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**PROCEDURE**

**FOR THE TRANSFER OF ACCREDITATION AND ASSESSMENT ASSIGNED BY/TO  
ANOTHER NATIONAL ACCREDITATION BODY**

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**List of amendments**

No	Date of amendment	Version, revision	Reason for amendment	In force by:
1.	15.01.2020	Version:2	Alignment with EN ISO/IEC 17011:2018 and EA-2/13 M:2019	15.01.2020

1

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**CONTENTS:**

	I'm sorry, Str. 4
1. <b>Purposes</b>	4
2. <b>Application area</b>	4
3. <b>Terms, definitions and abbreviations</b>	4
4. <b>Implementation of the cross-border accreditation policy of EA BAS.</b>	5
5. <b>Assessment assigned by / to another NAB</b>	7
6. <b>Transfer of accreditation</b>	9
<b>7 Records</b>	10
8. <b>Applicable documents</b>	11

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## 1. Purposes

This document regulates the policy and procedure for cooperation of EA BAS with other National Accreditation Bodies (NAB) in cases of accreditation granted to conformity assessment bodies (CAB) on the territory of the Republic of Bulgaria by other NABs, as well as for accreditation granted by EA BAS on the territory of other countries. This document provides guidance for CAB accreditation, which has several offices and some of them are outside Bulgaria.

The procedure refers to accreditation by EA BAS of CABs in other countries subject to Regulation (EU) No 765/2008. The procedure also applies to CABs that have subsidiaries in other countries, including in the EA region and/or carry out conformity assessment activities in other countries including the EA region.

The procedure is based on the rules laid down by Regulation (EU) No 765/2008, EA-2/13 M:2019 and IAF and ILAC documents and objectives for the cross-border policy of EA, ILAC and IAF.

The procedure also regulates the order and manner of carrying out assessment assigned to EA BAS as a subcontractor by another NAB, as well as assigning activities to another NAB on the basis of a signed Contract Agreement between the two accreditation bodies.

## 2. APPLICATION AREA

This Procedure is applicable in the following cases:

2.1 Accreditation granted by EA BAS to CAB established outside the Republic of Bulgaria on the territory of another NAB;

2.2 Accreditation provided by another NAB to CAB established on the territory of the Republic of Bulgaria;

2.3 Accreditation of the CAB whose main office is established on the territory of the Republic of Bulgaria and at the same time has activities requested for accreditation in offices (offices) in other EU Member States or countries and economies outside the Ea region, or the CAB shall carry out compliance assessment activities under the accreditation of EA in other countries on the territory of another National Accreditation Body.

2.4 Accreditation assessments carried out by EA BAS awarded by another National Accreditation Body.

2.5 Accreditation assessments carried out by another National accreditation body assigned by EA BAS.

This document covers all types of accreditation schemes in force and all types of assessments in the accreditation process – accreditation, reaccreditation, supervision and extension of the scope of accreditation.

## 3. TERMS, DEFINITIONS AND ABBREVIATIONS

### 3.1 Terms and definitions

For the purposes of this procedure, the relevant terms and definitions set out in ISO/IEC 17011, ISO/IEC 17000 and applicable Normative Acts governing the accreditation activity as well as the following terms and definitions shall be used:

**National Accreditation Body (NAB) – the only body in a Member State which has the power to grant accreditation;**

**Conformity Assessment Body (CAB) – a body carrying out conformity assessment activities, including calibration, testing, certification and control, or other activities subject to accreditation;**

**EA region**— the geographical area of EA Member States to which EA Association documents apply.

### 3.2 Abbreviations

EA	European accreditation organisation
EA MLA	European Accreditation Multilateral Agreement
IAF/ILAC MLA/MRA	IAF/ILAC Multilateral Agreement
ILAC	International laboratories accreditation cooperation
IAF	International Accreditation Forum
IA BAS	Executive Agency "Bulgarian accreditation service"

<b>NAB</b>	National accreditation body
<b>CAB</b>	Conformity assessment body

#### **4. Implementation of the cross-border accreditation policy of EA BAS.**

##### **4.1. General provisions**

Accreditation may be granted to legal persons/sole traders established:

- on the territory of the Republic of Bulgaria;
- in another Member State of the European Union, in another State Party to the Agreement on the European Economic Area, or in the Swiss Confederation;
- in third countries.

EA BAS performs accreditation of CAB, mainly located on the territory of the Republic of Bulgaria and for carrying out activities for conformity assessment on the territory of the Republic of Bulgaria.

EA BAS is guided by the principles for avoiding duplication of accreditation activities regarding foreign CABs, which are organizations or part of organizations located and legally registered outside the territory of the Republic of Bulgaria.

The Agency shall carry out CAB accreditation outside the territory of the Republic of Bulgaria in compliance with its cross-border accreditation policy, which relates to and complies with Art. 7 of Regulation (EC) No 765/2008, the LNCAB (EA-2/13) IAF and ILAC requirements.

EA BAS shall not grant accreditation to CABs established in other Member States of the European Union, a Party to the Agreement on the European Economic Area or in the Swiss Confederation or third countries subject to cross-border policies of ILAC and IAF, except where:

- The national accreditation body of the country in which the applicant for accreditation is established has not successfully completed a peer evaluation of activities for which the CAB applies for accreditation;
- The national accreditation body of the country in which the applicant for accreditation is established shall not carry out any accreditation activities for which it is applied.

In the aforementioned cases, EA BAS assesses whether it has the competence to conduct the accreditation, taking into account factors such as language, local laws and regulations, culture, etc. in addition to the normal technical competence requirements assessed in accordance with point 4.1.2 of BAS QR 2.

If it establishes that it possesses such competence, EA BAS shall notify the NAB to the Member State in which the applicant for accreditation is established of the application received and proposes cooperation with the local authority to carry out the assessment in accordance with its cross-border accreditation policy based on EA 2/13 of Article 7 of Regulation (EC) No 765/2008, LNCAB and the requirements of EA, IAF and ILAC.

If EA BAS finds that it does not have such competence, it shall refuse accreditation.

If EA BAS has granted accreditation to the CAB in another country due to the lack of the available competence of the National Accreditation Body to accredit the requested activity or because the National Accreditation Body has not signed the relevant agreement of EA, IAF, ILAC MLA/BLA/MRA, the CAB shall be informed that it will have to transfer its accreditation to the CAB as soon as these terms change. When the NAB becomes a party to EA, IAF, ILAC MLA/BLA/MRA, EA BAS will not accept an application for re-accreditation or extension of accreditation and will invite the NAB to request a transfer to the accreditation of the CAB. In any request of re-accreditation or extension of the scope of CAB accreditation, EA BAS will verify the circumstances with which it can implement its cross-border accreditation policy.

When EA BAS accredits CAB for a foreign regulatory act, it shall ensure through cooperation with the CAB of the State that issued the legal act the necessary competence for accreditation.

When the CAB accredited by EA BAS conduct conformity assessment activities under the accreditation of EA BAS in the territory of another country, EA BAS shall endeavor to entrust the NAB to the State concerned to carry out the assessment of such activities, including assessment by monitoring the activities when the NAB is a party to EA, IAF, ILAC MLA/BLA/MRA.

Where the NAB refuses to assessment or participate in an evaluation on behalf of EA BAS, the Agency shall carry out the necessary assessment itself.

EA BAS keeps records of the correspondence conducted for cooperation with the NAB.

#### **4.2. Additional requirements to be taken into account when managing the CAB accreditation process, which have a registered legal entity in the Republic of Bulgaria and offices in other countries**

For each CAB assessment, which have a main office in the Republic of Bulgaria and offices/locations in other countries other than the requirements of the current versions of the Accreditation Procedure BAS QR 2, the following requirements shall apply.

When an CAB that has legal registration on the territory of Bulgaria and offices in other countries has requested accreditation for its headquarters and other locations, the management of the organization have to unequivocally determine the status of the headquarters and other offices/locations, and this shall be unequivocally declared in the CAB application.

EA BAS can grand accreditation under the following conditions:

- EA BAS has established that it has the necessary competence to assess the headquarters and activities in other locations;
- All activities may fall under the responsibility of one legal person or if the individual offices/locations subject to the accreditation have different legal personality, are linked by contractual or other legal arrangements between the accredited legal person and its offices/locations and internal provisions that further specify those relations in relation to management and responsibilities
- All offices/places requested to be included under CAB accreditation shall operate under the same management and apply a common management system.
- The registered legal entity (CAB) shall be able to demonstrate that it has effective control and monitors the activities in its Offices/locations.
- The legal entity of the accredited EF shall be able to be responsible for the activities carried out by its offices/places that will include its accreditation.

The accreditation certificate is issued only in the name of the legal entity registered on the territory of Bulgaria and the accreditation order includes information about the evaluated offices/locations.

Where the offices/places covered by CAB accreditation are separate legal entities, they shall not offer accredited services on their local market on behalf of their local legal entity, but shall be entitled to offer conformity assessment activities on behalf of the accredited legal entity to which they belong/have business arrangements.

Individual CAB locations may offer local market conformity assessment activities only on behalf of the accredited CAB.

The conformity assessment documents issued under the accreditation of EA BAS must contain the name and address of the accredited legal person without reference to the name or logo of any of its offices/places.

Tenders, contracts, certificates and reports issued shall not create confusion with the legal entity (CAB) that holds the accreditation.

In addition to BAS QR 2 and BAS QI 2 EA BAS in developing an assessment programme and identifying the activities, locations and personnel to be assessed in accordance with the accreditation procedure of BAS, account shall be taken of the risk associated with activities and market conditions in the countries where the offices/locations are located. The risk review shall be carried out by taking information from the NAB on whose territory the offices/locations for the relevant markets and regulations are available.

Specific considerations to be taken into account in establishing the approach and extent of sampling for assessment include, without limiting themselves to:

- Different local provisions
- Knowledge of the local market
- A volume of the work done by the CAB at different locations
- Impact of CAB activities conducted under the accreditation of EA BAS on the local market, e.g. the share of the market share held by the CAB
- History of the assessment results of the conformity assessment activity and/or offices/location. Level of control and monitoring demonstrated by the CAB for each location/office.
- Whether the local office holds NAB accreditation for the same or different scope of activity, uses the same or different conformity assessment processes and whether it operates under the same or other management system.

Where the location holds an accreditation by the NAB, the planned assessments where possible shall comply with its programme.

## **5. Assessment assigned by / to another NAB**

### **5.1. General**

In cases where EA BAS has grand accreditation to CAB in the territory of another country or has grand accreditation of CAB that has offices/locations in another country, EA BAS shall endeavour to notify the State's NAB of the participation/evaluation of these CABs within three months before the beginning of the calendar year in which the evaluations will be carried out.

Where CAB accredited by EA BAS conducts conformity assessment activities in other countries, EA BAS shall endeavour to assign the NAB to the country concerned to carry out a certification assessment up to three months before the compliance assessment activity to be monitored.

For additional requests e.g. ad-hoc (for special purposes) assessments or extensions, EA BAS shall notify the NAB as soon as the request is known and cooperates with the NAB in order to make the necessary CAB assessment.

An agreement shall be concluded between EA BAS and the relevant NAB for the purpose of providing services in accordance with EA, ILAC and IAF Cross Frontier Policies before the NAB conducts an assessment of/by IAF Cross Frontier Policies, for the purposes of providing services in accordance with EA, ILAC and IAF Cross Frontier Policies.

Communication between EA BAS and NAB shall be made to determine the scope of the requested assessment with sufficient details and provide the necessary information to ensure reliable and efficient evaluation.

The information to be provided/received (where applicable) is the following:

- Report on the latest assessment of the central office, including details of discrepancies and actions;
- Up-to-date CAB information, including details of how it is organised and managed and how conformity assessment activities carried out at/from its locations are controlled;
- All specific additional requirements or activities to be specifically assessed by EA BAS/NAB;
- All requirements from regulators that may affect the activities of the location when accreditation is granted for notification purposes;
- Full range of activities that can be carried out from the local location under CAB accreditation;
- A detailed description of the scope to be assessed, including all sectoral schemes;

- Evaluation plan, including estimations of location throughout the accreditation cycle;
- A programme to evaluate all CAB activities, including estimations, if necessary;

EA BAS shall notify the NAB of any decision to suspend or withdraw accreditation for activities carried out in the country of the NAB.

## **5.2 Assessment assigned by another NAB**

Foreign NABs may assign EA BAS to conduct an assessment on the ground or monitor the activities of its accredited CAB on the territory of the Republic of Bulgaria. EA BAS agrees to carry out assessments on the territory of the Republic of Bulgaria on behalf of the foreign NAB, which has granted the accreditation for areas in which EA BAS performs accreditation activities and for which both NABs are parties to the Multilateral Agreement of EA.

EA BAS shall carry out **an assessment assigned** by another NAB under the following conditions:

- the existence of a legally binding contractual agreement between EA BAS and the foreign NAB for the provision of services in compliance with the cross-border policy of EA, ILAC and IAF under document EA-2/13 'Transboundary accreditation policy of EA and a cooperation procedure between EA members' and other relevant documents, if specified;
- notification by foreign NABs of the need to carry out the assessment at least three months before the assessment date;
- the availability of technical expertise to carry out the evaluation;
- there is an opportunity to perform the evaluation in instructions from the foreign NAB period.

When carrying out a cab assessment commissioned by another national accreditation body, EA BAS shall apply its accreditation procedure BAS QR 2 as well as the reporting forms specified in the procedure.

The assessment is carried out in the Bulgarian language. The results are presented by the team of assessors in Bulgarian after which they are translated into English and are provided to the NAB who has requested the assessment.

In the event that EA BAS has accredited CAB under a scheme of accreditation and scope of conformity assessment activities for which the NAB requests an assessment, EA BAS proposes to the NAB to submit the evaluation results translated into English – reports and other records (if desired by the IAB) carried out by IA BAS.

## **5.3 Assessment assigned to another NAB**

EA BAS may assign a foreign NAB to conduct an assessment on the ground or to monitor the activities of an CAB accredited by it outside the territory of the Republic of Bulgaria for areas where the NAB carries out accreditation activities and for which it is parties to the Multilateral Agreement of EA in compliance with the cross-border policy of EA, ILAC and IAF, on the basis of a signed legally binding bilateral contractual agreement between the two accreditation bodies.

When carrying out assessments assigned by EA BAS to the NAB, it applies its own accreditation procedures and is required to present the results of the evaluation in English.

In the event that the NAB has accredited the CAB under a scheme of accreditation and scope of conformity assessment activities for which EA BAS requests assessment, the NAB may submit the evaluation results translated into English – reports and other records (if necessary).

## **6. TRANSFER ACCREDITATION**

### **6.1. General positions**

In fulfilling the terms and conditions of this procedure for transfer of accreditation, EA BAS shall issue a CAB accreditation certificate with validity of 4 (four) years from the date of accreditation granted by the NAB to be transferred. In the event that a specific date cannot be fixed, the



accreditation shall be granted for four years from the date of a decision following a last on-the-spot assessment.

In case of transfer of accreditation, EA BAS shall endeavour to carry out the necessary actions without interrupting the validity of the CAB accreditation.

From the date of the official application for transfer of accreditation to CAB, the relevant CAB shall enter into force and the current versions of Accreditation Procedure BAS QR 2, Price list of the services provided by the Executive Agency "Bulgarian Accreditation Service" BAS QR 8, and all other documents from the management system of EA BAS, specifying rights and obligations of CAB.

### **6.2 Minimum requirements for the transfer of accreditation:**

- granted accreditation by the NAB party to EA MLA or to IAF or ILAC agreements;
- valid accreditation (accreditation is not suspended/withdrawn or in the process of suspension/withdrawal or in a complaint/address procedure or in an emergency evaluation procedure or in a transfer procedure to another NAB);
- the scope of accreditation for which a transfer is requested shall be the same as the scope of the accreditation granted. During a transfer procedure, the scope of the accreditation granted may be limited at the request of the CAB.

### **6.3 Acts and responsibilities in the transfer of accreditation**

EA BAS opens a transfer procedure for:

- CAB application for transfer of its accreditation from another NAB to EA BAS in free text. The application shall be signed by a representative of the legal entity to which the CAB belongs;
- written evidence of consent to the transfer of the NAB that has provided the accreditation provided by the CAB;
- accreditation certificate and data on the scope of accreditation provided by the NAB that granted the accreditation;
- the existence of a report from the latest on-the-spot assessment of the CAB provided by the NAB that granted the accreditation;
- the availability of information on complaints received and reviewed in relation to the activities of the CAB, whose accreditation will be transferred, provided by the NAB that granted the accreditation;
- Availability of an CAB declaration under Art. 19, Para.2 of the LNACAB (BAS QF 2.8).
- signed Accreditation Agreement BAS QF 2.8.1

Transfer may take place after:

- a) assessment of transfer from EA BAS (by document or on-site) of the CAB wishing to transfer its accreditation from another IA to BAS;
- b) an assessment carried out by EA BAS in its capacity as subcontractor of the NAB, which granted the accreditation;
- c) a joint assessment carried out on-the-spot by EA BAS and the NAB of another country;
- d) an evaluation by another NAB with the participation of a leading assessor and/or technical assessor of EA BAS.

### **6.4 Transfer assessment:**

Transfer assessment may be based on documents or on-the-spot assessments. Assessment by documents may be applied in cases where the decision on the last on-the-spot assessment is positive, the decision is taken within a period of no more than 6 (months) than the application for transfer and there are no changes in the circumstances under which the accreditation was granted.

When assessing the CAB to transfer accreditation, EA BAS shall require the NAB that has granted accreditation and shall take into account the CAB assessment reports and any other information relevant to the accreditation provided.

EA BAS may carry out an on-site assessment for transfer in the following cases:

- the last on-site assessment was carried out before 12 (twelve) or more months by the NAB that granted the accreditation;

- the decision on the last on-the-spot assessment was taken more than 6 months ago from the date of application for transfer;
- in the last on-site assessment carried out by the NAB that granted the accreditation, more than one significant discrepancy with the accreditation requirements have been identified;
- significant changes since the last on-the-spot assessment;
- the existence of information and circumstances which prevent the CAB compliance with the requirements by document assessment.

**The assessment and follow-up shall be carried out in accordance with the accreditation procedure BAS QR 2.**

**6.5 Maintenance of accreditation after transfer is carried out in accordance with item 5 of Accreditation Procedure BAS QR 2.**

In case of transfer after evaluation according to documents, EA BAS shall assess on-site from 9 to 12 months from the last on-site assessment.

**6.6 CAB located on the territory of a country, a full member of the European Accreditation Organisation (EA) and third countries.**

In the case of an application for accreditation or transfer from an CAB located on the territory of a State, a full member of the European Accreditation Organisation or third parties shall notify the local NAB. In this case, the assessment can be carried out by the local NAB and EA BAS or only by EA BAS, in cooperation with the local NAB.

**7. RECORDS**

All records established in connection with the implementation of this procedure shall be registered and managed in accordance with the procedure for the management of documents and records BAS QR 12 and the Instruction of Accounting and Documentation BAS QI 1.

**7.1. Documentation of assessments and reporting of results**

Legally binding contractual agreements between EA BAS and foreign NAB are signed in English. Correspondence shall be carried out if necessary in English. EA BAS may require translations of documents in English if necessary and provide an interpreter during the evaluations.

The documentation of the results of the evaluations carried out by EA BAS is carried out in Bulgarian and, if necessary, it is translated and provided to the foreign NABs in English.

The results of the evaluations carried out by the foreign NAB shall be documented in English.

**7.2. Requirements for accreditation certificates**

The accreditation certificate shall unequivocally indicate the address of the main office as such and the addresses of each of the units(s) together with the respective scopes of the accreditation. This information shall also be published in the register of accredited persons on the website of EA BAS in accordance with the rules established therefor.

**8. APPLICABLE DOCUMENTS**

BAS QR 2	Accreditation procedure for EA BAS
BAS QR 12	Document and records management procedure
BAS QI 1	Instructions for business activity and workflow

❖ *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.*

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