

LAW ON ACCREDITATION

I. GENERAL PROVISIONS

Subject matter of the Law

Article 1

This Law shall regulate the establishment and activity of the Accreditation Body of Montenegro, the manner of and procedure for accreditation, and other issues relevant to accreditation.

Definitions

Article 2

For the purposes of this Law:

- 1) **accreditation** means procedure by which the Accreditation Body of Montenegro attests that a conformity assessment body meets specific requirements and that it is competent to carry out specific conformity assessment activities;
- 2) **conformity assessment** means the process of determining whether the conditions and requirements relating to a product, process, service, system, legal or natural person or a relevant organisation form, are met;
- 3) **competence** means demonstrated ability to carry out specific conformity assessment activities;
- 4) **accreditation certificate** means a document certifying that a conformity assessment body has been accredited for a specified field and scope;
- 5) **conformity assessment body** means a legal person or a part of a legal person that performs conformity assessment which includes testing, calibration, certification and inspection.

Scope of application

Article 3

Accreditation shall be used to determine competence of conformity assessment bodies to carry out conformity assessment activities relating to relevant:

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

II. ACCREDITATION BODY

Organisation and activity

Article 4

(1) The accreditation activities in Montenegro shall be carried out by the Accreditation Body of Montenegro (hereinafter referred to as the "Accreditation Body") as an autonomous not-for-profit body founded by the Government of Montenegro (hereinafter referred to as the "Government").

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

Activity

Article 5

(1) The Accreditation Body shall determine competence of conformity assessment bodies:

1) by accreditation;

2) by other manner of determining the competence to carry out the process of assessment of conformity in accordance with technical regulations, where accreditation is not specified as a requirement for attestation of competence.

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

1) participate in the work of international and European accreditation bodies in accordance with the obligations under international agreements;

2) keep a register of accredited conformity assessment bodies;

3) perform other activities in the field of accreditation pursuant to this Law, its founding act and its Statute;

4) lay down rules of accreditation.

(3) More detailed contents and method of keeping of the register referred to in paragraph 2 item 2 of this Article shall be laid down by the Accreditation Body.

Prohibition of performance of certain activities Article 6

(1) The Accreditation Body may only perform the activities referred to in Article 5 and Article 9 paragraph 3 of this Law and it may not provide any services to the conformity assessment bodies including consultancy services.

(2) The Accreditation Body may not hold any ownership and managerial rights or otherwise have a financial interest in a conformity assessment body.

Organisation of the Accreditation Body Article 7

(1) The organisation and the method of work of the Accreditation Body shall be laid down under the founding act, the Statute and other general acts of the Accreditation Body, which shall be based on relevant international, European and Montenegrin standards and documents of international and European accreditation bodies.

(2) General acts referred to in paragraph 1 of this Article, shall be published on the web page of the Accreditation Body and shall be available to the public.

Procedure for accreditation Article 8

(1) The procedure for accreditation shall be initiated by a conformity assessment body by submitting a request for accreditation.

(2) In addition to the request for accreditation, the conformity assessment body shall submit relevant documents in accordance with the rules of accreditation.

(3) The Accreditation Body shall determine whether the requirements from relevant international, European and Montenegrin standards and/or documents of international and European accreditation bodies are met based on documents submitted and by direct insight concerning the compliance with the requirements.

(4) The obligations of the Accreditation Body and a conformity assessment body shall be regulated under an agreement in accordance with the rules of accreditation.

(5) The agreement referred to in Article 4 of this Article shall regulate mutual rights and obligations in the procedures for issuance, maintenance, extension, restriction, suspension and costs of accreditation, as well as confidential information and their use in accordance with law.

Accreditation body of another state **Article 9**

(1) In respect to the conformity assessment for which the accreditation is requested, the Accreditation Body may refer a conformity assessment body to a national accreditation body of another state which is competent to carry out accreditation.

(2) The representatives of the Accreditation Body may participate as observers in the procedure for accreditation referred to in paragraph 1 of this Article.

(3) The Accreditation Body may request the national accreditation body of another state to carry out a part of the activities pertaining to the accreditation procedure.

(4) The accreditation certificate issued pursuant to paragraph 1 of this Article by the national accreditation body of another state shall be registered in the register of accredited conformity assessment bodies.

(5) The registration in the register of accredited conformity assessment bodies referred to in paragraph 1 of this Article shall be subject to a fee.

ACCREDITATION CERTIFICATE **Article 10**

(1) When the Accreditation Body finds that a conformity assessment body fulfils the requirements referred to in Article 8 paragraph 3 and Article 9 paragraph 3 of this Law, the Accreditation Body shall issue an accreditation certificate.

(2) The accreditation certificate shall be issued for a specified period of time in accordance with the rules of accreditation.

(3) If a conformity assessment body does not fulfil the requirements referred to in Article 8 paragraph 3 of this Law, the Accreditation Body shall reject the request for accreditation.

(4) A decision referred to in paragraphs 1 and 3 of this Article shall be final and administrative dispute proceedings may be initiated against it.

WITHDRAWING ACCREDITATION CERTIFICATE **Article 11**

(1) Accredited conformity assessment body shall be obliged to comply with the accreditation requirements during the period of validity of accreditation.

(2) Checking of compliance with the requirements referred to in paragraph 1 of this Article shall be carried out by way of regular or special supervision carried out by the Accreditation Body in accordance with the rules of accreditation.

(3) If in the procedure referred to in paragraph 2 of this Article the Accreditation Body finds that the accredited conformity assessment body does not fulfil the accreditation requirements, it shall revoke the accreditation certificate.

(4) If in the procedure referred to in paragraph 2 of this Article the Accreditation Body finds that the accredited conformity assessment body partly fulfils the accreditation requirements, it shall restrict the accreditation in accordance with the rules of accreditation.

(5) A decision referred to in paragraphs 3 and 4 of this Article shall be final and administrative dispute proceedings may be initiated against it.

Bodies of the Accreditation Body Article 12

(1) The bodies of the Accreditation Body shall be as follows:

- 1) Managing Board,
- 2) Director and
- 3) Supervisory Board.

(2) The manner of establishing of the bodies referred to in paragraph 1 of this Article, their work and decision-making methods, and other issues relevant to the work of the Accreditation Body shall be regulated by the founding act and the Statute of the Accreditation Body.

(3) The Statute of the Accreditation Body shall be adopted by the Managing Board.

(4) The Government shall give consent to the Statute of the Accreditation Body.

Financing the Accreditation Body Article 13

(1) The financial resources for the work of the Accreditation Body shall be provided from:

- 1) accreditation fees,
- 2) the Budget of Montenegro,
- 3) other sources.

(2) Accreditation fee referred to in paragraph 1 item 1 of this Article shall be charged for accreditation and the registration referred to in Article 9 paragraph 5 of this Law.

(3) The amount of the fees for the costs of accreditation and the registration referred to in Article 9 paragraph 5 of this Law shall be determined by the Managing Board of the Accreditation Body subject to a prior consent of the Government.

(4) The funds referred to in paragraph 1 item 2 of this Article shall be provided for: - performance of activities laid down under the annual programme and work plan of the Accreditation Body; - payment of membership fees and participation of the Accreditation Body in the European and other international accreditation bodies.

(5) The amount of the funds necessary for the work of the Accreditation Body which are provided from the Budget of Montenegro shall be determined on the basis of the activities laid down under the programme and annual work plan of the Accreditation Body, subject to a prior 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.

Grants (donations)

Article 14

(1) The funds from other sources referred to in Article 13 paragraph 1 item 3 of this Law shall be considered grants (donations) and other income earned in accordance with law.

(2) The Accreditation Body may not receive grants (donations) from the users of services.

III. ACCREDITATION AND REFERENCE TO TECHNICAL REGULATIONS

Article 15

In technical regulations regulating the field of conformity assessment, it may be laid down that:

1) the accreditation certificate is an assumption of compliance with the requirements from the regulation in the procedure of designation and authorisation of conformity assessment bodies;

2) the accreditation certificate is a precondition for designation or authorisation of conformity assessment bodies.

IV. SUPERVISION OF THE WORK OF THE ACCREDITATION BODY

Article 16

Supervision of the work of the Accreditation Body in the performance of the activities laid down by law shall be performed by the ministry competent for quality infrastructure activities, and as regards the rational use of funds for the work of the Accreditation Body which are provided from the Budget of Montenegro, supervision shall be performed by the ministries competent for finance and quality infrastructure activities.

V. TRANSITIONAL AND FINAL PROVISIONS

Continuation of operations

Article 17

(1) The Accreditation Body founded by the Decision establishing the Accreditation Body of Montenegro (Official Gazette of the Republic of Montenegro 21/07) shall continue its operations in accordance with this Law and the founding act.

(2) The bodies of the Accreditation Body appointed before the entry into force of this Law shall continue their work until the expiration of their mandate.

Cessation of application of the law

Article 18

The Law on Accreditation (Official Gazette of Serbia and Montenegro 44/05) shall not apply from the day of entry into force of this Law.

Final provision

Article 19

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