ARAC Guidance for ARAC ABs on how to manage the accreditation process under crisis conditions

CLASSIFICATION

This document is classified as ARAC Guidance Document.

AUTHORIZATION

Issue Nº: 01
Prepared by: ARAC MLA Committee
Date: 20/10/2021
Revision Nº: 01
Approved by: Executive Committee
Issue Date: 12/12/2022
Application Date: Immediate
Document number: ARAC GD 003
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AVAILABILITY

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Original: English

1. Foreword:

This document has been issued in response the clauses of ISO 17011:2017, 4.2.a – 4.2.e, 4.2.i, 7.3.1 and 7.3.2, 7.4.4, 7.6.1, 7.9.3 and 7.9.5 on how to deal with extraordinary events.

This guidance was developed to support the ARAC ABs to be able to demonstrate reasonable due diligence, mutual understanding and trust and to establish an appropriate course of actions against the effect caused by extraordinary events or circumstances.

The purpose of this document is to provide guidelines for ABs to establish and implement appropriate course(s) of action against any effect(s) caused by an extraordinary event or circumstance that has an effect on the operations of:

- AB as well as CAB operations accredited by the AB
- AB Operations only

2. Definitions:

Extraordinary event or circumstance: A circumstance beyond the control of the organization, commonly referred to as "Force Majeure". Examples are war, riot, political instability, geopolitical tension, terrorism, pandemic, flooding, and earthquake, malicious computer hacking, other natural or man-made disasters.

Information and Communication Technology: Use of electronic technology to store, retrieve, transmit, or receive information electronically in a digital form. ICT refers to all communication technologies, including the internet, wireless networks, cell phones, computers/ laptops, robots, drones, software, middleware, video-conferencing, and other media applications and services (e.g. personal computers, digital television, email, or robots).

3. Review/evaluation of the effect of extraordinary event or circumstance and risk analysis

3.1. Review/evaluation of the effect of an extraordinary event or circumstance

When an extraordinary event or circumstance occurs, the accreditation body should investigate the effects on its accreditation activity and its accredited conformity assessment bodies' activities through an internal analysis and communication with conformity assessment bodies.

The following information should be covered by the internal analysis as appropriate:

- The extent of the effect on the AB's activities, facilities, equipment, and human resources;

- Whether or not a temporary deviation from the requirements in ISO/IEC 17011, other ILAC MRA requirements and/or AB's procedure has occurred or is expected to occur;
- The AB's recovery plan to resume its accreditation activities which may include information for a new facility, equipment and/or personnel;
- The AB's intention to voluntarily withdraw from regional or ILAC arrangements;
- Where relevant, the AB's justified action plan to address temporary deviation from the requirements in ISO/IEC 17011, other ILAC MRA requirements and/or its procedures.

Note: *Examples for 'Temporary deviation from accreditation requirements and/or CAB procedures" may includes but not limited to delay in performing periodic calibration and intermediate check of the measuring and test equipment, PT participation, outsourcing, internal quality control, internal audit and management review.*

An agreement on the action plan to address temporary deviations should be reached with the AB.

3.2. Risk analysis and action plans against the risk

The AB should analyse the risks of the effect caused by the extraordinary event(s) or circumstance(s) and establish an action plan to reduce or eliminate risks. The action plan to reduce or eliminate risks may include the following:

- rearrangement of the assessment plan,
- extension of valid date of the accreditation certificate,
- Development of possible measures to address the effects caused by the extraordinary event(s) to ensure further compliance with accreditation requirements,
- acceptance criteria for the temporary deviation from the ABs recognition criteria (i.e., ISO/IEC 17011, ILAC/IAF, ARAC, etc.)

3.3. Consideration of regulatory needs

The accreditation body should liaise with any regulatory authority who specify accreditation of CABs. Discussion should take into account the actions to be taken by the accreditation body and/or CABs and the needs of the authority.

4. Implementation of the action plan
4.1. Rearrangement of the assessment plan
The AB should review the action plan to make any necessary arrangement(s) to develop an alternative assessment plan taking the outcome of the risk analysis into consideration and rearrange the assessment plan when necessary.

Rearrangement of the assessment plan should include, but not be limited to:
- Replacement of on-site assessment by other means.
- Postponement of the scheduled assessments.

The remote assessment is a typical alternative assessment technique for on-site assessments (for other types of assessment techniques please refer to section 3.24, ISO/IEC 17011). In any case, the AB shall justify the use of remote assessment technique (see Cl. 7.9.3 of ISO/IEC 17011:2017).

Performance of remote assessments may depend on the effectiveness of the use of information and communication technology (ICT). The AB should document its policy and procedures for the use of ICT in remote assessments. The AB should evaluate the effectiveness of each ICT for the use in the remote assessment before its use. The AB should also make sure that its assessment teams make any necessary preparations to use ICT before and after starting the remote assessment.

> *Note:*
> *For details of the use of ICT, refer to IAF MD4:2018.*
> *For details on the use of remote assessments, refer to IAF ID 12:2015 "Principles on remote assessment"*

Document and file review itself cannot replace the on-site assessment. However, the original assessment programme during the assessment cycle should be kept for future. In addition, the AB shall ensure that a sample of the scope of accreditation is assessed at least every two years (see Cl. 7.9.3 of ISO/IEC 17011).

When circumstance will not allow the AB to replace the on-site assessment by other means, AB's may usually extend the date of assessment for up to 6 months, provided that appropriate action plans are approved

The AB should endeavour to arrange or re-arrange its activities so as to be able to continuously fulfil the requirements in ISO/IEC 17011 and the ILAC arrangement. If this is not possible, it should report to its regional accreditation organisation the following information:
- Which requirements it will not be able to fulfil
- The extent of operations affected by the inability to fulfil the particular requirements
- The duration during which it anticipates that it will not be able to fulfil the requirements
- What actions it plans to take in order to compensate for, or to remedy the situation resulting from the inability to fulfil the particular requirements

When ARAC receives information described above it should evaluate whether the actions taken by the AB are sufficient and appropriate or if the AB's MLA signatory status shall be suspended or withdrawn. In either case ARAC shall communicate its decision to ILAC and/or IAF.

4.2. Extension of valid date of the accreditation certificate

When circumstance does not allow the AB to perform the planned assessment(s) and decision making during the accreditation cycle due to the effect of extraordinary event or circumstance, the AB may extend its accreditation cycle for up to 6 months.

If a 5 year accreditation cycle is extended, the time added to the previous cycle is deducted from the total duration of the next cycle, also for any cycle duration 2, 3, or 4 years, if the cycle is extended for 6 months it should be deducted from the next cycle. (see Cl. 7.9.1 of ISO/IEC 17011)

4.3. Acceptance of temporary deviation from the accreditation criteria

Due to the effect of extraordinary event or circumstance, the CAB may not be able to comply for a period of time with the accreditation requirements including but limited to:

- overdue calibration of its equipment and instruments,
- PT participation,
- delay in payment of accreditation.
- facilities closed (for CAB with multiple sites)

For such cases, the AB may allow CABs temporary deviations from the accreditation criteria. However, the AB should have justified acceptance criteria for CABs temporary deviations from the accreditation criteria.

5. Communication with ARAC

The ARAC MLA signatory members should communicate with ARAC MLA Secretariat for its temporary arrangements against the extraordinary event or circumstance when it will undergo the peer evaluation. When the AB has a question about its temporary arrangement, it should consult with ARAC to ask for clarification.

6. References
IAF MD4: 2018 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
IAF ID3:2011 Management of Extraordinary Events or Circumstance affecting ABs, CABs and Certified Organizations
IAF ID 12:2015 "Principles on remote assessment"
ILAC draft document "Guidelines for Accreditation Bodies on Management of Extraordinary Events or Circumstances Affecting Accreditation"