WITH A LAW DECREE OF P AND On accreditation of conformity assessment bodies

(Bulletin of the Verkhovna Rada of Ukraine (BVR), 2001, N 32, art. 170)

{Amended by Laws

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N 882-VI ( 882-17 ) of 15.01.2009, BD, 2009, N 24, st.297 N 2735-VI ( 2735-17 ) of 02.12.2010, BD, 2011, N 21 st.144 N 4224-VI ( \frac{4224-17}{5463-17} ) of 22.12.2011, BD, 2012, N 36, st.420 N 5463-VI ( \frac{5463-17}{5463-17} ) of 16.10.2012}
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{The text of the Act the words "national accreditation body" and "central body of executive power on the economy" in all cases shall be replaced by the words "national accreditation body of Ukraine "and" central body of executive power on economic policy "in an appropriate case under Law N 4224-VI (4224-17) of 22.12.2011}

{The text of the Act the words "central body of executive power on economic policy "in all cases shall be replaced by "central executive agency that provides public policy in economic development "in appropriate cases pursuant to the Law N 5463-VI (5463-17) on 16.10.2012}

This Law determines legal, organizational and economic principles of accreditation of conformity assessment bodies in Ukraine.

Section I

Article 1. Basic Terms and Definitions

The terms shall have the following meanings:

accreditation of conformity assessment bodies (hereinafter - accreditation) - Ukraine's national agency certification of accreditation that conformity assessment body complies with national standards harmonized with relevant international and European standards, and, if necessary, any additional requirements for accreditation in the relevant areas for conducting certain activities of conformity assessment;

mutual evaluation - the process of evaluating national authority Ukraine accreditation by national accreditation bodies of other states shall be in accordance with the requirements adopted by the international, European and other regional organizations for accreditation, which is a member of the Ukraine national body of accreditation;

Consultancy – advisory services and other support to the development and implementation of management systems and procedures of conformity assessment bodies, as well as compliance with other requirements necessary for their accreditation;

national accreditation mark - a mark that certifies that the organization which uses this sign, accredited by the National Accreditation Authority of Ukraine;

inspection authority - conformity assessment body that performs conformity assessment procedures through observation and findings, which are accompanied by appropriate measurements, testing or calibration;

conformity assessment body - an enterprise, institution, organization, or of units that carry out activities to assess compliance, including calibration, testing, certification and inspection;

Assessment - the process of evaluating competency assessment body according to the specific field of accreditation, carried out Ukraine's national agency for accreditation on the basis of certain standards and / or other regulations;

Conformity assessment - a process that demonstrates that the established requirements for product, process, service, system, person or body have been fulfilled;

Staff Accreditation - Assessor and experts accreditation involved with Ukraine's national agency for the accreditation of accreditation. {Article 1, as amended by the Law N 882-VI (882-17) of 15.01.2009, as amended by Law N 4224-VI (4224-17) of 22.12.2011}

Article 2. Scope of the Law

This law regulates relations with accreditation Ukraine's national agency for accreditation bodies to assess conformity, including foreign agencies to assess compliance, and apply to executive agencies, a national body of accreditation and Ukraine bodies to assess conformity regardless of ownership. {Article 2 of the Law N 4224-VI (4224-17) of 22.12.2011}

Article 3. Legislation of Ukraine in the field of accreditation

Legislation of Ukraine in the field of accreditation consists of this Law and other legal acts regulating relations in the field.

Article 4. Objective Accreditation

The purpose of accreditation is: software unified technical policy in the assessment of conformity; ensure consumer confidence in the activities of assessment procedures; creating conditions for mutual recognition of the accredited internationally; elimination of technical barriers to trade.

Article 5. Basic principles of accreditation

Activities Accreditation is based on the following basic principles: ensure equality of rights and legitimate interests of all stakeholders; accessibility and impartiality of the work on accreditation; transparency of accreditation; professional competence of contractors; voluntary accreditation; ensuring the participation of authorities and civil society organizations on an equal basis; use harmonized with international and European standards concerning accreditation; compliance with the public interest; confidentiality of information obtained in the process of accreditation. Accreditation is carried out in accordance with the requirements established by law in the accreditation of national standards for accreditation, harmonized with relevant international and European standards and other documents for accreditation adopted by the national authorities of Ukraine with accreditation, European and international organizations for accreditation. List the names and designations of such acts and documents, texts of legal acts on Accreditation and other text documents on Accreditation adopted by Ukraine's national agency for accreditation, published on the website of Ukraine's national agency for accreditation online. {Article 5 supplemented with part two in accordance with the Law N 4224-VI (4224-17) of 22.12.2011}

Section II

Organization of accreditation

Article 6. Ukraine National Accreditation Authority

Accreditation is carried out by national authorities of Ukraine with accreditation. National Accreditation Authority Ukraine is a state organization that formed the central executive body to public policy in the field of economic development, and conducts non-profit activities.{Part two of Article 6 of the Law N 4224-VI (4224-17) of 22.12.2011}

The provisions of the national accreditation body of Ukraine (v0646731-12) is approved by the central executive body to public policy in the field of economic development.

The central executive body, to form public policy in economic development, has no right to interfere in the activities of the national accreditation body of Ukraine with accreditation. {Part five of Article 6 is eliminated by Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

The National Accreditation Authority Ukraine include: Accreditation Council; Technical Accreditation Committee; Commission appeals.

The main functions of the national authority of Ukraine accreditation are:

accreditation of conformity assessment bodies, including decisions on accreditation, denial of accreditation, expansion and limiting the scope of accreditation, temporary suspension and cancellation and renewal of certificate of accreditation;

monitoring the compliance of accredited him of conformity assessment accreditation requirements (hereinafter - monitoring) through the surveillance, conducting repeated and early estimates;

approval:

procedure for accreditation of programs of accreditation; Arrangements for monitoring grievance procedure relating to the activities of the accredited conformity assessment bodies;

qualification requirements, procedures and rules for personnel certification accreditation;

composition Attestation Commission accreditation personnel;

organization of selection, training, training and certification of accreditation personnel, attracting him to perform work on accreditation;

keeping a register of accredited conformity assessment bodies and accreditation personnel registry;

part in the work on harmonization of regulations, national standards and other documents on the accreditation of European and international rules and standards that define requirements for the Ukraine national authority for accreditation and accredited conformity assessment bodies;

organization of scientific research in the field of accreditation; organization providing information on accreditation. {Part Seven of Article 6 of the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

In cases prescribed by law, the national authority of Ukraine performs the functions of accreditation on accreditation others than conformity assessment bodies or certification of competence of persons with respect to its business, other than conformity assessment. {Article 6 paragraph eight supplemented by the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

National Accreditation Authority Ukraine publish on its website on the Internet information about the activities of conformity assessment in respect of which it has accredited, and of any related changes with reference to the relevant regulations and standards. {Article 6 part nine supplemented by the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

National Accreditation Authority Ukraine provides the central executive authority to form public policy on economic development, details of the proceedings it of accreditation in the amount and manner determined by the provisions of the national accreditation body of Ukraine. $\{Article\ 6\ added\ by\ part\ according\ to\ the\ Law\ N\ 4224-VI\ (\ 4224-17\)\ of\ 22.12.2011\}$

Article 6-1. Requirements for Ukraine's national agency for accreditation Ukraine national body for accreditation should be independent of the conformity assessment bodies, accreditation which he has, and from any commercial pressures and prevent conflicts of interest with conformity assessment bodies.

National Accreditation Authority Ukraine shall:

ensure objectivity and impartiality of its activities;

ensure that decisions on the accreditation of conformity assessment by persons other than those assessed such bodies;

maintain the confidentiality of the information received;

determine the activities of conformity assessment in respect of which it has accredited, with reference to the relevant regulations and standards;

carry out management of Accreditation and internal control in accordance with established procedures it;

have an adequate number of staff, including staff of accreditation for the proper performance of the tasks of the national authority Ukraine accreditation and to specify the duties and scope of responsibilities of this staff;

conducted in accordance with the procedure set forth by monitoring the level of competency accreditation and fulfillment of its duties;

verify compliance assessment by accredited bodies to prevent excessive stress on customers conformity assessment taking into account the number of employees and customers of such work areas where they carry out activities, structure, and characteristics of their production processes;

publish annual financial statements. {Act amended Article 6-1 according to the Law N 4224-VI (4224-17) of 22.12.2011}

Article 6-2. Limitation of the national authority for accreditation Ukraine

Ukraine's national agency for accreditation are prohibited:

carry out or suggest activities (including services), which carry (have) conformity assessment bodies;

exercise counseling;

be a shareholder or member (founder) of the assessment of conformity or otherwise participate in their management or to obtain benefits from their activities. {Act amended Article 6-2 according to the Law N 4224-VI (4224-17) of 22.12.2011}

Article 6-3. appointment and dismissal of the head of Ukraine's national agency for accreditation

National Accreditation Authority Ukraine headed by director, who is appointed and dismissed by the central executive authority to form public policy on economic development for five years.

The head of Ukraine's national agency for accreditation may be a citizen of Ukraine, residing in Ukraine, has a higher education, general experience in leadership positions not

less than five years experience in the field of accreditation of conformity assessment or the assessment of conformity is not less than two years.

The head of Ukraine's national agency for accreditation can not be the person who is the head of conformity assessment body or a part of the superior, executive, supervisory body or supervisory board conformity assessment body or a direct or indirect owner of shares (stock) of the body assessment of conformity or has been convicted of the crime.

The central executive body, to form public policy in economic development, taking into account suggestions of the Accreditation Council on candidates for the post of head of Ukraine's national agency for accreditation.

Head of the National Authority for Accreditation Ukraine dismissed if:

expiration of the term of office;

submission of dismissal at will;

entry into force of conviction;

termination of citizenship or departure from Ukraine for permanent residence;

detection or occurrence of circumstances under paragraphs two and three of this article xclude the possibility of a person to be the head of Ukraine's national agency for accreditation;

single gross violation of legislation in the field of accreditation;

non-performance of duties, including the state of health for more than four consecutive months; entry into force of a court decision recognizing a person incompetent.

The powers of the head of the national authority of Ukraine as Accreditation prematurely terminated in the event of death or a court decision declaring a person dead. {Act amended Article 6-3 according to the Law N 4224-VI (4224-17) of 22.12.2011}

Article 7. Accreditation Council

The Council is an advisory and supervisory body of the national authority for accreditation Ukraine

Accreditation Council formed on a parity basis with:

representatives of central executive bodies;

of accredited conformity assessment bodies;

representatives of research institutions, associations (unions, associations) entities and NGOs. {Paragraph four of Article 7 of the Law N 4224-VI (4224-17) of 22.12.2011}

The main functions of the Accreditation Council are:

develop recommendations for policy-making in the accreditation and supervision of its implementation;

oversight of accreditation in accordance with the principles, standards and requirements established by this Law and other normative legal acts, standards and other documents of accreditation for $\{\text{third paragraph of Article 7 as amended by the Law N 4224-VI (} \underline{4224-17}) on 22.12.2011\}$

provide advice on the procedure of accreditation and monitoring, to hear and determine the appeal fees for accreditation and monitoring; {Paragraph four of Article 7 of the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

approval of the qualification requirements, procedures and rules of certification accreditation personnel, warehouse personnel Attestation Commission of Accreditation $\{Paragraph five of Article 7 as amended by adding pursuant to Law N 4224-VI (4224-17) of 22.12.2011\}$

approval and dismissal of members of the appeals; approval of Regulations of the appeals and amendments thereto; preparation of proposals for supervision of the implementation of accreditation, organizational and financial activities of the national accreditation body of Ukraine {Paragraph eight of the second paragraph of Article 7, as amended by the Law N 4224-VI (4224-17) of 22.12.2011}

adoption of recommendations on contracts for cooperation and mutual recognition of accreditation of conformity assessment procedures; {Paragraph nine of Article 7 as amended by the Law N 4224-VI (4224-17) of 22.12.2011}

consideration of the annual report on the activities of the national authority of Ukraine accreditation and to express an opinion on the report. {Paragraph ten of Article 7 was amended according to the Law N 4224-VI (4224-17) of 22.12.2011}

Regulations on the Accreditation Council and its membership approves the central executive body, to form public policy in economic development.

Article 8. Technical Accreditation Committee

Technical committees established by national accreditation body for accreditation Ukraine. The main functions of the technical committees of accreditation are:

development of guidelines on accreditation; identify additional requirements for accreditation in relevant areas, preparation and submission of bids national authority for accreditation Ukraine. $\{Third\ paragraph\ of\ Article\ 8$ as amended by the Law N 4224-VI (4224-17) of 22.12.2011 $\}$

Regulation on technical committees approved national body for accreditation Ukraine.

Article 9. Commission appeals

Conformity assessment body may appeal against decisions, actions or inaction of the national authority for accreditation Ukraine, linked with the relevant accreditation body to assess compliance by filing an appeal to the Commission or the appeals court. {Part one of Article 9, as amended pursuant to the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

Regulations of appeals approves the national accreditation body of Ukraine. $\{Part\ two\ of\ Article\ 9$, as amended pursuant to the Law N 4224-VI (4224-17) of $22.12.2011\}$

Article 10. Persons who may be accredited or expertise which can be witnessed by Ukraine's national agency for accreditation{Title of article 10 of the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

National Accreditation Authority Ukraine may accredit conformity assessment bodies, namely {Paragraph one of Article 10 of Law N 4224-VI ($\frac{4224-17}{p}$) of 22.12.2011} testing and calibration laboratories; certification bodies of products, processes and services;

certification bodies of quality management system quality, environmental management systems {Paragraph four of Article 10 as amended by Law N 882-VI (882-17) of 15.01.2009} personnel certification bodies; inspection bodies {paragraph six of Article 10 in the wording of the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011} other conformity assessment bodies. {Article 10 amended by adding paragraph seven accordance with the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

In cases prescribed by law, the national body for accreditation Ukraine may accredit other persons than the bodies of conformity assessment, and certify the competence of persons with respect to its business other than the conformity assessment. {Article 10 the second paragraph is supplemented by the Law N 4224-VI (4224-17) of 22.12.2011}

Ukraine National Authority for Accreditation accredits or certifies the competence of persons identified in parts one and two of this article, regardless of their form of ownership and location both in Ukraine and abroad. {Article 10 the third paragraph is supplemented by the Law N 4224-VI (4224-17) of 22.12.2011}

Article 11. Procedure for accreditation {Part one of Article 11 has been deleted according to Law N 4224-VI (4224-17) of 22.12.2011}

The main stages of accreditation are: {The first paragraph of Article 11 of the Law N 4224-VI ($\frac{4224-17}{4224-17}$) of 22.12.2011} filing conformity assessment body (the applicant) for accreditation or expand the scope of its accreditation {Paragraph two of Article 11 changed and amended according to Law N 4224-VI (4224-17) of 22.12.2011} applicant to provide the information and documentation required for accreditation; appointment of assessors of the group; a program of accreditation and notification of the applicant; analysis provided information and documentation; assess the applicant's place of {seventh paragraph of the Article 11 as amended by Law N 4224-VI ($\frac{4224-17}{4224-17}$) of 22.12.2011} analysis of the collected material and the act of evaluation recommendations for accreditation of the applicant (expanding the scope of its accreditation) {Paragraph eight of the second paragraph of Article 11 as amended by Law N 4224-VI ($\frac{4224-17}{4224-17}$) of 22.12.2011} decision on the accreditation of the applicant (expanding the scope of its accreditation). {Part two of Article 11 added by paragraph nine pursuant to the Law N 4224-VI ($\frac{4224-17}{4224-17}$) of 22.12.2011}

Ukraine national body for accreditation under the application of conformity assessment body assesses the competence of that body for conducting certain activities in the application of

evaluation of conformity. {Part three of Article 11 of the Law N 4224-VI ($\underline{4224-17}$) of 22.12.2011}

Where a national accreditation body of Ukraine stipulates that the appropriate conformity assessment body is competent for the proceedings specified in the application of conformity assessment activities, the national accreditation body of Ukraine adopts a decision on its accreditation or expand the scope of its accreditation.

In case the decision on accreditation of conformity assessment it appears on the certificate of accreditation and is entitled to use the national mark of accreditation. The validity of the certificate of accreditation is five years. Description and rules ($\tt z0923-02$) The application of national accreditation mark set by the central executive body which provides public policy in the field of economic development. {Part four of Article 11 as amended pursuant to the Law N 2735-VI ($\tt \underline{2735-17}$) of 02.12.2010, as amended by Law N 4224-VI ($\tt \underline{4224-17}$) of 22.12.2011}

If the decision to deny accreditation or refusal to expand the scope of accreditation issued by the applicant (sent) written notice of such refusal, stating its reasons. {Part five of Article 11 of the Law N 4224-VI (4224-17) of 22.12.2011}

National Accreditation Authority Ukraine monitors through periodic supervision and / or reevaluations of accredited bodies, and on the basis of complaints filed in cases established by law, or claims related to the accredited bodies - implementation where appropriate their early estimates. $\{Part\ six\ of\ Article\ 11\ of\ the\ Law\ N\ 4224-VI\ (\ 4224-17\)\ of\ 22.12.2011\}$

Where a national accreditation body of Ukraine provides that accredited conformity assessment body has lost competence for carrying out certain activities of conformity assessment or has committed a gross breach of duty, the national body for accreditation Ukraine shall take all appropriate measures to restrict the scope of accreditation, temporary suspension or cancellation of the certificate of accreditation. $\{Part of Article 11 of the Law N 4224-VI (4224-17) of 22.12.2011\}$

The decision on accreditation, denial of accreditation, expansion and limiting the scope of accreditation, temporary suspension and renewal of certificate and cancellation of accreditation of the head of the national accreditation body of Ukraine, and if his absence - the person who replaces him. {Part of Article 11 of the Law N 4224-VI ($\frac{4224-17}{2}$) of 22.12.2011}

Deadlines determined by national accreditation body for accreditation Ukraine. {Part of Article 11 of the Law N 4224-VI (4224-17) of 22.12.2011}

Article 12. Obligations of accredited bodies to assess conformity

Accredited conformity assessment bodies must:

comply with the requirements of legal acts and standards for accreditation, against which they are accredited; {second paragraph of Article 12 changed and amended according to Law N 4224-VI ($\underline{4224-17}$) of 22.12.2011} refer to accredited only in respect of those activities on the implementation of which they are accredited; pay for all work related to their accreditation and monitoring {Paragraph four of Article 12 as amended by Law N 4224-VI ($\underline{4224-17}$) of 22.12.2011} stop reference for accreditation in their documentation and advertising in the event of temporary suspension or cancellation of certificate of accreditation. {Paragraph five of Article 12 as amended by Law N 4224-VI ($\underline{4224-17}$) of 22.12.2011}

Article 13. Responsibility for violation of the legislation of Ukraine in the field of accreditation

Persons found guilty of violating the laws of Ukraine in the field of accreditation shall be liable in accordance with the laws of Ukraine.

Section III

FINANCING ACTIVITIES IN THE ACCREDITATION

Article 14. Sources of funding for the areas of accreditation $\{\text{Title of article 14, as amended by the Law N 4224-VI } (<math>\frac{4224-17}{2}$) of 22.12.2011 $\}$

Funding of accreditation are: {Indent the first part of Article 14 changed and amended according to Law N 4224-VI (4224-17) of 22.12.2011} funds received as payment of accreditation and monitoring; {Paragraph two of Article 14 as amended by Law N 4224-VI (4224-17) of 22.12.2011} State Budget of Ukraine; other means provided by law.

Dedicated funds from the State Budget of Ukraine in the field of accreditation may be used only in the following areas: {Indent the first part of Article 14 of the Law N 4224-VI (4224-17) of 22.12.2011}

scientific research;

drafting of the National Standards and other documents on accreditation {paragraph three of Article 14 changed and amended according to Law N 4224-VI (4224-17) of 22.12.2011}

participation in international, European and other regional organizations, including membership dues to these organizations. {Paragraph four of Article 14 as amended by Law N 4224-VI (4224-17) of 22.12.2011}

Funding trends identified in part two of this article can also be due to other funds received as a result of accreditation.

{Article 14 the third paragraph is supplemented by the Law N 4224-VI (4224-17) of 22.12.2011}

The net income earned by the results of financial and economic activity, using national accreditation body of Ukraine to finance the development of its activities to meet the requirements of legislation. {Article 14 is supplemented by part four accordance with the Law N 4224-VI (4224-17) of 22.12.2011}

Article 15. Payments of accreditation and monitoring

The size and order of payment of accreditation and monitoring established by the National Accreditation Authority of Ukraine according to the method of determining the value of such work (${\tt z1589-12}$), approved by the central executive body to public policy in the field of economic development.

National Accreditation Authority Ukraine brings to the public information on fees for accreditation and monitoring. $\{Article\ 15\ of\ the\ Law\ N\ 4224-VI\ (4224-17)\ of\ 22.12.2011\}$

Section IV INTERNATIONAL COOPERATION

Article 16. Treaties

If an international treaty ratified by the Verkhovna Rada of Ukraine establishes norms other than those stipulated in this Law, the rules of the international treaty.

Article 17. International cooperation in the field of accreditation

To ensure international cooperation in national accreditation body for accreditation Ukraine:

represents and participates of Ukraine in international, European and other regional organizations for accreditation;

conclude agreements on cooperation and mutual recognition of accreditation of conformity assessment bodies;

may participate in the mutual evaluation conducted in the framework of international, European and other regional organizations for accreditation, which is a member of the Ukraine national body of accreditation;

cooperates with the national accreditation body other states;

may apply during the accreditation of national accreditation bodies of other states asking about the performance of certain of assessment bodies to assess conformity, surveillance or re-assessment of the extraordinary accredited. National Accreditation Authority Ukraine decides on the results of such work and shall issue a certificate of accreditation;

can fulfill requests from national authorities for accreditation of other states in the exercise of accreditation of individual work to assess the conformity assessment bodies, surveillance or re-assessment of the extraordinary accredited. {Act amended Article 17 in accordance with the Law N 4224-VI (4224-17) of 22.12.2011}

Section V MISCELLANEOUS

- 1. This Law shall enter into force on the date of publication.
- 2. Cabinet of Ministers of Ukraine, within three months from the date of enactment of this Act:

prepare and submit to the Verkhovna Rada of Ukraine draft laws on the laws of Ukraine in accordance with this Act;

adopt regulations arising from this Act;

ensure harmonization of their regulatory legal acts and other regulations and legal acts of ministries and other central executive bodies in accordance with the provisions of this Law.

- 3. By creating a national accreditation body of Ukraine performs its functions specially authorized central body of executive power on standardization, metrology and certification.
- 4. Certificate of conformity assessment issued by the state system of certification of products and services in force before the expiry of their validity. Thus the supervision of conformity assessment made by the authority of Ukraine with accreditation.

President of Ukraine Leonid Kuchma Kyiv, May 17, 2001 N 2407-III