership of IAF and ILAC international organizations	01.03.2017
6	06.03.2017, voted on 16.03.2017 by Accreditation Council	Version 7, *revision 5*	Update regarding to extention of the agreement with IAF for areas certification of management systems and products	01.04.2017
7	December 2017, voted on 09.02.18 by Accreditation Council	Version 7, revision 6	Update on EA BAS plan to reduce administrative burden and EA recommendations for improvement	01.03.2018
8	December 2019, voted on 11.12.19 by Accreditation Council	Version 8	Align with the requirements of БДС EN ISO/IEC 17011:2018	01.01.2020
9	December 2020, online voted on 11.12.2020 by Accreditation Council	Version 8, revision 1	Amendments and additions related on the improvement of the accreditation process and introduction of a flexible scope of accreditation	01.01.2021

1. INTRODUCTION

The Accreditation Procedure (the procedure) is developed on the grounds of the Law on National Accreditation of Conformity Assessment Bodies (LNACAB) and BDS EN ISO/IEC 17011:2018.

The fulfillment of the procedure guarantees performance of the accreditation in observation of the principles of lawfulness, independence, impartiality, publicity, equality, non-admission of competition and preservation of the manufacturing and commercial secrecy.

This document is applied for all CABs, including medical laboratories and environmental verifiers, carrying out activities either in regulated and non-regulated areas, and which are accredited or wish to obtain accreditation.

The present procedure acts jointly with other documents of the management system of Executive Agency "Bulgarian Accreditation Service" (EA BAS), and documents and guides noted in item 3 of the procedure.

All necessary documents for accreditation intended for CABs are published in Bulgarian and English languages on the agency's website: http://www.nab-bas.bg/, such as:

- Accreditation Procedure BAS QR 2;
- Rules of Accreditation Commission BAS QR 3;
- Rules of Appeals Commission BAS QR 4;
- Rules for the use of EA BAS Accreditation symbol BAS QR 5;
- Rules of Technical Accreditation Committees BAS QR 6;
- Price List of EA BAS accreditation services BAS QR 8;
- Rules of Procedure of the Accreditation Council BAS QR 10;
- Procedure for Implementation of Interlaboratory Comparisons and Proficiency Testing Schemes BAS QR 18;
- Procedure for settlement of complaints BAS QR 25;
- Procedure for application of EA "BAS" Traceability Policy BAS QR 27.
- *Instruction for Management of Assessment Programs BAS QI 2 and annexes thereto*;
- Instruction for accreditation of conformity assessment bodies in accordance with the requirements of Regulation (EU) No 305/2011 of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council's Directive 89/106/ EEC QI *2.4*
- Instruction on the criteria and methods of accreditation and surveillance of Environmental Verifiers according to Regulation (EC) 1221/2009 of the European Parliament and the Council BAS QI 4;
- Instruction on ethical conduct of the employees of the administration of EA "BAS" BAS QI 11;
- *Instruction on the criteria and methods of accreditation and supervision of Validation and verification bodies, BAS QI 12.*
- Instruction on Criteria and Methods of Accreditation and Supervision of Certification Bodies for Organic Products under Regulation (EC) No 834/2007 and Commission Regulation (EC) No 889/2008 BAS QI 19
- Instruction on the criteria and methods of accreditation and supervision of proficiency testing providers, as required by БДС EN ISO/IEC 17043 BAS QI 21
- *Instruction for management of extraordinary events or circumstances affecting bodies accredited by EA BAS and their clients, BAS QI 22*

These documents are valid from the date of approval, indicated on the first page of the document, except if else is explicitly specified. The amendments in the document are indicated in Italic font in the respective revision. When the amendments exceed 80%, a new version with a regular font shall be issued. In references to the documents is written their full identification with the respective version and revision. Exception is allowed in the cases when the date of reference can be exactly identified and is considered the present version and revision. When EA BAS refers to a document from its management system, it uses a short identification without version and revision, as it is considered that is used the latest valid revision of the document, except if else is specified with a transitional period

In the event of documents published in Bulgarian and English, the Bulgarian version is the definitive version.

For the purposes of this procedure shall apply the definitions laid down in Art. 2 of Regulation (EC) № 765/2008 and the definitions of the harmonized standards, data for which are published in the Official Journal of the European Union, according to Art. 11 of Regulation (EC) № 765/2008.

In this document "Accreditation procedure" shall mean all activities carried out by EA "BAS" on granting accreditation, re-accreditation and extension of accreditation.

2. SCOPE OF ACCREDITATION ACTIVITY OF EA "BAS"

Executive Agency "Bulgarian Accreditation Service" is the National Accreditation Body of the Republic of Bulgaria in compliance with Regulation (EC) № 765/2008 of the European Parliament and the Council.

EA BAS is the sole body in the Republic of Bulgaria, entitled to perform accreditation of bodies, carrying out conformity assessment activities, or other activities involving accreditation schemes, defined by a regulatory act.

The agency is a legal body seated in Sofia, a secondary distributor of budget funds at the Minister of Economy.

EA BAS performs accreditation of:

- Testing Laboratories, including Medical Laboratories;
- Calibration Laboratories;
- PT Providers;
- Inspection Bodies;
- Products Certification Bodies, including for organic manufacture and organic products;
- Validation and verification bodies;
- Management Systems Certification Bodies - ISO 9001, ISO 14001, OHSAS 18001/ *ISO 45001*, ISO 22000 *и* ISO/IEC 27001, ISO 50001, ISO 39001;
- Persons Certification Bodies;
- Environmental Verifiers (EMAS).

The scope of activity of EA "BAS" is updated following the order of Procedure on new activities BAS QR 17, after approval by the Accreditation Council.

EA "BAS" is a full member of EA and is a signatory to the Multilateral Agreement for mutual recognition of the accreditation schemes for the following fields:

- Calibration
- Testing, including Medical Laboratories
- Inspection bodies
- Products certification, including for organic manufacture and organic products
- Persons certification
- Management systems certification
- *Validation and verification bodies*

EA BAS is a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement - ILAC MRA for the following fields:

- Calibration
- Testing
- Medical Laboratories
- Inspection bodies

EA BAS is a full member of the International Accreditation Forum (IAF) and a signatory to the IAF Multilateral Recognition Agreement (MLA), for the following fields:

- Persons certification
- Management systems certification (ISO 9001, ISO 14001)
- Products certification
- *Validation and verification bodies*

EA BAS as a National Accreditation Body, responsible for the accreditation of Environmental Verifiers (EV) and for the surveillance of the activities, carried out by

the EV in compliance with Regulation (EC) № 1221/2009, participates in meetings of the Forum of the Accreditation and Licensing Bodies (FALB) and is subject to peer evaluation regarding the accreditation of Environmental Verifiers.

3. ACCREDITATION REQUIREMENTS

In this document accreditation requirements shall mean combination of criteria for accreditation (item 3.1), interpretations and guides (item 3.2) and accreditation rules (item 3.3).

Applicants for accreditation and accredited CABs shall fulfill the accreditation requirements. Non-observation of accreditation requirements may lead to reduction of scope of accreditation, temporary reduction of scope of accreditation, suspension, withdrawal or refusal of accreditation.

3.1. Accreditation criteria

The accreditation criteria on the basis of which EA BAS implements its activity are defined in harmonized standards, data for which are published in the Official Journal of the European Union, according to Art. 11 of Regulation (EC) № 765/2008, in accreditation schemes, defined by a regulatory act and in sector schemes for accreditation.
The accreditation criteria according to types of CABs are indicated in the following table:

Activities	Harmonized standards, documents with additional requirements and regulatory acts	Scope of activity of CAB	List of guides/external documents, applicable in the process
Calibration	БДС EN ISO/IEC 17025	All fields	Appendix BAS QR 2 - Calibration (ПрBASQR2-ЛК)
Testing, including medical laboratories,	БДС EN ISO/IEC 17025 BDS EN ISO 15189	All fields	Appendix BAS QR 2 – Testing (ПрBASQR2-ЛИ)
PT Providers	БДС EN ISO/IEC 17043	All fields	Appendix BAS QR 2 – PT Providers(ПрBASQR2-PT)
Inspection	БДС EN ISO/IEC 17020	All fields	Appendix BAS QR 2 – Inspection (ПрBASQR2-ОК)
Certification of products	БДС EN ISO/IEC 17065	All products, for which are available regulatory documents (standard, technical specification, practices and regulatory acts), defining the criteria against which the products are assessed	Appendix BAS QR 2 – Certification of products (ПрBASQR2-ОСП)
		Organic production and organic products	
Certification of management systems	БДС EN ISO/IEC 17021-1 БДС ISO/IEC 27006 ISO/TS 22003 *БДС ISO 50003*	ISO 9001	Appendix BAS QR 2 – Systems (ПрBASQR2-ОСС)
		ISO 14001	
		ISO 45001	
		ISO 22000	
		ISO/IEC 27001	
		ISO 50001	
		ISO 39001	
Certification of persons	БДС EN ISO/IEC 17024	All fields	Appendix BAS QR 2 – Certification of persons (ПрBASQR2-ОСПл)
Environmental Verifiers	БДС EN ISO/IEC17021 Regulation (EC) No 1221/2009	All fields	Appendix BAS QR 2 – EMAS (ПрBASQR2- EMAS)
Validation and verification bodies	БДС EN ISO 14065 *Regulation (EC) 2018/2067* Regulation (EU) № 757/2015	Appendix 1 *Regulation (EC) 2018/2067*	Appendix BAS QR 2 – ВО (ПрBASQR2- ВО)

3.2. Interpretations and guides

CABs shall have at their disposal all documents applicable to item 3.1, to be familiar with and observe them.

These documents also include guides and other interpretation documents of EA, IAF, ILAC and other authorized bodies, as well as interpretation documents. The documents applicable to the accreditation of the EMAS Verifiers are provided at the request of the EA BAS Secretariat.

The guides of EA, ILAC and IAF can be obtained in English language in the relevant internet pages, noted below from EA BAS.

- EA - www.european-accreditation.org;
- ILAC - www.ilac.org;
- IAF - www.iaf.nu

Lists of all documents applicable to accreditation process guides/external documents by fields of accreditation as Appendixes to BAS QR 2 (described in table under item 3.1), as well as the adopted decisions of TACs, are published in the website of EA BAS.

3.3. Accreditation rules

In addition to the accreditation criteria (item 3.1) and interpretations and guides (item 3.2), which shall be applied by the CABs, the accreditation requirements include also documents (rules) of the management system of EA BAS, publicly available on the Agency's website http://www.nab-bas.bg/ and referred to in item 1 of the procedure:

a) Accreditation Procedure BAS QR 2;
b) Rules for the use of EA BAS Accreditation symbol BAS QR 5;
c) Price List of EA BAS accreditation services BAS QR 8;
d) Procedure for Implementation of Interlaboratory Comparisons and Proficiency Testing Schemes BAS QR 18;
e) Procedure for the settlement of complaints BAS QR 25
f) Procedure for application of EA BAS Traceability Policy BAS QR 27;
g) Instruction for Management of Assessment Programs BAS QI 2 and its Annexes
h) Instruction for accreditation of conformity assessment bodies in accordance with the requirements of Regulation (EU) No 305/2011 of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council's Directive 89/106/ EEC QI 2.4
i) Instruction on the criteria and methods of Accreditation and Surveillance of Environmental Verifiers according to Regulation (EC) 1221/2009 of the European Parliament and Council, BAS QI 4;
j) Instruction on the criteria and methods of accreditation and supervision of Validation and verification bodies, BAS QI 12.
k) Instruction for the criteria and methods of accreditation and surveillance of Products Certification Bodies, including for organic manufacture and organic products, under Regulation (EC) Nº 834/2007 and Regulation (EC) Nº 889/2008, BAS QI 19;
l) Procedure for Flexible Accreditation Scope BAS QR 32
m) Instruction for management of extraordinary events or circumstances affecting bodies accredited by EA BAS and their clients, BAS QI 22

3.4. Amendments in the accreditation requirements

In the event of amendments in the accreditation requirements EA BAS informs interested parties and determines a suitable transitional period for setting the CABs' activities into compliance with the amendments. EA BAS strives to follow a transition period determined by EA, ILAC, IAF or other authorized bodies. Upon demand, a transition period may be determined by the agency after consultation with the interested parties.

At the end of the transition period the accredited CABs shall have set their activities in compliance with the amendments, otherwise EA BAS will identify non-fulfilment of the accreditation requirements.

In the event of a written notification submitted at EA BAS by a CAB regarding its decision not to implement the new requirements, EA BAS will proceed to procedure on withdrawal of accreditation.

3.5. Consumers of the accreditation services

Accreditation may be obtained by legal entities, established:

- On the territory of the Republic of Bulgaria;
- In another Member state of the European Union, in another country – signatory to EFTA, or in the Confederation of Switzerland;
- In third countries.

EA BAS is led by the principle of avoiding duplication of accreditation activities regarding foreign CABs, which are organizations or part of organizations, established and legally registered outside the territory of the Republic of Bulgaria.
The Agency performs accreditation of CABs outside the territory of the Republic of Bulgaria in observation of its Cross-frontier Accreditation Policy, based on Art. 7 of Regulation (EC) № 765/2008, LNACAB, the requirements of EA (EA-2/13), IAF and ILAC.

EA BAS does not perform accreditation of CABs established in other EU member states, signatories to EFTA or in Confederation of Switzerland, or third countries in compliance with the ILAC and IAF cross-border policies, except of the cases when:

- The National Accreditation Body of the member state, in which the accreditation candidate is established, has not passed successfully a peer evaluation regarding activities, for which the CAB applies for accreditation;
- The National Accreditation Body of the member state in which the accreditation candidate is established does not perform the applied accreditation activities.

In the abovementioned cases EA BAS notifies the NAB of the member state in which the accreditation candidate is established, of the received application and proposes collaboration with the local AB on performance of the assessment in compliance with its Cross-frontier Accreditation Policy, based on EA 2/13 and Art. 7 of Regulation (EC) № 765/2008, LNACAB, the requirements of EA (EA-2/13) IAF и ILAC.

3.6. Information system

EA BAS maintains an information system serving the accreditation activity. The agency's policy to keep customers and parties interested in accreditation spheres well informed is realized by means of the Accreditation Council, an Official Bulletin and a website. Each applicant for accreditation or accredited CAB may request and obtain the needed information by visitation in the agency's office, by mail, fax or e-mail.

3.6.1 Official Bulletin of EA "BAS"

EA "BAS" issues an Official Bulletin, in which European and International news, related to the accreditation activities are published. The Bulletin may also contain EA BAS policies and documents, concerning accreditation consumers, as well as any other information regarding the accreditation process at the discretion of the editorial college.

3.6.2 Website

EA BAS maintains a website**: http://www.nab-bas.bg/**, on which it:

- Announces data from the public register of the bodies with granted, reduced, temporary reduced, suspended or withdrawn accreditation, and a public register of the environmental verifiers on its website;
- Publishes information concerning the National Accreditation Bodies which meet the requirements of Art. 5a, Par. 2 of LNACAB.
- In section "Official announcements" are published announcements to accredited bodies or applicants for accreditation, which have not been found, refused to receive or not sought correspondence from EA BAS. *In the same rubric, in the events of problematic correspondence/communication, it publishes all important announcements to which is obliged to respond within a term.*
- Supplements and updates materials having regard to accreditation.

4. ACCREDITATION PROCESS

The accreditation process includes the following stages, described in detail further in the procedure:

- Submitting of Application and opening of procedure (item 4.1)
- Preliminary investigation (item 4.2)
- On-site assessment (item 4.3)
- Decision (item 4.3.7)
- Maintenance of accreditation (item 5)

The stages of the accreditation procedure are performed after fulfillment of all financial obligations of the CAB to EA BAS in relation to previous accreditation, if applicable, and related to preceding stages of present accreditation procedure, according to Price List of EA BAS accreditation services BAS QR 8.
The official language in which the CAB's accreditation procedure takes course is Bulgarian. When the applicant for accreditation is a foreign CAB, which is organization or a part of organization, established outside of the territory of the Republic of Bulgaria, the accreditation procedure is carried out in English or other language, after additional negotiations with the applicant.

4.1 Submitting Application and opening of accreditation procedure
4.1.1. Submitting Application for accreditation
The accreditation activity is based on the voluntary written Application for accreditation by the candidate CAB. A written Application may be submitted by any CAB, which is not in procedure of accreditation, re-accreditation or extension of accreditation. Any CAB may apply for re-accreditation or extension of accreditation scope if it is not in statute of suspended or temporarily reduced accreditation, or it is not in procedure on suspension, reduction or withdrawal of accreditation.
The accreditation candidate submits an Application for accreditation*, containing the applicable forms and documents, properly filled in and signed by the person stated in the documents. The forms for accreditation are published on the agency's internet page.
The Application form for accreditation is a set of documents, containing declaration by virtue of which the applicant is obliged to observe the accreditation requirements, the terms and rules of the agency***, agreement between EA BAS and CAB signed by the CAB in two identical copies***. The set of documents contains also all documents listed below sorted by types of activities, presented on paper and electronic bearer:

BAS QF 2.1 List of necessary documents, applicable to Application for accreditation of Testing Laboratory;

BAS QF 2.1 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Testing Laboratory (according to item 7 (1) of BAS QR 2);

BAS QF 2.2 List of necessary documents, applicable to Application for accreditation of Calibration Laboratory;

BAS QF 2.2 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Calibration Laboratory (according to item 7 (1) of BAS QR 2);

BAS QF 2.3 List of necessary documents, applicable to Application for accreditation of Product Certification Body;

BAS QF 2.3 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Product Certification Body (according to item 7 (1) of BAS QR 2);

BAS QF 2.4 List of necessary documents, applicable to Application for accreditation of Management System Certification Bodies;

BAS QF 2.4 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Management System Certification Bodies (according to item 7 (1) of BAS QR 2);

BAS QF 2.5 List of necessary documents, applicable to Application for accreditation of *Validation and verification bodies*;

BAS QF 2.5 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Validation and verification bodies (according to item 7 (1) of BAS QR 2);

BAS QF 2.6 List of necessary documents, applicable to Application for accreditation of Persons Certification Bodies;

BAS QF 2.6 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Persons Certification Bodies (according to item 7 (1) of BAS QR 2);

BAS QF 2.7 List of necessary documents, applicable to Application for accreditation of Inspection bodies;

BAS QF 2.7 (ES) List of necessary documents, applicable to Application for extension of scope of accreditation of Inspection bodies (according to item 7 (1) of BAS QR 2);

BAS QF 2.12 List of necessary documents, applicable to Application for accreditation of environmental verifiers;

BAS QF 2.14 List of necessary documents, applicable to Application for accreditation of medical laboratories.

BAS QF 2.15 List of necessary documents, applicable to Application for accreditation of PT providers.

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*application for accreditation – application for accreditation, re-accreditation or extension of the scope of Accreditation depending on the particular case

The Application for accreditation requires and refers to forms and documents with information concerning:

a) General characteristics of the CAB, including legal entity, name, addresses, legal statute, human and technical resources;
b) General information regarding the CAB, for example its activities, relations within the legal entity and addresses of all its physical *and virtual site*, which will be covered by the accreditation scope;
c) Clearly defined and stated accreditation scope (description of the conformity assessment services, which the CAB will provide, and a list of standards, regulatory acts, methods and procedures, for which the CAB applies for accreditation, including limitation of its capacity, if applicable).
d) Participation in Interlaboratory Comparisons/Proficiency Testing, where applicable;
e) Possessed accreditations, if applicable.

The set of documents, including the Application for accreditation and the applicable documents/records, which are submitted in EA BAS electronically, and the completed BAS application forms (BAS - forms) are also submitted in original on paper. The electronic documents/records should be recorded as separate files that are identified by the name of the document and structured into sections. The BAS application forms (BAS - forms) on electronic media should be saved in the original file format of the EA BAS forms. The set of documents shall be accompanied by a full inventory on paper, certified by a signature and a seal by a representative of the legal entity. The Application for accreditation with the applicable documents/records (set of documents on paper and electronic form) may be submitted by mail or at EA BAS Secretariat.

4.1.2 Evaluation of capability for fulfillment and review of the application

Within a term of 30 days from the application submitting date, the Agency shall perform an evaluation of its capability and competence for its fulfillment, and carries out an examination of completeness and regularity of the documents submitted. EA BAS assesses the ability and competence to carry out accreditation procedure in a particular application in respect of:

a) The scope of activity of EA BAS;
b) Availability of competence for performance of accreditation in respect to the scope applied for;
c) Availability of suitable, competent and available Lead Assessors and Technical Assessors/Experts;
d) Capability of realization of the accreditation procedure in respect to the location of the CAB's activity and/or in respect to the language used by the applicant or other specific

conditions related to the accreditation requirements;
e) Capability of observation of the terms of the accreditation procedure.
f) Impartiality risk assessment

EA BAS shall examine the application in terms of completeness and regularity, taking the following definitions:
Incompleteness – ascertained lack of one or more documents listed in item 4.1.1 and the supplemented documents, and/or unjustified lack of information in one or more of the presented documents;
Irregularity - ascertained lack of one or more attributes of the document, incorrectly completed document, presentation of a document with untrue content and/or invalid document and/or document belonging to other legal entity, and/or ascertained contradiction with or non-fulfillment/non- observation of policy of EA BAS adopted by the Accreditation Council, and/or ascertained contradiction with or non-fulfilment/non-observation of a decision adopted by TAC.
When EA BAS identifies an unacceptable risk of impartiality that cannot be reduced to an acceptable level, it refuses to open an accreditation procedure.
If the activity applied for accreditation is beyond the scope of activities under item 2 of this procedure, EA BAS shall inform the applicant and his explicit wishes may take action under the procedure for new activities BAS QR 17 or refuse opening of procedure.
The study of the possibility of expanding into a new activity of EA BAS is carried out according to BAS QR 17 within three months of requesting a new activity. On expiry of this period, EA BAS shall notify the applicant of the decision on the investigation and the time limits in which it could initiate a procedure in the field of the new activity.
If EA BAS determines that it is not competent to carry out an assessment for the requested scope or does not have a suitable lead assessor / technical assessors / experts, it offers the applicant finding evaluators from the National Accreditation Body, full member of EA, ILAC and IAF*, signatory to the EA, ILAC and IAF Multilateral Agreement.*
In this case, the timing of the procedure and the prices of the accreditation services may be changed. An accreditation procedure is initiated after written consent of the applicant to attract foreign assessors / experts. If the applicant does not agree, EA BAS refuses to open a procedure.
If the applicant accepts to be included in the evaluation team foreign experts within 15 (fifteen) days EA BAS conducts a study and sends a request to the NAB for the provision of experts and on the basis of the presented information up to 1 (one) month selects and agree with the CAB the proposed expert (s) and the possibilities for planning the on-site assessment.
If an Incompleteness or Irregularity of the accreditation application is established, the applicant shall be informed by a letter giving instructions and setting a term not longer than 1 (one) month for their removal in the case of initial accreditation and no longer From 7 (seven) days in re-accreditation and extension. The period begins to run from the date of receipt of the letter.
In compliance with the instructions given, the applicant is required to submit to EA BAS documents supplemented and revised in terms of regularity and completeness.
The documents must be accompanied by a letter describing in detail the corrections made in relation to the findings of the verification of the application for accreditation.
After submitting at EA BAS the documents, which are supplemented and reviewed in terms of completeness and regularity, the agency performs a second examination within a term of 30 days for application for initial accreditation and within 10 (ten) days in application for re-accreditation and extension of scope.
In case of non-correction of incompleteness / irregularity and / or failure to submit information on the given instructions within the stipulated period, the application with the presented documents shall be returned to the applicant with refusal of registration of the Application for accreditation.
Upon acceptance of an application for EV, EA BAS performed the review within 30 days of submission of the application and provides the necessary conditions for the implementation of the application for accreditation in accordance with Regulation (EC) №1221/2009.

4.1.3 Appointment of Lead Assessor, number of Indicators and opening of procedure

4.1.3.1. Appointment and concordance of Lead Assessor and number of Indicators

Within a term of 7 days after the completeness and regularity of all necessary documents has been ascertained, EA BAS appoints a Lead Assessor for the particular application.

The customer is notified by a letter of the appointed Lead Assessor and the number of determined indexes on the basis of which are defined the amounts to be paid according to Price List BAS QR 8.

Within a term of 5 days from receipt of the notification letter, the applicant has the right of a single objection against the appointed Lead Assessor and/or the determined number of Indicators.

- In the event of a written and argumented applicant's disapproval of the appointed Lead Assessor, on the grounds of objective data of availability of conflict of interest, for instance that the person is a consultant to the CAB, or has objective data that the person is (has been hired up to two years before the assessment/about to be hired) an employee (hired for services) of competitor organization and/or in terms of factual incompetence, than a new review under the manner of item 4.1.2 shall be carried out, respectively Appointment of a new Lead Assessor and new concordance with the accreditation applicant.
- In the event of a written and argumented applicant's objection against the determined number of Indicators, a new review shall be carried out and discussion between the parties with the aim to achieve agreement between the parties on the number of Indicators, determined according to "Instruction for determination of number of Indicators".

In the event that the applicant does not object in writing to the conformance letter within the prescribed term, EA BAS shall consider that the applicant agrees with the selection of the Lead Assessor and number of Indicators.

4.1.3.2 Opening of procedure

After the appointed Lead Assessor and determined number of Indicators are agreed by the applicant, the agency opens accreditation procedure with a registration number of opened procedure on the Application for accreditation.

A notification letter is sent to the client with information of the registration number of opened procedure for accreditation and the amount due for implementation of preliminary investigation, in accordance with an invoice attached to the letter. *With the same letter a signed the Agreement between the EA BAS and the CAB is sent to the CAB.* Within a term of 5 (five) days from receipt of the notification letter, the applicant is obliged to pay this amount due for preliminary investigation determined according to Price List BAS QR 8.

4.1.4. Refusal of opening a procedure

EA BAS refuses to open an accreditation procedure in case one or more of the following circumstances are present:

a) Activity applied for accreditation outside of the scope of activity of EA BAS;

b) Lack of competence for realization of accreditation regarding the scope applied by the client;

c) Lack of suitable, competent and available Lead Assessor and/or Technical Assessors/Experts;

d) Incapability of realization of the accreditation procedure in view of the location of the CAB's activity and/or in view of the language used by the applicant and/or other specific conditions in relation to the accreditation requirements;

e) Incapability of observance of the deadline for accreditation;

f) Non-fulfillment of financial obligations under opened procedures and/or maintenance of accreditation of the legal entity, to which the CAB belongs;

g) Non-observation of the term under item 4.1.2 for sending/provision of documents at EA BAS, supplemented and reviewed in terms of completeness and/or regularity;

h) Repeated presence of incompleteness or irregularity of the submitted documents for accreditation;

i) Unfinished procedure on accreditation, re-accreditation or extension of accreditation under application of the same applicant;
j) Suspended accreditation or commenced procedure on suspension or withdrawal of accreditation of the applicant; or in circumstances requiring an extraordinary assessment;
k) Period until expiry of the validity of the provided accreditation is less than 8 months – in case of application for re-accreditation and less than 9 (nine) months in a re- accreditation application with extension of accreditation;
l) Failure to submit evidence for closing of non-conformities with the accreditation requirements.
m) Unachieved agreement for appointed Lead Assessor and/or number of Indicators.
n) Disagreement of CABs to involve, leading assessor / technical assessors / experts from the National accreditation body member of EA, ILAC and IAF.
o) *An unacceptable risk of impartiality has been identified which cannot be brought to an acceptable level.*
p) *Existence of evidence of fraudulent conduct by the CAB or intentional provision of false information or intentional concealment of information from the CAB.*

Bodies which are refused accreditation may submit application for accreditation again after presentation of evidence for closing of the non-conformities with the accreditation requirements and the agency's accreditation procedures.
Accredited body wishing to be accredited against another standard shall proceed as in a new registration of application.

4.2 Preliminary investigation

The preliminary investigation consists of reviewing the documents and records and evaluation of their conformity with the accreditation requirements.
Preliminary investigation in re-accreditation and extension of accreditation scope includes also review of previous assessments.

At the stage of preliminary investigation for initial accreditation, in the event of expressed written request of the applicant, a preliminary on-site assessment may be carried out.
The preliminary investigation is carried out by the appointed Lead Assessor, who carries out a review of the provided by the applicant documents and records under item 4.1 and evaluation of the documented management system for its conformity with the accreditation requirements. If necessary, a technical assessor/expert may be included.
The preliminary investigation concludes with a report by the Lead Assessor containing expert conclusion and proposal for next stage of the procedure.

4.2.1 Preliminary investigation (review of documents)

The preliminary investigation is carried out within one month following the date of opening of the accreditation procedure, for which the client is provided with a report of the Lead Assessor. If any omissions are ascertained within this term, the client shall be provided with a report of findings and the term is extended by one month (two months from opening of the procedure).
Within 10 (ten) days following the date of receipt of the report of findings, the applicant is obliged to present in EA BAS documented evidence for elimination of the omissions.

4.2.2 Preliminary investigation (by means of preliminary on-site assessment) The preliminary on-site assessment allows the definition and detailed formulation of the accreditation scope of the applicant, enables the evaluation of the applicant's readiness for proceeding with initial assessment, as well as the facilitation of its planning. The CAB is obliged to enable EA BAS to carry out a preliminary on-site assessment within the period of the preliminary investigation.
The preliminary on-site assessment concludes with provision of report within the term of the preliminary investigation (one month from opening of the procedure) or in the event of ascertained omissions – with provision of report of findings (BAS QA 2.1.1) in the day of conclusion of the on-site assessment. Within ten days following the provision of the report of findings (BAS QA 2.1.1) the applicant is obliged to present in EA "BAS" documented evidence for the closing of the ascertained omissions (BAS QA 2.1.1).

In both cases under items 4.2.1 and 4.2.2, the documents shall be submitted with a letter,

containing detailed description of the undertaken corrective actions related to the findings of the preliminary investigation and the attached documents.
Within the extended term for the preliminary investigation (two months from opening of the procedure), EA BAS is obliged to carry out an evaluation on the provided documented evidence and to inform the applicant of the continuation of the accreditation procedure.
In the event that the omissions have not been closed or the terms have not been observed, EA BAS decides how to proceed with the accreditation procedure, namely implementation of on-site assessment or refusal of accreditation/ re-accreditation or suspension/limitation/ withdrawal of accreditation in assessments for re-accreditation.

4.3 Assessment

4.3.1 Principles and methods

If there is a positive expert conclusion of the preliminary investigation, an on-site assessment shall be carried out by assessment team, whose aim is to evaluate the conformity with the accreditation requirements.
The on-site assessment *of the CAB* includes one or more of the following methods:

a. Review of documents *and records* – evaluation of the quality manual and other documents of the CAB's management system for conformity with the accreditation requirements (see item 3). Review of the CAB's records of carried out activity, *for managing the competence of the* personnel, quality control, internal audits, management reviews, reports of previous assessments, assessment reports by other accreditation bodies, etc.
b. Office assessment – evaluation of the practical application of the CAB's documented management system by evaluation of documented evidence.
c. Witness assessment – witness and evaluation of activities carried out by the CAB (such as testing, calibration, certification of products, of systems, of persons, inspection,

verification of environmental report and others). The witness of activities is a mandatory element of the on-site assessment.

d. Proficiency Testing – evaluation of the CAB's competence in the participation in Interlaboratory Comparisons (ILC) in testing/calibration. This method is mandatory for the evaluation of testing and/or calibration laboratories.
e. Interview – evaluation of the competence of the CAB's personnel by means of purposeful interview.
f. Remote assessment - the assessment of the actual or virtual location of a conformity assessment body, using electronic means, where there is justified need and technical feasibility for implementation.

The assessment teams perform assessment on the execution on a sample of conformity assessment activities, representative of the requested/provided scope of accreditation, personnel/staff competence and impartiality management. Where the CAB conformity assessment activity is carried out at more than one sites, a sample of sites, activities and personnel shall be evaluated. The selection of the activities to be assessed shall be taken into account due to the risk associated with the activities, locations and personnel covering the accredited scope.

EA BAS develops for each particular assessment an evaluation plan that covers the activities to be assessed, the locations where the activities will be evaluated, the staff to be evaluated, where applicable, and the assessment methods to be used, including witness assessment. The order of determining the scope, methods, duration of assessment for each stage of the accreditation process and for each accreditation scheme is given in BAS QI 2.

4.3.2 Preparation of assessment

EA BAS determines a team of assessors, consisting of a team leader /lead assessor/ and an appropriate number of technical assessors and/or experts, so that the team of assessors has the competence to evaluate the scope of accreditation and to ensure the necessary impartiality and independence. At least 10 (ten) days prior to implementation of assessment, EA BAS negotiates with the CAB the period, *the composition (with information on the names of the team members - assessor and observers, as well as the organizations to which they belong)*, authorities of the assessment team and assessment plan. At least 5 (five) days prior to the assessment, the CAB shall confirm in writing its consent with the determined date and team, including observers, the authorities of the team and the assessment plan. In the event that there is justified disapproval of an assessment team member by the applicant*/ the accredited CAB*, EA BAS makes a new selection of the evaluation team and new conformance. If there is no available and suitable Lead Assessor/Technical Assessor/Expert, the assessment may be postponed and/or to involve a Lead Assessor/Technical Assessor/Expert from another national accreditation body, or the scope for which there is no available Technical Assessor/Expert not to be assessed at this stage of the accreditation process.

EA BAS may require the CAB to provide in writing additional information necessary for preparation of the assessment such as methods, procedures, instructions and other correlated documents. The CAB shall provide EA BAS with the required information and all changes made in its management system within a term defined by EA BAS. If the required documents are not provided within this defined term, the Lead Assessor shall plan additional time during the planning of the assessment, which is paid for according to Price List of EA BAS accreditation services (BAS QR 8).

When an applying or EA BAS accredited CABs:

- has one or more offices (locations), to which they are performed conformity assessment activities outside the territory of the country where the CAB head office is located; or
- performs conformity assessment activities on the territory of other countries under accreditation of EA BAS,

EA BAS carries out an assessment in compliance with EA cross-border EA accreditation policies, the requirements of Article 7 of EU Regulation 765/2008, ILAC and IAF.

EA BAS assigns the assessment of the local NAB when it has the necessary competence for the relevant scope of accreditation and has signed the EA MLA or ILAC/IAF MRA/MLA for this

scope.
In exceptional cases where the local NAB is unable to perform an assessment on behalf of EA BAS for which records are kept indicating the reasons, EA BAS carries out the evaluation, after approval and in cooperation with NAB.
Where the NAB of the country in which the activity is carried out has not successfully completed a peer evaluation with respect to the scope of activity performed by the CAB in the territory of that country or does not perform such accreditation activities, EA BAS carries out the evaluation with the participation of evaluators from the local NAB or the participation of its representatives as observers.
A CAB that has offices with major activities in another country or performs conformity assessment activities in another country may not refuse to carry out the assessment or participation in the assessment *of representatives from the local NAB*.

4.3.3 On-site assessment

The on-site assessment shall be carried out within a term of 3 (three) months following the date of conclusion of the preliminary investigation in procedures on initial accreditation, and within a term of 1 (one) month following the date of conclusion of the preliminary investigation in procedures for re-accreditation/extension of accreditation scope. Certification bodies of management systems, personnel, products and verification bodies are required to submit to EA BAS plan audits / verification in agreement for office - assessment. EA BAS does not perform office assessment if plan is no provided by the CAB for audit / verification.
The on-site assessment commences with an opening meeting, *which clearly defines the evaluation objectives, the accreditation requirements, the plan and the scope of the assessment*.
During the on-site assessment the team evaluates the degree of introduction, maintenance and efficiency of the management system and the competence of the CAB *and the compliance of CAB with the requirements for accreditation*. The Conformity Assessment Body shall demonstrate that it is competent to carry out all activities and in all fields, for which it has applied accreditation.
The assessment may not cover all records, documents and personnel of the CAB. The sample, subject to assessment, shall be representative as far as possible depending on the CAB's activity. Each selection of the team shall be made in view of risk and significance for the demonstration of competence on the part of the CAB. Due to the sample approach, it cannot be claimed that all existing non-conformities are identified.
Regarding the management system of the CAB, the evaluation team shall carry out assessment of at least one full cycle of internal audit and management review.

EA "BAS" may discontinue an on-site assessment in the following circumstances:

- The CAB has not provided all necessary conditions for work of the assessment/surveillance teams, as required by item 8.1.d) of this procedure;
- The CAB has not provided a possibility for implementation of a witness by the team of its activity, as required by item 8.1.f) of this procedure;
- The team ascertains non-conformity/non-conformities, which lead to suspension or withdrawal/refusal of accreditation, in the event of which continuing the assessment would not influence the result of assessment.

Discontinuation of an on-site assessment is made by decision of the Lead Assessor after conformance to the head of Department and director of ACAB directorate.
The on-site assessment concludes with a closing meeting at which the assessment team reports the findings from the evaluation and provides a brief written report summarizing the assessment results, including non-conformities, if any. The CAB is given the opportunity to request clarification on the findings.
The assessment of SCB, PrCB, PsCB and EV concludes after carrying out the necessary witness assessments of the activity, for which the CAB should allow EA BAS to perform them within three months of the on-site assessment at the office. After each observation of the activity, a closing meeting, with the witnessed team and/or the management of the CAB is held.

4.3.4 Reporting after an on-site assessment

After the assessment, the team shall prepare a report with the observations during the assessment, containing at least the following:

1. Records of carried out witnesses of activity;
2. Comments and Conclusion on the condition of the management system and the competence of the CAB;
3. Comments and Conclusion on the conformity of the CAB's activity with the accreditation requirements, *the assessed scope*
4. Raised non-conformities, if any *as well as team observations on areas for possible improvement, without recommending specific solutions.*

In the case of CAB assessments, where the assessment for witnessing the activity is not part of the on-site assessment, a report shall be provided after the office assessment has been completed and at the end of each witnessing of the activity. *At the closing meeting of each management system certification bodies assessment, a brief report containing a summary of the on-site assessment (section A) shall be provided, which shall contain at least the information indicated above, ie. 2,3,4.*

Where during the evaluation there were differences of opinion of the accredited CABs or candidates for accreditation on the one hand and on the other - EA BAS in relation to:
a) Interpretation of the requirements of the standard/ guidance of EA, ISO / IEC and Regulations (EC);
b) Interpretation of documents from the EA BAS Management System,

The CAB shall notify the Executive Director of EA BAS in writing about the existence of an argument/dispute on a particular issue not later than 10 (ten) days after the dispute has arisen.

An office evaluation report and a report with included monitoring results is provided to the CAB within 15 (fifteen) days of the closing meeting - an office evaluation / evaluation / assessment for the activity monitoring.

4.3.5 Non-conformities and corrective actions

4.3.5.1 Classification

Non-conformity means non-fulfilment of the accreditation requirements, defined in item 3 of the present document.
EA BAS classifies the non-conformities as Major or Minor, according to the following criteria:
Major non-conformity (L):
Ascertained **non-fulfilment** or lack of application or maintenance of one or more of the accreditation requirements (see item 3), which leads to the conclusion that the CAB's activity, the general competence and the management system are not capable of ensuring the necessary quality of the provided services, including the reliability of the documents issued by the CAB.

Minor non-conformity (S):
Ascertained **omissions** in the implementation of one or more of the accreditation requirements (see item 3), which leads to doubt regarding the quality of the provided services, including the reliability of the documents issued by the CAB.

For all kinds of non-conformities the CAB shall undertake corrective actions, which shall be evaluated by EA "BAS", before a decision is reached for granting accreditation/re-accreditation/extension of accreditation scope or confirmation of the accreditation for the period of its validity.
The classification of the non-conformities is a responsibility of the Lead Assessor.

4.3.5.2 Corrective actions

a) Reporting of the non-conformities is made at the end of the on-site assessment or at the end of an witness assessment of activity when that is not part of an on-site assessment during the closing meeting after they are classified by the Lead Assessor.

Assessments of certification bodies for management systems, products, persons and verification bodies shall be provided report after the office evaluation has been completed and at the end of each monitoring of the activity.

At the closing meeting of each MSCB assessment, a brief report with a summary of the on-site assessment (section A) shall be provided, which shall contain at least the information specified in 4.3.4; 2,3,4.

An office evaluation report and a report with included monitoring results is provided to the CAB within 15 (fifteen) days of the closing meeting - an office assessment / assessment / witness assessment.

The non-conformities are reported to a representative of the legal entity, who verifies that it is informed of the non-conformities by signing the relevant form. Non-signing the form by the CAB or the legal entity does not cancel the ascertained non-conformity.

Reporting of nonconformities may also be made after an assessment by document, with a legal representative being notified in writing.

b) In pursuance of the concept applied by EA BAS, namely that the corrective actions shall eliminate the reasons for occurrence of non-conformity and with the aim of prevention of its re-occurrence, when non-conformities are ascertained the management of the CAB is required:

- To perform root cause analysis which led to occurrence of the non-conformity;
- To undertake actions on closing of the non-conformity;
- To analyze the extent of the non-conformity and re-perform or correct the non-compliant service or product - correction;
- To undertake actions on elimination of the reasons leading to occurrence of the non-conformities – corrective actions;
- To perform self-evaluation and to demonstrate the efficiency of the undertaken actions.

The CAB shall present in EA BAS a full report of corrective actions including information on all actions concerning the activities stated above and the relevant documented evidence of their implementation.

c) Corrective actions after initial assessment:

Regardless of the classification of the non-conformities, the accreditation applicant has 2 (two) months following the reporting of non-conformities to implement corrective actions. Within this term the CAB shall present a report of corrective actions.

In the case of CAB assessments, where the assessment for witnessing the activity is not part of the on-site assessment, the deadline for submission of a report on corrective actions of non-conformities identified during the witness is 1 (one) month from the reporting of non-conformities found during witness.

d) Corrective actions after:

- Assessment for planned surveillance
- Assessment for surveillance upon a signal
- Extraordinary assessments except the ones for recovery of accreditation in suspension and temporary reduction, due to non-conformity with the accreditation requirements;
- Assessment for extension of accreditation scope;
- Assessment for re-accreditation

The CAB has 1 (one) month following the reporting of the non-conformities to implement corrective actions for the minor non-conformities ascertained during the assessment.

When one or more major non-conformities are ascertained the CAB shall present in EA BAS a detailed plan for implementation of corrective actions within 10 (ten) days following the reporting of the non-conformities. The plan shall include analysis of the prime reasons leading to occurrence of the non-conformities and all subsequent actions related to their elimination, and indicating terms and responsible persons for their implementation. EA BAS performs assessment of the analysis and the action plan within 5 (five) days from their receipt. A negative assessment of the analysis leads to undertaking immediate actions on temporary suspension of the accreditation, withdrawal or refusal of re-accreditation or extension.

After the analysis and the plan are approved by EA BAS, the CAB shall present a report of corrective actions within 1 (one) month from the reporting of the non-conformities.

e) Additional requirements for certification bodies for management systems, products, personnel and verification body

No matter the type of assessment, the cases of one or more major non-conformities in office assessment of certification bodies of management systems, products, personnel and *validation and verification bodies* which could have an impact on the certification/validation and verification process is not going to conduct witness assessment before approving the plan for taking effective corrective action.

The plan should be submitted to EA BAS to 10 (ten) days of reporting non-conformities and take into account the need to take effective corrective action before witness. The Plan must include an analysis of the root causes of non- conformities and any subsequent actions in relation to removing them with deadlines and persons responsible. EA BAS evaluates the elaborated by the CAB analysis and action plan within 5 (five) days of receipt.

4.3.6 Folow up assessment

The efficiency of the corrective actions undertaken by the CAB in relation to the non-conformities ascertained during the assessment is evaluated in a follow up assessment.

During the follow up assessment the CAB shall demonstrate that the undertaken corrective actions are based on appropriate analysis, which indicates the root cause analysis for occurrence of the non-conformity, and analysis of the distribution of the non- conformity. The CAB shall be able to demonstrate that it has made a verification of the undertaken corrective actions, and the verification has proved an efficient closing of the non-conformities.

4.3.6.1. **Type and scope of Follow up assessment:**

EA BAS is obliged within 1 month after the CAB's report under item 4.3.5.2 to perform a follow up assessment and report the results.

The type and scope of the follow up assessment are defined by the type and scope of the assessment, during which the non-conformity/-ies is/are ascertained, meaning:

- Ascertained non-conformity during a witness – the follow up assessment shall be implemented during a witness, except in cases where objective written evidence of effective corrective actions can be submitted
- Ascertained non-conformity in documents does not require a follow up assessment on-site.
- a nonconformity found during an office assessment whose closing cannot be assessed on documents, the follow up assessment should be carried out in the office;

The type and scope of the follow up assessment depends also on the character and number of the non-conformities find during the assessment. In principle, the follow up assessment of the efficiency of the undertaken corrective actions is carried out by the lead assessor/technical assessor/ and expert, who has find the non-conformity. If necessary, within the prescribed period the CAB may be required to present additional information concerning the implementation of the follow up assessment.

During the closing meeting dates and scope of the follow up assessment may be proposed, but they shall be confirmed by EA BAS.

The CAB has the right of only one follow up assessment after each implemented assessment.

Leaving a non-conformity unclosed in a follow up assessment may lead to the finding of a new non-conformity, related to the capability of the CAB to perform an adequate analysis of the root cause for occurrence of the non-conformities and undertaking efficient corrective actions.

4.3.6.2. **Reporting of results of Follow up assessment**

The reporting of the results of the follow up assessment is performed within the term for implementation of follow up assessment and is documented in Annex to the on-site assessment report.

If not all of the non-conformities are efficiently closed or are not closed within the defined term, it will be suggested a refusal of accreditation/re-accreditation, refusal of extension of accreditation, suspension of accreditation for the whole scope and suspension of accreditation

for a part of the granted scope (temporary reduction of scope) in the Annex to the assessment report. Within 10 (ten) days from the conclusion of the follow up assessment, the annex is sent to the applicant for information.

4.3.7. Accreditation decision

Reaching a decision for *granting, maintaining, extending, reducing, suspension or withdrawing accreditation* is based on three elements, as follows:

a) Recommendations of the evaluation team in the assessment report, based on the findings during the assessment;
b) Standpoint with proposal for a decision of the Accreditation Commission (AC) after acquaintance with the report of the lead assessor/team, and if necessary, with the documentation/records of the CAB. AC sits within a period up to 6 (six) months following the on-site assessment. If the noted period has expired, an extraordinary assessment shall be carried out within 1 (one) month at the expense of the party which is responsible for non-observation of the abovementioned term.
c) Decision of the Executive Director of EA BAS on granting, refusal, reduction of scope, temporary suspension, temporary reduction or withdrawal of accreditation after standpoint with proposal for decision of Accreditation Commission. The decision of the Executive Director may be consistent with the standpoint of the Accreditation Commission, or it may differ from it and shall be taken within 1 (one) month from the opinion of AC. In written application of the accredited body for voluntary withdrawal from initial accreditation/re-accreditation/extension of accreditation scope, reduction of scope, suspension, temporary reduction or withdrawal/refusal of accreditation, the decision is reached by the Executive Director without a standpoint of Accreditation Commission.

In the case of a negative decision, the body may apply for accreditation again not earlier than 3 (three) months following the date of receipt of the order. When ascertained that the body does not comply with the accreditation requirements, on the basis of decision of Executive Director or position ot AC, EA BAS refuses accreditation with a justified written order, which is communicated to the applicant within a 7 (seven) days term from its issue.

Decision after performed surveillance or extraordinary assessments, for maintaining of accreditation shall be taken by the Executive Director, as before that, the assigned supervising officer according to BAS QR 26 performs previous document control on reports and records of the EA BAS assessment procedures of CABs.

4.3.8 Accreditation documents

The accreditation certificate certifies the competence of the accredited bodies to carry out conformity assessment activities on the address of location indicated in the certificate.
When ascertained that the body complies with the requirements and with the accreditation procedures of the agency, the Executive Director issues an order and accreditation certificate within a term of 1 (one) month following the presentation of the written standpoint under item 4.3.7 b) of the procedure.

Accreditation certificate, containing:

a) Name and mark (symbol) of the agency;
b) Number and date of issue of the certificate;
c) Name, seat and address of management and uniform identity code – for a legal entity or a sole trader, or the equivalent data for a foreign legal entity;
d) Identification data of the accredited site (*name,* locations for which accreditation has been granted with a corresponding address *and accreditation scope of each location/premise*);
e) Grounds of issue – regulatory act, standard, Guide *(with information for the edition or version) against which CAB's compliance has been assessed*
f) Type of conformity assessment activity, scope, date of issue and validity term; the scope may be presented in annex to the certificate;
g) Signature of the Executive Director of the agency or signature of the Deputy Executive Director in the cases under Art. 10, Par. 5 of LNACAB;
h) Number and date of the annex, if any;
i) Date of initial accreditation in the cases when such is granted.

Annex to the accreditation certificate:
The annex to the accreditation certificate contains a detailed description of the scope of accreditation depending on the different types of *accreditation schemes*.
The accreditation certificate is issued in one original in Bulgarian language. The appendix, which is inseparable part of the certificate, is issued in two copies – one for the accredited body and one for the agency's archive.
The draft of the scope of accreditation is available for agreement by the CAB for acceptance of technical and terminological point of view, except in the case of a change requested by the CAB with declaration and when the change was not subject to the assessment of the site and has not been announced to the CAB via an assessment report. The draft of the scope of accreditation should be returned to EA BAS within 5 (five) days with signatures of CAB representative of each page.

Within 1 (one) month from the issue/re-issue of the accreditation certificate, the CAB is obliged to submit to the EA BAS the translation of the certificate and the annex thereto, made by a certified registered translator for the issuance by the EA BAS of the certificate and the annex thereto in English.

The accreditation certificate with the annex and order for accreditation shall be obtained by a representative of the legal body – the manager of the accredited CAB, or a person properly authorized by the manager, presenting a document for paid fee, according to Price List of EA BAS accreditation services (BAS QR 8).
The accreditation certificate is nominal and shall not be subject to remission or transferring on the part of the accredited body.
The issued accreditation certificates are registered in a public register of the bodies with granted accreditation. For the case of environmental verifiers, EA BAS informs the respective authorities.
The certificate and the annex are ownership of EA BAS. When obtaining new documents for accreditation, re-accreditation or re-issue, the CAB is obliged to return the originals of the provided and invalid documents, within the following deadlines:

- 14 days (fourteen) of receipt of a reducing order, temporary reducing of the scope of accreditation, suspension or withdrawal of accreditation;
- in all other cases, including re-accreditation and extension of accreditation, upon receipt of the new accreditation documents.

The CAB is required to obtain the accreditation certificate and its attachment within 15 (fifteen) days from the date of the notification. Upon failure to receive the accreditation documents within the stipulated time, EA BAS will suspend the accreditation.

5. MAINTENANCE OF ACCREDITATION

The accreditation's validity term is 4 (four) years from the issue date of the accreditation certificate. The maintenance of the accreditation shall be performed throughout the whole validity period of the accreditation certificate. The maintenance of the accreditation includes surveillance and other actions performed by the agency in order to ensure continuous conformity of the accredited bodies' activity with the requirements and the accreditation procedures of the agency and to sustain the confidence in the quality of services offered by the accredited bodies.
EA BAS develops and implements an assessment program to evaluate CAB activities during the accreditation cycle to ensure that conformity assessment activities representative of the scope of accreditation of the respective locations/premises are evaluated during the accreditation cycle. The assessment program shall be elaborated, taking into account the requirements of international standards and other normative documents containing requirements for CABs and the scope of accreditation, the information collected by EA BAS on the management system, activities and functioning of the conformity assessment body, and the evaluated in connection with these requirements and information risk.

EA BAS may perform extraordinary assessments as a result of complaints or amendments or other issues that may affect the ability of the CAB to meet the requirements for accreditation.

The assessment program includes two planned surveillance and an assessment for re-accreditation or surveillance. Exceptions are CABs, for which surveillance is required every year, as indicated below in item 5.1.

EA BAS can perform extraordinary assessments as a result of complaints or changes or other issues that may affect the CAB's ability to meet the accreditation requirements.
During the period of accreditation validity, accredited CAB may modify (reduce or extend) the scope of accreditation, as the validity term of the granted accreditation doesn't change.
Decisions for suspension of the accreditation for the entire or part of the granted scope (temporary reduction of scope), for reduction and withdrawal of accreditation, shall be made by implementing the rules of p. 4.3.7 of the present procedure.

5.1 Planned surveillance
Surveillance is realized by means of on-site assessment for ascertaining conformity of the accredited bodies with the accreditation requirements and the agency's accreditation procedures, also taking into account participation of the accredited laboratories in Interlaboratory comparisons, proficiency tests or other activities verifying the competence of the accredited bodies.
Planned surveillance is carried out on the basis of approved periodical competency assessment programs for accredited bodies.
After granted initial accreditation/re-accreditation, the first planned surveillance by on- site assessment shall be performed within 9 (nine) to 12 (twelve) months from the initial accreditation/reaccreditation certificate issue date. Every consequent planned surveillance/reassessment shall be carried out within a period not longer than *12* (*twelve*) to *18* (*eighteen*) months from the previous on-site assessment, as in the event of submitted application for re-accreditation the last planned surveillance is combined with assessment for re-accreditation (re-assessment).
Maintenance of accreditation of *Validation and verification bodies* is made for the whole period of the granted accreditation by means of annual surveillances with the purpose to verify the maintenance and application of the internal procedures, drawing attention to the distribution of responsibilities to the appropriately qualified verification teams. The first planned surveillance of a Verification Body shall be carried out not later than 12 (twelve) months after the date of issue of its accreditation certificate.
The maintenance of accreditation of organic farm certification bodies under Regulation (EC) No 834/2007 shall be carried out for the whole duration of the accreditation granted through annual surveillance assessments in accordance with EA-3/12 M: 2013 EA Policy on Accreditation of Bodies Certification of organic production.
Planning shall be made on the basis of the abovementioned rules and depending on the stability level achieved by the services offered by accredited CABs.
When objective circumstances are present, a CAB may request in written from EA BAS a postponement/alteration of the surveillance period provided that the laid-out term for performing surveillance is not violated.
Each refusal of the CAB for implementation of surveillance in violation of the stipulated terms for its implementation is considered as non-fulfilment of the accreditation requirements and leads to suspension of accreditation.
The surveillance on-site assessments are carried out following the rules described under items 4.3.3 to 4.3.6 of the present procedure.

5.2. Extraordinary assessment (including surveillance upon a signal)
EA BAS may decide to perform extraordinary on-site assessment in the events of:

- submitted information about changes occurred in the conditions under which the accreditation has been granted, according to item 8.2;
- submitted written signals for violations on the part of accredited bodies, published or announced critical materials in the mass media;
- signals of improper reference to accreditation;
- misleading use of accreditation in advertisement materials;
- order following performed control on documents according to Procedure on control of assessment and decision-making processes (BAS QR 26);
- missed term under item 4.3.7 b) of this procedure.

Extraordinary on-site assessment shall be carried out by EA BAS when there is received information from a Product Certification Body about its intentions to use a non-accredited

CAB as a subcontractor.
Extraordinary on-site assessment shall be carried out by EA BAS for recovery of the accreditation according to item 5.4.3 of the present procedure and in the case of a missed period under item 4.3.7. b) of the present procedure. The scope and type of the extraordinary assessment is determined by the specifics of each particular case, for which the EA BAS is referred or self-referred.
If a planned surveillance is planned within a period of up to three months from the date of receipt / disclosure of a signal / information, an extraordinary on-site assessment may be carried out in addition to the planned surveillance, the amounts for the payment of an extraordinary assessment being due.
In the case of an extraordinary on-site assessment by complaint (signal), EA BAS does not agree with the CAB the appointed team's date/s, the team's authority and the evaluation plan.
Upon receipt of information from the CAB on the occurrence of changes, EA BAS informs the sender of a 7-day (seven-day) deadline for the actions to be taken in relation to the reported changes. If necessary to carry out an extraordinary assessment of documents, the deadline for closing of the assessment is up to 2 (two) months from the date of the notify and the deadline for making an extraordinary assessment on-site depends on the nature and stage of the procedure, but not later than 3 (three) months from the date of the notify, except cases, accordance with a procedure for resolving complaints BAS QR 25.

5.3. Reissue of accreditation certificate and annex

5.3.1 EA BAS re-issues the accreditation certificate in case there is a change in an element of certificate's content pursuant to item 4.3.8.
The annex to the accreditation certificate is an inseparable part of it and, when necessary, it shall be re-issued along with re-issue of the certificate.
Conditions under which is performed a re-issue of the CAB's accreditation certificate:

a) The Conformity-assessment body fulfills the accreditation requirements;
b) Policy and the management system remain unchanged;
c) Management of the legal entity and the CAB and main personnel remain unchanged;
d) CAB's organizational structure remains unchanged;
e) Methods and conformity-assessment procedures remain the same;
f) Technical resources remain the same, if applicable (for instance Management Systems Certification Body).

The CAB shall present to EA BAS objective documented evidence verifying that the above conditions are fulfilled.

5.3.2 Conditions under which is performed transfer of granted accreditation to a CAB, according to Art. 22 of LNACAB:

a) Available documented evidence for transition of the CAB from one to the other legal entity;
b) Available evidence for loss of rights as accredited CAB of the original legal entity and transfer of the rights to the new legal entity;
c) Declaration on voluntary refusal of accreditation on behalf of the original legal entity
d) Public statement that the accreditation granted to the old legal entity is considered invalid from the date of issuance of the decision of the Executive Director of EA BAS to transfer the accreditation;
e) The CAB transferred to the new legal entity continues to be in conformity with the accreditation requirements;
f) The policy and the management system of the CAB are unchanged;
g) The CAB's management and main personnel remain unchanged;
h) The CAB's organizational structure within the legal entity remains unchanged;
i) The conformity assessment methods and procedures remain the same;
j) The technical equipment remains the same, if applicable (for instance Management Systems Certification Body).

The procedure for the transfer of accreditation starts with an application signed by the representatives of new and old legal entities. The CAB shall present to EA BAS objective documented evidence verifying that the above conditions are fulfilled.

Before reaching a decision for re-issue of accreditation certificate or transfer of the granted accreditation, EA BAS shall carry out an assessment at least through review of documents. If necessary, for instance if some of the conditions are not fulfilled or there are ambiguities in the provided documented evidence, EA BAS carries out on-site assessment for ascertaining the conformity of the CAB with the accreditation requirements.

The decision on re-issue/transfer of accreditation is reached by the Executive Director based on a report of the Lead Assessor/assessment team, which have performed the last on-site assessment, within 2 (two) months from the submission of the request / application for transfer provided accreditation of CABs in accordance with art. 22 LNACAB.

When a positive decision is reached, the CAB receives new documents for accreditation in which the occurred change is indicated as the registration number of the certificate does not change.

Planned surveillance and re-assessment activities for the respective CAB remain unchanged.

All open procedures for re-accreditation and extension of accreditation continue with respect to the new legal entity to which the CAB has passed after the transfer of accreditation. The old legal entity have right to refer to accreditation until the date of the decision to transfer accreditation. Transfer of accreditation is not allowed if the accreditation is suspended and / or temporarily restricted or a suspension, temporary suspension or withdrawal of accreditation is in progress.

5.4 Refusal on granting accreditation, suspension, reduction, withdrawal of accreditation

In case of ascertained non-conformity of accredited bodies or accreditation applicants with the requirements for accreditation, EA "BAS" shall reduce the scope of accreditation granted or applied-for, temporarily reduce the scope of accreditation, suspend, refuse or withdraw the accreditation, within 1 (one) month from the finding of non – conformity.

By means of a brief statement of the reasons, under the "News" section of the website, the agency declares any reducing / suspension / withdrawal or misleading reference / use of accreditation.

The CAB is obliged during the accreditation period to be constantly in compliance with accreditation requirements. The CAB should be able to demonstrate the permanency of its compliance with the requirements from the date of granting the accreditation/re- accreditation for the entire scope and in all fields of granted accreditation.

In case CAB comes to the conclusion that it will no longer be able to maintain its accreditation in a certain part of the scope/field, it shall immediately inform EA "BAS". Such announcement during an on-site assessment is not admissible.

Where CAB accreditation is suspended for all or part of the provided accreditation scope, reduced, temporarily reduced or withdrawn, it shall inform its affected customers of the circumstances involved and the related consequences within two weeks of suspending, limiting or withdrawing the accreditation.

5.4.1. Suspension of accreditation for the whole or a part of the granted scope (temporary reduction of the scope of accreditation)

Suspension or temporary reduction of the accreditation scope are imposed for a period not longer than 6 (six) months.

EA BAS proceeds to suspension of accreditation in case that objective evidence documented during on-site assessments or otherwise, demonstrate that the accredited body does not comply with accreditation requirements and agency's procedures within 1 (one) month from the discovery of the non-compliance. Suspension of accreditation is a process during which the accreditation is temporarily invalid.

EA BAS shall undertake temporary reduction of the accreditation scope in the event that the accredited body is temporarily incapable of performing part of the activities it has been accredited for, and this does not influence its capability of performing its activity within the remaining part of the scope.

Suspension or temporary reduction is a process during which the accreditation is temporarily invalid for the whole or a part of the accreditation scope.

During a period of suspended accreditation, the CAB shall not use the accreditation symbol of EA BAS or in any other way to refer to accreditation.

Certification Bodies shall not execute procedures on certification applications or grant certificates within the scope of suspended/temporary reduced accreditation. Granted certifications shall remain under the appropriate activities of surveillance.

A body whose accreditation is with reduced or temporarily reduced scope shall receive an accreditation certificate and the annex with reduced or temporarily reduced scope.

In case of suspension of accreditation, the accredited body is obliged to return in the agency the original certificate together with its Annex within a 14-days (fourteen-days) term from receipt of the order and to discontinue referring to the accreditation regardless of the fact whether the CAB has objected the order or not.

5.4.2 Circumstances for suspension/temporary reduction of accreditation

EA BAS suspends/temporarily reduces accreditation:

a) Within a term of 1 (one) month from ascertaining the following circumstances:

- finding non-conformity that lead to the conclusion that the activity of the conformity assessment body does not provide the necessary quality of the services provided, including the credibility of the documents issued by it;
- negative evaluation of the analysis and plan for the implementation of corrective actions.
- failure to obtain an accreditation certificate and its attachment within 15 (fifteen) days of notification to the CAB by fax and / or e-mail.

b) In the event of non-conformity with accreditation requirements (item 3) by the CAB and not-undertaking effective corrective actions within the defined term (item 4.3.5.2);

c) In the event of failure by the CAB to comply with its obligations set out in items 8.1 and 8.2;

d) In the event of other circumstances at the discretion of the EA BAS Executive Director (i.e. in case of changes which have temporarily negative effect on accreditation, such as changes in legal status, management personnel, technical equipment, policy, management, structure etc.);

e) In the event of written request from the accredited body for suspension/temporary reduction of the accreditation;

f) when is confirmed the validity of the complaint filed against CAB's;

g) in establishing that the CAB performs certification on standards used for accreditation of CABs, for example. ISO 17025, ISO 15189 and others.

h) in non-payment of accreditation services within, under the conditions specified in BASQR 8.

5.4.3 Recovery of accreditation

Upon an officially stated wish by a CAB for recovery of accreditation within a period not longer than 4 (four) months from the date of suspension or temporary reduction of the scope of accreditation, EA BAS performs an extraordinary on-site assessment within 1 (one) month from the announcement of the wish by the CAB. If during this assessment the CAB does not succeed to demonstrate conformity with the accreditation requirements, or if there is no stated wish of the CAB for recovery of accreditation, EA BAS proceeds to withdrawal or reduction of the scope of accreditation (see item 5.4.5).

In the cases of temporary reduction of the accreditation scope or suspension of accreditation on the grounds of art. 36 of LNACAB, during an extraordinary assessment for recovery of accreditation is allowed the raising of non-conformity, which shall be efficiently closed within a term according to item 4.3.5.2 of the present procedure.

The decision of recovery of accreditation is made by the Executive Director on the grounds of a proposal in assessment team report, within 1 (one) month from the registration.

5.4.4 Reduction of accreditation

EA BAS proceeds to reduction of the accreditation scope in case that objective evidence, documented during on-site assessments or otherwise, demonstrate that the accredited body does not comply with accreditation requirements for a particular part of the accreditation scope but this does not influence its capability of carrying out its activities within the remaining part of the scope within the period of temporary reduction of the accreditation scope, and the accredited body does not succeed in verifying its capability to perform the activities for which its accreditation has been temporarily withdrawn.

5.4.4.1 EA BAS reduces accreditation in the following cases:

a) Non-compliance with the accreditation requirements (item 3) by the CAB and not performing effective corrective actions within the defined term (item 4.3.5.2), with regard to part of the accreditation scope. Non-compliance with the requirements should not influence the remaining part of the scope of granted accreditation (CAB's activities and fields (offices/ premises)).

b) Written application by the accredited body for suspension of accreditation accompanied by the originals of accreditation certificate and annex.

5.4.4.2 Recovery of accreditation

The CAB may recover the scope/field of granted accreditation by means of a procedure for recovery of accreditation scope (under the terms and within the deadlines specified in item 5.4.3), but not later than 6 (six) months from entry into force of the order for temporary reduction/suspension of the accreditation scope.

5.4.5 Refusal of granting accreditation, extension of scope of accreditation or re-accreditation and withdrawal of accreditation

Refusal of granting accreditation, extension of accreditation scope or re-accreditation and withdrawal of accreditation is a process in which the applied-for or granted scope of accreditation is refused/permanently discontinued (withdrawn).

EA BAS proceeds to refusal/withdrawal of accreditation in case that the accredited body or accreditation applicant:

a. is incapable of performing the activities for which it has been accredited or applies for;

b. does not fulfill or does not maintain one or more of the requirements for accreditation (item 3), which leads to the conclusion that the CABs activity, its competence and management system are not able to ensure the necessary quality of the provided services, including the authenticity of its issued documents;

c. during accreditation period refers to accredited activities for non-accredited scope;

d. In the case of non-compliance by the CAB with its obligations set out in paragraph 8.1. And point 8.2. (Only on initial accreditation);

e. Deliberately issues false information, deliberately and knowingly violates the accreditation rules, issues a false or altered document, or a document of untrue content;

f. compromises the agency by its own acts or omissions, including if the agency considers that violations by the CABs of regulatory requirements would compromise EA BAS;

g. The CAB has failed within the prescribed period to demonstrate compliance with the accreditation requirements or does not inform of its wish to recover accreditation within the term noted in item 5.4.3;

h. CAB has not received the accreditation certificate within 1 (one) month following suspension due to non-receipt;

i. accreditation services according to the approved price list are not paid;

j. the written application by the accredited CAB for withdrawal of accreditation or refusal of accreditation. The Executive Director is obliged to conform the wish of CABs no matter if there are objective reasons for this.

In case of withdrawal of accreditation, the accredited body is required to return to the

agency the original accreditation certificate and the Annex thereto within 14 (fourteen) days from receiving the order and to discontinue referring to the accreditation regardless if it has contested the order or not.

For the Certification Bodies withdrawal of accreditation implies that they shall withdraw/terminate all certificates granted under accreditation within 2 (two) months from the date of withdrawal. Certification Bodies shall present to the agency a list of granted certifications with evidence of their withdrawal/termination.

A body whose accreditation is withdrawn may reapply for accreditation not earlier than *3* (*three*) months from the date of implementation of the order for withdrawal of accreditation and presentation of evidence that the non-conformities with the accreditation requirements are closed.

5.4.6 EA BAS informed IAF of any decision with the reasons for:

- suspension or withdrawal of accreditation in relation to item. 5.4.2 g) and item 5.4.5. d) from the current procedure;
- decision on an objection related items. 5.4.2 g) and item 5.4.5. d) from the current procedure.

6. RE-ACCREDITATION

Re-accreditation is a subsequent confirmation of the competence of the accredited body in the same regulatory act, standard or guide specified in the issued accreditation certificate.

Not later than 8 (eight) months prior to the expiry date of accreditation the CAB should submit an application for re-accreditation in EA BAS as set out in item 4.1.

When the applicant for re-accreditation wishes extension of the accreditation scope under (item 7 a from the current procedure), the application must be submitted within 9 (nine) months before the expiry of the certificate.

In case of request for re-accreditation and extension of scope in EA BAS all applications with marking (in bold) the new information in them shall be presented.

If the CAB fails to submit the application for re-accreditation within the prescribed period the initial accreditation procedure shall be followed, therefore the applicant should explicitly state its will to apply for initial accreditation under item 4.1. In this case the CAB will lose the registration number of the granted accreditation certificate.

Re-accreditation is similar to the on-site assessment for initial accreditation. The evaluation process follows the rules set out in item 4.3.3 to item 4.3.7 of the present procedure, as the assessment shall take into account the performance of the CAB during the period of validity of the accreditation certificate.

In case of starting a re-accreditation procedure the agency performs re-accreditation under item 4.1 within the expiry date of the certificate for already granted accreditation. If the agency fails to perform re-accreditation within expiry of validity of granted accreditation, because of circumstances within its control, upon request of the applicant, the executive director by an order shall extend to 6 (six) months the expiry period of the certificate of accreditation.

Extension of accreditation validity is made on the grounds of a proposal by the Lead Assessor who has carried out the last on-site assessment, after analyzing the fulfillment of the following requirements by the CAB:

1. Compliance with the deadline for submission of the application for re- accreditation;
2. Compliance with the deadline for payment of all financial obligations;
3. Absence of major non-conformities or, if there are such - adopted comprehensive plan for their correction.

7. EXTENSION OF SCOPE

Extension of the accreditation scope represents an addition to a granted scope or fields of accreditation, according to the criteria for accreditation, in which the CAB is accredited.

Accredited bodies may apply for extension of the accreditation scope in accordance with the regulatory act, standard or guide against which they are accredited under the conditions

and time limits in item 4.1 during the entire period of their accreditation, except in cases under item 4.1.4.

The accredited body must apply for accreditation by marking the "extension" of all documents set out in the list in item 4.1.1 with marking (in bold) of the new information. The process of extension of the granted accreditation shall start after opening a procedure of extension of scope pursuant to item 4.1.3.2.

Depending on the type and complexity of the requested extension of accreditation scope and of the accreditation procedures, the extension of accreditation scope is made through:

1. extraordinary assessment of documents or extraordinary assessment of documents plus extraordinary on-site assessment within 3 (three) months from the application submission (the assessment can also be performed during planned supervision) * and **;

* *to extension the scope within the meaning of item 1, the respective list marked with (ES) shall be applied. The relevant list of BAS QF 2.X (ES) provides an extention of the scope of expansion to which BAS QR 2 (7) (1) may apply.*

** *Taking into account that when extending the scope within the meaning of item 1, the requested scope is analogous to the accredited one, the stages of the accreditation procedure preliminary study and submission of an opinion by an accreditation commission do not apply. The requirements of Art. 10, para. 1, item 2a and art. 32 item 2 of the LNACAB*

2. *Other procedure for extension the scope of accreditation over 35%, in a new area of accreditation (including offices/premises where CAB performs conformity assessment activities) with on-site assessment for extension of the scope (area) within 8 (eight)) months from the opening of the procedure*

3. *In case of requested extension of the scope of accreditation in the granted scope (up to 35% of the provided scope), the assessment for extension may be performed during an assessment for planned surveillance and re-accreditation, and in case of planned surveillance the procedure for extension of the scope of accreditation is required to be opened at least two months before the planned surveillance.*

8. OBLIGATIONS

8.1. Obligations of the applicant or the accredited CAB

The applicant or accredited CAB is obliged to:

a) be always in accordance with the requirements for accreditation for the entire scope of granted accreditation for all fields (offices/premises) under accreditation *and provide evidence of compliance*.

b) look for any changes and/or additions to the accreditation requirements and adapt its activity in accordance with them within the prescribed term/transition period.

c) provide any information requested by EA BAS within the prescribed term.

d) cooperate, as necessary, to enable the accreditation body to verify compliance with the accreditation requirements, such as provide all necessary conditions for the assessment and surveillance teams, including provision of opportunity to review the documentation, access to staff and to all premises, records, reports from internal audits, etc.

e) inform EA BAS of requirements for security, safety, hygiene, health and ensure timely appropriate personal protective equipment for conducting on-site assessments.

f) make possible the witness of its activity by EA BAS assessment team; *to have, where applicable, legally binding agreements with CAB's clients that oblige them to provide access on request to EA BAS assessment teams for the purpose of evaluating the performance of CABs when performing customer site compliance activities*

g) during assessment or witness, accepts the attendance of observers for the purposes of trainings, monitoring, peer evaluations, etc.

h) reveal the contents of existing EA BAS reports, letters, certificates or scope of accreditation to third parties, providing the entire contents of the document and not part of it.

i) *not to use its accreditation in such a way as to disrepute of EA BAS,* not to compromise with actions or statements the accreditation of Conformity Assessment Bodies and EA BAS.

j) not to issue illegal protocols, certificates/reports that have formal status under the law.

k) fully complies with the accreditation requirements when referring to its accreditation in the mass media;

l) *declare accreditation only in respect of the scope for which the accreditation was granted and* not make public or provide false information regarding the status of accredited CAB in the media, documents, brochures, advertisements, etc.

m) not to use the accreditation symbol of EA BAS, in violation of the rules for its use.

n) stop using accreditation within its activities, including for advertising purpose after the expiry of the validity of the accreditation certificate, as well as suspension or withdrawal of accreditation.

o) return the original certificate and order for accreditation within 14 (fourteen) days of receipt of the notification/date of expiry of the accreditation in case of withdrawal, reduction, including temporarily reduction of the scope of accreditation or after the expiry of accreditation.

p) pay the cost of services provided by EA BAS in terms and conditions set out in the Pricelist of accreditation services of EA BAS (BAS QR 8).

q) pay each assessment or surveillance team member's in each case travel and daily costs in accordance with Ordinance on business trips in the country. Pay travel and daily costs, under prior agreement, to Lead Assessor/Assessor or technical expert from another national accreditation body participating in a team.

r) participate in Interlaboratory comparisons/proficiency testing in accordance with the requirements of the BAS QR 18.

s) not to put EA BAS Lead Assessors/Technical Assessors/Experts in situations that may compromise their impartiality and objectivity, or endanger their health and safety.

t) to assist and present the information requested by EA BAS in the investigation and resolution of all complaints related to its accreditation.

8.2 Obligations of accredited CABs in the event of changes of the conditions, under which accreditation has been granted

The accredited CAB shall inform EA BAS of any change in the conditions under which accreditation is granted within 15 (fifteen) days of its occurrence.

CAB should assess the importance of any change in terms of its influence on the accredited activities, taking into account that depending on the nature of the change, EA BAS can carry out extraordinary assessment on documents or on-site. Without being limited, significant changes are:

a) its legal, commercial, organizational status or ownership

b) organization, top management and key personnel (such as managers and personnel authorized to make decisions, personnel with specific and unique for the CAB functions);

c) resources and locations/premises;

d) accreditation scope;

e) other issues that may affect the ability of the conformity assessment body to meet the accreditation requirements.

EA BAS found major non-compliance in case of change of the above mentioned, which have not been notified in time.

In case of detection of major changes that EA BAS is not informed it carries out extraordinary on-site assessment, which can be in the framework of the ongoing *planned on-site assessment* of CAB. Amounts due to extraordinary assessment should be paid by the CAB according to the price list of services provided by the Executive Agency "Bulgarian Accreditation Service".

8.3 Obligations of EA BAS

EA BAS is obliged:

a) to carry out an assessment according to the applicable requirements for accreditation, it planning and preparing in such a way that the assessment to be done on time and to be

reliable;

b) not to provide confidential information about a particular CAB outside the accreditation body without the written agreement with the CAB, except when the law requires or permits the provision of such information without its agreement. With regard to the partnership of EA BAS within EA, EA BAS may provide documents of the CAB to other national accreditation bodies. *Information on the conformity assessment body received from third parties, such as complainant, regulatory authorities, etc. is treated as confidential information. The source of this information is not disclosed to the CAB unless agreed with the source.*

c) To notify the applicant or accredited CAB for the progress at any stage of the procedure in accordance with the specified rules and upon a request from the CAB;

d) To coordinate with the CAB the assessment team within a period and in a manner specified in the procedure.

e) To publish and maintain actual information on the accredited CABs on its website;

f) The assessment team should be restricted only to its designated authorities in relation to the concrete assessment;

g) Team members shall not accept gifts, items, articles etc. from CABs in order not to compromise their impartial, independent and objective assessment;

h) In case that during an assessment or surveillance, a team member becomes aware of a crime by the CAB or on its behalf, directly related to the scope of the assessment, he is required to report to EA BAS in order for a decision on future actions to be made.

i) Each Lead Assessor/Technical Assessor or expert who has access to CAB documents is required to sign a declaration of confidentiality. The CAB may obtain a copy of the declaration upon request.

j) To inform the CAB of any changes or additions to the accreditation requirements through the information system under item 3.6;

k) To include accredited environmental verifiers in the public register of environmental verifiers under Art. 135, par. 2 of the Law on Environmental Protection and to notify the competent authority for the occurred amendments.

9. DISPUTES, COMPLAINTS, OBJECTIONS, APPEAL

9.1 Disputes

EA BAS treats as disputes the arisen differences of opinion between accredited CABs or applicants for accreditation and EA BAS in terms of:

a) Interpretation of the requirements of a standard/EA Guide, ISO/IEC, EC Regulations;

b) Interpretation of documents from the management system of EA BAS.

The CAB should notify in writing the executive director of EA BAS of the existence of dispute on issue not later than 10 (ten) days from occurrence of the dispute.

The Executive Director of EA BAS, after consultation with the involved parties, will strive to reach an agreement between them. If necessary, controversial issues shall be reviewed and discussed on the corresponding TAC before a decision is made. EA BAS shall inform in writing the CAB of the outcome within 20 (twenty) days of registering the dispute.

A dispute which leads to an unfavorable decision for the respective CAB may lead to a complaint/appeal.

9.2. Complaints

EA BAS treats as complaint any expression of dissatisfaction, different from appeal from a body or organization related to actions of EA BAS or a CAB accredited by the agency, to which a response is expected. The complaints are considered under the order stipulated in BAS QR 25.

EA BAS treats as a signal any complaint related to activity of accredited or applying for accreditation CABs regarding observation of the accreditation requirements or announced critical materials in the mass media, misleading usage of accreditation in advertising materials, etc., incorrect reference to accreditation and others.

EA BAS will consider only complaints submitted in written with the appropriate argumentation, accurately identified complainant and subject of the complaint. The complainant shall be informed in written of the outcome of the complaint's consideration within a term of 1 (one) month from its receipt.

9.3. Appeal

9.3.1. EA BAS treats as objection any request expressed by a CAB for reconsideration of

any adverse decision reached by EA BAS related to the desired accreditation statute. Adverse decisions include:

- Refusal of opening the procedure for accreditation ;
- Refusal of providing part of the requested scope of accreditation / re-accreditation or extension;
- Refusal of accreditation / re-accreditation or extension;
- Withdrawal of accreditation
- Suspension of accreditation;
- Reducing the scope of accreditation or temporary reducing of the scope of accreditation;
- Any other action that prevents obtaining accreditation, including silent refusal

9.3.2. Objections shall be submitted in written with appropriate argumentation to the Appeals Commission (AppC) through the Executive Director of EA BAS, within 7 (seven) days from the date of notification of the order and shall be registered in the secretariat of the agency with a registry number and date.

9.3.3. In 7 (seven) 9.3.3. days from the receipt of the appeal, the BAS Executive Director may reconsider the matter and either withdraw the appealed act or amend it or issue the relevant act if it has not been issued or refer the matter to the resolves the respective appeal to the Chairman and Deputy-Chairman of the Accreditation Council.

9.3.4. AppC conducts a closed session at the office of EA BAS and operates in compliance with the requirements of LNACAB, Rules of work of the Appeals Commission and the present Accreditation Procedure.

9.3.5. AppC evaluates the correctness and legitimacy of the objected order and decides on the appeal by issuing a written argumented and reasoned decision. The deadline for delivery of AppC and preparation of a written argumented and substantiated decision is 1 (one) month from the date of receipt of the appeal.

9.3.6. The AppC Chairman shall provide the decision to the Executive Director of EA BAS and to the person submitting the appeal within 3 (three) working days from the date of the AppC decision.

9.3.7. The decision of AppC is mandatory for the Executive Director of EA BAS.

9.4. Objection

9.4.1. Decisions of the Executive Director for refusal of accreditation, re-accreditation or extension of the scope of accreditation, for reduction of scope, temporary reduction or suspension, and withdrawal of accreditation, are all subject to objection under the Administrative Procedure Act.

9.4.2. Entities may submit a complaint to the court, after having exhausted the possibility of art. 13, par. 2, or the term under Art. 13, par.1 of LNACAB has expired.

10. ADDITIONAL GUIDELINES

10.1 EA BAS is not responsible for any occurred material and non-material damage to CABs as a result of failure by the latter to demonstrate compliance with accreditation requirements.

10.2 In case of a delay in the accreditation procedure for a period of 3 (three) months on the part of the applicant for accreditation, EA BAS shall undertake action to unilaterally terminate the accreditation procedure.

10.3 EA BAS creates a file of the CAB, comprising of documents with all Annexes to BAS QR 2, all documents produced by BAS in relation to the accreditation procedure and all correspondence between EA BAS and CAB.

10.4 EA BAS stores the CAB file for a period of 5 (five) years from the date of granting/refusal of accreditation.

10.5 Throughout each stage of the accreditation procedure the CAB may refuse the services requested by the agency, paying to EA BAS the due withdrawal amounts in accordance with the pricelist of EA BAS.

11. TRANSITION PERIOD

11.1 Procedures for extension of the scope of accreditation, opened before 01.01.2020

should be completed in accordance with BAS QR 2 Version 7 / 01.03.2018, Revision 6.

11.2 The accredited CABs should sign an agreement between EA BAS and the CAB until 31.03.2020.

12. ABBREVIATIONS

БДС EN ISO/IEC 17011:2018 - Conformity assessment. General requirements for bodies operating the accreditation of bodies for conformity assessment (ISO/IEC 17011:2017)

EA BAS or "the agency" – Executive Agency "Bulgarian Accreditation Service"

EA - European co-operation for Accreditation

FALB - Forum of Accreditation and Licensing Bodies

EA MLA –European Accreditation Multilateral Agreement **ILAC –** International Laboratory Accreditation Cooperation **IAF** - International Accreditation Forum

ILAC MRA – ILAC Mutual Recognition Arrangement **IAF MLA –** IAF Multilateral Recognition Agreement **PT providers** – Proficiency testing providers

EA-2/13 - EA Cross Frontier Policy for Cooperation between EA Members

LNACAB - Law on National Accreditation of Conformity Assessment Bodies

Medical laboratory- clinical laboratory for the biological, microbiological, immunological, chemical, immune-hematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

NAB – National Accreditation Body of EU member state defined in compliance with Regulation (EC) No 765/2008 of the European Parliament and of The Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ, L218/30)

CAB - Conformity Assessment Body **PsCB** - Persons Certification Body **PrCB** - Products Certification Body

MSCB – Management Systems Certification Body

EV – Environmental Verifiers

VVB - *Validation and verification bodies*

AC – Accreditation Council

TAC – Technical Accreditation Committee

AccC – Accreditation Commission

AppC – Appeals Commission

- *This document translation has been prepared for the needs of activities related to the accreditation, based on the official document of EA BAS.*
  In case of discrepancies and differences between the Bulgarian document and its translation, the original document in Bulgarian shall be considered as leading.