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INSTRUCTION

**FOR THE MANAGEMENT OF EXCEPTIONAL EVENTS OR CIRCUMSTANCES
AFFECTING BODIES ACCREDITED BY EA BAS AND THEIR CLIENTS**

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1. Introduction

The purposes of this document is to determine the policy of EA BAS regarding:

- 1.1 Actions to be taken by accredited certification bodies in case of emergencies that impede access to certified customers so that planned certification activities cannot be carried out.
These situations include events preventing access to specific customers; common access to a geographical area (including critical locations); Or directly affecting the ability of the CAB to operate.
- 1.2 The actions to be undertaken by accredited conformity assessment bodies (testing labs, calibration labs, medical laboratories, PT providers, etc.) in the case of emergencies temporarily preventing the performance of conformity assessment activities.
- 1.3 The actions to be taken by EA BAS when an accredited conformity assessment body (CAB) is affected by situations that prevent the performance of the activities for the assessment and conduct of the accreditation procedure by EA BAS.
These situations shall include events preventing access to the CAB or CAB locations in order to conduct office evaluations or monitoring activities.
- 1.3 This document has been developed taking into account the requirements of IAF ID 3: 2011
'Management of exceptional events or circumstances affecting the Accreditation Body (AB), CAB and Certified Organisations'.
This document was created by the IAF for certification bodies, but by analogy it can also be applied as a guide to other accreditation activities that fall within the competence of the ILAC.

2. Abbreviations and definitions

CAB Conformity assessment body

AB Accreditation body

EA BAS Executive Agency "Bulgarian Accreditation Service".

BAS QR 2 Accreditation procedure for EA "BAS";

Definition of emergency event or circumstance:

A circumstance beyond the control of the organisation; usually referred to as "Formation" or "the act of God." Examples include war, strike, riots, political instability, geopolitical tensions, terrorism, crime, pandemic, floods, earthquakes, malicious computer hacking, other natural or man-made disasters. (IAF ID 3: 2011)

3. Tasks of the Certification Organisations (of products, systems, persons, validation bodies and verification)

3.1 General

In any case where there is an exceptional occurrence or circumstance, the certification body will have to assess the risks presented to the organisation and the certification concerned.

Firstly, it will be necessary to assess the extent of any impact of the situation on the ability of the certification body to continue to operate in accordance with certification requirements. The certification body will have to take into account the extent of the impact certified organisation or product and determine whether it is possible to maintain the certification in the circumstances.

For instructions on the content and scope of this assessment, use IAF Chapter 3 ID 3:2011 'Extraordinary event or circumstance affecting a certified organisation'.

The result of the review must be recorded and must be available for evaluation by EA BAS upon request.

CAB that must deal with an exceptional event or circumstance that may affect accredited certificates shall inform its designated Lead assessors of the existence of this event or circumstance within one month. The CAB shall provide the following information at the request of EA BAS:

- Scope and dissemination of services and business areas and locations concerned,
- Number of customers affected,
- When the certification body will be able to function normally within this scope of accreditation,
- Alternative assessment methods to be applied, e.g. remote assessments (IAF MD 4) or remote review of documents and records,
- Alternative programmes planned to maintain confidence in customer certified systems during the period during which access cannot be obtained,
- Planning for the recovery of regular supervision activities pursuant to

plans for the supervision of the Certification Authority in the recovery of the normal situation.

In addition, the certification authority must inform the lead evaluator under the procedure of all cases, taking into account the estimated timetable of the event, may lead to a high risk of the validity of the certificates concerned, During the period when access cannot be obtained.

3.2 Initial Certification and Extension of Certification.

Initial certification and extension of existing certification scopes may only be carried out where a fully planned audit and evaluation is possible, as in such cases it is not possible to support a certification decision with existing information arising from previous supervisory activities.

Therefore, in a period where, due to exceptional circumstances, normal work and carrying out audits is not possible, the initial certification and extension of the existing scope of certification is impossible to carry out.

3.3 Oversight activities

Supervision activities shall be carried out as soon as possible after the emergency status has been lifted and as soon as the normal situation and activities have been restored. Where possible, supervision must be carried out within the current year of certification. Follow-up actions must continue in accordance with the initial programme.

In the case of a first supervisory audit following initial certification, a postponement of the audit shall not exceed 6 months (18 months from the date of the initial certification).

In the case of ex post supervisory audits, the postponement of the audit shall not exceed 6 months.

The extended periods between the monitoring visits as mentioned above may lead to the need for additional surveillance visits for the remainder of the certification cycle.

During the postponement, the certification body should consider other means of monitoring that may be available, such as remote assessment (see IAF MD 4), reviews in the office of the Certification Body of the certified organisation of documents and records or other methods.

3.4 Re-certification

If, on the basis of the information collected, there is sufficient documented evidence to ensure that the certified management system is effective, the certification body may extend a certificate for a period not exceeding 6 months from the original validity date. If the recertification assessment cannot be carried out within 6 months, the certification

must be suspended. In this case, the adopted certification authority 's policy for suspension of certification shall be applied, if applicable.

3.5 Records

The certification body shall maintain complete documentation of the actions and deviations from the established certification programme, together with the justification for the action decisions taken. These records shall be made available to EA BAS for review upon request.

4. Tasks of the Conformity Assessment Organisations (testing labs, calibration, medical laboratories, PT providers, etc.)

4.1 Risk Assessment for Activity

In any event where there is an exceptional occurrence or circumstance, the conformity assessment body will have to assess the risks to its activities and the like possibility of temporary deviation from the CAB accreditation and/or procedures requirements.

A temporary deviation may include, for example, a delay in calibration and intermediate checks on measuring devices, measurement bench marks, use of CRM/RM software products, reagents and consumables, ancillary equipment that may affect the validity of the results (conformity assessment activities), participation in inter-laboratory comparisons and proficiency testing, internal quality control, internal audit and management review.

The CAB shall assess whether the extraordinary event or circumstance will affect the ability of the EF to carry out its activities and/or maintain compliance with the accreditation requirements.

The CAB shall apply its risk management procedures, including an assessment of the current and expected future situations, taking into account the following:

Scope and dissemination of the impact on conformity assessment services, CAB location and current activities, assessing

- whether it is necessary to stop the operation due to obstruction/deficiency of staff, limited access to supplies and services, supply of samples, additional loads, malfunction of technical equipment, etc.
- Do we need to deviate from the usual conformity assessment procedures and processes in order to continue providing a conformity assessment service?

Assessment the estimated time to deal with the situation and return to normal activity and planning the relevant activities.

4.2 Records

The CAB shall keep records of the risk assessment and actions taken to deal with any extraordinary event or circumstance.

Records shall contain information on:

- The scope and dissemination of the impact on services, the location of the CAB and the state of current activities,
- Actions taken, alternative actions or mitigating actions taken or planned to address the impact;
- CAB Action Plan to remove temporary deviation from accreditation and/or procedures requirements
- Evidence that CAB clients have been informed.

5. Actions of EA BAS in events or circumstances affecting the accreditation of conformity assessment bodies

5.1. General

An extraordinary event affecting CAB and/or EA BAS may temporarily prevent EA BAS from performing planned on-site assessments. Where such situations arise, the EA BAS accredited by the CAB must establish a reasonable planned course of action.

The possible actions that can be considered include:

- Postponement of planned assessments or
- the application of alternative assessment methods such as remote evaluations or
- Assessment by review of documents and records submitted.

When carrying out remote assessments, account shall be taken of the manuals of IAF MD 4 and IAF ID 12:2015

Remote assessments may be carried out in a reported risk analysis using information technology (IT) systems. These types of checks provide interactive communication between the team of evaluators of EA BAS and CAB representatives such as Internet meetings, teleconference, telephone or other electronic means. Operational aspects will be defined between EA BAS and CAB during the verification planning phase.

5.2. Initial accreditation and extension of scope in a new field of activity

During a period where, due to an extraordinary event or circumstance, normal activity of the EA Bas and on – the-spot assessment is not possible, estimates of initial accreditation and extension of the scope of accreditation in a new area of activity will not be carried out until the exceptional occurrence or circumstance is completed.

5.3. Oversight

Once the period of the extraordinary event or circumstance has been completed, the supervisory activities must be completed as soon as possible after the normal situation and activity have been restored, complying with the requirements of Item 7.9.3 of ISO/IEC 17011:2017 "sample of accreditation shall be evaluated at least every two years. The time between successive on-site assessments shall not exceed two years.';

The postponement of assessments shall be such that this period is not exceeded .

The extended periods between the assessments of supervision as mentioned above may lead to the need for further assessments of supervision for the remainder of the accreditation cycle.

If necessary to postpone the planned assessments, EA BAS will consider applying alternative methods of assessment, which may be:

- remote assessment,
- assessment of documents and records submitted, or
- It's other methods.

When carrying out remote assessments, account shall be taken of the manuals of IAF MD 4 and IAF ID 12:2015

5.4. Re-accreditation

The cycle of accreditation determined by EA BAS is 4 years.

According to paragraph 7.9.1 of ISO/IEC 17011:2017, the accreditation cycle shall not be longer than five years.

EA BAS will extend the accreditation period as specified in point 6 of the Accreditation Procedure BAS QR 2 to 6 (six) months, subject to the conditions laid down in BAS QR 2.

An extraordinary event affecting the CAB and/or EA BAS may temporarily prevent EA BAS from calling a meeting of the Accreditation Commission for accreditation decision. The accreditation committees will be postponed subject to the requirement of 4.3.7 b of BAS

QR 2 the Accreditation Committee to meet within a period of 6 (six) months from the on-site assessment.

If necessary to postpone the planned assessments and meetings of accreditation committees, EA BAS will consider applying alternative ways to evaluate and hold meetings, which may be:

- remote assessments,
- assessments of documents and records submitted, or
- other methods.

When carrying out remote assessments, account shall be taken of the manuals of IAF MD 4 and IAF ID 12:2015

5.5. Acts of EA BAS in case of an extraordinary event or circumstance in accredited CAB

5.5.1. Temporary inability to carry out the conformity assessment activity

In the case of an event requiring the CAB to stop work for a short period of time that does not significantly affect the provision of its service (e.g. minimal impact on service time), the EF does not need to notify EA BAS, but shall store records according to item 4 and provide upon request.

Where an extraordinary event or circumstance leads to a temporary inability of the CAB to carry out its activities or part thereof in a period not exceeding 6 months, the CAB shall notify EA BAS and provide information on the actions carried out under item 4 of this instruction.

In the event that the CAB has provided objective evidence of appropriate control and where it is able to resume operations, e.g. in respect of equipment and resources, the accreditation will not be suspended within 6 months.

Once normal activity has been restored by the CAB, EA BAS may carry out further assessment(s) of the CAB to verify its compliance with the accreditation requirements.

5.5.2. Permanent impossibility to perform the activity

In the event of high risk and permanent inability to recover the CAB after an extraordinary event or circumstance which has affected its activities or part of its activities, or because of liquidation or bankruptcy, the CAB shall immediately inform EA BAS in order to take action to suspend, limit, withdraw the accreditation pursuant to paragraph 5.4 of the Accreditation Procedure BAS QR 2.

5. Applicable documents:

BAS QR 2	Accreditation procedure
IAF ID 3: 2011	'Management of exceptional events or circumstances affecting the Accreditation Body (AB), CAB and Certified Organisations'
IAF MD 4	IAF MD for the Use of ICT for Auditing/Assessment Purposes
IAF ID 12:2015	Principles on Remote Assessment

- ❖ *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.*