

Law on Accreditation

I. BASIC PROVISIONS

Article 1

(1) This Law shall regulate the organisation and activities of the Institute for Accreditation of the Republic of Macedonia, the manner and procedure of accreditation for determining the competency of conformity assessment bodies, the surveillance over the accreditation requirements fulfilment and the international cooperation.

(2) The Institute for Accreditation of the Republic of Macedonia shall operate in accordance with the requirements contained in the respective harmonised national standards and documents of European and international accreditation organisations.

Article 2

Specific terms used in this Law shall have the following meaning:

1) “accreditation” shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised national standards and, where applicable, any additional requirements including those set out in relevant sectors, to carry out a specific conformity assessment activity;

2) “conformity assessment” shall mean a process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

3) “conformity assessment body” shall mean a legal entity that performs conformity assessment activities including calibration, testing, certification and inspection;

4) “accreditation certificate” shall mean a document or set of documents issued by a national accreditation body confirming the technical competency of conformity assessment bodies for a defined scope;

5) “peer evaluation” shall mean a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements provided for with this Law, and, where applicable, additional sectoral technical specifications.

Article 3

(1) Accreditation shall apply to bodies performing conformity assessment within a regulated and non-regulated area.

(2) Accreditation shall be generally applied on voluntary and compulsory basis, relating to conformity assessment.

II. INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF MACEDONIA

Article 4

(1) The accreditation activities and tasks shall be performed by the Institute for Accreditation of the Republic of Macedonia (hereinafter referred to as: the Institute), as a public institution of public interest.

(2) The Institute shall have the status of a legal entity.

Article 5

(1) The Institute shall draft an Annual Work Programme defining the activities of the Institute for the current fiscal year, in accordance with the allocated appropriations from the Budget of the Republic of Macedonia.

(2) The Annual Programme referred to in paragraph 1 of this Article shall be adopted by the Government of the Republic of Macedonia.

(3) The Institute shall submit for adoption a Report on the realised Programme referred to in paragraph 1 of this Article to the Government of the Republic of Macedonia.

Article 6

(1) The Institute shall perform the following activities and tasks:

1) Accreditation of:

- Testing and calibration laboratories;
- Product certification bodies;
- (Quality, environment, safety, security, etc.) management systems certification bodies;
- Persons certification bodies;
- Inspection bodies; and
- Other conformity assessment bodies;

2) Participation in the activities of European and international accreditation organisations so as to represent the interests of the Republic of Macedonia;

3) Provision of input to state administration bodies on issues concerning accreditation and provision of opinions on issuing approval for competency to carry out conformity assessment procedures; and

4) Evaluation of the competency of conformity assessment bodies, including the surveillance over the fulfilment of requirements of bodies performing conformity assessment pursuant to a given regulation; and

(2) In the course of carrying out its activities and tasks, the Institute shall be entitled to place the coat of arms of the Republic of Macedonia on its documents and the seal.

Article 7

In the course of performing its activities, the Institute shall comply with the following principles of non-competition and confidentiality:

- 1) It shall not provide services in the field of conformity assessment;
- 2) It shall not provide services outside the borders of the Republic of Macedonia, except in the cases and under the conditions defined in Article 35 of this Law; and
- 3) It shall treat as confidential all data obtained by clients, except for those which are publicly available.

Article 8

(1) The funds for the activities of the Institute shall be provided from the following sources:

- the Budget of the Republic of Macedonia;
- remuneration for provided accreditation services; and
- gifts, donations and other funds from national sources as well as funds from abroad pursuant to this Law.

(2) Using the appropriations referred to in paragraph 1, indent 1 of this Article, the Institute shall provide financial and human resources necessary for the delivery of its services including the adequate delivery of special tasks, such as activities in European and international accreditation organisations and those activities which are required to support public policies and are not self-financed.

(3) The Institute shall operate on a non profit basis.

Article 9

(1) The Institute shall charge a fee for the provided services, according to the Schedule of rates for the provided accreditation services in line with the incurred expenditures.

(2) The collected service fees referred to in paragraph 1 of this Article shall represent revenues of the Institute and shall be utilised in accordance with the Work Programme of the Institute.

Article 10

The following bodies shall constitute the Institute:

- Council;
- Director; and
- Supervisory Body for Material and Financial Affairs.

Article 11

- (1) The Council shall act as the governing body of the Institute.
- (2) The Council shall be comprised of 11 members, nominated by the Government of Republic of Macedonia following the proposal of the following:
 - Government of the Republic of Macedonia – four representatives;
 - Universities – one representative;
 - Chambers of Commerce – two representatives;
 - Conformity Assessment Bodies – two representatives;
 - Consumers Organization – one representative; and
 - Institute – one representative out of the employees.
- (3) The Government of Republic of Macedonia shall appoint a Chairperson of the Council out of the composition of the Council membership.
- (4) The Chairperson and the Council members shall have completed higher education, be competent, and have experience in the field of accreditation and activities related thereto.
- (5) The Government of Republic of Macedonia in the course of appoint the Chairperson and membership of the Council shall take into consideration the adequate and fair representation of all ethnic communities.
- (6) The mandate of the Chairperson and Council members shall be four years, with a possibility for one re-election.

Article 12

The Chairperson and the Council members can be relieved of duty prior to the expiry of the mandate in the following instances:

- Following their request,
- In cases of occurrences stipulated in the labor regulations as a result of which the labour relation contract has been terminated due to virtue of law in the authority, the organization or the institution of nomination
- If failing to act or work according to the Law, the Statute or the acts of the Institute or unjustifiably fail to attend three consecutive meetings of the Council, or
- If by means of their unethical and improper work cause significant damage to the Institute or by neglecting or not performing their obligations injure or potentially harm the regular activities of the Institute.

Article 13

- (1) The Procedure of nomination of new Chairperson and members of the Council shall start the latest of three months from the expiry of the mandate stipulated in Article 11, paragraph (6) of this Law.
- (2) Provided that by the expiry of the mandate of the standing constituency of the Council of paragraph (1) of this Article a new nomination procedure for Council constituency has not been initiated, the standing membership shall resume its activities until the nomination of the new constituency, the latest of six months.

Article 14

The Council shall perform the following activities and tasks:

- adopt a Statute and other general acts of the Institute and monitor their enforcement;
- define a financial plan and approve the annual balance sheet;
- adopt the Schedule of rates for services provided by the Institute in the field of accreditation;
- appoint and relieve of duty the Director of the Institute;
- submit at least once a year a Report on its work to the Government of the Republic of Macedonia;
- perform other activities pursuant to this Law and the Statute of the Institute.

Article 15

(1) The Institute shall be managed by a Director.

(2) The Director of the Institute (hereinafter referred to as: the Director) shall be appointed and relieved of duty by the Council.

(3) A person can be appointed Director provided that it meets the following requirements:

- has completed a minimum of higher education grade;
- has a minimum of five years working experience;
- has a minimum of three years experience as a manager;
- has experience in the field of accreditation and activities related thereto; and
- is fluent in at least one foreign language.

Article 16

(1) The Director shall be appointed by the Council following the announcement of a public competition

(2) The competition shall be published in at least two media.

(3) The competition shall last for 15 days from the day of its announcement.

(4) The Director shall be elected within 30 days from the day of announcement of the competition.

(5) If no one applies at the competition, or if the Council fails to appoint a Director from among the applicants within the time frame referred to in paragraph 4 of this Article, a new competition shall be announced within five days following the end of the deadline of paragraph (4) of this Article.

Article 17

(1) The Council shall appoint the Director by a majority vote of the members of the Council for a period of four years with the possibility for re-election upon expiry of the mandate.

(2) The decision for appointment and dismissal of the Director shall be endorsed by the Government of the Republic of Macedonia.

Article 18

(1) In the cases referred to in Article 16 paragraph (5) and Article 20 of this Law, the Council may appoint an acting director from among the employees of the Institute without a public competition.

(2) The acting director referred to in paragraph 1 of this Article may act as director until the appointment of a Director, for a maximum of six months following the date of its appointment.

(3) In case a Director has not been appointed within the time frame referred to in paragraph 2 of this Article, the Council shall appoint a new acting director, for a maximum period of six months following his/hers appointment.

Article 19

The Director shall perform the following tasks:

- organise and manage the work of the Institute;
- independently make decisions within its competencies;
- represent and support the Institute before third parties;
- have responsibility for the legitimacy of the Institute's work;
- carry out Council decisions;
- propose the Institute's organisational set-up;
- decide on allocation of employees to specific work tasks;
- make first instance decisions on exercising rights and obligations of the employees as regards labour relations;
- ensure transparent and impartial activities of the Institute;
- be responsible for the financial affairs of the Institute;
- prepare a Draft Budget of the Institute for the following year;
- have the right and responsibility to participate in the work of the Council, without the right to decide;
- adopt other general acts related to the operation of the Institute within the Director's powers, and

- perform other activities and tasks defined by law or regulations, the Statute or other acts of the Institute.

Article 20

(1) The Director may be relieved of duty prior to the expiry of the mandate, in the following cases:

- following his/her request;
- if by occurrence of any of the reasons due to which, according to the labour regulations, the actual labour agreement is terminated by virtue of the law;
- if the Director fails to operate or act pursuant to the law, the Statute and the acts of the Institute or unjustifiably fails to implement the Council decisions or acts contrary to them;
- if by unethical or improper activities causes significant damage to the Institute or neglects or fails to execute his/her responsibilities and thus brings about actual or potential disturbance to the activities of the Institute; and
- if by any means hinders or otherwise prevents the exercising of rights and obligations of the Institute's clients.

(2) Prior to adopting the Decision for Relief of Duty the Council shall familiarise the Director with the reasons for the dismissal and shall give him/her a chance to elaborate.

(3) The Decision for Relief of Duty shall be enforced on the day following the obtained consent by the Government of Republic of Macedonia.

(4) The Director shall have the right to appeal the Decision for Relief of Duty before the Court of jurisdiction within fifteen days following the agreement for Director's relief of duty by the Government of Republic of Macedonia.

Article 21

(1) For the purpose of conducting material and financial control of the Institute's activities, a Supervisory Board for Material and Financial Control shall be established (hereinafter referred to as: the Supervisory Board).

(2) The Supervisory Board shall be composed of Chairperson and two members.

(3) The Chairperson and Supervisory Board members shall have completed higher education, be competent and have knowledge and experience in the area of material and financial work for the purposes of delivery of their activities and tasks.

(4) The Chairperson and members of the Supervisory Board shall be appointed by the Government of the Republic of Macedonia, taking into consideration the adequate and fair representation of all ethnic communities.

(5) The mandate of the Chairperson and members of the Supervisory Board shall be four years.

(6) The Supervisory Board shall submit an annual report for the activities of the Institute to the Government of the Republic of Macedonia.

Article 22

(1) The Institute can establish technical working groups for the purposes of providing expertise on specific issues, as follows: Accreditation Board; Appeals Committee; Technical Committees, Sector Committees and Persons Evaluation Committees (assessors and experts) and others.

(2) The members of the technical working groups referred to in paragraph (1) of this Article shall have completed higher education, be competent and have experience in the area of accreditation and activities related thereto.

(3) The members of the technical working groups referred to in paragraph (1) of this Article shall not be entitled to remuneration for the services provided.

Article 23

(1) The Institute shall have a Statute regulating the following: the name, location and organisation of the Institute, the manner of conducting the activities and tasks, the Institute's authorities, the manner of constituting the technical working groups within the Institute referred to in Article 22 of this Law and their competencies and responsibilities, the governance, the management, the control, the rights and responsibilities of the clients and other issues related to the activities and tasks of the Institute.

(2) The Government of Republic of Macedonia shall give approval to the Statute of the Institute.

III. ACCREDITATION PROCEDURE

Article 24

The accreditation procedure shall be performed by the Institute pursuant to this Law, in accordance with the requirements contained in the corresponding harmonised national and European standards and documents of European and international accreditation organisations.

Article 25

(1) The accreditation shall be carried out upon request by national or international legal entities.

(2) The layout and content of the accreditation application shall be drafted by the Institute and shall be made publicly available.

(3) Upon receipt of the request referred to in paragraph (1) of this Article, the Institute shall conclude a contract with the applicant for initiating an accreditation procedure.

(4) The contract referred to in paragraph 3 of this Article shall regulate the manner of delivery of accreditation, as well as the rights and obligations of the Institute and the applicant.

Article 26

(1) For each separate accreditation, the Director of the Institute shall establish an Assessment Commission consisted of assessors and experts from the lists of assessors and experts of the Institute and of other national accreditation bodies.

(2) The lists of assessors and experts of the Institute shall be made publicly available.

Article 27

(1) If upon completion of the accreditation procedure it is found that the applicant meets all requirements pursuant to Article 25 of this Law, the Director of the Institute shall grant an accreditation certificate according to which the applicant has acquired the status of an accredited body.

(2) The accreditation certificate referred to in paragraph (1) of this Article shall be granted for a period of four years.

(3) The layout, content and manner of use of the accreditation certificate referred to in paragraph (1) of this Article shall be prescribed by the Director.

(4) No later than three months prior to the expiry of the validity of the accreditation certificate of the conformity assessment body, the Institute, in agreement with the legal entity, shall initiate a re-accreditation procedure.

Article 28

(1) If the applicant fails to meet the accreditation requirements referred to in Article 25 of this Law, the Director shall adopt a decision to reject the application for granting an accreditation certificate.

(2) The dissatisfied applicants shall be entitled to submit an appeal to the Appeals Committee of the Institute, against the decision referred to in paragraph (1) of this Article within 15 days from the day of receipt of the decision.

(3) The Appeals Committee within the Institute shall decide upon the appeals referred to in paragraph 2 of this Article.

Article 29

The accredited conformity assessment bodies shall be bound to continuously meet the accreditation requirements.

Article 30

(1) In the course of their work, the bodies accredited in a particular area shall use the appropriate accreditation mark.

(2) The Institute shall determine the types, layout, content and manner of utilisation of the accreditation mark used by the accreditation bodies.

Article 31

(1) The surveillance of the fulfilment of accreditation requirements shall be performed at least once a year.

(2) The surveillance referred to in paragraph (1) of this Article shall be performed by a Surveillance Team established by the Director.

(3) If the surveillance ascertains that the accredited body, which has obtained an accreditation certificate, fails to meet the accreditation requirements or is in serious breach of its obligations as defined by the contract referred to in Article 25, paragraph (3) of this Law, the Director of the Institute shall designate a time frame to remove the identified shortcomings.

(4) If within the designated time frame the shortcomings referred to in paragraph (3) of this Article have not been eliminated, the Director shall adopt a decision by which it will temporarily, partially or permanently withdraw the accreditation certificate or annul the accreditation certificate.

(5) Against the undertaken measures referred to in paragraph (4) of this Article, an appeal can be filed to the Appeals Committee under the Institute within 15 days following the day of receipt of the decision.

Article 32

The clients in the accreditation procedure or any other interested parties may submit a complaint to the Institute in the following cases:

- if they are not satisfied with the work performed or envisaged by the Institute and which is unrelated to the decisions against which the clients may file an appeal; and
- if they are unsatisfied with the work of the accredited bodies.

IV. INTERNATIONAL COOPERATION OF THE INSTITUTE

Article 33

The Institute shall be a member of and shall represent the Republic of Macedonia in European and international organisations related to accreditation, shall cooperate with them and take part in their activities and shall sign agreements for mutual recognition of the accreditation, i.e. the documents (reports and certificates) issued by the conformity assessment bodies.

Article 34

The conformity assessment body may request accreditation from an accreditation body outside the Republic of Macedonia, in any of the following cases:

- when the Institute does not perform the accreditation in respect of the conformity assessment activities for which accreditation has been sought; and

- when the Institute has not completed the procedure for mutual peer evaluation in respect to conformity assessment for which accreditation has been sought.

Article 35

(1) If the Institute receives an application from a conformity assessment body registered outside the Republic of Macedonia, it shall inform the national accreditation body within the country where the conformity assessment body which has submitted the application has been registered. In such case, the national accreditation body in the country where the conformity assessment body which submitted the application has been established may participate in the role of an observer during the accreditation procedure performed by the Institute.

(2) The Institute may request another national accreditation body to carry out a part of the assessment activities. In such case, the accreditation certificate will be issued by the Institute.

V. TRANSITIONAL AND FINAL PROVISIONS

Article 36

(1) The Institute for Accreditation of the Republic of Macedonia, established following a Decision for Establishment of the Institute for Accreditation of the Republic of Macedonia (Official Gazette of the Republic of Macedonia No. 14/2003), shall continue its activities as an Institute for Accreditation of the Republic of Macedonia with the competencies laid down in this Law.

(2) With the day of entry into force of this Law, the Council Chairperson and Council members as well as the Board for Material and Financial Control, shall continue to perform the functions of Chairperson of the Council, Council Members or Chairperson and Members of the Board for Material and Financial Control, until the expiry of their prescribed mandate.

(3) The Director of the Institute shall continue to perform his/her functions of Director of the Institute, pursuant to the provisions of this Law until the expiry of his/her mandate.

Article 37

The Institute shall be bound to harmonise its activities with the provisions of this Law within six months following the date of entry into force of this Law.

Article 38

The Law on Accreditation (Official Gazette of the Republic of Macedonia, No. 54/02 and 103/08) shall cease to be valid with the entry into force of this Law.

Article 39

This Law shall enter into force on the eighth day following the date of its publication in the “Official Gazette of the Republic of Macedonia”.

Adopted by the Parliament of the Republic of Macedonia on 29.09.2009 (No. 07-4158/1)

Signed by:

President of the Parliament
of Republic of Macedonia

Mr. Trajko Veljanovski

President of
the Republic of Macedonia

Mr. Gjorge Ivanov