
LAW ON ACCREDITATION

Published in the Official Gazette of Montenegro, Nos. 54/2009, 43/2015 and 51/2026.

I. GENERAL PROVISIONS

Subject Matter

Article 1

This Law governs the establishment and activities of the Accreditation Body of Montenegro, the accreditation process and procedure, as well as other matters of relevance to accreditation.

Definitions

Article 2

For the purposes of this Law, the following terms shall have the following meanings:

- 1) **accreditation** means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in specific sectors (relevant sectoral schemes), to carry out specific conformity assessment activity;
- 2) **conformity assessment** means the process demonstrating whether specified conditions and requirements relating to a product, process, service, system, legal or natural person, or the relevant organizational entity (body), have been fulfilled;
- 3) **competence** means the demonstrated ability to carry out specific conformity assessment activities;
- 4) **accreditation certificate** means a document attesting that a conformity assessment body has been accredited for a specified scope of accreditation;
- 5) **conformity assessment body** means a legal person, or a part thereof, that performs conformity assessment activities, including testing, calibration, certification and inspection
- 6) **harmonised standard** means a European standard adopted on the basis of a request made by the European Commission;
- 7) **peer evaluation** means an evaluation process whereby a national accreditation body is assessed by other national accreditation bodies in accordance with the rules of international and European accreditation organisations.
- 8) **making available on the market** means any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge.
- 9) **placing on the market** means the first making available of a product on the market;
- 10) **product recall** means any measure aimed at achieving the return of a product that has already been made available to a consumer or other end-user;
- 11) **product withdrawal** means any measure aimed at preventing a product in the supply chain from being made available on the market;
- 12) **Union harmonisation legislation** means European Union legislation harmonising the conditions for the placing of products on the market

Scope of Application

Article 3

(1) Accreditation shall determine the competence of conformity assessment bodies to perform conformity assessment activities relating to:

- 1) testing;
- 2) calibration;
- 3) inspection;
- 4) product and process certification;

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- 5) management system certification;
 - 6) certification of persons.

(2) This Law shall apply to accreditation, used on a compulsory or voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing accreditation.

II. ACCREDITATION BODY

Establishment and legal status

Article 4

(1) Accreditation activities in Montenegro shall be performed by the Accreditation Body of Montenegro (hereinafter referred to as the "Accreditation Body"), an independent non-profit organisation established by the Government of Montenegro (hereinafter referred to as the "Government").

(2) The Accreditation Body shall acquire legal personality by registration in the Central Register of the Commercial Court in Podgorica.

(3) The Accreditation Body shall be a member of the European co-operation for Accreditation (EA).

Functions and Responsibilities

Article 5

(1) The Accreditation Body shall determine the competence of conformity assessment bodies by accreditation.

(2) In addition to the functions referred to in paragraph 1 of this Article, the Accreditation Body shall:

- 1) participate in the work of international and European accreditation organisations in accordance with obligations assumed under international agreements;
- 2) maintain a register of accredited conformity assessment bodies;
- 3) perform other functions in the field of accreditation in accordance with this Law, the founding act and the Statute; and
- 4) establish accreditation rules.

(3) The detailed content of, and the manner of maintaining, the register referred to in paragraph 2, item 2 of this Article shall be determined by the Accreditation Body.

(4) In performing the functions referred to in paragraph 1 of this Article, the Accreditation Body shall ensure, through its general and internal acts, that it:

- has a sufficient number of qualified personnel;
- documents the duties, responsibilities and authorities of persons involved in the accreditation process, where such documentation is necessary for the proper conduct of assessment and attestation of competence;
- establishes, implements and maintains procedures for monitoring the effectiveness and competence of the personnel involved.

Restrictions on Activities

Article 6

(1) The Accreditation Body may perform only the functions referred to in Article 5 and Articles 9 and 9a of this Law and shall not provide services to conformity assessment bodies, including consultancy services.

(2) The Accreditation Body shall not have ownership or management rights, or any other financial interests, in conformity assessment bodies.

(3) The Accreditation Body shall not promote its services, carry out marketing activities in the territory of other countries, or compete with accreditation bodies of other countries in the conduct of accreditation procedures or compete with conformity assessment bodies.

(4) A conformity assessment body shall operate independently of the Accreditation Body and shall not have ownership, management or other financial rights, interests or relationships that could directly or indirectly affect the impartiality and objectivity of the Accreditation Body in its activities and decision-making.

Organisation of the Accreditation Body

Article 7

(1) The organisation and operation of the Accreditation Body shall be governed by the founding act, the Statute and other general acts of the Accreditation Body, which shall be based on the relevant international, European and Montenegrin standards and on the documents of international and European accreditation organisations.

(2) The general acts referred to in paragraph 1 of this Article shall be published on the website of the Accreditation Body and shall be available to the public.

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.

Accreditation Procedure

Article 8

(1) An accreditation procedure shall be initiated by a conformity assessment body through the submission of an application for accreditation.

(2) A conformity assessment body shall submit, together with the application for accreditation, the relevant documentation in accordance with the accreditation rules.

(3) Upon receipt of the documentation referred to in paragraph 2 of this Article, the Accreditation Body shall take appropriate measures to protect the confidentiality of the information received by promptly acknowledging receipt of the required documentation and assuming responsibility for safeguarding the confidentiality of such information throughout the accreditation process.

(4) The Accreditation Body shall determine whether the requirements laid down in harmonised standards and, where applicable, any additional requirements for carrying out specific conformity assessment activities have been fulfilled, on the basis of the documentation submitted and by conducting an on-site assessment of the conformity assessment body with regard to compliance with such requirements.

(5) The obligations of the Accreditation Body and the conformity assessment body shall be governed by an Agreement concluded in accordance with the accreditation rules.

(6) The Agreement referred to in paragraph 5 of this Article shall regulate the mutual rights and obligations relating to the granting, maintenance, extension, reduction, suspension and costs of accreditation, as well as confidential information and data and the manner of their use in accordance with the law.

Cross-border Accreditation

Article 9

- (1) The Accreditation Body may conduct an accreditation procedure upon the application of a conformity assessment body established in another country, if:
- 1) the country in which the applicant is established has not designated a national accreditation body;
 - 2) the accreditation body in the applicant's country does not provide accreditation for the conformity assessment activities for which accreditation is sought; or
 - 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) Where it receives an application for accreditation referred to in paragraph 1, items 2 and 3 of this Article, the Accreditation Body shall inform the national accreditation body of that country.
- (3) In the accreditation procedure referred to in paragraph 2 of this Article, the accreditation body of that country may participate as an observer.
- (4) Upon the request of the accreditation body of another country, the Accreditation Body may perform part of the activities within the accreditation procedure of a conformity assessment body established in that country.

Accreditation by an Accreditation Body of Another State

Article 9a

- (1) The Accreditation Body may refer a conformity assessment body established in Montenegro to the accreditation body of a Member State of the European Union for the submission of an application for accreditation where the Accreditation Body does not provide accreditation for the specific conformity assessment activities covered by the application for accreditation.
- (2) An accreditation certificate issued by the accreditation body of a Member State of the European Union 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 request the accreditation body of a Member State of the European Union to perform part of the activities within the accreditation procedure, in which case the accreditation certificate shall be issued by the Accreditation Body.

Accreditation Certificate

Article 10

- (1) The Accreditation Body shall issue an accreditation certificate where it determines that the conformity assessment body fulfils the requirements referred to in Article 8(4) and Article 9a(3) of this Law.
- (2) An accreditation certificate shall be issued for a specified period in accordance with the accreditation rules.
- (3) Where the conformity assessment body does not fulfil the requirements referred to in Article 8(4) of this Law, the Accreditation Body shall not grant the accreditation.
- (4) An administrative dispute may be initiated against the decisions referred to in paragraphs 1 and 3 of this Article.

Withdrawal of the Accreditation Certificate

Article 11

- (1) An accredited conformity assessment body shall continue to fulfil the accreditation requirements for the duration of its accreditation.
- (2) Compliance with the requirements referred to in paragraph 1 of this Article shall be verified through regular or extraordinary surveillance conducted by the Accreditation Body in accordance with the accreditation rules.
- (3) Where, in the procedure referred to in paragraph 2 of this Article, the Accreditation Body determines that an accredited conformity assessment body no longer fulfils the accreditation requirements, it shall withdraw the accreditation certificate.
- (4) Where, in the procedure referred to in paragraph 2 of this Article, the Accreditation Body determines that an accredited conformity assessment body no longer fulfils the accreditation requirements within part of its scope of accreditation, the scope of accreditation shall be reduced in accordance with the accreditation rules.
- (5) An administrative dispute may be initiated against the decisions referred to in paragraphs 3 and 4 of this Article.

Organs of the Accreditation Body

Article 12

- (1) The organs of the Accreditation Body shall be:
 - 1) the Management Board;
 - 2) the Director; and
 - 3) the Supervisory Board.
- (2) The founding act and the Statute of the Accreditation Body shall regulate the composition, operation and decision-making procedures of the organs referred to in paragraph 1 of this Article, as well as other matters relevant to the operation of the Accreditation Body.
- (3) The Statute of the Accreditation Body shall be adopted by the Management Board.
- (4) The Statute of the Accreditation Body shall be subject to the consent of the Government.

Financing of the Accreditation Body

Article 13

- (1) The funds required for the operation of the Accreditation Body shall be provided from:
 - 1) accreditation fees;
 - 2) the Budget of Montenegro; and
 - 3) other sources.
- (2) The accreditation fee referred to in paragraph 1, item 1 of this Article shall cover the costs of accreditation and registration in the register referred to in Article 9(5) of this Law.
- (3) The amount of fees for accreditation costs and registration in the register referred to in Article 9(5) of this Law shall be determined by the Management Board of the Accreditation Body, subject to the consent of the Government.
- (4) The funds referred to in paragraph 1, item 2 of this Article shall be provided for:
 - carrying out the activities established by the annual programme and work plan of the Accreditation Body;

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- payment of membership fees and participation of the Accreditation Body in European and international accreditation organisations.
- (5) The amount of funds for the operation of the Accreditation Body provided from the Budget of Montenegro shall be determined on the basis of the activities established by the annual programme and work plan of the Accreditation Body, subject to the consent of the Government.
- (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 and Donations

Article 14

- (1) The funds from other sources referred to in Article 13(1), item 3 of this Law shall include gifts, donations and other income received in accordance with the law.
- (2) The Accreditation Body shall not accept gifts or donations from users of its accreditation services.

III. ACCREDITATION AND TECHNICAL REGULATIONS

Article 15

Technical regulations governing conformity assessment may provide that:

- 1) an accreditation certificate constitutes a presumption of compliance with the requirements laid down in the regulations for the purposes of the designation and authorisation of conformity assessment bodies;
- 2) an accreditation certificate is a prerequisite for the designation or authorisation of conformity assessment bodies.

IV. SUPERVISION OF THE ACCREDITATION BODY

Article 16

- (1) Supervision of the Accreditation Body in the performance of the functions established by this Law shall be exercised by the ministry responsible for quality infrastructure. Supervision of the efficient use of funds for the operation of the Accreditation Body provided from the Budget of Montenegro shall be exercised by the ministries responsible for finance and quality infrastructure.
- (2) Where, in the course of the supervision referred to in paragraph 1 of this Article, the competent ministry determines that the Accreditation Body does not satisfy the requirements or fulfil its obligations laid down in this Law, it shall take measures in accordance with the regulations governing the competences of state administration authorities and shall inform the European Commission thereof.

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 its operations in accordance with this Law and the founding act.
- (2) The organs of the Accreditation Body appointed prior to the entry into force of this Law shall continue to operate until the expiry of their terms of office.

Cessation of Application of the Law

Article 18

Upon the entry into force of this Law, the Law on Accreditation (*Official Gazette of Serbia and Montenegro*, No. 44/05) shall cease to apply.

Final Provision

Article 19

This Law shall enter into force on the eighth day following its publication in the *Official Gazette of Montenegro*.