Document code  Approved by  Executive Director of EA "BAS" Eng. Irena Borislavova  Rules of Operation Technical Committee of Accreditation	Approved by  Executive Director of EA "BAS"  Eng. Irena Borislavova  Rules of Operation	Rules of Operation Technical Committee of Accreditation	Document name	Rules of Operation Technical Committee of Accreditation	Version Revision	6
Rules of Operation	Rules of Operation	Rules of Operation Technical Committee of Accreditation	Document code	BAS QR 6	Date	01.01.2020
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**List of amendments** 

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Nō	Date	Introduced amendment	Propos	sed by	Date of effect	Signature Quality
		on page №	Family name	Signature	enect	Manager
1.	20/12/2005	4, 5, 6	Pencheva	/s/	01/01/2006	/s/
2.	02/05/2006	4	Mihaylova	/s/	01/07/2006	/s/
3.	15.02.2011	New version	Borislavova, Georgieva,	Approved on AC session held 11.04.2011	11.04.2011	/s/
4.	08.08.2011	5	On the grounds Council of Minis 187/2011 - cha of Directorate A ACAB	sters ange of name	01.01.2011	/s/

Νō	Date	Version, revision	Reason for amendment	Effective from:
5	Amendments in APPENDIX BAS QR 6 were approved at the meeting of the Accreditation Council held on 14.11.2013.	V.5, r.1	Corrective actions against CN3 from the EA peer evaluation 2013	01.02.2014
6.	12.11.14 (were approved at the meeting of the Accreditation Council held on 12.11.14)	N.5, 12	Suggestion for improvement in the Management System of EA BAS	20.11.2014
7.	05.02.15 (voted on meeting of Accreditation Council held on 05.02.15)	Version 5, Revision 3	Suggestion for improvement in the Management System of EA BAS	01.04.15
8.	12/01/2019 (voted at a meeting of Accreditation Council held on 11.12.2019)		Addition in relation with the requirements of item 4.6.2 and item 5.8 of БДС ISO/IEC 17011:2017.	01.01.2020

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### 1. General conditions

Technical Accreditation Committees (TACs) are established on the grounds of Art. 15, par. 1 of the Law on National Accreditation of Conformity Assessment Bodies (LNACAB). The Technical Committees provide decisions and standpoints in terms of technical requirements for accreditation, included in the applicable international standards and normative documents. Propose procedural rules for application of accreditation requirements, including transitions, etc. relating to the accreditation process or conformity assessment activities, subject to accreditation.

- 1.1 TAC decisions are approved in terms of their adequacy and applicability, and are adopted by the Executive Director of the agency. They are published on the agency's webpage and are mandatory for the conformity assessment bodies (see item 3.2 of BAS QR 2).
- 1.2 TAC provides standpoints and proposals, based on scientific data and availability of practical evidence, with the purpose of support when reaching a decision based on contemporary knowledge and experience in particular fields of activity.
- 1.3 The documents developed by the TAC do not contradict or exclude any of the requirements included in the applicable international standards and/or other normative documents.

# 2. Requirements to the structure and membership of TAC and WG

- 2.1 TAC is established by Order of the Executive Director of EA "BAS" in the following main fields of accreditation:
  - Testing laboratories;
  - Calibration laboratories;
  - Medical laboratories and Good Laboratory Practice;
  - Inspection bodies;
  - Systems certification bodies and environmental verifiers;
  - Persons certification bodies;
  - Management systems certification Validation and verification bodies.

For each established TAC is appointed a Secretary, who also prepares the minutes of TAC. The Secretary stores all records of activity of TAC and its working groups.

- 2.2 TAC members can be specialists with the necessary education, technical knowledge, skills and experience (according to item 5) in order to be able to provide expert opinions, standpoints, proposals, etc. TAC members shall cover at least minimal criteria for qualification of technical assessors against the criteria "education" and "professional experience". TAC members shall be representatives of the following stakeholder parties:
  - Customers Accredited or applying for accreditation CABs, manufacturers, consumers;
  - Experts (from scientific and specialized institutes, universities, etc.)
  - State institutions state regulatory bodies.
- 2.3 The number of TAC members according to fields is odd number, and reaches 21 at the maximum, as the principle for balance of interests shall be observed. TAC membership is approved by the Executive Director of EA "BAS".
- 2.4 Each specialist meeting the requirements of items 2.2 and 5.1 of the present rules may apply for participation in TAC representing a stakeholder party, by sending to the Secretary of the respective TAC detailed data for competence and autobiography. The acceptance and consideration of application for a new member is made in the event of a free position in the TAC membership. After positive TAC decision for

- acceptance of the new member, the proposal is presented for adoption by the Executive Director of EA "BAS", who can reject the application with motivation.
- TAC members elect Chairman and Deputy Chairman with a simple majority. The 2.5 Mandate of the Chairman and Deputy Chairman is two years, as admitted is their reelection for one more mandate.
- Within the TAC can be established temporary and permanent Working Groups. 2.6

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- 2.7 For the correct implementation of the requirements of BAS QR 18 and for evaluation of the participation in Interlaboratory Comparisons and Proficiency Testing schemes, in which participate accredited or applying for accreditation CABs, are established temporary Working Groups to the respective TAC, for the respective field of comparison, which is subject to evaluation. The participation of inspection bodies in ILCs and PT schemes is considered by WG to the TAC in the field of testing. The working groups are established by virtue of Order of the Executive Director upon lodged notification with request for approval of comparison. Proposal for establishment of WG is made by the Chair/Deputy Chair of the relevant TAC, conformed to the Director of ACAB Directorate.
- 2.8 Upon proposal of TAC are established temporary or permanent working groups in the event of demand of standpoint/proposal in specific field of activity: for instance testing in the field of construction, chemical analysis, food testing, etc. The WG members are selected from the TAC members, but if necessary, also depending on the specifics of the considered issue, external specialists may be involved in the TAC.

### 3. Tasks of TAC and WG

- 3.1 Discuss and propose specific criteria and provide standpoint on issues related to the harmonized application of the international requirements for accreditation of CABs;
- 3.2 Discuss and propose specific criteria and provide standpoint on issues related to the harmonized application of requirements to the activity of the Conformity Assessment Bodies;
- 3.3 Propose specialized profile and requirements for assessors in the relevant field of activity;
- 3.4 Elaborate specific rules and specialized questionnaires for the particular field of activity;
- 3.5 Participate in events on enhancement of assessor qualification;
- 3.6 Support EA "BAS" in the introduction of new activities in the management system;
- 3.7 Discuss and provide standpoint on draft documents of the European Co-operation for Accreditation (EA), the International Accreditation Organizations (IAF and ILAC), the Forum of Accreditation and Licensing Bodies (FALB) and documents on international, European and national level in relation to the activity of EA "BAS";
- 3.8 Elaborate specific rules and documents, supporting the accreditation process for particular field;
- 3.9 Support EA "BAS" in organization and evaluation of interlaboratory comparisons and proficiency testing.
- 3.10 Prepare and submit for approval by the Executive Director of EA BAS List of technical assessors / experts Annex 1 to BAS Q (F) 6/1 for inclusion, if necessary, in the Accreditation Commissions for specific areas of accreditation.

# 4. Organization of TAC work

- 4.1 At the beginning of each year TAC adopts Annual Work Program BAS Q(A) 6/1/5;
- 4.2 The Technical Accreditation Committees carry out their activity by holding sessions or providing standpoints on issues through electronic mail;
- 4.3 TAC sessions are held at least once an year with the purpose of ensuring the realization of the Annual Program;
- 4.3.1 Sessions are held according to preliminarily announced agenda BAS Q (A) 6/1/6, approved by the TAC Chairman. The TAC Secretary sends invitation letter for TAC session BAS Q (A) 6/1/7, ten days prior to the meeting. In extraordinary sessions, the invitation letter may be sent five days prior to the session.
- 4.3.2 Sessions are held on the territory of EA "BAS".
- 4.3.3 TAC sessions are held if quorum is available (half of the members plus one) up to half an hour after the announced beginning in the agenda. Session can be considered held, if it is attended by the Chairman/Deputy Chairman. Attendance is certified in Attendance List BAS Q(A) 6/1/3.

- 4.3.4 In the event of incapability to attend an announced session for objective reasons, a TAC member can preliminarily present a written standpoint concerning the issue under consideration, sent to the TAC Secretary. The <u>standpoint</u> under item 4.3.4 is taken into account in the decision-making.
- 4.3.5 Sessions are chaired by the TAC Chairman. In the event of Chairman's absence, the functions are executed by the TAC Deputy Chairman.
- 4.3.6 TAC members reach decision with quorum, by voting with simple majority of the participating members. In the event of equal number of votes "in favor" and "against", the vote of the Chairman/Deputy Chairman is decisive. Standpoints under item 4.3.4 are taken into account in the decision-making.
- 4.3.7 The TAC Secretary prepares minutes of each session, which shall be approved by the TAC Chairman within a term of ten days following the sessions. The Chairman or Secretary present the minutes in the Secretariat of EA "BAS". The minutes contain details for the discussions and statements of the individual members, for submitted written standpoints and reached decisions. Minutes are prepared in the form BAS Q (A) 6/1/4 Minutes of TAC sessions.
- 4.4 TAC members can perform their duties under item 3 remotely, by presenting written standpoints concerning particular issue or a document draft.
- 4.4.1 The TAC Chairman, through the TAC Secretary, sends a circular letter to the TAC members with the assigned task. The letter is supplemented with the necessary information/documentation for which a standpoint is required.
- 4.4.2 The provided standpoints are summarized by the TAC Secretary in the form BAS Q (A) 6/1/10.
- 4.4.3 The summarized standpoint on particular issue or a document draft with filled adequate remarks received from the TAC members is sent again for discussion. In the event that the standpoints of the individual members are the same or there are no significant remarks, is prepared a common standpoint/draft document, presented for approval by the Executive Director.
- 4.4.4 If necessary (many various standpoints and remarks), attendance session under the order of item 4.3 is summoned, and the materials are presented for discussion.
- 4.5 In the event of a member's two consecutive absences of TAC session under item 4.3 or in the event of non-presentation of standpoint requested under item 4.4 for non-objective reasons, EA "BAS" will consider that the member voluntary refuses participation.
- 4.6 Minutes of TAC sessions are presented to the Executive Director for adoption of decisions under item 1.1 of the present rules. The decisions are adopted within a term of one month. The Chairman may invite experts to TAC sessions. The Executive Director of EA "BAS" or a duly authorized person may attend each TAC session. With the purpose of confidentiality, the invited experts shall sign a declaration on preservation of manufacturing and commercial secrecy.

## 5. Criteria for competence of TAC and WG members

- 5.1 Chairman / Vice. Chairman and secretary of TAC evaluates the competence of the members of TAC and technical assessors / experts included in the List Annex 1 to BAS Q (F) 6/1 on the following criteria:
  - Fundamental knowledge in the particular technical field of activity;
  - Actual knowledge on applicable National and European normative acts, standards and other documents and guides in the relevant field;
  - Practical and/or scientific experience in the relevant field;
  - Knowledge on the accreditation process;
  - Knowledge on the current terminology in the relevant field.

Recommendable is the fluency in a foreign language (English, French, German, Russian).

- 5.2 TAC members present evidence for fulfillment of the criteria under item 5.1
- 5.3 Each WG member shall have fundamental knowledge in particular scientific field of activity, as well as practical and theoretical experience in the field;

- 5.4 For WG, established under item 2.7, except of the criteria listed in item 5.1, members shall:
  - Have knowledge on ISO 17043 and documents for statistical processing of data from interlaboratory comparisons and proficiency testing schemes.
  - Be able to make expert estimations of presented information from these interlaboratory comparisons in the particular field of activity.
- 5.5 The members of the relevant TAC participate in regular trainings for technical assessors in the particular area of accreditation, including in case of a amendment in a standard or other legal document, on the basis of which EA "BAS" conducts accreditation. TAC members do not participate in trainings that are intended for technical assessors / experts with the purpose of harmonization of the application of the accreditation requirements. The quality manager develops training program which is published on the website of the Agency under section "Training" by the 20<sup>th</sup> of February each year.

# 6. Preservation of manufacturing and commercial secrecy

The entire internal information accessible for TAC members shall be used in full confidentiality. Every TAC member is required to sign Declaration on preservation of manufacturing and commercial secrecy BAS Q(A) 6/1/2 and not announcing information obtained during TAC sessions.

In the event of ascertained and proven non-fulfillment of the confidentiality engagements, or attempt for delusion, incompetence and protection of someone's interests, the membership is discontinued and the necessary actions are undertaken pursuant to the legislation of the Republic of Bulgaria.

### 7. Records

Members of TAC / WG fill BAS Q (A) 6/1/1 Information for members of TAC in including them in the composition of TAC and in change of circumstances relating to their competence and belonging to an interested party. Members of TAC / WG fill only once BAS Q (A) 6/1/2 Declaration for the protection of industrial and commercial secrecy after their acceptance as a member of TAC.

The purpose is to periodically actualize the data for TAC/WG members and their conformity with the requirements noted in item 5.1.

The records related to the members and activity of TAC/WG are identified by procedure BAS QR 12 "Procedure for management of documents and records".

## 8. Applicable documents

**BAS Q(F) 6/1 -** Technical accreditation committees for each specific field of accreditation - List of Members with *Appendix 1 - List of technical assessors / experts for inclusion in the AccC, if necessary.* 

BAS Q(A) 6/1/1 - Information for TAC members -Declaration on preservation of manufacturing and commercial secrecy BAS Q(A) 6/1/2 BAS Q(A) 6/1/3 - Attendance list BAS Q(A) 6/1/4 - Minutes of TAC session BAS Q(A) 6/1/5 - Program for TAC work BAS Q(A) 6/1/6 Agenda BAS Q(A) 6/1/7 Invitation letter for TAC session - Order on the grounds of Art. 15 of LNACAB BAS Q(A) 6/1/8

BAS Q(A) 6/1/9 - Approved TAC decisions

BAS Q(A) 6/1/10 - Summary of written standpoints of TAC members

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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