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INSTRUCTION
FOR MANAGEMENT OF ASSESSMENT PROGRAMS.

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List of amendments

№	Date	Introduced amendment on page №	Proposed by		Date of effect	Signature Quality Manager
			Surname	Signature		
1.	01.03.2009		Dushkova	/s/	01.03.2009	/s/
			Pencheva	/s/		
2.	15.09.2009	4,5,12,15	Dushkova	/s/	15.09.2009	/s/
3.	17.03.2010	8,9,15	Georgieva	/s/	17.03.2010	/s/
4.	09.04.2011	Due to change in numbering in BAS QR 2, in BAS QI 2, version 6, revision 1 is made technical amendment on page 5 in item 2.2.2 of the text "item 6.1.1 d) or item 6.2.1 b)" with "item 5.4.2 d) or item 5.4.2 b)", and on page 12 in item 4.4.2 the text "BAS QA 7.1.5 a) and BAS QA 7.1.5 b)" (in force until the end of 2009) becomes "BAS QA 7.1.5".				/s/
5.	01.01.2012	4,5,7,8,12,15	Ilieva	/s/	01.01.2012	/s/

List of amendments

№	Date of amendment	Version, revision	Reason for amendment	In force from
6.	15.05.2013	Version 3, revision 5	Introduced good working practices and unification of rules and texts in documents, concerning aspects of equal processes; Withdrew EA documents.	15.05.2013
7.	30.08.2013	Version 4	Corrective actions	01.09.2013
8	12.05.2014	Version 4, Revision 1	Preventive actions	12.05.2014
9.	12.09.2016	Version 4, Revision 2	Application of the requirements of IAF MD 17 and EA 3/13	01.10.2016
10	23.01.2017	Version 4, Revision 3	Changing the planning periods of CAB assessments Application of determination of sampling of a new activity in the field of the MSCB - ISO 39001	01.02.2017
11	15.12.2017	Version 4, Revision 4	Amendment and supplementation in regard to the findings of the EA Team conducted the first part of the peer-evaluation	01.01.2018
12	03.02.2020	Version 5	Amendment in regards with the transition to the new version of EN ISO / IEC 17011: 2018, revision of IAF MD 17, new structure of the AOO Directorate	03.02.2020
13	26.03.2020	Version 5, Revision 1	Terminological changes	26.03.2020

14	20.07.2021	Version 5, Revision 2	Amendment and supplement in connection with the findings of the EA team that conducted the first part of the peer evaluation	15.09.2021
15	13.09.2021	Version 5, Revision 2	Amendment of the effective date of the document in connection with a report from the quality officer Int. No. 20-02/005/B/13.09.2021	15.10.2021
16	01.01.2025	Version 5, Revision 3	Amendment and supplement in connection with the coordination of changed documents from the EA BSA management system	24.02.2025

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CONTENTS

SECTION	PAGE
1. MANAGEMENT OF THE PROGRAM PLAN FOR ON-SITE ASSESSMENTS	
2. PREPARATION AND ORGANIZATION OF ON-SITE ASSESSMENT	
2.1 APPLICATION FOR ON-SITE ASSESSMENT	
2.2.1. Assessment of testing laboratories, calibration laboratories, testing and calibration laboratories and inspection bodies	
2.2.2 Assessment of certification bodies and environmental verifiers	
3. FORMATION OF ASSESSMENT TEAM	
4. DETERMINATION OF THE AMOUNT OF TIME FOR IMPLEMENTATION OF ASSESSMENT	
Table 4.1. Testing laboratories, calibration laboratories, testing and calibration laboratories and inspection bodies	
Table 4.2. Certification bodies and environmental verifiers	
Table 4.3. Time in hours for traveling to the larger populated areas in Bulgaria	
Annexes:	
<u>Annex 1</u> Consolidation of economic sectors / activities in clusters for the purpose of determining the number of witnesses in assessments of certification bodies against ISO 9001, ISO 14001, ISO 45001, ISO 22000, ISO 50001	
<u>Annex 2</u> Internal guidelines for witness the activities of CABs by a EA BAS assessment teams	
<u>Annex 3</u> Guidelines for the submission of information from the CABs on their activity in the previous year	
<u>Annex 4</u> Instructions for transition to new EA, IAF and ILAC documents	
<u>Annex 5</u> Analysis of the risks to impartiality for a specific LA/TE/TA	
<u>Annex 6</u> Instructions for application of items 8.2 and 5.2 of BAS QR 2 for assessment of changes in the normative acts from the scope of CAB accreditation	
<u>Annex 7</u> Table for transition to	
<u>Annex 8</u> Instruction for assessment of CABs operating in more than one location (multi-site)	
<u>Annex 9</u> Instructions for assessing PCB that perform testing in the certification process themselves or use non-accredited subcontractor laboratories.	

The present instruction regulates the rules for planning of the on-site assessments, definition of the scope of assessment and the rules for formation of assessment team.

For some of the accreditation schemes, additional instructions have been developed that complement and apply together with this instruction, as follows:

Validation and verification bodies - BAS QI 12 Instruction on the criteria and methods of accreditation and supervision of validation and verification bodies.

Organic farming certification bodies, according to Regulation (EU) 2018/848 - BAS QI 19 Instruction on the criteria and methods for accreditation and supervision of organic farming certification bodies, according to Regulation (EU) 2018/848 of the European Parliament and of the Council.

- Conformity assessment bodies - BAS QI 2.3 Instruction on accreditation for the purposes of notification

- Construction product certification bodies for the purposes of notification under Regulation (EU) No. 305/2011 - BAS QI 2.4 Instruction on accreditation of conformity assessment bodies according to 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;

-Conformity assessment bodies BAS QI 2.6 instruction for accreditation of conformity assessment bodies - testing laboratories for the purposes of official control carried out by the Bulgarian Food Safety Authority - assessment together with the Bulgarian Food Safety Authority

- Certification bodies for management systems according to ISO 37001 Anti-bribery management systems - BAS QI 25. Instruction on the criteria and methods of accreditation and supervision of Certification bodies performing certification according to ISO 37001 Anti-bribery management systems

- Environmental verifiers according to Regulation (EC) No. 1221/2009 –BAS QI 4 Instruction on the criteria and methods of accreditation and supervision of environmental verifiers according to Regulation (EC) No. 1221/2009 of the European Parliament and of the Council.

1. Management of the program plan for on-site assessments

1.1 EA BAS introduces electronic management of the accreditation process and maintenance of accreditation by means of Program plan for on-site assessments, in fulfillment of the requirements of the Law on National Accreditation of Conformity Assessment Bodies, БДC EN ISO/IEC 17011, EA BAS Accreditation Procedure BAS QR 2. In the development of the Program plan are observed the recommendations of БДC EN ISO/IEC 19011.

The Program plan envelops planning of all on-site assessments under opened accreditation procedures and maintenance of accreditation of already accredited Conformity Assessment Bodies.

The Program plan is elaborated and updated by the Head of department ACIB/AL after consultation with Director of ACAB Directorate and is approved by the Executive Director of EA BAS.

Input data for development and actualization of the program are the following:

- Opened accreditation procedures;
- Accredited Conformity Assessment Bodies (CABs);
- Term for implementation of on-site assessment in initial accreditation
- Term for implementation of on-site assessment in re-accreditation/extension of accreditation scope
- Term for implementation of subsequent on-site assessment
- Term for planning of first surveillance after accreditation/re-accreditation
- Term for planning of each following planned surveillance/re-assessments
- Term, defined by the person who monitored the report of the lead assessor
- Term from reported occurred changes of the circumstances under which accreditation has been granted – up to 2 months from reporting;
- Term for assessment for recovery of accreditation;
- Available lead assessors for the relevant accreditation field;
- Work-load of the lead assessors;
- Observation of the principle each assessment of a CAB to be performed by different lead assessor, with the exception of extraordinary assessments;

- Observation of the requirements and criteria in the documented management system of EA BAS;
- Demand of participation of foreign technical assessor/expert from NAB, signatory to the EA MLA for the relevant field of accreditation.
- The program shall take into account the demand of assessment of all certification activities performed abroad (cross-frontier)

The planning of the scope of assessments is performed by the lead assessor, after completion of the initial assessment / re-accreditation assessment in the assessment report (Section F to BAS QF 2.9.5.4), so as to cover all accreditation requirements and conformity assessment activities, representative of the scope of accreditation at the respective places for each candidate for accreditation or accredited CAB for the accreditation cycle, taking into account the risk.

Justification for the risk assessment and actions when planning the accreditation cycle is presented in Annex 1 to BAS QF 2.9.5.4. Section F Analysis of the risks associated with the work of the CAB when planning the accreditation cycle. The annex is completed after each assessment carried out before the preparation/updating of BAS QF 2.9.5.4 Section F.

In the case of extension of the validity of an accreditation certificate in accordance with Art. 27 (4) of the ZAEA and item 6 of BAS QR 2, the accreditation cycle starts from the date of expiry of the validity of the accreditation certificate before the extension. In this case, depending on the extension period, after a risk assessment when preparing an assessment program for the accreditation cycle in BAS QF 2.9.5.4. Section F, additional planned surveillance may be planned to comply with the requirements of item 5.1 of BAS QR 2.

The lead assessor, before preparing the plan for the second planned surveillance, shall carry out a check and analysis of the coverage of the accreditation scope in the previous planned assessments in the accreditation cycle and, if necessary, adjust the assessment planning in BAS QF 2.9.5.4. Section F, so as to ensure assessment during the accreditation cycle of all accreditation requirements and conformity assessment activities representative of the scope of accreditation of the relevant locations provided in the scope of accreditation of the CAB.

Planning of the on-site assessments shall be updated after each assessment if necessary.

When planning on-site assessments, it is taking into account to the necessity of assessment of all CAB activities performed in other countries according to the requirements of EA 2/13, based on the amount of CAB activities, their criticality and feedback from the local Accreditation Body. The sample of activities performed by CABs in the territory of another country or CABs that have offices / locations in another country is determined on the basis of risk assessment of the activities and market conditions in the countries where the foreign locations are located, taking into account factors such as - different local legislation; knowledge of the local market; volume of work performed by the location of the CAB abroad; impact of the CAB activities performed under the accreditation of EA BAS on the foreign market; history of the results of the assessment of the conformity assessment activity incl. at the foreign location; level of control and monitoring demonstrated by the CAB for each location; whether the foreign office is accredited by NAB for the same or different scope of accreditation, and whether it operates under the same management system and process of activity on the basis of which accreditation was granted by NAB;

When it is necessary to carry out an assessment, including witnessing of the activity in another country, EA BAS seeks assistance to the relevant National Accreditation Body according to its cross-border accreditation policy and BAS QR 30

1.2 Conformance

The Program plan is prepared by Head of department ACIB/AL and is approved by the Director of ACAB Directorate after coordination with the responsible person for the field of activity of the CAB in accordance with the management system of EA BAS in November for the on-site assessments to be carried out in the period January - June and respectively in May for the period July - December and is approved by the Executive Director of EA BAS.

The executive director of the EA BAS, the director of the ACAB Directorate and the heads of the AL and ACIB departments have access to the plan-program in electronic form.

Each lead assessor one month prior to the start of the above-mentioned periods, respectively in December and in June, receives a sample of the Program plan concerning the particular engagements for conformance before its approval.

The conformance is made in view of:

- Presence of conflict of interests;
- Period for implementation.

In the event of ascertained incapability for realization of particular on-site assessment, the lead assessor informs in writing the director of ACAB Directorate, and after that a new selection of lead assessor is carried out, and proposes to the Executive Director of EA BAS for adoption.

Each Operation Logistics Person from the *department ACIB/AL* receives excerpt from the Program plan with records for the assessments of CABs for which he/she is responsible, follows the implementation and reports monthly to the *Head of department ACIB/AL*. The *Head of department ACIB/AL* prepares a report on the course of implementation of the program on each six months, which is presented to the Director ACAB Directorate and to the Executive Director of EA BAS.

1.3 Re-planning – Changes to the plan-program in accordance with the specified deadlines are made in the event of:

- Justified written request by a CAB for change of the initially defined period for on-site assessment;
- Extraordinary circumstances (meteorological conditions, illness and others)
- Demand of involving independent technical expertise – participation of foreign TA/TE from NAB, signatory to the EA MLA
- Other working engagement of the assigned LA.

Any change in the plan - program is made at the proposal of the HD AL/HD ACIB after coordination by the DD ACAB and is approved by the Executive Director of the EA BSA.

2. Preparation and organization of on-site assessment

2.1 Application for on-site assessment

2.1.1. Up to the third date of the previous month, for which the on-site assessment is planned, the applications are presented on paper and electronic holder by the lead assessor to the Head of *department ACIB/AL*, who registers them in the Program plan for on-site assessments, and forwards them to the operation-logistics person from the *department ACIB/AL*, responsible for the respective dossier of the CAB or open procedure for initial accreditation/re-accreditation/extension of scope. The noted period for application does not apply for witnesses of activity of Management Systems Certification Bodies, Product Certification Bodies, Persons Certification Bodies, validation and verification bodies or witness of the activities of laboratories and inspection bodies when the witness is carried out after the on-site assessment.

2.1.2. The lead assessor applies for the period for implementation of the relevant assessment by filling a form for formation of team BAS QA 2.1.13.

After reviewing the records of previous assessments, the LA completes the application with the documents provided for in the first part of BAS QA 2.1.13 (copy of application for accreditation / re-accreditation / extension; report from preliminary study (in case of accreditation, re-accreditation or extension) original of BAS QA 2.8.4, copies of annexes BAS QA 2.1.6 / 2.2.6 / 2.7.6 and BAS QA 2.1.8 / 2.2.8 / 2.7.8, etc. (in accreditation/re-accreditation/extension of scope); copy of order currently in force and certificate for accreditation with the necessary marking concerning the implemented and planned witness of activity; last on-site assessment report – copy of the conclusion, implemented witness of activity and planning of next on-site assessments; correspondence between the CAB and EA BAS or other type of documents, necessary for the competent implementation of the on-site assessment. The application is supplemented with a financial check when all payments are made.

2.1.3. The scope of the on-site assessment is determined by the lead assessor, according to the rules described in item 2.2.1 and item 2.2.2 of the instruction, after performing an analysis of the risks from the CAB activities, taking into account the type of assessment, the number of all premises in which one or more of the main CAB activities are carried out, CAB activities in other countries, CAB staff, planning performed in the report of the previous assessment, changes in the circumstances after the previous stage of the procedure, information received to the CAB on complaints / objections, reporting of weaknesses identified in previous assessments (with

instructions and examples of critical areas), number of issued protocols and certificates, recommendations from the responsible official made during the review of the report from the previous assessment, etc.

Regardless of the general rules under item 2.1.3 of the present instruction, after concordance with the assessors team, the lead assessor may extend the scope of the on-site assessment during its implementation, aimed at efficient evaluation of the implementation of the accreditation requirements.

2.1.4. Assessment methods:

- a) Review by vertical method for assessment of records in CAB's office verifying its competence to carry out the activities within the applied scope of accreditation, including records of completed calibrations, controls, audits, assessments, exams and certifications carried out by CAB/EV, as the sample shall be determined according to the rules set out in items 2.2.1 and 2.2.2.
- b) Review by a horizontal method of assessing records demonstrating that there is the necessary equipment, conditions, competent personnel for all specific functions - testing, calibration, control, audit, assessment, exams and certification in accordance with the relevant requirements.
- c) Witness assessment of activity.
- d) Interviews with the personnel of the CAB.

2.1.5 The purpose of witness assessment of the activity of CABs is to provide confidence in the competence of the CAB to carry out its activities within the scope of accreditation, assessing the practical application and efficiency of the procedures for testing, calibration, inspection, certification, etc., competence of personnel to carry out the relevant conformity assessment activities.

Witness assessment can also be done as a method of assessing complaints received and feedback from stakeholders.

2.1.6. In witness of the activity of CAB the preparation, performance, follow-up reporting and the competence of the personnel carried out testing, calibration, inspection, certification, and report verification are reviewed and evaluated.

2.1.7. Prior to conducting of witness assessment of the activity of the CAB, the Lead Assessor consulted by the Assessment Team and the respective person responsible for the accreditation area determines the scope of witness assessment according to the rules presented in 2.2.1 and 2.2.2, including the members of the personnel which will be witnessed in accordance with their competence, in a manner the competence of as many as possible CAB's members of personnel to be assessed during the accreditation period.

2.1.8. The witnessing of the activity is carried out by a technical assessor and an expert (if necessary) responsible for the assessed scope.

2.1.9. In the area of accreditation of testing laboratories, calibration laboratories, inspection bodies, proficiency testing providers, in general, the witnessing of the activity is carried out during the on-site assessment, as the necessary time for it is provided. If necessary, the witness of the activity for these areas of accreditation may also be carried out after the on-site assessment in the CAB's office / premises.

2.2.1 Assessment of testing laboratories, calibration laboratories, testing and calibration laboratories, inspection bodies and proficiency testing providers

2.2.1.1 Initial accreditation, Re-accreditation, Extension of scope

Assessment of 100% of the applied scope for accreditation shall be carried out. In exceptional cases, for instance a huge scope, this percentage may be reduced by maximum 20 %, with the exception of on-site assessments of calibration laboratories.

Exception from the scope cannot be testing methods, products and inspection processes considered risky in terms of: technical equipment, competence of the personnel, specific environmental conditions, methods required by a normative document or such used for assessing the conformity of products significant for the health of humans, animals and environment. Exception of the scope of assessment may be admitted for methods confirmed by means of successful participation in ILC/PT, even when they are considered risky.

- a) the sample shall be determined in view of:

- the risks regarding technical equipment, methods, competence of the personnel or hazard to the health of people, animals or hazard to environment, and with successful participation in interlaboratory comparisons.
- premises, in which main activities are performed – as each one of them is assessed.
- b) the assessment includes vertical method, horizontal method for assessment, interviews with CAB staff and witness of activity, as for:

WITNESS ASSESSMENT ACTIVITY:

General requirements:

The team determines the subject of witness, as priority shall be given to the ones which are risky in relation to technical equipment, methods, competence of the personnel or hazard to the health of people, animals or hazard to environment, and complying with TAC decisions in the relevant area, if available. Examples of witness are: methods, applied in testing of more than one product/characteristic, methods requiring specific environmental conditions or specific qualification of the personnel, methods for which information for ILC/PT participation is missing, or the information states unsatisfactory participation, etc.

In determination of the witnesses, the team shall also take into account the range of testing/calibration of particular characteristic/quantity, if it is significant for the competence of the laboratory.

Testing/calibration methods or inspection method/ procedures applied for accreditation, for which the CAB cannot present records for completed customer applications, are mandatory to be witnessed.

For calibration laboratories – calibration for each quantity of the applied scope;

For testing laboratories and inspection bodies - At least 60% of each main group of products/characteristics (inspected parameters) /methods of the scope applied accreditation.

For proficiency testing providers – for each type of program (scheme) for proficiency testing (including the activities of subcontractors)

2.2.1.2 Surveillance

In first planned surveillance - minimum 50 % of the accredited scope. In the cases, in which is applied reduction of the percentage of the assessed scope in initial assessment, the same is mandatory assessed.

In following planned surveillance - minimum 30 % of the accredited scope.

In one accreditation cycle is assessed the conformity of each of the premises, in which one or more of the main activities of the CAB are carried out.

In one accreditation cycle is assessed the conformity of the CAB with all applicable requirements for the entire accredited scope.

WITNESS ASSESSMENT ACTIVITY:

Representative sample, which composes minimum 60% of the scope of assessment.

Fields of the accreditation scope, which were not witnessed, if such exist, are mandatory.

In lack of activity in part of the granted accreditation scope within a period of 18 months prior to implementation of the on-site assessment, the CAB is obligated to ensure a witness in this part of the granted scope.

The general requirements in determination of witness remain the same as in initial assessment.

In each on-site assessment (surveillance and reaccreditation) the effectiveness of corrective actions taken to remove the nonconformities from the previous assessment is evaluated;

2.2.2. Assessment of Certification Bodies of products, management systems, persons and environmental verifiers

2.2.2.1 Rules for determination of the sample for assessment

1) In **initial accreditation, re-accreditation and extension of scope** EA "BAS" performs assessment of 100% of the applied scope for accreditation. In exceptional cases, this percentage may be reduced by maximum 20 %.

Exception from the scope cannot be applicable to schemes for certification of products, processes, persons and systems considered risky in terms of: technical equipment, competence of the

personnel, specific in terms of the process on implementation (for instance integrated management systems with multiple sites), as well as those for which assessment is required according to a regulatory document or such used for assessing the conformity of products significant for the health of humans, animals and environment.

2) In certification of products and persons, if possible, the sample shall be accorded with the groups of products/fields/types of competence (methods) which are considered to be risky in relation to competence of the CAB or hazard to the health of people, animals or hazard to environment.

3) In certification of systems within the accreditation cycle EA BAS shall assess the competence in the entire scope of accreditation for all applied codes, categories foods, etc. on each management systems by using the assessment methods set out in item 2.1.4.

4) Review under the vertical method for assessment of records of on the office of CAB, verifying its competence for the activities within the applied scope of accreditation, including records of closed audits and certification of CAB/EV - minimum 50 % of the sample, for which no witness of activity is foreseen.

5) Review under the horizontal method for assessment of records demonstrating, for example that CAB has competent personnel for all specific functions of certification according to the relevant requirements - for the remaining part of the sample.

6) In **first planned surveillance** is performed an assessment of minimum 50 % of the accredited scope. In the cases, in which is applied reduction of the percentage of the assessed scope in initial assessment, the same is mandatory to be assessed.

7) In **following planned surveillance** - minimum 30 % of the accredited scope.

8) In one accreditation cycle is assessed the conformity of each of the premises, in which one or more of the main (key) activities of the CAB are carried out.

9) In one accreditation cycle is assessed the conformity of the CAB with all applicable requirements for the entire accredited scope.

The sample is assessed by means of the methods described in initial assessment.

10) If it is not possible to be assessed the entire accredited scope within the accreditation cycle EA BAS reduces the scope of accreditation (e.g. for EA / IAF codes) for which no competence has been demonstrated.

11) For each on-site assessment (surveillance and re-accreditation), the effectiveness of the corrective actions taken to remove nonconformities from the previous assessment is assessed;

12) *Upon initial accreditation or extension of the scope of accreditation for a certification scheme, the CAB is required to have at least one conformity assessment activity performed, for which records must be submitted, so that the team of assessors of the EA BAS can assess the certification process.*

2.2.2.2 General requirements in determination of the sample for witness of activity and performing of witness of activity:

1) In determining the sample for witness activity, factors are taken into account, such as overall presentation of the CAB, complexity of processes and activities, legal and other requirements, feedback from stakeholders, including complaints, requirements of certification schemes, changes in the way CAB work (eg. sharp increase in workload), accumulated trust in the process of assessment and approval of staff competence, results of previous assessments (witnesses), number of certificates issued, number of auditors / examiners (internal or external), various stages of certification, initial, supervision, recertification, combined, integrated audits, with multiple sites, countries in which certification is performed, decision of TAK for determination of critical areas (if applicable), etc.

2) When selecting a witness assessment, the team should aim to witness various lead auditors / auditors / technical experts / examiners and with different clients.

3) With the coordinating letter for the EA BAS assessment team, the CAB is required to provide a complete and up-to-date timetable for the validated and planned activities of certification / verification with applicable information (e.g. dates, location, audit team / assessors / examiners, type and scope of the audit, etc.).

4) It is the duty of the CAB to ensure that its clients will give full access to the EA BAS teams for witness the activity of the Body.

5) Clients of CABs should be informed that if they refuse to accept a witnessed assessment by EA BAS, they should give a clear and acceptable by the CAB and EA BAS justification, which, if not

accepted, will be followed by appropriate sanctions (e.g. withdrawal of certification under accreditation / refusal to grant a certificate under accreditation).

6) EA BAS will take action to refuse or withdraw a specific scope of accreditation if it receives unjustified refusal from the CAB a witness of activity to be conducted in this specific scope and in case that the CAB has not taken appropriate measures towards the organization, when the refusal to conduct a witness comes from it.

7) In order EA BAS assessment team to carry out the necessary preparation for witness the activity, the CAB should provide appropriate information, such as an audit / evaluation / examination plan, previous audit reports, competency records of team members, justification for calculating audit time (if applicable), prior to the witness.

8) Witness of activity is usually carried out by the same assessment team of EA BAS who carried out the on-site assessment (technical assessors and experts), as the necessary competence and evaluation of the overall certification process to be ensured, additional assessors / technical experts can be included in the team. Also, the witnesses of the activity, when it is not part of the on-site assessment, can be performed by TA / TE that have not participated in the on-site assessment but have the necessary specific competence to assess the CAB conformity assessment activity.

The assessment team for carrying out witness assessment of activity shall be coordinated according to the procedure of item 4.3.2 of BAS QR 2.

9) The CAB has the obligation to agree the EA BAS team with its clients, giving them clarifications about the procedure for witness assessment of the activity.

10) The CAB should not change its team of auditors / assessors / examiners, the audit plan or the duration of an audit related to the witness assessment of activity. If there are such changes, the CAB shall provide appropriate justification for it.

11) Depending on the objectives of the witness assessment, the full audit / assessment / examination / verification or only certain parts of the audit / evaluation / examination / verification may be observed.

12) Where possible, the EA BAS assessment team conducts an opening meeting with the CAB assessment team, explaining the objectives of the witness assessment and the order of the witness assessment process. If it is not possible to conduct an opening meeting, the information is provided otherwise.

13) CAB's clients are obliged to inform in advance the team of auditors / assessors / examiners and the EA BAS assessment team for all applicable safety requirements. EA BAS assessors must observe the safety rules introduced by the organization.

14) The assessors act as observers without affecting the conduct of the assessment process by the CAB team. The information collected during the witnesses assessment of the activity is treated by the team of assessors of EA BAS as confidential. Detailed information about the rights and obligations of the assessment team of EA BAS during the witness assessment of the activity is presented in Annex N° 2 to this instruction.

15) EA BAS assessors are only entitled to report immediately or raise a non-conformity when there is an imminent danger to the health and safety of the assessment team or the environment.

16) The result of the witness assessment of activity, including any identified findings and non-conformities, shall be reported and discussed with the CAB assessment team when the witness assessment is completed. Evaluators of EA BAS have to conduct a closing meeting with the assessment team of the CAB and / or the CAB management as soon as possible after the end of the witness assessment, in the absence of the CAB clients. Where it is not possible to hold a closing meeting immediately after the end of the witness assessment, it can then be held through an additional meeting or to present and discuss the results by telephone and e-mail.

17) After completion of the witness assessment, the CAB is required to submit the records of the performed audit / evaluation / examination for review by the EA BAS team who has carried out the witness assessment.

18) The assessment team of EA BAS who carried out the witness assessment of activity prepare a witness assessment report (Section D of report BAS QA 2.9.5.4), which provides comments and evaluation of CAB planning, competence and coverage of the scope of the team of the body, the auditing / evaluation technique, comments for the CAB findings and conclusions, impartiality, the commitments regarding safety, confidentiality, compliance with legal requirements, follow-up action (if any), compliance with CAB procedures.

A conclusion is given on whether the CAB records submitted reflect the findings and conclusions actually established during the audit / evaluation / examination / verification.

2.2.2.3 Determination of the sample for witness of activity of CB

1) Certification of products:

- in initial accreditation, re-accreditation and extension of the scope of accreditation a witness assessment of activity shall be carried out on minimum 60 % of main groups of products/processes applied for accreditation.
- in surveillance a representative sample, which composes minimum 60% of the scope of assessment is determined, as fields of the scope of accreditation which have not been witnessed for the time being is mandatory to be witnessed (if applicable).

2) Certification of persons

- in initial accreditation, re-accreditation and extension of the scope of accreditation a witness assessment of activity shall be carried out on minimum 60 % of types of competence (methods) applied for accreditation.
- in surveillance a representative sample, which composes minimum 60% of the scope of assessment is determined, as fields of the scope of accreditation which have not been witnessed for the time being is mandatory to be witnessed.

For the two fields of accreditation in the absence of activities in part of the scope granted, the competence of the CAB can and should be assessed in other ways such as witness assessment of the activity of simulation of conformity assessment activities and assessing the competence of the personnel on documents and through an interview for the implementation of conformity assessment processes.

The general requirements for determination of witness assessment remain the same as in the initial assessment.

3) Certification of Management Systems

According to recommendations set out in IAF MD 17, EA BAS uses the proposed grouping of EA / IAF codes (according to IAF ID1) in a series of technical clusters for each type of management systems certification (QMS, EMS, OH & SMS) presented in Annex 1. Based on requirements specified in regulations or best international practices it has developed and adopted such for other management systems mentioned in the same Annex.

In the tables of the respective control systems, critical codes for each technical cluster have been identified.

Prior to conducting of an assessment, the certification body is required to provide EA BAS with a list of all upcoming audit activities within three months after the on-site assessment, type of the audits, certification schemes and the activity of the audited organization (also expressed through IAFC, NACE), designated assessment teams, dates and location of the audit, and information for the client from which the lead assessor makes the sample for witness assessment of activity.

When determining the sample for assessment of the applied/accredited scope of accreditation, by witness assessment of activity are followed the following rules on respective

CERTIFICATION SCHEMES

1. ISO 9001, ISO 14001, ISO 45001

Initial accreditation and extension of the scope of accreditation

1.1 When there is only one critical code per technical cluster a witness assessment of this code is conducted in order an accreditation to be granted for all EA/IAF codes in this cluster.

1.2 When in a technical cluster there are more than one critical code identified by "and" if one of the critical codes is witnessed, accreditation may be granted in non-critical codes by not providing accreditation for the critical code (s) which has not been witnessed.

1.3 When in a technical cluster there are more than one critical code identified by "or" if one of the critical codes is witnessed, accreditation may be granted to other critical and non-critical codes in the cluster.

1.4 When in a technical cluster there is more than one critical code identified by "and" and combined with parentheses "[...]" And then code (s) identified by "or", if one of the critical codes listed in "[...]", Accreditation may be granted in other non-critical codes, but in order to provide accreditation for a critical code in parentheses, witness assessment is required. For the code (s) indicated by "or" if witness assessment is performed, all non-critical and critical codes combined in "[...]".

1.5 When it is not possible perform witness assessment of activity in critical code, non-critical code witness assessment shall be performed by the cluster and accreditation may be granted for other non-critical codes for which the body's competence has been assessed by records.

1.6 When it is not possible to perform witness assessment of activity in critical code, accreditation can be granted for all codes in the cluster, after assessing the competence of the certification body for records and documents for all codes from the cluster and for all functions in the certification process, and provided that critical / non-critical codes are witnessed during the accreditation cycle (subject to the rules given above) before certification under accreditation for these codes is granted. In this case, if the result of the witness assessment is negative, EA BAS will limit the scope of accreditation for the respective code / s. If no witness assessment of the conditional codes is carried out in the accreditation cycle, the scope of accreditation is limited.

1.7 In case of extension of the scope of accreditation in non-critical codes, when the associated critical code has already been covered by witness assessment (i.e. accreditation for the critical code has already been provided), the competence is assessed by reviewing completed certification in the applied codes, (e.g. demonstrating that it has competent personnel for all specific certification functions according to Annex A of ISO / IEC 17021-1 and other applicable requirements).

1.8 For initial accreditation for each management system scheme, an audit of Stage 1 and Stage 2 should be performed for at least one of the Certification Body (CB) clients. Prior to performing witness assessment on stage 2 of the same audit, the Applicant CB should submit to EA BAS the report and / or audit findings of Stage 1.

If the CB does not have any new clients, it is possible to witness assessment one recertification or two surveillances covering the main processes.

Re-Accreditation and Surveillance

1.7 In the cycle of initial accreditation (from first surveillance to first re-accreditation) for each management system scheme, EA BAS performs at least one witness assessment in each technical cluster of each management system.

1.8 When the CB demonstrates sufficient experience and efficiency in carrying out its activity within the scope of accreditation (which must be justified) EA BAS may proceed for performing of at least one witness assessment in each technical cluster for each scheme of management system in a manner each technical cluster is assessed during two consecutive accreditation cycles.

1.9 The frequency of performing of witnessess established for the first cycle shall be restored if significant changes have occurred in the process of management of qualification of the CB auditors, auditing practices or results, and auditing personnel.

1.10 In order to ensure the abovementioned EA BAS has determined that at least three witnesses shall be made in different clusters during a planned assessment in the first cycle of accreditation for each certification scheme according to the order indicated above in item 1.7 or at least 2 witness assessment in different clusters during the planned assessment for maintenance of accreditation for each certification scheme in the next cycles of accreditation according to the above in item 1.8.

In the scope of accreditation, which includes a limited number of clusters, the scope of witness assessment the activity may be reduced (justified). For activities in other countries, the volume of witness assessment of the activity increases so that the performance of audits in other countries / from outsourced offices can be observed in proportion to the volume of activity.

2. ISO 22000

2.1 Initial Accreditation, Re-Accreditation and Extension of Scope for Accreditation

When determining the sample for the assessment of the requested scope of accreditation by witness assessment of activity the following rules are followed:

The activity of at least one cluster category according to Table 4 of Annex 1 is witnessed (where the food chain categories are grouped into six clusters according to Table A.1 of Annex A of *EN ISO 22003-1:2022* and item MD 7.4.5 of IAF MD 16) in order the clusters categories (and sub-categories) to be provided.

2.2 In extension of the scope of accreditation, the above applies to categories in a new cluster. In case of extension in cluster already provided it is not necessary a witness assessment to be performed, and assessment of competence is performed on records and documents.

2.3 EA BAS may decide to increase the sample for performing of witness assessment in case of doubts about conformity of the CB with requirements following the results of the office assessment and other risk factors.

2.4 For initial accreditation, a stage 1 and stage 2 audit witness assessment must be carried out for at least one of the CB's clients. Before conducting a stage 2 observation of the same audit, the applicant CB must submit to the EA BAS the prepared report and/or conclusions from the stage 1 audit. At least one of the witness assessment of the audit activity in the accreditation cycle must be of an initial certification stage 2 audit or a recertification audit.

Surveillance

2.6 In the accreditation cycle (*from the first surveillance to third supervision/re-accreditation*) on every surveillance/reaccreditation EA BAS carries out at least one witness assessment in a cluster 2 Processing of food and feed (categories C, D) if it is in the granted accreditation of the CAB and at least one audit in each of the other clusters in regard to cover all clusters in cycle of accreditation.

2.7 Wherever possible, during the accreditation cycle EA BAS seeks to carry out witnesses in categories and sub-categories which have higher risks to food safety.

2.8 The aim is to witness teams of auditors that have not been witnessed in previous audits, and not to witness audits of CB clients who have already been subject to witness assessment.

3. ISO / IEC 27001

In case of initial accreditation and extension of the scope of accreditation, the activity of at least one certification audit, stage 1 and stage 2, shall be witnessed and prior to the witness assessment of the stage 2 of the same audit the applicant CB shall submit to EA BAS the prepared report and / or findings(conclusions) from stage 1 of the audit.

In the case of re - accreditation, at least one audit shall be witnessed. At least one audit shall be witnessed during the accreditation cycle (when conducting planned surveillance) to maintain accreditation.

4. ISO 50001

4.1 Initial Accreditation, Re-Accreditation and Extension of the Scope of Accreditation

When determining the sample for the assessment of the applied scope of accreditation by performing of witness assessment the following rules are followed:

4.2 In case of initial accreditation and extension of the scope of accreditation, at least one witness assessment of activity in the technical field as defined in Table 5 of Annex 1 (according to Table 2 of ISO 50003) shall be carried out taking into account the following additional options:

- when witness assessment in the technical field No 2 is performed the technical field No 1 may not be witnessed.
- when witness assessment in the technical field No 5 is performed, the technical field No 4 may not be witnessed and
- when witness assessment in technical field No 1 or No 2 is performed, the technical field No 6 may not be witnessed.

4.3 In case of re-accreditation, at least one witness assessment of activity in the technical field as defined in Table 5 of Annex 1 (according to Table 2 of ISO 50003) shall be carried out taking into account the following additional options:

- when witness assessment in the Technical Field No 2 is performed, Technical Fields 1 and 3 may not be witnessed;
- when witness assessment in any of the technical areas is performed, the technical field No 4, No 6, No 8 may not be witnessed;

4.4 For initial accreditation, a witness assessment of the initial certification audit, Stage 1 and Stage 2, must be performed for at least one client of the CB. Prior to performing a witness assessment of stage 2 of the same audit, the Applicant CB shall submit to EA BAS the report and / or the conclusions of the Stage 1 of the audit.

Surveillance

4.5 In the accreditation cycle (from the first surveillance to the first re-accreditation), EA BAS carries out at least one witness assessment in each surveillance, as the number of witnesses depends on the number of certificates issued - at least:

- 1 witness assessment at < 25
 - 2 witness assessment at <50
 - 3 witness assessment at <100
- following this order.

5. ISO 39001

5.1 In initial accreditation and extension of the scope of accreditation, at least one witnessing of the activity in the critical groups of activities 2 and / or 3 according to Annex 1 shall be performed.

5.2 For initial accreditation, a stage 1 and stage 2 audit must be witnessed for at least one of the CB clients. Prior to witnessing stage 2 of the same audit, the applicant CB must submit to EA BAS the prepared report and / or conclusions from stage 1 audit.

5.3 *During re-accreditation, at least one audit shall be witnessed. During planned supervisions in the accreditation cycle, at least one audit shall be witnessed.*

5.3 The aim is to witness audits from different scopes, different teams of auditors that have not been witnessed in previous meetings, as well as not to witness audits of MSB clients who have already been witnessed.

6. PEFC BG ST 1002:2019 / PEFC BG ST 1003:2019

Upon initial accreditation and extension of the scope of accreditation, the activities of at least one certification audit, stage 1 and stage 2, are witnessed, and before witness assessment stage 2 of the same audit, the applicant CB must submit to the EA BAS the prepared report and/or conclusions from the stage 1 audit.

At least one audit shall be witnessed during re-accreditation. At least one audit shall be witnessed during the accreditation cycle (planned surveillance).

7. FSSC 24000:2022

In the case of initial accreditation and extension of accreditation, at least one certification audit (at least stage 2) shall be witnessed. The initial certification audit shall be witnessed on-site.

At each subsequent planned assessment, at least one audit shall be witnessed (may be a surveillance audit). This assessment may be conducted on-site or remotely. When a remote witness assessment is conducted, a clear justification for the reasons shall be provided and a feasibility assessment shall be made to ensure that Information and Communication Technologies (ICT) are available to observe the full audit and achieve the objectives of the witness assessment.

In all witness assessments, an assessment of the full duration of the FSSC 24000 audit shall be carried out.

3. Formation of assessment team

3.1. The assessment team includes Technical Assessors and/or Technical Experts with competent to assess the defined scope of accreditation, who perform assessment, guided by a lead assessor. The assessment team may include:

- technical assessor in training;
- lead assessor in training;

3.2. The completeness and regularity of the documents presented in item 2.1.1 and item 2.1.2 are confirmed by a signature of Head of department ACIB/AL on BAS QA 2.1.13. In case of incompleteness and irregularity, ascertained by Head of department ACIB/AL during review of the necessary documents under items 2.1.1. and item 2.1.2., there is no formation of assessment team and the application is returned to the lead assessor for corrections. The new application follows the order set out in item 2.1.1. and item 2.1.2.

3.3. In completeness and regularity, the application for formation of team and the supplying documents are presented to the operation-logistics person for selection of TA/TE, accorded to the scope of the assessment. After made check for the technical competence of the technical assessor/technical expert (TA/TE), according to BAS QF 7.7 "Register of lead assessors/technical

assessors/technical experts”, accorded to the scope of the particular assessment, the selected team is confirmed with signature of the responsible operation-logistics person.

An analysis of the possible risks to impartiality in conducting the on-site assessment, which is documented in Annex 5 to BAS QI 2, is carried out in the selection of the TA / TE.

When establishing the presence of a risk that can be managed, such as the TA has been trained, certified or other possible risks, or has received other services from the CAB under assessment and due to the requirement of specific competence cannot be replaced by another competent TA/TE, the Technical Assessor is included in the assessment as a TE and works as a TE together with the TA/LA. After approval of the proposed team, the determined TA/TE are contacted for confirmation of the assessment plan and dates.

3.4. Up to the 15 days prior to the applied assessment, the responsible operation-logistics person prepares original of conformance letter and plan for on-site assessment. The organization of the team’s work is determined according to Plan for implementation of assessment activity (BAS Q(A) 2.9.6). The plan includes distribution of responsibilities in the on-site assessment, indicating to each Lead assessor, Technical Assessor /Technical Expert the particular tasks for assessment/witness of the elements of the relevant accreditation standard, depending on the field of competence, and determines the implementation of the assigned tasks on hour basis. The signed documents are sent by Secretariat B for written confirmation by the CAB and its agreement for the defined date and team, authorities of the team and plan for assessment.

After coordination of the period, the team and the on-site assessment plan, team members shall be provided with the on-site assessment plan through the Secretariat B. The dissemination shall be entered in the request for on-site assessment BAS QA 2.1.13.

3.5. The order for on-site assessment is signed by the Executive Director of EA BAS or a duly authorized person after receipt of a positive response from the CAB. The number of the order is entered in BAS QA 2.1.13 by secretary in Secretariat A. In the event of argued written non-approval by the candidate of a certain team member, and/or dates for implementation of the assessment, EA BAS performs a new selection of TA/TE and/or proposal for new dates, in observation of the terms defined in BAS QR 2. The operations-logistic person informs the Head of ACIB/AL Department about determination of new date and/or team, and the CAB is sent a new conformance letter.

3.6. The set of documents for on-site assessment is received by the lead assessor in Secretariat A. The set of documents can also be obtained from the TA from a Secretariat A, when he / she perform witness the activity, which is not part of the on-site assessment and the lead assessor does not participate in the witness assessment (certification bodies).

3.7. Specification of details concerning the traveling of the team and particular requirements to each TA/TE in terms of the forthcoming assessment are within the responsibilities of the lead assessor.

3.8. Confidentiality and sending of documents and records necessary for the preparation of the assessment.

The lead assessor sends, to the team members by email, BAS Q(A) 2.9.1 Declaration of Impartiality and Protection of Production and Trade Secrets. After completing and receiving the declarations by email from each team member, the lead assessor sends by email the necessary documents and records for the preparation of the assessment.

4. Determination of the amount of time for implementation of assessment

Table 4.1 Testing laboratories, calibration laboratories, testing and calibration laboratories, medical laboratories, PT providers and inspection bodies

The table determines the base time for assessment in days depending on the type of assessment and number of indicators (according to BAS QR 8), for one office.

Accreditation procedure/ areas of accreditation	LA TA TE	on-site assessment A/RA/ES				On-site assessment for surveillance			
		up to 5	6-20 20-50	51-150	151-300 Over 300	to 5	6-20	20-50 51-150	151-300 Over 300
A/RA/ES/PS/PSES for TL, CL, TCL, ML, IB, PT	LA	up to 1.5	up to 2	up to 2.5	up to 3	up to 1	up to 1.5	up to 2	up to 2.5
	TA (TE)	up to 1.5	up to 2	up to 2.5	up to 3	up to 1	up to 1.5	up to 2	up to 2.5

Preliminary assessment is carried out for 1 day

Additional time which is added to the basic time given in table 4.2:

Giving additional time for the on-site assessment is justified by the LA (if necessary after coordination with the HD/SM) in Section B of BAS QA 2.1.13 Analysis of the risks of the CAB activities during planning.

1. The base time is given for the number of technical areas that are assessed by 1 TA/TE.

When it is necessary to include more than one TA/TE in the team of assessors, the assessment time is increased by 0.5 days.

2. To expand the scope of accreditation, during planned supervision or re-accreditation, depending on the requested scope (new testing methods, calibration, control, new assessment standards or a new technical area) and the number of assessors included in the team, an additional 0.5 to 1.5 days is given to the total assessment time.

3. When the team of assessors includes a TE who works together with the HD/TE, the time is increased by 0.5 days to 1 day per HD/TE to which it is attached.

4. Where a CAB has more than one office operating under a common management system, 0.5 to 1 day for each office is determined depending on the activities carried out and the number of assessors who will participate in the assessment.

Travel time is added to the required assessment time, according to Table 3.3.

Table 4.2. Certification bodies, environmental verifiers and validation and verification bodies.

The table determines the basic assessment time in days depending on the type of assessment and the number of indicators (according to BAS QR 8), for one office.

Accreditation procedure/ areas of accreditation	LA TA TE	on-site assessment A/RA/ES				On-site assessment for surveillance			
		up to 5	6-20 20-50	51-150	151-300 Over 300	to 5	6-20	20-50 51-150	151-300 Over 300
A/RA/ES/PS/PSES for MSCB, PCB, PersonCB, VVB	LA	up to 1.5	up to 2	up to 2.5	up to 3	up to 1	up to 1.5	up to 2	up to 2.5
	TA (TE)	up to 1.5	up to 2	up to 2.5	up to 3	up to 1	up to 1.5	up to 2	up to 2.5

Preliminary assessment is carried out for up to two days

Additional time that is added to the basic time given in table 4.2:

Giving additional time for the on-site assessment is justified by the LA (if necessary after coordination with the HD/SM) in Section B of BAS QA 2.1.13 Analysis of the risks of the CAB activities during planning.

1. The basic time is given for the number of schemes from 1 to 2, for which 1 TA/TE is determined. For each subsequent from 1 to 2 schemes, a subsequent TA/TE is determined. For each subsequent TA/TE, the assessment time is increased by 0.5.

2. For Extension the scope of accreditation, during planned surveillance or re-accreditation, an additional 0.5 to 1.5 days is given depending on the requested scope (new schemes or new codes, methods of competence, etc.) and the number of assessors included in the team to the total assessment time.
3. When the team of assessors includes a TE who works together with the HD/TA, the time is increased by 0.5 days to 1 day per HD/TA to which it is attached.
4. When the CAB has more than one office that operates under a common management system, it is determined for each office depending on the activities performed and the number of assessors who will participate in the assessment from 0.5 to 1 day for each office.

The time required to conduct witness assessment of the activities of the certification body is determined depending on the time determined by the CAB for performing conformity assessment services provided for witness assessment.

In the case of VVO, the witness assessment of the activities is carried out by the LA/TA and TA/TE. When determining the duration of assessments of organic certification bodies (OCBs), the requirements of BAS QI 19, Annex 6 "Minimum duration of assessment for OCBs operating in the territory of EU Member States" and Annex 8 "Minimum duration of assessment for third countries" also apply.

Travel time is added to the time required for assessment, according to Table 4.3.

Abbreviations

TL	- testing laboratory
CL	- calibration laboratory
ML	- medical laboratory
TCL	- testing and calibration laboratory
PT	- proficiency testing
IB	- inspection bodies
MSCB	- management system certification body
EV	- environmental verifier
PCB	- product certification body
PerCB	- persons certification body
VVB	- validation and verification body
LA	- lead assessor
TA	- technical assessor
TE	- technical expert
A	- initial accreditation
RA	- re-accreditation
ES	- extension of scope of accreditation
PS	- planning surveillance
PSES	- planning surveillance and extension of scope of accreditation
ED	- Executive Director
DD	- Director of ACAB Directorate
HD	- Head of Department
SI	- State Inspector
CM	- Scheme manager
ACIB	- Department "Accreditation of certification and inspection bodies"
AL	- Department "Accreditation of laboratories"
CAB	- Conformity assessment body

Table 4.3 Time in hours for traveling to the larger populated areas in Bulgaria

The table below gives the approximate time in hours for traveling to the relevant populated areas by public transport.

CITY	DISTANCE, km	TRAVELLING TIME, hours
Blagoevgrad	102	1,5
Burgas	392	7
Varna	470	7
Veliko Tarnovo	247	4
Vidin	211	4,5
Vratsa	116	2
Gabrovo	223	3,5
Dobrich	512	8
Kulata	188	4
Kardzhali	259	4
Kyustendil	91	2
Lovech	173	3
Montana	109	2
Pazardzhik	120	2
Pernik	32	1
Pleven	176	3
Plovdiv	156	2,5
Razgrad	370	5,5
Ruse	324	5,5
Silistra	446	7
Sliven	279	4,5
Smolyan	255	4,5
Stara Zagora	234	3
Targovishte	345	4,5
Haskovo	234	3,5
Shumen	386	6,5
Yambol	300	5

- ❖ 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.