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The consolidated text of the Law on Accreditation includes the following regulations:

1. Law on Accreditation ("Official Gazette of Montenegro", No. 054/09 of 10.08.2009),
2. Law on Amendments to the Law on Accreditation ("Official Gazette of Montenegro", No. 043/15 of 31.07.2015),

## LAW ON ACCREDITATION

("Official Gazette of Montenegro", No. 054/09 of 10.08.2009 and 043/15 of 31.07.2015)

### I. GENERAL PROVISIONS

#### Subject of the Law

##### Article 1

This Law regulates the establishment and operation of the Accreditation Body of Montenegro, the organisation and process of accreditation, as well as other issues of importance for accreditation.

#### Definitions

##### Article 2

Certain terms used in this law have the following meaning:

- 1) **accreditation** is the attestation by a national accreditation body that a conformity assessment body meets the requirements set out in harmonised standards and, where applicable, any additional requirements including those relevant for specific fields (sectoral schemes), to carry out a specific conformity assessment activity;
- 2) **conformity assessment** is a process demonstrating whether specified conditions and requirements relating to a product, process, service, system, legal or natural person, or body have been fulfilled;
- 3) **competence** is proven ability to carry out specific conformity assessment tasks;
- 4) **accreditation certificate** is a document confirming that a conformity assessment body is accredited for a specific technical area and scope;
- 5) **conformity assessment body** is a legal entity or part of a legal entity that performs conformity assessment activities, including testing, calibration, certification and inspection;
- 6) **harmonized standard** is a European standard adopted on the basis of a request from the European Commission and whose reference number has been published in the Official Journal of the European Union;
- 7) **peer evaluation** is a process for the assessment of a national accreditation body by other national accreditation bodies, in accordance with the rules and procedures of international and European organizations for accreditation.

#### Scope

##### Article 3

Accreditation confirms the competence of conformity assessment bodies to perform:

- 1) testing;
- 2) calibration;
- 3) inspection;
- 4) certification of products and processes;
- 5) certification of management systems;
- 6) certification of personnel.

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## **II. ACCREDITATION BODY**

### **Organization and tasks**

#### **Article 4**

- (1) Accreditation in Montenegro is performed by the Accreditation Body of Montenegro (hereinafter: Accreditation Body) as an independent non-for-profit organization established by the Government of Montenegro (hereinafter: Government).
- (2) The Accreditation Body acquires the status of a legal entity by registration in the Central Registry of the Commercial Court in Podgorica.

### **Tasks**

#### **Article 5**

- (1) The Accreditation Body determines the competence of conformity assessment bodies by accreditation.
- (2) In addition to the task referred to in paragraph 1 of this article, the Accreditation Body also performs the following tasks:
  - 1) participate in the work of international and European organizations for accreditation in accordance with the obligations assumed under international agreements;
  - 2) maintain a register of accredited conformity assessment bodies;
  - 3) performs other tasks in the field of accreditation, in accordance with this Law, the founding act and the statute;
  - 4) establishes the rules of accreditation.
- (3) The detailed content and manner of keeping the register referred to in paragraph 2 point 2 of this article shall be determined by the Accreditation Body.

### **Prohibition on the performance of activities**

#### **Article 6**

- (1) The Accreditation Body may only perform the tasks referred to in Article 5 and Articles 9 and 9a of this Law, and shall not provide other services to conformity assessment bodies including consulting.
- (2) The Accreditation Body shall not have ownership and management rights or other financial interests in conformity assessment bodies.
- (3) The Accreditation Body shall not compete with conformity assessment bodies and shall not promote its services, nor perform marketing activities, in the territory of other countries or compete with other accreditation bodies.

### **Organization of the Accreditation Body**

#### **Article 7**

- (1) The organization and functioning of the Accreditation Body is determined by its founding act, statute, and other general acts of the Accreditation Body which shall be based on the relevant international, European and Montenegrin standards, as well as on the documents published by international and European organizations for accreditation.
- (2) The general acts referred to in paragraph 1 of this Article shall be published on the website of the Accreditation Body and be available to the public.

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## **Accreditation process**

### **Article 8**

- (1) The accreditation process shall be initiated by a conformity assessment body, by submitting an application for accreditation to the Accreditation Body.
- (2) Along with the application for accreditation, the conformity assessment body shall also submit relevant documentation in accordance with the rules of accreditation.
- (3) The Accreditation Body shall determine the fulfillment of all requirements prescribed by the relevant harmonized standards and, where applicable, any additional requirements for performing specific conformity assessment tasks, based on documentation submitted and through on-site assessment visit at the premises of the conformity assessment body.
- (4) The obligations of the Accreditation Body and the conformity assessment bodies shall be governed by an Agreement in accordance with the rules of accreditation.
- (5) The Agreement referred to in paragraph 4 of this Article shall govern the mutual rights and obligations of the parties in connection with the granting, maintenance, extension, reduction, and suspension of accreditation, including the associated fees, as well as the handling and use of confidential information and data in accordance with applicable law.

## **Cross-border accreditation**

### **Article 9**

- (1) The Accreditation Body may conduct an accreditation process at the request of a conformity assessment body from another country if:
  - 1) the country where the applicant is based does not have an established accreditation body;
  - 2) the accreditation body in the applicant's country does not perform accreditation in relation to the conformity assessment activities for which accreditation is sought;
  - 3) the accreditation body in the applicant's country has not undergone peer evaluation in relation to the conformity assessment activities for which accreditation is sought.
- (2) If the Accreditation Body receives an application for accreditation referred to in paragraph 1, items 2 and 3 of this Article, it shall notify the national accreditation body of that country.
- (3) In the accreditation procedure referred to in paragraph 2 of this Article, the national accreditation body of that country may participate as an observer.
- (4) The Accreditation Body may, at the request of an accreditation body of another country, carry out part of the activities in the accreditation process of a conformity assessment body from that country.

## **Accreditation body of another country**

### **Article 9a**

- (1) The Accreditation Body may instruct a conformity assessment body established in Montenegro to submit an application for accreditation to the accreditation body of another country, if the Accreditation Body does not perform accreditation for certain conformity assessment activities from the submitted accreditation application.
- (2) The accreditation certificate issued by an accreditation body of another country in accordance with paragraph 1 of this Article shall be entered in the register of accredited conformity assessment bodies maintained by the Accreditation Body.
- (3) The Accreditation Body may ask the accreditation body of another country to perform a part of the accreditation activities from the accreditation process, and in that case the accreditation certificate is issued by the Accreditation Body.

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## **Accreditation certificate**

### **Article 10**

- (1) The Accreditation Body shall issue an accreditation certificate when it determines that the conformity assessment body meets the requirements referred to in Article 8, paragraph 3 and Article 9a, paragraph 3 of this Law.
- (2) The accreditation certificate shall be issued for a specific period of time in accordance with the rules of accreditation.
- (3) If a conformity assessment body does not meet the requirements referred to in Article 8, paragraph 3 of this Law, the Accreditation Body shall reject the granting of accreditation.
- (4) The accreditation decision referred to in paragraphs 1 and 3 of this Article is final and an administrative dispute may be initiated against it.

## **Withdrawal of accreditation certificate**

### **Article 11**

- (1) An accredited conformity assessment body shall, for the duration of its accreditation, comply with all accreditation requirements.
- (2) Monitoring of compliance with the requirements referred to in paragraph 1 of this Article shall be carried out by means of regular or extraordinary surveillance activities carried out by the Accreditation Body in accordance with the rules of accreditation.
- (3) Where, in the course of the procedure referred to in paragraph 2 of this Article, the Accreditation Body determines that the accredited conformity assessment body does not meet the accreditation requirements, it shall withdraw the accreditation certificate.
- (4) Where, in the course of the procedure referred to in paragraph 2 of this Article, the Accreditation Body determines that an accredited conformity assessment body only partially complies with the accreditation requirements, the scope of accreditation shall, in accordance with the rules of accreditation, be reduced to the areas where such requirements are fulfilled.
- (5) The accreditation decision referred to in paragraphs 3 and 4 of this Article is final and an administrative dispute may be initiated against it.

## **Governing bodies of the Accreditation Body**

### **Article 12**

- (1) The governing bodies of the Accreditation Body are:
  - 1) Management Board;
  - 2) Director;
  - 3) Supervisory Board.
- (2) The manner of constituting the governing bodies referred to in paragraph 1 of this Article, their tasks and responsibilities, procedures and decision-making, as well as other matters of significance for the functioning of the Accreditation Body, is regulated by its founding act and Statute.
- (3) The Statute of the Accreditation Body is adopted by the Management Board.
- (4) The Statute of the Accreditation Body shall require the consent of the Government.

## **Financing of the Accreditation Body**

### **Article 13**

- (1) The funds for the operation of the Accreditation Body are provided from:
  - 1) accreditation fees;

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- 2) the budget of Montenegro;
  - 3) other sources.
- (2) The accreditation fees referred to in paragraph 1, item 1 of this Article are charged for accreditation services provided to conformity assessment bodies ~~and their entry in the register referred to in Article 9, paragraph 5 of this Law.~~
  - (3) The amount of accreditation fees ~~and registration costs referred to in Article 9, paragraph 5 of this Law~~ shall be determined by the Management Board of the Accreditation Body, with the consent of the Government.
  - (4) The funds referred to in paragraph 1, item 2 of this Article are provided for:
    - conducting activities determined by the annual work program of the Accreditation Body;
    - payment of membership fees and participation of the Accreditation Body in European and international organizations for accreditation.
  - (5) The amount of funds for the operation of the Accreditation Body to be provided from the budget of Montenegro shall be determined based on the activities and tasks set out in the annual work program of the Accreditation Body, to which the Government has previously given its consent.
  - (6) The decision on the amount of accreditation fees referred to in paragraph 3 of this Article shall be published in the "Official Gazette of Montenegro".

### **Gifts (donations)**

#### **Article 14**

- (1) Funds from other sources referred to in Article 13, paragraph 1, item 3 of this Law are considered gifts (donations) and other income generated in accordance with the law.
- (2) The Accreditation Body shall not accept any gifts (donations) from users of its accreditation services.

## **III. ACCREDITATION AND RELATIONSHIP WITH TECHNICAL REGULATIONS**

#### **Article 15**

The technical regulations governing the field of conformity assessment may establish that:

- 1) accreditation certificate provides presumption of fulfilment of conditions for designation and authorization of conformity assessment bodies;
- 2) accreditation certificate is a prerequisite for the designation or authorization of conformity assessment bodies.

## **IV. SUPERVISION OF THE WORK OF THE ACCREDITATION BODY**

#### **Article 16**

Supervision of the work of the Accreditation Body in performing tasks determined by Law shall be carried out by the ministry responsible for quality infrastructure, and with regard to the rational use of funds for the operation of the Accreditation Body provided from the budget of Montenegro, by the ministries responsible for finance and quality infrastructure.

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## **V. TRANSITIONAL AND FINAL PROVISIONS**

### **Continuation of operations**

#### **Article 17**

- (1) The Accreditation Body established by the Decision on the Establishment of the Accreditation Body of Montenegro ("Official Gazette of the Republic of Montenegro", No. 21/07) shall continue to operate in accordance with this Law and the founding act.
- (2) The managing bodies of the Accreditation Body that were appointed before the entry into force of this Law shall continue to operate until the expiration of their mandate.

### **Cessation of application of the Law**

#### **Article 18**

On the day this Law enters into force, the Law on Accreditation ("Official Gazette of Serbia and Montenegro", No. 44/05) shall not apply.

### **Final provision**

#### **Article 19**

This Law enters into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".