

Document name	Instruction for accreditation for purposes of notification	Version: <i>Revision:</i>	<b>1</b> <b>1</b>
Document code	BAS QI 2.3	Date:	<b>15.10.2021</b>
Approved by	Executive Director of EA BAS: Eng. Irena Borislavova		

**INSTRUCTION FOR ACCREDITATION  
FOR PURPOSES OF NOTIFICATION**

**List of amendments:**

Order No	Date of amendment	Version, revision	Reason for amendment	In force by:
1	20.07.2021	Version 1, Revision 2	Amendment and supplementation in regard to the findings of the EA Team conducted the first part of the peer-evaluation	15.09.2021



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## 1. PURPOSE AND SCOPE

This instruction shall specify the specific assessment and accreditation rules for the purposes of notification, in addition to the general accreditation rules of BAS as specified in BAS QR 2 and BAS QI 2.

## 2. GENERAL INFORMATION FOR ACCREDITATION FOR PURPOSES OF NOTIFICATION

EA BAS perform assessments for proof of competence and checks the requirements for notified persons in accordance with Decision 768/2008 and European Directives/Regulations for which it has been authorised by the respective Competent Authority in the Republic of Bulgaria.

In the above cases, EA BAS shall apply the requirements of EA-2/17:2020, further the Guide and grand accreditation for the conformity assessment modules / procedures according to the preferred accreditation standard specified in Table 1 and Table 2 of the Guide.

This requirement does not apply only in cases when the relevant Competent Body in Bulgaria has set another standard for accreditation in its notification procedures which are public. (See EA-2/17:2020 3.2, 4, Annex A).

## 3. BASIC REQUIREMENTS FOR NOTIFICATION BODIES/CANDIDATES FOR NOTIFICATION TO BE ASSESSED BY EA BAS.

In case of accreditation for the purposes of notification, EA BAS shall apply Guide EA-2/17:2020 of 14.04.2021, which is mandatory for the accreditation bodies and the accredited CABs for the purposes of notification.

CABs wishing to continue to perform activity for which they have been notified shall notify EA BAS as soon as possible if they perform activities for which accreditation standard has to be demonstrated, other than the standard to which they are accredited. This may require an extension of the scope and criteria of the evaluation by EA BAS, according to the approach 1+ in Guide EA—2/17:2020 Annex B.

If the notified body or candidate for notification uses in its activities conformity assessment results only by CABs accredited for these activities, the approach 1+ for EA assessments may not apply.

*For example:*

*A product certification body using non-accredited laboratories or conducting tests itself during the certification process and within the scope of the accreditation granted under БДC EN ISO/IEC 17065:2012, will be assessed by EA BAS for fulfilling the requirements of БДC EN ISO/IEC 17065:2012, and additionally for the requirements of EN ISO/IEC 17025:2017 for the performed tests.*

*If the product certification body uses an accredited laboratory for the necessary tests in the certification process, the assessment of the additional requirements of EN ISO/IEC 17025:2017 may not be carried out by EA BAS when assessing the PCB.*

## 4. ASSESSMENT BY EA BAS OF NOTIFIED BODIES/CANDIDATES FOR NOTIFICATION.

EA BAS grant accreditation for notification purposes in the areas for which it is authorised, in compliance with the basic rules of the Agency set out in the BAS QR 2 Accreditation Procedure and Instructions for Management of Evaluation Programmes BAS QI 2 and additional specific rules described in this procedure.

Applicants for accreditation shall sign in advance a Declaration of refusal of confidentiality with regard to the information provided by EA BAS to the Competent Body concerned.

When assessing notified bodies/candidates for notification, in the areas for which it is authorised, EA BAS shall verify compliance with the requirements of:

- The preferred accreditation standard set out in Table 1 and Table 2 of Guide EA-2/17:2020;
- The applicable additional requirements of other standards set out in Annex C to Guide EA-2/17:2020;
- The applicable additional requirements of the relevant European Directives/Regulations.

The assessment results, including the additional requirements, shall be documented by the assessment team in the assessment report.

EA BAS shall endeavour to perform the assessments of notified bodies/candidates for notification, in the areas for which it is authorised, in conjunction with the relevant Competent Body or with participation in the assessment teams of the Competent Body.

In determining the sample for witnesses, EA BAS is guided by the mandatory requirements set out in Annex C of Guide EA-2/17:2020.

EA BAS covers with witnesses all modules/procedures in one accreditation cycle and in accordance with the requirements of Annex C of Guide EA-2/17:2020 seeks to optimise the number of witnesses to the minimum necessary.

*EA BAS provides only a fixed scope of accreditation for the purposes of notification with dated versions of the harmonized standards.*

## **5. SPECIFIC REQUIREMENTS**

### **5.1. REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC**

When perform accreditation for notification, the following documents shall additionally apply:

— Instructions for accreditation of conformity assessment bodies as required by Regulation (EU) No 305/2011 of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

— Annex F of Guide EA-2/17:2020;

= Table 6 of Annex C of Guide EA-2/17:2020 for determination of witnessing activity.

The assessments are performed jointly with the Competent Authority – Ministry of Regional Development and Public Works (MRDPW).

### **5.2. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union**

In the case of accreditation in the field of rail interoperability within the European Union, EA BAS further assesses the requirements of the scheme described in the ERA Technical Document — ERA Assessment scheme 000MRA1044.

The scope of accreditation shall include the scheme and shall be expressed as follows: Accredited according to standard EN ISO/IEC 17065:2012 and ERA — Assessment 000MRA1044”.

The assessments are carried out with participation in the assessment teams of experts from the Executive Agency “Railway Administration” (EA RA).

All subsystems of the European railway system are witnessed in one accreditation cycle.

## **6. TRANSITION PERIOD:**

- The instruction shall be applied by the EA BAS from 14.04.2021;
- Accredited notified bodies and applicants for notification purposes, for the areas for which EA BAS has been authorised, shall demonstrate compliance with the requirements of EA-2/17:2020 and this instruction by 14.04.2023.

## **7. RELEVANT DOCUMENTS:**

BAS QR 2 Accreditation procedure

BAS QI 2 Instructions for Management of Assessment Programmes

BAS QI 2.4 Instruction for accreditation of conformity assessment bodies in accordance with the requirements of Regulation (EU) No 305/2011 of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.