DSTU 3413-96 (State Standard of Ukraine)

#### STATE STANDARD OF UKRAINE

Certification system for Ukrainian certification of products

#### PROCEDURE FOR CERTIFICATION OF PRODUCTS

Official Publication

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#### THE PROCEDURE FOR CERTIFICATION OF PRODUCTS

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#### 1 FIELD OF APPLICATION

This standard hereby establishes general requirements regarding the procedure for certification of products, processes and services (hereinafter referred to as products) in certification system for Ukrainian certification of products (hereinafter referred to as the System).

The procedure for certification of concrete products shall be established by products certification body with taking into account requirements of this standard and peculiarities of production, tests and supplies of concrete products.

The standard shall take into account provisions of directives ISO/IEC 7, 27, 28, 60.

#### **2 NORMATIVE REFERENCES**

References in this standard shall be made to the following normative documents:

DSTU 2296-93 National Sign of Compliance. Form, Sizes, Technical Requirements and Rules of Application

DSTU 2462-94 Certification. Main Meanings. Terms and Definitions

DSTU 3230-95 Regulating by Quality and Ensuring of Quality. Terms and Definitions

DSTU 3414-96 Certification System for Ukrainian Certification of Products. Production Attestation. The Procedure to Conduct

DSTU 3415-96 Certification System for Ukrainian Certification of Products. Register of the System

DSTU 3417-96 Certification System for Ukrainian Certification of Products. The Procedure to Recognize Results of Certification for Imported Products

DSTU 3419-96 Certification System for Ukrainian Certification of Products. Quality Systems Certification. The Procedure to Conduct

DSTU 3498-96 Certification System for Ukrainian Certification of Products. Documents Forms. Types and Description

DSTU ISO 9002-95 Quality Systems. The Sample (Model) to Provide Quality in the Course of Production, Assembling and Service

Directive ISO/IEC 7:1994 Directives on Development of Standards Applicable to Evaluation of Compliance

Directive ISO 27:1983 Directives on Conducting Correcting Measures by Certification Body in Case of Wrong Application of Compliance Mark to Goods

Directive ISO/IEC 28:1982 General Rules of Typical Certification for Products by a Third Party

Directive ISO/IEC 60:1994 ISO/IEC Code of Generally Accepted Practice to Evaluate Compliance

DSTU 3400-96 Metrology. State Tests of Measuring Technical Devices. Main Provisions, Organization, Procedure to Conduct and Consideration of Results.

#### **3 DEFINITIONS**

Meanings, terms and their definitions used in the standard comply with DSTU 2462 and DSTU 3230

#### **4 GENERAL PROVISIONS**

- 4.1 Certification of products in the System shall be conducted exclusively by certification bodies, and if there are no such bodies by organizations acting as bodies for certification of products on behalf of the State Standard of Ukraine.
- 4.2 In general the procedure for certification of products provides for the following:
  - submission and consideration of the application for certification of products;
  - analysis of submitted documentation;
- making a decision according to the application with mentioning scheme (model) of certification:
  - inspection of the production;
- attestation of manufacturing for products under certification or the quality system certification if this provided by the scheme of certification;
  - selection, identification of products samples and their tests;
- analysis of received results and making a decision on the possibility to issue the compliance certificate and issue of licences;
- issue of the compliance certificate, issue of licences and inclusion of certified products to the Register of the System;
  - recognition of the compliance certificate issued by a foreign body;
  - technical surveillance over certified products in the course of manufacturing;
  - information on results of activity for certification.
- 4.3 Schemes (models) used in the course of compulsory certification of products shall be established by the certification body.

Peculiarities of the production, tests, supplies and use of concrete products and possible costs of an applicant shall be taken into account. Schemes should be mentioned in the document which establishes the procedure for certification of concrete products.

Scheme of voluntary certification shall be established by an applicant in agreement with certification body.

While choosing schemes (models) for certification of products in the System, it is recommended for certification body to observe the following rules:

- 1) a certificate for a single item shall be issued on the basis of positive results of this item's tests conducted in the testing laboratory (center) that is accredited in the System;
- 2) a certificate for the group of items (goods) shall be issued on the basis of positive results of products (goods) samples tests in the testing laboratory (center) that is accredited in the System. Certification body shall establish the procedure and quantity of products (goods) samples to be selected.
- Note 1. Volume of the group (pieces, kilograms, meters, m<sup>2</sup>, etc.) shall be mentioned by an applicant in the application for certification. Identity of products in the group according to safety indexes should be guaranteed.

- Note 2. When the application is submitted for the group of products (goods) planned for manufacturing, certification body together with an applicant shall consider the issue on economic necessity of attestation for the production of these products;
- 3) the licence on the right to apply the compliance certificate with regard to products (goods) manufactured by the producer serially within the period established by the licence shall be issued by the certification body on the basis of positive results of products' samples certification tests in the laboratory accredited in the System (the certification body shall establish the procedure and quantity of products samples to be selected) and/or the following measures:
- inspection of the production, technical surveillance and control tests of products samples selected in the production or in trade in quantity, within terms and under the procedure established by the certification body in the program of technical surveillance over certified products;
- attestation of the production and further technical surveillance over manufacturing certified products conducted by the certification body or by other organizations on its behalf;
- certification of the quality system regarding manufacturing products that are subject to certification, and further technical surveillance over compliance of the quality system with established requirements. This technical surveillance shall be conducted by a competent body accredited in the System.

Note 1. The following shall be considered as a item of products:

- one artificial product;
- a group of products accompanied by one compliance certificate or one accompanying document where there is a reference to the compliance certificate;
- a group of products manufactured from the same group of initial raw materials, materials and the same melt of the ore, etc.
- Note 2. Measures of certified quality system in the course of the production can meet only requirements for ensuring compliance of products peculiarities with requirements of normative documents for compliance with which certification shall be conducted.
- Note 3. The certification body shall have the right to conduct tests of products that are subject to certification with the aim of technical surveillance only in the testing laboratory accredited in the System.

A body for certification of products can also apply other rules regarding selection of certification scheme (models) depending on specificity of products and peculiarities of their production.

Recommended schemes (models) of products certification are provided in Annex A.

- 4.4 Characteristics (peculiarities) of products shall be checked in the course of certification and tests methods shall be applied that allow the following:
- to conduct identification of products including check-up of belonging to classification group, technical documentation compliance, origin and belonging to appropriate group, etc.;
  - to confirm fully and surely compliance of products with mentioned requirements.

### 5 GENERAL REQUIREMENTS TO NORMATIVE DOCUMENTS FOR PRODUCTS THAT ARE SUBJECT TO CERTIFICATION

- 5.1 Compulsory certification of products shall be conducted on compliance with mandatory requirements of normative documents registered under the established order as well as requirements of international and national standards of other countries enforced in Ukraine.
- 5.2 Voluntary certification shall be conducted on compliance with requirements of normative documents agreed with a supplier and a consumer.
- 5.3 Technical requirements that are confirmed by certification should be mentioned clearly and synonymously in normative documents for products applied in the course of compulsory certification. Norms and allowed deviations should be set in such a way that it could provide the possibility of their measurement with set or known preciseness in the course of tests.

Introduction of a normative document or section "Field of Application" should include the instruction on the possibility to apply the document for certification (for example, "standard is suitable for compulsory certification").

- 5.4 Special section of normative documents for products applied in the course of compulsory certification or through references to the other normative document should establish methods, terms, volumes and the procedure of tests to confirm compliance with technical requirements. Requirements on preciseness indexes of measurements and tests that ensure comparison of results received by various testing laboratories should be established. If succession of tests influence on tests results, it should be mentioned.
- 5.5 Normative documents on methods of tests are compulsory if references are made to these normative documents in normative documents for products in the part of mandatory requirements' check-up.
- 5.6 Marking requirements established by normative documents should ensure synonymous identification of products as well as include directions on the method of drawing compliance mark.
- 5.7. Bodies for certification of products shall notify enterprises, to which they provided the right to apply the compliance certificate, on planned changes in standards covering certified product not later than six (6) months before the effective date of the changed standard.

### 6 GENERAL RULES AND THE PROCEDURE FOR ACTIVITY ON CERTIFICATION

- 6.1 Submission and consideration of the application
- 6.1.1 To conduct certification of the products an applicant shall submit the application to the accredited body for certification of products. Form of the application is enclosed in Annex B.

Information on bodies for certification of products accredited in the System is included in reference materials that are worked out according to data of the System's Register and are published by the Derzhstandard of Ukraine (*State Standard Committee of Ukraine*).

- 6.1.2 Applications for products certification of foreign origin under schemes with inspection and attestation of the production or the quality system certification shall be submitted to the Derzhstandard of Ukraine.
- 6.1.3 If there is no a body for certification of products accredited in the System at the date of the application's submission, the application shall be submitted to the Derzhstandard of Ukraine. The Derzhstandard of Ukraine shall consider the application and shall notify an applicant on its decision not later than one (1) month from the date of the application's submission. The decision shall be prepared pursuant to the Annex C. A copy of the decision shall be provided to the organization determined by the Derzhstandard of Ukraine for certification.
- 6.1.4 If there are several accredited bodies for certification of concrete products type, an applicant shall have the right to submit the application to any of them.
- 6.1.5 A body for certification of products shall consider the application and not later than one (1) month from the date of its submission shall notify an applicant on its decision which should include main conditions of certification. A form of the decision is enclosed in Annex D. Copies of the decision shall be distributed as follows:
  - to the body for certification of quality systems (if required);
  - to the testing laboratory which shall be involved in tests;
  - to the body which shall conduct technical surveillance (if required);
- to territorial center for standardization, metrology and certification in the place of an applicant's location.

#### 6.2 Analysis of documentation

- 6.2.1 Analysis of documentation shall be conducted with the aim of checking its compliance with established requirements.
- 6.2.2 The following shall be checked in the course of analysis of submitted documentation:
  - availability of normative documents for products (if required);
  - availability of the document that confirms products origin;
- availability of the producer's document on guarantees and compliance of products with effective requirements;
- availability of the document that confirms volumes of the group and date of manufacturing for products;
- availability (if required) of the conclusion of appropriate controlling organizations (the Ministry of Health Protection, the State Inspectorate for Veterinary Medicine or Plants Quarantine, the Derzhnaglyadokhoronpratsi [State Committee of Ukraine for Control over Labor Safety] and others);
  - authenticity, correctness of filling in and validity of documentation;
  - authenticity of requirements on marking and labeling products.
- 6.2.3 Negative results of documentation analysis shall be prepared in the form of conclusion which is submitted to an applicant to remove defects. Positive results shall be used for preparation and issue of compliance certificates.

#### 6.3 Inspection of the production

- 6.3.1 Inspection of the production shall be conducted with the aim of establishing compliance of actual status of the production with documentation requirements, confirming possibilities of an enterprise to manufacture products according to requirements of effective normative documents, giving recommendations on periodicity and forms to conduct technical surveillance over manufacturing certified products.
- 6.3.2 Expertise of normative, technical and technological documentation shall be conducted in the course of the production inspection that provides for as follows:
- check-up of products' peculiarities and characteristics compliance established by technical documentation with requirements of normative documents that cover products and technological processes of their manufacturing;
- evaluation of sufficiency of control operations and tests provided by technological documentation to ensure certainty in complete compliance of manufactured products with requirements of normative documentation that cover them (*products*);
- evaluation of the system of initial control of raw materials and the system of indexes' control of technological process;
- check-up of preciseness indexes' compliance of applied measuring devices and testing equipment with requirements of technical documentation on allowed deviations of indexes and characteristics:
- check-up of availability and effectiveness of metrology provision system of applied measuring devices and testing equipment.
- 6.3.3 According to the results of inspection a document of inspection shall be prepared which should include grounded conclusions and, if required, recommendation on removal of found defects. The document shall be signed by Members of the Commission and shall be approved by the Head of the body.

#### 6.4 Attestation of the production

- 6.4.1 Attestation of the production shall be conducted with the aim of an enterprise-producer's technical possibilities estimation to provide stable quality produce that comply with requirements of normative documents, and issuing recommendations on tests periodicity, samples (essays) quantity tested in the course of certification and methods and way of their selection.
- 6.4.2 A body for certification of products shall conduct attestation of the production upon an applicant's initiative or upon the decision of a body for certification of products. The procedure to conduct this activity is established in DSTU 3414.
- 6.4.3 Results of attestation shall be prepared in the form of the production certificate which is submitted to an applicant.

#### 6.5 Certification of the quality system

6.5.1 Certification of the quality system with regard to manufacturing products that are subject to certification shall be conducted with the aim of ensuring certainty of a body for certification of products in the fact that products manufactured by the enterprise

comply with compulsory requirements of normative documents; all technical, administrative and human factors that influence the quality of products are under control, products of bad quality are found in a timely manner and the enterprise takes measures on prevention of manufacturing such produce on a permanent basis.

- 6.5.2 Certification of the quality systems shall be conducted by bodies accredited in the System with the right to conduct such activity, and shall be conducted upon an applicant's initiative or upon the decision of a body for certification of products. The procedure to conduct this activity is established in DSTU 3419.
- 6.5.3 Results of the quality systems certification shall be prepared in the form of the certificate on the quality system which is submitted to an applicant and copies to a body for certification of products.

#### 6.6 Tests with the aim of certification

- 6.6.1 Tests of products with the aim of certification shall be conducted by the testing laboratory (center) accredited in the System with the right to conduct tests types provided by normative documents for products or with the right to conduct tests of these products.
- 6.6.2 An applicant shall submit samples (essays) of products for tests and technical documentation for them. A body for certification of products shall establish the list of technical documentation.
- 6.6.3 A body for certification of products shall establish a number of samples for tests and rules of their selection.
- 6.6.4 Tests of imported products shall be conducted by testing laboratories (centers) accredited in the System, including cases when there is the agreement on mutual recognition of tests results.
- 6.6.5 If results are positive, minutes of tests shall be submitted to a body for certification of products and a copy to an applicant.
- 6.6.6 If results are negative even for one of indexes, tests with the aim of certification shall be stopped, information on negative results shall be submitted to an applicant and to a body for certification of products which shall cancel the application.

Repeated tests can be conducted only after submission of a new application and submission to a body for certification of products of persuasive evidence of conducting correcting measures by the enterprises on removal of reasons that have caused non-compliance.

6.6.7 Samples of products that have passed tests with the aim of certification, including destructive, shall be the property of an applicant. The procedure of writing-off, utilization and return and storage of samples that are evidence should be regulated by a body's documentation.

#### 6.7 Issue of the compliance certificate

6.7.1 The compliance certificate shall be issued exclusively by a body for certification of products. The certificate shall be issued for a single item, for the group of products or for products manufactured by the enterprise serially within terms established by the license agreement, with the right to mark with the compliance mark of each item of products.

Note. Pursuant to DSTU 3400 the Derzhstandard of Ukraine shall issue the compliance certificate of measuring devices with approved type. On the basis of this certificate, territorial center for standardization, metrology and certification of the Derzhstandard of Ukraine can issue the compliance certificate of the System to the enterprise-producer without additional tests and procedures of consideration.

6.7.2 A body for certification of products shall prepare the compliance certificate, register it in the Register of the System according to DSTU 3415 and issue it to an applicant if there are minutes of tests with positive results, the certificate on the quality system or the certificate of the production depending on approved scheme (model) for certification.

Forms of compliance certificates are provided in DSTU 3496. Form of the licence agreement is provided in Annex E.

- 6.7.3 Selection of the compliance certificate form shall depend on the extent of confirmation of normative documents requirements, and in particular:
- if compliance of products with all compulsory requirements has been confirmed, form 1 shall be applied;
- if compliance of products with all requirements has been confirmed, form 2 shall be applied;
- if compliance of products with individual requirements has been confirmed, form 3 shall be applied and the certificate shall list confirmed requirements.
- 6.7.4 An additional compliance certificate in Russian with the same number and issue date can be given to an applicant upon its request.
- 6.7.5 The following can be applied to confirm the fact of products (services) certification:
  - the compliance certificate original;
  - mark of compliance pursuant to DSTU 2296 requirements;
- the compliance certificate copy certified by the body issued the certificate or by the territorial center for standardization, metrology and certification;
- information in documentation enclosed to products with mentioning the number of the certificate, the term of its validity and the body issued it (information can be provided as a supplier's declaration on compliance).
  - 6.7.6 An applicant shall mark products with the compliance mark.

An applicant shall have the right to mark products with the compliance mark on the basis of the license agreement (Annex E).

6.7.7 If tests of products for individual indexes have been conducted by several accredited in the System or recognized in the System laboratories (centers) of other systems, then the compliance certificate shall be issued if there are all required minutes with positive results of tests. In this case all minutes of tests with mentioning testing laboratories (centers)

conducted tests as well as recognized certificates (if there are any) shall be listed in the compliance certificate.

6.7.8 A body for certification of products shall establish validity term of the certificate for products manufactured by the enterprise serially within the term established by the licence agreement, with taking into account validity term of normative documents for products, the term for which the quality system has been certified or the production has been attested and guaranty term of products before the moment of their sale or term of products storage (but not more than for two (2) years) if the production has been attested and not more than for three (3) year if the quality system has been certified. Validity term of the compliance certificate should not exceed one (1) year while conducting certification of products manufactured serially under the scheme with inspection of the production.

The term established in the license shall not be extended. A body for certification of products shall establish the procedure to issue a new license instead of invalid in each concrete case according to requirements of the procedure for certification of concrete products.

- 6.7.9 In case of making changes to the design (composition) of products or the technology of their manufacturing that can influence on indexes confirmed in the course of certification, an applicant shall be liable to inform about this the body issued the license. Such information should be provided in advance. A body for certification of products shall make the decision on necessity to conduct new tests or to evaluate the status of products manufacturing.
- 6.7.10 If norms established by standards on index confirmed in the course of certification have been changed for more strict, then the decision to terminate validity of each issued license shall be made by a body for certification of products upon agreement with the Derzhstandard of Ukraine (*State Standard Committee of Ukraine*).
- 6.8 Recognition of the compliance certificate issued by bodies of other certification system
- 6.8.1 The decision on recognition of certificates issued by certification bodies of other countries that are not Members of Certification system for Ukrainian certification of products for goods imported into Ukraine shall be made by a body for certification of products applying DSTU 3417. Selected procedures of recognition should be grounded and confirmed documentary in case of registration of the recognition certificate.
- 6.9 Technical surveillance over stability of indexes for certified products in the course of their production
- 6.9.1 Technical surveillance (in the course of products manufacturing) over stability of indexes confirmed by the compliance certificate shall be conducted by the body issued the certificate. Upon proposal of a body for certification of products, surveillance can be conducted by bodies for certification of quality systems or territorial centers for standardization, metrology and certification.

Specialists of the Derzhnaglyadokhoronpratsi [State Committee of Ukraine for Control over Labor Safety] and the Derzhsannaglyad (State Sanitary Committee), etc. can be

invited to participate in technical surveillance to ensure certainty of information on special issues of control.

General procedure to conduct technical surveillance is established in Annex F and recommended form of report according to results of technical surveillance - in Annex G.

- 6.9.2 Volume, the procedure and periodicity of surveillance shall be established by a body for certification of products in the course of certification and shall be regulated by the program of technical surveillance developed by the body and approved by its Management.
- 6.9.3 According to results of surveillance a body for certification of products can terminate or eliminate validity of the licence in the following cases:
  - infringements of requirements to products in the course of compulsory certification;
- infringements of requirements to technology of the production, acceptance rules, methods of control and tests and products marking agreed with a body for certification of products in the course of products certification;
- changes of normative documents for products or for methods of their tests without prior agreement by a body for certification of products;
- changes of the design (composition) and the complete set or technology of products manufacturing without prior agreement by a body for certification of products.
- 6.9.4 The decision on termination of validity of the licence and/or the compliance certificate shall be made in case if through taking correcting measures approved by a body for certification of products the enterprise can remove found reasons of non-compliance and confirm compliance of products with normative documents without repeated tests by accredited testing laboratories. On the contrary, the licence or the certificate shall be eliminated.
- 6.9.5 A body for certification of products shall notify an applicant and the National body for certification of products information on termination or elimination of the compliance certificate validity. It should be done in written.

Validity of the compliance certificate shall stop from the moment of its withdrawal from the Register of the System according to DSTU 3415.

6.9.6 The following correcting measures shall be conducted in case of the certificate validity elimination:

A body for certification of products shall:

- inform bodies of the Derzhspozhyvzakhyst of Ukraine (*State Committee of Consumers' Interests Protection*), State Customs Committee of Ukraine and other concerned organizations on elimination or renewal of the compliance certificate validity;
  - establish the term of correcting measures fulfillment;
  - control correcting measures fulfillment by an applicant.

An applicant shall:

- establish volume of inconsistent products and a new marking for distinction of products manufactured before and after correcting measures;
- inform a consumer on the threat (or undesirability) of used products (exploitation) and the procedure to remove found non-compliance or products exchange;
- remove non-compliance in products that are under exploitation or ensure their return and completion, exchange products for consumer if removal of found non-compliance is impossible or purposeless;

- conduct measures to remove reasons of products non-compliance.
- 6.9.7 A body for certification of products shall inform bodies of the Derzhspozhyvzakhyst, State Customs Committee of Ukraine and other concerned organization in case of the compliance certificate elimination. An applicant shall be liable to return originals of certificates and all copies to a body that issued them. Returned originals and copies shall be destroyed pursuant to the document.
- 6.9.8 In case of finding out the compliance certificate issued incorrectly, the Derzhstandard of Ukraine shall cancel its registration pursuant to DSTU 3415 and notify this to an appropriate body for certification which conducts correcting measures according to paragraph 6.9.7.
  - 6.10 Information on the results of products certification
- 6.10.1 A body for certification of products shall register certificates issued by it and send their copies to the Derzhstandard of Ukraine.
- 6.10.2 The Derzhstandard of Ukraine on the basis of the System's Register shall publish directories which include information on certified products.

#### **7 CONFIDENTIALITY**

A body for certification of products and organizations that act on its behalf shall be liable for disclosure of commercial and professional secrets related to confidential information.

#### 8 APPEALS

8.1 If an applicant wishes to appeal measures on its application for certification of products, recognition of the certificate or the decision on its elimination, it should submit written application to a body for certification of products not later than one (1) month from the date of receiving notification on the decision made. Submission of the appeal shall not terminate validity of the decision made.

Appeal commission shall be established to consider each appeal.

- 8.2 Appeal commission of a body for certification of products shall consider the appeal not later than one (1) month from the date of its receiving.
  - 8.3 Appeal commission should have the following documents to consider the appeal:
  - an applicant's appeal;
- correspondence on the dispute between an applicant, the testing laboratory and a body for certification of products;
  - minutes of products tests;
  - samples or photos of products;
  - technical documentation for products (if required).

A body for certification of products shall submit documentation to members of appeal commission not later than two (2) weeks prior to the commission's meeting.

8.4 An applicant shall have the right to speak at the commission's meeting.

- 8.5 Appeal commission shall consider the dispute confidentially. While making the decision, only members of the commission and all of them should be present.
  - 8.6 Appeal commission, as a rule, shall make one of the following decisions:
  - to issue the certificate (licence);
  - to refuse issue of the certificate (licence);
  - to eliminate issued licence.

The commission's decision shall be notified in writing to an applicant and a body for certification of products.

- 8.7 Costs related to the appeal's consideration shall be recover by each party.
- 8.8 An applicant shall have the right to appeal to the Commission on appeals of the National body for certification if its does not agree with appeal commission's decision.

#### 9 FINANCING OF ACTIVITY FOR CERTIFICATION OF PRODUCTS

- 9.1 All activity for certification of products shall be paid by an applicant according to agreements for activity concluded with a body for certification of products, a body for certification of the quality systems and testing laboratories (centers), except activity mentioned in the paragraph 8.7.
- 9.2 Costs of an applicant to conduct activity for certification of products shall be considered as self-cost of products.
- 9.3 The procedure to determine cost of activity for certification is enclosed in Annex H.

## ANNEX A (recommended)

### SCHEMES (MODELS) FOR CERTIFICATION OF PRODUCTS IN CERTIFICATION SYSTEM FOR UKRAINIAN CERTIFICATION OF PRODUCTS

Table A. 1

Serial production for products that are subject to certification		Compulsory activity with	regard to products that are	subject to certification on		Documents issued by a body for certification
	inspection of their production	attestation of their production	the quality system certification of their production	their tests with the aim of certification	technical surveillance over their production	of products
A single item	Not conducted	Not conducted	Not conducted	Conducted for each item	Not conducted	The compliance certificate for each item
The group of products (items)	Not conducted	Conducted if decided by a body for certification of products an applicant	Not conducted	Conducted with samples selected under the procedure and in quantity established by a body for certification of products	Conducted only if there is the agreement between an applicant and a body for certification of products on attestation of the production under the procedure established by a body for certification of products	The compliance certificate for the group of products (items) with mentioning volume of certified group
Products, produced serially	Conducted	Not conducted	Not conducted	Conducted with samples selected under the procedure and in quantity established by a body for certification	Conducted under the procedure established by a body for certification of products	Certificate with term of its effectiveness established by license agreement (up to one year)

			of products		
Not conducted	Conducted	Not conducted	Conducted with samples selected under the procedure and in quantity established by a body for certification of products	procedure established by a body for	Certificate with term of its effectiveness established by license agreement with regard to the term of effectiveness of production attestate (up to two years)
Not conducted	Not conducted	Conducted by the body for quality system certification	Conducted with samples selected under the procedure and in quantity established by a body for certification of products	procedure established by a body for	Certificate with term of its effectiveness established by license agreement with regard to the term of quality system certificate's effectiveness

### Annex B (obligatory)

Application form for the certification of products Name of the certification body, address.\*

### Application

for the certification under UkrSEPRO system

1
name of the producer, supplier (hereinafter referred to as applicant), address, EDRPOU code
in the person of
in the person of (name, surname of the head of organization and his title)
declares, that
(name of products, OKP code)
produced in the form of product of one time production, produced or intended to be produced in the batch of $\underline{\hspace{1cm}}$ , produced in batches ** according to (items, tones, m <sup>2</sup> , m <sup>3</sup> , etc.)
(name and number of the producer's normative document)
meets requirements
2. Certification examination shall be conducted in
examination laboratory and its address. If there are no information in this paragraph, it shall be omitted)
<ul> <li>3. Applicant has the following obligations: <ul> <li>to fulfill all terms of the certification</li> <li>to provide constant parameters(characteristics) of the products, confirmed by the compliance certificate</li> <li>-pay all expenses for the certification</li> </ul> </li> </ul>
4.Additional information
Head of the enterprise :(name, signature) Chief accountant(name, signature) Seal

<sup>\*</sup> If there are no certification body for the products, application shall be submitted to the Derzchstandard of Ukraine.

<sup>\*\*</sup> Relevant information shall be filled in

# Annex C (obligatory)

Form of the decision on the application for the products certification (If there are no accredited certification body)

## STATE COMMITTEE ON STANDARTIZATION OF UKRAINE Decision

		#	of «	;	»	199	9		
	on the applica	tion(s) for	r the pro	ducts	certificati	on in the U	JkrSEP	RO System	n
havii	ng considered ap	plication(	s)			andard of U			
	(	name of the				ipplier of pro		ication in t	ha
(herei	nafter referred to as	applicant),				101 u1	e certiii	ication in t	iic
UkrS	SEPRO System_								
			(n	ame of	f products)				
				Dec	eided:				
1. To	allow	(name	e of the or	ganiza	tion authoriz	zed to fulfill			<del></del>
		work	cs - herein:	after a	uthorized or	ganization)			
to		Woll		lfill	amonzea or	gumzutony		cert	ification
whic	h is produced by	series (or	ne time,	etc.) _					
						(nan	ne of the p	producer and	l supplier)
2.	Selection	of	sample	S	and	identific	ation	assign	to
				_		(name	e of the ap	ppointed org	anization)
3.	Certification	shal	1 b	e	fulfilled	in	con	npliance	with
									(code and
			name of the	he nor	mative docu	ments)			
						,			
	ertification mode -examinati -attestation	on of the	production	on;		_	y):		
	-certification -examination -technical	on of prod				n purposes	s <b>;</b>		
5. ]	Examination of	f produc	ets for	certi	ification	purposes	shall	be fulfi	lled in

(name of the testing laboratory (center), accredited in the system and its address)

	at the technical compet tation certificate	ence or at the techn	ical competence and	independence of
6. As an ex	ception, grant the right	to sign products co	onformity certificate	
	1 /6 6		=	nuation of Annex C
	(name of the	ne head of the appointed	d organization)	
7.*	Technical	survey	over	certified
		name of j	products	
shall	be		assigned	to
Periodicity developed by	(name of the appointed or and method of the toy the	<u> </u>	•	· · · · · · · · · · · · · · · · · · ·
de veloped i		e of the authorized orga	anization	
8. Certifica	tion works are fulfilled	on the basis of the	economic contract.	
	e functional Division of dard of Ukraine	the		
			name, signature)	

\* Paragraph shall be included if necessary.

-

# Annex D (obligatory)

Form of the decision on the application for the products certification

Name and address of the products certification body

### Decision

on the Application for the Products Certification

Having	considered	application	of	the
	(N	Tame of the production enterp	rise, supplier of produ	cts)
	for the certification of	f		
(date)			lucts, OKP code)	
We would like 1. Certification	e to inform: n will be fulfilled to checl	k if products meet requir	ements	
	(code and name	e of the normative documents	)	
-stu -atto -cer -exa	on model shall include (creaty of the production; estation of the certified prediction of the certified emination of products for hnical survey.	oducts manufacturing; products' quality system	•	
3. Certification	on of the quality system w	ill be conducted		
			(name a	nd address
4. Examinatio	of the accre	edited body on quality system fication purposes will be		
5. Technical	(name and a survey over manufacturin	ddress of the accredited testing of the certified produc	-	
Periodicity of	(name of the the surveys and forms of	organization and its address) the technical survey will	be informed addit	tionally.
6. Works shal	l be conducted on the bas	is of the	contracts or other a	greements
Head of the ce	ertification body			
	Ž	(signature) (name)		
		Date		

# Annex E (obligatory) Sample of the License Agreement

#### **License Agreement**

					aa			_ 199
							#	
		(nar	ne of the pr	oducts certific	ation body )			
Registered b	y the address	s:						
hereinafter	referred	to	as «ce	ertification	body»	and	represented	by
	(Ti	tle and 1	name of the	head )				
grants to the								
	(na	me of th	ne enterprise	e, manufacturi	ng products)	)		
registered	t	у		the	follo	wing	ado	dress:
hereinafter	referred	to	o as	«licens	ee» a	nd	represented	by
			(title	, name of the	head)			
license for t	the right to	utilize	conform	ity certifica	ate registe	red in	the Register o	f the
certification	System Uk	rSEPR	O «	»	199	#	and to mark	with
conformity 1	nark every i	tem of	products	indicated i	n the certi	ificate	and produced by	y the
licensee with	nin the term	of this	license ag	reement on	the basis of	of the b	elow indicated:	-

#### 1. Licensee

- 1.1 Undertakes to fulfill all terms and conditions of the products certification in the UkrSEPRO System.
- 1.2 Undertakes to ensure correspondence of the manufactured and supplied products to all requirements of the normative documents indicated in the conformity certificate and also specimens tested for the purposes of certification.
- 1.3 Undertakes to provide free access to the representatives authorized by the products certification body to all production areas of the certified products without preliminary notification.
- 1.4 Undertakes to preliminary inform products certification body of all modernizations (modifications) of products, changes in its structure, production technology, testing and controlling methods. Fulfills envisaged modernization (modification) and other changes only with the consent of the body why has issued a certificate.
- 1.5 Undertakes to register all reclamations (claims) at the certified products and immediately inform about them products certification body.
- 1.6 Undertakes to pay according to the established procedures all expenses connected with the fulfillment of the products certification works according to the adopted model.

For the right to utilize conformity certificate and to mark products with conformity mark licensee undertakes to transfer to the settlement account of the certification body

\_\_\_\_\_

(amount of payment in per cents, periodicity of payments)

from the sales volume of the certified products (excluding VAT and excise duty).

- 1.7 Has the right to use information about certified products for advertisement purposes.
- 1.8 Has the right to appeal to the certification body with all discrepancies connected with products certification.

#### 2. Certification Body

- 2.1 Is obliged to fulfill technical survey for the production of the certified products itself or introducing authorized for this representatives of the bodies of quality certification, regional centers on standardization, metrology and certification of the Derzchstandard of Ukraine, other organization.
- 2.2 Is obliged to inform licensee, not later than six months, prior to by the recommended latter (or another similar way) licensee about intended changes in the current normative documents providing obligatory requirements.

#### 3 Other terms and conditions

3.1. This Agreement comes into force starting from \_\_\_\_\_

	(date)			
remains valid up to	until it is eliminated due to stipulated			
(date, but not longer than three years)				
reasons or terminated by one of the parties provide	led that another party is informed within			
determined terms.				
3.2 On occasion of termination of the license following terms depending on				
reasons shall be determined:				
Situation that requires notification on	Term of the preliminary notification on			
termination of the license	termination of the license			
Desire of the producer to stop validity of the	30 days			
license agreement				
Certification body has discovered danger of the	Not determined			
products for the consumers				
Provision of the correspondence of the products	Not determined			
to the new requirements of the normative				
documents				
Not fulfillment of the financial obligations under	30 days			
the contract with the contractor				

Information on elimination of the license shall be sent to another party by the recommended latter (or another way) indicating reasons of elimination and date of its termination.

3.3 If licensee informs certification body about his own unfitness to comply with new requirements within determined terms breaks terms or if results of the products' examination for compliance to the changed terms and conditions are negative, license is

considered to be terminated starting from the moment when new terms and conditions were implemented.

3.4 Legal responsibility for the quality of the certified products is determined by the current legislation of Ukraine.

On behalf of the products certification body	On behalf of the licensee				
(Title)	(Title)				
(Signature) (Name)	(Signature) (Name)				
Seal	Seal				

### Annex F (obligatory)

#### **Procedure**

of technical survey of the products certification

#### F.1. General Provisions

- F.1.1. Technical examination of the products certification is an integral part of the certification process provided by the system. Technical examination shall be carried out within the period of certificate's validity according to the license agreements by the technical examination program.
- F1.2. Technical survey is conducted with the following purposes:
- F1.2.1. To ensure correspondence of the certification products to the requirements of the normative documents.
- F1.2.2. To support confidence of all interested parties that certified products still correspond to the indicated in the certificate requirements and that correspondence mark is made correctly.
- F1.2.3. To predict conditions that may lead to the production of goods not corresponding to the requirements of the normative documents.
- F1.2.4. To determine reasons of the product's not correspondence discovered during the technical survey.
- F1.2.5. To assess fulfillment of the terms and conditions of the license agreement by the enterprise.
- F1.2.6. To assess fulfillment of the correction measures by the enterprise.
- F1.2.7. To clarify reasons of the reclamations to the certified products.
- F1.2.8. To register certified products.
- F1.3. Technical survey over certified products is organized, coordinated and conducted by the certification body for these products.
- F1.4. Certification body may authorize another body on certification of products or quality systems, regional body of the Derzchstandard(State Standard) which are able to fulfill technical survey taking into account following requirements to conduct technical survey.
- F1.5. If for the purposes of the products certification attestation of the production or certification of the quality system by a different body, then it would be expedient to entrust this body with technical survey (except controlling tests).
- F1.6. Volume, subject and periodicity of the technical survey procedures for the definite products is determined by the certification body under the program of technical survey which is developed by the products certification body taking into account below listed requirements and results of the works on certification of definite types of products.
- F1.7. Requirements to the elements of the quality and production system included into the program of technical survey over the certified products are determined by the certification body taking into account requirements DSTU ISO 9002.

- F1.8. Technical survey at the enterprises is performed by the auditors of the certification bodies. When necessary, non-staff auditors and component experts of the controlling organizations at the contractual basis can be attracted to the conduction of the technical survey.
- F1.9. Works subject to technical survey are to be paid by the customer. Cost and type of payment are determined by the technical survey contract.
- F1.10. Negative summary of the certification body according to the results of the technical survey cannot be a reason for changing cost of works or return of the earlier payment.
- F1.11. Technical survey does not free enterprise and its staff of responsibility for the manufacturing of the not proper products and cannot be reason for transferring this responsibility for the certification body and its employees.

#### F2. Organizational structure

- F2.1. Responsible person shall be appointed in the body which shall bear responsibility for the organization, coordination and conduction of the technical survey and the structural subdivision on technical survey shall also be established (if number of employees allows).
- F2.2. In general, organizational structure of the technical survey of the certification body consists of:
  - -head of the certification body;
  - -responsible official for the technical survey;
  - -structural subdivision on the technical survey or/and stuff and non-stuff auditors;
- -component organizations (for instance regional bodies of the Derzchstandard, quality systems certification bodies), with have contracts on cooperation on technical survey.

#### F3. Documents of the technical survey

- F3.1. General procedures of technical survey over certified products, contained in the accreditation area, shall be put down in the documentary form and be an integral part or Annex to the Resolution on the quality of the certification body. Separate documents on the procedures are also possible referenced in the Resolution on quality.
- F3.2. Technical survey procedures shall provide:
- F3.2.1. Development of the technical survey and control over its fulfillment.
- F3.2.2. Development of the programs of technical survey over the certified products.
- F3.2.3. Conclusion of the contracts on the fulfillment of the technical survey.
- F3.2.4. Preparation for the fulfillment and fulfillment and reporting about technical survey.
- F3.2.5. Requirement as to the stuff, fulfilling technical survey, its training and maintainance of the qualification. Implementation of the auditors catalog.
- F3.2.6. Requirements to the competence of the organizations authorized to fulfill works on technical survey. Standard form of the contract on cooperation in technical survey. Introduction of the catalog of such organizations.
- F3.2.7. List of the documents on technical survey. Place and terms of its custody.

- F3.2.8. Confidentiality during fulfillment of the works on technical survey.
- F3.2.9. Instructions to the employees carrying out technical survey.
- F3.2.10. Standard programs of the technical survey over the certified products.
- F3.2.11. Requirements of the body concerning the quality and production system, which is controlled during technical survey.
- F3.2.12. Procedure of the selection and identification of the specimens of products for tests, their delivery and storing.
- F3.2.13. Inspection control of the body over meeting requirements of the technical survey by the organization which is authorized to conduct technical survey.
- F3.2.14. Procedures of taking measures according to the results of the technical survey.

#### **F4.** Development of the technical survey

- F4.1. Plan of the technical survey is being developed and controlled by the person responsible for the technical survey. Plan is being developed for a period of one year. Amendments to the plan are made only by the responsible executive officer. Plan shall be confirmed by the head of the body.
- F4.2. Plan shall include name of the enterprise, name of the certified products, executor, term of the procedures on technical survey and the mark on fulfillment.
- F4.3. Periodicity of the technical survey procedures (including final tests of the products samples) shall be determined depending on complexity of products, probability of the danger caused by their utilization for the life and health of the people, environment and taking into account results of the certification works and term of the certificate validity.
- F4.4. On the basis of the plan assignment to the auditors for conducting technical survey in the current year is being formed.
- F4.5. Technical survey with the purpose, indicated in p.p. F1.2.6. and F 1.2.7. shall be conducted in addition to the plan and shall be also paid by the customer.

#### F5. Fulfillment of the Technical survey

- F5.1. Technical survey includes following stages:
  - -development of the program of technical survey;
  - -conclusion of the contract for the conduction of technical survey;
- -conclusion of contracts with organizations which are authorized to fulfill technical survey (if necessary);
  - -preparation to the technical survey;
  - -fulfillment of the technical survey;
  - -preparation of the report on technical survey.
- F5 .2. technical survey program shall be developed by the certification body according to the results of the fulfilled works on products certification for every specific production according to the requirements of the paragraph E 7., confirmed by the head of the certification body and sent to all participants of the technical survey.

- F5 .3. Contracts shall include all works on technical survey, terms and conditions of their fulfillment and payment, defined executors and time limits for the fulfillment of all stages of works on technical survey.
- F5 .4. At the preparation stage group of the auditors shall be established (as a rule not exceeding 2-3- persons) and the head of this group shall be determined. Assignment for conducting technical survey confirming authorities of the auditors shall be executed. It is recommended that regional body of the Derzchstandard at which territory examined enterprise is located shall be informed on fulfillment of the technical survey.
- F5 .5. Fulfillment of the technical survey at the enterprise shall include: introductory meeting, fulfillment of the survey according to the program of the technical survey and final meeting.
- F5 .5.1. At the next meeting head of the enterprise and heads of the interested subdivisions acquaint themselves with the objective of the technical survey and its program. Issues concerning allocation of the group of auditors, arrangement of the working places, cooperation of the auditors with representatives of the enterprise, preparation and submission of the appropriate documents, information, notes, etc. shall be also clarified.
- F5 .5.2. Every auditor according to the program of technical survey and insructions of the head of survey carries out his work independently.
- F5 .5.3. If the program of technical survey provides scheduled tests then selection and identification of the samples is made, samples shall be sent to the determined by the body accredited in the System testing laboratory which submits to the body protocol with the results of scheduled tests.
- F5 .5.4. Discovered during survey discrepancies shall be put down in documentary form and shall be submitted with the signature of the auditor to the head of the survey.
- F5 .5.5. At the end of the survey final meeting with the top management of the examined enterprise and heads of the examined subdivisions. Head of the survey submits comments and conclusion according to the results of the technical survey.
- F5 .6. Technical survey report is drawn up by the auditors which have conducted the survey, signed by all participants of the survey and confirmed by the top management of the certification body.
- F5 .6.1.Report shall include results of all fulfilled works provided by the program of technical survey, discovered discrepancies and comments.
- F5 .6.2. Report shall contain definite conclusions by the received results and proposals as to the development and fulfillment of the corrective measures.
- F5 .6.3. If program of the technical survey provides scheduled tests of the production samples, final decision on the results of the technical survey is made after receiving protocols of tests. This information shall be submitted to the enterprise additionally.
- F5 .6.4. Reports on technical survey and information on the fulfillment of the corrective measures are subject to obligatory custody in the certification body.

#### F6. Staff

F6.1. Personnel participating in the technical survey, stuff and non-stuff auditors shall undergo appropriate courses, meet qualification criteria determined by the body, be attested for the right to fulfill works and shall undergo periodical reattestation in the System.

- F6 .2. Every auditor in the body shall have instructions determining requirements as to the education, skills, technical knowledge and experience, obligations and authorities of the auditors.
- F6 .3. Entire staff shall be aware of their duties and authorities determined by the instructions.
- F6 .4. Payment to the personnel shall not depend on periodicity or results of the technical survey.
- F6.5. There has to be a record of technical survey auditors, which periodically actualizes.

#### F.7. Technical examination program

- F.7.1. Depending on the specific features of certified products and its production, certification authority shall determine the elements of the system of quality and production, examined at the time of implementing technical examination at the enterprise, and requirements set for these elements.
- F.7.2. Mentioned elements are included in sample technical examination program, basing on which programs of technical examination over particular certified products are developed according to the results of certification works, done at particular enterprise.
- F.7.3. Sample and detailed technical examination programs are developed by authorities, they shall be signed by developers and approved by the head of certification authority.
- F.7.4. In general, the following items can be included in the sample program:
  - -examination of the system of amending of documentation;
  - -examination of system of incoming control;
- -examination of system of control and testing of technological requirements and final products, including reliability tests;
- -examination of conformity with technological process requirements, which can affect characteristics, tested under certification;
  - -control over correction measures;
  - -requirements for selection of samples and their identification;
  - -requirements for control and (or) random tests;
  - -control of accuracy of utilization of certificate and conformity mark;
  - -examination of package, storage and loading-unloading works;
  - -claims analysis;
  - -examination of fulfilling of terms of license agreement;
  - -accounting of certified products;
  - -terms of reporting results of technical examination, depending on obtained results;
- -rights and obligations of the head of examination mission, taking into consideration obtained negative examination results;
  - -possible decisions basing on results of technical examination.
- F.7.5. Control tests are done in test laboratory assigned by certification authority and accredited in the system. Control tests can be conducted at the enterprise in case all necessary conditions are provided. In this case, the program of tests is determined by the

head of examination mission. Tests can be conducted by enterprise personnel, but exclusively under examination of authority auditor.

- F.7.6. During technical examination head of examination mission has the right to make changes to the program of technical examination in order to guarantee its reliability. These changes shall be indicated in the report on results of tests.
- F.7.7. Program of technical examination for certain products can be corrected by authority depending on results of previous examinations with respect to changes in the list of technical examination procedures and their time frames.

#### F.8. Selection and identification of samples.

- F.8.1. Certification authority shall develop basic instructions on selection of samples of products, included in accredited industry, and rules of their identification.
- F.8.2. Certification authority shall have rules of delivery of samples of products to test laboratory, as well as rules of their acceptance, storage, returning or liquidation.
- F.8.3. These regulations shall be implied in a separate document or be included as a part of Rules of quality of certification authority.

#### E.9. Correction measures based on results of technical examination.

Basing on the results of technical examination and according to the decision of certification authority the following measures of influence can be applied:

- F.9.1. Cancellation of certificate and termination of license agreement takes place in the following cases:
- -non-conformity of products with requirements of normative acts concerning their safety;
  - -lack of pre-conditions for production of safe products;
- -changes in design, technological and normative documentation without acquiring prior consent from certification authority;
  - -breach of rules of utilization of certificates and conformity marks;
  - -claims against certified products;
  - -failure of an enterprise to pay for technical examination works.
- F.9.2. Certificate or license agreement are suspended in the following cases:
- -creation of conditions, which can lead to production of products, which do not conform with requirements of normative acts;
- -failure of enterprise to perform according to recommendations of authority based on results of technical examination;
  - -breach of term for implementation of correction measures;
  - -breach of conditions of license agreement;
- -non-production of certified products for substantial period of time (longer than 6 months);
  - -failure to of an enterprise to pay for technical examination works in agreed term.

F.9.3. Certificate can be again invalidated under condition of successful results of liquidation of the above mentioned breaches and their pre-conditions.

#### E.10. Confidentiality

- F.10.1. Authority shall satisfy applicant's requirements for confidentiality of information.
- F.10.2. Personnel, participating in technical examination, shall be informed about the rules of authority on guarantees of confidentiality and requirements of the applicant regarding non-disclosure of information.
- F.10.3. Certification authorities and organizations, assigned by them, are responsible for disclosure of confidential information according to the legislation.

#### F.11. Appeals

- F.11.1. In case applicant wants to appeal against measures, taken basing on the results of technical examination works, or against decision on termination of certificate of conformity or license agreement, it can file written appeal to certification authority.
- F.11.2. Appeals are considered according to the procedures and terms, provided for in Chapter 8.
- F.11.3. Filing of an appeal does not suspend previously taken decision.

# Annex G (recommended)

### STATE COMMITTEE ON STANDARTIZATION OF UKRAINE

(name of certification authority)

on results o	REPORT f technical examination
	APPROVED  Head of certification authority
	(signature, name) ""199
(na	me of enterprise)
199,#	(address) chnical examination contract of ""
Name of certified products:	
Registration number of conformity cert	
Registration number of production certi	
Report is developed by auditors:	
	(title, signature, name)
In presence of representatives:	(title, signature, name)
in presence of representatives.	(title, signature, name)
	(title, signature, name)

### **RESULTS OF EXAMINATION**

ш	Technical examination mass dynas			Contant of
#	Technical examination procedures		narks,	Content of
		breaches		remarks, Annex #
		MOG	no	Aillex #
1	2	yes 3	no 4	5
		3	4	3
1	Documents			
1.1	Analysis of normative, design and			
1.0	technological documents			
1.2	Changes in documents, which can influence			#1
1.0	safety of products			
1.3	Analysis of notifications regarding changes			
	in documentation, their approval by			
1.4	certification authority			
1.4	Analysis of conformity with procedures of			
1.7	amending documentation			
1.5	Protocols of pattern tests of products for			
	confirmation of absence of influence of			
	amendments made			
2	Situation with controlling and testing			
2.1	Analysis of situation with incoming control			
	of raw materials, sub-products and spares			
2.1.1	List of raw materials, sub-products,			
	affecting safety of products, approved by			
	authority			
2.1.2	Documented proof of utilization of raw			
	materials, sub-products and spares			
	according to the agreed list and document			
	requirements			
2.1.3	Examination of conformity with document			
	requirements for periods, procedures,			
	methods and measures of control and tests			
	of raw materials and sub-products, than			
	may influence the safety parameters			
2.1.4.	Analysis of obtained results of control and			
	testing of raw materials and sub-products			
	and their registration			
2.2.	Analysis of situation with control of			
	technical parameters			
2.2.1	List of technological parameters, affecting			
	safety of products, approved by authority			
2.2.2	Examination of conformity with document			
	requirements for periods, procedures,			
	methods and measures of control of			
	technological parameters, than may			
	influence the safety parameters			

222	Analysis of obtained results of control of	
2.2.3	Analysis of obtained results of control of	
	technological parameters and their	
2.0	registration	
2.3	Analysis of control of ready products on	
	safety parameters	
2.3.1	Examination of conformity with document	
	requirements on periods, procedures,	
	methods and control measures of safety	
	parameters	
2.3.2	Analysis of obtained results of control over	
	examination of safety parameters for used	
	products and their registration	
2.4	Condition of control, measuring and testing	
	equipment	
2.4.1	Examination of conformity with document	
	requirements for selection and utilization of	
	equipment	
2.4.2	Implementation of schedule of repairing	
	and checking of control and measuring	
	equipment	
2.4.3	Changes in control and measuring	
	equipment	
2.5	Selection and identification of samples,	#2
	certified products and control testing	
2.6	Analysis of results of control testing of	#3
	certified products	
3	Condition of technological equipment	
3.1	Conformity of used technological	
0.1	equipment with document requirements	
3.2	Implementation of schedule of planned and	
3.2	preventive actions	
3.3	Changes in technological equipment	
4	Situation with technological discipline	
4.1	List of operations subject to periodic	
4.1	examination, agreed upon with authority	
4.2		шл
4.2	Examination of conformity with	#4
4.2	technological document	
4.3	Organization of control of technological	
4.4	discipline	
4.4	Examination of conformity with sanitary	
_	and hygiene requirements	
5	Situation with storage, packaging and	
_	shipping	
6	Analysis of claims	#5
7	Control of implementation of correction	
	measures based on results of previous	
	examinations	

9	and conformity mark Registration of manufactured certified	=	#6	
10	products, distributed with customers			
10	Conclusions and proposals		<u> </u>	
10.1	Examination found drawbacks, that can lead to production of non-conforming products	:	#7	
10.2	Examination did not find drawbacks, that can lead to production of non-conforming products			
10.3	Enterprise shall develop and implement correction measures			
<ol> <li>Act</li> <li>Prot</li> <li>Prot</li> <li>Info</li> <li>Rep</li> </ol>	es: ort on amendments to documentation. on selection of samples. ocol of control testing. ocol of examination of technological operation on claims. ort on distribution. es and breaches, determined as the result of te		ation.	
Note: L	ist and description of notes and breaches shall be impliation in the table of report (section 5) or in form of annual control of the control	ied for each proced		
Audito	ors:			
	(title, signature, na	me)	_	
	(title, signature, na	me)	_	
Inform	(title, signature, na		_	
	Informed on the contents of report and received 1 copy  Head of enterprise:			

(title, signature, name)

### Annex K Rules for determination of value of certification works.

#### K.1. GENERAL PROVISIONS.

- K.1.1. Calculation of spendings on certification works is based on the following principles:
- -all actually done certification works, except those, performed according to the legislation on account of state budget, are paid on account of funds of enterprises, organizations, persons, applying for respective works, not depending on the results taken by them;
  - -level of profit on obligatory certification works shall not exceed 25 percent;
- -technical examination of certified products (services) is paid according to practical spendings of organizations, conducting such works;
- -profits from obligatory certification works are distributed according to the established procedures of existing legislation.
- K.1.2. Value of certification works, calculated according to this rules, does not include traveling expenditures and VAT. Applicant pays for them additionally, according to existing legislation.
- K.1.3. Average daily salary fund for experts, conducting obligatory certification works, including works on technical examination of conformity of certified objects with requirements of normative documents (hereafter ND), is calculated basing on wage of expert according to the wage scale and bonus regulations of certification body (CB) or test laboratory (TL). At the same time, it shall not exceed untaxable minimum wage, established by existing legislation.

### K.2. RULES OF CALCULATION OF VALUE OF CERTIFICATION WORKS AND SERVICES.

- K.2.1. Within certification process the following actions are to be paid:
- -decision on application, including determination of certification scheme;
- -selection, identification and testing of samples;
- -estimation of production processes (if not provided for in certification scheme);
- -analysis of obtained results and making decision on issuing (or rejection) of certificate of conformity;
  - -issuing of certificate of conformity and negotiating of license agreement;
- -technical examination of certified products (if provided for in certification scheme);
- -correction measures in case of non-conformity of products with established requirements and wrong application of conformity mark;
  - -information on results of certification.
- K.2.2. In general cases, accumulative expenditures of applicant for certification of certain product (services) (B) is calculated according to the following formula:

$$B=B1 + B2 + B3 + B4 + \sum_{I=1}^{n} B5_{i} + \sum_{j=1}^{n} B6_{j} + B7 + B8$$
 (K.1.)

where:

- B1 value of works, conducted by CB, in Hryvnias;
- B2 value of samples, taken from manufacturers for tests (for certification schemes, which include testing of products), in Hryvnias;
  - B3 value of tests of products in accredited TL, in Hryvnias;
  - B4 value of certification of quality system (or production process), in hryvnas;
- B5<sub>i</sub> value of one examination, conducted under technical examination procedures for certified products (services), in hryvnas;
- n number of examinations, provided for in the program of technical examination of certified products;
- $B6_j$  value of one examination, conducted under technical examination of conformity of certified quality system (production process) with ND requirements, in hryvnas;
- m number of examinations of conformity of certified quality system (production process) with ND requirements, which are provided for in the program of technical examination:
- B7 expenditures on selection, identification, packaging and transportation of samples to the test-sight during certification, in hryvnas;
- B8 value of works, conducted during obligatory certification of imported products;

Depending on current situation and established certification scheme the formula for calculation of costs of certification works include only those elements, which correspond to the list of actually done works.

K2.3. Value of works, conducted by CB, on certification of certain products (services) is calculated basing on the formula:

$$B1 \times (B4) = t1 \times T \times (1 + [K1 + K2]/100) \times (1 + P/100)$$
 (K.2.)

where.

- 1 labor consumption for certification of certain products (services) according to determined scheme of certification or certification of quality system (production process) for B4, person per day;
  - T average daily salary of expert, in hryvnas;
- K1 ratio, which includes taxes on salary (social security, employment fund, Chornobyl fund and other) according to existing legislation, expressed in percent;
- $K2\mbox{ -}$  ratio of operative expenditures, calculated on basis of accountancy for last month, expressed in percent ;
  - P profit level, expressed in percent.
- K.2.4. Margin normative of labor consuming and works, conducted by CB during certification of certain products, are implied in Table K.1.
- Table K.1. List (description) and margin normative of labor consumption of works, conducted by CB during obligatory certification of certain products and paid for by applicant.

Description of works 1)	Margin normative of labor consumption,
Description of works	persons per day
Decision on application, including	Frank Promise
determination of certification scheme:	
-acceptance, incoming control and	0,4
registration of application;	
-consideration of documents, attached to	1,5
the application;	
-preliminary study of production	2,0
processes of certified products;	
-determination of certification scheme;	0,4
-selection of organizations co-contractors	1,0
for works;	
-development of decision on application;	1,0
Selection, identification and testing of	
samples:	
-selections and identification of samples;	1,0
-analysis of testing protocols;	1,0
Analysis of production processes (if	
not provided in certification schemes):	
-study of production;	Labor consumption normative of
	production are determined according to
	the table K.3. with ratio 0,5
-certification of production process;	Labor consumption normative of
	production are determined according to
and fination of avality and	the table K.4.
-certification of quality system;	Labor consumption normative of production are determined according to
	the table K.3.
Analysis of obtained results and	1,0
making decision on issuing (or	1,0
rejection) of certificate of conformity;	
Issuing of certificate of conformity and	1,0
negotiating of license agreement <sup>2)</sup>	
Technical examination of certified	
products (if provided for in	
certification scheme);	
-development of program of technical	1,5
examination;	
-conducting of one technical	Value is calculated according to section
examination, including analysis of data	K.3.
on quality of certified products;	
Correction measures in case of non-	
conformity of products with	
established requirements and wrong	
application of conformity mark 3)	
-suspension of certificate and license	0,4
agreement;	

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-informing of interested parts of	1,0
certification about such suspension;	
-determination of term of implementation	1,0
of correction measures;	
-control of implementation of correction	2,0
measures by applicant;	
-determination of new marks for	1,0
differentiating of products before and	
after correction measures;	
-informing of interested parts of	0,4
certification on implementation of	
correction measures;	
-termination of certificate and license	0,4
agreement in case of failure of applicant	
to implement correction measures;	
Information on results of	
certification <sup>4)</sup>	

- Note 1. List of works, conducted during certification of certain products, is determined according to selected certification scheme.
- Note 2. Payment of certificate of conformity is calculated basing upon:  $0.1~D_{min}$ ; authorization of the copy of certificate  $0.1~M~D_{min}$ , where: M number of copies of certificate;  $D_{min}$  untaxable minimum profit, established by existing legislation.
- Note 3. Labor consumption is calculated along with calculation of B8 section K.3. of this document.
- Note 4. In case of necessity, CB renders consultative services to applicant according to its competence, they are paid: 1 hour not more than 0,4 D  $_{\min}$

K.2.5. Margin normative of labor consumption and list of works, conducted by CB during obligatory certification of services, are indicated in table K.2.

Table K.2 - List (description) and margin normative of labor consumption of works, conducted by CB during obligatory certification and paid for by applicant.

Description of works 1)	Margin normative of labor consumption,
	persons per day
Decision on application:	
-acceptance, incoming control and	0,4
registration of application;	
-consideration of documents, attached to	1,5
the application;	
-preliminary study of production	1,0
processes of certified services;	
-determination of certification scheme;	0,4
-development of decision on application;	1,0
<b>Testing (examination) of services:</b>	
-random examination of results of	1,0
testing;	
-estimation of expert's professionalism;	0,5
-estimation of the process of rendering	0,5
service;	
-certification of quality system;	Labor consumption normative are
	determined according to the table K.3.
-certification of production process	Labor consumption normative are
(enterprise);	determined according to the table K.4.
Analysis of obtained results and	1,0
making decision on issuing (or	
rejection) of certificate of conformity;	
Issuing of certificate of conformity and	0,5
negotiating of license agreement;	
Technical examination of certified	
products;	
-selection of program of technical	1,0
examination;	
-conducting of one technical	Value of works is calculated according to
examination, including analysis of data	section K.3.
on quality of certified service;	
Information on results of	
certification. <sup>2</sup> )	

Note 1. List of works, conducted during certification of services, is determined according to selected certification scheme.

Note 2. In case of necessity, CB renders consultative services to applicant according to its competence, they are paid: 1 hour - not more than  $0.4~D_{min}$ , where  $D_{min}$  - untaxable minimum profit, established by existing legislation.

K.2.6. Marginal rates of the aggregate labor intensity (LI) of works carried out by the certification body (CB) during certification of the quality systems in the course of mandatory certification of produce (services) depending on the model of the quality system and a number of employees involved at an enterprise, are set out in table K.3.

Table K.3 - Marginal rates of LI of CB's works that are paid by the applicant during certification of the quality system to be conducted within the framework of mandatory certification of products and services.

Number of employees at an enterprise, persons	Marginal rates of labor intensity, person-day (1 group of the product complexity)  Quality system model		
	DSTU ISO 9001-95	DSTU ISO 9002-95	DSTU ISO 9003-95
less than 100	15,0	10,0	10,0
from 101 to 1000	28,0	23,0	16,0
from 1001 to 5000	53,0	43,0	21,0
from 5001 to 10000	68,0	58,0	28,0
more than 10000	78,0	68,0	38,0

**Note:** Until the marginal rates of labor intensity during certification of the quality systems of products of the 2<sup>nd</sup> and 3rd complexity groups are determined the coefficients 1.5 or 2.0 shall be applied, respectively, to the marginal rates mentioned in table K.3. The Produce complexity groups - table K.6.

K.2.7 Marginal rates of the aggregate labor intensity of works to be carried out during attestation of production in the course of mandatory certification of products (services), depending on complexity of products and production are set out in table K.4.

Table K.4 - Marginal rates of CB of works that are paid by the applicant during attestation of production to be conducted within the framework of mandatory certification of products and services.

Group on	Marginal rates of labor intensity, person-day		
production	Group on production complexity <sup>2)</sup>		
complexity 1)	1	2	3
1	27,0	30,0	35,0
2	35,0	39,0	51,0
3	45,0	52,0	55,0
4	53,0	55,0	66,0

Note 1 According to K.5 Note 2 According to K.6

Table K.5 - Groups on production complexity

Group	Average number of production operations during the
on production	manufacturing of goods
complexity	(services rendering)
1	less than 200
2	from 201 to 2000
3	from 2001 to 5000
4	more than 5000

Table K.6 - Groups on produce complexity

Groups on produce	Types of produce
complexity	
1	Materials (metals, alloys, building materials, etc.)
	Fuel
	Oil and chemistry products, textile, fur articles
	Construction elements and car parts
	Food raw materials
2	Articles of general machine building design
	Instrument
	Electrical and radio elements
	Furniture
	Clothes
	Footwear
	Food products
3	Machines, equipment
	Transport vehicles
	Devices, automatic equipment
	Radio electronics
	Calculating machines

K.2.8 During mandatory certification of products imported into Ukraine, the works, which are actually performed by the CB based on the documents presented by an applicant are subject to payment.

K.2.8.1 The description and marginal rates of labor intensity of works on recognition of foreign certificates for produce imported into Ukraine are set out in table K.7.

Table K.7 - The description and marginal rates of labor intensity of works on mandatory certification of imported produce

Description of work	Rate of labor intensity person-day
Verification of conformity of the foreign certificate (sign) of correspondence with the samples	0.1
Verification of the proper use of the certificate (sign) of correspondence in respect of the imported consignment of	0.75
goods Analysis of documents confirming the safety of goods	1.25
Carrying out tests	Payment is made under a contract in accordance with actual expenses as per the program of tests (level of profitability calculated upon the actual cost but not exceeding 25 percent)

K.2.8.2. The description and marginal rates of payment for works that may be carried out during the works on recognition of foreign certificates for produce imported into Ukraine are set out in table K.8.

Table K.8 - The description and marginal rates of payment for works performed during mandatory certification of imported goods, and drawing up of the certificate of correspondence

Description of works	Unit of measurement	Rate of payment*
Preparation of references (opinions) for the customs control bodies	hour	4×D <sub>min</sub>
Translation and confirmation of authenticity of translated documents confirming the safety of goods	printed pages	$8 \times D_{min}$
Supervision over the consignment of goods		Payment is made under tariffs set by the State Customs Committee of Ukraine

 $<sup>*)</sup>D_{min}$  - untaxable minimum profit, established by existing legislation

 $<sup>^{*}</sup>$  ...... - non-taxable minimum citizens' income established by the current legislation

K.2.8.3. The cost of works on recognition of foreign certificates for produce imported into Ukraine (B9) is calculated under formula:

$$B = T \times (1 + [K1 + K2]/100) \times (1 + P/100) \times \sum_{i=1}^{s} t_i + \sum_{j=1}^{z} B9_j \times O_j$$

- where: t<sub>i</sub>. labor intensity for carrying out i work during mandatory certification of products imported, person-day;
  - s number of works performed by CB during mandatory certification of imported goods;
  - B9j rate of payment of j work carried out by CB during mandatory certification of imported goods, in hryvnias;
  - Oj actual volume of work of ... type performed during mandatory certification of imported produce;
  - z number of kinds of work executed during mandatory certification of imported produce.
- K.2.8.4. In case of several consignments of goods being included in one customs declaration for products that differ by their name (type, mark, code number), country of origin, producer and date of production, works on mandatory certification are paid for each consignment of goods. In such case the norms set out in table K.7 and K.8 shall be applied for each consignment of goods.
- K.2.8.5.During execution of the said works on weekends and holidays the payment shall be made under current legislation..
- K.2.9.The cost of tests during product certification is calculated by the accredited VL on the basis of the independently set standards on material and labor expenses in current prices taking into account the requirements of K.1.1 and K.1.3 and need to be notified to the parties concerned.
- K.2.10 Technical supervision of conformity of the certified products (services, quality systems, attested production) shall be paid in compliance with the procedure established in Section K.3.

### K.3 PAYMENT FOR TECHNICAL SUPERVISION OVER MANDATORY CERTIFICATION OF PRODUCE (SERVICES)

- K.3.1 Payment for technical supervision shall be covered by the applicant. In case of the CB being involved in conducting technical supervision over a specialized organization, its services shall be paid by additional amounts, at the expense of the applicant.
- K.3.2 The cost of technical supervision (Cts) along with adjustment measures is calculated according to formula:

$$Cts = B_a + \sum_{j=1}^{q} B_{mj} \dots \qquad (K.4)$$

where:. B  $_{\rm a}$  - cost of works on collection and analysis of data on quality of certified

produce (services) quality and provision of adjustment measures, in hryvnias;

B  $_{mj}$  -cost of one checking conducted within the framework of technical supervision, in hryvnias;

- q number of checks conducted within the framework of technical supervision within the validity period of the certificate of correspondence.
- K.3.2.1 The cost of works on collection and analysis of data on the quality of certified produce (services) shall be calculated on the basis of actual labor expenses taking into account the requirements of K.1.1. and K.1.3. Marginal rate of labor intensity for adjustment measures is set out in table K.1.
  - K.3.2.2 The cost of one check conducted within the framework of technical supervision over certified produce (Ctsj...) is calculated according to formula:

$$Ctsj = t_c \times T \times N \times (1 + [K1 + K2]/100) + C_s + B2 + C_d + C_{ct} + C_{ss}...$$
 (K.5)

where: t<sub>c</sub> - checking period, days;

C<sub>s</sub> - cost of the samples taken from the seller for tests, in hryvnias;

C<sub>d</sub>..- cost of the samples selection and delivery to the testing site, in hryvnias;

C<sub>ct</sub> - cost of control tests, in hryvnias;

N - number of commissioners taking part in the tests, persons;

 $C_{ss}$ - cost of supervision to ensure uninterrupted production (quality system operation), in hyvnias.

Note: Only elements which reflect the actually completed works, depending on the certification scheme chosen, and which are confirmed by appropriate documents, are included in the formula.

- K.3.2.2.1. The cost of the samples taken from the producer is calculated according to their actual par value<sup>\*</sup>.
- K.3.2.2.2. Payment for the samples taken from the producer is made according to their retail price on the basis of documents certifying the fact of the purchase.
- K.3.2.2.3. Expenses on the samples selection and delivery to the testing site include actual expenses of CB for transportation, loading-unloading works, preservation and utilization which are confirmed by relevant documents.
- K.3.2.2.4. Payment for control tests is made under tariffs of relevant VL.... on a cost recovery basis.
- K.3.2.2.5. The cost of technical supervision over attested production (certified quality system) is calculated according to tables K.3 and K.4.
- K.3.3 The cost of one check carried out within the framework of technical supervision over certified service is calculated under formula:

$$Ctsj = t_c \times T \times N \times (1 + [K1 + K2]/100) + C_{ss} + C_{cc}...$$

where: C<sub>cc</sub> - cost of the consumers' opinion poll procedure, in hryvnias.

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<sup>\*</sup> If the samples of products for testing have been provided by an applicant free of charge, their cost is not considered.

Note: Only elements which reflect the actually completed works, depending on the certification scheme chosen, and which are confirmed by appropriate documents, are included in the formula

# K.4. LICENCE PAYMENTS FOR THE RIGHT TO APPLY THE CERTIFICATE OF CORRESPONDENCE AND LABEL PRODUCE WITH THE MARK OF CORRESPONDENCE

- K.4.1. During certification the payment shall be collected from the applicant based on the licence agreement between him and CB for the right to apply certificate of correspondence and label produce with the mark of correspondence.
- K.4.2. License payments shall be established in the amount 0.01 percent of the volume of sold certified produce (without VAT and excise duty).
- K.4.3. License payments shall be transferred by a licensee to the settlement CB's account according to the payment requisites indicated in the licence agreement.
- K.4.4. In case of an advance termination of the license agreements, the obtained license payments shall not be returned.

\* If the samples of products for testing have been provided by an applicant free of charge, their cost is not considered.

**Key words**: certification system, certificate and mark of correspondence, produce, certification scheme, certification bodies, testing laboratories, normative (standard) document. application, attestation of production, quality system certification, technical supervision, licence, recognition, appeal