

CONTENTS OF THE LAW ON ACCREDITATION

I General provisions

Article 1

This Law lays down the establishment, organization and operation of a public institute, performing the assignments and operations of a national accreditation service and specifies the field in which the accreditation procedure shall be performed in accordance with this and other laws and regulations based on this Law.

Article 2

Some terms, used in this Law mean:

1. **Accreditation** - an experts procedure by which the public institute, performing the assignments and operations of a national accreditation service, by granting accreditation certificate, on the basis of established criteria, gives formal recognition of competence to the entities, for carrying out specific tasks in the field of conformity assessment;
2. **Conformity assessment** – activity concerned with determining, directly or indirectly, that relevant requirements are fulfilled;
3. **Accreditation certificate** – a document issued by accreditation body making clear that entity fulfills the conditions for carrying out the operations and tasks in the specific field
4. **Conformity assessment body** - is a laboratory, a certification body, an inspection body, or some other body, involved in the conformity assessment, which can be either a government body, an another legal person or a natural person;

5. **Designation of conformity assessment bodies** – designation of bodies, for performing specified conformity assessments, in accordance with the regulations established by the competent Ministry.

Article 3

The accreditation is performed to:

1. Testing and calibration laboratories;
2. Bodies which perform certification of products;
3. Bodies which perform certification of quality systems;
4. Bodies which perform certification of environmental systems;
5. Bodies which perform certification of personal;
6. Bodies which perform inspection activities, and
7. Other areas which be decided by the accreditation body.

Article 4

Accreditation is an activity of public interest.

II Macedonian Institute for Accreditation

Article 5

The assignments and tasks, in the field of accreditation specified by this and other laws shall be performed by the Macedonian Institute for Accreditation (hereinafter referred as Institute), as a public institution established by the Government of the Republic of Macedonia.

The Institute shall perform the following assignments and tasks:

1. Accreditation in accordance with article;

2. Participation in European and international accreditation organizations, representing the interests of the Republic of Macedonia;
3. Shall provide advice to State administration in matters concerning accreditation and shall provide advice for approvals of competence for carrying out conformity assessment procedures, and;
4. Performs other activities and services in accordance with its Foundation Document and Statutes.

In performance of its assignments and tasks the Institute shall have the right to use the coat of arms of the Republic of Macedonia, on its documents, seal, marks and stamps.

The Institute shall perform its operations in accordance with the laws and other regulations applying to public institutes, unless this Law regulates particular issues differently.

The activities performed by the Institute will not be performed in view of making profit.

The funds for its foundation and beginning of work will be obtained from the budget of the Republic of Macedonia.

Article 6

The Government of the Republic of Macedonia shall adopt the Institute Foundation Document.

The Institute Foundation Document shall include regulations for:

- The seat and activities of the Institute;
- The amount of the funds, obtained by the Republic of Macedonia, intended for foundation and beginning of work;
- The sources, conditions and manners of providing operating funds, as well as the manner of disposal with assets, obtained by surplus of the Institute's revenues in ratio to its expenditures;

- The rights and obligations of the Founder, regarding performance of the Institute activities, as well as the mutual relations between the Founder and the Institute
- The legal rights and obligations of the Institute;
- The term for the Statutes adoption; and
- Other provisions in compliance with the legal regulative.

The Director of the Institute, as a temporary executive manager, shall be appointed by the Government of the Republic of Macedonia, as defined in the Foundation Document, in order to execute the preparations for the beginning of the Institute's activities.

Article 7

The Council of the Institute shall be the governing body of the Institute.

The Council of the Institute shall consist of representatives of the Founder, representatives from the Institute, as well as representatives from all interested parties.

The President and the members of the Council of the Institute will be appointed by the Founder by a decision, for the period of four years.

The Council of the Institute shall:

- Adopt the Statutes and other general decisions of the Institute and follows their execution;
- Define the financial plan and approve the balance-sheet;
- Determine the prices of the services, in the field of accreditation, performed by the Institute;
- Appoint and release the Director of the Institute;
- At least once a year shall submit business report to the Founder;
- Perform other activities based on the Law, Foundation Act and the Statues;

The Council shall decide if majority of the members are present.

The Council shall adopted decisions, in case majority of present members have declare for it, if other is specified in the Statute.

The decision under paragraph 4, line 3 of this Article, where the prices of the accreditation services performed by the Institute are indicated, will be considered as adopted, in case, the representatives of the Founder in the Council have declared themselves for it.

Article 8

A Director shall manage the Institute.

The Director of the Institute shall organize and manage the activities of the Institute, shall represent the Institute in front of third parties in public and shall be responsible for the legal performance of the Institute's activities.

The Director of the Institute shall be appointed and released by the Council, by public announcement.

The Decision regarding appointment and release of the Director of the Institute shall be considered as adopted, in case two thirds of the members of the Council have declared for it.

The Director shall be appointed for period of five years and after this mandate has expired he may be elected again.

Article 9

The Director of the Institute can be released before the expiration of the period he has been nominated:

- Upon his request;
- In case of appearance of any of causes, which, pursuant to the regulations for employees, his employment has to be ceased and it will cease by force of the applicable Law;
- If his work acts and works in contrary to the Law, the Statute and general acts of the Institute or unjustifiably he do not carry out the decisions of the governing body and expert's body of the Institute, or he acts in contrary to them;
- When he causes significant damage to the Institute by his irregular or unconscientiously work, or he neglects or do not carry out his duties, because of which, serious violations in the performance of Institute's activities are caused or could be caused;
- In case he disturbs or in any other way makes impossible the accomplishment of the rights of the beneficiaries of the Institute's activities.

The competent body, before adoption of release's decision, is obliged to inform the Director about reasons for release and to give him an opportunity to declare himself for it.

Article 10

The Institute shall have Statute, where its name, seat, organization, the number of members of Council and the structure of the governing, managing and administration bodies, their tasks and responsibilities, as well as other issues regarding the activities the Institute, will be regulated, in accordance with this and other laws and the Foundation Document.

Article 11

Funds for the work of the Institute shall be obtained through:

- Reimbursement for the provided accreditation services;
- State budget;
- Assets, donations and other sources from the country and from other countries, in compliance with a Law.

Article 12

The Institute shall be member and representing body of the Republic of Macedonia in the European and international accreditation organizations shall cooperate with them and participate in their work.

Assets for payment the membership fees under paragraph 1 of this Article shall be ensured from the State budget.

Article 13

In order to perform the tasks under paragraph 2 of Article 5 of this Law, as well as to develop accreditation in the Republic of Macedonia, the Council of the Institute shall adopt annual work program.

The performance of the program under paragraph 1 of this Article shall be funded by the State budget, taking into account the assets obtained by the Institute, from other sources under the statements in this Act.

Article 14

Institute shall perform accreditation on the base of acts adopted in compliance with Statutes and other regulations, as well as in compliance with the requirements comprised in relevant national, European and international standards and documents of the European and international accreditation organizations.

Accreditation shall be carried out upon requests of legal or natural person (hereinafter referred to as customer).

Article 15

Upon receiving a request for obtaining an accreditation certificate, under paragraph 2 of Article 14, a contract shall be settled between the Institute and the customer.

The Contract under paragraph 1 of this Article lays down the manner of performing accreditation as well as the rights and obligations of the Institute and the customer.

Article 16

For each accreditation separately, the Director shall establish an assessment team.

Director of the Institute shall prescribe conditions and procedure for establishment of the assessment team and settle its rights and responsibilities.

The members of assessment team, members of the governing bodies and employees of the Institute are obliged to keep in confidence the data concerning operation of customer, which are collected during the accreditation.

At the end of accreditation procedure, if it is found that the customer fulfill the requirements in compliance with the statement of the paragraph 1 of Article 14 of this Law, the Director shall grant an accreditation certificate, which provides the customer with the status of accredited body.

If customer does not fulfill the requirements for accreditation the Director shall adopt decision for rejecting of request for accreditation.

An accreditation certificate shall be granted for a limited period determined by a contract under paragraph 2 of Article 15 of this Act.

The certificate for accreditation shall be announced in “Official Gazette of Republic of Macedonia”.

The customer can lodge a complaint to the Council of the Institute concerning the decision under paragraphs 3 and 4 under this Article.

Article 17

If the customer requires accreditation for performing the procedures determined by law or other regulations, he is obliged to fulfill and apply relevant requirements incorporated in that laws or regulations.

If the legal or natural body that fulfills the requirements of paragraph 1 of this Article, the Commission shall issue an accreditation certificate, which approves the competence of the conformity assessment body pursuant to requirements of the conformity assessment regulations.

Article 18

Bodies accredited in particular field shall use proper accreditation stamp within their activities.

Institute's Council shall determine types, forms, content and manner of use the accreditation stamp in certificates and seals used by accreditation bodies.

Article 19

Persons that are appointed by the Director shall perform the surveillance for fulfillment of requirements.

If accreditation body fails to meet the prescribed requirements during the period specified by the accreditation certificate for related activities, the Director shall adopt a decision for prohibition of performing of those activities.

The Decision under paragraph 2 of this Article shall specify the term for removing of stated nonconformance.

In case when the nonconformance are not removed in the term stated in paragraph 3 of this article, the Director shall adopt decision for termination of performing activities specified with accreditation certificate.

The customer can lodge a complaint to the Council of the Institute concerning the decision under paragraphs 3 and 4 under this Article.

III Transitional and final provisions

Article 20

Republic of Macedonian's Government shall adopt the Foundation document of the Institute within six months after the effective date of this Law.

Article 21

The Founder shall provide the necessary premises for undisturbed performance of

accreditation tasks of the Institute, and shall transfer into its unredeemable use the tangible assets, equipment and archives of the Bureau of Standardization and Metrology, intended for the performance of accreditation tasks.

Article 22

Employees of the Bureau of Standardization and Metrology, who are performing the accreditation tasks, shall continue to perform these tasks in the Institute, in accordance with the Act on organization of work and systematization of tasks in the Institute.

Article 23

Accreditation procedures initiated before the effective date of this Law shall be conducted in accordance with the regulations in force to the date.

Until Institute starts to operate the Bureau of Standardization and Metrology shall perform procedures under paragraph 1 of this Article.

Article 24

On the effective date of this Law, the provisions of the Law on Standardization (“Official Gazette of Republic of Macedonia” No.23/95), intended for the performance of accreditation tasks, shall cease to apply.

Article 25

This Law shall become effective on the eighth day after its publication in the “Official Gazette of Republic of Macedonia”.