

**MINISTRY OF ECONOMY**

**LAW ON ACCREDITATION**  
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# LAW ON ACCREDITATION

## I General Provisions

### Article 1

This Law lays down the establishment, organization and operation of the Macedonian Institute for Accreditation, as a public institution, which is performing the operations and assignments of a national accreditation service, as well as the accreditation procedure to be performed in accordance with this and other laws and regulations based on the law and surveillance of the fulfillment of the accreditation requirements.

### Article 2

Some of the terms used in this Law, shall mean as follows:

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

5. **Designation of conformity assessment bodies** shall mean designation for the performance of conformity assessment in accordance with the regulations issued by the relevant ministry.

### **Article 3**

Accreditation shall be an activity for the public interest.

## **II. Institute for Accreditation**

### **Article 4**

In order to assure performance the operations and assignments in the field of accreditation specified by this and other laws, the Government of the Republic of Macedonia shall establish the Institute for Accreditation (hereinafter referred to as Institute), as a public institution.

The Institute shall have the function of a legal person.

The Institute shall perform the following operations and assignments:

1. Accreditation in accordance with article 14 of this Law;
2. Participating in European and international accreditation organizations and representing in them the interests of the Republic of Macedonia;
3. Providing advices to the state administration in matters concerning accreditation and for approvals of competence for carrying out conformity assessment procedure;
4. Performing assessments and approvals of competence for conformity assessment bodies, including assessment of the fulfillment for the requirements by the conformity assessment bodies pursuant to given regulations; and
5. Performing other activities and providing as laid down in the Foundation Document and Statute.

For the performance of these operations and assignments, 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 operate in compliance with the laws and other regulations applying to public institutions, unless this Law regulates it differently.

The activities of the Institute shall not be performed in a view of making profit.

The funds for the Institute's foundation shall be obtained by the State Budget.

## **Article 5**

The Institute Foundation Document shall include provisions for:

- The location and activities of the Institute;
- The funds which the Government of the Republic of Macedonia shall provide for the foundation and beginning to work of the Institute;
- The resources, conditions and manners of providing funds for operating the Institute, as well as disposal of the funds;
- The bodies of the Institute;
- The rights and obligations of the Founder, regarding performance of the Institute activities, as well as the relations between the Founder and the Institute;
- The legal rights and obligations of the Institute;
- The term for the Statute adoption; and
- Other provisions in compliance with the law;

## **Article 6**

The bodies of the Institute are:

- Counsel;
- Director; and
- Financial Control Board

## **Article 7**

The Council shall be the governing body of the Institute.

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

The Government shall appoint the President and the members of the Council for a period of four years.

The Council of the Institute shall:

- Adopt the Statute and other general decisions and follow their realization;
- 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;
- Submit report to the Founder, at least once a year;
- Perform other activities based on the law, Foundation Act and the Statute;

The Council shall make decisions if majority of the members are present.

The Council shall adopt decisions with majority of the present members unless the Statute specifies it differently.

The decision under paragraph 4, item 2 of this Article on the prices for accreditation services performed by the Institute shall be considered as adopted if the representatives of the Founder in the Council voted for it.

## **Article 8**

The Director shall manage the Institute.

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

The Director shall be appointed and released by the Council. The Decision shall be considered as adopted if two thirds of the members of the Council have declared for it.

The Government of the Republic of Macedonia shall approve the Decision for appointment or release of the Director.

The Director shall be appointed by the period of four years and he may be re-elected after this mandate has expired.

### **Article 9**

The financial control Board shall be established to supervise the financial activities. The Government of the Republic of Macedonia shall appoint the members of the Board.

### **Article 10**

The Institute shall have Statute, where its name, location, organization, the bodies of the Institute and their tasks and responsibilities, as well as other issues regarding the activities the Institute will be regulated. The Minister of Economy shall approve it.

### **Article 11**

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

- The budget of Republic of Macedonia;
- Reimbursement for the provided accreditation services;
- Grants, donations and other resources from the country and from other countries in compliance with the law.

### **Article 12**

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

### **Article 13**

In order to perform the operations and assignments, the Government of Republic of Macedonia, by recommendation from the Institute, shall adopt annual working program for the Institute.

For the performance of the working program under paragraph 1 of this Article, the Institute shall inform the Government at least once a year.

## **III. Procedure for Accreditation**

### **Article 14**

The accreditation shall be performed particular to:

1. Testing and calibration laboratories;
2. Bodies for certification of products;
3. Bodies for certification of quality systems;
4. Bodies for certification of environmental systems;
5. Bodies for certification of personal; and
6. Bodies for performing inspection activities;

### **Article 15**

The Institute shall perform the accreditation procedure on the basis of this and other laws in accordance with the requirements of the corresponding national, European and international standards and documents of the European and international accreditation organizations.

## **Article 16**

The Accreditation shall be carried out upon application submitted by domestic and foreign legal or natural persons.

Upon receiving the application under paragraph 1 of this Law, the Institute and the applicant shall conclude a contract concerning the receipt of accreditation.

The contract under paragraph 2 of this Article shall lay down the manner of performing the accreditation, as well as the Institute's and applicant's rights and obligations.

## **Article 17**

For each accreditation separately, the Director shall establish an assessment team consisting of members of the Institute and external competitive experts.

The members of assessment team, the members of the governing body and the employees of the Institute shall be obliged to keep in confidence the data concerning operation of the customer collected during the accreditation procedure.

At the end of the accreditation procedure, if it is found that the applicant fulfills the requirements in compliance with Article 15 of this Law, the Director of the Institute shall grant an accreditation certificate with which it shall provide the status of accredited body.

If the applicant does not fulfill the requirements for accreditation, the Director shall make decision for rejection of the request for accreditation.

The accreditation certificate pursuant to paragraph 3 of this Article shall be granted for a limited period determined by the contract under paragraph 2 of Article 16 of this law.



### **Article 18**

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

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

### **Article 19**

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

If the surveillance determines that the accredited body fails to meet the prescribed requirements for the related activities during the period specified by the accreditation certificate, the Director shall make decision for prohibition of activities.

The term of removal the determined nonconformance shall be specified by the Decision under paragraph 2 of this Article.

If the nonconformance is not removed for the limited term specified under paragraph 2 of this article, the Director shall make decision for prohibition of activities specified within the accreditation certificate.

The requester can submit a complaint to the Institute concerning the decision under paragraphs 3 and 4 under this Article.

## **IV Transitional and final provisions**

### **Article 20**

The Government of the Republic of Macedonia shall adopt the Institute's Foundation Document within six months at least after the effective date of this Law.

## **Article 21**

The Founder shall provide the premises for the work and transfer into its unredeemable use the tangible assets, equipment and archive of the Bureau of Standardization and Metrology intended for the undisturbed performance of the accreditation activities.

## **Article 22**

The employees of the Bureau of Standardization and Metrology, who are performing the accreditation tasks, shall continue to perform these tasks, in accordance with the Act for organization the work and the Act for systematization of the operations and assignments in the Institute.

## **Article 23**

The accreditation procedures initiated before the effective date of this Law shall be completed in accordance with the regulations in force to that date.

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

## **Article 24**

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