 <p><b>AKREDITACIONO TIJELO</b> Crne Gore</p>	<p>ACCREDITATION BODY OF MONTENEGRO</p>	<p><b>Reference/Date</b> PA.03/14.09.2020.</p>
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## RULES FOR CROSS-BORDER ACCREDITATION

	Name and surname	Position	Date	Signature
Reviewed by	Tanja Radović	Head of Accreditation Department / QMS Manager	10.08.2020	
Approved by	Aleksandar Vujović	Chair of the ATCG Management Board	14.09.2020.	

## 1. SUBJECT AND SCOPE

The subject of this document is to define the policies and activities implemented by the Accreditation Body of Montenegro in cases of cross-border accreditation.

This document applies to:

- conducting accreditation of conformity assessment bodies established outside the territory of Montenegro (Article 6(3) of Regulation (EC) No 765/2008),
- conducting accreditation of conformity assessment bodies established in Montenegro that have locations and/or perform conformity assessment activities outside the territory of Montenegro.

## 2. ABBREVIATIONS AND DEFINITIONS

### 2.1 Abbreviations

**ATCG** – Accreditation Body of Montenegro

**CAB** – Conformity Assessment Body

**NAB** – National Accreditation Body

**EA** (European co-operation for Accreditation) – European co-operation for Accreditation

**ILAC** (International Laboratory Accreditation Cooperation) – International Laboratory Accreditation Cooperation

**IAF** (International Accreditation Forum) – International Accreditation Forum

**EA MLA** - Multilateral agreement on mutual recognition of equivalence of accreditation systems within EA

**ILAC MRA / IAF MLA** – Multilateral agreements on mutual recognition of equivalence of accreditation systems within ILAC/IAF

### 2.2 Definitions

#### **accreditation**

third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

#### **national accreditation body**


authoritative body in a country that performs accreditation

#### **local accreditation body**

national accreditation body of the country in which the conformity assessment body is established

#### **conformity assessment body**

body that performs conformity assessment activities and that can be the subject of accreditation

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### **conformity assessment**

process demonstrating whether specified requirements relating to a product, process, service, system, person or body are fulfilled

### **3. RELATION TO OTHER DOCUMENTS**

- **Law on Accreditation** (“Official Gazette of Montenegro”, No. 54/09, 43/2015)
- **Regulation (EC) No 765/2008** of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products
- **MEST EN ISO/IEC 17011:2018** – Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies
- **EA-2/13 M:2019** – EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
- **ILAC-G21:09/2012** – Cross Frontier Accreditation – Principles for Cooperation
- **IAF ML 1:2023** **Guidance for the Exchange of Documentation among MLA Signatories for the Assessment of Conformity Assessment Bodies** 2(amendment dated 03 July 2023)
- **ATCG PA.01** – Accreditation Rules
- **ATCG PR.01** – Assessment of Conformity Assessment Bodies

### **4. DESCRIPTION OF ACTIVITIES AND RESPONSIBILITIES**

#### **4.1 GENERAL PRINCIPLES**

In accordance with the provisions and guidance of the documents listed in clause 3, ATCG applies the following general principles related to cross-border accreditation:


- ATCG primarily performs accreditation of CABs that are legal entities with headquarters in Montenegro;
- ATCG does not promote accreditation services or conduct marketing activities in the territory of other countries;
- ATCG does not compete with other national accreditation bodies in performing accreditation activities;
- ATCG may accept an application for accreditation from a CAB established outside Montenegro in the following cases:
  - a) if the country where the CAB is established does not have a national accreditation body (NAB) or has not decided to use the services of another national accreditation body;
  - b) if the NAB does not provide accreditation services for the conformity assessment activities for which accreditation is sought;
  - c) if the NAB is not a signatory to the relevant multilateral recognition arrangements (EA MLA/BLA, ILAC MRA or IAF MLA) for the specific accreditation scheme.

ATCG shall timely inform an accredited CAB established outside Montenegro of the obligation to transfer accreditation to the NAB when the above conditions are no longer met. After the relevant NAB becomes a signatory to the applicable multilateral recognition arrangements (EA MLA/BLA, ILAC MRA or IAF MLA) for the relevant accreditation scheme, ATCG shall not undertake further activities related to renewal of accreditation or extension of the granted scope of accreditation of such CABs. During each reassessment of a CAB established outside Montenegro, ATCG shall verify whether the above conditions for cross-border accreditation are still met and maintain appropriate records of this review.

- ATCG may direct a CAB established in Montenegro to submit an application for accreditation to the national accreditation body of another country if ATCG does not provide accreditation services for the conformity assessment activities for which accreditation is sought;
- When ATCG accredits a CAB established in Montenegro for conformity assessment activities in accordance with the national technical legislation of another country, ATCG shall, in cooperation with the NAB of that country, ensure the necessary expertise and information related to that legislation.
- When accrediting a CAB established in Montenegro that has locations and/or performs conformity assessment activities outside Montenegro, ATCG shall confirm the following:
  - that the CAB retains full responsibility for all accredited activities, including those performed at locations outside Montenegro;  
NOTE: This responsibility shall be demonstrated through contractual or other legal arrangements between the CAB and its locations outside Montenegro, as well as through internal documents defining responsibilities and relationships with the parent organization
  - that the CAB and all its locations operating outside Montenegro function under the same management and within the same management system;
  - that the CAB has appropriate mechanisms to effectively control and influence activities carried out at its locations outside Montenegro;  
NOTE: The CAB shall be able to demonstrate that such control and influence are established and implemented
  - that locations operating outside Montenegro do not offer services within the scope of accreditation on the local (foreign) market under their own name and logo;
  - that statements of conformity (e.g. certificates, reports, etc.) issued by such locations contain only the name and address of the accredited CAB as a legal entity established in Montenegro, without indicating the name and/or logo of the location;  
NOTE: Such documents may include contact details of the location, but shall not create confusion regarding the identity of the accredited CAB.

NOTE: For further clarification of the above provisions, see the Annex to document EA-2/13 M:2019, which is applied as a mandatory document.

- After successful completion of the accreditation process for a CAB established in Montenegro that has locations and/or performs conformity assessment activities outside Montenegro, ATCG shall issue the Accreditation Certificate exclusively to

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the CAB as the holder of accreditation. The scope of accreditation shall list all locations covered by accreditation, including those outside Montenegro. In cases where, due to non-fulfilment of requirements, a location outside Montenegro is removed from the scope of accreditation, ATCG shall assess the impact on the overall granted scope of accreditation. Particular attention shall be given to the CAB's compliance with requirements related to control of activities and responsibility for their performance at such locations.

- When a CAB established in Montenegro has locations and/or performs conformity assessment activities outside Montenegro, and the relevant NAB is a signatory to the applicable multilateral recognition arrangements (EA MLA/BLA, ILAC MRA or IAF MLA) for the relevant accreditation scheme, ATCG shall cooperate with that NAB (including the possibility of subcontracting) in carrying out accreditation activities (e.g. on-site assessments) for the part of activities performed in that country. ATCG retains full responsibility for the accreditation of the CAB.
- ATCG shall, to the greatest extent possible, cooperate with the national accreditation body of another country in the accreditation process of a CAB established in that country that has locations and/or performs conformity assessment activities in Montenegro.

#### **4.2 ACCREDITATION OF CABs ESTABLISHED OUTSIDE THE TERRITORY OF MONTENEGRO**

Based on the submitted application for accreditation, ATCG may initiate the accreditation process for a CAB established outside Montenegro only in the cases described in clause 4.1 (cases a), b) and c)).

If a national accreditation body (NAB) exists in the country where the CAB is established, ATCG shall, upon receipt of the application, request from the CAB:


- justification for not submitting the application to the NAB,
- consent for ATCG to inform the NAB about the received application,
- consent for ATCG to initiate and establish cooperation with the NAB during the accreditation process.

ATCG shall also request from the CAB a statement confirming that the same application has not been submitted to another national accreditation body.

ATCG shall exchange information and, to the greatest extent possible, cooperate with the NAB both in the preliminary phase and during the accreditation process.

Before accepting the application for accreditation, ATCG shall inform the NAB about the receipt of the application and its intention to accept it, stating the reasons for acceptance.

After communication with the NAB and acceptance of the application by ATCG, the accreditation process for a CAB established in another country shall be conducted in the same

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manner as for a CAB established in Montenegro, in accordance with ATCG accreditation rules.

The Accreditation Agreement concluded between ATCG and a CAB established outside Montenegro shall include provisions regarding the CAB's consent to the use of NAB resources and the exchange of relevant information obtained during the accreditation process between ATCG and the NAB. During the accreditation process, ATCG shall ensure appropriate competence, taking into account available NAB resources and factors such as language, local laws and regulations, culture, etc. ATCG shall request relevant information from the NAB in this regard.

For the purpose of conducting on-site assessment, ATCG shall propose:

- that the NAB nominates competent assessors from its register who may be appointed to the ATCG assessment team;
- that representatives of the NAB participate as observers in the assessment carried out by the ATCG assessment team;
- conducting joint assessments;
- other forms of cooperation.

Upon completion of the accreditation process, ATCG shall inform the NAB of the outcome.

In a similar manner, ATCG shall cooperate with and inform the NAB regarding activities related to maintaining the accreditation of the CAB.


In exceptional cases, where ATCG and the NAB are unable to establish cooperation in accordance with this rule, aligned with the provisions of EA-2/13 M:2019, ATCG shall record the reasons why such cooperation was not established. This information shall be documented, retained and made available upon request.

#### **4.3 ACCREDITATION OF CABs ESTABLISHED IN MONTENEGRO WITH LOCATIONS AND/OR ACTIVITIES OUTSIDE THE TERRITORY OF MONTENEGRO**

The CAB shall, through the Accreditation Application, inform ATCG of its intention to include locations outside Montenegro within accreditation.

During the accreditation process, the CAB shall cooperate with both ATCG and the NABs of the countries where its locations are situated. Each location shall also accept the involvement of the NAB in the processes of granting, maintaining and renewing accreditation. These provisions shall be included in the Accreditation Agreement concluded between ATCG and the CAB.

The language to be used during assessment of locations and in assessment reports shall be agreed in advance between ATCG, the NAB and the CAB.

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Upon receipt of the application, ATCG shall inform the NAB and propose the manner of cooperation and involvement of the NAB in the assessment of locations operating within its territory. In this regard, ATCG may propose:

- that the NAB performs the assessment of locations on behalf of ATCG (subcontracting in accordance with clause 6.4.4 of MEST EN ISO/IEC 17011:2018), provided that the NAB is a signatory to the relevant multilateral recognition arrangements (EA MLA/BLA, ILAC MRA or IAF MLA) for the relevant accreditation scheme;
- To have NAB propose competent **assessors/experts** from its register who could potentially be appointed to the ATCG assessment team **(in which case ATCG will request that NAB provide relevant evidence of their competence)** 1 (amended on 05 August 2021)
- that representatives of the NAB participate as observers in the assessment conducted by the ATCG assessment team;
- other forms of cooperation.


Following prior communication, ATCG shall conclude a cooperation agreement with the NAB(s) of the countries where the CAB has locations.

NOTE: The template for the cooperation agreement may be obtained from the EA Secretariat upon request.

In accordance with documents PA.01 Accreditation Rules and PR.01 Assessment of Conformity Assessment Bodies, ATCG shall define the assessment programme for the CAB, taking into account risks related to activities performed at locations and specific characteristics of the local market. In this context, ATCG shall cooperate with and use information provided by the NAB. When establishing the assessment programme, ATCG shall consider factors such as:

- knowledge of local regulations,
- knowledge of the local market,
- scope of activities performed by the CAB at its locations,
- impact of CAB activities on the local market (e.g. market share),
- previous assessment results of the CAB and/or locations,
- level of control and monitoring demonstrated by the CAB over its locations,
- possible accreditation of the location by the NAB for the same or other conformity assessment activities and the cycle/frequency of NAB assessments,
- etc.

ATCG shall inform the NAB of the assessment programme immediately after its adoption. ATCG shall also inform the NAB annually of the need for its involvement in the implementation of the assessment programme, at the latest three months before the beginning of the calendar year, enabling the NAB to plan resources accordingly. In cases of scope extension or need for extraordinary assessment at locations, ATCG shall inform the NAB without delay.

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At the latest three months before the planned assessment of a location, ATCG shall inform the NAB of the scope of the assessment and provide all necessary information. ATCG shall define the scope of assessment as precisely as possible to minimize the risk of misunderstanding. ATCG shall provide all relevant information to ensure effective assessment within agreed timelines, including:

- report from the last assessment of the CAB headquarters (including nonconformities and corrective actions),
- updated information on the CAB (organization, management, control of locations),
- any additional requirements or activities to be verified by the NAB,
- any legislative requirements relevant to notification purposes,
- detailed description of activities performed by the location,
- detailed scope of assessment, including sector schemes if applicable,
- assessment plan,
- overall assessment programme, including frequency of witnessing where applicable.

During assessment of locations, the NAB may use its own procedures, systems and reporting formats. However, the assessment report shall contain sufficient information and evidence to enable ATCG to make an appropriate decision.

In accordance with the cooperation agreement, ATCG shall request from the NAB:

- results of assessment of locations,
- assessment report,
- statement regarding closure of findings, where applicable.

ATCG shall inform the NAB of the accreditation decision immediately after it is made, as well as any decision to suspend or withdraw accreditation related to activities performed at locations within the NAB's territory.

ATCG shall provide the NAB with any valid and relevant information (e.g. assessment results, complaints, market feedback) related to locations within its territory.

#### **4.4 CONTACT PERSON**

The contact person within ATCG responsible for communication with other national accreditation bodies regarding cross-border accreditation is the Head of the unit responsible for international cooperation.

### **5. FORMS**

This document has no associated forms.