

LAW of UKRAINE

No. 2407-III

On Accreditation of Conformity Assessment Bodies

This law sets up legal, organizational and economic framework for accreditation of conformity assessment bodies in Ukraine.

Chapter 1. General provisions

Article 1. Main terms and their definitions

In this law terms are used in the following meaning:

accreditation - a procedure in the course of which a national accreditation body conducts documentary certification of the competence of a legal entity or a conformity assessment body to carry out specific activities (testing, calibration, certification, inspection);

inspection body – a body that carries out conformity assessment by means of monitoring and conclusions, accompanied by relevant measurements, testing and calibration;

conformity assessment - an activity, connected with identification of the fact that products, quality systems, quality management systems, environment management systems, personnel comply with requirements established by legislation;

quality system – an aggregate of interconnected and interacting elements of the organizational structure, established mechanisms of responsibility, authorities and procedures of the organization, as well as processes and resources securing general management of quality and its conformity to established requirements;

quality management system – an aggregate of bodies and objects of management, interacting with the help of material and technical and informational means while managing product quality;

environment management system – an aggregate of the organizational structure, activity and relevant resources and methods of development, implementation, analysis and actualization of the environmental policy;

conformity assessment body - testing or calibration laboratory, certification body, inspection body that conducts its activity in the sphere of conformity assessment of products, processes, services and personnel in compliance with requirements established by legislation.

normative document – a document that establishes rules, general principles or characteristics of various types of activity or their results.

Article 2. The scope of this Law

This Law regulates legal relationships, connected with accreditation of conformity assessment bodies, and extends to bodies of executive power, local self-government bodies, national accreditation body, enterprises, institutions and organizations that operate within the territory of Ukraine, regardless of the their form of ownership and type of activity (hereinafter – enterprises, institutions, organizations).

Article 3. Legislation of Ukraine in the sphere of accreditation

Legislation of Ukraine in the sphere of accreditation consists of this law and other normative and legislative acts that regulate relationships in this sphere.

Article 4. The goal of accreditation

The goal of accreditation is to:

ensure the uniform technical policy in the sphere of accreditation;

ensure consumers' confidence in conformity assessment activities;

lay down the basis for mutual recognition of the results of the accredited bodies activities on the international level;

eliminate technical barriers to trade.

Article 5. The main principles of accreditation activity

Accreditation activity is based on the following main principles:

equal rights and lawful interests of all interested parties;

accessibility and impartiality of accreditation activities;

transparency in accreditation;

professional competence of the accreditation personnel;

voluntary character of accreditation;

participation of bodies of executive power and public organizations on a parity basis;

application of accreditation requirements, harmonized with international and European standards;

observance of public interests;

confidentiality of information, obtained during the process of accreditation.

Chapter 2. Organization of accreditation

Article 6. National accreditation body

Accreditation is carried out by the national body of accreditation.

The national accreditation body is a state non-profit organization, established by the central body of executive power for economic issues.

Provision on the national accreditation body is approved by the central body of executive power for economic issues.

The central body of executive power for economic issues does not have the right to interfere with the accreditation activity of the national accreditation body.

The national accreditation body is managed by the head, that is appointed and dismissed by the central body of executive for economic issues.

The national accreditation body consists of:

Accreditation Council;

technical committees for accreditation;

commission for appeals.

Following are the principal functions of the national accreditation body:

accreditation of conformity assessment bodies with subsequent inspection of their compliance with accreditation requirements, making decision on resumption, suspension or invalidation of accreditation;

development of rules of procedures, and approval of programs of accreditation of conformity assessment bodies as well as rules of inspection of their compliance with accreditation requirements;

organization of training of accreditation personnel and its authorization to conduct accreditation activity according to requirements established by legislation;

keeping the registers of accredited conformity assessment bodies as well as of accreditation personnel;

representation of Ukraine in international, European and regional organizations for accreditation;

signing of international agreements on cooperation and mutual recognition of accreditation of conformity assessment bodies according to the procedure established by legislation;

participation in the work on harmonization of legislative acts and normative documents with the relevant international and European rules and standards that set up requirements for the national accreditation body and accredited bodies;

keeping the archive of legislative acts and normative documents, related to accreditation;

providing information on accreditation issues.

Article 7. Accreditation Council

The Council is an advisory and supervision body of the national accreditation body. The Accreditation Council is formed on a parity basis from:

representatives of central bodies of executive power;

representatives of accredited conformity assessment bodies;

representatives of enterprises, institutions and organizations, the National Academy of Sciences of Ukraine, other scientific institutions and public organizations.

The principal functions of the Accreditation Council are:

development of policy recommendations in the sphere of accreditation and supervision over the policy implementation;

supervision over the conformity of accreditation activity to the principles, norms and requirement, laid down in this Law and other legislative acts;

provision of recommendations on approval of the rules of procedure and management of accreditation activity, inspection and consideration of appeals, including fees for services in the sphere of accreditation;

approval of qualification requirements, procedure and rules for attestation of accreditation personnel, of members of the commission for appeals;

appointment and dismissal of members of the commission for appeals;

approval of the provision for the commission for appeals and amendments to it;

development of propositions regarding control over accreditation activity and over the organizational and financial aspect of the national accreditation body activity;

approval of recommendations on signing international agreements on cooperation and mutual recognition of accreditation of conformity assessment bodies;

consideration of the annual report on the national accreditation body activity.

The Provision on the Accreditation Council and its members is approved by the central body of executive power for economic issues.

Article 8. Technical committees for accreditation

Technical committees for accreditation are set up by the national accreditation body.

The principal functions of technical committees for accreditation are:

development of methodological recommendations on accreditation issues;

elaboration of special requirements and additional criteria for accreditation in relevant sectors, development and submission of proposals to the national accreditation body.

The provision on technical committees is adopted by the national accreditation body.

Article 9. Commission for appeals

A conformity assessment body can appeal on the actions and decisions of the national accreditation body related to denial to accreditation by means of submission of an appeal to the commission for appeals, or in compliance with the court procedure.

The provision of the commission for appeals is approved by the head of the national accreditation body.

Article 10. Conformity assessment bodies that can be accredited by the national accreditation body

In accordance with this law, conformity assessment bodies of any type of ownership can be accredited - in particular:

testing or calibration laboratories;

bodies dealing with certification of products, processes and services;

bodies dealing with certification of quality systems, quality management systems, and environment management systems;

bodies dealing with certification of personnel;

inspection bodies.

Article 11. Accreditation procedure

Accreditation of conformity assessment bodies is carried out by the national accreditation body in accordance with the procedure, laid down in this Law and other legislative acts, adopted according to this Law.

The accreditation procedure shall include:

submission of application by the conformity assessment body (applicant) for accreditation or expansion of the sphere of its activity;

provision by the applicant of information and documentation, required for accreditation;

designation of an auditor accreditation group;

elaboration of a work program on accreditation and informing the applicant about it;

performance of the analysis of the submitted information and documentation;

inspection of the applicant at its location;

analysis of the collected materials, and drawing up the inspection report accompanied by recommendations on accreditation or denial to do so.

The decisions on the accreditation of conformity assessment bodies are made by the head of the national accreditation body. In case of making a decision in favor of accreditation of the conformity assessment body, it shall be given the certificate on accreditation of the established form that has a validity term of up to three years, and shall be given the right to use the national accreditation sign. Providing accreditation is denied, a letter of accreditation denial shall be sent (issued) to the applicant in a written form, wherein the grounds for such denial shall be stated.

The national accreditation body shall periodically perform the inspection of accredited conformity assessment bodies. In case there are violations of legislation in the sphere of accreditation, it shall make a decision on termination of validity or recognition as invalid of the certificate of accreditation.

The national accreditation sign – a sign that certifies that the organization that uses this sign is accredited by the national accreditation body.

Description and rules of the use of the national accreditation sign are determined by the central body of executive power for economic issues.

Article 12. Obligations of accredited conformity assessment bodies

Accredited conformity assessment bodies shall:

comply with the requirements of legislative acts, in accordance to which they have been accredited;

make references to accreditation only for the types of activity they have been accredited for;

pay fees for all the works, related to their accreditation;

terminate references to accreditation in their documentation and advertisement in the case of termination or invalidation of the certificate of accreditation.

Article 13. Liability for violation of the legislation on accreditation

Persons guilty of violation of Ukrainian legislation on accreditation are liable in accordance with legislation.

Chapter 3. Financial activity in the sphere of accreditation

Article 14. Sources and directions of financing

Sources of financing of accreditation works are:

funds, obtained as payment of fees for accreditation works;

funds of the state budget of Ukraine;

other funds envisaged by legislation.

The following is financed through allocated budget funds:

scientific research;

development of draft legislative acts and normative documents on accreditation issues;

participation in the activities of international and other regional organizations;

Article 15. Payment for accreditation works

The amount of fees and the procedure of payment for accreditation works is established in accordance with the rules of calculation of costs of accreditation works, approved by the central body of executive power for economic issues.

The national accreditation body shall inform the public about the amount of fees for services in the sphere of accreditation.

Chapter 4. International cooperation

Article 16. International agreements

If international agreements of Ukraine, ratified by the Verkhovna Rada contain other provisions than those contained in this law, the provisions of the international agreements shall be applied.

Chapter 5. Final provisions

1. This law becomes effective from the date of its publication.

2. The Cabinet of Ministers of Ukraine within a three-month period after this law has become effective shall:

develop and submit to the parliament of Ukraine propositions on bringing Ukrainian laws into line with this law;

adopt legislative acts, arising from this Law;

ensure the bringing its legislative acts, legislative acts of ministries and other central bodies of executive power into line with this Law;

3. Before the national accreditation body is set up, its functions shall be exercised by the specially authorized central body of executive power for standardization, metrology and certification.

4. Certificates of accreditation of conformity assessment bodies, issued within the state system of certification of products and services remain valid up to the expiry of their terms of validity. Supervision over activities of conformity assessment bodies shall be performed by the national accreditation body.

President of Ukraine

L. KUCHMA

Kyiv

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