

Document name	Rules of Operation Technical Committee of Accreditation	Version: Revision:	6 2
Document code	BAS QR 6	Date:	01.01.2025
Approved	Executive Director of EA "BAS"  Eng. Irena Borislavova		

## Rules of Operation

### Technical Committee of Accreditation

*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.*

## List of amendments

№	Date	Introduced amendment on page №	Proposed by		Date of effect	Signature Quality Manager
			Family name	Signature		
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 of Decree of Council of Ministers 187/2011 - change of name of Directorate AACGLP to ACAB		01.01.2011	/s/

№	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)	V.5, r.2	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)	Vesion 6	Addition in relation with the requirements of item 4.6.2 and item 5.8 of БДС ISO/IEC 17011:2017.	01.01.2020
9.	19.12.2022r. (voted at a meeting of Accreditation Council held on 19.12.2022r.)	Версия 6, Рев. 1	Merger of TKA "Testing and Proficiency Testing Laboratories" and TKA "Calibration and Proficiency Testing Laboratories") for the purpose of improvement Update of BAS Q(A) 6/1/7- Invitation letter for TAC session in accordance with the procedure	01.01.2023
10.	28.11.2024 (voted at a meeting of Accreditation Council held on 28.11.2024)	Version 6 Revision 2	Proposal for improving the organization of TAC meetings at the EA BAS	01.01.2025

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**CONTENTS:**

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<b>Section</b>	<b>Page</b>
1. General conditions	<b>Error! Bookmark not defined.</b>
2. Requirements to the structure and membership of TAC and WG	<b>Error! Bookmark not defined.</b>
3. Tasks of TAC and WG	<b>Error! Bookmark not defined.</b>
4. Organization of TAC work	<b>Error! Bookmark not defined.</b>
5. Criteria for competence of TAC and WG members	<b>Error! Bookmark not defined.</b>
6. Preservation of manufacturing and commercial secrecy	8
7. Records	<b>Error! Bookmark not defined.</b>
8. Applicable documents	<b>Error! Bookmark not defined.</b>

## 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 are established, merged, divided, restructured and closed by order of the Executive Director of the EA "BAS". TAC are established in the following main fields of accreditation:*

- *Testing, calibration and proficiency testing;*
- *Medical laboratories, good laboratory practice and proficiency testing;*
- *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. Members of the TCA may be specialists with the necessary education, technical knowledge, skills and experience (according to item 5) to be able to provide expert opinions, statements, proposals, etc. The members of the TCA should at least meet the minimum criteria for qualification of technical assessors according to the criteria "education" and "professional experience". The members of the TCA should be representatives of the following interested parties:

- Clients – accredited CABs or candidates for accreditation, producers, consumers;
- Experts (from scientific and specialized institutes, higher education institutions, etc.)
- State institutions – state regulatory bodies;

2.3 *The number of members of each TAC by representatives of interested parties is odd, the minimum is 3, and the maximum reaches 7 (seven) members in each TAC, and the total number of members of all TCAs is no more than 21 (twenty-one), and the principle of balance of interests should be observed. The number of members of each*

- TAC is determined by the Executive Director of the EA "BAS" by order, and the membership of each TAC is approved by the Executive Director of the 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 areas* 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..
- 2.5 TAC members *by area* elect Chairman and Deputy Chairman with a simple majority. The Mandate of the Chairman and Deputy Chairman is 2 (two) years.
- 2.6 *Permanent and temporary working groups may be established within the TAC by areas with tasks, subject matter of activity and term of the working groups determined by the Executive Director. The working groups are established by order of the Executive Director of the EA "BAS" at the request of the EA "BAS" or at the proposal of the Chairman or Deputy Chairman of the TAC, who also propose their members, after assessing the necessary competence, depending on the subject matter of work. Only experts assessed by the TCA with expertise in the relevant field, according to the task and subject matter of the WG, may be proposed as members of the working groups. The working groups shall hold meetings according to the TAC rules. The working groups, which are not of a temporary nature, shall be closed by order of the Executive Director of the EA "BAS" at the request of the EA "BAS".*
- 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 or BAS, *by area* 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 TKA by areas 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 work of TKA**
- 4.1 *By the end of January of each calendar year, each TAC of the EA BAS adopts a program for its work, in areas BAS Q (A) 6/1/5.*
- 4.2 *Each TAC conducts its activities through in-person sessions, including those held via videoconference, through in remoot sessions or by providing written opinions submitted via e-mail or through the online platform of the EA BAS.*
- 4.3 *Each TAC of the EA BAS must hold an annual in-person meeting in January of each calendar year, at which it adopts a report on the implementation of the annual program for the previous year, the TAC 's annual program for the current calendar year, training programs, and considers other issues within its competence and at its own discretion. All other meetings of the TAC are held in remoot sessions or by taking a position, unless there is an explicit request from the EA BAS for another way of holding the meeting.*
- 4.3.1 *Sessions are held according to preliminarily announced agenda BAS Q (A) 6/1/6, approved by the TAC Chairman, with the agenda necessarily indicating the format of the meeting - in person, in remoot or by giving opinions. The TAC Secretary sends invitation letter for TAC session BAS Q (A) 6/1/7, to each member of the respective TAC through the online platform of the BSA Executive Agency up to five days before the meeting in the case of in-person meetings and 5 days before the deadline announced in the invitation for written participation or written statement in the case of in-person sessions or when giving standpoints.*
- 4.3.2 *In-person TAC sessions, including those via videoconference, are held in the building of the EA BAS. The sessions in remoot are held by exchange of papers, with the participation and voting of each member being certified by a handwritten or qualified electronic signature. In the case of sessions in a remoot, the announced agenda also includes a deadline within which each member should provide the relevant signed statements in order to be considered to have participated/voted in the relevant session.*
- 4.3.3 *In-person 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. A sessions in person or in remoot may be considered held if the chairman/deputy chairman are present. In the case of meetings in person, an Attendance List BAS Q(A) 6/1/3 is kept to certify attendance. The chairman, deputy chairman or secretary of the relevant TAC by area shall confirm the participation of members in the attendance list via videoconference.*
- 4.3.4 *At in-person session, if a member of the TAC by region is unable to attend an announced meeting for objective reasons, a TAC member can preliminarily present a written standpoint concerning the issue under consideration, sent to the TAC Secretary. The standpoint under item 4.3.4 is taken into account in the decision-making.*
- 4.3.5 *Sessions are chaired by the relevant one TAC Chairman. In the event of Chairman's absence, the functions are executed by the TAC Deputy Chairman. In the case of in-person session, the Chairman of the respective TAC, the Deputy Chairman or the Secretary shall certify by signature in the minutes of the meeting the participation, statements and votes of the members who take part in an in-person meeting via videoconference.*
- 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 *For each in-person session, the secretary shall prepare written minutes, which must be approved by the chairman of the relevant TAC within 10 (ten) days of the sessions.*

*For remoot sessions, the secretary shall prepare written minutes within 10 (ten) days of the announced deadline for participation, and shall submit them for approval to the chairman of the relevant TAC, together with all received documents. The chairman or secretary of the relevant TAC shall submit the minutes of the meeting signed by them to the registry of the EA BAS, together with all documents related to the relevant meeting, including the invitation, written opinions, votes. The minutes shall contain information about the discussions and statements of the individual TAC members, about the received written opinions and the decisions made. The minutes of meetings of the general TAC and TAC by areas shall be kept in the form BAS Q (A) 6/1/4 Minutes of TAC sessions..*

4.4 *TAC members may perform all other tasks under item 3, with the exception of participating in a meeting, and by providing written opinions on a specific issue or draft document.*

4.4.1 The TAC Chairman, through the TAC Secretary, sends letters with a task to the members of the TAC *through the online platform of the EA BAS*. 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 20th of February each calendar year.

## **6. Preservation of manufacturing and commercial secrecy by area**

The entire internal information accessible for TAC members by area 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 about TAC members, Assessment of the competence of TCA members, Requirements for and assessment of technical assessors/experts for inclusion in the CA, if necessary

**BAS Q(A)6/1/2** - Declaration on preservation of manufacturing and commercial secrecy

**BAS Q(A)6/1/3** -Attendance list

**BAS Q(A)6/1/4** -Minutes of TAC

**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 a TAC session

**BAS Q(A)6/1/8** - Order on the grounds of Art. 15 of LNACAB

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

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