Bal'-Prylypko L.V., Slobodianiuk N.M.,
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Standardization, metrology, certification and quality management

Manual

Under the guidance of doctor of technical sciences.
Professor Bal'-Prylypko L.V.

Kyiv
TsP "Komprint"
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The manual describes the principal problems of regulation of safety and quality of production arising in light of requirements of modern system of State technical regulation. There are characterized the basic constituents of the system, namely metrology, standardization, assessment of conformity including the stage of certification, as well as problems of accreditation of bodies by evaluation of conformity. The manual briefly describes international and domestic institutions operation in spheres of metrology, standardization, certification and accreditation. Using describes materials, there are given fundamental notions used in system of guaranteeing of quality of production, and principles of ensuring of safety and quality of foodstuffs of domestic and foreign origin.

The manual may be used in training of students of level of qualification of "Bachelor" by direction of training of 6.051701 "Alimentary technologies and engineering", as well as experts of specialties of "Marketing", "Economics of enterprise", "Management", "Merchandising", "Expertise of commodities and services" etc. Learning of problems described in the manual will also assist in training of specialists by problems of technical regulation, standardization, certification, accreditation and quality management.

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Introduction

The changeover of structure of public economy of Ukraine and its opening to conditions of the competitive market economy lead to origination of new principles of operation of enterprises and organizations on internal and external markets, where the manufacturers compete for the trust of buyers. This, in turn, requires of modernization of principles of the State technical regulation, namely of methods of standardization, certification and accreditation of bodies, which assess the conformity to the international norms of quality and safety of produced goods, given services and the grade of observance of modern principles of realization of processes of operation of national economy.

The principles of development of Ukrainian system of technical regulation comply mainly to those that are character for processes occurred in the global economy, what resulted in harmonization of the present-day methods of management with those that are used worldwide, especially those that are realized in EU member-countries. At the same time, the routine of operation in spheres of standardization, certification, accreditation and quality management changes in parallel with the changes in conditions of functioning of national economies and are linked indivisibly with use of the fundamental principles of metrology.

Metrology, standardization and certification are the indivisible parts of activities of humankind, which directly influence on standards of life. Meantime, they are understood and interpreted by various people differently. Therefore, it is necessary to give the clear interpreting of tasks of these activities, and the purposes, what is the principal aim of this manual. Knowing of fundamentals of standardization, certification, and principles of quality management are equally necessary for both specialists, who produce production, and those who this production distributes and uses (consumes). Hence, the main objective of studying of discipline of *"Standardization, metrology, certification and quality management"* is giving students of basic knowledge of principles of operation of public economy used in assuring of its more effective functioning.

The manual consists of seven chapters. The *first* one briefly characterizes the role of metrology in functioning of constituents of System of State technical regulation: standardization, certification and accreditation, and describes the basic principles of activities of bodies, which operate in these spheres of modern economy.

The *second* chapter gives the characteristic of main tasks, which arise in carrying out of metrological works; the legal base and notions of metrological activities used the most often; measurements as an object of metrological science; notions of physical magnitudes and their units; means of measurement; inaccuracy of measurement; the list and structure of global and Ukrainian metrological bodies.

The *third* chapter describes the basic notions used in modern standardization; structure of the system; characteristics of objects of standardization; categories of standards valid in Ukraine; procedures of carrying out of works by standardization and methods of control of observance of provisions of normative, technical and legal documents. There is also described the characteristics of global and regional structures, which include as members the standardization bodies of EU and CIS countries, principles of their operation and the norms of work of Ukrainian institutions in harmonization of national base of standardization with the international and European ones.

The *fourth* chapter contains information on the Ukrainian system of attestation of conformity and certification of goods, processes and services and describes the objectives and practice of functioning of Ukrainian national system of certification of UkrSEPRO used in Ukraine the most often, procedures of certification of goods and services, including the agricultural production and systems of environmental management. There is also given the brief information on procedures of State control and State supervision used in process of certification.

The *fifth* chapter describes the role of accreditation in the sphere of distribution of authorities and issuing of permissions on carrying out of metrological works, the basic terms used in its practice, principles and procedures of accreditation in Ukraine and abroad, and the main global organizations, which operate accreditation.

The *sixth* chapter gives the characteristic of notion of *"quality"* and identifies the principal documents and methods of its assuring, as well as principles of quality management. There is also given the brief characteristic of international standards of quality, history of their development, listed the fundamental quality standards used in manufacturing and servicing.

The final, *seventh* chapter, describes the procedures of assuring of quality and safety of foodstuffs lists the fundamental norms of the basic treaties of World Trade Organization, and gives the information on procedures of trade and movement of foods and food raw materials used in their fabrication. The given materials describe the basic norms of regulation of routine of producing of foodstuffs and norms of global trade with foods, including those that contain the genetically modified organisms. There are listed the basic principles and procedures of State regulation of quality of foodstuffs in Ukraine, and the documents, which regulate the processes of import in Ukraine of foodstuffs and their ingredients.

The materials of the manual comply to the structural and logical scheme of training of specialists by management, marketing, expertise of goods and services, and may be used in training of students of OKR "Master of sciences" of specialties of 8.05170104 "Technologies of storage and processing of meat", 8.05701056 "Technology of storage and processing of aquatic biological resources", 8.18010010 "Quality, standardization, certification", students of OKR "Bachelor" of direction of training of 6.051701 "Alimentary technologies and engineering", as well as on studying of disciplines of "*Marketing*", "*Economics of Enterprise*", "*Management*", "*Merchandising*", "*Expertise of Goods and Services*", "*Quality Management*" etc. Studying of problems set forth in the manual would assist in training of specialists by problems of technical regulation, standardization, and attestation of conformity and managing of quality of production produced in Ukraine.

1. The Concept of the State Technical Regulation

The human community passed the long way of development of means and methods of manufacture and in progress and increasing of quota of serial production in its total output, there occurred in parallel the essential changes of indices of quality of goods and services. Their principal purposes were ensuring of interchangeability of details, mechanisms and machines made in various places, global unification of conditions of manufacturing and harmonization of norms of their mass production, introducing of novel technologies of manufacturing and servicing, as well as creation of social and economical norms of protection of interests of juridical and natural persons. The work in normalization of conditions of material production at national level resulted finally in introduction of norms of the *State Technical Regulation* based on use of provisions of normative and legal deeds developed in purposes of regulation of operation of legal persons.

> *Normative and legal deed means the official written document intended for manifold use and drawn up in observance of norms of legislation and approved by the authorized legal person, which contains the instructions of normative character in establishing of norms of functioning of public and economical relations*

Such documents may be classified by two big groups as follows:

- legal norms (Constitution and laws of Ukraine),
- legal deeds (decrees and orders of President of Ukraine, Decrees of Council of Ministers of Ukraine, departmental deeds etc.).

it is necessary to note that there is absent the univocal interpreting of notion of *"technology"*. However analysis of sources of scientific and technical literature permits to formulate it as follows. Technology is the special information on operations to be used in development, fabrication and use of products, which contains the complex of data on properties, form of raw materials and methods of their processing and change of the aggregate state, consumables and the semi-manufactured products used in process of fabrication of new types of products.

Ukraine introduced the term of *"technical regulation"* on the eve of her joining to the World Trade Organization (WTO) interpreted in Ukrainian legal documents without alterations as *"технічне регулювання"*. Its main goals are assisting in solving of two basic tasks, which arise in functioning of national economy:

1. *Regulation of procures of operation of domestic market* induced in necessity of development of mechanisms of fabrication of qualitative production, evaluation of compliance of produced goods to the established norms, increasing of competitiveness of production in international markets and raising of level of its social orientation. The principal directions of such activities are regulation of quality of production, carrying out of works, servicing, assessment of quality of goods and services, as well as the control of correctness of realization of processes of their producing.

2. *Work in conditions of globalization*. The existing mechanisms of technical regulation must be harmonized with the international practice and assist in realization of economically favorable policy of the State in foreign barter. The basic norm of operation in it is the mandatory observance by the legal and natural persons of the normalized conditions of operation carried out under the threat of official sanctions in cases of their violation. Therefore, the principal tasks of the State in execution of business-processes are:

- guaranteeing of civilized conditions of operation and trade,
- protection of interests of citizens and conditions of environment against the negative influence of processes of manufacturing and its products,
- harmonization of national normative and technical documents of national category with their international analogues,
- stimulation of legal and effective methods of development of the public economy,
- guaranteeing of observance of the normalized indices of quality and safety of consumables and services.

These problems may be classified by two groups. The *first* one includes the norms used in domestic market, namely:

- compliance of structure of system of technical regulation to the existing state of material, scientific and technical base of the State,
- use of uniform methods of guaranteeing of proper quality of production in processes of its projecting, fabrication, tuning, exploitation, transporting, sale and servicing,
- forming of mechanisms of regulation based on evaluation of grade of riskiness in observance of procedures of use and specificity of objects of regulation,
- independence of control bodies of influence of manufacturers, traders and other parties interested in results of their work.

The *second group* establishes the norms of prevention of transformation of regulated parameters of quality of production and services in barriers in international trade.

The norms used in sphere of responsibility of the State technical regulation relate to the processes of development, approval, use and fulfillment of duties of obligatory character, guaranteeing of roper quality of production, including erections and constructions, norms of accomplishing of the attributed processes of its projecting, manufacturing, construction, assembling, adjustment, exploitation, storage and utilization, procedures of servicing, as well as work in assessment of compliance of execution of listed duties to norms stated by the State deeds and other type normative and regulatory documents.

Such norms are not attributed to the social, economical, organizational, sanitary, hygienic, medicinal, prophylactic and rehabilitating measures carried out in sphere of protection of labor, State educational standards, standards of bookkeeping, auditing and valuating activities, standards of dissemination, giving or disclosing of information, minimal social standards, standards of giving of State and municipal services.

The State does not regulates also the relations pertinent to development, approval, use and fulfillment of sanitary and epidemiological measures, measures by protection of environment, procedures of protection of labor and industrial safety, norms of safely exploitation of objects of nuclear power, safety of technological processes

at the hazardous industrial objects, procedures of ensuring of reliability and safety of power-producing systems and objects (excluding the cases of development, approval and use of products), processes of their projecting, fabrication, construction, assembling, adjustment, exploitation, storage, transporting, realization and utilization.

The obligatory norms attributed to 1) products (works, services) of defensive destination, 2) secret and/or confidential information, 3) norms of projecting of objects of nuclear power, their construction, adjustment, exploitation, as well as storage, transporting, realization, utilization (disposal) of attributed products, establish the State requesters, which operate in spheres of assuring of State safety, defense, external reconnaissance, protection of information, use of nuclear power and execution of the State contracts. If the international contract by problems, which are in sphere of State technical regulation, holds other norms, there should be used the provisions of this contract, and if the work in execution of international contract requires of enactment of special State deed, there have be used the norms of said contract and provisions of national legislation modified accordingly to its norms.

At that, the principal documents used in realization of said principles are the *technical regulations*, the documents, which contain the generalized norms used in functioning of national economy, especially in development of technical specifications as the part of the specialized standards. The term of *"technical specifications"* is understood here as the set of norms and procedures, which normalize the character indices of quality of certain technical objects, methods of their manufacturing, grade of safety of use, used terminology and symbolism, methods of testing, used packing, methods of marking and labeling etc.

> *Technical regulations means the legal normative deed of general or special character, which was approved by the Supreme Soviet of Ukraine, or the Council of Ministers of Ukraine, or is based on recommendations of the European legal bodies (European Commission, Council of Europe, European Parliament), which determines the characteristics of production(servicing) or processes of its manufacturing*

obligatory for observance. The technical regulations may contain also the requirements to terminology, symbols and indications, packing, marking or labeling, which are used in identification of certain types of production, processes or methods of operation. The technical regulations do not establish sanitary measures. In absence of technical regulations of national category concerned of certain object of regulation approved by the Supreme Soviet of Ukraine of the Council of Ministers of Ukraine, the persons of economy should use the respective EU technical regulations, if exist

Origination of such kind documents of national category is closely associated with the approval of one of the most significant documents in regulation of international trade relations – the WTO Agreement of Technical Barriers in Trade (see Chapter 7.6.3). This document stipulates the condition of inadmissibility of producing in international trade of excessive restrictions of technical character, such as differences in the set of the normalized parameters of production, various methods of identification of indices of its quality etc. Putting such kind documents in practice, WTO recommended its member-countries to legalize them by mode, which should not have more restrictive character that it is necessary for realization of principles of fair trade. The wording of *"technological regulations"* is some consonant to the term of *"technical regulations"* used in Ukraine since the earlier times, however the former term may be attributed to the documents, which regulate the details of technologies of producing of certain products at the existing manufacturing enterprises, and the latter class documents normalize the principles of regulation of processes of functioning of enterprises operating in sphere of the *all-State economy*.

There exist two principal approaches to realization of principles of State regulation: the *directing* one, which prescribes the methods of reaching of normalized indices of quality of production in choose of one of possible methods of realization of set goals. The second approach is regulation *oriented on obtaining of prescribed result*, when the person of economy is free in choose of any method of its reaching.

The system of regulation developed in Ukraine, which has to assist in realization of the State policy in reaching of conditions of sustainable progress of her economy, is developed in observance of conditions as follows:

- assurance of metrological servicing of persons of economy and ensuring of traceability of results of measurements,
- harmonization of procedures of calibration of means of measuring technique with the international norms,
- participation in development of international and regional normative and technical documents and their harmonization at the national level,
- reaching of international recognition of the domestic system of attestation of conformity of production, goods and services.

The basic principles of functioning of the System are in the line of prescriptions of the European Directive 98/34/EU *"A procedure for the provision of information in the field of technical standards and regulations and of rules on Information society services"*, and fully conform to modern tendencies of liberalization of global trade. The *technical regulations* include de facto the norms of:

- legal and administrative regulation of procedures of manufacturing and servicing,
- concluding of voluntary agreements with the bodies of the State legal authority in interests of society to guarantee the compliance of routine of work of the subject of regulation to the set norms,
- development of technical specifications and rules of use (consumption) of goods or giving services, which conform to their norms. The exclusions are the norms of national safety.

The work in introduction of modern principles of functioning of market permits to harmonize the norms of national systems of technical regulation with the international ones and opposes to turning of norms of legal, normative and technical documents of national category in the instrument of protectionism. At the same time, the states, which take such kind regulatory documents are free in introduction of norms specific for their national economies in grade they consider as the necessary in

protection of their inner markets. Such regulations must have, however, the minimal restrictive character. Therefore, they have to normalize the exploitative, but not the constructive requirements and eliminate the differences of provisions of normative documents of technical character (units of dimensionality, for example), which existence leads to additional spending of means and time of interested parties in purchasing of goods of foreign origin. These actions permit also the operators to organize co-operation of subcontractors of different countries in segregating of their work in manufacturing of goods and giving services worldwide.

The principal objectives of such reforms are assisting in fabrication of competitive products, easing of their circulation worldwide, protection of domestic markets against marketing of low-grade products, as well as proper informing of population on real indices of quality of consumables and services they bought. The work in identification of conformity of indices of quality of production to the established norms is the principal task of measurements, which are in sphere of responsibility of the specialized science of *metrology*, the one of constituent parts of the global system of technical regulation.

> *Metrology means the science on units of measurement, means of measurement, procedures of measurement, methods of assuring of uniformity of measurement and modes of reaching of necessary precision of measurement*

The other spheres of State technical regulation are:

- *standardization* as the instrument of practical realization of the system of regulation of the market, which permits to assure the compatibility, interchangeability and safety of production, as well as to introduce the identical procedures of manufacturing of the same products,
- *attestation of conformity* of production, processes and services to norms of legal, normative and technical documents in force, which has to guarantee their proper quality and safety during the term set in their attestation and assist consumers in informed choice of the marketed products,

- *accreditation* means the work in witnessing of technical competence of persons specialized in assessment and attestation of conformity of their services to provisions of the normative and technical documents they declare.

The notion of *"Consumer"* and concepts of *"Service"* and *"Contract"* are linked indivisibly with these activities and are used in meanings as follows.

> *Consumer means the natural person, who buys, receives, orders, uses or has intentions to buy/to order for own needs the production not related directly to his business operation and/or earning of wage*
>
> *Service means the activity in giving (passing) the consumer of certain material or non-material welfare detailed in contract concluded by his individual order*
>
> *Contract means the verbal or written legal deed concluded by the consumer (buyer) and the seller (executor), which details the quality, terms, price and other conditions of producing and realization of production and/or servicing detailed in this document*
>
> *Safety of production means the absence of any risk for consumer's life, health, property and any damage for environment at usual conditions of its use, storage, transporting, producing and utilization*

The listed types of works reflect the objective laws of evolution of technical means and indices of quality of substances and selection of materials used in manufacturing, which have to guarantee the high quality of consumables (servicing). Thanks to standardization, the humankind knowingly regulates its technical and economical policy in the material producing and procedures of objective evaluation of its quality accomplished by the competent persons of economy. Hence, the system of technical regulation is the unique phenomenon, which synthesizes in one the modern scientific, business, economical, juridical, aesthetical and political aspects of functioning of national economy.

The works in spheres of metrology, standardization and certification in all spheres of public economy heads in Ukraine the integrated body of State regulation – the State Service of Technical Regulation and Consumer's Policy of Ukraine, which controls the attributed activities and works on harmonization of their national norms with the global ones.

The means used in process of the State technical regulation are:

- governmental ordering,
- licensing, patenting and quoting,
- issuing of documents of resolving character,
- forcing the persons of economy to use the normalized methods of operation, as well as granting them the investments, privileged taxes, subsides, compensations of losses, purposeful financing of innovative works etc.,
- regulation of prices and tariffs.

The modern tendencies of development of national, regional and global economies lead to founding of transnational companies and intensification of international trade. These processes are associated with augmentation of quantity of international contracts on mutual operation and/or co-work in various brunches of economy, as well as convergence and mutual accommodation of structures of national economies, what leads to absence in perspective of any discrimination of business persons of any country and development of close interrelations in division of labor universally.

The procedures of business operation in Ukraine regulate presently more of 60,000 legal and normative deeds, such as governmental resolutions and decrees, technical regulations, standards, specifications, instructions of ministerial and governmental departments etc. However, despite the different principles put in base of these documents, there have to be established the uniform norms of identification of indices of quality of objects of regulation, procedures of their recognition and data as follows:

- procedures, forms and limiting terms of evaluation and attestation of conformity of objects of regulation,
- specific terminology,

- procedures of packing, labeling and marking of finished products.

  Labeling – words, descriptions signs used in identification of goods and services, appellations of trademarks, images or symbols placed on any type packing, label, tare, counter-label, stopper, inserted sheet, supplementing document, message and other elements of packing

After the structure of Ukrainian regulatory policy would have been harmonized with the norms used in Europe, the obligatory norms of all listed documents have to be replaced gradually by norms of respective EU technical regulations harmonized in Ukraine. Being in competitive conditions, the domestic manufacturers have to demonstrate compliance of their production, depending of sphere of their realization, to norms of national, regional and international legal and normative documents in force. At the same time, there may arise the cases of ambiguous (multiple) interpreting of rights and obligations of business persons and control bodies because of enormous quantity of valid documents of regulative character to be considered in the administrative courts. Therefore, developing any technical regulations of national category, their developers have to take into consideration the respective EU directives based on principles of normalization of business activities by documents of the following two categories:

- the first level documents are technical regulations, which state the obligatory conditions of safety of production,
- the second level documents are standards and other kind normative and technical deeds, which list the norms of voluntary observance.

The determinative criterion of the national system of technical regulation is compliance of procedures of business activities to legal norms as follows:

1. *"Use of uniform procedures of normalization"* means that all norms of quality and safety of production, as well as processes of its producing have to be formulated uniformly and do not depend of their type, form of property and juridical status of the person of economy, which uses these norms.

2. *"Compliance of procedures normalized by the system to the state of development of national economy"*.

3. *"Independence of activities of certifying and accrediting bodies of interests and influences of manufacturers, sellers, executors and consumers"* declares that the accreditation and certification bodies must not have any business relations with the natural and juridical persons they service. The administration of organizations operating attestation of conformity, certification and accreditation must use the measures directed on prevention of their illegal relations with the persons interested in gaining of financial and other benefits capable to influence on objectivity of their decisions.

4. *"Uniform system and procedures of accreditation"*: The operations in accreditation of certifying bodies and testing laboratories (centers) has to be done in the maximum use of methods conforming to international norms.

5. *"Identity of procedures and methods of investigations (testing) in process of assessment and attestation of conformity"*. Use of this norm presumes the uniformity of procedures used in attestation of conformity of tested objects to the established norms.

6. *"Uniformity of norms of technical regulations"* must not depend of type of works in manufacturing, delivery of production, servicing and carrying out of other type works.

7. *"Inadmissibility of limiting of competition and access of interested parties to work in accreditation and certification"* prohibits creation of preferences for certain categories of applicants, inadmissible containment or speeding of taking of decisions by problems of their interest, as well as the work in favor of certain parties.

8. *"Inadmissibility of combining of functions of certification and control in one hands"* delimits the spheres of responsibility of bodies authorized on such activities. Despite both ones have to control operation of certified (to be certified) persons, the spheres of their control differ: the certification body controls the observance by the certifying persons of provisions of normative documents used in process of authorization they exercise, but the supervising bodies control the observance of the same

norms in process of operation of persons of economy authorized on execution of such jobs in earlier time.

9. *"Inadmissibility of unifying of authorities of accreditation and certification in one hands"*. Prevents the possibility of work in authorization (certification) by the license issued themselves.

10. *"Inadmissibility of off-budget financing of works of the State control bodies"* refuses the possibility of influence of private capital on conditions of carrying out of operations, which are in the exclusive competence of the State regulative bodies.

The basic principles of development of modern system of State technical regulation in Ukraine are:

- development of system of control of quality and safety of production and mechanisms of prevention of producing and realization of faulted production; handing over to Council of Ministers of Ukraine of projects of related laws for approval,
- perfecting of procedures of authorization of bodies, which attest conformity of production, processes and services,
- development and introduction of technical regulations of national category,
- shortening of list of production to be certified in obligatory manner, excluding from this listing of products character by low level of risk in their use, as well as products, which properties regulate norms of technical regulations,
- cancellation of out-of-date documents, development of normative documents and harmonization of provisions of valid standards with the regional and international norms,
- assisting in modernization of testing, calibrating and measuring laboratories, what permits to improve the quality of their work, level of protection of interests of consumers and assist in recognition of results of their activities abroad.

Measuring (testing) laboratory means the enterprise, institution, organization or their structural department, which measures the values of physical magnitudes and determines the

chemical composition, physical, chemical, mechanical and other properties of substances, materials and products

Realization of the concept of State technical regulation acquires the especial value in view of globalization of trade relations, removing of borders in free movement of capital, goods, people, information, processes, systems and services worldwide. The first and the most important stage in solving of this task is establishing of the uniform units and methods of measuring of properties of physical objects, which are the objects of interest of *metrology*, which is the basement of the system of State technical regulation.

2 Fundamentals of Metrological Science

2.1 Basic Concepts of Metrology

The existing physical objects possess by some character *properties* understood as the categories specific for certain aspects of objects, processes, phenomenon and common for the set of homogeneous objects and specifying their interrelations. Their principal groups are:

- *material properties*, which express the character physical and chemical characteristics of substances and materials (mass, density, chemical composition etc.). To identify their numerical values, one should use the specialized means of measurement that form the signals, which values may be measured and used as the quantitative criteria of the property,
- *energetic properties*, which express the effects of transformation, transmission and use of energy (value of current intensity, energy of interaction of objects etc.),
- *properties, which characterize their variation of their values in time*, i.e. changes of modular values of spectral characteristics etc.

Some properties may be expressed in qualitative expression only, but most of them – both qualitatively and quantitatively. The qualitative characteristics reflect the category of the magnitude of the value of object of interest (length, mass, duration, list of elements that form the compound etc.), and quantitative one – its numerical value.

However, any property does not exist by itself, but in existence of the object possessing with it. The value of physical magnitude represents the number of certain magnitude chosen as the unit of its ranking and named as the *unit of physical magnitude*. This one may be quantified in series of precise measurements and used in quantitative measurements of the characteristic of the object in question. Such quantified numbers of the measured parameters are named as values of measured parameters, not their dimensions, e.g. *"the value of mass"*, but not *"the dimension of mass"*.

The consecutive sequence of values of any property taken in order of their rise, unit-by-unit, forms the totality of numbers known as the *scale of measuring*, i.e. the ordered sequence of values of the physical magnitude. Such scales are classified conditionally by five basic groups as follows.

1. *Scale of appellations* classifies the empirical parameters in characters of their equivalence only and expresses their relationship. There are absent units of their measurement and such notions as *"null"*, *"more"* or *"less"*. The example may be gradation of colors of diamonds (Table 2.1).

Table 2.1

Tints of color of diamonds used in jewelry by system of the Gemological Institute of America (GIA)

Category	*Table of tints of colors*	*Grade of coloration*
D	Extremely white +	Colorless
E	Extremely white	
F	Very white +	Almost colorless
G	Very white	
H	White	
I	White, but having light coloration	Lightly colored
J		
K	White with coloration	
L		
M	Colored	Weakly colored
N		
O		
P		
Q		
R		
S		Having light coloration
T		
U		
V		
W		
X		
Y		
Z		

2. *Scale of orders (ranks of magnitude)* used in cases of variation of the module of property of the object. Its use permits to identify the interrelation of modules of the measured characteristic in terms of "more" or "less". In some cases, such scales have the null-point of indication, but it is impossible to specify the grade of this type variation numerically because of absence of units of their measurement. The example may be

intensity of coloration of diamonds: it is possible to find what of these ones has the more intense color, but the difference in intensity of coloration cannot be expressed quantitatively because of differing of their tints, so, to characterize the property, one has to use the standardized materials ranked conditionally by this characteristic as seen from the same Table 2.1 above.

3. *Scale of intervals (differences)* permits to classify the measured values by notions of equivalence, degree and additivity, and is character by sameness of intervals and existence of units of measurement. Such scale has the zero-point chosen voluntarily, e.g. the scale of chronology, and the one of characteristic features of such type scales is possibility of quantitative comparison of intervals of normalized values (properties).

4. *Scale of ratio* characterizes the measured properties of objects by criterions of equivalence, order, additivity and, in many cases, proportionality. This is, for instance, the scale of temperature. This type scales are character by normalization of values of units of measurement by consent of the interested parties and existence of the univocal criterion of zero-point in the origin of coordinates. The values identified in this type scale systems are subordinated to all arithmetic operations.

5. *Absolute scale*. This is the scale that possesses by all characters of the scale of ratio, but is character also by the standardized coefficients of identification of units of measurement, e.g. their amplification factors.

The scales of appellations and orders are named as the *non-metrical*, and the scales of intervals and ratio – the *metrical* ones.

Historically, almost all values of units of physical magnitudes were taken from nature, for instance, of dimensions of human body. These are units of width of finger (inch), width of palm (palm), length of foot (foot), distance from elbow to the end of middle finger (elbow) and the distance between the ends of middle fingers of stretched arms (sajene). However, such quantitative expressions were not unequivocal because of differences in dimensions of human bodies. Therefore, it is not surprising that values of units standardized as early, as in ancient times, differ one of other, though have the same appellations. Moreover, the number of systems of measurement used in earlier time became the more as the time

goes by. For example, the first edition of handbook of *"Taschenbuch der Munze, Maas und Gewichtkunde, der Weschel-, Geld und Fondcurse u.s.w. fur Kaufleute"* (Germany, 1762), listed 56 systems of measures, but the 20th edition of the same book (1892) informed on more than 700 of that time systems.

The great variety of units of measurement standardized in multiple systems impeded the progress of global system of barter. Thus, there arose the necessity of introducing of the uniform system of measures and the uniform principles of measurement to be used internationally, what lead to origination of new science – the *metrology*, which appellation was composed of two Greek words of *μετρον – measure*, and *λογοξ – doctrine* used in meaning of "*science on measures*". As defined the global organization responsible for development and safe keeping of units of physical magnitudes, the *International Bureau of Weighs and Measures (BIPM* in French abbreviation: *Bureau International des Poids et Mesures*), metrology is the science on principles of measurement, units of measurement, methods of measurement, means of measurement, which norms are attributed both in theoretical and experimental spheres of human activities in this sphere.

> *State metrological system means the complex of legal, normative and technical deeds, which represents itself the documented organizational and scientific structure of metrological activities in assuring of the uniform conditions of carrying out of measurements in the State*
>
> *Measurement means the process of experimental determining of values of physical magnitudes carried out with use of special technical means*
>
> *Method of measurement means the complex of the normalized consecutive procedures of measurement, which execution ensures obtaining of objective results character by the guaranteed precision*
>
> *Attesting of method of measurement means the work in identification of conformance of used procedures of*

measurement to their normalized parameters done in the normalized sequence of execution

The precision and reliability of results of measuring have to be expressed in presenting of the mean value of the measured property together with the value of *error of measurement*. Summarizing the information, one should note that the principal problems of metrological science are:

- development of general theory of measurement,
- establishing of units of measurement and systems of expression of physical magnitudes,
- development and validation of standards (not the documents, but the materials of standardized composition and/or properties) and exemplary means of measurements,
- development of methods of passing of values of units of measurements from the exemplary means of measurement to the operative ones,
- development of methods of determining of precision of measurements,
- development of fundamental principles of ensuring of uniformity of measurement.

Uniformity of measurements means the characteristic of quality of measurements, which permits to express the results of measurements in generally accepted legalized units of magnitude divisible in set limits in dimensionality of units of physical magnitude reproduced by the primary etalon of measured value with errors of measurement, which do not exceed the set limits

The principal norm of operation in sphere of metrology is assuring of trustworthiness of results of measurement character by certain level of its *uncertainty* interpreted in the *International Vocabulary of Basic and General Terms in Metrology (VIM)* as:

Uncertainty means the notion used in various spheres of science and economy, e.g. in physics, statistics, engineering and information technologies, in purposes of forecasting of

reliability of results of physical measurements, whether executed in earlier time or to be done in future

The fact of origination of variability of measured values, which range of representation is expressed in their mean value given with the uncertainty of measurement origins of numerous causes including the following ones:

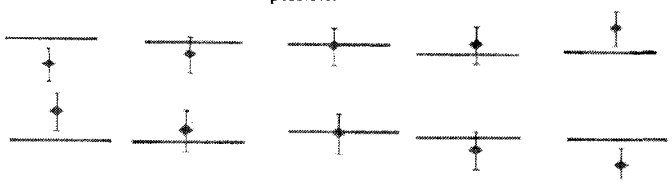
- imperfection of means and methods of measuring of values of tested objects,
- non-representative extracts of results chosen to count the uncertainty of measurement,
- variation of climatic factors of the environmental surrounding in process of measuring,
- imperfection of used means of measurement by criteria of their resolution and sensitivity,
- influence of subjective factors on results of measurement,
- approximations and assumptions committed by the operator in counting of results of experiment, etc.

The parameter of uncertainty is used in evaluation of grade of coincidence of value of the measured parameter to its normalized value, and the criterion of conformance used in it is:

Case 1	Case 2	Case 3	Case 4	Case 5
The measured result is under the upper limit, even when the extended upward by half of the uncertainty interval The product therefore complies with the specification	The measured result is below the upper limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state compliance. However where a confidence level of less than 95 % is acceptable, a compliance statement may be possible.	The measured result is on the limit itself; it is therefore not possible to state compliance nor non-compliance. However, where a confidence level of less that 95 % is acceptable, and the specification limit is defined as $\leq$, a compliance statement may be possible. When the specification limit is defined as $<$, a non-compliance may be possible.	The measured result is above the upper limit but by a margin less than half of the uncertainty interval; it is not possible to state non-compliance. However where a *confidence* level of less than 95 % is acceptable, a non-compliance statement may be possible.	The measured result is beyond the upper limit, even when extended downwards by half of the uncertainty interval. The product therefore does not comply with the *specification*.

Specified upper limit

Specified lower limit



Case 6	Case 7	Case 8	Case 9	Case 10
The measured result is above the lower limit, even when extended downwards by the half of the uncertainty interval. The product therefore complies with the specification.	The measured result is above the lower limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state compliance. However, where a confidence level of less than 95 % is acceptable, a compliance statement may be possible.	The measured result is on the limit itself; it is therefore not *possible to state* compliance nor non-compliance. However where a confidence level of less than 95 % is acceptable, and the specification limit is defined as $\geq$, a compliance statement may be possible. When the *specification* limit is defined as a non-compliance statement may be possible.	The measured result is below the lower limit, but by a *margin* less than half of the uncertainty interval; it is therefore not possible to state non-compliance. However, where a confidence level of less than 95 % is acceptable, a non-compliance statement may be possible.	The measured result is beyond the lower limit even when extended upwards by half of the uncertainty interval. The product therefore does not comply with the specification.

= measurement result with agreed method

= uncertainty interval of agreed method

The key concept of metrology in measurement is assurance of *metrological traceability* reached the most often by means of calibration

of testing equipment, i.e. collation of power of signals of the operative measuring equipment with the indications of exemplary means of measurement in measuring of the standardized parameters, defined in *VIM* as:

> *Traceability of measurements is the property of the value of the measured parameter to be calculated in use of unbroken chain of collations, where the precision of each one may be identified with use of standards of the highest precision*

To prove observance of norms of traceability, the experimenter has to document the whole process of measuring of value in question and provide the clear description of the set of comparisons used in it. To witness the trueness of traceability, there have to be used such elements as:

- clearly defined parameter to be measured,
- complete description of the used system of measurement,
- clearly stated result of measurement indicated with its uncertainty,
- completely specified reference materials and standards used in the experiment,
- authentic program of assuring of trustworthiness of measurements necessary for identification of sufficiency of status of used system of measurement and working standards for the moment of carrying out of the experiment.

To make the process of measurement traceable, the experimenter has to use the technique of collation of parameters of the same value measured by two or more independent methods of measurement in the whole diapason of their validity. The example is measuring of distance between two layers of atoms of crystal by methods of x-ray irradiation, and its bombardment by beam of electrons. Assuring of traceability permits to identify the level of confidence to results of measurement, whether the person of economy obtained them presently, or some time before, or the analogous measurements were carried out in any other region.

The principal branches of metrological science are the *legislative*, *scientific* and *industrial* metrologies.

Legislative metrology means the branch of metrological science, which sphere of responsibility is development of means of expression of values of units of measurement, methods of measurement, means of measurement and procedures of work of measuring, testing and calibration laboratories

Scientific metrology means the branch of metrological science related to the spheres of development of general theory and practice of use of units of measurement, studying of properties of means of measurement and methods of representation of uncertainty of measurement

Industrial metrology normalizes the practice of everyday measurements carried out in processes of manufacturing of production and inspection of its quality. The typical works executed in this sphere are calibration of means of measuring technique, metrological control of processes of manufacturing and their results, as well as procedures of use of measuring equipment.

2.2 Units of Physical Magnitudes

The practice of business operation needs therefore the continuous measuring of values of *physical magnitudes*, which are understood in metrology as the characteristic parameters of the objects (phenomenon and/or processes) common for their whole totality in qualitative expression, but individual for each one quantitatively. The elements of metrology appeared since the ancient times in form of use of units of dimensionality of physical magnitudes recognized by the community. If so, there has to be established the system of their normalization used in the whole territory of the country. The correct measuring of values of physical magnitudes is one of the crucial problems of metrology to be solved in way of unification of units of measurement and development of systems of reproduction and passing of their normalized values to the operable means of measurement.

The measurement carried out by different experimenters even in use of correctly chosen instruments of the same time would not obligatory give the equal result, for the condition to be observed in it is the obligatory

observance of norms of *uniformity of measurements*, which observance would permit to compare the results of measurements done in different places with use of different equipment and different methods of measurement carried out in different time but in use of the same units of physical magnitude and same principles of measurement.

The first known means of support of metrological needs of the society became *standards of comparison (etalons)* of length, time and mass, which values were approved by deeds of bodies of local or regional administration. The measures they legalized were usually the dimensions of everyday use items or the human body. For example, Charles the Great, Emperor of the Holy Roman Empire (768–819), fixed the length of his foot as the basic measure of length named as *"king's foot"*, and British king Henry the First (1100–1135) fixed the basic measure of *"ell"* equal with the length of his scepter.. Similarly, the British king Edward the First issued in 1324 the law, which prescribed to regard the length of three round and dry grains of barley placed in the raw by their length as an inch.

Based on such kind magnitudes, there were legalized the reference standards of length made of metal rods safe kept in strictly guarded State buildings (some kind of that time *"chambers of measures and weighs"*). The ancient Israelites stored their basic measure of length in the main temple in Jerusalem, and Romans – in Rome in Capitol. However, as the time goes by, the standards wear off in their collations with the operating standards of physical magnitudes and there arose the periodical necessity to reproduce their initial dimensions (values) in the new-made etalons. In most cases it was impossible to keep the highest precision in this job, and dimensions of new standards were not precisely equal with those of earlier ones. That is why the humanity tried to found the basic standards, which dimensions (values) may be reproduced with the maximally possible precision.

However, the universal introduction of modern principles of measurement hampered use of differing units of physical magnitudes in different countries and even in different regions of the same country. The attempts to spread the norm of use of uniform units of measurement worldwide were begun in medieval France. It was the end of XVI century,

when there was mounted the ferrous caliber on walls of the ancient Paris castle near its heavy gates (Figure 2.1):

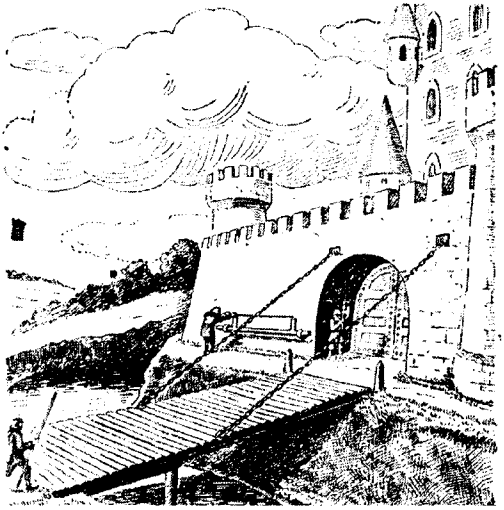


Fig. 2.1 The iron rod mounted on the wall of the castle — French tuaz

The size of tuaz, which was that time basic unit of measurement in France, was equal to the the length of the rod placed tightly between the end points of this caliber. Its length was subdivided in 6 feet, the feet – in 12 inches, and the inch – in 12 lines. It was believed that collating of length of operative standard of tuaz with the length of the State etalon would permit to produce the following measurements in its use with the precision of 0.05 line (of about 0.1 *mm*) in one tuaz. There were made also some the reference copies of tuaz, and two of these ones were used in 1735–1737 in determining of length of 1 arc degree of the Peruvian meridian of the Earth. These etalons were conveyed to Paris, and the unit, which value was found with their use, was approved as the French national standard of length named as *Peruvian tuaz*. The used caliber represented itself the forged polished ferrous rod of rectangular cross-section of 40.1×77 *mm* used up to the time of introduction of metric system of units in 1790-s. The calibrated distance of one tuaz was marked on one of its sides by two points of P' and P" and the second side of the

etalon had the figured shape, and the distance between its two end surfaces (E' and E'') represented also the same unit. (Figure 2.2):

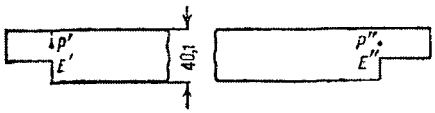


Fig. 2.2Peruvian tuaz

The end of XVI century was character by differentiation of directions of development of physical knowledge and numerous attempts to establish the scientific substantiation of processes of measurement, what became the first systematical work put in the base of metrological science. The sufficient contribution in its progress made chemists and physicists in times of scientific and technical revolution in Europe in period began in epoch of late Renaissance and up to the end of XVIII century. In progress of knowledge character by beginning of mass-production in industry and internationalization of economical relations, there arose the need of comparison of theoretical and experimental results, therefore development of rational system of units of physical magnitudes. Scientists proposed many variants, especially in France, where Bem proposed as early as in 1771 to introduce the unit of length represented by the path, which a physical body passes in a second, the one more fundamental physical magnitude, in free fall in the fixed place. The French scientists Buger and Condamint proposed, in turn, for the same the length of pendulum oscillating with periodicity of one second in the fixed latitude.

However, the first systematical work in development of universal system based on use of metrical units of physical magnitudes changeless in time and linked indivisibly with the fundamental physical constants was began in France in the end of XVIII century when the deputy of French the Constitutional Council of General Assembly of France Talleyrand-Perigord informed in 1790 on pressing necessity of legalizing of the national unit of length. In 1791, the French National Assembly decided in 1791 to introduce the first universal system of physical magnitudes, which included the units of length, area and mass. Following this decision, the French Academy of Sciences appointed the specialized

commission, which presented in March 1792 the proposal to approve the unit of length (*the meter)* as the fundamental constant of universal system of units of physical magnitudes it proposes and recommended to fix its value was the one ten millionth part of one quarter of length of the Earth' meridian (the quadrant). To fix its dimensions, the special commission of scientists, which included such known persons as Berthollet, Coulomb, D'Alembert, Lagrange and Laplace, measured the length of arc of meridian between Dunkirk and Barcelona and published results of this work in the editions of the *"Base du système métrique décimal, ou mesure de l'arc du méridien entre Dunkerque et Barcelone" (Paris, Vol.1, 1806; Vol. I, 1807; Vol. III, 1810*). The first known international standard of meter was made in the beginning of XIX century (see Figure 2.3 below):

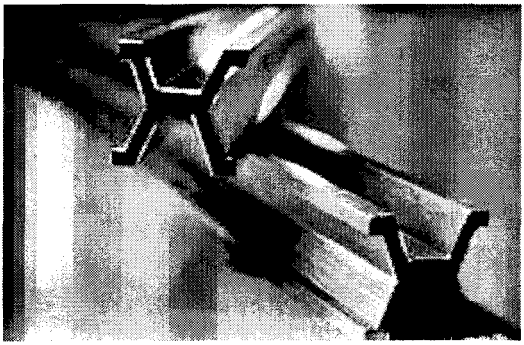


Fig. 2.3 Historical prototype of meter

After this work was finished, the French Academy of Sciences appointed the commission, which principal job was development of new unit of mass taken as the mass of one cubic decimeter (one thousandth part of cubic meter) of distilled water at temperature of its maximum density taken from river Seine near Paris. The standards of meter and kilogram were recognized in category of international units of measurement and put on storage in National Archive. The possibly precise copies of French national units of physical magnitudes were recognized as the international standards and put in storage in *Bureau des Longitudes* in Sevres near Paris.

The metric system became gradually the obligatory for use in most countries, first in Germany (1872), Mexico (1874), Denmark, Egypt, Portugal, Spain, Sweden, Switzerland, Turkey (1875), Austria-Hungary, Belgium, Italy, Netherlands (1876), and the practice of measuring, hence use of set of units of physical magnitudes required of their normalizing in equations of interdependence of their standardized values, hence development of regular system of units of measurement. The first systematical one, which represented itself the complex of basic and derived units of magnitudes proposed in 1832 the German scientist K. Gauss. The basic units of magnitude in it were millimeter, milligram and second. In progress of physics and technique, there were established some new modifications of metric system differing one of other because of differences of series of basic units of physical magnitudes taken as a base. The basic notions used in expressing of their values and systems may be formulated as follows.

> *System of units of measurement means the aggregate of basic and derived units of physical magnitudes, which interrelations are represented by equations of their interdependence*
>
> *Basic physical unit means the unit of physical magnitude, which value does not depend of values of other physical units of used system*
>
> *Derived physical unit means the unit of the system of physical units of measurement, which value is expressed as the combination of its basic units taken in respective powers*

In the Russian Empire, the metrological science progressed in specific conditions because of existence of three parallel systems of standardized units of measurement – the specific national, British and metrical ones. Following this phenomenon, Russia legalized in 1894 by proposal of D.I. Mendeleyev the standard of length, which had configuration of three-rayed star. One of its bounds was marked, respectively, by the size of arshine, the second – of yard, and the third – by the unit of meter. The Russian empire used the metric system of physical magnitudes optionally, in parallel with two others, but use of the

latter ones was abolished in 1918 by the Decree of Council of People' Commissars of Soviet Russia *"On introduction of international metrical system of measures and weighs"*.

The principal problems of metrological science are producing of maximally precise etalons of units of measurement and their use in determination of numerical values of properties of tested objects. The basic stages of their producing are:

- determination of value of unit of magnitude based on use of fundamental physical constants, such as absolute zero, point of crystallization of water in the standardized conditions etc., or its fixation on the base of the international consensus,
- materializing of the State (international) etalon of such unit and designation of its attested value,
- calibration of lower-rank etalons by passing them of the attested value of characteristic parameter of the State (international) standards.

The basic units of any system of physical magnitudes are named as the *system-formatting (meter, kilogram, etc.)*, and those that are not in its structure and cannot be expressed with use of basic units – the *non-system-formatting ones (liter, calorie etc.)*. The magnitudes, which efficient have one or more indices of dimensionality, are named as the *dimensional magnitudes* (velocity, density), and those that have no dimensionality – the *dimensionless* ones (e.g. hardness).

> *Dimensionality of physical magnitude means the monomial, which includes the multipliers of symbols of basic units of magnitudes in respective powers and reflects their correlation with the units of used system of physical magnitudes*

The dimensionality of physical magnitude is symbolized as dim (shortened of *dimensionality)*, and the dimensionality of magnitude X in the system of units of L, M and T, for instance, will be:

$$dimX = L^l M^m T^t \ldots ,$$

where $L, M, T \ldots$ – symbols of units taken in this system as the basic ones

l, m, t ... – numbers, whether positive or negative, which show the powers of dimensionalities of basic units that constitute the dimensionality of the unit of physical magnitude expressed in the equation above

2.3 International System of Units of Physical Magnitudes

The existence of numerous systems of units of physical magnitudes used in earlier time complicated the uniform interpreting of results of measurement because the equations of interdependence of various physical magnitudes expressed in different systems use in most cases the differing units of measurement and coefficients of their proportionality, e.g. the systems of electric *(CGSA: centimeter – gram – second – Ampere)*, luminous *(CGSL: centimeter – gram – second – lumen)*, engineering (MKGFS*: meter – kilogram of force – second)*, caloric (*CGSC centimeter – gram – second – Celsius degree)* systems of units, etc. Besides, there were extensively used the *"out-of-system"* units: calorie, horsepower, kilowatt-hour, bar and so on. Therefore, there arose the understanding of necessity of unification of units of physical magnitudes in the system common for use in all spheres of human activities. As a result, the *International Committee of Measures and Weighs* founded the commission, which principal job was development of international system of units of physical magnitudes to be used worldwide.

Based on results of its work, the 10th *General Conference by Measures and Weighs* approved in 1954 the *basic* units of new system, and the 11th General Conference by Measures and Weighs held in 1960 gave this system the name of *International System of Units of Magnitudes* having the acronym of *SI* (*Le Systeme Internationale d'Unites* in French), used in all spheres of science and technique, which dimensionality cannot be deduced in use of other units of physical magnitudes. These ones were the units of mechanics and time (meter, kilogram, second), strength of electric current (Ampere), thermodynamic temperature (Kelvin) and luminous intensity (candela).

As early as in 1960, the system was completed by two subsidiary units of plane angle of *radian* and space angle of *steradian*, and forming of the system was finalized in 1971 with the approval of basic unit of quantity of substance of *mole*. Table 2.2 gives the modern list of *SI* basic units:

Table 2.2

Basic and subsidiary units of SI system

Property	Unit		
	Name	Symbol of dimensionality	
		Ukrainian	International
Basic units			
Length	meter	м	m
Mass	kilogram	кг	kg
Time	second	с	s
Strength of current	ampere	А	A
Thermodynamic temperature	Kelvin	К	K
Luminous intensity	candela	кд	cd
Quantity of substance	mole	моль	mol
Subsidiary units			
Plane angle	radian	рад	rad
Space angle	steradian	ср	sr

Time unit (second) means the duration of 9,192,631,770 periods of emanation resulting in transition of electron among two ultra-thin levels of the basic state of atom of Cesium-133.

Length unit (meter) means the length of path of running of light in vacuum at 1/299,792,458 part of the second.

Mass unit (kilogram) means the mass of the international prototype of kilogram.

Unit of strength of electric current (Ampere) means the value of the permanent current, which generates the force of magnetic interaction of 2×10^{-7} N on each meter of two straight extremely long round conductors of the infinitely small cross-section located in vacuum in distance of 1 meter between.

Unit of thermodynamic temperature (Kelvin) means the 1/273.16 part of thermodynamic temperature of the triple point of water (it is permitted also to use in the SI system the Celsius scale, which unit is equal with the Kelvin unit value).

Unit of luminous intensity (candela) means the intensity of monochromatic radiation of frequency of 540×10^{12} Hz emanated in the set direction with the energetic power of 1/683 *W/sr*.

Unit of quantity of substance (mole) means the quantity of substance, which contains as many structural units as the quantity of atoms of Carbon-12 having the mass of 0.012 *kg*.

Radian (rad) is the unit of the plane angle formed by two radii of the circle that turn on points, which form the arch of length equal with the length of radius of said circle. The units used in quantitative measuring of plane angles are the angular degrees, minutes and seconds, and the value of the angle of 1 *rad* is 57°17'44.8''.

Steradian (sr) is the unit equal to the space angle of Ω, which have the apex in the center of the sphere and cuts the area of its surface equal numerically to its squared radius (65°32'). There are absent the instruments, which permit to measure the space angles in steradian units, therefore their dimensions may be calculated only in use of formula of:

$$\Omega = 2\pi [1 - \cos \alpha/2]$$

where α is the plane angle at the summit of the cone inscribed in the sphere.

The subsidiary angular units are used only in theoretical calculations and deducing of derived units of measurement (angular velocity, angular acceleration etc.). The principle used in approval of such units was selection of those ones that were used in earlier time and have values convenient for use. Based on listed units, the XI and XII General Assemblies of the Conference on Measures and Weighs approved 33 subsidiary units of physical magnitudes (Table 2.4) formed by the algebraic operations of multiplication and division of the basic SI units used in all branches of science and technique:

Table 2.4

Some of derived units of SI system having own names

Physical magnitude	Unit name	Expression of the unit	
		using other SI units	using basic units of SI system
Frequency	Hertz	-	s^{-1}
Intensity	Newton	-	$m \cdot kg \cdot s^{-2}$
Pressure	Pascal	N/m^2	$m^{-1} \cdot kg \cdot s^{-2}$
Energy, work, quantity of heat	Joule	$N \cdot m$	$m^2 \cdot kg \cdot s^{-2}$
Power, energy flow	Watt	J/s	$m^{-1} \cdot kg \cdot s^{-3}$
Quantity of electricity	Coulomb	A s	$s \cdot A$
Voltage, electric potential	Volt	Wt/A	$m^2 \cdot kg \cdot s^{-3} \cdot A^{-1}$
Electrical capacity	Farad	Cb/V	$m^{-2} \cdot kg^{-1} \cdot s^4 \cdot A^2$
Electric resistance	Ohm	V/A	$m^2 \cdot kg \cdot s^{-3} \cdot A^{-2}$
Electrical conductivity	Siemens	A/V	$m^{-2} \cdot kg^{-1} \cdot s^{-3} \cdot A^2$
Magnetic induction	Tesla	Wb/m2	$kg \cdot s^{-2} \cdot A^{-1}$
Flow of magnetic induction	Weber	$V \cdot s$	$m^2 \cdot kg \cdot s^{-2} \cdot A^{-1}$
Inductivity	Henry	Wb/A	$m^2 \cdot kg \cdot s^{-2} \cdot A^{-2}$
Luminous flux	lumen	-	$cd \cdot sr$
Luminosity	lux	-	$m^{-2} \cdot cd \cdot sr$
Nuclei activity	Becquerel	Bq	s^{-1}
Irradiation dose	Grey	Gy	$m^2 \cdot s^{-1}$

To express the bigger/smaller values of all of these magnitudes, one has to use adapters, which existence means that the value of the attributed unit must be multiplied or divided by certain integral number (the power of number of 10). For example, the adapter of *"kilo"* means multiplication of the value of the unit by factor of 10^3 (kilometer = 1000 meters), *"milli"* – multiplication by factor of 10^{-3} (millimeter = 0.001 meter). The denotation of indices of powers of multiple and partite units used in modern terminology gives the Table 2.3:

Table 2.3

Multipliers and adapters, which form the divisible and partial units of physical magnitudes, and their designations

Multiplier	Prefix	Designation of adapters	
		International	Ukrainian
10^{18}	eksa	E	Е
10^{15}	peta	P	П
10^{12}	tera	T	Т
10^{9}	giga	G	Г
10^{6}	mega	M	М
10^{3}	kilo	k	к
10^{2}	hecto	h	г
10^{1}	deca	da	да
10^{-1}	deci	d	д
10-2	centi	c	с
10-3	milli	m	м
10^{-6}	micro	μ	мк
10^{-9}	nano	n	н
10^{-12}	pico	p	п
10^{-15}	femto	f	Ф
10^{-18}	atto	a	а

The *SI* system found the unprecedented use, and the only states, which had not introduced the SI units yet, are Liberia, Myanmar and USA. The United Kingdom accepted this system too, but has no intentions to replace with it the traditional system of British units of magnitudes, but to introduce the new system in parallel use.

The General Conference by Measures and Weighs took also the decision on *"permittance of use"* of some units absent in the list of *SI* systemic units (Table 2.5):

Table 2.5

Out-of-dimension units of physical magnitudes allowed for use in parallel with CI units

Unit	International abbreviation	Value in CI units
Minute	min	60 s
Hour	h	60 min = 3600 s
Day	d	24 h = 86 400 s
Angular degree	°	(π/180) rad
Angular minute	′	(1/60)° = (π/10 800)
Angular second	″	(1/60)′ = (π/648 000)
Liter	l, L	1/1000 m^3
Tonne	t	1000 kg
Neper	Np	dimensionless
Bel	B	dimensionless
Electronvolt	eV	≈1,602 177 33·10−19 J
Unified atomic mass unit, Dalton	u, Da	≈1,660 540 2·10−27 kg
Astronomical unit	ua	≈1,495 978 706 91·1011 m
Nautical mile	M	1852 m
Knot	kn	1 nautical mile = (1852/3600) m/s
Are	a	10^2 m^2
Hectare	ha	10^4 m^2
Bar	bar	10^5 Pa
Angstrom	Å	10^{-10} m
Barn	b	10^{-28} m^2

The international metrological organizations may also take decisions on temporary and/or permanent use of other units of magnitudes, whether basic and/or derived ones.

The norm of use of magnitudes normalized by the International System of Units of Physical Magnitudes in Ukraine introduced the standard of GOST 9867-61 *"International system of units [of magnitudes]"*. The interstate standard of GOST 8.417-2002 *"GSI. Units of magnitudes"* permitted also to use the units of *grad, light year,*

parsec, diopter, kilowatt-hour, volt-ampere, var, ampere-hour, carat, tex, gal, revolution per second, revolution per minute, as well as relative and logarithmic units, such as *percent, per mille, millionth part, fon, octave, decade*, and units of time, e.g. *week, month, year, century, millennium*. Besides, the regulations of system SI allow to practice the units specific for certain spheres of technique and science, which may be subdivided conditionally by categories as follows: 1) units used together with the SI basic units (kilometer per hour, kilowatt-hour etc.), 2) units permitted for use temporarily and have to be abolished in future, 3) units non-recommended for systematical use. Ukraine, in turn, recommended for the practical use the following units of physical magnitudes:

1) basic *SI* units:
   - *meter* as the unit of length,
   - *kilogram* as the unit of mass,
   - *second* as the unit of time,
   - *ampere* as the unit of strength of electric current,
   - *Kelvin* as the unit of thermodynamic temperature,
   - *candela* as the unit of luminous intensity,
   - *mole* as the unit of quantity of substance.
2) derived *SI* units,
3) decimal, multiple and partial *SI* units,
4) units not used in *SI* system but allowed for use by the State Service of Technical Regulation and Consumer' Policy of Ukraine,
5) combinations of *SI* units and units permitted for use as non-dimensional ones.

The principal advantages of use of SI norms are:

- *unification* of units: each physical magnitude is expressed in use of one unit only,
- *universality*: the system permits to use its units in all branches of science, technique and economy, e.g. *joule* is the unit of mechanical and electrical power simultaneously. Contrary to

previous practice, the System uses the differing units of mass (kilogram) and force (newton),

- *co-ordination:* all derived units are constituted by the same rule, what excludes origination of coefficients in formulas and simplifies calculations,
- *possibility of establishing of new derived units* on base of existing ones in progress of science and technique,
- *suitability:* all basic and most of derived units are of size handy for use.

The units of SI system have their own appellations (see the SI brochure of *"International metrological vocabulary"*, ISO 80000). The general principles of orthography of units of physical magnitudes, including the units of the system SI in development were introduced as early as in 1948 by the Sixth General Conference by Measures and Weighs as follows:

- appellations of units have to be written by the straight print, what should differ them of designations of physical magnitudes, which have to be given in italics, e.g. m (unit of meter) and *m* (mass),
- to avoid mistakes and uncertainties, it is prohibited to use the shortened appellations of SI units instead of their official contracting, e.g. sec. instead of s, or sq. m instead of m^2,
- it is prohibited to combine the designations of units with their full appellations: shortening km/hour is incorrect, it should be used the symbol of km/h,
- the designations of units have to be written by small characters, if they were not formed of personal names, but the first character of its shortened designation is always capital. At the same time, if their appellations are written in whole, all their letters have to be small, e.g. 2 N, but 2 newton; 200 μF, but 200 microfarad,
- the symbols of units should be placed after their numerical values using the blank, e.g.
  10 m/s, 15 °, and carryover of their designations is prohibited,

- one can use the symbols of units in form of product of their designations in respective powers (positive and negative): $Wt \cdot m^{-2} \cdot K^{-1}$, $A \cdot m^2$,
- if the numerical value of the unit is represented by fraction having the slanting line, this one has to be put in brackets, e.g. $(1/60)\ s^{-1}$. The mark of division has to be represented usually by the slanting or the horizontal line. In use of slanting line and placing of product of units in denominator, this one has to be given in brackets, e.g. the correct symbol is $Wt/(m \cdot K)$, and the incorrect one – $Wt/m \cdot K$,
- the values of units given with indication of limiting deviations have to be given in brackets seconded by their symbols, otherwise symbols of units have to be written in both cases, i.e. after the averaged value of the parameter and the index of its deviation: $(100{,}0 \pm 0{,}1)\ kg$ and $50\ g \pm 1\ g$,
- the prefixes, if used, have to be placed before the appellation of the basic unit and written with it in one word, i.e. kilogram, millimeter,
- the designations of units are mathematical expressions, not their contractions. Therefore, it is prohibited to put the point after their appellations except of cases of location in the end of the sentence,
- in multiplying and division of units, there have to be used the generally accepted algebraic rules of multiplication and division. The operation of multiplication has to be shown by the blank or the point put in the middle of height of the line: (·). It is prohibited to use in this purpose the sign of multiplication of "×". The operation of division has to be shown by the horizontal or slanting line, or the negative index of power, e.g. $N\ m$, or $N \cdot m$ for multiplication, and m/s or $m \cdot s^{-1}$ – for division. In need of combining of some units in groups, it is necessary to use brackets or negative indices of power to avoid the uncertainty in their reading. Besides, the slanting line must not be used in one formula twice or more times, e.g. the correct writing would be $kg/(m \cdot s^2)$, or $kg \cdot m^{-1} \cdot s^{-2}$, but not $kg/m/s/s$.

At the same time, the titles of units may be written and enunciated in different languages, for instance, *kilogramme* in French, *kilogram* in English, *quilograma* in Portuguese, *cilogram* in Welsh, *килограм* in Bulgarian, *χιλιόγραμμο* in Greek, 千克 in Chinese, キログラム in Japanese. The countries of former Soviet Union and Mongolia, which use the Cyrillic and national alphabets, introduced also the symbols based on use of appellations of units of magnitude in national spelling, e.g. *"килограмм" (кг)* російською, *"кілограм" (кг)* українською, *კილოგრამი (კგ)* грузинською.

2.4 Etalons of Units of Physical Magnitudes

The etalons (materials of the standardized composition, standard reference materials) of units of physical magnitudes mean the objects used as the official reference standards of properties (compositions) used in purposes of obtaining of results of measurement the maximally close to real values of the measured properties (compositions).

> *Etalon means the object used in transmitting of its standardized property to means of measuring technique, as well as the standard reference material used in reproducing of said parameter in process of measurement*

The one of basic requirements to quality of the etalon is precision of attesting of the parameter to be referenced with the minimal uncertainty in calibration of the reference and operational means of measuring technique. There exist some gradations of precisions of reference materials, e.g. the standards of State category used in attesting of properties of materials with the highest precision in the State, and the international ones.

> *State etalon of unit of physical magnitude means the item, which value was recognized by decision of the authorized State body as the material, which attested property has the highest precision in the whole country*

International etalon means the item, which attested characteristic is the international norm used for adjusting with it the State etalons of countries worldwide

The etalons differ by the primary, secondary and initial classes of precision:

Primary etalon means the material used in reproduction of value of its attested property (parameter) with the highest precision in the State

Secondary etalon means the material, which is character by the attested property (composition) standardized with use of the primary State etalon, or in its absence – in use of the respective etalon of the foreign country

Initial etalon means the material character by the most precise metrological property in the set of uniform units of measurement possessed by the State, enterprise, institution or organization

Besides, there exist the *special* etalons used in passing of their attested parameter with the necessary precision (e.g. in extreme conditions: at elevated temperatures, high pressures etc.) instead of primary ones in impossibility (undesirability) of their use. There are known also the *witnessing etalons*, i.e. the materials used for replacement of primary etalons in cases of damage or loss, as well as for the control of their invariability in time.

The one of key problems of metrology is the need of the continuous perfecting of etalons. This problem found its display, for example, in development of etalon of meter fixed initially as one ten-millionth part of the Earth quadrant. However, in progress of science, there was identified incorrectness of the idea put in the base of such assumption: the planet is not the ideal spheroid; moreover, it changed continuously its shape. Respectively, there arose the problem of affixment of dimension of the etalon of this property to the fundamental physical constant – the speed of light in vacuum.

To guarantee the uniformity of measurements worldwide, the International Bureau of Measures and Weighs organizes the scheduled

synchronization and collation of international etalons with their national analogues. This work permits to identify the systematical errors in reproducing of values of physical magnitudes by the State etalons to workable means of measurement, find the grade of their conformance to global standards of precisions of measurement, as well as to identify the need of their in-time replacing.

The character example of such activity is the practice of collation of national standards of mass with the international ones. By decision of General Conference of Measures and Weights, there were produced 42 prototypes of kilogram made of platinum and iridium alloy, which were given its member-states as the national standards of mass stored typically on quartz pedestals covered by two glass cups in the steel safes at 20 ± 3 ^{0}C and relative humidity of about of 65 %. The masses of such standards deviate in general case of the mass accepted as the international unit of physical magnitude. For example, the sample # 12 stored in the Russian Federation has the accepted mass of 1.000,000,087,7 *kg* and is collated once per 10 years with its international analogue and used as the base in normalization of values of other etalons of kilogram used in practice of measurement. The typical result of collation of masses of some national etalons of kilogram with their international analogues shows the Table 2.6:

Table 2.6

Results of collation of masses of national etalons of some countries with the international one

Country	**Number of standard**	**Deviation of mass in two consecutive scheduled collations**, *mg*	
		First collation	**Second collation**
International standard	31	0.162	0.128
France	35	0.191	0.183
Russia	12	0.068	0.085
USA	20	- 0.039	- 0.019
Japan	6	0.169	0.170
Italy	5	0.018	0.018
Switzerland	38	0.183	0.214

In Ukraine, the fundamental principle of the national metrological system is use of complex of State etalons of units of physical magnitudes consisting of 28 items, especially the standards of mass, length, temperature, luminous intensity, time, frequency, energy of combustion, pressure, volume, free fall acceleration, magnetic induction, molar parts of components of gas mixtures. Except of national etalons collated with their international analogues, many of industrial companies/institutions/associations, whether big or small, use their own (internal) etalons, which satisfy their specific needs.

2.5 Measurements as a Base of Metrological Activity

Measuring of value of any property means the work in execution of the consecutive totality of operations, which represent in fact the comparison of indications of operative means of measurement with the value of the respective unit of physical magnitude. There exist three types of measurement based on differing principles as follows.

The *first type* comprises methods based on expression of equivalence and/or ratio of measured values. These are relations of type of *"softer", "warmer", "bigger"* etc. The examples of this type units used in measurement are hardness expressed as the property of physical object to resist to penetration of another object inside, temperature as the process of evaluation of grade of warming etc. Such measurements require of use of special means of comparison, and their results are deduced in monitoring of consequences of influence of the tested object on other ones and/or the instruments used in process of measurement.

The *second type* measurements are character by evaluation of values of measured magnitudes as differences of results obtained in pairs of determinations, e.g. the work in evaluation of equality of gaps between the marks of measuring scale obtained in pair of experiments results in witnessing on equality of measured values.

The *third type* measurements relate to cases of determining of values of the measured properties character by additivity of used units of measurement, as well as calculation of their values by addition or extraction of differences of measured values to those ones that were

obtained in previous experiments. These ones are parameters of length, mass, intensity of current etc. measured in parts and represented as the summarized multivalued magnitude of their individual constituents. For instance, the sum of masses of two objects is equal to the mass of another one of known mass balanced with them on the equal-arm balances.
The basic notions used in measurements are:

- *measuring instruments* are the means of measurement used for finding and representing of results of measurements in form available for direct understanding,
- *methods of measurement* means the totality of means of measurement used in the chosen method of experiment,
- *result of measurements* means the value of the magnitude found experimentally.

The metrological science differ the notions of true and real values of physical magnitudes. The *true* value of physical magnitude reflects the certain property of the object free of errors of measurement. It is impossible however to found the true characteristics of physical objects, for the results of measurements cannot be free of inevitable errors of experiment. So, the values of physical magnitudes found in the measurement it and character by minimum deviation of their true values obtain the appellation of *real* values of physical magnitudes.

Measurements play the crucial role in most branches of economy because they permit to monitor the causes of lack of compliance of concrete parameters to established norms of operation, therefore impossibility of reaching of necessary quality of production. Generally speaking, the process of measuring of physical magnitudes is the multistep process, which includes the stages of measurement proper and the preparatory and finishing work done before and after measurements by stages as follows:

- planning of experiment and carrying out of preparatory procedures,
- carrying out of actions on ensuring of uniformity of measurements,
- carrying out of measurements,

- processing and analysis of results of measurement.

The basic notions used in practice of measurements are:

Principle of measurements means the physical phenomenon or the complex thereof used as the base of measurements (e.g. measurements of temperature in use of thermoelectric effect)

Method of measurement means the complex of principles of measurement to be carried out with use of the attested technical means of measurement

Unit of measurement means the physical magnitude character by the attested value used in quantitative representation of values of the same dimensionality

Error of measurement means the deviation of the result of measurement of true value of the measured physical magnitude

Precision of measurement means the closeness of result of measurement to true value of measured magnitude

Trueness of measurement means the quality of measurement, which reflects the closeness to zero of systematical errors in determination of values of measured magnitudes

Trustworthiness of measurement means the level of confidence to its result. Depending of knowledge or lack of knowledge of value of probable deviation of found experimental characteristics of their true values, the measurements may be trustworthy and non-trustworthy

To find the real value of physical magnitude, the experimenter has to observe the following conditions:

- to choose the property to be measured,
- to choose the unit of measurement to be used in the experiment,
- to ensure reproducibility of result of measurement of the chosen value,
- to be sure in constancy of value of the chosen property in limits of established precision at least during the time of measurement.

The types of measurement may be classified represents the Table 2.7 below:

Table 2.7

Classification of types of measurement

Attribute of classification	Type of measurement
By indices of precision	Uniformly precise, non-uniformly precise
By quantity of measurements	Single, multiple
By grade of variation of value to be measured	Static, dynamic
By metrological destination	Technical, metrological
By method of representing of result	Absolute, relative
By method of obtaining of results of measurement	Direct, mediate, overall, cumulative

Uniformly precise measurements mean the series of measurements carried out in the same conditions with use of instruments of equal precision.

Non-uniformly precise measurements mean the series of measurements carried out in absence of the same conditions of measurement and/or use of the same precision instruments.

Single measurement means the measurement carried out once.

Multiple measurements mean the measurements of the same value of physical magnitude in series of four and/or more single determinations. The result of multiple measurements is the arithmetical mean of results of set of single measurements.

Static measurement means the measurement of physical magnitude carried out in conditions considered as the changeless during the whole time of experiment, e.g. in measuring of length at the stable temperature.

Dynamic measurement means the measurement of physical magnitude, which value is variable in time. This category operation includes the cases of fixation of dynamics of variation of measured properties, e.g. measurements of variation of voltage during the set time.

Technical measurement means the measurement carried out with use of working means of measurement, e.g. measuring of linear dimensions of detail in its processing on the machine-tool.

Metrological measurement means the experiment carried out with use of reference materials and standardized means of measurement done in purposes of transmitting of their standardized characteristics to working means of measurement.

Absolute measurement means the experiment based on direct measuring of value of the magnitude to be used in calculations with use of fundamental physical constants, e.g. determining of force of pressure of detail on the surface *(F)* based on measuring of mass and constant of free fall acceleration *(g)*.

Relative measurement means the measurement of ratio of modules of values of measured magnitudes.

Direct measurement means the identification of value of unknown parameter, e.g. measuring of length with use of the ruler.

Mediate measurement means the experiment carried out indirectly. The unknown value of physical parameter is determined in this case on base of results of direct measuring of physical magnitudes coupled with the unknown parameter functionally, e.g. on determining of volume of the cylinder by its height and diameter.

Cumulative measurement means the measuring of two or some dissimilar values of the same physical magnitudes carried out in one time in purposes of determining of their interdependence, e.g. measuring of length of the pattern of material at different temperatures to calculate the coefficient of its thermal linear expansion.

The basic principle of each measurement is comparing of its result with the value normalized as the attributed unit of measurement. As the metrology postulated, the *quality of measurement* means the complex of its properties centered on guaranteeing of trustworthiness of results of experiment obtained in certain space of time, and the main its constituents are precision, reproducibility and uniformity of results of measurement.

The precision of measurement means the grade of coincidence of results of measuring of the same parameter at the same conditions of

experiment (temperature, humidity, pressure etc.) carried out by different operators in different places, by different methods and in different time. *Reproducibility* of results of measurements means their closeness to one other in measuring of the same parameter repeatedly or many times at similar conditions, by the same operator and in use of the same means and method of measurement. The observance of conditions and precision of measurements guarantees use of the State etalons and realization of the complex of attributed norms of measurement and methods of their execution. The instrument of control of possibility of reaching of the set precision of measurement is *verification* of technical means used in measurement by the State control bodies.

> *Verification of means of measuring technique means the identification of appropriateness of instruments subordinated to the State metrological supervision to preserve their normalized metrological characteristics in use by destination*

The means of measuring technique subordinated to verification of the State control bodies are:

- imported, just produced, repaired and operating means of measurement to be verified in planned manner,
- means of measuring technique used by the State institutions, which operate testing, metrological attestation, verification and calibration of means of measurement,
- etalons used by metrological centers, territorial bodies, organizations and enterprises.

The services in verifying render the State metrological centers and accredited legal persons, which obtain this right in possessing of necessary etalons and exemplary means of control of metrological characteristics of means of measurement. In appropriateness of the verified means of measurement for exploitation, the responsible control person marks it by special stamp, which witnesses its verification and/or issues the *"Certificate of verification"*. There exist the following types of such control:

- *initial verification* carried out just after manufacturing, repair, and importing of means of measurement,
- *periodical verification* to be carried out after expiring of the scheduled period of their exploitation,
- *inspectorial verification* to be carried out in process of planned and extraordinary metrological control of workability of measuring equipment,
- *extraordinary verification* to be carried out in cases of:
  - damage of sign of verification, and/or losing of certificate of verification,
  - putting of means of measurement in operation after their non-operation in period, which duration was longer of the normalized term of verification,
  - tuning of means of measuring equipment done after their verification, shocking and cases of unsatisfactory operation.

Etalons of composition and properties used by bodies of the State Metrological Service, as well as the means of measurement not subordinated to attestation have to be controlled by the State metrological centers once just after manufacturing. At the same time, some of means of measurement subordinated to periodical metrological control but not verification have to be exposed to procedure of *calibration* with use of exemplary means of measurement carried out by metrological services of legal persons. The word *"calibration"* was used first in the time of US Civil War of 1861-1865. Initially, it was the artillery term, but presently the International Bureau of Measures and Weighs interprets it as *"the process of finding of interconnection of indications of exemplary or verified secondary means of measurement with those of the controlled means of measurement obtained in measuring of the same property of object of control"*.

Calibration is the activity carried out voluntarily in need of control of correctness of results of measurement indicated by the exploited means of measuring technique. The work in calibration carry out the State metrological centers subordinated to the State Service of Technical Regulation and Consumer' Policy of Ukraine and the State metrological

service bodies and centers attested on right of carrying out of this work in spheres of their authorization, as well as the specialized laboratories, which operate calibration of instruments used by other enterprises, and the authorized laboratories of persons of economy, which have the right of calibrating of instruments used themselves.

The objects of calibration are:

- new instruments,
- repaired or modified instruments,
- objects offered for control after expiring of term of their metrological attestation,
- metrological objects used in critically necessary measurements,
- metrological objects after use in unpredictable events, e.g. vibrations or unfavorable climatic conditions,
- means of measurement, which show the problematic results etc.

The instruments that show the appropriate metrological characteristics are supplemented by the corresponding certificate or the record in their exploitation documents and marked with the special stamp. There exist the following types of calibration of means of measuring technique:

- *initial* used in relation to each unit of measuring technique just after its fabrication,
- *periodical*, carried out accordingly to the approved schedule plan developed by its owner,
- *extraordinary*, carried out by claim of its user in cases as follows:
  - damaging of the calibrating stamp,
  - transfer of the means of measuring technique to another place of use,
  - putting of the equipment in operation after the durational term of its non-use.

Generally, calibration represents itself the process of adjusting of indications of the measuring unit to their normalized values in receiving of the standardized incoming signal of etalon used in this procedure, e.g. in adjusting of standardized indications of the thermometer, which

operates by principle of measuring of resistance at different temperatures, at points of fixed thermal constants.

By character of indication, the means of measuring technique are subdivided by categories of *digital* and *analogous* ones and by principle of their operation – by *instruments of direct, comparative, integrating,* and *summarizing* types. Depending of sphere of use, the instruments are subdivided by categories of *universal*, i.e. used in measuring of properties of objects of wide range of use, and *special* used in measuring of one-type parameters of the same type articles (for instance dimensions of cog-wheels) or the same parameter of various items (e.g. temperature, roughness, hardness etc.). The measuring instruments have the mechanical, optical, pneumatic, electric and other principles of operation.

All measuring instruments are of principally same block-scheme consisting of the element sensitive to action of measured physical magnitude, as well as the measuring and indicating blocks. The measuring block of mechanical principle of indication has the scale that have the set of marks with some digits to indicate succession of values of measured magnitude, as a rule, and the indicator, which have the view of needle or beam of light. The digital instruments are equipped with the tableau that indicates the numerical values of measured parameter. The terms used in practice of exploitation of means of measurement are:

Constant of scale is the difference of values of the measured property represented by the gap between two neighboring indications of the scale of the instrument

Diapason of indications means the range of values of measured magnitude in the diapason of measurement character by the normalized permissible error of the measured property

Limits of interval of measurement means the interfacial (the biggest and the smallest) values of diapason of measurement character by the normalized permissible error of the measured property

Variation of indications means the difference in indications of the instrument in certain point of measurement

obtained in conditions of two directions of approaching to it of power of incoming signal

Stability of indications of means of measurement means the characteristic index of variance of metrological characteristics of the instrument in time

There exists the register of means of measurement used in Ukraine. The principal goals of its compiling are:

- forming of total and rational list of means of measurement and State etalons registered in Ukraine, dissemination of related information on it among the interested persons, including the specialized institutions of foreign countries,
- in-time identification of need of organization of manufacturing of new and discontinuing of fabrication of obsolete means of measurement and etalons,
- maintaining of the centralized State funds of information data on means of measurement, and materials of standardized composition (properties) allowed to fabrication and circulation in the country.

The objects of said list are the means of measurement proposed for importing, means of control of quality of materials and articles, means of measuring technique used in control and regulation of technological processes etc. The experimental samples of means of measurement of domestic origin proposed for serial fabrication and samples of imported items, whether serial or experimental, have to pass the *State accepting testing* of means of measurement before they would have been included in the State list of means of measurement. The purpose of this work is identification of expedience of organization of their serial manufacturing domestically or buying abroad of their analogues, capability of national metrological services of their verifying, warranty and post-warranty repair, as well as control of compliance of indices of their operation to provisions of normative documents. There exist two types of testing, namely the primary and scheduled actions done at stages of their development or serial fabrication, respectively. The subject of inspection is identification of compliance of indices of quality of tested products is

the control of correspondence of their exploiting characteristics to norms declared in their specifications and possibility of use of proposed items in control of processes of manufacturing, exploitation and repair. At the same time, the means of measuring technique not subordinated to the State accepting tests but subjected to the State metrological supervision have to be certified in obligatory manner.

The objects of *State control tests* are the items of startup series, means of measuring technique of serial production and the means to be produced serially after amending of their design or technology of manufacturing that influence on their metrological characteristics, as well as batches of imported instruments. Besides, the control bodies test the non-used items after expiring of guaranteed term of their non-use. In process of the control testing, there have to be identified the compliance of exploitative parameters of means of measurement to norms set by technical documentation, as well as observance of norms of fabrication of new and servicing of exploited means of measurement.

2.6 Precision and Inaccuracy of Measurements

All types of measurement are character by certain inaccuracy, therefore, the principal characteristic of any measurement is its precision understood as closeness to zero of deviation of its results of real value of measured parameter. Its origination may result of numerous causes: imperfection and insufficient grade of precision of used means of measuring technique and methods of measurement, poor experience of experimenter, insufficient carefulness of operator in carrying out of work, influence of environmental conditions etc. The integrated index, which characterizes the grade of deviation of results of measurement of real value of measured property is the error of measurement.

> *Error of measurements (absolute) means the difference of result of measurement and true value of measured property*

Because the *true* value of measured property x_d is unknown, the experimenter takes in evaluation of magnitude of error of measurement

its *real* value x_r, found in the single experiment as the difference of the value obtained in the measurement X and real value of parameter x_r:

$$\Delta X_{measur} = X - x_r$$

The character of dispersion of results of measuring of value of parameter, which is under influence of many occasional factors, describes the curve of normal (Gauss) distribution of results of measurement, which typical shape shows the curve below (Fig. 2.4):

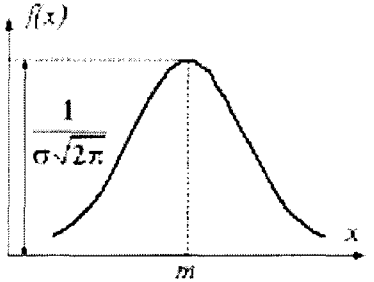


Fig. 2.4 Law of normal distribution: the symmetric bell curve (σ – the root-mean-square deviation of result of measurement of true value of X)

The errors of measurement are of systematical and accidental nature. Besides, there exist the rough (very big) errors and misses. Hence, it is necessary to classify the errors of measurement by categories as follows.

Systematical error is the constituent part of error of measurement, which remains unchanged or regularly varied in repeated measurements of value of the same property. The result of measurements deviates of true value in this case by the known factor because the values of systematical errors are known in most cases in advance.

The value of the *accidental error* of measurements, contrary to the systematical one, is unknown and varies fortuitously in repeated measurements of the same property. Their values characterize the axioms as follows:

- the less is error, the most often it occurs,
- the negative and positive deviations of parameter of its mean value occur the equally often,
- the arithmetical mean of totality of accidental errors and the algebraic sum of such deviations of mean value tent to zero,

- the averaged value of the accidental error is the less, the more is quantity of results of measurement of the property to identify.

Therefore, to guarantee the closeness of the averaged result of measurements to real value of the measured parameter, the experimenter has to carry out the series of its repeated measurements.

Misses and *rough errors* mean the errors of measurement, which value exceeds sufficiently the values of systematical and accidental errors expected in existing conditions of experiment. So, they may be identified and eliminated from the set of the individual measurements taken into consideration in calculation of the final result. The main sources of origination of such errors are misses of experimenter, sharp and unexpected changes of the surrounding conditions of the surrounding nature and malfunction of used instruments.

The existence of errors is the natural property of any process of measurement. The principal reasons of their origination are the insufficient knowing of properties of tested objects, imperfection of methods and means of measurements, variability of conditions of experiments, errors committed in plotting of scales of instruments, rough and multiple rounding of results of the successive measurements. Depending of causes of origination, the errors are classified as follows:

- *error of method of measurements*, which results of its imperfectness, use of approximated formulas of calculation etc.,
- *instrumental error* caused by incorrect graduation of means of measuring technique, their constructional and technological imperfection and so on,
- *subjective (personal) error* resulted of individual conditions of experimenter in process of measurement (defects of vision, fatigability etc.),
- *basic error* occurred as the normal variation of properties of used means of measurement during the term of exploitation indicated in their passports,
- *subsidiary error*, which results because of variation of influential factors of environmental conditions (temperature, pressure, relative humidity etc.),

- *systematical error* as the constituent part of integral error of measurement that remains in repeated measuring of the same value changeless or varies regularly in action of factors, which influence cannot be eliminated,
- *accidental error*, which results of fluctuation of indications of used instruments in repeated measurements carried out in the same conditions,
- *crude error* is the error of measurement, which value is sufficiently bigger of usual deviation of results taken in experiment of expected size of real value of the measured property,
- *static error* means the averaged difference of results of measurement of the averaged value of measured changeless property obtained in numerous measurements carried out in any fixed time,
- *dynamic error* is the difference of values of the error determined in measurement in dynamic conditions of the *static* one,
- *absolute error* means deviation of value of property got in measurement and expressed in dimensionality of used units of physical magnitudes of its real value,
- *relative error* means the ratio of value of absolute error of measurement to real value of the measured property expressed in dimensionless units or in percents.

The procedure of measurement includes the following basic stages: 1) choose of model of measurement, 2) choose of the concrete method of measurement, 3) choose of means of measurement, 4) carrying out of measurement proper, 5) calculation of numeral (and/or other) value of result of measurement. Doing measurements, one has to take into consideration the fact of existence of errors and inaccuracies in absolute majority of cases, therefore the process of measurement is reckoned as the completed one only after there would have been calculated the summarizing value of error of the experiment. However, there exist some specific cases of absence of error of measurement, especially:

- in absence of incoming signal, e.g. in absence of incoming voltage on voltmeter, when the value of measured parameter is zero with the absolute precision,
- in measuring of values taken as constants, e.g. of the ternary point of water (273.16 K).

2.7 Uniformity of Measurements. Means of its Assuring

Uniformity of measurements is the crucial characteristic of quality of this work and one of principal norms of metrology, which assuring is one of basic functions of the State technical regulation. Its observance is the obligatory precondition of effective management, successful trade, and rational use of natural resources, reliability of results of R&D activities and assurance of compatibility and interchangeability of products of manufacture and their constituents. Ensuring of norms of uniformity is necessary in comparing of results of measurements done in different places and different time, including those that were carried out with use of different methods and means of measurement. The work in observance of criterions of uniformity of measurement may be done only on condition of solving of the main problems of metrology, which *first*, the most significant, is unification of units of physical magnitudes by norms of the universal SI system.

To find the real value of any measured magnitude, one should use the etalons of properties and composition. So, the *second* principal problem in assuring of uniformity of measurement is producing and continuous perfecting of etalons carried out in observance of advancement in studying of physical phenomenon based on fundamental physical constants.

Farther, the *third* basic task in solving of the problem is producing of exemplary means of measurement, development of procedures of their verification and transmission of values of physical magnitudes to the working instruments.

Because the work in the uniform conditions stipulates the requirement to assess the trueness of results of measurement, the *fourth* condition to be observed in it is development of methods of expression

of indices of precision of obtained results, which permit to compare the data got in work of different operators in uniform conditions. To solve this problem, there were developed the numerous procedures of carrying out of experiment and analysis of its results.

The dominant normative and technical documents used in assuring of uniformity of measurement are the specialized standards and attested methods of measurement used in the sphere of the State metrological control. The work in attestation and control of observance of their norms execute the specialized State metrological centers, their territorial branch-offices, accredited organizations and their departments specialized in this job.

The main problem, which arises in process of measurement and interpreting of its results, is reliability of got results because no one instrument does not permit to obtain the unconditionally true result, for it depends in many cases of concrete conditions of experiment, existence of inevitable errors of measurement and use of derived units of physical magnitudes. For example, the display of balances that run by principle of measuring of *weight*, not the *mass*, depends of height of weighing over the sea level.

Existing of these factors causes origination of methodological deviations of results of measurement of true value of measured magnitude, which cannot be eliminated by rising of precision of used instruments. This and some similar problems may be solved in use of special means of control of trueness of obtained results – the materials of standardized composition (standards). Depending of kind of attested characteristic and type of unit of physical magnitude they reproduce, such materials are classified by categories of standards of composition and standards of properties to be used in purposes as follows:

- metrological attestation of methods of measurement,
- calibration, graduation and verification of means of measuring technique,
- control of correctness of results of measurement,
- determining of values of errors of measurement.

To minimize errors of measurement, the attested characteristics of standards used in calibration of measuring equipment have to be maximally close to tested parameters of object of control. In this case, the variable conditions of experiment and probable imperfections of used instruments influence on the chosen standard and the tested object uniformly, what permits to minimize the deviation of results of measurement of the true value of the measured parameter.

Depending of grade of accuracy, the standards are subdivided by three categories.

- *State standards (ДСЗ – державні стандартні зразки)* mean the standards, which passed the State accepting tests, approved by the State Service of Technical Regulation in this category and registered in the State Register of materials of standardized composition. They are used for carrying out of the especially precise measurements,
- *sectoral standards (ГСЗ – галузеві стандартні зразки)* mean the standards, which characteristics were attested by procedures established by the respective Ministry. They are used for control of accuracy of results of measurements carried out by enterprises of the subordinated branch of economy and legal persons, which operate in sphere of activities regulated by this Ministry,
- *standards of organizations (СТП – стандартні зразки підприємства)* mean the standards of the lowest class of precision, which were attested by procedures approved by directorate of the enterprise itself. They are used for graduation of working means of measurement of the enterprise and control of accuracy of results of measurements carried out by its structural units (by contracts, this kind standards may be used by other enterprises too).

The attested parameters of materials of standardized composition are individual for each standard and registered in their certificates/passports.

2.8 International Metrological Organizations

The metrological norms and rules are uniform worldwide, so the work in conditions of uniformity of measurement, as well as global unification of methods of measurement and standardization of technical characteristics of means of measurement used in it are the obligatory elements of work in elimination of technical barriers in international trade. The necessity of introduction of norms of unified technical policy is the reason of joining of more and more countries to international metrological organizations, what assists in strengthening of their collaboration, introduction of innovative technologies and exchange by knowledge in all spheres of economy concerned with use of means of measurement.

The decision on founding of fundamentals of modern metrological science to be used worldwide was taken by proposition of the St. Petersburg' Academy of Sciences in 1870. One of results of this event was making in 1872 of international prototypes of etalons of meter and kilogram. Some later, the Paris diplomatic conference of 17 that time advanced countries, including the Russian Empire, approved 20.05.1875 the *Metric Convention* establishing so the basic principles of modern metrology. Accordingly to its clauses, any country may join to the Convention freely. To do it, she has to send her application to the Ministry of Foreign Affairs of France, which has, in turn, to inform on such intention all member-states and the Chairperson of the one more influential metrological international organization: the *International Committee of Measures and Weighs*. At present, there are 52 signatories of Metric Convention (Argentina, Australia, Austria, Belgium, Bulgaria, Brazil, Cameroon, Canada, Chile, China, Czech Republic, Greece, Denmark, Dominican Republic, Egypt, Finland, France, Germany, Hungary, India, Indonesia, Ireland, Islamic Republic of Iran, Israel, Italy, Japan, Malaysia, Mexico, Montenegro, Netherlands, New Zealand, Norway, Pakistan, People's Democratic Republic of Korea, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Serbia, Singapore, Slovak Republic, South African Republic, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom, Uruguay, USA, Venezuela), and 18 more countries are its associated members

(Byelorussia, Costa-Rika, Croatia, Cuba, Ecuador, Estonia, Hong Kong, Jamaica, Kenya, Latvia, Lithuania, Philippines, Republic of China, Slovenia, Ukraine, and Vietnam).

The Metric Convention, despite its appellation, some similar to "Contract", became the first international *association*, which main task is development of unified principles of metrology, and its especial significance in this role is:

- Metric Convention is a base of expanding and enforcement of international collaboration in unification and use of units of physical magnitudes,
- the Convention became a powerful stimulus of expanding and perfecting of global metric system of measures and principles of metrology itself.

The problems of identification of properties of etalons of substances and materials of standardized composition are in sphere of responsibility of the *International Committee of Measures and Weighs (Comite International des Poids et Mesures — CIPM)*, the Metric Convention operative body, which structure includes nine consultative committees by normalizing of the module values of meter, second, units of electricity, photometry and radiometry, thermometry, ionizing radiation, units of mass and quantity of substance. The main function of CIPM is preparation for and carrying out of meetings of the General Conference of Measures and Weighs convoked once per 4÷6 years under aegis of the Paris Academy of Sciences. The resolutions of the Committee on revision and normalization of values of units of physical magnitudes have the status of the official metrological deeds of international category.

The other main international organizations operating problems of modern metrology are:

2.8.1 *International Bureau of Measures and Weighs (BIPM)*

The International Bureau of Measures and Weighs (Bureau International des Poids et Mesures — BIPM) has its headquarters in Sevres nearby Paris and is one of organizations founded by decision of the Metric Convention. The BIPM parent organization is the International Committee of Measures and Weighs, which supreme body is the General Conference of Measures and Weighs.

The principal task of the Bureau is guaranteeing of uniformity of measurements carried out worldwide and assuring of use of unified principles of measurement by operators located in the Metric Convention member-countries. BIPM is the scientific institution storing the international etalons, investigating their physical and chemical properties and stability, working out methods of rising of precision of measurement, and accomplishing the periodical collations of primary national etalons of physical magnitudes of its member-countries. Its laboratories develop new and perfect the existing etalons of physical magnitudes and modernize methods of their reproducing. Initially, BIPM worked on development of standards of units of length, mass and temperature only, but since 1927 its activities were spread on problems of measurements in sphere of electricity. In 1937, BIPM began to work in photometry, and since 1960-s develops units of intensity of ionizing radiation.

The Metric Convention signatories do not work in development of the advanced aspects of legislative metrology. Hence, there arose the need in founding of the specialized body, which function would be assistance in progress of metrological servicing in manufacture and intensification of international cooperation in global markets of goods and services. The result was founding in 1955 of the *International Organization of Legal Metrology (L'Organisation Internationale de Metrologie legale — OIML)* with iits headquarters in Paris.

2.8.2 *International Committee of Legislative Metrology (OIML)*

OIML lists for the present 54 its full members, and 41 corresponding members (including Ukraine since 1997). Its main task is studying and clear identification of principal problems that arise in progress of legal metrology. The supreme body of the Organization is its General Conference convened once per 4 years, and supreme executive body – the International Committee of Legislative Metrology. The OIML structure includes 18 technical committees, working on more of 150 projects by directions as follows:

1. general problems of metrology,
2. procedures of measurement,
3. metrological servicing in public economy.

The sessions of the Committee occur each two years and the principal problems to discuss are:

- typical procedures of operation of national metrological services, and principles of their organization,
- priorities in development of global metrological science,
- procedures of use of measuring instruments.

The OIML standing executive body is the *International Bureau of Legislative Metrology*, which convenes the OIML General Assemblies, governs activities of its secretariats, publishes documents of the Organization and coordinates its co-work with other international metrological organizations. The OIML operative bodies are its technical groups named as *pilot secretariats*, which include as the constituent branches their *reporting secretariats*. These structures develop recommendations and documents to be used in OIML member-countries obligatorily, and their principal points of interest are:

- general problems of metrology,
- development of optimal structures of national metrological services and projects of their regulations,
- scientific and technical servicing of developing countries in organization of their metrological structures,
- unification of global systems of testing,

- unification of metrological characteristics of equipment to be used in measurement,
- development of uniform procedures of verification and calibration of means of measurement,
- development of procedures of attesting of standards of properties and composition, exemplary and working means of measurement,
- establishing of uniform principles of training of laborers, who work in sphere of interests of metrology.

2.8.3 *International Conference of Measuring Technique and Instrument Making (IMECO)*

The one more influential international organization operating metrological problems is the *International Conference on Measuring Technique and Instrument Making (IMEKO)* founded in 1958 by initiative of Soviet, Hungarian and Polish instrument producing associations. IMEKO is the one of five biggest global interregional metrological organizations and represents itself the confederation of national scientific and technical services operating development of measuring technique and working on problems of theory and practice of its use. Its principal purpose is *"assisting in international exchange by scientific and technical information on projecting fabrication and use of means of measuring technique in R&D works and industry".*

IMEKO is the non-governmental and non-commercial organization accredited in UNESCO and UNIDO and opened to joining of any country. The Conference unifies 36 member-states representing both advanced and developing countries of all five continents, namely Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Croatia, Czech republic, Egypt, Finland, France, Germany, Greece, Hungary, Italy, Japan, Kazakhstan, Kenya, Korea, Mexico, Nigeria, Poland, Portugal, Republic of South Africa, Spain, Romania, Ruanda, Russian Federation, Serbia, Slovakia, Slovenia, Sweden, Switzerland, Thailand, Turkey, and United Kingdom. Its headquarters are located in Budapest and most works by problems of theory and practice of metrology execute 24 technical

committees, all located in Hungary. These are the problems of assuring of uniformity of measurements, theories of development of etalons and scales of physical magnitudes, as well as substantiating of theoretical and practical limits of their precision.

The IMEKO structures operate on voluntary basis, hence its members pay their expenditures independently. The principal form of its activities is convoking of international congresses each three years. If necessary, the Conference holds the extraordinary symposiums by special problems. After determining of place of conferencing, the host organization forms its organizational committee and carries out all necessary technical work. The journal of *"Acta IMEKO"* publishes the full texts of transactions of symposiums in three official languages: English, French and Russian.

It is necessary to identify clearly also the positions in international metrological structure of such organizations as ISO and IEC. Formally, they have no relation to metrological activities and operate mainly in standardization. However, they issue the numerous recommendations on metrological terminology and propose methods of carrying out of measurements used in testing of production. The ISO structure includes also some technical committees of pure metrological orientation, for instance:

- TC 12 "Magnitudes, units, designations, multipliers",
- TC 30 "Measuring of characteristics of stream of liquid in closed channels",
- TC 57 "Structure and properties of surfaces",
- TC 113 "Measuring of characteristics of stream of liquid in open channels".

2.9 European Metrological Organizations

2.9.1 European Association of National Metrology Institutes (EURAMET)

In parallel with founding of regional economical structures, the metrological services of European countries founded the net of organizations oriented on intensifying of their

regional cooperation and optimization of organizational structures in accomplishing. Such works were began in Europe in 1973 after founding of the West-European pool of EU and EFTA member-countries. In progress of processes of their economical, there were founded the first all-European metrological institution – the *European Association of National Metrology Institutes (EURAMET)*, which began its activities 1st of January 1988 in approval of recommendations of Memorandum of Understanding (MoU) signed 23.09.1987 in Madrid. The list of members of the Association includes 33 national metrological institutions of the following countries: Austria, Albania, Belgium, Bulgaria, Croatia, Cyprus, Czech republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland, United Kingdom, Turkey, and Ukraine (as the Observer).

The EURAMET working body is its Committee, which staff includes one representative of each member-country, one delegate of European Commission and one observer, who represents interests of EFTA member-countries. Meetings of the Association occur annually, and representatives of other European metrological organizations have the right to participate in their work as observers. The members of the EURAMET Standing Committee elect its Chairman for the term of two years and may re-elect him for one term again, but not more. The Chairman heads also the EURAMET Executive Committee, which includes 8 members and co-ordinates work of the Association in period between its sessions. The Association has no permanent headquarters, therefore its Secretariat is located in the country, which citizen its Chairman is.

The Association issues the periodical of *"Metrology in Europe"* and executes about of 50 R&D works annually, which concern of problems of reproducing of fundamental constants, rising of precision of measurement. In absence of centralized financing the EURAMET members finance their works from own budgets. The four basic directions of their activities are:

1) *co-operation in carrying out of R&D works*,
2) *collation of standards and means of measurement* in purposes of their unification,
3) *control of identity of norms* of metrological standards of the Organization member-countries,
4) *mutual consultancy* and assistance in optimization of procedures of operation of national metrological services and measuring and calibration laboratories.

The basic spheres of activities of 12 EURAMET technical committees are:

- acoustics, ultrasound and vibration,
- electricity and magnetism,
- measuring of stream,
- ionizing radiation,
- interdisciplinary metrology,
- determination of dimensions,
- mass and units of its measuring,
- metrology in chemistry,
- photometry and radiometry,
- quality of measurements,
- time and frequency,
- thermometry.

The principal goal of operation of EURAMET is assuring of mutual recognition of certificates of testing and metrological control of means of measuring technique issued by national metrological bodies of its member-countries.

2.9.2 West-European Association by Legislative Metrology (WELMEC)

WELMEC began its activities after signing by 18 national metrological committees of EU and EFTA countries in Bern in 1990 of the Memorandum of Understanding. The acronym of the Association means, the *Western European Legal Metrology*

Cooperation. However its present-day geography sufficiently spreads, and having the same acronym. Its members are 37 countries of Central and Eastern Europe: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, as well as Albania, Bosnia-Herzegovina, Croatia, Montenegro, Serbia and Turkey as observers. Its central body is the Standing Committee, which consists of representatives of WELMEC members and observers, representatives of European Commission and EFTA Secretariat, as well as the observing members, who represent other regional and global metrological associations. WELMEC holds the annual meetings, which agendas presume, among other, election for the term of three years its direction consisting of Chairman, Vice-chairman and Secretariat of two persons, who may be re-elected for the one term more.

WELMEC coordinates its day-to-day work with numerous organizations, particularly with the European regional and national trade and metrological institutions. Its main task is development of harmonized norms of metrology and collaboration with metrological associations of other regions interested in progress of metrology in Europe. The principal points of its interest are:

- perfecting of etalons of units of physical magnitudes and standards used in calibration and measurement,
- optimization of norms of operation of WELMEC members, assistance in supply of their metrological services with the means of measurement developed by its members and optimization of procedures of their use.

Besides, its tasks are:

- assisting in use of the uniform principles of interpretation and use of provisions of normative documents,
- harmonization of activities of national profile organizations and creation of atmosphere of mutual confidentiality of metrological services,

- identifying of problems, which arise in structure of European metrological system and organization of exchange by information,
- assisting in elimination of technical barriers in trade by means of measurement.

WELMEC closely collaborates also in its current work with EFTA, OIML, EURAMET, European Organization by Collaboration in Accreditation (EA) and other regional and international organizations operating metrological problems.

2.9.3 *Metrological Organization of Central and Eastern Europe (COOMET)*

COOMET with headquarters in Bratislava (Slovakia) was founded in 1991. At present, the Organization lists 18 member - countries (Azerbaijan, Armenia, Belarus, Bulgaria, Cuba (associated member), Democratic People's Republic of Korea (associated member),Georgia, Germany (associated member), Kazakhstan, Kyrgyzstan, Lithuania, Moldova, Romania, Russian Federation, Slovakia, Tajikistan, Ukraine and Uzbekistan), and is open to joining of any country. Its official languages are Russian and English.

Its supreme body is the Committee, which consists of chairpersons of national metrological institutions of its member-countries. The agendas of meetings, which it convenes at least once a year, include election of President for the term of three years, who may be re-elected for the one term more. The President proposes the Committee the candidatures of four vice-presidents and appoints the Secretariat, which staff consists of laborers of national metrological service of his own country. The President, vice-presidents and Head of Secretariat form the COOMET Presidential Council, which co-ordinates activities of the Organization, chooses problems to discuss in period between meetings, and represents the COOMET interests in international and regional metrological organizations, associations and unions.

The principal objective of founding of the Organization was assisting in effective solving of problems of unification of etalons of units of physical magnitudes used in Central and Eastern Europe countries and regional associations of metrological profile of activity, especially EURAMET, speeding and simplifying of conditions of international barter and assisting in strengthening of collaboration of metrological services of its member-countries. The basic spheres of its activities are development and perfecting of etalons of physical magnitudes, solving of problems of legislative metrology etc. The concrete problems of investigation are: acoustics, ultrasound, vibration, electricity and magnetism, measuring of streams, ionizing radiation and radioactivity, length and angles, mass and related characteristics, photometry and radiometry, physical chemistry, thermometry and thermophysics, time and frequency, standard materials, general problems of measurement (general metrology), legislative metrology, accreditation and quality systems, information and information technologies, training and raising of qualification of experts. The main directions of collaboration of the COOMET members are:

- development of procedures of operation of the calibration and accreditation services corresponding to global norms,
- development and perfecting of primary standards of units of physical magnitudes,
- collation of national etalons of physical magnitudes of its member-countries and development of methods of passing of their magnitudes to etalons of lower level of use,
- coordination of works in development of materials of standardized composition and properties,
- perfecting of methods of transmitting of values of physical magnitudes of national standards to standards of lower levels,
- development of new methods and types of measurement,
- solving of problems of theory of measurements and identification of values of committed errors,
- development of system of collecting and dissemination of metrological information,

- unification of requirements to quality of means of measuring technique subordinated to the State metrological control,
- development of norms of mutual recognition of results of metrological control.

The COOMET working structures operating these problems are: the Amalgamated committee of standards of measurement, Technical committee of legislative metrology, Technical committee of information and training, Technical committee of mutual investigations in metrology, and the COOMET Quality forum. The latter institution represents itself the structure, which activities are centered on concluding of agreements on mutual recognition of results of operation of measuring departments working in observance of provisions of standard ISO/IEC 17025 *"General Requirements to Competence of Measuring and Calibration Laboratories"*. The decisions of the Organization are of recommended character and do not influence on rights and obligations taken by the bilateral and multilateral treaties of participants of the Organization operating metrological problems.

Each member-country has right on access to national bases of standards of other ones (in consent of partner-countries), ask for their help in solving of existing metrological problems, propose themes to investigate and participate in mutual works by their execution, obtain information on results of activities of the COOMET working groups. The COOMET members have to observe in it the obligations as follows:

- give the reasonable information on the finished and planned works to be done by the COOMET programs,
- keep confidence to results of testing carried out in other COOMET member-countries,
- observe recommendations of COOMET in optimization of work of their national metrological services.

Basing on mutual interests, COOMET collaborates with the following regional organizations:

- European association of national metrological services (EURAMET),

- European organization by collaboration in sphere of legislative metrology (WELMEC),
- European organization by collaboration in accreditation (EA),
- Asian-Pacific metrological program (APMP),
- Asian-Pacific metrological forum (APLMF),
- Asian-Pacific organization by collaboration in accreditation of laboratories (APLAC),
- Scientific and technical commission by metrology of Euro-Asian Council by standardization, metrology and certification (EASC),
- South-African association by collaboration in sphere of traceability of measurements (SADCMET),
- Pan-American metrological system (SIM) and others.

2.10 Metrological System of Ukraine

The metrological servicing is one of spheres of the system of State technical regulation, which principal task is methodological assuring of work of enterprises in conditions of uniformity and sufficient precision of measurements, rising of effectiveness of their operation and betterment of quality of production they produce. These works execute the regional offices of the State Service of Technical Regulation and Consumer Policy of Ukraine and the specialized enterprises operating by its licenses. To realize the collegial consideration of conceptual problems of assuring of stable functioning and progress of the State metrological system in Ukraine, it was founded the consultative and advisory department of *Scientific and technical commission by metrology*, which principal purpose is substantiation of priorities in scientific and technical work in metrology. The technical base of the system of metrological servicing in Ukraine includes:

- system of the State etalons of units of physical magnitudes used in transmitting of their values to etalons of lower ranks,
- system of working etalons and exemplary means of measuring technique used in transmitting of values of units of physical magnitudes to working means of measurement,
- system of standards used in calibration of means of measurement,

- system of working means of measuring technique used in all branches of public economy.

The structure of State Service of Technical Regulation and Consumer' Policy of Ukraine comprises 25 regional centers located: in Autonomous republic of Crimea, Cherkasy, Chernihiv, Chernivtsi, Dnipropertrovsk, Donetsk, Zhytomyr, Zaporizhzhia, Ivano-Frankivsk, Kharkiv, Kherson, Khmelintskii, Kiyv' urban ("Ukrmetrteststandart"), Kyiv' provincial (in Bila Tserkva), Kirovograd, Lugansk, Lviv, Mykolaiv, Odesa, Poltava, Rivne, Sumy, Ternopil', Transkarpatian, Vinnitsa, Volyn' and 9 city centers in Chervonograd, Drohobych, Gorlivka, Kramatorsk, Kremenchuk, Kryvyi Rig, Mariupil, Melitopol, and Sevastopol. Besides, the structure of Ukrainian metrological servicing comprises some R&D institutions, as well as the specialized State services of Unified Time and Reference Frequencies, Standards of Composition and Properties as well as the Service of Standardized Reference Data on Physical Constants and Properties of Substances and Materials, which execute the following functions:

- *State Service of Unified Time and Reference Frequencies* accomplishes the inter-regional and intersectoral coordination of works on assuring of uniformity of frequencies and measuring of global time and parameters of circulation of Earth,
- *State Service of Standards of Composition and Properties of Substances and Materials* accomplishes the inter-regional and intersectoral coordination of works on development and introduction of standards of composition and properties of substances and materials,
- *State Service of Standard Reference Data on Values of Physical Constants and Properties of Substances and Materials* accomplishes the inter-regional and intersectoral coordination of works in development and introduction of standardized reference data on physical constants and properties of substances and materials.

The graphical structure of the State Metrological Service of Ukraine shows the Figure 2.5 below:

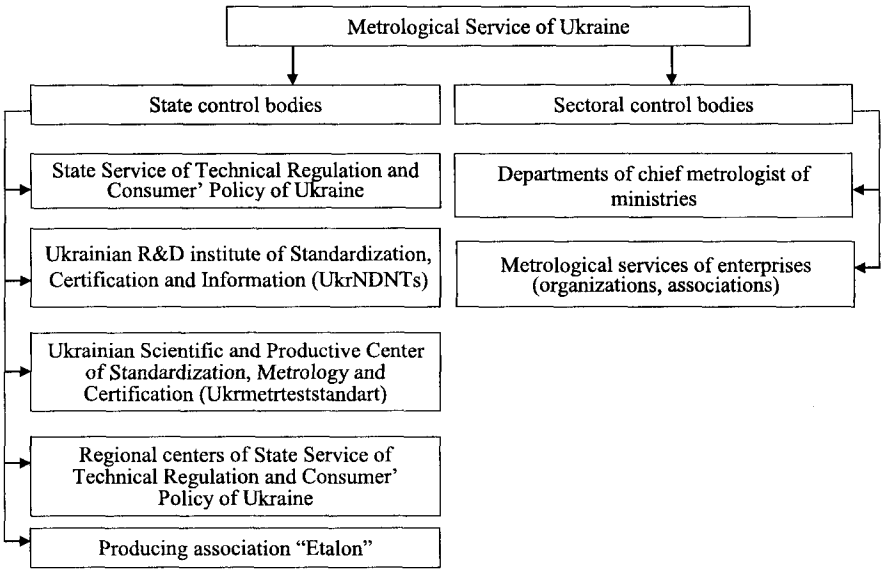


Fig. 2.5 Structure of Metrological Service of Ukraine

The dominant volumes of work in metrological servicing execute the territorial centers, which have the following authorities:

- carrying out of State testing and verification of means of measuring technique, perfecting of procedures of verification,
- State metrological control and supervision of conditions of metrological servicing,
- accreditation of measuring, calibrating and analytical laboratories, testing centers and services,
- development and introduction of procedures of metrological servicing in public economy,
- methodical servicing of activities of departmental metrological services and training of metrologists.

Except of metrological services subordinated to the State control and supervision, this kind works execute the authorized *enterprises, organizations* and *metrological servicing departments of bodies of executive power,* as follows:

- central bodies of executive power (including their regional offices) ensure uniformity of measurements at the State level and carry out metrological control of operation of persons authorized on this job,
- branch-wise metrological departments of ministries and central bodies of State executive power co-ordinate works on the intra-branch control of observance of metrological norms and procedures in subordinated enterprises and organizations.
- specialized metrological services of associations, enterprises and organizations control observance by their specialized departments of norms of carrying out of measurements.

The departments of the ministerial Chief metrologists accomplish the organizational and procedural managing of activities of subordinated persons of economy and control correctness of their work in carrying out of works as follows:

- determining of principal directions of functioning of metrological services in spheres of their responsibility,
- development of proposals by advancement of procedures of metrological servicing in progress of public economy,
- introduction of norms of the national and sectoral standards and other normative and technical documents of metrological character at subordinated enterprises and organizations,
- assistance in founding of metrological services in subordinated enterprises and organizations,
- training of specialists of metrological services and rising of level of their professional skill.

Metrological departments of enterprises and organizations:

- co-ordinate work of structural departments of their enterprises, which carry out works in measurement,
- assist in rising of precision of measurement, introduction of modern means and methods of measurement and materials of standardized composition,
- organize training of laborers by problems of metrological servicing,

- develop the long-term and running plans of buying of means of measurement and control their execution,
- accomplish metrological expertise of technical documentation used in their enterprises,
- control correctness of use of procedures of storage and exploitation of means of measurement in their enterprises,
- draw up the schedule plans of repair and verification of means of measurement,
- report to higher organizations and bodies of the State Service of Technical Regulation of Ukraine and assist them in work in metrological servicing at the subordinated enterprises.

The spheres of the State metrological control and supervision are:

- measures by protection of health,
- procedures of producing of foodstuffs,
- observance of norms of carrying out of geodesic and hydrometeorological works,
- settling of vexed questions in determining of quality of goods,
- accounting of material resources (electric and thermal energy, gas, oil products etc.),
- routine of accomplishing of tax, custom and postal operations,
- expertise and registration of national and international sports records,
- works, which demand of obligatory certification of production.

The objects of metrological control are means of measurement, information and measuring systems, methods of measurement, packed goods in any type packs and other specified objects.

The sphere of *metrological servicing* comprises the activities as follows:

- accreditation of specialized calibration, testing and measuring laboratories,
- attestation of means of measuring technique and methods of measurement,
- calibration of means of measuring technique,
- metrological expertise of documentation.

Said works execute the persons as follows:

- metrological services of central bodies of executive power – at enterprises and organizations subordinated to their control,
- leading and basic organizations (their specialized departments) attested on work in metrological servicing – at the subordinated enterprises and organizations,
- metrological services of enterprises and organizations – in their own structural departments.

The topics of their control are:

- observance of metrological norms,
- observance of procedures of use of means of measuring technique,
- observance of procedures of attested methods of measurement,
- timeliness of carrying out of servicing, verification and calibration of means of measurement.

The basic types of the State metrological supervision are centered on control of correctness of carrying out of works as follows:

- approval of types of means of measurement,
- observance of procedures of the State control testing of means of measurement,
- observance of norms of verification and metrological attestation of means of measurement,
- control of observance of procedures of licensing on right of manufacturing, repair and importing of means of measurement,
- control of observance of procedures of issuing of permissions on right of carrying out of work in verification, calibration, lease and sale of means of measurement,
- control of quantity of packed goods in process of their packing and sale.

Test Questions

1. What are the objects of metrological science ?
2. The basic branches of metrology (legislative, scientific and practical metrologies)
3. What is the sphere of legislative metrology ?
4. What are the subjects of scientific metrology ?

5. What are the subjects of practical metrology ?
6. What is the structure of the State metrological system in Ukraine ?
7. What is understood under the notion of measurement ?
8. What is physical magnitude ?
9. What is understood under practice of uniformity of measurement ?
10. What is the system of units of measurement ?
11. What is basic unit of physical magnitude ?
12. What is derived physical magnitude ?
13. What is dimensionality of physical magnitude ?
14. What is understood under the notion of "measurement of value of physical magnitude" ?
15. Which year there was introduced the International system of physical magnitudes ?
16. What is the metrological etalon ?
17. What is the error and uncertainty of measurement ?
18. Explain the essence of notion of precision of measurements
19. What is calibration of means of measuring technique ?
20. What is standard of measurement ?
21. Year of signing of Metric Convention and sphere of its responsibility
22. What are functions of International Committee of Measures and Weighs ?
23. What are functions of International Bureau of Measures and Weighs ?
24. What international metrological organizations joined Ukraine ?
25. What are the objects of metrological control and supervision ?

3 Standardization as the Constituent Part of the System of State Technical Regulation

3.1. Basic Concepts of Standardization

Standardization is the constituent part of the system of State technical regulation, which finds the extensive use in most spheres of public economy. Its main task is establishing of clear and understandable norms of quality of production (military equipment, atomic energy, space industries, everyday–use goods and so on) and services, conditions of their safety and assuring of its competitiveness in use by destination.

To guarantee unequivocal interpreting of terms and concepts used in standardization, the organizations specialized in this science – the *International Organization for Standardization (ISO)*, the *International Electrotechnical Commission (IEC)* and the *International Telecommunication Union (ITU)* seconded by the International Organization for Cooperation in Accreditation of Laboratories *(International Laboratory Accreditation Cooperation – ILAC)*, developed the ISO/IEC Guide 2 *"Standardization and related activities — General vocabulary"* published first in 1976. The basic idea of this work was guaranteeing of mutual understanding of businesspersons and control bodies in their operation and elimination of barriers in international trade. This idea was realized in development and validation of series of standards of character uniform worldwide and publishing of numerous documents of specialized international structures, which specified the principles of methods of their practical realization. The final result was the manifold updating of notions used in this Guide and publishing in 2004 of its eighth version.

As formulates ISO, the leading organization operating standardization, this one is a kind of activities in normalizing of indices of quality of production and procedures of carrying out of works. The function of normalization used in it consists in simplifying of procedures of projecting and manufacturing of objects, as well as decreasing of their unjustified diversity, what requires of development of great variety of documents, doubling in most cases of basic norms of quality of

standardized items of similar destination. Standardization and its constituent parts, their unification, typification, safety in use are the effective means of guaranteeing of proper quality, compatibility and interchangeability of products and uniformity of principles of work in giving of services.

The Ukrainian national standard of DSTU 1.0-2003 *"National standardization. Fundamentals"* formulates the notion of this work as:

> *Standardization is the kind of activity in founding of norms of general and reiterated use directed on reaching of optimum grade of regulation in certain aspects of operation*

The *State system of standardization* establishes the basic concepts, main objectives, general norms and principal procedures of carrying out of all type works in development of normative documents and actualization of their provisions in the whole country. Use of this kind documents assists in normalization of procedures of execution of repeated tasks, and their systematical use in category of the norm or the rule. The influence of activities in standardization in unification of norms of functioning of public economy is realized through the work in introduction of complex of documents known as *standards*, which regulate methods of operation of persons of economy, properties and characteristics of finished production and raw materials, ingredients, semi-manufactured products, uniform methods of its testing and means used in it, as well as component parts, equipment and auxiliaries used in serial production. The standard is the etalon of the latest achievements in scientific and technical progress of society, hence the efficient instrument of innovative policy. There exist two parallel synonymous terms related to such kind documents – the *Standard*, and the *Norm* (e.g. *EN* – the European Norm).

> *Standard is the document meant for general and repeated use, which normalizes the rules of operation, characteristics of production, processes or services, as well as modes of operation or their results developed by principle of consensus and approved by the authorized body of technical regulation*

Consensus means the condition of absence of serious objections and existence of general consent of most interested parties in relation to substantial norms of quality of object of standardization reached in agreeing of principal aspects of normalization and lessening of differences in opinions of participants

Activities in standardization began in structures of individual enterprises, and were continuously extended on activity of bigger communities. The works in standardization execute presently central bodies of State regulation, specialized departments of governmental structures and sectoral economies, individual organizations, enterprises and their associations. Standardization influences greatly on essence of technical policy in public economy, and is, in fact, the base of technical legislation realized through its economical, communication, social and information functions.

The *function of normalization* is realized in way of simplification and limiting of unjustified variety of types of objects of standardization (too large nomenclature and existence of too much documents of regulative character).

The *economical function* includes the work by aspects of:

- normalization of indices of quality of objects of standardization, choose of the prospective destinations of their use and optimization of structure of investments and use of raw materials in their fabrication,
- raising of effectiveness and productivity of labor,
- perfecting of systems of management,
- reaching of compatibility and interchangeability of objects of standardization.

The *communication function* has prime the missions of simplifying of barter, assisting in scientific, technical and economical cooperation of businesspersons in use of channels of communication and information.

The *social function* is realized in establishing of indices and parameters of quality of production, which correspond to norms of work in protection of health, and assuring of safety of men, as well as reaching

of good sanitary and hygienic natural conditions in processes of its fabrication, storage, transporting, use and utilization.

The *information function* consists in guaranteeing of objectivity of information on all aspects of human activity, including the processes of testing of produced items, normalizing of terms and definitions to be accepted generally, variants of drawings etc.

Some norms of national standards and the analogous rank normative documents are obligatory for observance, and some are of voluntary character. The obligatory ones are:

- norms of safety of production for life, health and property of men; norms of its compatibility and interchangeability; standardized indices of quality of products and methods of their identification, as well as the normalized procedures of work in protection of environment,
- norms of safety and hygiene of labor cited in related hygienic and sanitary norms and rules,
- norms of uniformity in processes of development, producing and exploitation (use) of production,
- metrological norms, rules and procedures of assuring of trustworthiness and uniformity of measurements,
- concepts and terms used in operation with wastes; norms of their classification, certification and identification of composition and classes of harmfulness; procedures of storage, reprocessing and use of wastes by modes friendly for environment; norms of their use as the secondary raw materials.

All other norms of national standards are of *recommended* character and their observance becomes the obligatory:

- *by all persons of economic activity* if it is foreseen by technical regulations or other legal or the same rank deeds and documents in force,
- *by parties of contracts (agreements)* in segment of development, fabrication and supply of production to be made by norms of standards specified in their contracts,

- *by manufacturers or suppliers of production* if the documents, which supplement their batches inform on compliance of their quality to norms of related standards, or information on said documents is given in their marking (labels), or the production they propose has to be attested on compliance to norms of the document in question.

The norms of national standards regulate in practice the conditions of free movement of goods at the domestic market. However, differences of normalized parameters of goods they establish on national level may result in inducing of negative influence on conditions of their free movement internationally, complicating so the processes of scientific and technical collaboration of interested parties. Therefore, the processes of advancement of international business contacts lead to need of global unification of normalized indices of quality of production and methods of their identification, as well as realization of principles of fair trade based on use of norms recognized universally.

The evidence of successful realization of this practice is that the integrated degree of international trade increases 3÷4 times quicker of averaged global rate of rise of volume of global output of marketable products and services. To assist in it, there exist some levels of standardization, which differ by the criterion of geographical location of participants of these processes. For example, the international level of standardization presupposes harmonization of norms to be used in countries located worldwide, and the level of use of regional standards relates to activities of persons of economy of countries of certain geographical, political or economical region. Summarizing, one should note that the practice of use of international, regional and national normative documents leads to formation of global system of standardization, which now covers practically all spheres of economical and public life of mankind.

3.2. History of Progress of Standardization

The history of progress of human community counts many centuries, and even millenniums: craftspeople tried to select since the ancient times

the optimum means of work, the most perfected mechanisms, and the most valued technological processes to produce the most valuable products, what resulted finally in formulation of basic principles of unification of designs of produced items and principles of their fabrication. The roots of such processes are seen even in ancient Egypt, where builders used in construction of erections the stone blocks of strongly normalized dimensions of 410×200×130 mm. Builders of Ancient Rome used the water-pipes of the only diameter of 5 fingers. Later, in the Middle Ages, methods of unification and standardization progressed in parallel with evolution of craftsmanship. For example, the European weavers fixed in their workings the unified width of cloth and the same number of threads in its base. However, the modern stage of standardization was begun only in 1785 with the beginning of serial producing in France of fire arms, which have the interchangeable details.

In the very beginning, in conditions of mass production and strong competition of manufacturers, almost all big enterprises standardized their operations individually and separately of other market participants and developed their own rows of dimension-types of articles and procedures of operation. Later, in parallel with progress of cooperation in manufacture and trade, there originated the problem of use in their own manufacture of interchangeable details produced by other fabricants, what began the initial stage of modern standardization realized first in boundaries of certain geographical areas and provinces and spread gradually to territory of the whole country and finally to the global level.

The one more hindrance in unification of norms of operation of national economies were difficulties in recognition and correct use of units of physical magnitudes, which have the same name but differ by their numerical values. The one of the most indicative example of such kind differences demonstrate the units of mass expressed by pounds of *Troy* (373.2 g), *Russian* (409.5), *British* (453.6), *Swiss* (500.0) and *Viennese* (560.1) ones. So, the modern stage of work in international standardization began in 1875, when representatives of 18 countries (Austria-Hungary, Argentina, Belgium, Brazil, Britain, Denmark, France, Germany, Italy, Norway, Peru, Portugal, Russia, Spain, Sweden,

Switzerland, Turkey, USA and Venezuela) signed in Paris the *Metric Convention*, which had the objective of introduction of units of measurement to be used internationally. Later, in 1886, the First International Congress by problems of standardization of 10 the most advanced for that time countries (including the Russian Empire) held in Dresden (Germany) discussed the principal problems of international standardization, especially the practice of coordination of works in development of substances of standardized composition to be used in measurement as the reference materials. The result was founding of the *International Association of Testing of Materials* as the forum for discussion of problems of standardization and harmonization of its norms worldwide. The first national institution by standardization was the *Committee of Technical Standardization* founded in Britain in 1901. In progress of international trade, the analogous services were organized in Netherlands (1916), Germany (1917), France, Switzerland, USA (1918) and other countries.

The next step in internalization of standardization was holding in 1921 of the conference of seven national profile secretariats, which developed the organizational principles of *International Federation of National Standardizing Associations (ISA)* found in New York in 1926. ISA did not developed the norms of international category, but its activities greatly influenced on progress in global unification of rules of standardization. Particularly, the Association technical committees developed more of 180 recommendations for its 30 member states (including the USSR) setting so the basement of future international system of standardization.

This work was stopped, however, with beginning of WW II. However, despite the wartime, in London was founded in 1943 the *Committee by Coordination of Standards (CCS)*, which members became 18 countries of anti-Hitlerite coalition. The main task of the newly founded organization was preservation of accumulated experience in international standardization. After the WW II was finished, the CCS members and participants of 25 more countries of London October 1946 Congress took the decision on reorganization of ISA into the

International Organization for Standardization. Because this one has the differing acronyms in different languages (for example, *"IOS"* in English, *"OIN"* in French for *"Organisation internationale de normalization"* etc.), its founders decided to give the Organization the short and all-purpose name, so chose *"ISO"* derived of Greek *isos (ισος, equal)*. Just after its founding, ISO unified the specialized profile organizations of 43 member-countries (including Ukraine as one of UN founders), each having one vote.

By that time, Ukraine was however not aside of global processes of development of principles of metrology and standardization because had for that time in it the long history began at times of Kyiv Russ: it was 966, when the Duke Volodymyr the Great' Statute established the uniform principles of measurement and weighing. After founding of the Moscow State, which unified about of 80 % of ethnical Ukrainian territory, her great dukes tried to introduce the uniform physical units to be used throughout the whole country and norms of their reproducing. It is known also that the Duke Ivan the Terrible ordered in 1550 to produce the State standard of *os'mina* (the unit used in measuring of free-flowing substances), send it to Northern Dvina region to use it in making of its *zapiatnanykh (stamped)* copies and return after to Moscow for storage as the State standard of unit of measurement.

Because that-time Russian empire had no specialized institutions by collation of exemplary standards of measures and weighs, it was founded in XVI century the *prikazes* specialized in this kind activities, which were reorganized in the beginning of XVIII century in *collegiums* responsible for the work in normalization of values of national standards of measures and weighs and control of correctness of their use. In mid-XVIII century, these functions adopted the supreme State body – the *State kamer-collegium*, when the Empress Anna Ioannovna attempted to organize the central and provincial State verification services and founded in 1736 for this purpose the specialized State committee. However, such activities were finished in 1747 after making of exemplary standard of Russian pound and establishing of normal value of *arshine*, the Russian national unit of length. In progress of economy, the Russian government founded

the Commission headed by the academician A. Kupfer, which main goal was development of norms of control of observance of correctness of measurements. The Commission developed the project of the State Decree on Measures and Weighs approved in 1832, produced with the most possible for that time precision the standards of Russian units of *sagene* and *[Russian] pound* and passed them for storage into the *State Mint* and the *Oruzheinaya Palata.*

The quick progress of industry and transport in Russian Empire in XIX century induced the need of intensifying of works by standardization. For example, in 1860 there was standardized the unified width of railway gauge (1524 mm = 5 feet in British system of units of measurement), in 1889 – the first Russian specifications on projecting and building of railroads, in 1900 – the *Codex of Rules and Norms on projecting and exploitation of electrotechnical instruments* and so on. The Russian Empire became one of the first countries, which organized the specialized institution for standardization – the *Central Palata of Measures and Weighs* (1906) headed by D.I. Mendeleyev. However, the progress of metrological science and standardization in Russia, as well as development of her relations in these spheres of economy with other countries was complicated because of use of three parallel systems of units of measurement: the traditional Russian one (arshine, [Russian] pound), British (inch, [British] pound), and metrical (meter, kilogram). Moreover, the traditional Russian units used in practice in most cases were intricate for understanding and conversion in metric ones by her foreign counterparts. The example is identification of Russian national unit of mass given in *"Statute of Measures and Weighs"* of 1899 as: *"The basic Russian unit of mass is the [Russian] pound represented by the standard of 1835 made of iridium-platinum alloy, which reproduces the value and is used instead of the bronze gold-plated monetary standard of pound of 1747. Its mass is equal to forty million nine hundred and fifty one thousand and two hundred and forty one units of one hundred millionth part of international unit of kilogram."*

To simplify the work in unification of provisions of Russian (Soviet) State standards with global norms, the Council of People's Comissars of

the Russian Soviet Federal Socialistic Republic issued just after its formation in 1917 the universal *"On Introduction of International Metrical System of Measures and Weighs"*, what had the great positive effect: the quantity of dimension-types of metal articles used in serial manufacturing, for example, was reduced after its legalization sixfold.

The official date of founding of system of standardization in the USSR was 15th of September 1925, when there was organized the *Committee on Standardization of Council of Labor and Defense*. The first Soviet national standard was *"Flour. Selected Sorts of Grain. Nomenclature"* approved in 1926. In 1956, this Committee obtained the status of the *State Committee of Standards, Measures and Measuring Instruments* renamed in 1970, in turn, in the *State Committee of Standardization (Gosstandart SSSR)*.

After Ukraine declared in July 1990 the State sovereignty, her Council of Ministers issued the Decree of 24th of May 1991 # 12 on founding of the *State Committee of the Ukrainian Soviet Socialist Republic by Standardization, Metrology and Quality of Production*. After Ukraine became the independent State, this structure was reorganized 08 of April 1992 in the *State Committee of Ukraine by Standardization, Metrology and Certification (Derzhstandart of Ukraine)*, which principal functions were the State administration by problems of metrology, standardization, certification and State supervision on observance of their norms. In optimization of structure of governmental administrative bodies, the Derzhstandart of Ukraine incorporated the *State Committee by Problems of Protection of Interests of Consumers* and was reorganized by the Presidential Decree of 17.12.1999 # 1573/99 into the *Ukrainian State Committee by Problems of Standardization, Metrology and Certification* preserving however its earlier appellation *(Derzhstandart of Ukraine)*. In expanding of its authorities, the Derzhstandart of Ukraine was reorganized in 2002 (Decree of President of Ukraine of 01.10.2002 # 887/2002) in the *State Committee of Ukraine by Problems of Technical Regulation and Consumers Policy (Derzhspozhivstandart of Ukraine)* subordinated to the Minister of Economy of Ukraine. Later,

in realization of program of optimization of State administrative structures, the President of Ukraine issued 09.10.2010 the Decree # 1085/2010 on reorganization of Derzhspozhivstandart of Ukraine into the *State Service of Technical Regulation and Consumers Policy of Ukraine* and saving of all functions executed by its predecessor. The system of said Service includes the institutions as follows:

- State Enterprise *"Ukrainian Research, Development and Training Institute by Problems of Standardization, Certification and Quality" (ДП "УкрНДНЦ"*, Kyiv),
- State Enterprise *"Ukrainian Center by Problems of Certification and Protection of Interests of Consumers"* (Kyiv),
- National Scientific Center *"Institute of Metrology"* (Kharkiv),
- State Enterprise *"Research and Development Institute of Metrology and Measuring Operating Systems"* (Lviv),
- 28 State regional centers of standardization, metrology and certification,
- 27 territorial administrations by problems of protection of interests of consumers.

3.3 Objectives and Principal Functions of Standardization

Standardization is the constituent and indivisible part of work in development of new technique, which is character by the considerable economical effectiveness, because the work in normalization of processes of economy permits:

- to establish the efficient nomenclature of indices of quality of production and bring them in conformity to the latest advancements in science and technique,
- to shorten terms and cut laboriousness of R&D works in use of existing standardized situations and objects,
- to provide the unified normative and technical base of evaluation and attestation of conformity of products to their normalized quality indices,

- to control in serial operation the observance of optimized norms of legal, normative and technical documents,
- to raise reliability of works in use of items of specific design, for technical decisions used in their development were checked in practice,
- to simplify the procedures of repair and servicing of workings of complicated design, for their standardized details and assemblages would be of interchangeable type,
- to reach the conditions of mutual understanding of norms of fabrication and use of products of standardized design among their developers, producers, suppliers, sellers and consumers,
- to introduce the uniform systems of documenting and cataloging of information materials.

The Code of established practice in standardization lists the following *obligatory conditions* to be taken into consideration in development of standards:

- standards have to be written in observance of needs of markets of goods and services and assist in progress of free trade relations worldwide,
- standards must be neither the means of fixing of prices, nor avoiding of competition or restraining of trade to a greater extent that it is foreseeing by the legal and/or governmental and local administrative deeds,
- if the standards of international category were just developed or are on finishing stages of development, they or their chapters must be used in development of the advanced versions of corresponding national or regional standards. The exclusions are cases of ineffectiveness or inexpedience of their use in cases of insufficiency of their norms in guaranteeing of reaching of proper conditions of environment because of climatic or geographic specificity of objects of standardization, and/or existence of technological problems in use of solutions they propose,

- standards must not produce preferences for certain types of production based on place of its fabrication and/or interests of local manufacturers,
- standards must not block technical progress, and have to give priority to the exploitative norms of standardized items, but not their constructive and outward appearances,
- the object of standardization must not be patented if it is not the obligatory condition stated in the technical order on its development,
- if some technical solutions stated by the normative document are patented, their interested persons have to receive the permission of owner of patent rights on their use valid during the specified term.

The *objective* of activities in standardization is ensuring of conditions of:

- raising of level of safety of life and health of citizens, property of natural and juridical persons, objects of State and municipal property, objects, which may be exposed to risks of occurrence of emergencies of natural and technogeneous character, increasing of level of environmental safety, safety of life and health of animals and plants,
- assuring of rational use of resources, competitiveness and proper quality of production (works, services), as well as and free movement of commodities in domestic and international markets,
- unification of basic designs and parametrical and dimension-type series of standardized items and their constituent parts,
- assuring of uniformity of measurements and comparability of R&D works and measurements, technical, economical and statistical data,
- assuring of technical and information compatibility and interchangeability of production and its constituent parts with the analogous items fabricated by other manufacturers,
- development of systems of classification and codification of technical, economical and social information, systems of

cataloging of production (works, services), systems of scanning and transmission of information.

The basic principles of the *State policy in standardization* are:

- compliance of norms of standards to norms of related clauses of legal deeds, technical regulations and other documents of normative and technical character,
- complexity of principles of standardization of interrelated objects and optimality of the normalized parameters,
- ensuring of possibility of participation of any natural and/or legal person in development of standards and other type normative documents,
- openness and transparency of procedures of development and validation of standards,
- adaptation of modern technical norms to existing conditions of national economies,
- harmonization of provisions of normative documents of national category and procedures of their development with the international, regional and interstate norms.

The notion of *harmonization* mentioned above represents itself the event of bringing of content of certain national normative document in compliance to provisions of standards of other categories of similar destination, whether it will be the international or regional norm, or the national standard of other country.

Dependently of probable range of use, works in development of standards accomplish the following parties:

- individual enterprises (associations),
- authorities of certain branch of economy,
- State authorized institutions,
- specialized bodies of interstate communities (CIS countries, for example),
- specialized bodies of regional (international) communities of some geographical or economical areas (EFTA or EU countries, for example),
- specialized global organizations and associations.

3.4 Principles of Modern Standardization

The fundamental problems of interest of modern standardization are:

1. *Maximal balance of interests of projecting and manufacturing parties with the interests of persons, which use their products.* To reach consensus, the developer of the document has to reach the balance of interests of interested parties, for the designer tries to develop the best quality product, the manufacturer tries to reach its smallest prime cost and the consumer is interested in satisfying of his basic needs in paying of reasonable price. The only condition to be observed in it is inadmissibility of approval of standards, which norms conflict with norms of technical regulations.
2. *Use of international standards as models in development of standards of national category.* The exclusions are cases of impossibility of use of international norms because of their discordance with climatic and geographical features of Ukraine, technical and/or technological specificity of object of standardization unsuitable for Ukraine or cases when the Ukrainian State stepped against approval of the whole or separate statements of the international standard by problem.
3. *Dynamicity and advancement in development of standards* based on use of fundamental canons of standardization in taking into consideration of probability of developing in future of advanced articles (services) of the same destination and alternate processes of their fabrication. The work in development of advanced standards became obligatory for the items still produced by norms of out of date normative documents.
4. *Effectiveness of standardization.* Use of norms of advanced standards must bring the economical or social effect expressed in saving of resources, rising of reliability of items in their use as the consequence of normalization of standardized procedures of their fabrication, as well as factors of normalization of the bettered conditions of protection of environment and norms of protection of health and safety of men.

The basic principles used in solving of listed problems are (Fig. 3.1):

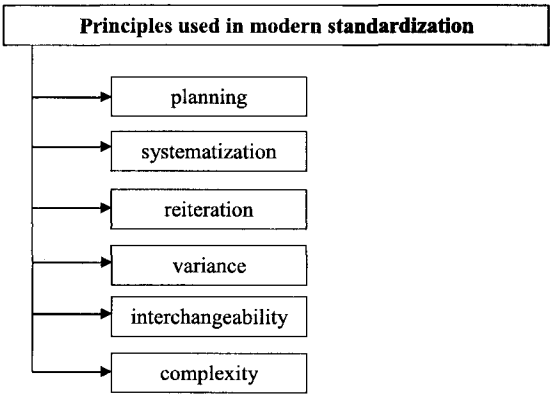


Figure 3.1 Principles of modern standardization

Principle of *planning* consists in development of current and prospective plans of standardization oriented on steady progress of public economy and optimization of structure of distribution of resources it uses.

Principle of *systematization* presumes development of complex of interrelated norms, which have the objectives of reaching of mutual concordance of interested parties and unification and excluding of doubling of regulating norms.

Principle of *reiteration* signifies determining of set of objects character by some concrete property reiterated in time and/or in space.

Principle of *variance* presumes minimizing of rational variety of standardized elements character for objects used in the same destination.

Principle of *interchangeability* is attributed mainly to technical sphere and presumes the possibility of assembling of the whole unit in use of uniform interchangeable elements (details, blocks, assemblies etc.) made in different time and by different manufacturers.

Principle of *complexity* presumes the purposeful and optimum planning of complex of interrelated properties of standardized objects, its constituent parts and other material and non-material factors, which influence on their quality.

Standards establish the uniform systems of units of physical magnitudes, terminology and metrological procedures, normalize

methods of marking, packing and transporting of production, set the rules of drawing up of manuals and information necessary for consumers etc.

To realize these principles, the work in standardization functions in taking of consideration of objectives as follows (Fig. 3.2):

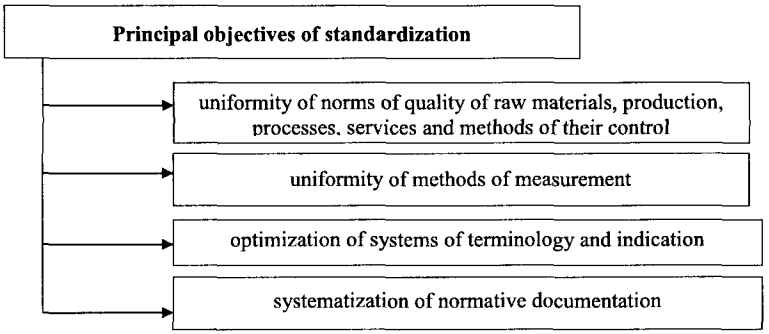


Figure 3.2 Principal objectives of standardization

Use of standards simplifies procedures of operation of manufacturers and assists in reaching of compliance of norms of quality of production they produce to criteria used in evaluation of its market competitiveness, what becomes possible because:

1. Norms of standards comply to modern level of development of technique and are used as the recognized technical norms in settlement of disputes, particularly in courts of justice.
2. Observance of norms of standards and other kind normative documents by manufacturers and suppliers is the obligatory element of governmental purchases of products they produce, carrying out of tenders and concluding of contracts on fabrication and delivery of production and carrying out of marketing and advertising campaigns.

Compliance of indices of quality of production to norms of mutually recognized standards assists in elimination of technical barriers in international trade, and is the condition of adequacy and harmonicity of processes of technical and economical progress of the community.

3.5 Methods of Standardization

Methods of standardization include the complex of rules and norms, which observance permits to reach the goals of: ***1)*** ordering, ***2)*** parametricity, ***3)*** unification, ***4)*** aggregation, ***5)*** complexity, ***6)*** forestalling.

ORDERING

The constituent of ordering of the system of standardization includes the work in selection and systematization of objects of normalization, simplification of their parametrical series and typification and optimization of chosen objects, which basic notions are understood as follows:

- *Selection* means choose of objects of normalization recommended for the repeated use.
- *Systematization* consists in scientific classification and ranking of objects of standardization by certain common criterion of their totality.
- *Simplification* means the norm of limiting of nomenclature of components and materials, which use in process of manufacturing ensures preservation of the whole set of normalized indices of quality of its products, e.g. decreasing of variety of dimension-types of details to be produced and decreasing of amount of consumables and semi-manufactured items used in it.
- *Typification* is the kind of activity, which presumes fixation of rational nomenclature of typical objects of standardization. Its character peculiarity is extending of the uniform characteristics of quality on all objects of the same destination of use. For example, typification of technological processes includes two interrelated directions of work, which complete one other: 1) typification of stages of realization of multi-stage technological processes and 2) typification of individual operations to be executed in it.
- *Optimization* consists in establishing of optimum set of basic parameters of objects of standardization, which observance guarantees reaching of the planned level of their quality.

PARAMETRICITY

The modern structure of public economy presumes producing of numerous types of products. In many cases, their fabrication and servicing becomes the more costly because of big nomenclature of articles used in the same destination but character by minor differences in design. To simplify conditions of serial manufacturing and decrease the prime cost of its products, there are used the principles of parametrical standardization representing itself the complex of actions in selection of rational set of character parameters of production and its dimension-types classified as the *basic* and *main* ones.

- *basic* parameters represent itself the set of specific constructional, technological and exploitation properties of articles and procedures of their fabrication,
- the notion of *main* parameters is more general and is applied usually to those ones that are character by stability in process of manufacturing and do not depend of specificity of realized processes, characterizing so the indices of quality of produced articles the best.

UNIFICATION

Unification is a kind of activity directed on rational decreasing of nomenclature of objects of the same functional destination in development of novel items character by minimum quantity of assemblies and details of original design and use of the standardized ones instead. The main directions of work in unification are:

- development of parametrical series of production,
- development of typical designs of articles and their constituent parts,
- development of typical technological processes,
- limiting of nomenclature of articles and materials used in fabrication of serial production to the reasonable level.

Unification assists in increase of demand for typical standardized details, assemblies and auxiliary parts used in fabrication of wide range of production. Use of this principle permits to organize producing of standardized parts of commodities, and enterprises specialized in their

serial fabrication separated in most cases of places of assembling of finished products.

AGGREGATION

Aggregation is the method of designing of machines and equipment by principle of use in their construction of assemblies of standardized design character by functional and geometrical interchangeability. The principal advantage of articled assembled in their use is the constructive reversibility and refusing in many cases of use of assemblages and aggregates of original design. Use of principle of aggregation permits to solve the numerous problems, which exist in various spheres of public economy, for example:

- broadening of nomenclature of production in use of new variants of composing of details of typical design,
- carrying out of highly productive repair and effective renovation of worn-out details of articles, machines and equipment in use of interchangeable componentry.

COMPLEXITY

This is the method based on use of interrelated requirements to quality of the standardized items, their constituent parts and material and non-material factors, which influence on their properties and parameters of exploitation. The essence of work in complex standardization consists in systematization of optimized designs of objects of normalization, what results in reaching of optimum level of their quality in minimum productive expenses.

ADVANCED STANDARDIZATION

The progress of science and technique inevitably leads to speeding of moral ageing of numerous traditional products and shortening of gap in time between origination of the idea and its practical realization. For example, introduction of radio occurred in 32 years after origination of idea of possibility of its development (1867 and 1895, respectively), television – after 14 years (1922 and 1936), but transistors appeared after 5 years period only (1948 and 1953). So, the essence of the advanced standardization consists in dynamic activity directed on predicting of prospective needs and expectations of participants of economical

processes. This results in continuous perfecting of designs, working parameters, conditions of exploitation, quality of standardized products and means of their fabrication.

The criteria of taking of any item out of fabrication are the economical, technical, ergonomic and other advantages of its newly developed analogue. This leads to need of development of advanced normative documents to be urgent for the moment of beginning of its serial production.

The major objects of standardization mentioned in the national standard DSTU 1.0:2003 *"National standardization. Fundamentals"* are:

1) organizational, methodological and technical objects, especially:
   - procedures of standardization,
   - terminological systems,
   - principles of classification and codification of technical, economical and social information,
   - systems of physical magnitudes and units of measurement,
   - standard reference data on physical constants and properties of substances and materials,
   - metrological assuring of processes of manufacturing (protection of interests of citizens and national economy against consequences of doubtful results of measurement),
   - methods of control of quality of standardized items and procedures of quality management of the enterprise as a whole,
   - systems of technical and other type documents of general use,
   - dimension type series and typical constructions of articles used in general machinery (bearings, fastenings, tools, details etc.),
   - systems of labeling, especially the graphical ones, dimensional systems (tolerances, fittings, geometry of surfaces etc.) and methods of their control,
   - informative technologies, especially the technical and programming means used in informative systems of general use,
2) production used in various branches of public economy and everyday use practices,

3) objects of public economy and their constitutive parts, especially the transport means, communications, energy systems, natural resources etc.,
4) practices of protection of interests of consumers and conditions of environment, norms of protection of labor, ergonomics, technical aesthetics etc.,
5) constructional materials, technological processes, complicated erections, typical constructions and systems of their maintenance and control,
6) needs of national safety and readiness for mobilization.

The State approves the annual plans of development of new standards in observance of specific conditions of national economies. Some of their provisions may differ of related norms of other countries, what may result in origination of technical barriers in trade. To avoid such complications, the interested countries conclude treaties on mutual recognition of validity of the normalized procedures practiced in the partner-countries and try to introduce the related regional and international norms instead. The expressive examples are the EU directives, which foresee free movement of goods, capital and services throughout its whole area in use of provisions of normative documents accepted generally are the cases of free use of any foreign-made good produced by norms of European standards in the whole territory of European Economical Area without their repeated testing in country of destination.

3.6 International Standardization Organizations

The one of the main peculiarities of modern standardization is dramatic growth of number of international organizations operating in this sphere, which quantity is now more of 400 of existing 4,000 global and regional specialized organizations. The necessity of their founding resulted of progress of public relations, science and technique, when the members of international community began to produce their production by norms of specialized normative documents of regional and international ranks in quantities, which exceed their own demand, hence

need to export them in other countries. The most influential global and European organizations, which develop such documents, are (Table 3.1):

Table 3.1

International and regional standardization organizations

Name of organization	Acronym
International Organization for Standardization	ISO
International Electrotechnical Commission	IEC
International Organization of Legislative Metrology	OIML
International Telecommunication Union	ITU
International Conference of Instruments and Measuring Technique	IIECO
International Bureau on Standardization of Synthetic Fibers	BISFA
International Standardization and Testing Organization	ISTO
International Consultative Committee on Telegraphy and Telephony	CCITT
International Lighting Committee	CIE
International Acetylene Association	IAA
International Atomic Energy Agency	IAEA
International Grain Chemistry Association	IGC
International Milk Association	IDF
International Cocoa and Chocolate Documentation Bureau	IOCC
International Silk Association	ISA
World Quality Council	WQC
Committee of European Norms	CEN
European Committee by Standardization in Electrical Engineering	CENELEC
European Quality Organization	EOQ
European Quality Management Fund	EFQM
European Electronic Components Committee	EECC
Interstate Standardization, Certification and Metrology Council (CIS countries) (registered in ISO as European and Asian Standardization Council)	МДР (EASC)

3.6.1 *International Organization for Standardization (ISO)*

ISO is the biggest operator in optimization of structure of global fund of standards and harmonization of national norms of business operation with the established norms of global economy. This Organization was founded by decision of the October 1946 London conference of 25 industrial countries. The UN General Assembly legalized its status as the non-governmental UN consultative body and approved the functions of operation of its structural departments, stating that: *"... the goal of the Organization is assistance in progress of global processes of standardization in purposes of facilitation of conditions of global trade and assisting in intellectual, scientific technical and economical collaboration of its participants"*. The original directions of ISO activities were centered on issuing of recommendations on coordination of content of national normative documents of ISO member-countries practically till 1970. However, in progress of international relations, it was cleared the tendency of internationalization of economical relations and trade. The predominant sphere of work of ISO was shifted therefore to development of international standards to be used as the means of unification of global norms. Therefore, the ISO priorities are:

- unification of norms of national and regional standards in purposes of their harmonization with the norms recognized internationally,
- development and dissemination of international standards,
- collaboration with specialized international organizations by problems of mutual interest.

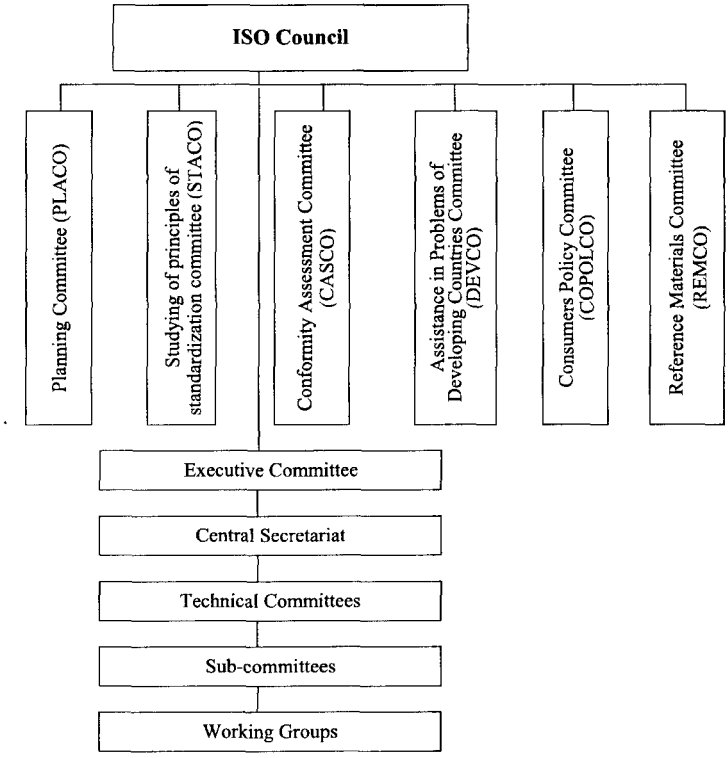
The working board of ISO is located in Geneva (Switzerland). Its official languages are English, French and Russian. Its members are national organizations by standardization and certification of more of 80 states, which pay the member fees (full members), have the right to be represented in staff of all ISO structures including its administrative departments, have access to all ISO workings, receive all documents of Organization and apply propositions concerning thereof. The Organization staffs also about of 25 corresponding members of

developing countries, which have no own standardization organizations. These ones receive all set of published international normative and informative documents on condition of payment of reduced membership fees but are limited in access to documents of the Organization in development. Besides, there exist the ISO subscribing members, which represent countries, which economies are small, hence they pay the favorable membership fees but receive the whole set of informative materials on the state of international standardization.

The Supreme body of the Organization is the annual General Assembly of representatives of its member-countries and delegates of ISO committees. Each national organization, which has the status of full member, is represented here by three delegates with the right of casting vote. The corresponding and subscribing members participate in such meetings with the right of consultative vote. The work of the Organization in period between meetings guides the ISO Council, which fixed members are People's Republic of China, France, Russian Federation, United Kingdom and USA. The Council disseminates by procedures of written inquiry the information on current activities of the Organization in purposes of obtaining of consent by problematic questions of its operation.

The structure of the Organization includes more of 30 thousand specialists of different countries, who developed for the present more of 15,000 international standards. To do this job, the ISO General Council appoints technical committees responsible for specific directions of work coordinated by the ISO Central Secretariat. There existed also more of 3300 technical bodies in the ISO system, which include more of 2700 ISO technical committees, subcommittees and working groups. The ISO structure includes the principal departments as follows (Figure 3.3):

Fig. 3.3 ***Organizational structure of ISO***



The principal directions of work, which execute the ISO profile committees, are:

Planning Committee (PLACO) coordinates operation of ISO working structures, identifies the spheres of their activities and considers proposals by postponing and breaking up of work of existing and founding of new technical committees and commissions.

Standing Committee for the Study of Principles of Standardization (STACO) develops the fundamental principles of standardization and works up methods of obtaining of optimal results in their realization, as well as gives the ISO Council the methodological and informative assistance in development of procedures of international standardization. The Committee develops also the special terminology

used in it and organizes seminars by norms of use of provisions of international standards in practice of global economic relations.

Conformity Assessment Committee (CASCO). The Committee had initially the name of *Committee of Certification (CERTICO)* but was renamed in 1995 because of extending of sphere of its responsibility. The Committee:

- develops methods of assessment and attestation of conformity of products, processes, services, personnel and quality systems,
- assists in introduction of norms of international standards in practice of evaluation and attestation of conformity,
- develops criteria of global recognition and systematizes the practices of operation of ISO member-states in attestation of conformity,
- develops procedures of accreditation of testing, measuring, calibrating laboratories and auditors, who work in this sphere.

Committee by Problems of Developing Countries (DEVCO) services said states by problems of international standardization, certification and metrology. Its main functions are: organization of discussions by all aspects of standardization; training specialists in teaching centers located in advanced countries; assisting in exchange by experience and stimulation of interrelations of specialists of advanced countries with their colleagues, who work in developing countries.

Committee by Protection of Interests of Consumers (COPOLCO) informs the interested parties by aspects of international standardization and certification and carries responsibilities for communication of ISO with the international organizations operating in this sphere. The principal tasks of the Committee are:

- assisting in reaching of maximum effectiveness in standardization of consumables,
- development of procedures of protection of interests and comprehensive information of consumers on parameters of quality of items they use in everyday practice,
- summarizing of experience of participation of consumers in standardization and assisting them in this work,

- communication with other ISO departments by problems of interest of consumers.

Reference Materials Committee (REMCO) provides the technical assistance in development, producing and use of etalons, calibration and reference standards of international category, as well as on synchronization of values of national standards. The main directions of its operation are:

- development of principles of classification of reference materials,
- establishing of criteria of choose of standard materials to be used in arbitrary and precise measurements,
- development of procedures of use of reference materials.

The natural persons and enterprises have no right of membership in ISO structures but may participate in their work by modes as follows:

- national organizations by standardization may delegate the natural persons in ISO structural departments as experts,
- natural persons and enterprises may participate as the individual or collective experts in work of profile bodies of ISO member-countries, which operate international problems and work in ISO technical committees as advisors.

The main mode of operation of ISO is development of normative documents of international category, publishing of technical reports, technical specifications, publicly available specifications (documents used at stages, which precede the work in development of international standards), technical corrigenda and guides.

The *ISO standards* have the designation of *ISO[/IEC] nnnnn [p]:[yyyy] Title*, where *nnnnn* is the number of standard, *p* – its sequence number in series (if the latter includes more than one document), *yyyy* – year of publishing, and the *Title* specifies the subject of normalization. The supplementing index of *IEC*, if present, is acronym of the *International Electrotechnical Commission* added in cases of participation in development of the document of this international standardization body specialized in development of standards used in

electric engineering. The list of abbreviations used in development of other ISO includes:

- PWI – *Preliminary Work Item*,
- *NP or NWIP – ISO/IEC NP 23007 (New Proposal / New Work Item Proposal*,
- AWI – *ISO/IEC AWI 15444-14 (Approved new Work Item)*,
- *WD ISO/IEC WD 27032 (Working Draft)*,
- CD – *ISO/IEC CD 23000-5 (Committee Draft)*,
- *FCD – ISO/IEC FCD 23000-12 (Final Committee Draft)*,
- DIS – *ISO/IEC DIS 14297 (Draft International Standard)*,
- *FDIS – ISO/IEC FDIS 27003 (Final Draft International Standard)*,
- *PRF – ISO/IEC PRF 18018 (Proof of a new International Standard)*,
- *IS – ISO/IEC 13818-1:2007 (International Standard)*.

Developing the document, the national experts, who work in the technical committee in question, meet regularly to discuss the topic of development until they would reach consensus on the content of its preliminary version and send it for discussion and obtaining of remarks and requests. The corrected version of the document obtains the status of Draft International Standard (DIS) disseminated among the interested ISO member-countries for comment. The developers of the document take then into consideration the commentaries and remarks they received, make the necessary corrections in formulating of the final version of the document and send it for voting. If its results would be positive, the finished version of the document obtains the status of the Final Draft International Standard (FDIS). To be accepted as the regular international standard, its content must be approved by at least two-thirds of ISO members, who participated in voting and not be disapproved at the same time by more than a quarter of voters.

The normative document obtains the category of *technical report* in cases of differing of its content of the full list of provisions to be observed in the text of international standard, e.g. in absence of reference data and explanations used generally in its formalization. The numbering

of such documents is the same as full standards, but is supplemented in its coding with lettering of *TR*, for instance:

- *ISO/IEC TR 17799:2000 Code of Practice for Information Security Management,*
- *ISO/TR 19033:2000 Technical product documentation — Metadata for construction documentation.*

The category of *"Technical specifications" (TS)* obtain the normative document if *"the subject of standardization is still in stage of development or in existence of other reasons of postponing of its validation in category of international standard"*. The one more category of normative documents, the *"Publicly Available Specifications" (PAS)*, are developed *"... if the subject of normalization is still in stage of development and the document is published before its introduction in category of international standard"*, for instance:

- *ISO/TS 16952-1:2006 Technical product documentation — Reference designation system — Part 1: General application rules,*
- *ISO/PAS 11154:2006 Road vehicles — Roof load carriers.*

Sometimes, ISO publishes the *"technical corrigenda"*, e.g. ISO/IEC 13818-1:2007/Cor. 1:2008, the documents, which introduce the correctives in texts of valid standards in purposes of introduction or annihilation of some statements, or correction of minor discrepancies in their basic texts, or in necessity of adding of unimportant addendums, put usually in basic texts in following revisions of such documents. The abbreviations used in designations of corrigenda in standards are:

- *NP Amd – ISO/IEC 15444-2:2004/NP Amd 3* (New Proposal Amendment),
- *AWI Amd – ISO/IEC 14492:2001/AWI Amd 4* (Approved new Work Item Amendment),
- *WD Amd – ISO 11092:1993/WD Amd 1* (Working Draft Amendment),
- *CD Amd / PDAmd – ISO/IEC 13818-1:2007/CD Amd 6* (Committee Draft Amendment / Proposed Draft Amendment),

- *FPDAmd / DAM (DAmd) – ISO/IEC 14496-14:2003/FPD Amd 1* (Final Proposed Draft Amendment / Draft Amendment),
- *FDAM (FDAmd) – ISO/IEC 13818-1:2007/FD Amd 4* (Final Draft Amendment),
- *Amd – ISO/IEC 13818-1:2007/Amd 1:2007* (Amendment).

The one more category of ISO documents of regulatory character, are the *"ISO Guides"* used in purposes of detailing of specific norms of work in international standardization. These ones have the format of *"ISO/IEC Guide #:yyyy: Title"*:

- *ISO/IEC Guide 2:2004 Standardization and related activities — General vocabulary*
- *ISO/IEC Guide 65:1996 General requirements for bodies operating product certification*

The other abbreviations ISO uses usually are:

- *TTA – ISO/TTA 1:1994* (Technology Trends Assessment),
- *IWA – IWA 1:2005* (International Workshop Agreement).

The provisions of normative documents developed by the Organization are voluntary for use. However, countries may decide to harmonize them in category of national norm to be recognized internationally, what gives their users the advantages as follows:

- *Business operators* can develop and offer their clients products and services, which would comply to norms used in their acceptance in global markets.
- For *innovators of new technologies*: international standards speed up dissemination of information on innovations and assist in shortening of terms of settling of producing of manufacturable goods.
- For *customers* the conformity of goods to norms of international standards guarantees their proper quality, safety and reliability in use independently of place of their manufacturing.
- For *governments* international standards provide the base in development of norms of protection of health, safety and proper conditions of life of population.

- For *trade officials* use of norms of international standards is the crucial condition in concluding of contracts with their foreign counteragents.
- For *developing countries* international standards are the important sources of technological knowledge, for their norms represent the modern *"state-of-art"* of object of normalization.
- For *the planet we inhabit* use of international standards on quality of air, water and soils, norms of emission of gases etc. assists in rising of effectiveness of work in preservation and improvement of natural conditions.

ISO collaborates with the UN Organization and her specialized agencies and commissions, especially with those that are involved in harmonization of norms of life and public policies globally, e.g.:

- Codex Alimentarius Commission on food safety,
- UN Economic Commission for Europe (UN/ECE) on safety of motor vehicles and transportation of dangerous goods,
- World Health Organization (WHO) on problems of development and use of norms of protection of health,
- International Maritime Organization (IMO) on transport security,
- World Tourism Organization (UNWTO) on quality of tourism services, and so on.

ISO closely cooperates in this work with the UN subordinated organizations, which provide assistance and support to developing countries, such as the UN Conference on Trade and Development (UNCTAD), UN Industrial Development Organization (UNIDO), International Trade Center (ITC) and others. The ISO' technical committees have, in turn, the formal liaison relations with more of 600 international and regional organizations, which represent different groups of stakeholders, especially:

- World Economic Forum (WEF),
- Consumer International (CI),
- World Business Council for Sustainable Development (WBSCD), and
- International Federation of Users of Standards (IFAN).

ISO collaborates regularly also with the major regional organizations operating metrology, attestation of conformity and quality management, especially:

- African Regional Organization for Standardization (ARSO),
- Arab Industrial Development and Mining Organization (AIDMO),
- European Committee for Standardization (CEN),
- Pan American Standards Commission (COPANT),
- Euro Asian Council for Standardization, Metrology and Certification (EASC),
- Pacific Area Standards Congress (PASC),
- ASEAN Consultative Committee for Standards and Quality (ACCSQ).

The spheres of ISO activities in standardization cover all spheres of global economy in exclusion of branches of electrical engineering and telecommunications, for these works execute the *International Electrotechnical Commission (IEC)* and the *International Telecommunication Union (ITU)*, respectively.

3.6.2 International Electrotechnical Commission (IEC)

The cooperation of national agencies operating standardization in electrical engineering began in 1881 at the specialized International Congress convened in view of urgent necessity of unification of units of measurement used in this sphere of economy. In later time, representatives of 13 countries founded at the 1906 London conference the International Electrotechnical Commission, the today leading international non-governmental organization operating standardization in electrical power engineering, development of means of transmission of energy and electromagnetic compatibility, semiconductors, fiber-optical technique, autonomous sources of power, solar energetics, nanotechnologies and adjoining problems, e.g. development of specific technical terminology and symbols.

The IEC main office is located in Geneva, the regional centers – in Singapore, Sao Paulo, and Boston. Now IEC includes 60 member-countries (its *full members* are Australia, Austria, Byelorussia, Bulgaria, Brazil, Canada, China, Greece, Croatia, Czech Republic, Denmark, Egypt, Finland, France, Germany, Hungary, Israel, Indonesia, Iran, Ireland, Italy, Japan, Luxembourg, Mexico, Montenegro, Netherlands, New Zealand, Norway, Pakistan, Philippines, Poland, Portugal, Republic of Korea, Republic of South Africa, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovak Republic, Spain, Sweden, Switzerland, Thailand, Turkey, USA, Ukraine, the *associated members* – Bosnia and Herzegovina, Colombia, Costa-Rica, Cuba, Cyprus, Eritrea, Estonia, Iceland, Latvia, Lithuania, Malta, Tunisia, Uruguay) and 69 affiliated members covering all together nearly 85 % of global population.
The supreme managing body of the Commission is its Council, which members are representatives of profile national committees of IEC members. The Council convenes the annual sessions in its member-countries in turn and takes decisions by simple majority of votes (in case of equal quantity of votes the IEC President has the right of casting vote).

In 1947 IEC joined to ISO as its autonomous branch, preserving, however, its financial and organizational independence. Expanding the sphere of its activity, the Commission opened the Program of collaboration with the developing countries and allows them to use norms of IEC standards in national normative documents and technical regulations and participate in discussion of projects of standards of the Commission with the right of consultative vote.

The IEC standards develop more of 10,000 experts, who represent the generalized interests of enterprises, which operate in the electrical engineering industry. The IEC standards are of two types: the first category norms are of specifically technical character used in normalizing of terminology, parameters of voltage and frequency, recommended methods of testing etc. The second ones specify the technical parameters of wide range of concrete products used in electric engineering industry.

The IEC standards give typically more details as compared with the ISO norms and normalize in most cases the indices of quality of products

and methods of their testing but not only their generalized characteristics. The Commission staffs 179 technical committees (TC) and sub-committees (SC), which form, in turn, the standing and temporary working groups that carry out the R&D works and develop modern methods of standardization and the IEC normative documents and recommendations. The annual programs of R&D works of the Commission include typically more of 500 themes by problems of international standardization. The priorities in this work are:

- systematization and analysis of information on global trends and tendencies of scientific and technical progress of electric engineering industry,
- solving of problems of standardization and safety of any-kind electrotechnical and electronic equipment
- global harmonization of norms of national standards used in spheres of radio-electronics, electrical and electronic engineering,
- development of international schemes of certification of profile production.
- development of trilingual vocabulary of standardized terms and symbols (indications) used in sphere of its responsibility,
- development and publication of international standards. For the information: to unify the system of their numbering with those that is used by the International Organization for Standardization, the coding of IEC standards was changed in 1997 by adding of 60,000 to numbers of standards IEC developed in earlier years and replacing of acronym IEC for ISO. For example, the standard *IEC 27* became the standard of *ISO 60027*. The new standards, which IEC develops in cooperation with ISO, are assigned with numbers of 80000 series, e.g. ISO 82045-1. At the same time, numbers of standards of 60000 series preceded by lettering *EN* are in fact the IEC standards harmonized with the European norms: for example EN 60034 is really the IEC 60034 standard adapted to European realities.

The principal objects of IEC standardization are:

- materials used in electric engineering industry (liquids, solids, gases, dielectrics, metallic copper, aluminum and their alloys, magnetic materials etc.),
- equipment used in electric engineering (welding apparatus, motors, photometric equipment, relays, low-voltage apparatus, tools, cables etc.),
- power producing equipment (steam and hydraulic turbines, electric power transmission lines, generators, transformers etc.),
- production of electronic industry (integrated circuits, microprocessors, printed circuit boards etc.),
- satellite communication equipment,
- household electric and electronic equipment, electric tools and so on.

The norms of IEC standards have nominally the voluntary character but observance of their norms becomes obligatory in marketing of respective production in global markets. The principal procedures of attesting of conformity quality indices of standardized products to their normalized parameters are put in the base of the so-called *CB Scheme*, which *purpose* is elimination of noncoincidence of provisions of normative documents of IEC member-countries and assuring of conditions of mutual recognition of results of testing of items of regulated quality. These are the household electronic and electrotechnical devices, lighting goods, medical electronic apparatus, computing machinery, electric equipment used in industrial and office premises etc. The idea of founding of CB-scheme emerged in 1926, when the representatives of Germany, Netherlands, Norway and Sweden held the conference by problems of development of norms of safety of products of electric engineering industry. This resulted in founding of *CEE* (*The "European Commission for Testing of Electrical Equipment"*) that was merged into the IEC structures in 1985 as its autonomous department under the name of *IECEE ("The IEC Schemes of Assessment of Conformity for Electrotechnical Equipment and Components")*.

There are 56 participants of this system located in Australia, Austria, Argentina, Bahrain, Belgium, Brazil, Bulgaria, Byelorussia, Canada,

Colombia, Denmark, Germany, Croatia, Czechia, Finland, France, Greece, Hungary, India, Indonesia, Iran, Ireland, Israel, Italy, Japan, Kazakhstan, Kenya, Libya, Malaysia, Mexico, Netherlands, New Zealand, Norway, Pakistan, Peoples' Republic of China, Poland, Portugal, Republic of Korea, Republic of South Africa, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand, Turkey, Ukraine, United Kingdom, USA, Vietnam. There exist two forms of membership, and the principles used by the persons authorized on operation in structure of IECEE are:

- members who *"recognized validity of activities of national certifying bodies of foreign countries" and CB certificates they issue"*,
- members who *"recognized validity of activities of national certifying bodies of foreign countries and accomplish the analogous actions"*. To be recognized in this category, the country in question has to accredit by norms of CB-system one or more its laboratories, which will test the objects of normalization.

One of norms of CB Scheme is the obligatory placing by the authorized person of economy of its logotype on documents it issues, what would permit to identify him by this attribute. Such necessity is conditioned by those that many of normative documents used by most countries of location of participants of CB-Scheme formalize methods of testing, which deviate of international norms and the items tested by national procedures should formally be tested repeatedly in the country of destination. However, existence of CB certificate demonstrates compliance of quality of tested products to mutually recognized norms, what excludes this need.

To get the right on issuing of CB-certificate, one may use one of two alternate procedures. The ***first*** one presumes organization of control of quality of tested items by the authorized national body themselves, and the principal feature of the ***second*** procedure consists in issuing of CB-certificate by the national certifying body in positive results of control carried out by the accredited third party. The manufacturers located in

countries, which have no national body authorized on work in structure of CB-system, may use only the first of these two procedures.

3.6.3 International Telecommunication Union (ITU)

The one more influential international organization operating global standardization is the UN agency of *International Telecommunication Union (ITU)* with headquarters in Geneva. It was founded in 1865 as the *International Telegraphic Union* and obtained the present appellation in 1932 at Madrid conference after signing of International Convention on *Telecommunication*, what permitted to preserve its initial abbreviation.

The Union members operate mainly the information and communication technologies. Its participants work in 191 UN member-countries and Vatican-city and Palestine as territories, which possess the special status. Its parties are not the centralized State agencies only, but the standardization organizations, non-governmental companies specialized in production of telecommunication equipment, developers of means of wireless communications and computer software, network operators etc. There exist five categories of ITU membership:

- *category A* – national ministries and departments of communications,
- *category B* – big private corporations operating telecommunications,
- *category C* – scientific establishments, which produce the specialized means of communication,
- *category D* – international organizations operating standardization, e.g. the International Organization for Standardization,
- *category E* – organizations interested in collaboration with the IYU structures but not operating telecommunications directly.

The rights of casting vote have in voting the persons of first two categories only.

The principal Union tasks are:

- assistance in strengthening of collaboration of ITU member-countries and participation in work in global, regional, interstate and non-governmental organizations operating telecommunications,
- assistance in development of means of telecommunication and raising of effectiveness of their use.

ITU co-ordinates distribution of radio diapason frequencies among operators, optimizes infrastructure of telecommunications in developing countries, assists in choose of orbits of satellites operating communication servicing and so on.

The supreme managing body, which operates standardization in the ITU structure is the *Global Assembly by Standardization in Telecommunications* convened once every four years. The Assembly establishes priorities and approves the current programs of work and drafting of profile standards in period between its scheduled sessions, as well as examines reports on finished ITU R&D works. The structural units operating under its supervision are:

1. *Sector of Standardization in Telecommunications (ITU-T)* includes in its structure 14 R&D groups, which develop the specific international standards and recommendations. Its members are:
   - profile State bodies of executive power and national telecommunication ministries and agencies,
   - R&D organizations and industrial enterprises, which produce equipment for telecommunication,
   - other institutions and organizations that operate the telecommunication services,
   - international organizations, which operate the satellite telecommunication systems.

   The objects of their control are notation systems, multimedia means and systems, telecommunication nets, communication operating systems and procedures of their servicing, methods of transmission of signals etc.
2. *Telecommunication Standardization Bureau* is the executive body of the ITU Standardization Sector. The Bureau co-ordinates the work

in development, approval, publishing and dissemination among the ITU members of newly developed documents, renews databases of normative documents of ITU interest, and executes the registration and information functions of *Bureau of the Universal International Freephone Numbers (UIFN)*.

3. *Telecommunication Standardization Advisory Group* assists the Bureau of Standardization in Telecommunications in specifying of priorities of its work, develops the guiding recommendations by betterment of procedures of collaboration with other persons of standardization, holds conferences of manufacturers of means of telecommunication etc.

The three global standardization organizations listed above form together with the *International Organization of Legislative Metrology* and the *International Conference by Measuring Technique and Instrument Making* the largest global standardization net, which strategical course of progress develops the *Working Group by Policy in Standardization*, the structural unit of the *United Nations' Economical Commission for Europe (UNECE)*. Some other international leading organizations operating standardization and working out the interstate norms by profile of their activities are:

a) "Codex Alimentarius" Commission (CAC) – analytical methods of control of quality and safety of foodstuffs, assessment of compliance of their quality to established norms and assisting in development of structures of systems of foods quality management,
b) International Labor Organization (ILO) – problems of social accountability of employers and protection of rights and interests of employees,
c) International Marine Organization (IMO) – conditions of safe keeping of freights, standardization of maritime constructions and development of drafts of standards of management with risks in the sphere of its responsibility,
d) World Tourist Organization (WTO/OMT) – classification of hotels and informative symbols they use in servicing,

e) World Organization of Intellectual Property (WIPO) – protection of rights of authors, registration of electronic products, trademarks and logos they use.

f) International Trade Center (ITC) – development of international norms of quality of consumables to be observed by their producers and distributors.

The work in development of norms specific to various global geographical and/or economical regions is in sphere of responsibility of persons, which operate in sphere of regional standardization. The most influential organizations operating in this sphere in Europe are the *Committee of European Norms (CEN)*, *European Committee by Standardization in Electrical Engineering (CENELEC)* and the *European Telecommunications Standardization Institute (ETSI)* subordinated to the regulatory European supranational institutions – the *European Parliament*, *Council of Europe* and *Eurocommission*.

3.7 Structure of European Management. European Organizations for Standardization

The European integration structures unify presently 28 countries joined in the *European Union (EU)*. These are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom, and the authorized standardization services of these countries operate as the wholly integrated interstate unit. At the same time, two countries of Western Europe – Liechtenstein, Norway and Switzerland participate in realization of norms of European standardization partially, observing, however, the norms of some European directives. The structure of European economical relations incorporated also the tiny European countries of Andorra, Monaco, San-Marino and Vatican City, which cooperate with the EU countries in their economical policy and use their general currency – the euro.

The EU members and most of their partner-countries harmonized the whole set of their national legal codes, what assists in creation of the unified European economical market, what guarantees free movement in its borders of men, goods, capital, and services. These countries develop for the present the uniform policy in trade, agriculture, fishing and regional development and the principal institutions, which operate these problems, are the *European Parliament*, the *EU Council,* and the *European Commission.*

The *European Parliament* is the institution, which delegates are elected by direct voting of citizens of EU countries. It is the EU *"supreme legal institution"* referred in EU treaties the first that possesses the ceremonial seniority over other EU integrated institutions. The Europarliament realizes its power authorities through the *European Commission (Eurocommission)*. These two structures are the base of the two-chamber EU legal structure. The *European Commission* is formed for the term of five years and its members are the former heads and ministers of national governments and 28 commissars (one person from each EU member-country) appointed by consent of all governments of EU members. The Eurocommission proposes the Europarliament the candidature of its Chairperson, who is at the same time the member of the Council of Heads of Industrial Countries (Group of Seven). The principal objectives of activities of said structures are:

- coordination of work of bodies of executive power of EU member-countries,
- development of recommendations by problems, which are in sphere of responsibility of the Europarliament,
- development of initiatives on bringing of national legal norms in line with the European legal norms,
- providing of systematical consultations of all national governments in purposes of forming of the EU unified economical, military and cultural policy.

The European Commission accomplishes also the functions of the European central body of executive power, which ensures functioning of legal, executive and administrative structures of European countries in

accordance with the norms of Rome treaty of 1958 on establishing the European Economic Community.

The progress of interrelations in EU structure was continued with signing 13th of December 2007 of *"The Lisbon Treaty on amending of the Treaty on European Union and the Treaty on establishing of the European Community"* on amendment of structure of management of EU institutions put into operation 1st of December 2009. As provided its clauses, there were introduced the position of President of Council of Europe and the Supreme Commissar of the Union by problems of foreign policy elected for the term of 2.5 years. The one more its constitutive amendment was cancelation of principle of unanimity in taking of decisions and its replacing by the norm of their approval by qualified majority of voters, i.e. introduction of the norm of so-called *"twin majority"* (the practice of taking decisions by the simple majority of voters on condition of their quorum in discussion of problems of discussion). The European Parliament obtained also more legal power authorities, especially the right to approve the deeds developed by the Eurocommission by the norm of *"usual legal procedure"*, i.e. in reaching of the consent of the Europarliament and the Council of Europe by procedures of operation as follows. The Parliament clarifies its attitude toward the project of the deed in process of first consideration and sends it with its remarks on rework to the Council of Europe. Otherwise, it has to develop its own variant and send it to examining of the Parliament. However, the Parliament may refuse in approval of the text proposed by the Council or to authorize the commission of experts specially appointed on this job to make the necessary amendments. If the Eurocommission would not reach the acceptable decision as to the problematic text, the norm of qualified majority is abolished, and the deed can approved by the Council by principle of unanimity only.

The Lisbon Treaty altered also the structure of valuables of the European Union and the main purposes of its activities. These are now the norms of 1) protection of interests of EU citizens worldwide, 2) economical, social and territorial integrity of the Union, 3) cultural diversity of its nations. The one of basic tasks of the European Union

became the formation of its *"interior market"* and realization of the set of the first-priority goals: full employment of EU residents, social progress of the whole society, protection of environment, struggle against discrimination of certain groups of population, social fairness, protection of interests of children etc. The principal reforms the European Union produced after signing of the Lisbon Treaty are:

- strengthening of role of national parliaments: the projects of EU normative and legal deeds ("green books", "white books", programs of communicative and legal character etc.), as well as the preliminary versions of EU directives have to be passed to national parliaments for detailed examination, and the EU Council may ratify these documents after their approval at national level only,
- taking of decisions of the Community in voting by procedure of qualified majority: to approve it, it is necessary to have minimum 55 % of votes of the EU member-countries, which represent at least 65 % of its population,
- control of immigration: the European Union pursues the policy of *"control of activities of foreign persons and supervision of crossing them the EU outer boundaries"*.

However, there arose the numerous problems, first, the need to annihilate the crucial differences in structures of national economies, hence introduction of uniform norms of development of regional documents of normative and regulatory character. As a result, the national bodies operating technical regulation participate in development of special type legal deeds used in structuring of economic relations at the whole territory of the European Economical Area, what norm provides the Clause # 288 of the *TEEC Treaty*, especially the European directives. The directive as such formulates the "vertical" legal relations (among private persons and bodies of public administration) but not the "horizontal" ones (among the private persons).

The debatable problems of any project of European directive in development have to be solved by the Eurocommission members in coordination with the invited experts of all EU countries. At the first stage

of discussion, the projects of directives agreed by procedures of the Lisbon Treaty study the Europarliament and Council of Europe and give their comments to be taken into consideration in final agreeing or rejection of proposed versions of these documents. After the directive would have been approved, the European guiding institutions publish them in the *EU Official Journal* and pass their texts to national governments for the obligatory legalization in term of 18 months. As provided the European Court (resolution of 04.12.1974 # 41/74), the norms of directives obtain the legal force in cases as follows:

- the norms of directive are sufficiently stringent and indisputable,
- there was expired the time-limit of their implementation in national legislation.

After the Council of European Union approved in 1985 the *"New Concept of Standardization and Technical Harmonization"*, there was amended also the whole system of interdependence of EU directives and European standards. The European directives became the normative documents of the first category, which have priority over the national laws and legalize among others the norms of concluding of interstate treaties and basic principles of operation of businesspersons in certain spheres of public economy. Sometimes, the existing norms of national legislations coincide with the norms of directives and the only job is to give them validity. However, to introduce the norms of newly developed directive, the EU member-state must make in most cases certain amendments in its national legal code.

In process their adaptation to norms of European legislation, each EU member-country has to apply to the Eurocommission the text of project of each novel technical norm and give it the legal and regulatory substantiations of differing of introduced norms (if exist) of those that are set in the directive. For example, the developer of the national norm may inform the Commission on cases of limiting of marketing of certain products specified by the directive domestically and unwanted effects and risks of their use, as well as to explain the motives of taking of this decision (need of protection of interests of consumers or conditions of environment etc.). The Commission informs, in turn, all EU members on

content of the project of the document sent for commentary, and returns the developer her remarks and objections (if exist), which have to be taken into consideration in final editing of national legal deed in question.

However, there are known cases, when the EU countries refuse in amending of norms of national legislation. The one more variant is the case of formal validation in certain EU member-state of norms of EU directive, but refusing to pass them in practice. In such cases the European Commission has the right to lodge a suit to the European Court against this country.

To give the Commission and other EU members the possibility to react, the country, which have intentions to introduce the amended norm has to postpone its approval for the term of three months after sending of its project to Eurocommission. This term may be prolonged up to six months if the Commission would send the developer the substantiated conclusion on negative influence of planned actions on free movement of goods in the EEA common market. Furthermore, if the Commission would have the intention to validate in this time the legal deed of the same directivity, or the provisions of the project of technical regulations in question would fall under the norms of projects of directives it develops, the country in question has to postpone validation of the problematic technical norm for the term of twelve months, and if the Council of Europe would not come during this term to mutual thought on the problematic topic, the period of postponing of validation of norms of new directive in the interested country may be prolonged for the six months more (i.e. 18 months after the directive would have been published).

The norms of directives are attributed to all types of products excluding foodstuffs, products of agriculture, drugs and cosmetics, which are character by special norms of manufacturing and acceptance regulated by the second-level normative documents, the *European standards (Euronorms)*, which observance is the *reason for recognition of conformity* of indices of quality of items of normalized quality to norms of EU directives.

The European Commission accomplishes also the functions of central body responsible for carrying out of work in technical harmonization

having to realize the purposes set by the Rome *Treaty Establishing the European Economic Community (TEEC)* of 1958 on creation of the unified European market of goods and services. The principal object of its work initially the problem of elimination of technical barriers in trade, which had be solved in way of unification of norms of national standards of European countries. It was cleared soon, however, that this problem cannot be solved satisfactorily in this way, and the one of principal tasks of the Commission became coordination of activities of European standardization organizations in development of standards to be used directly in all EEA member-countries. To arrange and quicken actions on convergence of procedures of standardization, there were approved the norms as follows:

- harmonization of provisions of legislations of EU member-countries by problems of safety, protection of health and preservation of healthy environmental conditions,
- delegation of functions of harmonization of normative documents of national category with the European norms to national standardization bodies of EU member-countries,
- mutual recognition of conformity of quality of items produced in observance of Euronorms to norms of Euronorms.

The existing European system of technical regulation formally limits recognition of international standards in category of Euronorms. Therefore, to be used as the official European norms, these ones have to be accommodated to local conditions and approved in this category. The three regional organizations, which carry out these works and develop Euronorms are:

1. *CEN (Comite Europeen de la Normalisation)* operates in all sectors of standardization except of electrical engineering and telecommunications. Almost 30 % of its standards are identical with the international ones.

2. *CENELEC (Comite Eurpoeen de normalisation en electrotechnique)* operates in electrical engineering. About 70 % of CENELEC standards are identical with the IEC normative documents, but

their principal difference of international analogues is more rigid norms of safety.

3. *ETSI (European Institute of Telecommunication Standards)* develops normative documents used in sphere of wireless communications. Contrary to two previous organizations, its members are not the national standardization organizations but juridical persons. The Institute members are 696 participants including the Ukrainian specialized companies.

The structure of European standardization is in close compliance with this one of global one: CEN executes the same functions in Europe as ISO worldwide, sphere of activities of CENELEC coincides with this one of IEC, and ETSI operates same problems as ITU.

By statutes of the [West] European organizations for standardization, Ukraine represented by her State Service of Technical Regulation and Consumer' Policy cannot join them in category of full member, but has the right of participation in their work as the affiliated (not voting) one. Possessing this right, Ukraine may harmonize European standards on condition of informing on respective European structures and use them as norms equivalent with the European ones.

3.7.1 Committee of European Norms (CEN)

The Committee of European Norms with its headquarters in Brussels was founded 21.03.1961 by resolution of the European Economical Community and European Free Trade Association as the *European Committee by Co-ordination of Standards* and was renamed in changing of priorities of its operation (see above). Its members are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom represented by their national profile organizations. Besides, its member is Liechtenstein, which has no national standardization body. Because CEN is closed to joining of new members, there was introduced in 1992 the novel category of associated membership, what permitted to ingress in its structures the specialized standardization bodies of Bulgaria, Cyprus, Czechia,

Hungary, Poland, Romania, Slovakia, Slovenia and Turkey, which work in CEN structures without right of casting vote.

The main goal of the Committee is assisting in giving of services and progress of trade by commodities produced in observance of norms of European directives. The supreme body of the Committee is the General Assembly of representatives of profile national organizations and governmental technical regulation bodies of CEN member-countries, as well as the EU and EFTA working bodies, who participate in this work without the right of casting vote. The General Assembly elects the Administrative Council responsible for execution of regulatory functions in period between sessions of the Committee, especially:

- co-ordination of works by standardization of [West] European countries,
- determining of expedience of taking of national or international documents in category of European standards,
- control of observance of provisions of Euronorms in national economies.

The CEN founded the numerous technical committees. Its organizational structure is shown below (Fig. 3.4):

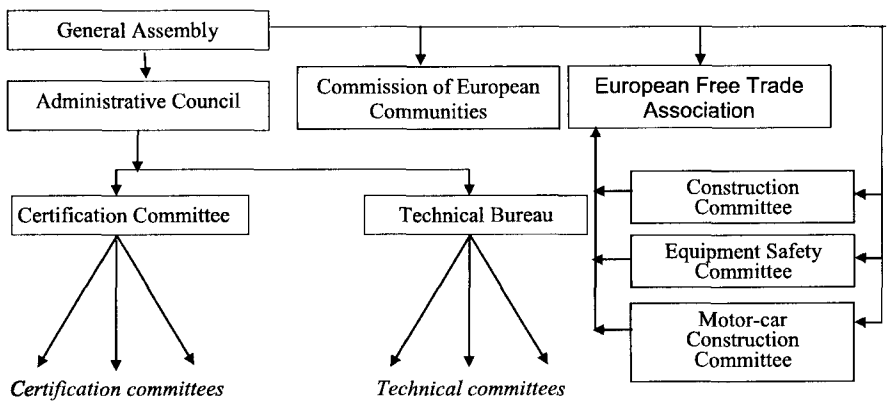


Figure 3.4 Organizational structure of CEN

Operation of CEN is closely associated with activities of the International Organization for Standardization because its members are at

the same time the ISO members. The mechanisms of interrelations of these two organizations regulate clauses of the Viennese Treaty, which observance controls the co-ordination group of representatives of their technical steering bureaus. The group members meet annually to analyze results of execution of common projects, approve the adapted versions of ISO and IEC standards in category of European ones, co-ordinate plans of work of CEN and ISO technical groups and departments and inspect the prospective plans of standardization in Europe.

The policy of the Committee in standardization develops the Collegium of Directors to be approved by the CEN General Assembly, which consists of persons authorized by the specialized national organizations of its member-countries. The work of CEN departments controls the Mutual Group, which consists of representatives of its managing bureaus. The Group holds the CEN scheduled sessions, discusses problems of technical coordination of planned works, analyses results of execution of its R&D projects and validation of new CEN standards. Choose of priorities in CEN activity is grounded by economical necessity and potential influence of provisions of prospective standards on progress of mutually beneficial relations of European persons of economy. The priorities in adaptation of ISO standards to European realities are strengthening of role of CEN as one of leading providers of European standardization and its effective collaboration with EU, EFTA and other regional structures in spheres of CEN responsibility.

As provide the EU internal norms, the European standards are the documents of voluntary character, which have to be transposed on national levels. However, unlike the normative documents of pure national character, the EN standards may be used directly on the whole territory of the European Economical Area. Therefore, to assist in integration of economies of EU member-countries, it is highly desirable to revoke their standards of national category and use the Euronorms instead. Besides, CEN develops documents of such specific categories as Technical Specifications (TS), Technical Reports (TR), Guides and Workshop Agreements (GWA). The one more category of norms developed by CEN structures is the document by harmonization (HD) to

be used in cases of existence of sufficient differences of practices of operation of CEN members in certain spheres of their activities. The Commission develops also the preliminary (transient) standards (ENV) to replace in future the respective national norms, but permitted for use just after their approval in parallel with the valid national standards of the same destination. The ENV standards normalize usually the properties of innovative objects character by fast change of their characteristics (technologies of manufacturing). The main goal of their development is accumulation of data on objects of normalization and specifying of prospective norms of future standards.

In impossibility of use of international and other category standards, the CEN technical committees develop by claim of members of the Committee and EU and EFTA structures the specialized technical specifications defined by Directive of European Parliament and Council of Europe # 98/34/EU of June 22, 1998 as the normative documents, which regulate the procedures of information of interested persons on content of technical standards and regulations used in the Information Society services. The CEN technical committees use extensively in their work the national normative documents of its member-countries, especially the German (DIN), French (AFNOR), and British (BN) standards.

The procedures of adoption of European standard include approving of its project by working group of the technical committee authorized on this job and its sending to national standardization bodies of all CEN member-countries for revision and voting. Such kind project would be reckoned as satisfying with the set purposes and approved as the regular norm if there would be not more of 20 % negative votes of parties, which took part in voting. The information on approved versions of standards is included in the catalogue of European norms and their official versions are sent for use to national standardization bodies of all CEN member-countries including the parties voted negatively. The CEN Administrative Council considers thereafter their content from the viewpoint of importance for economies of CEN member-countries and recommends

using of provisions of these documents in development of European directives.

3.7.2 *European Committee by Standardization in Electrical Engineering (CENELEC)*

The first European regional organization, which began development of standards used in sphere of electrical engineering (CENEL) was founded in 1960. Its members became that time EU (Belgium, France, Germany, Italy, Luxembourg and Netherlands) and EFTA member-countries (Austria, Denmark, Norway, Portugal, Sweden, Switzerland and United Kingdom). In 1963, the EU national electrotechnical committees cancelled their membership in CENEL and founded the parallel regional organization operating standardization in the same sphere of economy – the *European Committee by Coordination of Electrotechnical Standards (CENELCOM)*. After Denmark, Ireland and United Kingdom joined EU in 1971, CENEL and CENELCOM unified their structures, establishing so the [West]European non-commercial organization – the *European Committee by Standardization in Electrical Engineering (CENELEC)* with headquarters in Brussels, which structure shows Figure 3.5:

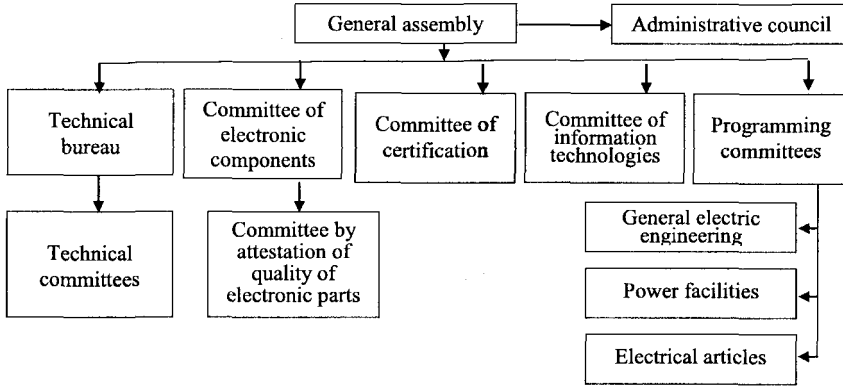


Figure 3.5 Organizational structure of CENELEC

Its members are now the profile national standardization bodies of 33 European countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom. The CENELEC affiliated members are 14 countries located mostly in Northern Africa and Central and Eastern Europe: Albania, Bosnia-Herzegovina, Byelorussia, Egypt, Georgia, Israel, Jordan, Libya, Moldova, Montenegro, Morocco, Serbia, Tunisia and Ukraine. The status of affiliated member permits the country to work in structures of the Committee and harmonize freely her normative documents in status of their national standards. The official languages of the Committee are English, French and German. Допускається також видання національною мовою титульного листа стандарту при офіційній заяві про індосамент (посвідчення про передачу певного документу від однієї особи до іншої, тут – від CENELEC до національної організації). It is permitted also to publish in national language the title sheet of the standard on condition of official announcement on its indossament (the certificate, which witnesses the fact of handing of the document over one person to the other one. In this case these are CENELEC and the national organization interested in use of standard in question). In this case any national differences, if present, may be included in such documents in form of information addendums only.

The main objects of CENELEC standardization are:

- industrial and household equipment, which operate at alternate current of 50 ÷ 1000 *V* voltages, and direct current of 75 ÷ 1500 *V* voltages,
- electrical equipment used in medicine,
- equipment used in highly explosive atmosphere,
- metrological servicing of the profile means of measurement.

CENELEC operates in assistance of specialists of CEN and other standardization organizations and plans its works in observance of current EU and EFTA priorities. To avoid doubling of works and shorten terms

of development of normative documents, CENELEC and IEC concluded in 1996 the so-called *"Dresden Treaty"* on their mutual activities in this sphere. In origination of necessity, CENELEC proposes IEC to do this work, and in its refusal develops the document independently, but has to inform IEC on progress of this job and give it the right of free comment of results of this work. After the project of the standard in development would be agreed by most of interested parties, it is published in category of Euronorm under the aegis of IEC as the supreme instance in European standardization.

The standards developed by CENELEC may be of three categories: European standards (***EN***) with numbering began from #50001, preliminary European standards (***EVN***) and documents on harmonization (***HD***). The procedures of validation of CENELEC standards foresee the variant of their publishing and issuing of the official announcement on its endorsement (the bill on giving the interested national organization of right of its use as the standard of national category).

3.7.3 European Telecommunications Standardization Institute (ETSI)

ETSI is the independent organization operating standardization in the European telecommunication industry. It was founded in 1988 and now is officially recognized as such by the EU and EFTA secretariats. The main office of the Institute is located in the city of Sofia Annapolis (France). Its members are representatives of EU and EFTA member-countries, countries of Eastern Europe, Cyprus, Malta and Turkey. Contrary to CEN and CENELEC, the status of membership in ETSI may be given to any national or regional specialized company, institution and organization. Its structure includes presently 699 members located in 55 countries of Europe proper and other geographical regions. Its full members are:

- national profile departments and services,
- national standardization organizations,
- owners of telecommunication nets,
- manufacturers of equipment used in telecommunications,
- users of means of telecommunication,

- R&D organizations and some other categories of persons of economy.

The principal goal of the Institute is solving of problems of interest of parties specialized in telecommunications and development of standards on means of wireless communication to be put in base of their infrastructure, as well as guaranteeing of compatibility of equipment and uniformity of services used in wireless communication. The one more constituent part of ETSI activities is development of standardized procedures of testing of specialized equipment used by most of operators of communication networks. Following these tasks, the Institute focused its work on development of documents of two principal types:

- procedures of assessment and attestation of conformity,
- procedures of interrelations of operators.

The spheres of ETSI standardization are: electric communication, broadcasting, telecommunication and adjoining sectors of economy including the intellectual communications, internet-technologies and work in nets of transmission of power.

The procedure of validation of ETSI standards differs of this that is used in structure of CEN, CENELEC and other international and regional organizations: each member-country has in it the only one casting vote independently of quantity of her representatives in the Institute; therefore her position in voting has to be agreed before the decisive voting.

Introduction of ETSI standards assists in perfecting of structure of EU legislation in the sphere of setting of tariffs on electronic services and regulation of interrelations of operators of system of *Unified European Sky, European Communication Net*, as well as in normalization of the harmonized provisions of European directives that regulate procedures of servicing in telecommunication and assuring of compatibility of products and minimizing of misunderstandings in their exploitation.

To regulate operation of the ETSI technical committees, there is organized the *Center of Testing and Coordination of Works in Standardization of Information and Technologies of Communications*, which gives the following services:

- assisting in introduction of the standardized procedures of good telecommunication practices, as well as methods of their validation, analysis and simulation,
- development of standardized methods of testing (based on norms of standard ISO/IEC 9646 *"Information Technology – Open Systems Interconnection – Conformance testing methodology and framework – Part 7: Implementation Conformance Statements"*),
- preparation of manuals and guides by use of specific languages and procedures of exploitation and servicing of telecommunication equipment.

3.7.4 Interstate Council by Standardization, Metrology and Certification (MDR – EASC)

The Interstate Council by Standardization, Metrology and Certification founded in 1992 by twelve former USSR republics (including Ukraine) is the one more regional organization, which operates standardization. Its Standing Committee form heads of central national bodies of technical regulation of their countries. Each country has one vote in the Council, which full appellation is the *Interstate Council by Standardization, Metrology and Certification of Commonwealth of Independent States (MDR – Міждержавна Рада із стандартизації, сертифікації та метрології)* recognized internationally as *the Euro-Asian Interstate Council for Standardization, Metrology and Certification (EASC)* (resolution of ISO Council of 26/1996). Its official language is Russian. Each Party is free in leaving MDR on condition of information in writing on her decision of Depositary of the Council not later of 12 months before.

The chairmanship in the Council is committed for the term of not more of one year to each its member country in turn, and the Chairman co-ordinates its work in period between the scheduled meetings. The person, who was the MDR Chairman in previous period, has the right of co-chairmanship for one term after expiring of his authorities. The Council supreme managing body is its *Bureau of Standards* located in

Minsk and consisting of experts, who work in the *MDR Regional Information Center*. The Council holds sessions convened in its member-countries in turn at least twice a year. These meetings may be also visited by the representative of the CIS Executive Committee, who participates in this work with the right of advisory vote. The delegations of the Council member-countries may also engage advisers and experts for participation in their sessions. The MDR Council co-works closely with the Inter-Parliamentary Assembly of CIS member-countries in development of drafts of legal deeds and recommendations by introduction of novel procedures of standardization, attestation of conformity, accreditation and introduction of norms of advanced metrology.

The CIS parties are free in development of norms of national systems of technical regulation, which may differ of interstate norms, but have to take into consideration the basic principles of their development and harmonize them preferably with the international and regional norms, recognize the still valid "GOST" standards as the interstate norms and co-work in development of new normative documents of the same category preserving their codification of "GOST".

The Council founded more of 300 interstate technical committees, which developed more of 6,000 interstate normative documents and amendments of valid interstate standards. Procedures of their operation regulate norms of the interstate standard GOST 1.0–92 *"Principles of work in interstate standardization. General norms"*.

The principal directions of activities of the MDR technical committees are:

- development of uniform principles of standardization, metrology and certification in the MDR member-countries by problems of interstate interest,
- approval of the harmonized imperative norms of quality and safety of production, its compatibility, interchangeability and environmental friendliness,
- development of norms and regulatory documents of interstate category (interstate standards, procedures, recommendations,

classifiers of technical and economic information, systems of codification etc.),

- forming, keeping and maintaining of the fund of standards of interstate, regional and international categories, their dissemination among the MDR members,
- running of interstate services of time and reference frequencies,
- development of the system of reproducing of values of physical magnitudes and keeping of the fund of reference standards of interstate category,
- keeping of the information net on means of measurement used in the CIS member-countries and development of norms of mutual recognition of results of their testing, metrological attestation, verification and calibration,
- development of rules of mutual recognition of results of work of accredited testing, calibration and measuring laboratories (centers), and certificates they issue,
- assisting in collaboration of national bodies specialized in work in spheres of interstate technical regulation.

To assist in progress of this work, the MDR founded in 2004 the *Scientific and Technical Commission by Harmonization of Provisions of National Normative Documents.* MDR is free in use of clauses of international and European norms in development of standards of interstate category, and its member-countries have the same right in development of national norms independently of their status of membership in international and regional organizations, which documents they use.

3.8 Specialized International Organizations Operating Standardization

Except of listed international and regional organizations operating standardization, there exist other ones, which do not develop and approve normative documents themselves, but coordinate such works of third parties.

3.8.1 *Food and Agriculture Organization (FAO)*

The *UN Food and Agriculture Organization (FAO)* was founded by 45 UN member-countries including the Ukrainian Soviet Socialist Republic, in view of crucial growth of global population and progressing tendencies of degradation of nature and lands available for agricultural manufacturing, and lists presently 185 members. The motto of the Organization is *"To liberate the planet of hunger"*, and its main goal was declared as *"... betterment of agricultural technologies and improvement of standards of life, nourishing and well-being of rural population worldwide"*. The Organization began its operation in Quebec (Canada) 16th of October 1945 on the base of the *International Agricultural Institute*. The supreme FAO body is its Conference assembled biannually. Its functions accomplish in period between sessions the FAO Council, which consists of representatives of 49 countries.

The structure of the Organization includes the profile departments as follows:

- department of agriculture,
- department of fishery,
- department of forestry,
- department of stable development,
- department of economical and social policy,
- department of technical problems of collaboration.

Ukraine gained the status of the FAO full member in 2003, and the institution representing her interests in this Organization is her Ministry of Agricultural Policy appointed by the Council of Ministers of Ukraine *(Decree of 13.09.2002 *"On Participation of Central Bodies of Executive Power in Activities of International Organizations which Member Ukraine is"*). Ukraine is the active participant of works carried out by the following five FAO technical committees and two commissions: Committee by problems of raw materials, Committee by fish resources, Agrarian committee, Committee by problems of global food safety, Committee of forest resources, Commission "Codex Alimentarius", and Commission by problems of genetic resources.

FAO acts as the leading UN institution in development of infrastructure of rural regions and assisting in progress of agricultural technologies. FAO accomplishes simultaneously about 1800 undertakings, attracting annually more than 2 billion US dollars of donations. FAO promotes the special national programs, which assist governments of its member-states in solution of critical social, economical, technological, organizational, legal and financial problems of agricultural sectors of their economies.

The principal directions of activities of the Organization are:

- assistance in development of international and national agricultural legislations,
- assistance in introduction of effective agricultural reforms and programs,
- participation in development of international standards of quality of marketable agricultural production,
- assisting the International Convention by Protection of Plants, which Depositary is FAO, in raising of effectiveness of work in protection of plants,
- development of programs of help for starving men in rising of quality of their nourishment,
- development of effective systems of protection of environment and use of land, water, forest and fish resources,
- assisting in work of national departments of veterinary medicine and control of epidemics of farm animals.

Despite standardization is not the main priority in work of FAO structures, many of its departments are specialized in development of norms of international category, especially:

- department of soil and water (problems of drainage, irrigation and supply of water into the rural areas),
- department of agricultural technique (problems of mechanization of agricultural manufacture and farm building),
- department of growing and protection of plants,
- department of products of cattle breeding,
- department of fish resources,

- department of forestry,
- department of timber industry,
- department of use of atomic energy in food industry and agriculture.

FAO co-works with more of 25 ISO technical committees and the UN Commission "Codex Alimentarius" in development of international standards on foodstuffs of international category and publishes scientific information bulletins, reports and books, distributes specialized journals and compact-discs by special problems of its activities, as well as holds the host-site opened for general use.

3.8.2 World Health Organization (WHO)

The *World's Health Organization* lists presently 193 member-countries and has the main office in Geneva. WHO was founded in July 1946 by 51 UN member-countries, including the Ukrainian Soviet Socialist Republic Ukraine at the New York International conference by problems of protection of health. WHO began its operation 7th of April 1948 after 26 UN countries ratified its Statute. It was stated, that the WHO principal goal is *"reaching of possibly good conditions of health of all nations"*. The notion of "*health*" was interpreted here as the "*state of absolute physical mental and social well-being of men, but not only absence of their diseases and physical defects*". It was declared first in global practice the right of each person on healthy conditions of life and proclaimed the principle of responsibility of governments for assurance of proper conditions of health of their nations.

The principal tasks of the Organization are assisting in development of net of institutions specialized in protection of health, prophylactics and control of diseases, solving of problems of nourishment, medical servicing and rehabilitation and creation of conditions of environmental safety.

Accordingly to its Statute, the WHO operates as the managing and coordinating body in concluding of international conventions and contracts by profile of its activities and assisting in creation of scientific

base of work of the *Commission "Codex Alimentarius"*. The WHO supreme managing body is the *Global Assembly by Problems of Protection of Health* convened annually. In period between sessions, work of the Organization manages its Executive Council, which consists of representatives of 52 countries and holds sessions twice a year. The profile departments of the Organization are unified into five groups as follows:

- hygiene of environment,
- sanitary statistics,
- protection of health of family,
- infectious diseases,
- training of specialists specialized in medicinal problems.

WHO possesses the consultative status in ISO and participates in work of more of 40 of its technical committees, hence takes part in numerous works in standardization and organizes for this job the specialized groups by problems of protection of health, pharmacology and toxicology. The international standards they develop are of multifold character and normalize relations in spheres of protection of environment, control of sanitary and epidemiologic situations in human communities and evaluation of quality of actions, which influence on physiological and psychological parameters of *"quality of life"*. The basic criteria used in this work are:

- *validity* of scientific, practical and technical aspects of normalization,
- *appropriateness* of all regulated norms for practical use, i.e. compliance of quality of recommended medical services to existing conditions of national systems of protection of health,
- *reliability* of recommended actions, development of documents of regulative character by principle of consensus,
- *clearness* of documents, i.e. formulation of univocal formulations and clear distribution of authorities in execution of normalized works,

- *effectiveness*, i.e. the systematical control of observance of valid norms of standards by persons of economy, and periodical analysis and revision of content of normative documents.

WHO co-operates in work in standardization with numerous interstate and non-governmental organizations and unions, especially the *International Atomic Energy Agency (MAGATE), UN Organization by Problems of Education, Science and Culture (UNESCO), UN Global Children's Fund (UNISEF), International League of Communities of Red Cross and Red Crescent, Global Medical Association* etc.

3.8.3 Commission "Codex Alimentarius" (CAC)

The *Commission "Codex Alimentarius"* (*CAC*, in Latin – *"Legislation on foodstuffs")* founded in 1963 by the mutual decision of XI session of FAO Conference and XVI WHO Assembly as its founders in result of systematical lobbying of interests of enterprises and organizations, which operate in pharmaceutics. Its members are presently 173 states and one regional organization (the European Union), which represent 98 % of global population.

The Commission operates as the FAO/WHO auxiliary body in realization of their mutual program of development and introduction of standards of safety and quality of foodstuffs. Besides, these two organizations endow CAC with the function of co-ordination of works by standardization of norms of quality of foods, which execute other international governmental and non-governmental organizations and unions.

The historical roots of "Codex Alimentarius" documents are traced in the set of consolidated standards on foods of *"Codex Alimentarius Austriacus"* developed in Austrian-Hungarian Empire during 1897 – 1911. Later, in period of 1954 – 1958, it was Austria, which actively assisted in development of regional European code of *"Codex Alimentarius Europaeus"* and proposed FAO and WHO in 1961 to

use the set of its standards as the base in development of international codex of norms of quality of foods. The main objectives in this work are:

- control of observance of norms of good practices in producing and trade by foods,
- assistance in unification of set of indices of quality of foodstuffs to be standardized,
- final editing of projects of the specialized regional and international standards on foods and their publication in the "Codex Alimentarius" code.

There exist the only one category of membership in the Commission, namely the *"Observer status"*, and the persons who have the right to obtain it, are:

- International non-governmental organizations, which possess by the specialized consultative or liaison status in the Food and Agriculture Organization,
- International non-governmental organizations, which have the official relations with WHO and were founded at least three years before they apply for the Observer status,
- International non-governmental organizations that:
  - operate in spheres of CAC interests,
  - are concerned with matters, which cover the part or the whole range of activities of the Commission,
  - operate in purposes set in the Statute of the Codex Alimentarius Commission.

The Observer:

a. shall be entitled to send its representatives to sessions of the Commission, who may be accompanied by advisers (having no right of voting); to receive from the Secretary of the Commission, before the session would have begun, all working documents and discussion papers; to circulate to the Commission its views in writing, without abridgement; and participate in discussions when invited by the Chairperson;
b. shall be entitled to send its representatives to sessions of specified Subsidiary bodies, who may be accompanied by advisers (having

no right of voting); to receive from secretariats of the subsidiary bodies, in advance of the session, all working documents and discussion papers; to circulate to these bodies its views in writing, without abridgement; and to participate in discussions when invited by Chairperson;

c. may be invited by Directors-General to participate in meetings or seminars on subjects organized under the joint FAO/WHO food standards program, which fall within it fields of interest, and if it does not so participate it may submit its views in writing to any such meeting or seminar;
d. will receive documentation and information about meetings planned on subjects agreed upon with the Secretariat;
e. may submit, under the authority of its governing body, the written statements on matters before the Commission, in one of languages of Commission, to the Secretary, who may communicate them to the Commission or the Executive Committee as appropriate.

The Codex technical norms and regulations include the chapters, which concern of procedures of producing, treatment, transportation and storage of foodstuffs necessary for keeping of their safety and appropriateness for consumption. The basic points of interest of the Commission relate to:

- quality of foodstuffs and hygienic norms to be taken in their production, including the criteria of their microbiological purity and procedures of use of food additives,
- maximum permissible content of pesticides, veterinary preparations and pollutants in foods,
- methods of marking of foodstuffs,
- methods of sampling and evaluation of risks.

Food additive means any substance, which is not the food proper or its component but the ingredient added in the foodstuff in process of its production. This term does not relate to components added to foods to improve their nutritious properties
Pollutant means any biological substance, including the organisms, microorganisms and their pieces, or chemical

substance, or extraneous impurity, or other substance, which falls into the foodstuff unintentionally and worsens the state of its safety

The standards and other CAC documents have no obligatory character, but may be considered as the FAO/WHO recommendations recognized by the World Trade Organization as the international reference point for resolution of disputes by problems of quality and safety of foodstuffs. The Commission developed themselves more of 300 projects of international standards and 40 regulations, as well as the numerous recommendations on permissible quantities and grade of purity of food additives, limiting of residual quantities of undesirable admixtures and methods of determining of their content in foods. The Codex Alimentarius contains standards on all basic types of foodstuffs, including the documents, which establish the norms of quality of raw materials and semi-manufactured products used in their production. The Codex normalizes also the norms, which observance guarantees the proper hygienic state of foodstuffs and procedures of marking and labeling of finished products.

The code of normative documents of "Codex Alimentarius" consists of chapters as follows:

Volume 1A. General requirements

Volume 1B. Hygienic conditions of foodstuffs

Volume 2A. Residues of pesticides in foodstuffs (general)

Volume 2B. Residues of pesticides in foodstuffs (maximum permissible levels)

Volume 3. Residues of veterinary preparations in foodstuffs

Volume 4. Foodstuffs for special dietetic use (including foodstuffs for babies and children)

Volume 5A. Altered and frozen fruits and vegetables

Volume 5B. Fresh fruits and vegetables

Volume 6. Fruit juices

Volume 7. Cereals, beans (bean cultures) and derivatives, vegetable albumen

Volume 8. Fats, oils and their derivatives

Volume 9. Fish and fish products

Volume 10. Meat, meat products, soups and bouillon

Volume 11. Sugar, cocoa products and chocolate, mixed products

Volume 12. Milk and dairy products

Volume 13. Methods of analysis and sampling

The collection of the Commission documents includes also the lists of compounds, which presence in foods is the subject of strict control:

- *"Food additives"* includes the list of additives permitted by FAO and WHO for consumption, as well as norms of their use normalized by the *"Codex Alimentarius General Standard on Food Additives"*,
- *"Polluting admixtures"* includes information on maximum permissible concentrations of polluting admixtures in foods, as well as the residual quantities of pesticides and veterinary preparations normalized by standards developed on base of the *"Codex Alimentarius General Standard on Polluting Admixtures and Toxins Present in Foodstuffs"*.

The Commission methodological documents contain also the information on useful properties of foods, description of recommended diets, as well as conditions of producing, sale and marking of *"green products"*, and foodstuffs *"permitted for use by Moslems" ("halal")*. Some of CAC documents regulate also the procedures of evaluation of safety and methods of certification of foods, which may contain the genetically modified plants and organisms.

3.9 International Organizations Operating Standardization of Production of Agriculture

The one of crucial problems in development of standards on products of agricultural complex is establishing of norms of safety and minimization of risks in their consumption, which the most important factors of influence are:

- pollution of drinking water,
- pollution of soils and ground water by pesticides,
- presence of chemical pollutants (toxicants) at working places,

- pollution of atmospheric air (by unnatural gases and aerosols),
- accumulation of radioactive radon in premises.

Soil means the top layer of the Earth's crust located between the bedrock and its surface and composed of mineral particles, organic matter, water, air and living organisms

Organic compound means any compound, which contains the element Carbon and at least one or more atoms of hydrogen, halogens, oxygen, sulfur, phosphorus, silicon or nitrogen. The exceptions are carbon oxides and inorganic carbonates and bicarbonates

The first three of factors listed above are the most dangerous for life of men, because the pollutants may ingress into the live organisms with foods. Therefore, observance of norms of their quality is the key problem of economical safety of the State. The work in assurance of proper quality of foods is the object of permanent attention of many of influential global organizations, prime of *the Organization of United Nations, World Trade Organization, Committee of Global Food Safety, Commission "Codex Alimentarius", UN Food and Agriculture Organization, World Health Organization*, and *International Organization for Standardization*. The listed and some other persons of international law developed the complex of norms of producing, reprocessing, transporting and storage of foodstuffs to be observed to guarantee their safety and suitability for consumption. First of all, these are the standards of ISO 22000 series *"Systems of Management of Quality of Foodstuffs"*.

As provided the clauses of the Treaty on establishing of the European Union, its members are free in introduction of national norms of food hygiene differing of international ones, but the critically significant condition of their validation is founding of the competent in this job body of State regulation and establishing of norms of national category developed in taking into consideration of provisions of international standards of quality of foods, which are not less stringent of norms of Directive 93/43/EEC *"On Hygiene of Foodstuffs"* (see Chapter 7.1) and do not impede in free global trade by foods. The EU governing bodies developed also the directive of # 2001/95/EU *"On General Product*

Safety", which sets forth that the product may be recognized as *"safe"*, 1) if it does not produce any risk for its consumers, or 2) if any risks, which may arise in their consumption, may be eliminated, or 3) it is character by the minimum probability of infliction of harm. Besides, manufacturers must give consumers the reasonable precautionary information on probable risks of consumption of their products, especially:

- information, which may be used by consumers in identification of grade of risk in consumption of the product during the guaranteed term of its service life,
- rules of avoiding of risks, procedures of withdrawal of dangerous product from the market and adequate actions of recall of products sold for that time.

The Directive normalized also the system of warning of RAPEX on mutual exchange by information on dangerous production and organization of work in mutual testing and control of foods in the EU structure.

To operate in these conditions, the EU member-countries put in practice the set of good practices (see Chapter 7.3) developed in observance of related norms of documents of *"Recommended International Code of Practice. General Principles of Food Hygiene"*, and *"General Principles of Food Hygiene of the Codex Alimentarius"*. The term *"hygiene of foodstuffs"* is used here in meaning of creation of conditions of absence of harm for health of men in their consumption in hygienic norms.

The control of execution of necessary actions has to be done by norms of Directive 89/397/EEC *"On the official control of foodstuffs"*, which declares that the EU member-states shall guarantee that the national competent authorities possess in their countries the sufficient stuff of suitably qualified and experienced specialists or have access to their services. This condition relates particularly to persons experienced in chemical engineering, food chemistry and technology, medicine, veterinary medicine, food microbiology and food hygiene. The Member States shall ensure also the compliance of qualification of laboratories, which execute the control functions to general criteria laid down in related

standards of international and European category. The Eurocommission shall appoint, in turn, the officials, who would cooperate with the competent authorities of the EU Member States in monitoring and evaluation of equivalence of official food control systems to EU general norms.

The principal document used in it in EU countries is *"General Principles of Hygiene of Foods"* on basic norms of systems of managing of safety of foods and *HACCP (Hazard Analysis and Critical Control Points* – see chapter 7.4*)* that establishes the sequence of operations, which permits to identify the microbiological, chemical and physical hazards existing in producing of foods and introduce the necessary precautionary actions. After the UN Food and Agriculture Organization and the World Health Organization approved the HACCP norms, they were legalized in numerous countries and provisions of this system became the base in development of systems of food safety worldwide.

At the same time, the numerous international organizations develop, in turn, the normative, technical and regulatory documents, which have to assist in solving of problems of healthy nutrition by products produced in specific brunches of food industry. The most influential of these ones are:

3.9.1 UN Economical Commission for Europe (UNECE)

UNITED NATIONS
ECONOMIC COMMISSION
FOR EUROPE

The *Commission*, which headquarters are located in Geneva is one of five UN regional commissions (for Africa, Europe, Asia, Asian-Pacific region, and Latin American and Caribbean region) founded in 1947 by the *UN Economical and Social Council (ECOSOC).* UNECE is the basic institution in coordination of UN economical activities, which operates nearly 70 % of UN budget means. It was founded as the temporary organization assisting in restitution of economies of European countries suffered in WW II, but since 1951 UNECE has the standing status of the UN Committee operating problems of economical progress and collaboration of European countries.

In later time, its geography was expanded, and now the Commission lists 56 member-countries, including those that do not belong to the

European region: Austria, Azerbaijan, Albania, Andorra, Armenia, Byelorussia, Belgium, Bulgaria, Bosnia and Herzegovina, Canada, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Greece, Holland, Hungary, Iceland, Israel, Ireland, Italy, Germany, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Monaco, Montenegro, Norway, Poland, Portugal, Romania, Russian Federation, San-Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland Tajikistan, Turkey, Turkmenistan, Ukraine, United Kingdom, USA and Uzbekistan.

The UNECE chairperson is its Executive Secretary, and the UNECE supreme managing body is the Council, which consists of representatives of its member-countries (by one of each country). The list of Council members is renewed each year by 1/3, i.e. there are elected 18 or 19 its new members instead of those who worked in it during previous 3 years. To establish the principal directions of activities of the Commission and approve recommendations for ECOSOC, the Council of the Commission organizes the biannual scheduled sessions. The basic directions of operation of UNECE are:

- assisting in collaboration of member-countries in scientific, technical, industrial, agricultural, energetic and transport branches of regional economy,
- solving of problems of domestic and international trade and assistance in its advance,
- assisting in realization of investment projects,
- assisting in work in protection of nature in its member-states and minimization of content of pollutants in atmospheric air,
- development of recommendations by procedures of business undertakings in countries with transient economics,

- work in development of international norms of standardization and attestation of conformity.

The practical work of the Commission execute its sectoral committees specialized in agriculture, coal industry, power engineering, construction, urban development, machinery, wood, transport, ferrous metallurgy, foreign commerce, water resources, as well as its three special departments operating problems of R&D development, economics and international justice. Besides, structure of UNECE includes the Conference of European statisticians and seven sectoral committees, namely Committee of environmental policy, Committee of domestic transport, Committee of stable energetics, Committee of trade, Committee of wood products, the Committee of housing and utilization of land, and the Committee of economical collaboration and integration.

The Commission develops the typical forms of contracts (general norms of supply of industrial and agricultural production, wooden materials, norms of contracting in building of big industrial objects etc.) and other documents used in practice of international economical relations. The principal task of UNECE in standardization is development of basic directions of its progress and speeding up of works in normalization of the most significant problems of global economy. The dominant working department of UNECE, which operate standardization, certification and quality management, is its specialized Working Group, which engages in this work the competent bodies of interested countries and the non-governmental, governmental, regional, and international trade organizations. For the present, UNECE co-worked in development of more of 100 standards to be harmonized with most of business norms used in European Union.

The UNECE Agricultural committee develops the commercial standards on products of agriculture and assists in interpreting and practical use of their provisions. The priority objects of normalization are fresh fruits and vegetables, dry and dried fruits, seeded potato, meat and meat products, eggs and products of their reprocessing, cut flowers etc. Besides, the Commission co-works in development of uniform procedures of control of quality of products of agriculture with the

governmental and interstate organizations. These documents assist in forming of unified language of communication of sellers and buyers, normalize the minimum indices of quality and commercial gradation of products of standardized quality (the extra, first and second classes of quality), norms of their ripeness, forms of packing, rules of labeling and marking. The Commission regularly holds seminars, symposiums and training courses by problems of development of standards and principles of their use for specialists of governmental bodies and enterprises, which work in private sector of economy. The UNECE collaborates closely in this work with the UN Organization for Economic Cooperation and Development, disseminates the specialized informative and explanative materials by its standards and issues explanatory brochures with colored photos, which illustrate defects of fruits and vegetables and so on.

3.9.2 International Organization of Organic Agriculture Manufacturing (IFOAM)

The notion of *"organic agriculture"* is understood as the practice of operation in conditions of:

- minimum ploughing of soil,
- refuse of use of synthetic chemicals (mineral fertilizers, pesticides, antibiotics),
- refuse of use of genetically modified products in cultivation of plants, breeding of cattle, farming of poultry, gardening etc.

Control of observance of these and some other special problems is in sphere of responsibility of *International Federation of Organic Agriculture Movements* founded 5th of November 1972 in Versailles (France) at the specialized international congress. Its founders were the *Association of Soils of Great Britain*, *Swedish Biodynamic Association*, *Association of Soils of South Africa*, agency *"Rodale Press"* (USA), and French farmers' community *"Nature et Progrès"*. The Federation, which has the headquarters in Bonn (Germany), lists presently more of 750 organizations of 108 countries. Its Supreme body is the General Assembly, which elects for the term of three years its

executive body – the IFOAM Global Council that operates in this category in period between its sessions. The Council members are the natural persons, who work in it without payment. The Council recommends IFOAM to invite or to reject in invitation to organizations, which pretend on membership in it, as well as appoints the members of its working committees and working groups, particularly of:

- Committee by development of the IFOAM standards,
- Bureau by communication with FAO,
- Organic Trade Forum,
- Agricultural group,
- Bureau of the Association of Retail Traders.

The purposes of operation of the Federation are consolidation of manufacturers, which work in all spheres of organic ("green") agriculture and dissemination of information on essence and principles of realization of its policy. The principal directions of this work are participation in development of standards of organic agriculture and attestation of persons operating in it. The Federation developed the fundamental documents of *"Basic standards of IFOAM in sphere of producing and reprocessing of products of organic agriculture"* and *"Criteria of IFOAM in accreditation"*, and controls observance of their norms using in this job the Federation daughter organization of *"International Organic Accreditation Services (IOAS)"*. For the present, IOAS accredited or works on accreditation of 29 certifying bodies from countries of Europe and Latin America, USA, Japan, Australia, China, which give about of 60 % of global services in certification of activities of persons operating in green agriculture.

IFOAM collaborates actively with the specialized international organizations by problems of agricultural manufacturing and protection of environment and is accredited in it in such international institutions as:

- International Organization for Standardization (ISO),
- UN Economical and Social Council (ECOSOC),
- UN Food and Agriculture Organization (FAO),
- Commission "Codex Alimentarius",
- UN Conference by Trade and Development (UNCTAD),

- International Labor Organization (ILO),
- UN Organization by Economical Cooperation and Development (OECD),
- UN Commission by Programs of Protection of Environment (UNEP).

Realization of principles of organic farming requires of extensive knowledge of the problem. Therefore, IFOAM assists in progress of sector of organic agriculture in developing countries. The principal role in this work plays the process of training. To assist in it, the Federation developed the Internet-platform, which permits to receive freely the complex of related materials and programs of 170 manuals, tutorials, and more of 75 training programs.

3.9.3 Cooperation Center for Scientific Research Relative to Tobacco (CORESTA)

The Organization was founded in Paris in 1956 in purposes of intensification of international collaboration in research of problems of planting of tobacco and producing of tobacco products. Its acronym origins of French "*Centre de Cooperation pour les Recherches Scientifiques Relatives au Tabac*" ("*Cooperation Centre for Scientific Research Relative to Tobacco*" in English). CORESTA lists more of 190 full members located in 48 countries of Europe (55 %), Asia (17 %), USA/Canada (17%), Latin America (7%), Africa (3 %), and Oceania (1 %). The status of full membership obtain the organizations (companies, institutes, laboratories and other business persons), which carry out at their own expense the R&D works in spheres of planting and reprocessing of tobacco (agronomy, selection, phytopathology), sectoral chemistry, metrology and choose of materials used in fabrication of tobacco products (cigarette paper, filters etc.).

CORESTA holds the annual non-formal scientific seminars, and biannually its General meetings. The managing bodies of the Center are its General Assembly and the Council, its executive body, which consists of 14 member-organizations. The official program of meetings include

holding of technical sessions, where the delegates solve the administrative problems and award premiums and research grants for scientists who made and/or would make big contribution in studying and solving of profile problems of the tobacco industry, as well as invite the leading specialists to report on the state of key problems in the field of their competence.

The CORESTA scientific Commission, which works under guiding of its Council, consists of 20 specialists subdivided by groups of: 1) agronomy, 2) phytopathology, 3) technologies of producing of tobacco goods, 4) science of fume. The groups concentrate their activities on solving of problems as follows:

- *Agronomy*. Rising of productivity of tobacco plants and improvement of their quality; systematization of information on effectiveness of use of agrochemicals; introduction of methodology of Good Agriculture Practice in effective and stable planting of tobacco.
- *Phytopathology*. Studying of cycles of living of pests and development of methods of control of their reproduction and spreading; studying of troubles, which arise in planting of tobacco; selection of nonperishable genotypes of plants.
- *Research Group "Technology of Manufacturing"*. Studying of problems of reprocessing of tobacco; development of methods of control of quality of tobacco plants and tobacco goods; development of methods of producing of high-quality tobacco products; development of procedures of protection of environment in processes of planting and reprocessing of tobacco.
- *Research Group "Science of Fume"*. Development of methods of identification of individual components of tobacco fume and determining of their mass parts in it; studying of composition of tobacco fume and problems of smoking; biochemical research of tobacco and tobacco fume.
- *Sub-group of biological markers*. Studying of methods of identification in tobacco fume of content of benzopyrene,

admixtures of aromatic amines, volatile compounds and other harmful components.

- *Agrochemical consultative committee.* Accumulation of data on agrochemical research, informing the CORESTA members on novel agrochemical technologies of planting of tobacco.

The Center holds the annual non-formal scientific seminars, and biannually – the Congress of delegates coming from all regions of the world. The problems to discuss include the specificities of technologies of planting, chemistry of tobacco and its fume, physical methods of testing of the plant and products of its reprocessing, environmental problems, pest control, methods of smoking, human response on fume and smokers, methodology of work with non-smoking persons etc.

3.9.4 International Dairy Federation (IDF)

The Federation was founded in 1903 and represents itself the non-commercial association of national dairy unions of more of 50 countries, which basic task is assisting in development of infrastructure of producing and reprocessing of milk. The IDF structure is shown on Figure 3.6:

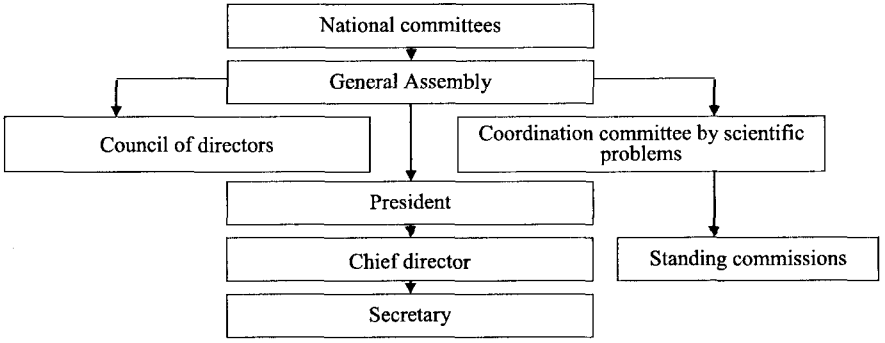


Figure 3.6 Organizational structure of International Dairy Federation

The IDF supreme body is its General Assembly headed by the President, who manages the current work of the Federation in period between its sessions. The IDF executive body is the Council of Directors,

which assists in collaboration of national federations of manufacturers, which produce approximately 75 % of dairy products present in the global market. The principal directions of co-work of the Federation members are:

- coordination of activities in popularization of understanding of significance of milk and dairy products in rational and healthy feeding,
- assistance in advance of methodology of keeping of ranch and breeding of cattle, development of methods of storage of milk and dairy products,
- tracing of novel tendencies in progress of milk industries, assistance in carrying out of profile R&D works and solving of problems of marketing of their products.

The Federation uses services of more of 1200 experts of the specialized scientific organizations, governmental institutions, and industrial enterprises all over the world. Organizationally, they co-work in 17 IDF standing working and 2 executive groups. They solve problems of rational nutrition and protection of health; develop projects of standards of consumption of milk and milky products and methods of their sampling and analysis; work on development of technologies of protection of health of livestock; norms of hygiene and safety of products of milky industries; develop technologies of protection of environment and problems of State regulation of functioning of milk industries.

The standing and special IDF committees collaborate with the numerous international organizations, such as the Commission "Codex Alimentarius", FAO, WHO, OIE, ISO etc. The Federation signed in 2000 the treaty on mutual work with the International Organization for Standardization, hence publishes since 2002 the applicable standards with the acronym of ISO.

3.9.5 International Seed Testing Association (ISTA)

The International Seed Testing Association was founded in 1924 and the main goal of its work is development of the standardized procedures of testing of

seed and dissemination of related information. This is the non-profitable organization, which participants are 48 full and 22 associated members. ISTA co-works with more of 170 specialized laboratories of 74 countries, which service its activities.

The full member of the Association may be the country represented by the structure authorized on this job by her government. *The associated* member is the person authorized by the country, which has no status of full member but follows the ideas of the Association. The right to be the *corporative member* and work in ISTA structures without the right of casting vote has any country, which follows the ideology of the Association, pays annual member fees and complies with the established criteria. Besides, the Association engages the individuals, who made big contribution in her advance, in the category of its *honorary members*. *The specialized laboratory* obtains this category in ISTA if it carries out the work in technical control of quality of seed.

The administrative functions in ISTA structure accomplish its President, First Vice-president and Second Vice-president elected for the term of three years without right of their re-election. The staff of the Executive Committee of the Association includes eight members and accomplishes the following functions:

- appoints the ISTA administrative persons and members of its technical committees,
- recommends candidatures of new members of the Association,
- convenes international congresses by the ISTA profile problems,
- develops norms of accreditation of laboratories, which test seed, and procedures of recognition of certificates of conformity they issue.

The structure of the Association includes 14 technical committees, which develop procedures of sampling and testing of seed of basic products of agriculture, flowers, forest trees, shrubs, including the seed of genetically modified plants. The first-priority ISTA task is development and validation of standardized procedures of control of quality of seed and introduction of uniform methods of its attestation, as well as development of projects of international standards by the following problems:

- interpretation of scientific and technical aspects of quality of seed and technologies of its farming,
- carrying out of R&D works by problems of storage and treatment of seed after its harvesting,
- upgrading of methods of testing of seed.

The sphere of activities of the Association comprises also training of specialists and propagation of knowledge having to assist in trade by seed at national and international markets.

The Association co-works closely with the Organization for Economic Co-operation and Development (OECD), International Union of Protection of Plants (UPOV), signatories of the International Convention on Protection of Plants (IPPC), Convention on Protection of Biological Diversity (CBD), UN Food and Agriculture Organization (FAO) and the World Organization by Protection of Rights on Intellectual Property (WIPO).

3.9.6 International Organization of Grape and Wine (OIV)

The OIV predecessor, the *International Coordinating Center of Viticulture*, was founded by five countries – France, Italy, Switzerland, Austria-Hungary, and Germany at the international congress held in Montpellier, France in period of October 26-30, 1874. Its participants came to decision to co-work in control of extension of pests in response on epidemic of phylloxera ruined the whole structure of European Viticulture. The WW I (1914 – 1918) postpones activities of the Center, but works by this problem was reanimated at the post-war time, which result became founding 24th of November, 1924, of the interstate association of *International Bureau of Grape and Wine* with headquarters in Paris. Accordingly to the Treaty of 3rd of April, 2001, the Bureau was reorganized in 2003 in the *International Organization of Grape and Wine (OIV – Organisation Internationale de la Vigne et du Vin)*. The tasks of the Organization became broader, and now OIV represents itself the scientific and host organization operating problems of viticulture and producing of wine and

wine products. The sphere of its responsibility spreads on problems of planting of table and wine varieties of grape and production of raisins, wine products and drinks, which contain grape juice.

For the time of 29th of July, 2009, OIV members were 44 countries: Algeria, Argentina, Australia, Austria, Belgium, Bosnia-Herzegovina, Brazil, Bulgaria, Chile, Croatia, Cyprus, Czechia, Finland, France, Georgia, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Lebanon, Luxembourg, Macedonia, Malta, Moldova, Montenegro, Morocco, New Zealand, Netherlands, Norway, Peru, Portugal, Republic of South Africa, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Switzerland, Sweden, Turkey, and Uruguay. Its supreme governing body is the annual General Assembly, and the executive structure – the Council, which holds its sessions three times a year to solve the current OIV problems and appoint the technical committees responsible for their solving. The principal tasks of the Organizations are:

- protection of interests persons, who work in planting and processing of grape, producing of wine, wine products and drinks,
- assisting in harmonization of national legal deeds and development of recommendations and projects of normative documents of international category by problems of interest of OIV manufacturers and consumers of their products,
- optimization of procedures of producing, analysis, storage and marketing of grape and wine-products.

OIV assists in introduction of scientific and technical innovations, especially in dissemination of standards and profile guiding documents. To prevent falsification of products of viticulture and unfair competition in spheres of their responsibility, the Organization approved the list of recommended methods of analysis of wine and grape.

3.9.7 International Federation of Fruit Juice Producers (IFU)

IFU with the headquarters in Paris was founded in 1949 as the institution, which unified interests of the biggest European producers of fruit juices. In later time, the

geography of its activities was spread and now the Federation comprises more of 30 countries including Australia, Argentina, Brazil, China New Zealand, Republic of South Africa, Russian Federation and the USA.

There exist three categories of IFU membership:

- *collective members* (22 persons), which represent the majority of big national associations of producers of juices,
- *individual members*. This category embraces 21 participants, who are both the individual producers and big international groups and companies,
- *associated members*. These ones are the persons, who participate in IFU activities in spheres of its interest. They are represented by 22 trade organizations, suppliers, laboratories etc.

The IFU purposes are:

- representing of interests of manufacturers of juices worldwide,
- harmonization of provisions of the specialized national normative and technical documents with international norms,
- accomplishing of functions of the specialized information and communication center,
- coordinating of R&D works carried out in interests of the profile industry.

To reach the set goals, IFU:

1. Cooperates with the international organizations, especially CAC, FAO, WTO and others.
2. Coordinates its activities with works of national associations and unions of producers of juices, which are not the IFU members.
3. Holds the specialized international conferences, symposiums, working meetings etc.
4. Assists in exchange by information among the Federation members, especially by problems as follows:
   - development of projects of specialized normative documents of international category,
   - assistance in development of bettered technologies of manufacturing, and optimization of compositions of juices,

- development of norms of good practices to be realized in juice industries,
- assistance in development of criteria of assessment of quality of juices, new methods of their analysis, packing, labeling and so on.

3.9.8 International Commission for Irrigation and Drainage (ICID)

This association with headquarters located in New Delhi (India) was founded 24th of June, 1950 as the non-governmental non-commercial non-profitable scientific and technical organization of 11 countries. The Commission lists presently 105 national profile organizations all over the world and possesses by the consultative status in FAO, WHO, UN, ECOSOC and UNESCO. The organization heads the President, who has nine deputies in status of Vice-presidents, all elected for the term of three years.

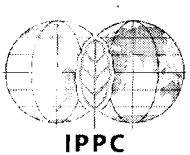
The ICID principal goals are assisting in collaboration of national committees of its member-countries; improvement of quality of superficial and subterranean water, stimulation of development of high-tech technologies of irrigation and drainage; assisting in work in improvement of conditions of natural environment; solving of social and scientific problems of management by water and land resources.

The problems to be solved in these works are identified at global congresses and regional conferences held each three years in the Commission member-countries in turn. Besides, one of regional associations of Africa, Europe, Asia and America holds, in turn, one of the scheduled annual ICID conferences, and the current work of the Commission execute 30 working groups administered by the ICID International Executive Council plus one representative of each member of the Commission appointed by the ICID national committees. The problems of supply and draining of water at sites are in sphere of responsibility of regional working groups of experts in Africa, Europe, Asia, America and Basin of Aral Sea. Particularly, the Commission assists in betterment of procedures of cultivation of products of agriculture,

protecting of land against consequences of floods and softening of after-effects of flood and natural disasters.

The ICID members develop also the projects of international and regional standards by specific problems of irrigation and drainage. Its central library numbers more of 30 thousand books of technical character and subscribes 65 periodicals by problems of the Commission. Its base lists more of 30,000 publications and informative materials on current works of the Commission member-countries. The interested parties may obtain also all necessary information through the delivering service of the Commission and acquaint with the data put in its official web site.

3.9.9 International Plant Protection Convention (IPPC)



IPPC began its operation in 1952 after signing by 177 countries interested in protection of health of flora of the related international treaty. The functions of its Secretariat located in Rome execute seven specialists in phytosanitary problems appointed by FAO. The two more auxiliary IPPC structural bodies are its *Standardization Committee* and the *Auxiliary Body by Consideration of Vexed Questions*. The Convention members hold the annual sessions, which programs develop nine specialized interstate commissions located in different regions. The principal purposes of functioning of IPPC are:

- assisting in conservation and development of biological diversity,
- protection of ecosystems against loss of their viability because of excess of pests,
- protection of farmers against losses dependent of bursts of population of pests.

The basic directions of IPPC activities are development of advanced methods of protection of cultivated and wild plants and assuring of detailed informative exchange by information on methods of limiting of reproduction of pests.

The parties of the Convention assist the developing countries in rising of effectiveness of work of national authorities specialized in this work.

The basic problems, which the Convention members consider at their meetings are:

- tracing of current situation in work in protection of plants worldwide,
- problems of introduction of modern methods of control of reproduction of pests,
- development of methods of dissemination of information of phytosanitary character and procedures of solving of disputable problems,
- collaboration with international organizations by profile of activities of the Convention.

IPPC curates works in development of standards on phytosanitary methods of protection of vegetative resources all over the world, and documents by topics as follows:

- current state of processes of harmonization of normative documents of national character by problems of control of pest-related risks with the international norms,
- procedures of phytosanitary inspection,
- procedures of control of vital activities of pests,
- procedures of introduction of quarantine measures,
- procedures of eradication of forms of pests exotic for the concrete region.

3.9.10 International Commission for Uniform Methods of Sugar Analysis (ICUMSA)

ICUMSA International Commission for Uniform Methods of Sugar Analysis

ICUMSA is the non-governmental organization founded in Hamburg (Germany) in 1897, which integrated activities of national committees that work in sphere of analysis of sugar in 30 countries. Each country, which has the intention to join ICUMSA, has to found the respective specialized national body of any form of property and mode of operation. The only condition is that norms of its Statute should not contradict to provisions of the ICUMSA Constitution.

The basic purposes of work of ICUMSA are:

- development of methods of analysis of sugar, and raw and auxiliary materials used in its producing and reprocessing,
- assisting in harmonization of normative documents and recommendations with the international norms of analysis of sugar.

The basic tasks of the Commission are:

- rising of level of studying of problems of analysis of sugar and by-products of its production,
- guaranteeing of international level of consideration of problems of analysis of sugar and related products,
- publication of recommendations of international category on introduction of newly developed methods of analysis of sugar.

The governing body of this organization is its Administration (President, Vice-presidents, Secretary General and Treasurer) seconded by the Executive Committee (includes the persons listed above, and the previous President of the Committee). The quantity of delegates, whom each country may send on sessions of the Committee, is not limited. However, the number of her voices in solving of discussed problems depends of amount of produced and imported sugar, as shown in Table below:

Quantity of conventional units* of turnover	Quantity of voices
Less than 3	1
From 3 to less of 6	2
From 6 to 12	3
More of 12	4

* One conventional unit is amounted to 100 thousand ton of produced and imported sugar (in total) during two years before the scheduled ICUMSA session

The countries, which had not formed their national committees, may participate in ICUMSA sessions without right of casting vote.

ICUMSA executes its regulatory functions in standardizing of methods of analysis of sugar and development of classification of its

properties and indices of quality used worldwide. The standards developed by the Commission obtain initially the status of *"T" (tentative)*. After their consideration and approval on the scheduled ICUMSA session, they obtain the status of *"O" (official)*. Methods, which showed in later time their utility and are recommended for regular use, obtain the status of *"A" (accepted)*. Validity of such standards recognized most of global influential associations and communities, such as European Union, Commission "Codex Alimentarius", International Organization of Legislative Metrology and others.

3.10 Standardization Bodies of Foreign Countries

3.10.1 American Institute of Standards and Technologies (NIST)

USA introduced the system of voluntary standardization in most branches of national economy. The profile national body operating in it is the American National Institute of Standards and Technologies (NIST), which represents interests of the USA in ISO, IEC, and other international specialized organizations. Its predecessor was the American Committee by Technical Standardization reorganized in 1928 into the American Standardization Association (ASA) existed less of three years and reorganized, in turn, in the *American National Standardization Institute (ANSI)*, now NIST.

NIST is the non-governmental and non-profitable organization, which members are more of 1,200 firms, 250 producing and trade companies, R&D institutions, scientific, technical and engineering associations. The Institute supreme governing structure is its Council of Directors, which manages activities of its technical councils and committees, and the NIST principal standing departments are:

- *Executive council by standardization*. Coordinates the NIST profile activities.
- *Council by revision of valid standards*. Assigns terms of actuality of national standards, postpones and cancels their validity.

- *Commission by control and accreditation*. Controls observance of methodology of standardization by developers of normative documents and accredits organizations on right of carrying out of this work.
- *Committee by certification*. Develops programs of certification of products and puts in practice the newly developed certification systems of general use.
- *Advisory council by international standardization*. Approves the priorities in harmonization of normative documents of international rank and co-works with the specialized global structures in development of normative and regulatory documents of international and regional category.
- *National council by collaboration of US standardization bodies with the international structures* specialized in this work. Coordinates activities of 211 national working technical groups and manages work of secretariats of 15 ISO and IEC technical committees.

NIST develops national programs of standardization. The priorities taken into consideration in this work are the procedures of operation used in branches of manufacturing and transporting of fuel; supply of electric energy; use of solar, nuclear and other types of energy. The Institute does not develop standards themselves, but coordinates works of more of 400 organizations and firms accredited by NIST on development of national (federal) normative documents and harmonization in USA of national norms of other countries and standards of regional and international organizations. The most influential organizations operating these works are:

- American Society of Testing of Materials (ASTM),
- American Society of Quality Control (ASQC),
- American Society of Mechanical Engineering (ASME),
- Union of Testing Laboratories of Insurance Companies,
- Society of Automobile Building Engineers (SAE),
- Institute of Engineers by Electrical Engineering and Electronics (IEEE).

Except of work in coordination of activities in development of State standards, the Institute manages works in development of technical regulations executed by the State bureaus: Ministry of Trade, Ministry of Defense, Bureau of Services of General Management, Federal Agency of Protection of Environment, Federal Agency of Protection of Labor and Health at Manufacture, Federal Agency of Safety of Foodstuffs and Medicines, Commission by Safety of Consumables etc. The listed and some other governmental structures participate also in development of standards of firms, which acquire in this case the category of national norms.

The Institute coordinates works of the State administrative bodies with local authorities in assurance of uniformity of measurements, develops national etalons of properties and composition and controls procedures of their use. Because USA had not introduced the uniform norms of measurement at national level yet, each her State solves these problems by its own discretion, and if results they obtain are problematic and/or give rise to doubt, they ask the responsible structures of states of their location to solve the questionable problems at the national level. Therefore, there arose the need in solving of controversial situations, which arbitrary role plays NIST.

The Institute stores also the American national etalons used in mechanical and thermal measurements, measuring of time, frequencies, chemical composition, strength of optical and ionizing radiation, standards of and others. The Institute gives services in calibration and verification of means of measuring technique, and co-operates in this work with more of 1,300 governmental and non-governmental calibration and testing laboratories, which operate in structure of the *National Conference of Standards Laboratories International (NCSLI)*. NIST has no formal authority of control of operation of metrological laboratories of states, but accredits laboratories and federal metrological organizations and collaborates with the specialized in this work supervisory federal institutions using in it services of the *National Conference on Weights and Measures (NCWM)*.

The USA governmental bodies introduced the numerous laws on safety of production (services) and the fundamental document used in it is the *Law on Safety of Consumer Commodities* of 1972 (with addendums of 1976). As provided the national legislation, the products, which quality has to be declared as conforming to norms of the State standards (whether they were produced domestically or abroad), must be certified in obligatory manner, and there exist three basic categories of US programs of attestation of their quality:

- *first category* – obligatory certification of safety of goods and services,
- *second category* – attestation of quality of samples of serial production taken randomly,
- *third category* – programs of attestation of serial manufacture by norms of quality standards.

The one of logotypes used by the Institute in witnessing of fact of carrying out of this work is shown below (Fig. 3.7):

Fig. 3.7 Logotype of NIST

The programs of the first category have to be realized in certification of automobiles, containers, vessels, main pipes etc. The programs of second category are of obligatory use too and have to be realized in control of quality of goods used by the governmental institutions (Department of Defense, Department of Trade, Administration of Rural Electrification and so on). The programs of third category are mainly of voluntary character. The exclusion is the obligatory certification of certain categories of foodstuffs (eggs, tobacco etc.), which quality has to be controlled on safety and absence of delayed harmful effects in their use. The normative base of certification includes the standards developed by bodies as follows:

- National Institute of Standards and Technologies (NIST) – general procedures of assessment and attestation of conformity,
- American Society for Testing Materials (ASTM) – consumables and everyday-use goods,

- National Equipment Manufacturers Association (NEMA) – production of electric engineering industry,
- Commission by Safety of Consumer Commodities (CSPS),
- Federal Agency by Protection of Environment (EPA) – certification of manufactures, internal combustion engines, means of transport and so on.

The general management by this work accomplishes in USA the NIST certification committee. Its principal functions are development and registration of programs and procedures of certification, as well as control of competence of certifying bodies. The work in identification of conformity of goods to be certified carry out more of 2,000 testing laboratories of R&D institutes, universities, insurance companies, and laboratories of bodies of national rank (National Association of Manufacturers of Electrical Equipment, American Gas Association, National Association of Fire safety, Bureau of Safety of Foodstuffs and Drugs etc.). To avoid the unfair competition in certification, the ASTM Council of Directors decided to organize the unified national structure of attestation of conformity, which participants work under guidance of 15 ASTM technical commissions.

3.10.2 British Standards Institute (BSI)

The *British Standards Institute (BSI)* was founded in 1901 by initiative of societies of mechanical, shipbuilding, electrical and metallurgy engineers. In 1918, the Institute expanded the sphere of its activities in standardization, hence was it was reformed the structure of the Institute, which operates in all branches of national economy – the *British Engineering Standards Association*, which obtained the present appellation of BSI in 1931 after signing of the Royal Charter. The revision of this Charter in 1998 enabled the Institute to diversify and expand its activities, so it was renamed finally in *BSI Group*.

Accordingly to *Memorandum of Understanding* signed by BSI and UK Government in 1952, the Institute is the only body responsible for development of national standards and has the status of authorized British

representative in ISO, IEC, CEN, CENELEC and other global and regional structures operating standardization. The Institute manages also the work of 111 ISO, 26 IEC and 11 CENELEC technical committees. BSI now is the independent structure, and its main function is coordination of activities in Britain in development and validation of standards. The Institute closely collaborates with the collective and individual persons (more of 15 thousand companies, organizations and individuals) seconded by the professional institutions, certification, testing and inspecting bodies, educational establishments, R&D organizations; UK notified bodies, governmental departments and organizations of consumers).

The staff of the Institute numbers 1,300 laborers including its President, Vice-president, Head of Financial committee and representatives of industrial associations, Congress of British trade-unions, Council of British manufacturers, Ministry of Trade and Industry, Ministry of Defense, Ministry of Protection of Environment and other British influential organizations. The BSI Supreme managing body, its General Conference, holds the annual sessions, approves the priorities in operation of the Institute, reviews results of works carried out in period between its sessions, elects the President, Vice-President, Deputy Presidents of the Institute and nominate its financial inspectors. The BSI Supreme executive body is the Managing Council subordinated to the BSI General Conference. The one more managing body of the Institute, its Council of Directors, administrates its activities in standardization, development of procedures of quality management, giving of information services and so on.

BSI, being the one of the biggest global provider of standards in modern world, works in almost all spheres of public economy. . The Institute structural departments and transient technical groups (of about 3,500 in total) develop each year more of 2,000 new standards. The advanced level of their work witnesses the fact that more of 16 % of British standards are recognized in category of international and regional norms. In response to commercial demands, BSI develops also such

commissioned standards, as the Public Available Specifications (PAS), Private standards and Business Information Publications.

The work in development of a standard begins after receiving of the order of the authorized State structure, association of consumers, manufacturer of production or any other interested person and approval of this work by the BSI Governing Council. In positive decision, the profile BSI technical committee develops the preliminary version of the document. If the problem in development is in sphere of interests of certain governmental structure, its representative participates in this work as well. After finishing of this work, the Institute sends the text of the first version of standard to all interested parties, makes necessary corrections after obtaining of their remarks, and passes the revised document for approval to the BSI General Council.

BSI is the subscriber of documents of more of 50 national specialized information services, is the participant of the ISO automated structure of ISONET and co-works with German and French national organizations by standardization as the member of their mutual informative structure of REINFORM. The Institute collects and disseminates the information on British national normative documents, norms of international and regional category, their amendments and annexes, dates of their validation and cancellation.

Except of work in standardization, BSI heads the work by quality management in Britain, which is in sphere of responsibility of its Council by Quality. To accomplish these functions, BSI organized the servicing center, which tests the serial production on its compliance to provisions of normative documents declared by its owners, keeps the reference book of *"Register of firms, which produce and sell the certified production"* and marks the tested items and their supplementary documents with Kitemark, the British certification symbol used since 1903 (Fig. 3.8):

Fig. 3.8 BSI Kitemark certification symbol

Being the *"Notified"* body, BSI carries out testing of products on compliance to European regional norms, licenses their owners on the right to mark them by the European sign of conformity **CE** and attests quality of items falling under the norms of 15 EU directives, e.g. the construction materials, marine equipment, equipment operated under the supertension and personal protective equipment. The Institute' testing center is considered as one of the most competent worldwide, and its certificates are recognized in almost all countries of the world, especially at the biggest global markets located in Europe, the United States, Australia, Canada, Japan, Peoples Republic of China, Republic of China and Republic of Korea.

3.10.3 French Association by Standardization (AFNOR)

The head organization operating French standardization since 1926 is the private non-commercial *French Association by Standardization (AFNOR)*, which works under the guidance of the State Commissar by standardization and is subordinated in this work to the Ministry of Economics and Industry of France. Its members are the State, public and private organizations as follows:

- central staff of the Association,
- associated members (about of 3,000 companies),
- commercial subsidiaries.

AFNOR carries out the following functions:

- organization and management of activities in standardization,
- composing of annual national standardization programs,
- analysis of applications of interested persons, development of normative documents of national category and control of observance of norms they state,
- control of correctness of marking of production by symbols of conformity,
- representing of France in international profile organizations,
- training and retraining of specialists in its exposition center of *"Espace"*.

There exists the two-level structure of management in AFNOR, which presumes servicing of its basic structural units by the *Committee by Orientation and Planning*, and the *Committee of Strategic Planning in Structural Branches of Economy*. The Association publishes the reference books, manuals and instructions by profile of its activity, the annual *"Reference book of French standards"* and monthly journal *"Enjeux"*, which informs on progress in national and international standardization, development, revision and cancellation of standards, as well as on planning of work in development of new normative documents of national and international categories.

Being the biggest operator on the market of certification, AFNOR develops procedures of attestation of conformity and certifies production, services and systems of quality. Most problems, which arise in everyday functioning of this system, are in sphere of responsibility of the AFNOR Managing Committee, but questions of supreme interest solve the head managing structures of the Association. The structure of national certification comprises also more of 20 organizations that operate by principle of decentralization. The most influential of these ones are: *French Center of Foreign Commerce (CNCE), Center of Information on Norms and Technical Regulations (CINR), Union of Electric Engineering (UTE)* and the spheres of their responsibilities are:

- AFNOR licenses the net of services, which have the right of certification and accredits testing centers and laboratories on right of giving of services in evaluation of conformity of goods to be attested, and co-ordinates their relations with foreign and international partners,
- CNCE certifies commodities to be imported and exported,
- CINR accomplishes the information servicing of subjects of economy by problems and procedures used in certification in France.

The conformity of goods, which quality have to be attested, may be witnessed by several methods:

- self-declaring by manufacturer (supplier, exporter) of conformity of his production to norms of European directives and standards,

- self-declaring by manufacturer (supplier, exporter) of conformity of his production to norms of French standards,
- attestation of quality of production by the authorized third party.

The procedure of certification presumes carrying out of actions as follows:

- handing of application by manufacturer to the specialized certifying body he chooses freely,
- carrying out of inspection by persons appointed by the certifying body chosen by the applicant and testing of the representative samples of production to be attested,
- certification proper and issuing of the license on right of independent marking of production of the attested quality by the national sign of conformity (Fig. 3.9) registered in France accordingly to provisions of the *Law on Trade and Service Signs*,
- periodical testing by the authorized third party of samples of the production, which quality was attested in earlier time, taken in manufacturing premises, markets and sales, as well as periodical control of observance of conditions of certification on site.

Fig. 3.9 Sign of conformity of AFNOR

The control of quality of production to be certified accomplish more of 60 accredited laboratories of the State, firms, public and private organizations. As provided the French legislation, the production marked with the sign of conformity ***NF*** must also have the signs (marks, labels), which would permit to identify the person that issued such permission, as well as be supplemented by the certificate containing information on certified properties of the product and their numerical values. The national sign of conformity may be used also for marking of production of foreign origin (if it conforms to norms established for the analogous French products). The work in assessment of conformity of such goods may be done by AFNOR only.

Generally, certification in France is of voluntary character. The only exclusion are products and services of medical destination (materials, preparations, clinical tests systems and medical equipment) to be certified obligatorily and marked with the sign of *NF-MEDICAL*.

3.10.4 German Institute of Standards (DIN)

The *Committee of norms for general machinery* was founded in Germany in 1917 as the basic organization of national standardization. It was renamed in 1926 in the *German Committee of Standards*, and later, in 1975, in *The German Institute of Standardization (DIN – Deutsches Institut für Normung e.V),* the non-governmental organization, which possesses the leading position in Germany in development of national standards. To do this work, the Institute organized 74 technical committees, which use services of 26 thousand experts, enterprises, unions, State organizations, scientific institutes, manufacturing and trading firms, which effective work results in recognition of DIN as one of global leaders in international and regional standardization. The basic principles of operation of German system of standardization are:

- *voluntariness and participation of all interested parties* means the right of any person to participate in work in standardization and development of any standard,
- *openness* means the norm of official publication of any finished standard and taking into consideration of any critical remark in its development,
- *unity and consistency* means development of details of assemblies, which parameters are compatible with those ones of units of similar destination produced by various manufacturers including the items produced by persons located in foreign countries,
- *concreteness* means the compliance of national practice of development of standards with the modern scientific and technical norms,

- *observance of public interests* means the norm of prevailing of interests of the community over the interests of individuals,
- *orientation on economical realities* means the principle of normalizing of only the necessary but not minor indices of quality of objects to be standardized,
- *international character of standardization* means participation of DIN structures in development of norms, which may be used universally.

Any national organization (enterprise) may send to the Institute its application on development of standard and participate in this work delegating for this purpose its experts to the related DIN technical committee. The preliminary versions of the standard should be presented on open discussion, and the finishing stages of this work include approving and publication of the document. Most of German standards are of recommended character and observance of their norms may be considered as witnessing of proper technical order of manufacture or proper quality of object of standardization. However, the norms of standards become obligatory in cases of their use in spheres regulated by federal legislation.

The DIN structure includes also the filial organizations managed by its Supreme administration. These ones are the publishing and information house of *"Boit"*, community of *"Software"*, *German community by giving of information on production, German community by certification of systems of quality, German community by marking of production* and others.

The one more basic direction of DIN activities is certification of production. Its legal base constitute laws, which regulate the norms of protection of life and interests of consumers, protection of environment, economy of resources, safety of labor etc. The German businesspersons may certify their products by norms of one of the following systems:

- *A* – system of voluntary certification of conformity of production of domestic and foreign origin to provisions of German technical regulations,

- A_1 – system of voluntary certification of conformity of products to norms of DIN standards,
- A_2 – system of certification of industrial and household electrotechnical items used by the German Union of Electrical Engineers (VDE),
- A_3 – system of certification of products of persons, which supply gas and water (DVGW),
- B – system used by the German Quality Institute in certification of products of agriculture and building materials,
- C – system of voluntary certification of safety of instruments (GSG),
- D – system of attestation of construction materials on conformity to German federal and provincial norms carried out under guidance of German Institute of Building Technologies. Unlike other systems of certification, this one is of obligatory character,
- E – system of certification of means of measurement and standards of properties and composition,
- F – system of certification of industrial processes on compliance to norms of German industrial legislation.

Works in the system of "A_1" carried out in Germany the most often accomplishes the DIN center of DIN CERTCO. Its clients are both German persons and foreign organizations interested in certification of their production in Germany. The items attested in this system are marked with the sign of *DIN GEPRTUFT ("conforms to the DIN standards")* shown on Figure 3.10):

Fig. 3.10 Sign of conformity used by German Institute of Standardization

The works in the system of "A_2" in certification of all kinds of electrotechnical and electronic items on observance of VDE norms and provisions of DIN standards accomplishes the German Institute of Certification and Testing. This system is used since 1982 also in assessment of items on conformity to norms of IEC standards. The existence of VDE certificate witnesses compliance of the certified product

to norms of German laws *"On Safety of Industrial Equipment"*, or *"On Protection Against Radio Noises"*.

The system of "A_3" is used in control of observance of norms of norms of *"Law on Safety of technical devices"*. The work in certification of devices used in supply of gas and water has to be done in obligatory manner, and other type devices may be certified in this system voluntarily.

The "C" system is used in certification of safety of instruments to be marked with the sign of *"GS"*.

The "E" system is used in obligatory certification of testing and measuring equipment exploited by the authorized centers of federal lands of Germany, which operate under guidance of the *Federal Physical and Technical Institute*.

The "F" system is used in certification of steam boilers, balloons and equipment exploited under the elevated pressure, means of transporting of flammable liquids and the dust-ignition-proof equipment.

3.10.5 Japanese Committee of Industrial Standards (JISC)

JISC The *Japanese Committee of Industrial Standards (JISC)* founded in 1949 by the Ministry of Foreign Trade is the head organization operating standardization in Japan and accomplishing simultaneously the functions of its Secretariat. The JISC structure includes the principal subdivisions as follows:

- Council of standardization,
- councils of sectoral departments,
- technical committees.

Accordingly to the Japanese *"Law on standardization"*, there exist the categories of industrial standards, branch-wise standards and standards of firms.

- *Industrial standards* are the normative documents of voluntary character used preferably in mining and manufacturing industries and revised every three years. The exclusions are standards on medical preparations, mineral fertilizers and means of protection of plants, which norms are obligatory for observance.

- Provisions of *sectoral standards*, which complement in most cases norms of national ones.
- *Standards of firms* developed on base of provisions of national and sectoral standards. However, norms of such category documents may differ of national ones because of specificity of manufacturing processes realized at individual firms in their aspiration to satisfy needs of specific categories of consumers, win in competitions etc. At the same time, said documents do not normalize the environmental conditions of operation of persons of economy, as a rule, and are not directed on solving of social problems of the society.

The JISC departments participate also in development of international standards, accrediting of measuring and testing laboratories, and dissemination of information on Japanese experience in quality management and protection of environment.

Realizing the program of integration of national economy in global community, the Japanese government founded in 1949 the special Group by investigation of problems of quality subordinated to National Union of Scientists and Engineers and introduced for the end of 1960-s the national program of total control of quality of products at places of their producing, which main principles are:

- development of the all-Japanese campaign of propagation of ideas of quality,
- introduction of the norm of total control of quality of operation of enterprises carried out in conditions of involvement of all their laborers in this work,
- training of employees by problems of quality,
- work of societies of quality,
- control of work of persons of economy by the specialized off-site organizations.

Using norms of Japanese legislation, the Institute certifies production on conformity of its quality to national norms and issues licenses on marking of certified products by the national sign of conformity (Fig. 3.11):

Figure 3.11 JISC sign of conformity

The procedures of use of sign ***JIS*** based on provisions of *Law on Industrial Standardization* establishes the *Japanese committee of industrial standards*. Presences of this sign on the item witnesses the stability of conditions of work of its manufacturer, maintaining of proper conditions of environment in process of manufacturing and safety of marked items in their use by destination. The Japanese sign of conformity may use since 1980 also the foreign persons on condition of their servicing by the specialized accredited Japanese testing and measuring laboratories.

The Japanese certification laws protect interests of the domestic market, therefore no one manufacturer, who operates in branches of ferrous and non-ferrous metallurgy, chemical, mining, pulp and paper industry, engineering, motor-car construction, shipbuilding, electrical engineering, railway transport, aviation techniques, construction and architecture will not get the order of Government or any prestigious Japanese company if his production would not be certified in Japan, and the documents, which supplement goods produced independently of place of their production, must be written in Japanese.

The works in certification in Japan are accomplished under the State control and the right of issuing of certificates of conformity and marking of certified items gives the minister of respective branch of economy. There exist three forms of certification in Japan:

- *obligatory* – attestation on conformity of goods to provisions of Japanese normative and legal documents carried out by the authorized persons of Governmental subordination,
- *voluntary* – attestation on conformity of goods to provisions of Japanese normative and legal documents carried out by the authorized persons of Governmental subordination,

- *voluntary* – attestation on conformity of goods to provisions of Japanese normative and legal documents carried out by the accredited private persons.

The procedures of *obligatory* certification regulate norms of Japanese legislation, which establish also the list of production, which may be certified. The work in certification of systems of quality is carried out under the control of Japanese association *JAB*, which operates under the JISC control. Its principal functions are:

- accreditation of applicants, training and attesting of auditors of quality systems,
- development of norms of attestation,
- co-ordination of norms of profile works with its foreign partners.

3.10.6 Gosstandart of Russian Federation

The State regulation of work in standardization in Russia executes the State Committee of Russian Federation by Standardization and Metrology (Gosstandart of Russia) and other federal bodies of executive power (in spheres of their competence).

The Russian State System of Standardization (Gosudarstvennaya Systema Standartizatsii – GSS) introduced 01 January 1993 structures the fund of national standards and details methods of their development, approval, postponing of validity and cancellation. These activities are carried out in purposes of elimination of monopolizing of work in standardization, taking into consideration of realities of market economy and movement of practice of this work in Russian Federation towards the global realities. The initial step of such activities was introduction of category of new type normative documents – the technical regulations, which settle the modern norms of functioning of national economy. The fundamental GSS principle is use of the four-level fund of laws, by-laws and documents subdivided by categories as follows:

I. Technical legislation – the complex of laws, and by-laws of Russian Federation by standardization (State laws, presidential and governmental decrees, technical regulations, orders of Federal bodies of executive power).

II. State standards (GOST R), national classifiers of technical and economical information (OKTEI).

III. Sectoral standards (OST) and specifications of persons of economy (TU).

IV. Standards of enterprises (STP) and standards of scientific, technical, and engineering associations – STO.

The biggest in number group of normative documents by standardization are technical specifications developed by enterprises themselves, which normalize the specific characteristics of products they propose. Being formally the category of documents, which protect intellectual property of their owners, specifications are in fact the norms used in regulation of interrelations of manufacturers and consumers by problems of quality of objects of normalization and procedures of their use (consumption).

The one of the most significant spheres of operation of Gosstandart is the obligatory and voluntary certification of goods, services, personnel, quality systems etc. The Russian Federation established 16 systems of *obligatory certification*, which may be classified by types of attested production (services). Such work, similarly with the practice used in other countries, has to be done mainly in purposes of confirmation of their safety and environmental friendliness. The list of products subordinated to this type work is inscribed in the official State register. These ones are agricultural products and foodstuffs, household chemical goods, products of textile and light industry, electrical and radio-electronic apparatus, medical technique and instruments, motor transport, sport and hunting weapons, household heating means and technique etc. This work is carried out in most cases by the Gosstandart bodies. The one more category of persons, which may service works in obligatory certification, is the non-commercial organizations (associations) of any form of property accredited on this job by the specialized State bodies.

The quality of products free of obligation of certification of production to be exported may be attested certified by initiative of applicants *voluntarily* by contracts with the accredited certifying bodies they choose freely by procedures of 131 systems, which are registered in

Russia and based on use of workings of ISO, ISO/IEC guides, European standards of EN 45000 series harmonized in Russia. Said systems may be of national category (System of voluntary certification of production by Gosstandart of Russia, Systems of voluntary certification of "HACCP" etc.) or bear the specific character (Regional system of voluntary certification of trade services in city of Moscow, System of voluntary certification of Metrological academy and so on).

The basic rules of carrying out of certification in Russia are:

- the objects of certification and their attested characteristics have to be clearly stipulated and documented in observance of provisions of normative documents used in process of attestation,
- any system of voluntary certification is free in establishing and use of specific form of certificate and sign of conformity. The only condition is presence of all necessary information in the certificate and patent purity of used documents (signs).

3.11 Persons of Standardization in Ukraine

The structure of Ukrainian system of standardization guarantees the close collaboration of all parties (manufacturers of production, its consumers, representatives of public organizations, individual specialists etc.) interested in development and use of standards. To organize and co-ordinate the proper functioning of the system, the State founded the specialized central body, which main function is development, postponing and cancellation of validity of normative documents, control of observance of their norms and representing of national interests in the specialized international and regional associations and unions. The net of offices operating said problems includes the following persons:

Central body of executive power in sphere of standardization:

Accordingly to Law of Ukraine *"On standardization"*, these functions are delegated to the State Service of Technical Regulation and Consumer' Policy of Ukraine (its former appellations: Derzhstandart of Ukraine in period of 1992-2002, and Derzhspozhivstandart of Ukraine in 2002-2010). Its principal tasks are:

- realization of State policy in development, harmonization and validation of standards done in observance of principles of *International Code of Conscientious Practice* and provisions of WTO Agreement on technical barriers in trade (see Chapter 7.6.3),
- servicing of the *National fund of normative documents* and the *National center of ISONET*,
- founding of technical committees by standardization and continuous control of their competence,
- development and approving of technical regulations and other type regulatory documents by problems of standardization,
- development, validation, revision and cancellation of national standards, as well as establishing of procedures of their registration, indication, codification by classes etc.,
- participation in works of the specialized international organizations in development of international, regional and interstate standards and norms of attestation of conformity,
- collaboration with the international and regional organizations, which operate standardization and adjoining spheres of regulation.

Council by Standardization and Technical Regulation

The Council represents itself the corporate consultative and advisory body that consists of 17 persons, who work under guidance of the State Service of Technical Regulation and Consumer' Policy of Ukraine. It is formed of representatives of Council of Ministers of Ukraine, central State bodies of executive power, manufacturers, R&D institutions and organizations by protection of rights of consumers. Representatives of last three categories have to constitute at least the half of its staff.

Technical committees by standardization

These ones are the voluntary non-profitable associations organized by the State Service of Technical Regulation and Consumer' Policy of Ukraine, which operate on base of organizations, institutions, scientific and projecting institutes, manufacturers, associations of manufacturers, universities. Their staffs include also representatives of interested parties, especially the plenipotentiary bodies of executive power and local governments, scientific, technical and engineering companies, public

organizations and leading scientists by problems of their specialization. At present, in Ukraine exist 152 technical committees of standardization, and the principal problems they solve are:

- development of programs of standardization in entrusted spheres of their activity,
- designation of priorities in harmonization in Ukraine of international and regional standards and participation in work of structures, which develop such documents,
- examining and preparation for approval of projects of national (DSTU) and interstate (GOST) standards and their annexes and amendments,
- collaboration with persons of economy, which use norms of standards in their work, especially with the communities of consumers, testing centers (laboratories) and certification bodies.

Other persons operating standardization represented by central bodies of executive power and specialized organizations work in limits of their authorities and carry responsibility for correctness of procedures they use in work in spheres as follows:

- participation in works by development, validation, revision and amending of texts of national standards and other type normative documents,
- representing of interests of Ukraine in the specialized international and regional organizations by standardization, publishing and dissemination of their documents,
- keeping of registers of reference documents and dissemination of information by profile of their activity.

3.12 Procedures of Development and Validation of Standards in Ukraine

Planning of activities in standardization is the integral part of work in assuring of economical and social progress of the country. To optimize procedures of standardization, modernize the structure of works in this sphere and augment the number of normative documents in the Ukrainian

national fund of regulatory documents, the State Service of Technical Regulation of Ukraine approves each year the program of work in development of standards carried out in observance of current priorities of evolution of national economy proposed by ministries, specialized technical committees, enterprises, organizations and other interested persons. Accordingly to the Clause 8 of Law of Ukraine of 15.01.2015 *"On Technical Regulations and Assessment of Conformity"*, the profile technical committees consider the list of national standards planned to development. In absence of the committee specialized in problem in question, these works accomplish organizations, which have the necessary scientific and technical experience in spheres of their interest. After approval of the plan, the State Service of Technical Regulation and Consumer' Policy of Ukraine sends it to ministries and/or their leading (basic) organizations to obtain proposals on terms of carrying out of planned works and their executors.

The basic norms of development and use of standards are set by the complex of normative documents of *"National Standardization"*. The principal rules to be observed in this work are:

- standards can be developed only in existence of real need in their use in structures of public economy,
- the principal problems to be taken into consideration in their development are safety of products (services, processes), their interchangeability and compatibility with other standardized objects, as well as guarantees of protection of environment in their production and exploitation (use),
- the methods of control of indices of quality of objects of standardization have to be attested on their objectivity,
- texts of standards have to be clearly stated, be understandable and unambiguous in interpretation of their statements.

The procedures of normalization used in national standardization establishes the fundamental standard of DSTU 1.2:2003 *"National standardization. Procedures of development of normative documents of national rank"*, and the basic stages of this work are:

1. *Organizational stage.* The Chairperson of the organization, which would develop the normative document, appoints executors of this work, issues the related order (signs the contract), and defines the content, terms and stages of carrying out of necessary works.

2. *Development of initial version of standard.* The developer of the document prepares its preliminary version. To choose the optimum parameters of object of development, he carries out the necessary R&D, projecting and construction works, verifies their patent purity, draws up the executive summary and sends it with the basic text of the document and necessary supplementing materials to interested parties for revision.

3. *Development of the final version of the standard.* The parties, which received the pack of documents on prospective standard, send its developer their remarks on the content of this document in a month term. The latter takes them into consideration, makes the necessary corrections, draws up the final version of the text and sends it for approval to the State Service of Technical Regulation and Consumer' Policy of Ukraine.

4. *Approval and State registration of standard.* The State Service of Technical Regulation and Consumer' Policy makes the expertise of the final version of the document and takes decision on its approval and registration in the State register or returning it for rework. After the document would have been registered, it receives the respective index (DSTU, TU etc.), registration number in the catalogue of State normative documents and numeral index of year of its approval.

5. *Publication and distribution of national standard.* The information on the registered standard is published in the month term in the information catalogue of *"Standards"*, and the full list of valid standards – in the annual edition of *"Catalogue of normative documents"*. Publishing and dissemination of national standards, as well as identifying of terms of their validation or cancellation can be done by the State Service of Technical Regulation and Consumer' Policy of Ukraine exclusively. However, users may use norms of said documents in their work even before their validation, if such use does not contradict with provisions of other documents in force.

The extraordinary revision of normative documents has to be done in cases of development of advanced items to be normalized, betterment of technologies and introduction in practical use of new substances etc. This work has to be done also in cases as follows:

- in nonconformity of valid versions of standards with norms of newly developed technical regulations,
- in harmonization of new versions of international and regional documents, which norms contradict with provisions of the related standard.

The normative documents on products (processes, services) have to be revised in obligatory manner in necessity of introduction of novel norms of safety of the normalized items, breaking of their compatibility with the items produced in observance of provisions of new normative documents, as well as in cases of varying of norms of protection of environment. The information on prospective amendments of standards is published in monthly reference book of normative documents not later of six months before the amended version of the document would have become validated. The scheduled revisions of versions of valid standards accomplish at least once per five years the profile technical committees by standardization or organizations, which developed these documents. The registered number of document after its revision remains the same, but there are changed the ciphers of index of year of its registration.

The standards are cancelled in cases of loss of their actuality (e.g. when the normalized process is not used, service is not given etc.), its obsolescence, as well as in cases of development of normative documents, which would be used instead of versions of documents used before. The respective information has to be published in the State information reference book not later of three months before cancellation of the standard in question.

3.13 Categories of Ukrainian Normative Documents

The base of system of Ukrainian State standardization is the fund of laws, by-laws and other type documents of regulatory character.

Depending of kinds of objects of normalization, these documents are of categories as follows (Figure 3.12):

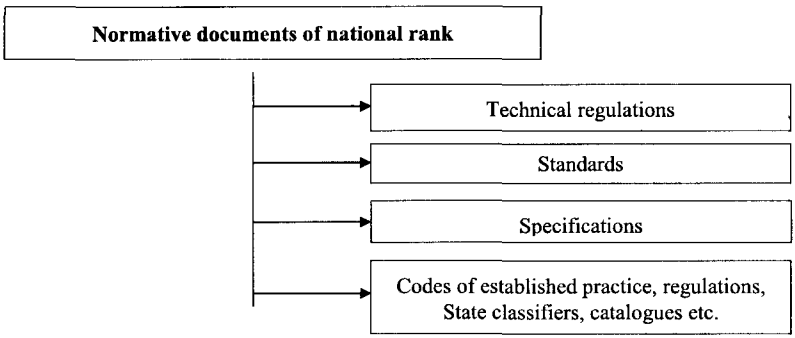


Fig. 3.12 Main types of normative documents of national rank

Accordingly to legal norms, the terms above are used in meanings as follows:

- *technical regulations* is the legal and/or normative deed obligatory for observance approved by the Council of Ministers of Ukraine, which normalize the list and numerical values of indices of quality of products, methods of their producing and/or servicing, terminology, methods of packing, design of marks and conditions of marking and labeling of goods of normalized quality. Except of technical regulations valid in Ukraine only, there exist the technical regulations of interstate category developed by the MDR and used freely in the borders of its member-countries,
- *standard* means the normative document approved by the State authorized body and assigned for general use. Standards regulate procedures used in work of persons of economy and/or their results, parameters of quality of production and methods of their identification, as well as procedures of their use, servicing, storage, transporting etc.,
- *specifications* means the normative document developed by their owner themselves and assigned for his use only, which establishes

characteristics of goods, processes and services same with those, which are normalized by standards,

- *code of established practice* means the document used in absence of national standards, which describe the procedures of projecting, producing, assembling, servicing and exploitation of equipment, constructions etc.
- *classifier* means the document, which classifies objects of regulation by coded groups. The norms of State classifiers of technical, economical and social information are obligatory for use in development of State informative resources,
- *catalogue* means the systematic statute book, which ranks normalized objects by any parameter, index or other specific characteristic,
- *State standards of former USSR (GOST)* and *Republican standards of former Ukrainian Soviet Socialistic Republic (RST UkrSSR)* are the normative documents of national rank valid in Ukraine till their cancellation or replacement by other norms.

The first rank normative documents, which normalize the basic principles of operation of national economy, are *technical regulations*. This category documents: 1) establish the procedures, which normalize indices of quality of production and methods of its marking and labeling, 2) formalize norms of protection of environment, 3) establish norms of safety in use of production, functioning of technological processes and giving of services, 4) establish the minimally required veterinary and sanitary norms of quality and safety of products to be imported in Ukraine, 5) prevent misleading of consumers in procedures to be observed in use of production, 6) assist in solving of problems of national safety. The norms of technical regulations establish the minimal conditions of ensuring of:

- safety of emissions,
- biological safety,
- nonexplosiveness,
- mechanical safety,

- fire safety,
- safety of production (technical devises used at hazardous industrial facilities),
- thermal safety,
- chemical safety,
- electrosecurity and other types of safety,
- radiative safety of population,
- electromagnetic compatibility of instruments and tools used in work,
- uniformity of measurements.

At that, the norms of standards used in earlier time in absence of technical regulations lose their regulatory character. Formation of complex of national technical regulations has to guarantee the scientific and technical advancement and technological safety of the State. It is necessary to note, that technical regulations establish characteristics of objects, as a rule, but not their design and methods of manufacturing, which developers, designers and technologists may choose on their own discretion.

The next class normative documents used in Ukraine are *national standards*. Accordingly to specificity and probable spheres of their sphere of regulation, there exist the categories of national normative documents as follows (Figure 3.13):

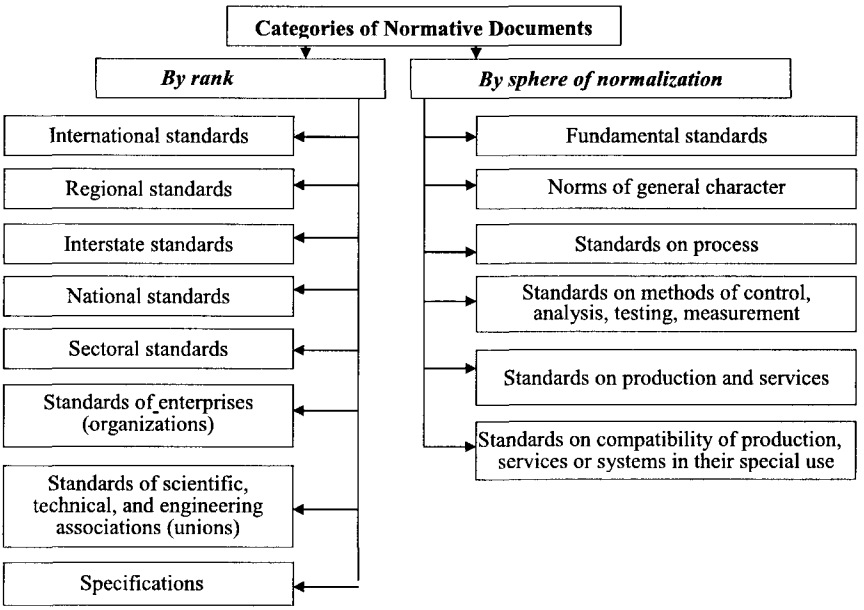


Figure 3.13 Categories of normative documents valid in Ukraine

By categories, the Ukrainian national standards may be classified as follows:

Standards of national category mean the normative documents developed by the State Service of Technical Regulation and Consumer' Policy valid in Ukraine only. Said documents reflect the specific features of her national economy in concrete social, historical and geographical conditions.

Standards of interstate category mean the documents developed by the Interstate Council of CIS member-countries by standardization, certification and metrology and considered as the specific type of regional norms. This category documents have the coding of GOST and may be used in CIS countries in parallel with the standards of national category without the need of their harmonization.

This is not the exhaustive list of standards used by persons of economy in Ukraine. Joining of Ukraine to the World Trade Organization

and her aspiration for more close integration with the European Union community obliges the country to harmonize the structure of national system of technical regulation with the global and European norms. Meantime, the norms of many standards of different countries on the same materials and articles differ, as a rule, what is the serious barrier for development of international exchange by technologies, consumables and services. To avoid such complications, Ukraine harmonizes the numerous ISO and European standards, what permits her to unify principles of manufacturing, raise its state to level of advanced countries in a short time and export the advanced technologies of own development. Such standards may be ranked by categories as follows.

Standards of regional category harmonized in Ukraine are the normative documents developed by the standardization organizations, which operate in certain geographical, political and economical regions. The content of such documents clearly reflects the specificities of corresponding regional economics and content of trade treaties concluded by neighboring countries pooled by traditional interrelations.

Standards of international category harmonized in Ukraine mean the normative documents developed and approved by the international standardization organizations in observance of the latest achievements of science and technique.

The work on harmonization of standards is carried out frequently in framework of two- or multilateral treaties, and meaning of appellations of related documents are as follows:

- *standard harmonized on multilateral base* means the document harmonized by three or more national bodies by standardization,
- *standard harmonized on bilateral base* means the document harmonized by two national standardization bodies,
- *agreed standard* means the document, which norms coincide with the respective ones of any foreign standard taken as a model,
- *comparative standards* mean the normative documents that regulate quality of the same product but differ by some of its parameters to identify.

The process of validation of international (regional) standard in category of national norm has the form *of its publication in category of national standard, which have the analogous content as the model document. In some cases, these documents are published in category of amended of non-equivalent document to their international (regional) analogues because of existence of deviations of their provisions of norms of standards taken in harmonization as the model.

Organization of works in standardization is the urgent problem of functioning of any national economy, for standards permit to identify the level of scientific and technical development of the State and witness her capability to work autonomously during the specific time period.

By spheres of normalization standards may be ranked by the following groups:

Fundamental standards are the documents used usually as the norms of organizational, methodological and technical character used in certain spheres of economy in establishing of procedures of business-operation, development, approval and validation of normative documents of general character, norms of metrological support etc. The typical problems they regulate are: 1) coordination of works by development, producing, storage, transportation and utilization of production, 2) measures by protection of environment, 3) terminology and definitions, etc.

Standards on production (services) normalize indices of quality of groups of uniform products (services), conditions of their purposeful use and methods of control of their observance; procedures of acceptance, packing and marking of finished products; norms of safety of goods in process of their fabrication and exploitation; norms of protection of environment etc.

Standards on procedures of work (process) establish the principal norms of development, producing, storage, exploitation, repair and utilization of products. Such documents normalize also the permissible norms of throwing of pollutants into the neighboring nature, methods of avoiding of accidents in business operation and liquidation of effects of non-regular situations.

Standards on methods of control (testing, measuring, analysis, calibration) establish methods of identification of indices of quality and properties of one of more groups of products to be tested in processes of their fabrication, attestation of quality and use, as well as metrological norms of fixing and formalizing of taken results.

Standards on safety normalize methods of assessment of grade of potential hazards of objects of normalization for the sake of attaining of reasonable level of safety in their exploitation (use).

Terminological standards establish terms, their definitions (methods of interpretation) and demonstrate examples of their use.

The normative documents, which are in process of development, have the same code as the valid documents in sphere of their responsibility, but are supplemented with abbreviation of "*pr*" (project) placed before, *prDSTU*, for example.

Besides, there are used in business practice the normative documents of lower ranks, for example.

Methodological norms and recommendations, which have to assist in reaching of compliance of objects of regulation to the established norms and describe the methods and means of realization of processes they specify.

Regulations – the document, which contains usually the generalized description of design and list of component parts, dimensions of regulated items, composition of raw materials used in their production and analysis etc. Furthermore, these kind documents may specify procedures of use of objects of regulation to be used in process of their exploitation.

The standards of technical character, as well as the methodological norms, are associated usually in groups (systems) of normative documents used in public economy to simplify the routine of work and procedures of development of objects of normalization, cut the prime cost and improve quality of modernized products. The examples of intersectoral complexes of standards are the *"Unified system of development of documentation" (YeSKD), "Unified system of technological documentation" (YeSTD), "System of standards of safety of labor" (SSBP), "Unified system of technological preparation to manufacturing" (SRTPV), "System of*

development and introduction of technologies of manufacturing" (SRPV), "System of standards of work in protection of environment", "System of standards of codes and coding of information" etc.

The principal spheres of use of normative documents in Ukraine are:

National standards (including the versions of international and regional standards harmonized in Ukraine) are used freely by persons of economy of all forms of property, and the objects they normalize the most often are:

- organizational, methodological and technical norms, which describe the basic principles of operation in spheres of metrology, standardization and attestation of conformity,
- procedures of statement and use of scientific and technical terminology, norms of attestation of conformity and coding of documentation,
- properties and indices of quality of materials and substances,
- norms of quality of finished production and methods of their identification.

In need of accumulation of data necessary for substantiation of norms used temporarily, there are used the *test standards*:

> *Test standard means the temporary norm used in purposes of accumulation of necessary experience in sphere of normalization*

The documents used usually in their development are the international, regional and national norms of countries advanced in use of items of the same destination. The valid national standards and the test standards are used by the same procedure independently of type of normalized products and processes of their fabrication, exploitation, storage, transporting, realization and utilization.

The test standards are character by lower level of consensus to be reached among persons of the authorized technical committee of standardization or even members of its working group responsible for development of the document. There may be used in this category also such new types of documents of international organizations for standardization as *PAS*

(public access specifications), *TS* (technical specifications) and *ITS* (intersectoral technical specifications).

In impossibility of approval of projects of the finished text of standard in category of regular norm, these ones may be ranked as technical reports formalized in cases as follows:

- in absence of consensus of interested parties by separate topics of the document,
- if the object of standardization is still projected, therefore the document cannot be introduced as the regular norm,
- if the working contains all necessary data, but the form of its presenting does not comply to the established norms,
- if conditions of use of the item (process, service) to be standardized was varied dramatically during the process of development of the document, what makes unnecessary its approval as the regular norm,
- if there was published the amended version of international or regional standard taken as the model in development of national norm, what refuses necessity of continuing of work in harmonization of the obsolete version of the document.

Sectoral standard of Ukraine (GSTU – galuzevyi standart Ukraiiny) is the obsolete form of the document used by the State sectoral ministries in normalization of properties and quality of production (services) in spheres of their responsibility in absence of respective national standards. Despite the obsolescence of documents of this category, the sectoral norms developed in earlier time are still in use. The observance of provisions of such documents are obligatory for all enterprises and organizations of given branch of economy, as well as for institutions, organizations and enterprises of all forms of property applied for their use.

Specifications (TUU – tekhnichni umovy Ukraiiny) means the normative document developed by legal persons of any form of property, which provisions are valid all over the Ukrainian territory. Specifications are developed usually in need of normalization of indices of quality and methods of their identification not regulated by norms of State and/or

sectoral standards. Such documents may be considered also as the specific form of protection of rights of intellectual property, hence their norms cannot be used by third parties without the written permission of their owner.

At the initial stage of development of specifications, the developer draws up their test version, agrees it with any person interested in use of object of the TUU normalization and approves the document, which will be valid in a year. The principal purpose of its introduction is specialization of parameters of experimental parties of object of normalization to be optimized during this term and/or working-off of details of production it normalizes.

The following stages of development of specifications presume their registration in the State register, and the kinds of registered documents of TUU category are:

- specifications on serial and mass production of own manufacture,
- specifications on services,
- specifications of products of foreign origin, which use is permitted by contracts (licenses) on their import in Ukraine,
- specifications on production, which properties differ of norms of standards.

In consent of owner of the document and customer of his production, the unique products and products made in small series, or the items and their constituent parts to be exported, as well as substances and materials used in their fabrication, may be produced one time by norms of contract or preliminary specifications, constructional or technical documentation, or technical description in absence of TUU or in use of the exemplary sample as the model.

The conditions of registration of specifications are adequacy of regulated properties of production to norms of technical regulations, and/or related legal and normative documents of the State category. The criteria to be taken into consideration in their approval are:

- for units of production – observance of norms cleared-up by the authorized commission,

- for the measuring instrument – existing of permission on its State registration,
- for items of medical destination – existence of permission of the State regulatory body(ies) on their use.

The list of items, which specifications are not subordinated to the State registration, includes the unique and artisan's production, souvenirs and decorative goods (excluding the articles made of precious metals), industrial wastes, raw materials, auxiliary substances, semi-finished products and items used in manufacturing by individual orders.

Standards of enterprises (STP) and *standards of organizations (SOU)* are the basic organizational and methodological documents developed, approved and used by persons of economy for their own needs. Such standards normalize indices of quality of self-made production (specific features of processes and procedures of giving of services). The norms of STP and SOU must not contradict with the obligatory requirements of normative documents of higher rank. In case of written consent of their owner, these type standards may use other persons of economy too. Besides, enterprises may use in execution of international contracts in category of STP any international, regional and national standard of any other country.

Standards of scientific, technical, and engineering associations (unions) of Ukraine (STU) have the purpose of dissemination of information of interested parties and introduction by contracts in practical use of the systemized and generalized results of fundamental and applied R&D works they executed.

Guiding normative documents mean the documents, which regulate norms of operation of persons of economy, as well as procedures of organizational, methodological, and technical character developed in purposes of normalization of specific properties of production (process, service) in absence of corresponding norms of higher rank. The category of guides includes also the informative documents on the normalized methods of calculation, typical regulations of juridical bodies etc.

The national standards and equal rank normative documents contain norms of obligatory and voluntary use. The norms obligatory for observance are:

- measures of ensuring of safety and hygiene of labor and protection of health,
- measures by assuring of compatibility and interchangeability of component parts of production and observance of norms of technical unity in their development, producing, and exploitation (use),
- measures by protection of environment,
- normalized indices of quality and methods of their identification and control,
- concepts and terminology used in treatment of wastes; classification and methods of identification of their composition and class of danger; procedures of control of technical state of objects by safe storage, processing and use of wastes as the secondary raw materials.

All other norms of standards are of voluntary character and ranked as the recommended ones. However, they become the obligatory for observance in cases as follows:

- if the norms of standards used in business practice are cited in technical regulations,
- if the contracting persons develop, produce and/or supply production by contracts, which contain references on compliance of its quality to norms regulated by standards in question.

The normative documents used in Ukraine are encoded as follows:

- *national standards:*
  - **DSTU** – national standard,
  - **GOST...** – standards of former USSR, as well as standards developed by the CIS Interstate Group by standardization, metrology and certification in category of interstate norms and recognized as national standards of Ukraine,
  - **DSTU GOST** – the harmonized interstate standards (GOST) modified in observance national specificities,

- **DSTU B** – standards approved by Derzhbud of Ukraine and used in spheres of building and producing of construction materials,
- **DSTU-P** – tentative standard,
- **DSTU-N** – directions, rules, codes of rules, codes of established practice not approved in category of national standards,
- **DSTU-ZT** – technical reports,
- **RST UkrSSR** – republican standards of former Ukrainian Soviet Socialistic Republic,
- **DK** – State classifiers,
- **DSTU ISO** – standards of International Organization for Standardization harmonized in Ukraine,
- **DSTU IEC** – standards of International Electrotechnical Commission harmonized in Ukraine,
- **DSTU ISO/IEC** – the ISO and IEC common standards harmonized in Ukraine,
- **DSTU EN** – European standards harmonized in Ukraine.

➢ *other rank normative documents:*

- **GSTU** – sectoral (branch-wise) standards of Ukraine,
- **TUU** – specifications valid at the whole territory of Ukraine,
- **STP** – standards of enterprises,
- **SOU** – standards of organizations,
- **STU** – standards of scientific, technical, and/or engineering communities and unions,
- **TR** – technical regulations,
- **KND** – guiding normative documents.

3.14 Procedures of State Control of Observance of Requirements of Normative Documents

The normative and legal base of work in spheres of State control and State supervision on observance of provisions of standards, norms and rules includes the fundamental documents as follows:

- Decree of Council of Ministers of Ukraine of 09.04 1993 # 30-93 "On State Supervision on Work to be carried out in Observance of Standards, Norms, Rules and Responsibility for their Infringements",
- Law of Ukraine of 15.05.2014 # 1315-VII "On Standardization",
- Law of Ukraine of 15.01.2015 # 124-VIII "On Technical Regulations and Assessment of Conformity",
- Law of Ukraine of 16.11.2006 # 361-V "On Veterinary Medicine",
- Law of Ukraine of 23.12.1997 # 771/97-VR "On Safety and Quality of Foodstuffs",
- Law of Ukraine of 24.02.1994 # 4004-XII "On Ensuring of Sanitary and Epidemic Well-being of Population",
- Law of Ukraine of 01.12.2005 # 3161-IV "On Protection of Rights of Consumers".

The work of bodies authorized on supervision and control of activities of businesspersons is the key element of the system of State technical regulation, which essence may be worded as follows:

> *State control is the complex of organizational and legal measures carried out by the authorized bodies of executive power in* ***purposes of issuing of permission*** *on accomplishing by the specialized control bodies of work in registration and accreditation of enterprises and their testing departments, attestation and verification of means of measuring technique, carrying out of sanitary and hygienic expertise and control of observance by persons of economy of norms of protection of labor, fire safety etc.*
>
> *State supervision is the work of the authorized bodies of executive power and persons they authorize on this job in control of observance by businesspersons of provisions of standards, norms and rules in process of their operation carried out in* ***purposes of prevention of origination and/or revealing of their infringements*** *and assuring of interests on community and consumers in producing of goods of proper quality,*

guaranteeing of integrity of property of population and community, safety of environment etc.

Said activities have the form of scheduled inspections (not more that once per year) carried out by plans of State control and supervision bodies, orders of Council of Ministers of Ukraine, motivated claims of bodies of executive power and offices of public prosecutors in form of selective or total control of operation of inspected persons to be done in observance of requirements of standards, norms and rules. In case of systematical reclamations to quality of produced production and/or absence of conditions of stable manufacturing of products of proper quality, there are introduced the extraordinary inspections and/or permanent control actions. Doing this work, control bodies have the right to postpone or even prohibit in extreme cases fabrication and realization of production produced by the controlled persons.

The terms above are used in meanings as follows:

Selective control means the work, which decisions are taken by results of control of quality of one or some extracts of serial production taken randomly

Extracts means the units of production taken for analysis from the controlled party

Total control means the control of quality of each unit of production of the controlled party

Quality of production means the complex of properties of goods, which imparts their ability to satisfy needs of consumers and reflects their safety, newness, longevity, reliability, economy, ergonomics, aesthetics and environmental compatibility in use by destination

Rules mean the document, which represents themselves the normative and legal code of norms of work of the enterprise in certain sphere of regulation. These ones may be the metrological, sanitary, fire-preventing, environmental, organizational, technological, and other characters pertinent to use of goods (realization of processes, giving of services) by destination

The *objects of control* are:

- scientific and technical production, products used in manufacture and technique, consumables, products of agriculture, foodstuffs, processes of cattle breeding and their products – on compliance to national norms,
- production intended for export and bought by the State expenses, – on compliance to norms of related regulative documents (if clauses of contracts on their supply don't foresee another conditions),
- production of foreign origin – on conformity to Ukrainian norms of their environmental friendliness and safety for life and health of men.

Coordination of works in control of most objects carry out the commissions appointed by the State Service of Technical Regulation and Consumer' Policy of Ukraine and its territorial bodies. The activities of businesspersons, which operate in sphere of construction controls the Derzhbud of Ukraine. Besides, the analogous works execute in spheres of their responsibility the ministerial departments (Figure 3.14):

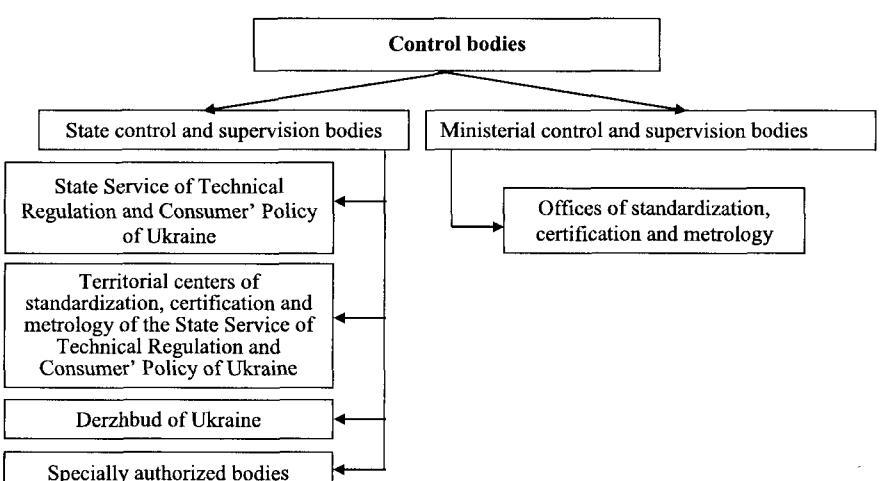


Fig. 3.14 Bodies controlling observance of provisions of normative documents

The *objects of State supervision* are:

- state of observance by persons of economy of provisions of standards, norms and rules (except of constructional, sanitary, hygienic, epidemic-preventive and veterinary norms, which operate in sphere of responsibility of organizations specially appointed on this work),
- normalized procedures of development, fabrication, storage, transporting, exploitation, realization and utilization of products of normalized quality,
- procedures of producing and realization of production of enterprises of public catering,
- procedures of servicing,
- observance of conditions of assurance of stability of quality of certified production,
- state of observance by persons of economy of procedures of testing of certified goods.

The procedures used in this work regulate the norms of Law of Ukraine of 02.12.2010 # 2735-VI *"On the State Market Surveillance and Control of Inedible Production"* used in relation to all products of food industry with the exception of:

- food additives, scenting and dietetic additives,
- auxiliary materials used in re-processing of foodstuffs,
- products of animal origin,
- forages, forage additives and premixes,
- live animals,
- products of men, vegetation and animal vital activities used as the reproductive materials,
- alcoholic beverages and tobacco goods,
- drugs and veterinary preparations,
- narcotic and psychotropic agents, their analogues and precursors,
- special fissile materials and other products used in generation of nuclear power,
- articles of military assignment,
- objects of urban economy,

- objects of aviation.

The information on procedures of surveillance and control of quality of foodstuffs is given in Section 7 of this manual.

The basic principles of market supervision and control used in it are:

1) adequacy of measures of market supervision to the level of public interests,
2) coordination of work in market supervision with the Custom Service bodies,
3) objectivity, impartiality and sufficient competence of market supervision bodies and custom services,
4) transparency in carrying out of actions of market supervision and control of quality of production, as well as accessibility and openness of information obtained in this work,
5) collaboration of the controlled persons with the market surveillance and custom service bodies,
6) observance of rights of persons of economy and consumers, and inadmissibility of discrimination of their interests,
7) equality of procedures used in work in market surveillance and control of quality of production of domestic and foreign origin,
8) prevention of conflicts of interests in expertise (testing) of taken samples of production,
9) confidentiality of information obtained by the control bodies in process of their work,
10) responsibility of bodies of market surveillance, custom service and their functionaries for damage caused to subjects of economy because of their disproportionate and illegal activities in process of control.

The principal functions of the State bodies, which control observance of requirements of standards, norms and rules by persons of economy, are:

- control of observance of provisions of legal and normative documents used by persons of economy in their work,
- making of suggestions on revision of normative and regulatory documents, which norms are unsatisfactory or insufficient for

preservation of the proper state of environment, producing of qualitative production and securing of safety of life, health and property of men,

- proposing to postpone the operations, which procedures contradict with statements of related normative documents in force,
- making of proposals on prolonging of terms of validity of normative documents,
- making of proposals on elimination of causes of origination of typical infringements of provisions of norms, rules and regulations committed by persons of control,
- summarizing of results of State supervision and control, analysis of causes of found infringements and informing of State and local power bodies on findings of inspections.

The State inspectors, who accomplish the control actions, have the rights as follows:

- freely visit enterprises, institutions and organizations of all forms of property after showing them the instructions on carrying out of inspection during their operating time of persons of control,
- demand the necessary documents by problems of inspection,
- take samples of the controlled production for testing (analysis). The cost of taken samples and expenses on their transportation and testing are attributed to expenses of the inspected person. However, the losses caused in result of illegitimate actions of State inspectors have to compensate the inspecting parties,
- lease and/or use the necessary technical means and engage for inspection the qualified specialists of third organizations, institutions and enterprises, if necessary,
- issue prescriptions on elimination of found infringements,
- prohibit to use the working documents of construction, technological and project character not satisfying to provisions of normative and regulative documents in force,
- prohibit realization of production (including the imported one), which quality does not conform to established norms. The exceptions are cases, when the found deviations were

substantiated in clauses of contracts on fabrication, repair, storage, transporting, use and realization of the inspected production,

- prohibit fabrication and realization of production pertinent to certification but not certified during the prescribed period, as well as the products, which production is subjected to licensing, but is produced in absence of respective permission,
- prohibit realization and producing of production in non-observance of obligatory conditions of safety,
- draw up prescriptions on fining of inspected persons for violation of established norms,
- introduce special procedures of acceptance of production in systematic violation of normalized conditions of its fabrication,
- propose the authorized State bodies to cancel validity of pre-existed licenses on business operation they issued, if necessary.

The inspections have to be carried out in observance of procedures as follows.

1. To start inspection, the administration of the authorized inspecting body appoints the person(s) responsible for its carrying out.

2. To begin work in inspection, the appointed inspector(s) studies the accessible documents of object of control and materials of previous inspections (for the period not less of one year); acquaints with the documents, which establish norms of quality of products to control and permissions on deviation of said norms (if exist), clarifies necessity of their obligatory certification and controls whether the actions listed in prescribes and resolutions issued in earlier inspections (if exist) were done.

3. The chief of the inspection arrives to the enterprise and hands its head person the prescription on inspection, informs him on topics of control, organizes sampling of production and asks for necessary reference documents.

4. The chairperson of the inspected enterprise is obliged to ensure for the inspecting persons the necessary conditions for carrying out of their work, namely:

- to assure free access of inspector(s) to place(s) of inspection during the whole term of its scheduled period,
- to appoint the persons, who have to assist inspectors in their work and authorize them on signing of protocols of sampling of production, reports on its testing and other documents drawn up by the inspecting commission,
- to give inspector(s) premises, documentation, materials and equipment necessary for carrying out of their duties,
- to ensure transporting of samples of production to places of their testing if this work would be done in other place.

The shipment of batches of production, which samples were taken for the control, is prohibited from the inspected enterprise till the end of inspection. However, if the product to control may be spoiled in a short time, it may be shipped in earlier terms on condition of ***1)*** attestation of compliance of its quality to established norms, ***2)*** issuing of declaration of its conformity and existence of protocols of previous positive tests of such products, and ***3)*** receiving of permission on its shipping issued by the State Sanitary and Epidemiological Service of Ukraine (if the inspected products are subordinated to its control).

If testing of the taken samples would be done by specialists of the inspected enterprise, this work has to be done in presence of the inspector competent in this problem. Otherwise, their testing has to carry out the accredited enterprises specialized in this job.

5. In necessity of testing of individual assembling units (details) and assemblages already positioned in the finished article, the inspector has the right to organize their disassembling. In case of big expenses of means and time for this job, there may be checked the assembling units, which were not put in the assemblage yet, but verified by subdivisions of the enterprise in earlier time as the qualitative ones.

In need of testing of the assembled units, which have to be shipped in disassembled state, the employees of the enterprise shall make the control assembling of items, which will contain the constituents to control and test the assemblage by the established procedure.

6. The persons, who inspect the enterprise, have to draw up after finishing of testing the report on its results, which has to be signed by all persons, who took part in this work, including the representatives of the inspected enterprise appointed on this job.

7. The chief inspector draws up the final report by results of inspection, which conclusions would be the reason for taking of measures of punishment for infringements in case of their non-elimination during the prescribed period. The representatives of the inspected person appointed on participation in work in inspection may state their remarks and pretensions to its results in the report directly or inform on their opinion in the separate deed supplementing the report. If they refuse to sign the report, the chief inspector has the right to sign the document themselves and make the record on such refusal. The protocol of inspection in this case is reckoned as the valid one.

The list of measures of punishment that could be implemented by results of inspection is established the Decree of Council of Ministers of Ukraine *"On State Control of Observance of [Requirements] of Standards, Norms and Rules, and Responsibility for their Violations"*, Law of Ukraine *"On Withdrawal from Circulation, Reprocessing, Utilization or Following Use of Poor-quality and Dangerous Production"* and *"Ukrainian Code of Administrative Penalties"*.

8. By conclusions of the report, the inspecting body issues and sends the inspected person the list of measures to be executed as follows:

- to eliminate the identified infringements and violations, or
- to postpone realization of parties of production deviated of established norms (excluding those, which were produced by contracts, which clauses permit such deviations).

If the owner of the party of production prohibited for realization has intentions to reprocess it in purposes of following use, or to utilize, or to annihilate it, he must apply to the authorized State inspecting center documents, which corroborate his right on carrying out of such activities or to engage for this job the specialized third party.

9. By results of control, the inspected person has to develop the plan of organizational and technical measures by elimination of found

unconformities (infringements, violations) and causes of their origination, send its stamped copy to the inspecting body and inform it in future on their execution. The latter takes this information into consideration, or carries out the repeated inspection to control the results of such work. In repeated founding of serious violations, the body, which accomplished the inspection, may recommend d to stop operations, which resulted in producing of poor-quality production or the manufacturing in whole. The right on issuing of such order has the Chief State Inspector of Ukraine by the problem and his deputies only. To control execution of this prescription, the control body may appoint the special commission and issue in positive results the document, which would recommend giving of permission on renewing of postponed operation.

3.15 Objectives and Priorities of Internationalization of Work in Standardization in Ukraine

The modern tendency of progress of global economy is internationalization of cooperation in fabrication of goods, mutual recognition of validity of given services and intensification of global trade. At the same time, the existing differences in the list and standardized values of characteristics of the same materials and articles in different countries hamper the progress of international trade. Therefore, there exists the crucial necessity to unify norms of quality of products to be exported with the related norms of countries of destination. The best way to do it is the mutual harmonization by the partner-countries of the same international and regional standards by the problem. To be sure in correctness of such work, one has take into consideration the differences in systems of standardization used in different geographical regions. There exist its three principal models: the North-American, Japanese and European ones:

The North-American model is based on use of principles of free market and centered on satisfying of interests of individual persons of economy. So, the standards used in this structure develop the scientific, technical and professional associations and enterprises by individual orders of interested parties in absence of direct intervention of other

persons of economy, including the national standardization bodies. The system is character by great variety of standards, which provisions may double or discard norms of the same destination valid in the same country. The typical representative of states, which use such system, is USA.

The Japanese model is character by close partnership of businesspersons and the State regulation bodies, therefore standards of national category develop in many cases the professional associations and enterprises in close partnership with respective ministries. The character peculiarity of this system is clear direction of work in standardization on protection of domestic market. So, the interested foreign parties have no rights to participate in most cases in development of Japanese standards, accordingly, cannot defend their interests.

The European model of standardization is based on concept of development of regional economy in principles of free market and co-ordination of needs of business operators with interests of the community, therefore presumes collaboration of all [West] European services realized on base of intergovernmental treaties actual in the Community.

The work in international and European regional standardization is one of Ukrainian priorities in development of structure of technical regulation, which directions define the Working Group by Standardization founded in 1990. The Group holds its meetings annually and processes the problems as follows:

- organization of work in standardization in Ukraine in observance of international, regional and national norms,
- analysis of information on advances in sphere of mutual recognition of results of operation of testing and calibration laboratories and harmonization of procedures of their accreditation,
- approving of programs of works to be done during the next year.

The Working Group closely collaborates with the international and regional standardization organizations, and the most significant result of its work is approval of the Complex of recommendations in standardization, which systemizes the set of norms of operation in observance of principles established by ISO, IEC, European and other

standardization organizations. Based on acquired knowledge, the Group developed the regulatory documents of *"Procedures of International Harmonization of Standards and Technical Regulations"* and *"List of Matters to be Harmonized with the International Standards"*, which observance has the absolutely mandatory character.

Integration in process of international standardization opens Ukraine the global markets of production and services, and her main tasks in realization of this policy are:

- harmonization of principles of operation of national system of standardization with the international and regional ones,
- perfecting of fund of national normative documents in harmonization of advanced international, regional and national norms used in other countries,
- participation in development of international and regional standards, what permits to take into consideration in their editing the interests of Ukrainian persons of economy.

The routine of carrying out of these works regulates the State Service of Technical Regulation and Consumer' Policy, which represents the interests of Ukraine in international and regional organizations operating standardization, namely in ISO and IEC in category of their full members since 1993 and the affiliated member of International Organization of Legislative Metrology (since 1997), Committee of European Norms (since 1997) and others. Being participants of ISO, IEC, CEN and CENELEC activities, Ukrainian technical committees of standardization receive annually more of 1100 working documents of these organizations, and taking into consideration the distinguished scientific potential of Ukrainian scientists and their active work in development of international standards, the ISO Managing Bureau deposited Ukraine governing of work of the Secretariat of ISO Technical Committee 218 *"Wood"*.

Ukraine actively collaborates with foreign partners on principles of bilateral and multilateral relations. For the present, there exist more of 50 treaties on cooperation in spheres of standardization, metrology and attestation of conformity signed with almost all CIS member-countries, EU members, Argentina, Brazil, Chile, China, Croatia, Cuba, Egypt,

Israel, Iran, Macedonia, Mongolia, Serbia, Turkey, USA, and Vietnam. Since 01.03.1998, there became valid the *"Treaty on Partnership and Cooperation of Ukraine with the European Union"* which numerous articles presume rapprochement of principles of Ukrainian system of technical regulation with those that use the EU member-countries. The methodological base of such activities established the Decrees of President of Ukraine of 11.06.1998 # 615/98 *"Strategy of Integration of Ukraine in European Union"*, of 14.09.2000 # 1972/2000 *"Program of Integration of Ukraine in European Union"*, and Law of Ukraine of 18.03.2004 *"On the State Program of Adaptation of Legislation of Ukraine to Norms of European Union"*.

The grade of use of international and regional standards in various countries differs. The biggest quantities of their norms use developed countries, which economy is integrated in global business processes the most. In Austria, Belgium, Denmark, France, Netherlands, Sweden, for example, where the part of international trade in general barter reaches 80 %, the national standardization services do not develop standards in existence of the analogous international and regional norms, but harmonize and use them in category of national ones.

Ukraine uses the same principles, and harmonizes preferably the international and regional normative documents but not develops in their presence norms of pure national character. The main principle used in this work is the preferable chose of documents by problems of ***1`)*** harmonization of terms and definitions, ***2)*** introduction of novel methods of analysis and testing, ***3)*** introduction of modern procedures of attestation of items of standardized quality, ***4)*** harmonization of norms, which observance guarantees safety of labor, and ***5)*** introduction of methods of rational use of energy, natural resources and protection of environment.

Taking into consideration the need of speeding up of processes of harmonization of documents of international category, the State Service of Technical Regulation and Consumer Policy of Ukraine joins to the Global information net of ISONET and its 154 technical committees by standardization actively work in the ISO structure. The national standard DSTU 1.7:2001 *"National Standardization. Rules and Methods of*

Validation and Use of International and Regional Documents" normalizes the following methods of harmonization of normative documents of international and regional categories:

1. *method of case (cover),*
2. *method of re-edition,*
3. *method of acknowledgement.*

As provided the *method of case*, the norms of chosen international standard are used in public economy directly without their official translation in Ukrainian, when the original text of the document remains changeless, and is supplemented only with the interlinear translation. The only difference of such standard of its foreign original is adding of national cover.

Method of re-edition includes variants of legalization of the standard by methods of its translation, reprinting or revision. The method of *translation* represents itself presenting of the official text of the harmonized standard in Ukrainian. The variant of *reprinting* presumes the direct reproducing of the original text of related normative document in its official language without any alteration, when the national edition contains also the national cover, title sheet, national preface and official translation of the body text, all in Ukrainian. Method of *revision* consists in publishing of the edited text of the standard in Ukrainian and information on alterations made in its official text.

Method of acknowledgement presumes *(ISO/IEC Guide 21-1:2005 "Regional or national adoption of International Standards and other International Deliverables -- Part 1: Adoption of International Standards")* publishing in specialized editions of the official information on event of harmonization and date of validation of the standard as the national normative document of purely national category.

Depending of grade of conformance of the text of the standard o the document used in its harmonization, there exist the following categories of harmonized standards:

- the standard equivalent with its official version obtains the category of *identical* (labeled *as IDT*) by its technical content, structure and

used terminology, or identical by its technical content but containing the minimal technical alterations,

- the category of *modified* (*MOD*) standards includes the harmonized normative documents, which have the clearly identified and reasoned technical alterations in their text as compared with their versions taken for harmonization but reflect their structure in whole and the existing technical alterations are stated by mode, which permits to find the identity of both type documents despite the existing differences,
- if the text of the standard contains alterations that result in origination of sufficient differences with the norm taken as a model and have alterations not identified clearly as compared with it, the resultant document is not the equivalent with the respective norm and obtains the status of national normative document labeled as the *non-equivalent* (*NEQ*) version.

Test Questions

1. What is the sphere of responsibility of standardization ?
2. Organization having responsibility for organization of works in sphere of standardization
3. What are principles of modern standardization ?
4. What are basic tasks of standardization ?
5. What are methods of standardization ?
6. What is the parametrical standardization ?
7. What is the complex standardization ?
8. What is the advanced standardization ?
9. What are objectives of activities in sphere of standardization ?
10. What are objects of standardization ?
11. What are subjects of standardization in Ukraine ?
12. What are functions of Central body of State regulation in sphere of standardization ?
13. What are functions of technical committees of standardization ?
14. What are concepts of State control and State supervision ?

15. What are basic documents of system of State supervision over observance of requirements of standards, norms and rules ?
16. List the State supervision bodies in Ukraine
17. What are functions of bodies by State supervision ?
18. What is the principal form of State and departmental supervision ?
19. What are procedures of carrying out of actions by State supervision ?
20. List the responsibilities of subjects for infringements of requirements of normative documents
21. What are the principal functions of standardization bodies in Germany ?
22. What are the principal functions of standardization bodies in France ?
23. What are the principal functions of standardization bodies in USA ?
24. What are the principal functions of standardization bodies in Japan ?
25. What are the principal functions of standardization bodies in United Kingdom?
26. What are the principal functions of standardization bodies in Russian Federation ?
27. List the international organizations operating in sphere of standardization
28. What are functions of the International Organization for Standardization ?
29. What are functions of the International Electrotechnical Commission ?
30. What are functions of the International Telecommunication Union ?
31. List the regional organizations operating in sphere of standardization
32. What are functions of the Commission "Codex Alimentarius" ?
33. What are differences in structure of global and Ukrainian standardization systems ?
34. What are Levels of standardization in Ukraine ?
35. What are categories of normative documents legal in Ukraine ?
36. What are spheres of use of normative documents in Ukraine ?

37. What are obligatory and voluntary requirements of Ukrainian national standards?
38. What are the international standards harmonized in Ukraine ?

4 Fundamentals of the National System of Attestation of Conformity

4.1 Essence and Tasks of Works in Attestation of Conformity

The character peculiarity of market economy is absence of deficit of commodities. However, in parallel with the unrestricted growth of their proposal, there increases the probability of marketing of goods of improper quality, what is especially character for States, which are in process of transition from the administrative to market system of management. In absence of "excessive" money, consumers who live in such countries prefer to buy cheaply goods of poor quality, and the manufacturers take no efforts in betterment of quality of consumables he produces. To avoid such tendencies and improve quality and raise safety of commodities present at the market, the State introduces the complex of operations in *attestation of conformity* of goods, services, processes, personnel, quality systems, systems of management of quality and conditions of protection of environment to norms of related decrees, directives, technical regulations, standards and other kind normative and technical documents. As provided the standard ISO/IEC17000:2004 *"Conformity assessment – Vocabulary and general principles"*, this notion is used usually in meaning of *"...demonstration that the requirements relating to the attested product, process, system, person or body are fulfilled"*. The result of this work is typically their certification (witnessing of conformity), which appellation origins of Latin *"certum"* – properly and *"facere"* – made. The complex of works in certification of quality of objects of attestation should be considered as the succession of three consecutive actions: *"selection"*, *"determination"* and *"review and attestation"*.

The *"Function of selection"* foresees planning of works necessary for realization of the following actions on attesting of proper quality of items to be controlled, which may be:

- batches of identical items (packs of foodstuffs, mechanisms, equipment etc.),

- parties of homogenous objects (secondary raw materials, auxiliaries),
- objects, which have the characteristics instable in time (sewage, gas emissions in atmosphere),
- dangerous, complicated and precise objects or items of high cost (weapons, space technique, drugs),
- technical objects or erections and buildings,
- systems of quality management and so on.

The typical actions carried out in realization of this function are:

- choose of program of testing (inspection, evaluation of quality, control of observance of established norms etc.),
- modification of existing and development of new methods of control,
- choose of documents to be used in work in evaluation of quality of objects of attestation,
- choose of existing or development of novel methods of identification of conformity of objects of attestation,
- choose of methods of sampling,
- choose of mode of transporting of samples to be tested to the place of destination located outside,
- choose of mode of preservation of samples-witnesses in undamaged state till the end of work in attestation of quality of the product.

The function of determination presumes collecting of information about the tested object to be used in assessment of its conformity, especially:

- *identifying of competence* of the attesting body carried out usually by specialists of institutions specialized in this work,
- *testing* of taken samples in use of attested methods of analysis (chemical, microbiological, mineralogical, isotopic), measurements (physical and chemical, radiative, angular, electrical), investigation (metallographic, structural, toxicological),

- *control* of compliance of quality indices of tested objects to their normalized values (this type work is used usually in control of quality of solitary and unique objects: planes, bridges, erections),
- *audit*, i.e. the systematical, independent and documented process of collection of information about the attested object and its objective analysis in purposes of identification of grade of observance of established norms in process of regular work of the controlled person,
- *inspection of worksheets* used in process of attestation (e.g. of results of comparative interlaboratory testing, content of projecting documentation and working instructions).

The function of attestation of conformity presumes taking of decision on recognition of compliance of the object of inspection (his actions) to the established norms or refusing in it. The commission of the inspecting person analyzes the collected information to convince in its consistency and adequacy and draws up the respective report. In positive decision, the attesting body issues the document on observance of set norms of attestation by the person of inspection. If the collected information is insufficient for taking of well-grounded decision, the inspecting group has to go back to function of selection and repeat the work in selection and determination again to collect new or refine the existing information. The one more type of operation at this stage is the scheduled inspecting control because parameters of objects of attestation and conditions of work of the attested person may vary as the time goes by.

The one of important mechanisms of State regulation in identifying of conformity of object of control is *"certification"* permitting to make the objective evaluation of quality of its work (compliance of indices of quality of its production), raise its competiveness at the domestic and international markets and give consumers assurance in goodness and safety of certified products (services) for their life and health.

The formulation of notion of certification as the constituent part of work in attestation of conformity gave the ISO structural department CERTICO (the present appellation – CASCO) in the guiding document

of *"General Terms and Definitions in Spheres of Standardization, Certification and Accreditation of Testing Laboratories"* as:

> *Certification is the procedure used by third party in the form of giving of the written guarantee that the attested production, process or service conforms to the established norms*

The Ukrainian legislation formulates this action some differently:

> *Certification is the procedure of documented attestation of conformity to the established norms of indices of quality of production, qualification of personnel, norms of quality systems, quality management systems and environmental management systems, carried out by the body specially appointed on this work*

The work in certification:

- confirms the guaranteed interchangeability of elements of complicated structures,
- assists in reaching of uniformity of normalized indices of similar products produced in different places,
- assists in exchange by scientific and technical information among the interested parties,
- assists in progress of trade,
- speeds the scientific and technical progress worldwide.

The methods of certification used the most often are the *professional certification* representing itself the process of confirming of proper competence of individuals in execution of their functions, as well as attesting of quality of production on compliance of indices of its quality to norms of normative documents used in attestation.

The work in certification includes carrying out of two consecutive procedures: the first one is the control of correctness of information applied by declarant on the product to be certified. The second stage is certification proper and issuing of the certificate of conformity and the license on right of giving of this information in the passport of the product, on its label etc. This work includes carrying out of the following operations:

- sampling of products to be tested and their testing,
- studying of results of testing,

- documented witnessing of compliance of the controlled indices of the object to the established norms executed by the authorized party specialized in this work.

The work in attestation of conformity includes the activities of parties of three types identified by the international standard ISO/IEC 17000 as follows:

- *first-party* means the person or organization, which produces the object of attestation or puts it on the market,
- *second-party* means the person or organization interested in use of object of attestation (its consumption),
- *third-party* means the person or organization, which has no financial, organizational and other type interests in activities of parties that produce and/or are interested in use of object of attestation.

The persons, which represent interests of the *first party* are manufacturers; sellers of production; owners of object of attestation; employers (in relation to conditions of labor); State or municipal administrative bodies (in giving of objects of attestation, such as enterprises, constructions, water resources in lease or use); State enterprises, which give the medical, inspection and other kind services, and so on. The competence of the first-party persons in their work attest and accredit the third-party bodies, which operate in spheres of their responsibility. The parties they certified (accredited) obtain the license on issuing of *"declarations of conformity"* and/or marking by the sign of conformity of products of attested quality they propose.

Declaration of conformity means the document of established form issued by the manufacturer (supplier) in witnessing of conformity of indices of quality of his production to provisions of normative documents it declares and full liability for correctness of information given in this document

Sign of conformity means the sign of established form put on objects of attestation in witnessing of conformity of their quality indices to their normalized values

Production means any product (good) of domestic or foreign origin, semi-manufactured item and raw material used in processes of its fabrication, reprocessing, storage, transporting, realization and packing

The fact of issuing of declaration of conformity does not signifies that the declarant certified the product (process, service) named in this document but points that he informs on its proper quality and has the right to do this job.

The *second party* persons are buyers of raw and other type materials, componentry and finished production; consumers and their associations; State bodies (in segment of protection of interests of consumers) etc.

The *third party* persons are the authorized bodies specialized in work in attestation of conformity. The results of their activities witness *"certificates of conformity"* they issue.

Certificate of conformity means the document issued in observance of normalized procedures of certification, which witnesses the overall compliance of certified indices of quality of the attested object to their normalized values

The fact of certification reaches the especial significance in view of global tendency of toughening of legal norms of safety of production, norms of healthy life of men and quality of surrounding nature. Taking these factors into consideration, the Organization of United Nations approved the document of *"Collection of General UN Guiding Principles by Protection of Interests of Consumers"*, which recommends national governments to develop legal systems of safety of consumables in their use by destination and introduce their basic provisions in national norms or to use the procedures proposed by the set of said documents. The crucial requirement of ensuring of safety of products and protection of interests of consumers force the State regulatory bodies to introduce in national legal practice the norm of responsibility of supplier, manufacturer, distributor, seller for marketing of dangerous and poor quality production, namely the norms of the Law of 01.12.2005 # 3161-IV *"On Protection of Interests of Consumers*, which established the norms of interrelations of consumers of

consumables (except of foodstuffs), works and services with their producers and sellers, executors of works and servicing persons. The products, which may be identified as the dangerous ones by criteria of this Law are:

- products not conforming to requirements of normative and legal documents in force,
- products not conforming to established norms of their safety for life, health, property of men and conditions of environment,
- products, which some properties and/or appearance were knowingly modified by manufacturer (seller) to give them the outward similarity with products of famous manufacturers but cannot be identified as such,
- products, which marking differs of legal norms in used language of marking and/or content and completeness of information given in their labels and marks,
- products with expired terms of realization or use,
- products, which have no documented confirmation of their proper quality and safety.

The tendencies of development of norms of certification have the strategic purpose of global recognition of goodness of products of attested products, which quality was certified by mutually recognized mechanisms of its identification. Attesting (declaring) of conformity of production to norms recognized worldwide becomes more and more urgent because the whole practice of international trade witnesses that the non-certified products may be sold in global markets only on condition of their sufficiently smaller price as compared with the certified analogues. The international guiding documents, which detail procedures of assessment and attestation of conformity to be used worldwide, are:

- ISO/IEC Guide 7:1994 "Guidelines for drafting of standards suitable for use for conformity assessment",
- ISO/IEC Guide 23:1982 "Methods of indicating conformity with standards for third-party certification systems",

- ISO/IEC Guide 27:1983 "Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity",
- ISO/IEC Guide 28:2004 "Conformity assessment – Guidance on a third-party certification system for products – Guidelines",
- ISO/IEC Guide 43-1:1997 "Proficiency testing by interlaboratory comparisons – Guidelines, Part 1: Development and operation of proficiency testing scheme",
- ISO/IEC Guide 43-2:1997 "Proficiency testing by interlaboratory comparisons – Guidelines, Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies",
- ISO/IEC Guide 53:2005 "Conformity assessment -- Guidance on the use of an organization's quality management system in product certification",
- ISO/IEC Guide 60:2004 "Conformity assessment -- Code of good practice",
- ISO/IEC Guide 65:2012 "General requirements for bodies operating product certification systems",
- ISO/IEC Guide 67:2013 "Conformity assessment -- Fundamentals of product certification",
- ISO/IEC Guide 68:2004 "Arrangements for the recognition and acceptance of conformity assessment results".

Meantime, the persons of authorization certify the more often not quality of products they fabricate, but systems of their operation by norms of so-called quality standards (see Chapter 6.6), because all totality of goods they produced may be sold in this case without certification. The condition of certification of quality systems both in EU countries and Ukraine gives producers the right on declaring of quality of the whole set of products of own manufacture and permits them to mark the goods of attested quality by the sign of conformity. The stages of work to be carried out in it are:

- attestation of manufacture,

- continuous control of quality of finished production, manufacturing processes, given services and other normalized procedures of operation of the certified person,
- existence in structure of the enterprise of accredited testing divisions or regular use of services of contractors accredited on analysis of items to be supplemented by their owner by the declaration of conformity.

4.2 Principles of Assessment and Audit of Conformity

The primary sense of work in assessment of conformity of production (services) is giving the interested parties of corroboration of observance of their normalized parameters of quality. The principal factors to be observed in this work are:

- *Observance of principle of "One – One – One" (one standard – one testing – one sign of conformity)*, what may be kept the best in use of norms of international standards of operation in work of the person of control. Observance of such norms permits to do this work once, and its results will be recognized everywhere.
- *Safety*. The fact of execution of work in attestation of conformity guarantees safety of tested products in their use by destination, as well as confidence of interested parties that it would not inflict any harm and/or damage for interests of their users (consumers). Therefore, it is preferable to use services of third party, but not declare the proper quality of products themselves, for this produces the univocal confidence in independent and unprejudiced confirmation of observance of set norms in their manufacturing. It is also the paramount interest of manufacturers and sellers of goods of certified quality in preservation of their reputation, as well as interest of insurance companies in avoiding of unnecessary expenses in compensation of losses, which may arise in cases of use of non-certified products of poor quality.
- *Observance of norms of exploitation of the attested production* guarantees its fitness for use by destination. In this case, the term of *"quality of operation"* relates also to their effectiveness in use,

productivity of operation and maximum fullness of use of resources (materials, energy etc.) in minimization of their negative influence on state of environment.

- *Effectiveness in use of certified goods in complex with other items*. The fact of attestation of conformity of goods guarantees that they would operate (be properly adjusted etc.) in coupling with the other ones correspondingly to their normalized technical characteristics.
- *Demand of markets / Interests of community*. The procedures of work in attestation of conformity have to be regulated in observance of current needs of the community, but not of parties, which have the commercial interests in their marketing.
- *Operation in conditions of free market*. The activities in attestation of conformity have to be based on use of principle of competition of persons authorized on this job. The exclusions are cases of introduction by governments of special measures of regulation to be executed by persons specially appointed on this job.
- *Use of standards*. The work in attestation of conformity has to be done by the non-discriminative mode and in observance of standardized procedures of operation.
- *Traceability*. If results of work in assessment of conformity may depend of mode of control, the party accredited on carrying out of this work has to do it in observance of norms of the State standards as documents of the upper regulative category.
- *Innovations and trade*. The chosen schemes of attestation of conformity must not put obstacles in trade and assist in introduction of innovations.
- *Minimal harm for business activities*. One has to choose in process of assessment of conformity the procedures, which are the minimally burdensome for businesspersons interested in attestation of quality of their products.

The principles, which use would assist in realization of listed factors, establish the norms of standard ISO/IEC 17000:2004 as follows:

1. *Functional approach*. Each group of consumers (users) has its own specific needs. Therefore there exist various modes of attestation of

conformity. This work has to be done by the attested methods of control (analysis), as a rule, and carried out in observance of specific features of object of control and character of its quality indices. The inspecting body has to use in it the methods of control the most fitted to conditions of carrying out of such works and prove goodness of the inspected products in issuing of certificate of their conformity.

2. *Selection*. The object of control may consist of big quantity of identical items (i.e. the batch of production) produced serially. Therefore, the successful realization of this function presumes taking of representative samples of objects to be controlled on the next step of *identification* and if the object of control is the individual article, the samples have to be taken from its representative parts.

3. *Identification*. The principal purpose of stage work is collection of information on grade of observance of the established norms of quality of object of attestation. The necessary actions to be done in this stage include operations of expert estimation, control etc. Moreover, one has to take into consideration that choose of the most appropriate method of testing (measurements) depends sometimes of terms of carrying out of this work.

4. *Final control of conformity*. The finishing stage of work in attestation of conformity is control of observance of the normalized requirements to the object of attestation. In positive results, the authorized third party issues the *"Certificate of conformity"* drawn up in the form understandable for potential users and containing the generalized information on important norms of quality of proposed goods (services) and the license on right of declaring by manufacturer of proper quality of items of the same destination during the term of validity of this document. It's necessary to note, that the body, which accomplishes the work in certification, witnesses *the proper skill of applicant in producing of products* tested in process of control but not quality of the proposed items proper.

5. *Inspecting control*. The certifying persons carry out during the term of validity of the license named above the periodical control of stability of observance of the attested parameters of quality of serial production in produced directly on site. The controlling person may cut some of stages

of inspection, and carry out this work by the program shortened as compared with this one that was used at stage of attestation. The variants of choose of segment of control may differ as well: it may be the certain group of normalized indices each time differing of their set controlled previously. Such type systemized control known in the modern world as *audit* (origins of Latin *audit* – to hear) or the *auditing control* is in fact the process of periodical verification of conformity to the certified norms of procedures of operation of the attested person.

> *Audit means the systematical, independent and documented process of collecting and objective evaluation of information about the object of inspection carried out in purposes of control of correctness of data on the object of control declared by its owner*

The need in carrying out of audits arose in ancient China nearly 700 B.C. and was closely associated with evolution of interrelations in barter. This kind works were subdivided finally in two big groups comprising most types of business activities carried out in financial and industrial (technical) spheres. There exist also the operational, environmental audits, audit of quality systems and so on. The types of this work done in Ukraine the most often, are the auditing control of observance of norms of bookkeeping, as well as procedures of management of projects, quality management, managing by works on use of natural resources, saving of energy.

The *technical audit* by its entity is the process of control of process of manufacturing, observance of scheduled terms of verification of technical conditions of machines and equipment, inspection of technical state of constructions and buildings, control of observance of norms of operation of information systems and nets, control of correctness of technical and projecting documentation and so on. The activity closely associated with this type works is *inspecting* audit carried out in way of comparing of real values of indices of quality of certain products with their normalized values. In revealing of any deviation, it is necessary to identify causes of its origination, carry out the required correction and control compliance of real indices of quality of production after the

recommended actions would be carried out. The typical procedures used in control of observance by businesspersons of established norms of operation are identifying of correctness of carrying out of prescribed sequence of operation. The variants of technical audit are the *environmental audit* (determination of grade of burdening of the environment in result of activities of the audited person of economy) and *energy audit*.

Dependently of persons, which execute these works, there are known such subkinds of audit known as the internal and external ones. The *internal* audit is the work, which the businesspersons accomplish by own initiative themselves or in service of the off-site organization that operate by their orders. The results they obtain permit the organization be sure whether it operates correctly and carry out the necessary actions by elimination of found drawbacks and unconformities. The typical reasons of its carrying out are:

- need in revealing of causes of origination of defects of production,
- change of organizational structure,
- preparation to certification of quality system.

The *external* audit executed by second or third parties has the main purpose of identification of effectiveness of work of the inspected persons and appropriateness of procedures used in it. The second-party audits carry out typically the parties interested in detailing of certain aspects of operation of persons of control, e.g. associations of customers or persons of economy operating by their orders. The third-party audit execute the organizations specialized in certification of conformity, as well as the qualified persons (auditors), who have licenses on carrying out of this type work individually.

The initial step of auditing is appointing of the chairperson of the inspecting commission and engagement of its stuff persons. The next one is meeting of the commission with the administration of object of control and agreeing of sphere of audit, procedures of work and necessary administrative and organizational measures. The chief auditor draws up the plan of work, which lists the problems to control as follows:

- purposes of audit and principal works to be done in it,

- identification of documents to be inspected,
- identification of language to be used in process of audit (if necessary),
- identification of auditors and list of persons of the inspected enterprise responsible for carrying out of planned works,
- list of departments of enterprise to be controlled,
- terms of beginning and execution of each stage of audit,
- planned terms of meetings of auditors with administration of the enterprise in process of audit and reporting on its results,
- norms of confidentiality.

The principal reasons of carrying out of audit are:

- assessment of compliance of norms of operation of the audited businessperson to norms of standards used in its operation,
- need in evaluation of competence of potential business partners,
- expiring of the scheduled term of attestation.

Its initiators are typically:

- consumers, who want to verify actuality of the system of assurance of quality introduced by their supplier,
- organizations, which desire to examine operation of their own systems of operation on conformity to norms of quality standards,
- authorized auditing organizations, which have to put information about the audited enterprise in official registers.

The audit is named as the *combined* one in cases of accomplishing of control activities by persons of the second and third parties jointly, and if the audit is accomplished by two or more off-site organizations jointly, this is the *mutual* type of audit.

The typical cases of origination of need in extraordinary auditing are the substantial amendments of systems of management and organizational structure of the enterprise, as well as necessity in control of execution by the audited person of recommendations by elimination of unconformities found in earlier time.

The forms of industrial audits carried out the most often are audits of system of management, quality of processes, and quality of production.

- *audit of system of management* has the purpose of confirmation of compliance to the approved norms of procedures of operation of the enterprise or its individual department(s),
- *audit of quality of processes* consists in attesting of compliance to established norms of processes of operation realized at the enterprise,
- *audit of quality of production* has to identify the conformity of factual indices of quality of produced goods to their normalized characters. This type audit has typically the form of repeated testing of products, which are stored by the enterprise before shipping.

The materials of audit drawn up by results of inspection must describe the procedures of activities of the applicant to be regarded as unconformities to norms of documents used in its operation. To avoid the disputable situations, the auditing commission has to document the consent of representative person(s) of inspected object on objectivity of results of control stated in the final report. The finishing stage of audit is its presenting the responsible persons of the audited object. The basic points of this document would be:

- name of the report, its number and identification,
- list of auditors,
- subsidiary information, e.g. purposes of audit, its scope and terms of execution,
- detailed plan of work done in process of inspection,
- list of documents used in audit,
- brief description of activities of controlled departments,
- information on results of evaluation of adequacy of activities of the audited person to the established norms,
- conclusions, especially the list of found unconformities and recommended corrective actions.

In case of external audit, the group of audit assigns also the list of addressees of sending of copies of the final report agreed with the administration of the controlled party.

4.3 Origination and Development of System of Certification

The roots of modern certification are traced since the early stages of evolution of society. Initially, it was the manufacturer, who was the person interested in confirmation of proper quality of his goods the most. The evidences of carrying out of such works are marks, which witness the high quality of work of artisans put on goods found in excavation of antique settlements. The Ancient Greece organized for this purpose even the specialized body of metrological control: the *"collegium of agoronomes"*, which members inspected observance of conditions of conscientiousness in trade using in it the measuring vessels and bronze weights stamped with the city emblems.

The modern stage of work in certification in Europe began conditionally in 1700-s, but the first known document witnessed the proper quality of controlled production was issued by the specialized German authority in the end of XIXth century only. Now certification is the norm in trade relations. In most cases, such functions execute the authorized national institutions specialized in standardization. Somewhere these ones are the responsible State authorities (Japan), but in most countries governmental structures influence on work in certification indirectly establishing for this purpose the basic norms of attestation of quality of objects of certification and appointing the authorized governmental representatives in organizations authorized on work in this sphere (e.g. France) or contracting with the independent organizations operating certification (Germany).

Existence of big variety of national systems of certification resulted in use of differing methods and norms of attestation of quality of the same production. Therefore, in many cases the items certified in country of origin has to be certified repeatedly in country of destination, what is one of sources of origination of technical barriers in trade that impede in creation of the unified global economical space.

To eliminate such problems, ISO founded in 1970-s the committee specialized in development of norms of mutual recognition of principles of national systems of certification and signs of conformity used in it (CERTICO). The following evolution of norms of attestation of

conformity lead to its reorganization in 1985 in the specialized ISO Committee by Assessment and Attestation of Conformity (CASCO), which developed the complex of documents of "*Code of ISO/IEC Norms of Certification by Third Party*".

Using its recommendations, the EU Council approved 21th of December 1989 the *"Global Concept of Certification and Investigations"* realizing so the norms of business operation in the unified European Economical Area (EEA), which main ideas are:

- harmonization of infrastructure of bodies operating testing and certification in EU countries,
- use of European standards of EN 45000 series, which establish the uniform procedures of work of certification bodies.
- use in work in attestation of conformity of regional standards of quality of EN 29000 (i.e. international standards of ISO 9000 series harmonized in observance of specificity of European economies),
- concluding of bilateral and multilateral treaties with third (non-EU) countries on mutual recognition of results of testing of items to be certified and preferable use in this work of services of testing, measuring and calibration laboratories accredited by norms of standard ISO 17025,

To be recognized at international and regional levels, the national systems of certification of EU member-countries were reorganized in observance of modern trends of progress of global economy and are based now mainly on use of norms developed by the specialized international and European organizations listed in Table 4.1:

Table 4.1

International certification organizations

Full name of the organization	**Adopted acronym**	**Spheres of activity**
1	**2**	**3**
International Laboratory Accreditation Collaboration	ILAC	Norms of accreditation of laboratories

International Committee by Certification of Electric Equipment	CEE	Systems and criteria of attestation of quality of electric equipment
International Organization for Standardization	ISO	Standards and procedures of certification of conditions of operation of persons of economy, personnel, quality systems, goods and services
International Electrotechnical Commission	IEC	Standards and procedures of certification of conditions of operation of persons operating electrical engineering problems and goods and services they propose
UN Economical Commission for Europe	UNESE	Attestation of quality systems, norms of safety of equipment and methods of its testing and inspection
European Organization by Investigations	EUROLAB	Operation of testing laboratories
European Organization by Cooperation in Analytical Chemistry	EUROCHEM	Operation of analytical laboratories
European Committee by Introduction and Certification of Systems of Quality Management	EQS	Development of norms and certification of quality systems valid in Europe
European Committee by Investigations and Certification of Information Technologies	ECITS	Information activities
European Committee by Fire Safety	ESIF	Measures of fire safety
European Organization by Testing and Certification	EOTC	Union of ECITS, ELSECOM and ESCIF founded in purposes of harmonization of methodology of certification in Europe
European Cooperation in Accreditation of Testing Laboratories and Certification Bodies	EA	Norms of confidence to results of works by testing and certification in Europe

The modern methods of certification to be introduced worldwide highlights the Resolution of UN General Assembly # 39/248 on general principles of protection of interests of consumers. Its basic principles are uniformity of procedures of protection of rights and interests of consumers, as well as assurance of safety of consumables (services) they use. The principal conditions of work in certification detail the normative and regulatory documents developed by the European organizations for standardization, especially the following European standards:

- EN 45001 "General criteria for the operation of testing laboratories",
- EN 45002 "General criteria for the assessment of testing laboratories",
- EN 45003 "Calibration and testing laboratory accreditation systems. General requirements for operation and recognition",
- EN 45011 "General requirements for bodies operating product certificate systems",
- EN 45012 "General requirements for bodies operating assessment and certification/registration of quality systems",
- EN 45013 "General criteria for certification bodies operating certification of personnel",
- EN 45014 "General criteria for supplier's declaration of conformity".

The certifying bodies have to realize their norms in observance of criteria of operation as follows:

a. objectivity,
b. amenability for correctness and transparency of decisions taken in attestation of persons of certification,
c. maintaining of actuality, prolonging, postponing and nullifying of licenses on right of issuing of declarations of conformity by the applicant,
d. appointing of supervisor (commission, group of natural persons, individuals) responsible for control of observance of:
    - the attested norms of operation,

- established procedures of carrying out of works in testing, control, assessment of conformity and certification of objects of control,
- norms of taking of decisions on certification or refusing in it,
- observance of financial discipline,
- correctness of taken decisions on delegation of authorities on carrying out of works in assessment of conformity to committees or individuals.

e. existence of documentation identifying the juridical status of the certifying body and guaranteeing impartiality in its work,
f. existence of certified quality system, which guarantees the capability of the enterprise to carry out work in certification in sphere of its authorization,
g. existence of documented policy and procedures, which permit to differentiate the work in certification of any other kind of activity,
h. independence of staff of the enterprise of persons, which apply for certification,
i. possession by the technical means, materials and resources necessary for work in certification,
j. completeness of staff, which has the sufficient level of education, technical knowledge and skill in carrying out of work in certification,
k. absence of commercial, financial and any other kind pressure upon the administration and staff of enterprise, which may influence on results of its profile activities,
l. existence of official regulations and structure of appointing and functioning of commissions operating certification,
m. guaranteeing of confidentiality, objectivity and correctness of work in certification, avoiding of events of:
    - projecting and supply of production certified themselves,
    - giving applicants of advices on ways of overcoming of barriers in certification of production they declare,

- giving of any services, which may influence of confidentiality, objectivity and correctness of carrying out of work in certification,

n. existence of established procedures of considering of pretensions, appeals and vexed questions arising in process of certification.

The principal objectives of certification are (Figure 4.1):

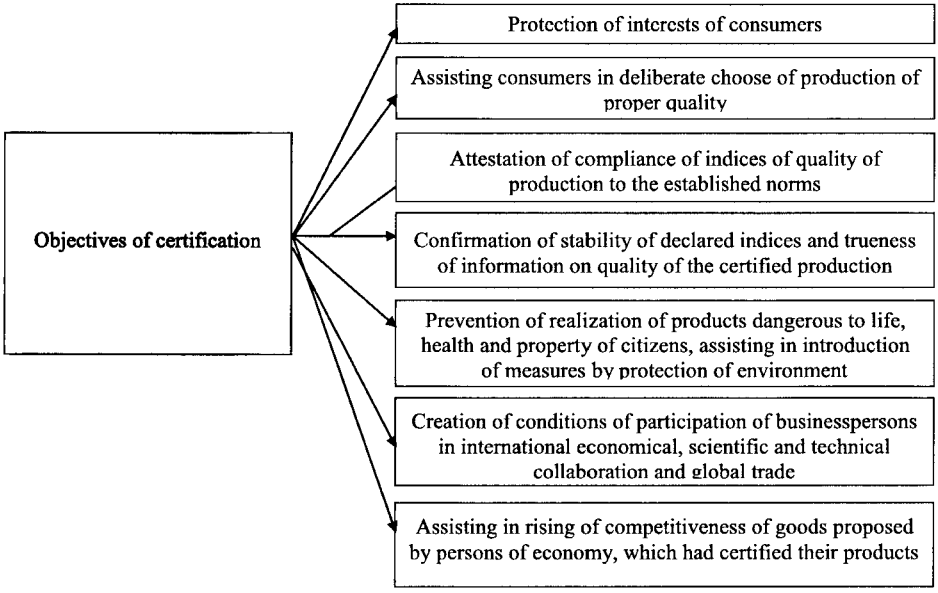


Fig. 4.1 Principal objectives of certification

The basic principles of certification in Ukraine are:

1. *Observance of legal norms*. Certification activities in Ukraine are carried out in observance of provisions of Law of Ukraine 17.05.2001 # 2406-III *"On Assessment of Conformity"*, Law of 15.01.2015 # 124-VIII *"On Technical Regulations and Assessment of Conformity"* and Law of 01.12.2005 # 3161 – IV *"On Protection of Interests of Consumers"*.
2. *Objectivity, authenticity and independence of information* of manufacturer, supplier and seller on quality of the certified production they propose.

3. *Openness of information on results of certification*. Certification may be accomplished by any specialized organization of any form of property authorized on this job. The only condition is its independence of producer (owner, supplier) of production to be certified and other persons interested in its realization.
4. *Harmonization of procedures of certification with the international norms* The work in certification has to be accomplished preferably by the international procedures. If this process is of special character, its procedures have to be developed in observance of norms of international standards of ISO 9000, 10000, 14000, 17000, 22000 and 26000 series, European standards of EN 29000 and 45000 series, ISO and IEC guides, as well as the organizational and regulatory documents of international organizations operating certification.
5. *Confidentiality of information obtained in attestation* if it may be the source of commercial secret.
6. *Right of applicant on free choose of the attesting body*.
7. *Excluding of discrimination of foreign applicants*.

4.4 Certification of Goods in the European Market

After Ukraine joined WTO, she opened her inner market for access of goods of foreign fabrication. Meantime, the sufficient quantity of imported products to be certified in Ukraine obligatorily was not attested in exporting countries. Therefore, the specialized Ukrainian legal persons have to be ready to identify the need of their certification in Ukraine or recognize validity of declarations of conformity of such production produced in country of origin in observance of norms of international (regional) standards harmonized in Ukraine. Associating with the European Union, Ukraine has to harmonize her national norms of attestation with the European ones and introduce the principles of so-called *"New approach"* normalized in Europe by Resolution of EU Council of 07.05.1985 # 85/C 136/01 *"On a new approach to technical harmonization and standards"*, especially the following ones:

- the EU members have to observe norms of technical regulations developed after approval of said Resolution. At the same time, the norms of analogous destination developed in earlier time lose their validity,
- the EU members have to introduce the practice of mutual recognition of results of testing and harmonize the regional rules of operation of certifying bodies,
- the EU members have to introduce the norm of observance of technical characteristics and norms of quality of finished production, but not technologies of its fabrication,
- the EU members have to intensify the tendency of passing of activities in standardization on the European level.

Except of norms of "New approach" related mainly to activities in standardization, this Directive established also the norms of so-called *"Global approach"* used in attestation of conformity of items produced outside the EU and EEA borders, what has to simplify the process of recognition of results obtained by the competent and properly equipped body of any foreign country open to collaboration with the specialized certification services of EU member-countries. The so-called *basic* (essential) norms to be taken as a proof of compliance of quality of goods to norms of directives of New Approach are:

- mechanical resistance and stability,
- safety in use,
- good hygienic conditions and absence of harmful influence on health of men and conditions of nature,
- safety in fire,
- protection against electromagnetic noises,
- energy efficiency and heat retention.

The newly introduced norms of *"New Approach"* established also the following four fundamental principles:

- harmonization is limited by the set of basic norms of safety (or other aspects of general interest) of production passed on sale in the unified EU market,

- the norms of standards lose their obligatory character becoming so voluntary for observance,
- the right of development of technical specifications of quality of products is entrusted to persons competent in this work only,
- the administrative bodies have to recognize that quality of products produced in observance of norms of harmonized international (regional) standards complies to basic norms established by the Directive of 22.06.1994 # 98/34 EU hence needs not attestation. At the same time, if the product was produced in observance of norms of national standards, its manufacturer has to certify its compliance to essential norms.

The fact of compliance of characteristics of the product to the essential norms leads to automatic recognition of its proper quality. At that, the notified EU certifying bodies are accountable only for authenticity and correctness of legalization of declarations of manufacturers on proper quality of their production, and the real conformance of their quality to the established norms may be confirmed only in case of its certification by third party. The exclusions from this rule are limitations assigned by the European Economical Community as the priority problems of public interest (assurance of public security, protection of health etc.). The specific feature of the new principle of New Approach is that there is established the norm of assessment of conformity referenced to the attributed European norms. Therefore, use in process of business operation of provisions of European standards, which are formally voluntary, becomes the obligatory in case of their citing in certain EU directive as the document, which provisions, hence the norms of referenced documents, are of absolutely obligatory for observance. Most of directives contain more than one method of assessment of conformity of items of regulation, what permits businesspersons to choose the most appropriate one, and the detailed procedures of assessment and attestation of conformity used in it and recognized internationally establish the norms of standards as follows:

- ISO/IEC 17000:2004 "Conformity assessment -- Vocabulary and general principles",

- ISO/PAS 17001:2005 "Conformity assessment – Impartiality – Principles and requirements",
- ISO/PAS 17002:2004 "Conformity assessment – Confidentiality – Principles and requirements",
- ISO/PAS 17003:2004 "Conformity assessment – Complaints and requirements and appeals – Principles and requirements",
- ISO/PAS 17004:2005 "Conformity assessment – Disclosure of information – Principles and requirements",
- ISO/IEC 17011:2004 "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies",
- ISO/IEC 17020:2012 "General criteria for the operation of various types bodies performing inspection",
- ISO/IEC 17021:2011 "Conformity assessment. Requirements for bodies providing works on audit and certification of management systems",
- ISO/IEC TS 17021-2:2012 "Conformity assessment. Requirements for bodies providing works on audit and certification of management systems – Part 2: Competence requirements for auditing and certification of environmental management systems",
- ISO/IEC TS 17021-3:2013 "Conformity assessment. Requirements for bodies providing works on audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems",
- ISO/IEC 17024:2012 "Conformity assessment – General requirements for bodies operating certification of persons",
- ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories",
- ISO/IEC 17030:2003 "Conformity assessment. General requirements for third party marks of conformity",

- ISO/IEC 17040:2005 "Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies",
- ISO/IEC 17050-1:2004 "Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements",
- ISO/IEC 17050-2:2004 "Conformity assessment. Supplier's declaration of conformity – Part 2: Supporting documentation".

The key factor in marketing of production is the full responsibility of its producer (seller, owner) for goodness of its declared parameters of quality production and safety. Therefore, the State attesting bodies interfere in their activities and certify the products of serial manufacture in cases of absolute necessity only. To regulate conditions of sale of goods in EU member-countries, the Europarliament issued the Resolution of 9th of July 2008 # 768/2008, which specify that their proper quality have to be notarized by documents as follows:

- certificates the third party issues by results of testing of marketed items and/or signs of conformity placed directly on the certified goods,
- declarations of conformity issued by the manufacturer, which trueness control periodically the specialized controlling and supervising bodies,
- other modes of attestation established by EU directives.

The EU Council founded also the fund of *"Certificate"*, which contains information on all European certifying bodies and testing laboratories that operate in observance of norms as follows:

- mutual recognition of equivalence of national systems of attestation of conformity
- obligatory accreditation of conformity assessment bodies, mutual recognition of certificates of conformity they issue and signs of conformity used by their licenses,
- right of the authorized inspecting bodies of EU and EEA member-countries on participation in work in control of quality of certified products in other members of said unions.

The manufacturers or their authorized representatives must witness the fact of observance of basic norms in producing of goods they fabricated in use of European sign of conformity (Figure 4.2), if the EU technical legislation did not assigned otherwise.

Fig. 4.2 European sign of conformity

The goods, which fall under the effect of this rule, are:

- children's toys (directive 2009/48/EU),
- production and materials used in construction (regulation 305/2011/ EU),
- devises of protection of individuals (directive 89/686/ EU),
- non-automatic instruments for weighing (directive 2009/23/ EU),
- new hot-water boilers, which operated on liquid or gaseous fuel (directive 92/42/ EEC),
- medical equipment (directive 2007/47/ EU),
- instruments and protective systems used in dangerously explosive premises (directive 94/9/EEC),
- systems and installations (equipment), which operate under pressure (directive 97/23/EEC),
- means of radio communication and telecommunication (directive 1999/5/ EU),
- measuring instruments (directive 2004/22/ EU),
- means of assuring of electromagnetic compatibility (directive 2004/108/ EU),
- machines and equipment (directive 2006/42/ EU),
- low-voltage systems, means of ensuring of electrosecurity (directive 2006/96/ EU),
- vessels operating under pressure (directive 2009/105/ EU),
- equipment used in burning of gaseous fuel (directive 2009/142/ EU),
- explosives used in civil applications (directive 93/15/EEC),

- cable installations used in transporting of men (directive 2000/9/ EU),
- elevators and lifting mechanisms (directive 95/16\ EU),
- active medical devices used for implantation (directive 90/385/EEC),
- medical means of laboratory diagnostics in-vitro (directive 98/79/ EU),
- sailing vessels (directive 94/25/ EU).

The shortening of **CE** origins of French *"Conformite Europeen"*, and the norms of its use approved the EU Council by its Directive # 93/68/EEC. The permission on its use issue the authorized national certification bodies on condition that the person, which pretend on the right of marking 1) is the citizen of one of EU countries, 2) is the permanent resident of European country, or 3) uses services of agent/representative citizen of one of EU countries who is ready to take legal responsibility for the conformity of product in question. The items marked by this sign may circulate freely in territories of countries that constitute the European Economical Area, and the only exclusion, which may impede in their free sale in any EU country, is absence of manual written in her national language. If possible, the **CE** marking must be put on the item proper. The person who has the right of marking may freely choose the color and method of placing of this sign (labeling, engraving etc.). However, this one must have the height not less of 5 millimeters and be legible, seen well and does not rubbed. The sign may be imprinted also on packing, in manuals, application instructions and/or warranty papers. At the same time, the products may be marked with any other sign more on condition that its placing would not worsen visibility and intelligibility of sign **CE** and does not distort the sense of marking of the item by the European sign of conformity.

Following the norms of Global Approach, the work in attestation of conformity has to be executed by procedures normalized by the module scheme (Table 4.2).

Table 4.2

Schemes of attestation of conformity used in EU countries

<table>
<tr><th>Stage of projecting</th><th>Stages of manufacturing</th></tr>
<tr><td colspan="2">Module A
Control of process of business operation by the manufacturer themselves</td></tr>
<tr><td rowspan="4">Module B
Testing of pilot samples of production by the authorized third party</td><td>Module C
Independent control of coincidence of quality indices of goods produced serially with those ones of the attested sample</td></tr>
<tr><td>Module D
Control of validity of quality system used by the businessperson by third party</td></tr>
<tr><td>Module E
Independent control of steadiness of observance of provisions of the used quality system</td></tr>
<tr><td>Module F
Control of validity of the certified quality system by the authorized third party and its participation in work in control of quality of production produced by the attested person</td></tr>
<tr><td colspan="2">Module G
One-by one testing of items by the authorized third party</td></tr>
<tr><td colspan="2">Module H
Independent control of validity of systems of quality used in process of operation of the enterprise</td></tr>
</table>

The works to be attested by procedures of any of listed modules may be carried out independently, what permits businesspersons to combine the methods listed above and choose the most appropriate their combination. Said norms of attestation are not introduced in Ukraine yet. However, domestic manufacturers have to know the principal norms of attestation of conformity used in Europe and introduce the analogous practice in origination of such need, what is especially necessary in view of association of Ukraine with the EU community.

4.4.1 *Modules used at stages of projecting, adjustment of technologies and manufacturing*

Module "A". "Control of Process of Business Operation by the Manufacturer Themselves". The manufacturer declares conformity of quality of each batch of finished production and marks each its unit by the sign of conformity and applies to the authorized body the related information, which has be stored during ten years after producing of the last item of attested quality.

Module "Aa" (modified module "A"). The manufacturer carries out the same actions as above. The person, which had certified his activities, reserves, in turn, the right to demand of him of execution of the following additional works:

a) repeated testing of one or more indices of quality of the certified product to be done under the control of the person authorized on this job,
b) periodical control of observance of certified norms of quality of products of serial production chosen by the authorized body.

Module B "Testing of Pilot Samples of Production by the Authorized Third Party". The declarant applies to the authorized body he chooses themselves the items as follows: a) representative samples of articles to be certified, b) full description thereof, c) concept of project, necessary drawings, and designs of components to be tested, d) list of normative documents to be used in their serial production, e) results of calculations and expertise of quality, f) protocols of testing of items fabricated at previous stages of development of technology of producing of items to be tested sufficient for attestation of their quality. In positive results of examining of received information and testing of given samples, the authorized attesting body issues the certificate of conformity of the controlled batch of production and informs on it all persons of EU countries specialized in certification. In case of modification of the attested product in future, the same body has to carry out their repeated attestation.

Module "G" "One-by-one Testing of Items by the Authorized Third Party". This module is used in control of quality of each article

produced in small series (as well as the individual items). The certifying body chosen by the manufacturer:

a) attests each item on conformity of its quality indices to their normalized values,
b) issues in positive results the certificate of their conformity and gives the license on use of his registered number and/or registered symbol in marking of items together with the sign of conformity.

Module "H" "Independent Control of Validity of System of Quality Used in Process of Operation of the Enterprise". The manufacturer introduces and certifies the system of quality management and officially informs the interested EU parties on conformity of conditions of his operation to established norms. The normalized procedures of supervision on its work carried out by the specialized third parties include sampling of produced products and control of observance of certified parameters of their quality in process of their producing. Each item of finished production has to be marked by the sign of conformity and identification number of the person responsible for the third-party control.

4.4.2 Modules used at stage of serial manufacturing

Module "C" "Control by the Manufacturer of Compliance of Quality of Goods Produced Serially to those ones of the Attested Sample". The manufacturer declares the compliance of indices of quality of items of each butch of his production to their normalized values, marks them by the sign of conformity or uses in this purpose services of the person he authorized on this job. If necessary, the license agreement fixes in it one of the following criterions:

a) the manufacturer or his authorized representative carries out by demand of the license holder the repeated test(s) of one or few indices of the product of certified quality,
b) the authorized body chosen by the manufacturer inspects periodically the compliance of indices of quality of finished production to their certified values.

Module "D" "Control by Third Party of Validity of the Quality System to be attested by norms of standards of EN 29000 series.

Module "E" "Independent Control of Steadiness of Observance of Provisions of Quality System". The manufacturer declares the existence of conditions of stable fabrication of qualitative production, issues the declaration of its conformity and marks the goods it produces by the sign of conformity. The authorized certifying body chosen by manufacturer carries out periodically the selective control of quality of marked articles using in it one of the following procedures:

Procedure 1. The inspecting party tests the samples of finished production taken randomly by indices detailed in the declaration.

Procedure 2. The authorized inspecting party controls quality of serial production in planned manner directly at place of its manufacturing.

Module "F" "Control of Validity of the Certified Quality System by the Authorized Third Party and its Participation in Control of Quality of Production Produced by the Attested Person". The authorized control body tests the products produced in sphere of actuality of the certified quality system. In positive results, its manufacturer issues the certificate of its conformity and marks the articles of the tested batch by the sign of conformity and symbol of the person, which gave him this right. By decision of the manufacturer, the authorized laboratory he chooses freely tests each item of finished production.

As seen, only three of listed eight modules presume use of services of third parties and the procedures established in structure of other five modules permit the businessperson to declare the proper quality of his production themselves. This fact witnesses the gradual narrowing of sphere of certification of production proper. Moreover, in many cases the manufacturer supplements his declaration by documents, which inform on certification of quality system existing in his enterprise, what has to witness the proper quality of all set of products it produces in structure of this system, what excludes the need in their one-by-one certification. To keep this right in force, the businessperson has to apply to the certifying body documents as follows:

- document on certification of quality system,

- reports on stable compliance to the established norms of quality of production identified by results of tests carried out by laboratories accredited on this job,
- certificates of conformity of raw materials, materials, auxiliaries used in process of manufacturing,
- sanitary and epidemiological findings, veterinary certificates (if necessary),
- certificate of fire safety,
- other documents, which witness conformity of their production to established norms, directly or mediate.

4.4.3 Procedures of Attestation of Conformity in CIS Member-countries

The one more European regional structure, which operates attestation of conformity, is the *Interstate Council by Standardization, Certification and Metrology (MDR – Mizhderzhavna Rada Standartizatsii, Tsertifikatsii I Mertologiji)* of CIS member-countries. The principal procedures of its work established the *Treaty on Unification of National Systems of Certification* approved in 1994. Its basic norms are:

- mutual recognition of norms of national systems of attestation.
- use of uniform procedures of accreditation of certifying bodies and testing and calibrating laboratories, mutual recognition of national signs of conformity and protocols of testing and certificates they issue,
- identity of norms of attestation of quality and safety of production in all MDR member-countries,
- right of the authorized bodies of the MDR member-countries on carrying out of mutual inspecting control of quality of certified production in country of its origin.

To mark the products of attested quality, each country established its own sign of conformity recognized by all other participants as equal with their national ones. Here are examples of the signs met in our country the most often (Figure 4.3):

Russian Federation *Byelorussia* *Kazakhstan* *Moldova*

Fig. 4.3 Signs of conformity of some CIS countries

In progress of interstate relations and intensification of collaboration in structure of the Unified Economical Space of CIS members, there was introduced also the *Sign of Eurasian Conformity* (Figure 4.4), which presence indicates compliance of quality of marked products to norms of interstate technical regulations:

Fig. 4.4 Sign of Eurasian Conformity

4.5 International Standards of Social Accountability

The most significant factors to be taken into consideration in process of functioning of human society recognized internationally are interests of individuals, problems of protection of their life and health, as well as assuring of healthy conditions of environment. Assessing results of work of any person of economy, the human community has to consider the whole complex of results of its work: state of finance, grade of care on conditions of life and work of laborers, observance of interests of inhabitants and the whole community of territory of its operation. The totality of influences of listed factors forms the index of *social accountability* of the society, the notion interpreted usually in structure of three basic methods. The *first*, the traditional one, emphasizes that the sole variant of accountability of the employer is rising of income of stockholders of the enterprise. The *second point of view* is antipodal to the first one and declares that *"the corporation must make the sizeable contribution in improvement of quality of life of its laborers and the society in whole"*. The *third position* represents the theory of *"wise egoism"*: *"Social accountability is simply the good business. The*

work in observance of the normalized principles of protection of life, health and interests of laborers cuts the short-term losses of profit but assists in creation of favorable social surrounding, hence obtaining of stable income in future".

The last position gains the more supporters, and the global structures devoted the more attention to progress of systems of social accountability of employers. So, the *World Business Council for Sustainable Development (WBSCD)* provided that the principal conditions of stable progress of society includes the constituents of introduction of principles of the corporal social accountability and guaranteeing of environmental stability.

4.5.1 Standard of Social Accountability SA 8000

To solve the problem named above, the British organization of "*Social Accountability International" (SA)* founded the international advisory council of interested parties (associations) by protection of rights of men, trade unions and others, which principal purpose was development of norms of social and ethical management. The result was validation in 1998 of the standard of *SA 8000 "Social accountability"*, which sets that the person of law has to operate in observance of norms of the following international documents:

- Convention of International Labor Organization (ILO) # 29 on forced labor,
- ILO Convention # 67 on hours of work and rest periods,
- ILO Convention # 98 on right of use of principles of law in organization and concluding of collective agreements,
- ILO Convention # 100 on equal remuneration,
- ILO Convention # 105 on abolition of forced labor,
- ILO Convention # 111 on discrimination (employment and occupation),
- ILO Convention # 135 on worker's representatives,
- ILO Convention # 138 on minimum age,
- ILO Convention # 155 on occupational safety and health,

- ILO Convention # 159 on vocational rehabilitation and employment,
- ILO Convention # 177 on home work,
- ILO Convention # 182 on prohibition and immediate action for the elimination of the worst forms of child labor,
- UN General Declaration of Human Rights,
- UN Convention of rights of children,
- Convention on liquidation of all forms of discrimination of women.

The purpose of development of this document was toughening of norms of accountability of employers for betterment of conditions of labor and standards of life of their employees based on norms of protection of social interests of laborers established by Declaration on basic rights of laborers and applicable in both advanced and developing countries, big and small enterprises, companies and public organizations. These are the norms of engagement of children, avoiding of forced labor, extermination of discrimination, right of laborers on free-associating and contracting, conditions of protection of health and safety of laborers, limiting of duration of operating time and principles of maintaining of discipline. The standard gives the formulations as follows:

> *Company means any organization or business structure responsible for introduction of norms of standard SA 8000 in practice of its operation, which personnel (including administration, managers of structural units, controlling departments and producing personnel) works by contracts or any other mode of protection of its interests*
>
> *Child means any person younger of 15 years (if the local legislation did not fix the elder age). As provided the ILO Convention # 138, this age in developing countries may be of 14 years*
>
> *Young laborer means any laborer younger of 18, but elder of the child*
>
> *Forced labor means carrying out by any person of any work under threat of any type sanctions, as well as execution of this*

work on account of acquittance if the employee does not proposes to do this work voluntarily

The basic norms of standard of SA 8000 may be divided conditionally by four groups as follows:

a) Social Rights of Personnel

Freedom of associations and right on collective agreement. The company has to respect the right of employees on founding of trade unions and take part in development of provisions of collective agreement and concluding of individual contracts with its laborers. The trade union members and/or representatives of personnel, who participate in development and concluding of collective agreements and/or work in sphere of protection of rights and interests of employees must not be discriminated for this job and have the right on free access to working places of their colleagues.

Salary. The value of salary of laborers has to be assigned in taking into consideration of its minimal value fixed by national legislation and its average value in related sector of economy and region of location of the enterprise. The list of disciplinary penalties for infringement of basic norms of work must not contain any measures of fining of wages.

Duration of business hours. The business companies has not force their laborers and members of partner teams to work more of 48 hours or six days a week even in case of occurrence of such need. The personnel must have typically at least two rest days in each seven days period. The duration of extra-time work of any laborer of the company must not be more of 12 hours a week.

Discrimination. The company must not use or support the discriminative actions against its laborers by criterions of their race and nationality, religion, invalidity, sex, membership in any public organization, political views or age in their engagement, change of position, dismissal or outcome upon pension. The company must not impede its laborers in realization of their rights, if this does not put obstacles and strafe rights in execution of their and their colleagues' productive functions.

Protection of labor. The company has to ensure the safely conditions of labor, which correspond to specificity of work and eliminate the potential threats for health of its personnel. The measures to be used have to decrease maximally the probability of origination of hazards specific for its activities and assist in organization of regular training of employees by norms of safety and protection of labor.

b) Social guarantees

Retraining and compensatory payments in dismissal of laborers. The company has to retrain regularly its laborers in purposes of rising of their qualification or obtaining of new specialty having to simplify their transition to new workplaces in modernization of technologies of operation or changing of administrative structure of the company, as well as to guarantee the compensative payments in their dismissal.

Help for the studying persons. The company must not impede its laborers in their evening, correspondent and remote training in universities and grant them vacations for this job in cases specified by legislation.

Paid vacations. The company must not impede its laborers to use their vacations and pay this time by legal norms.

Protection of motherhood. The company must observe the legal norms of protection of motherhood, and create the healthy and safe conditions of work of pregnant womankind.

c) Quality of production, services and works

The company must produce and/or supply production, give services, carry out works adequate to procedures of operation it declares and introduce the necessary measures by protection of conditions of environment. The company must not produce the counterfeited production, give the counterfeit services and carry out the counterfeited works.

d) Protection of environment

Prevention of harmful influence on environment. The company has to develop, produce and supply production or give services character by absence of harmful influence on environment and conditions of

agriculture, as well as use and maintain in working conditions the means of identification and response on emergencies for nature, which may result of its activities.

Environmental training and education of personnel. The company must to ensure the regular training and attest the necessary environmental competence and skill of laborers in carrying out of works hazardous to conditions of nature.

After the company would have executed all necessary actions, it obtains the certificate of *"Social Accountability 8000"*, which existence assists in betterment of its image in views of its contractors, consumers and buyers. The term of certification is three years on condition of carrying out of the regular audit of its activities each six months. The control of observance of the interrelated basic elements of standard SA 8000 listed above would permit auditors to make resolve on compliance of procedures of operation of the controlled company to modern norms of protection of social interests of its laborers. In founding of serious drawbacks and existence of appeals of interested parties, the auditors have to perform the extraordinary detailed inspection of activities of the company.

The one of principal peculiarities of control of the factual level of observance of standardized norms of social accountability is subjectivity in its characterization. Thereby, in many cases clarification of subjective feelings of personnel on conditions of their work is the only method of identifying of correspondence of provisions of used system to its normalized rate.

Introducing norms of standard SA 8000, the *brand and trade companies*, obtain some advantages, which result of betterment of conditions of labor and improvement of interrelations with trade unions and other associations of hired workers. Use of norms of this standard assists in normalization of moral climate in labor collectives, rising of productivity of their work, decreasing of rate of sickness, raise of confidence of investors and improvement of quality of production of the company, which obtains also the right to mark its production with the sign

that witnesses the fact of attestation of the system of management carried out in observance of norms of social accountability.

Suppliers and contracting parties are sure in competitiveness of products of partners, which introduce and attest the norms of standard SA 8000, what assists in their contracting for the longer terms.

Laborers of the company are satisfied by conditions of their work and receive the adequate payment for their jobs. They are free in associating in trade unions, coordination of their activities with the planned works of the non-governmental profile organizations and informing of colleagues on their rights in social sphere. The laborers have also the possibility to take part in solving of problems of the company and influence on decisions taken in optimization of its operation.

4.5.2 *Standard ISO 26000 "Guidance on Social Responsibility"*

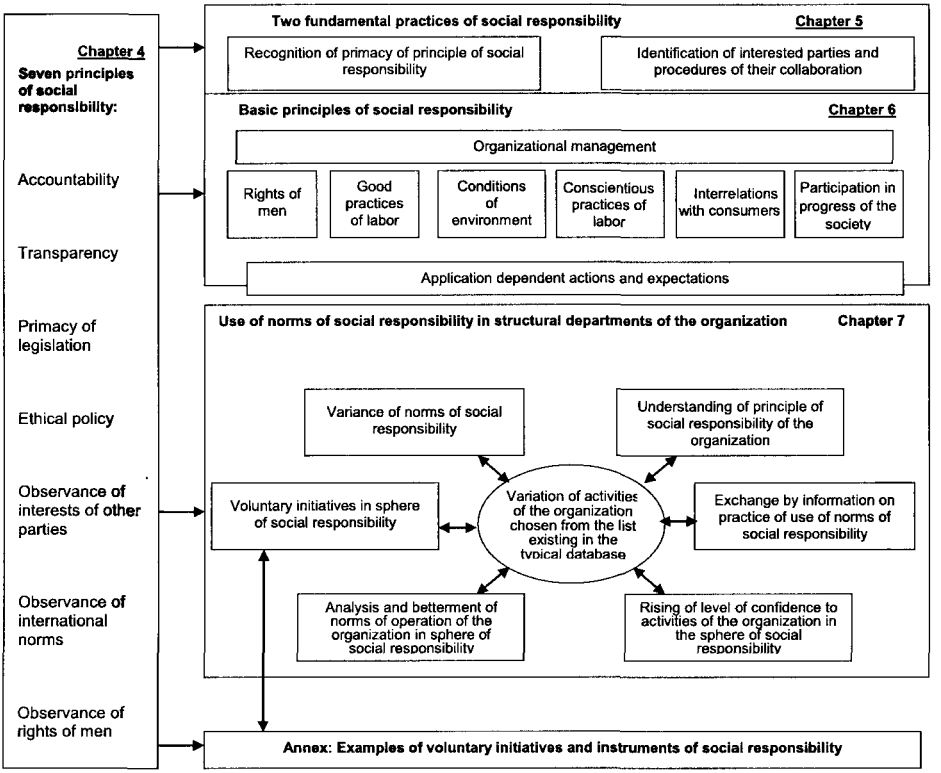
This document is the alternative by its essence to the SA 8000 standard. The decision on its development was taken by resolutions of the World Summit by problems of protection of environment held in Rio-de-Janeiro in 1992, and the World Summit by problems of sustainable progress of global economy in Johannesburg (Republic of South Africa) in 2002. The reason of its taking was the need in internationalization of norms of social responsibility of employers in conditions of stable development of their enterprises. To do this job, the ISO Technical Council specially organized in 2003 the specialized servicing department in structure of the ISO Committee by Protection of Interests of Consumers (COPOLCO) and engaged on this job more of 400 experts and 200 observers of 94 ISO member-countries, who represented six groups of interested parties, namely: consumers, governmental structures, industrialists, laborers, non-governmental organizations and institutions operating this problem.

Their priorities in development of this standard were assurance of equality of rights of hired men and women and taking into consideration the norms of balance of interests of industrial and developing countries. The Group reviewed during 18 months the global experience in

realization of principles of social responsibility, classified its principal problems and developed the basic norms of the document coded as standard ISO 26000. Its developers scrutinized in this work the differences in methods of solution of the problem resulted of too different understanding of essence of concept of *"social responsibility"*. The official text of the standard was published 28th of October 2010 and, unlike standard SA 8000 does not contain any recommendations of obligatory character to be used in formal certification of system of social accountability. In reality, it is the reference document, which has the purpose of normalizing of conditions of reaching of sufficient level of social harmony of employers in relations with their employees and lists methods of integration of socially accountable policy in strategy and practice of operation of persons of economy. Its structure includes the following basic chapters:

- sphere of use,
- terms and definitions,
- concept of social responsibility,
- principles of social responsibility,
- general norms,
- interested parties,
- guides by solving of problems of key interest in sphere of social responsibility,
- examples of practical use of instruments of social responsibility.

The first three chapters *"Sphere of use"*, *"Terms, definitions and shortenings"* and *"Understanding of notion of social responsibility"* are of general character and the specificity of norms of standard ISO 26000 describe the following chapters, which content shows schematically the chart given in Figure 4.5:



4.5 Structural chart of content of standard ISO 26000

It's necessary to note that norms of standards SA 8000 and ISO 26000 are in close similarity and regulate the same problems of work in protection of social and ethical interests of employers.

4.5.3 Standards of management of professional safety OHSAS

The unsatisfactory conditions of protection of labor still existing at individual enterprises impede the economical and social progress of the whole country. The experts of International Labor Organization calculated that losses resulted of professional diseases and accidents at manufactures decrease the global output approximately for 4%. Therefore, the problem of optimization of norms of protection of labor and unconditional observance of interests of laborers became the more

actual. However, it was not solved comprehensively till 1999 because of absence of uniform global practice of assuring of professional safety. At that time, the British Standards Institute published the document of OHSAS 18001:1999 *"Occupational Health and Safety Management Systems – Specifications"*, which acquired in 1999 the category of specification to be used worldwide and recognized in 2007 in version of OHSAS 18001:2007 as the international standard after its final editing by national standardization organizations of United Kingdom, Japan, Ireland, Republic of South Africa and some other countries. Working out its norms, developers took into consideration the requirements of the International Labor Organization and provisions of national norms of protection of labor by the following key aspects:

- identification, evaluation of grade of influence and measures to be used in control of potential risks,
- management of system of safety and hygiene of labor,
- structure of the system of protection of labor and distribution of responsibilities,
- training of personnel and procedures of attestation of its competence,
- mutual consultancy and exchange by information,
- operational control,
- norms of response on accidences,
- norms of assessment and continuous improvement of effectiveness of operation.

The standard establishes norms of operation of system of management of safety and hygiene of labor (*BiGP – bezpeka i gigiyena pratsi*) and guides organizations in development of procedures of their work in control of risks that may arise in their operation. Ukraine harmonized the initial versions of said documents in category of test standards of DSTU P OHSAS 18001:2006. The work in upgrading of norms of said standard was continued in revision of procedures of realization of norms of OHSAS 18001 in publishing in 2008 of standard OHSAS 18002:2008 *"Occupational Safety and Health Management Systems. Guidelines for the implementation of OHSAS 18001:2007"*,

which purpose was the *"... response on pressing demand of consumers to recognize the standard OHSAS 18001 as the guiding document by protection of mental and physical health of laborers to be referenced in introduction of norms of certification of systems of protection of labor".*

Although the International Organization for Standardization did not participate in development of these documents, their norms are wholly compatible with those of standards ISO 9001 and ISO 14001. The basic purposes of use of norms of standards of OHSAS 18000 series by persons of economy are:

- development, introduction, supporting and perfecting of systems of management of professional safety,
- diminishing of probability of origination of professional risks for health and safety of laborers, clients of enterprises and the community in whole,
- demonstrating the interested parties of compliance of their systems of management to norms of standards of professional safety used internationally,
- carrying out of self-rating of compliance of systems of management to global norms.

The principal advantages reached in introduction of norms of standards of OHSAS 18000 series are:

- decreasing of nonproductive expenses and payments of fines,
- minimization of risks of origination of accidents and emergencies, therefore decreasing of unforeseen expenses spent on their liquidation,
- rising of loyalty of laborers of organization and creation of its positive image as the socially oriented one.

The typical structure of activities of department of protection of labor normalized by standard OHSAS 18001 is shown on Figure 4.6:

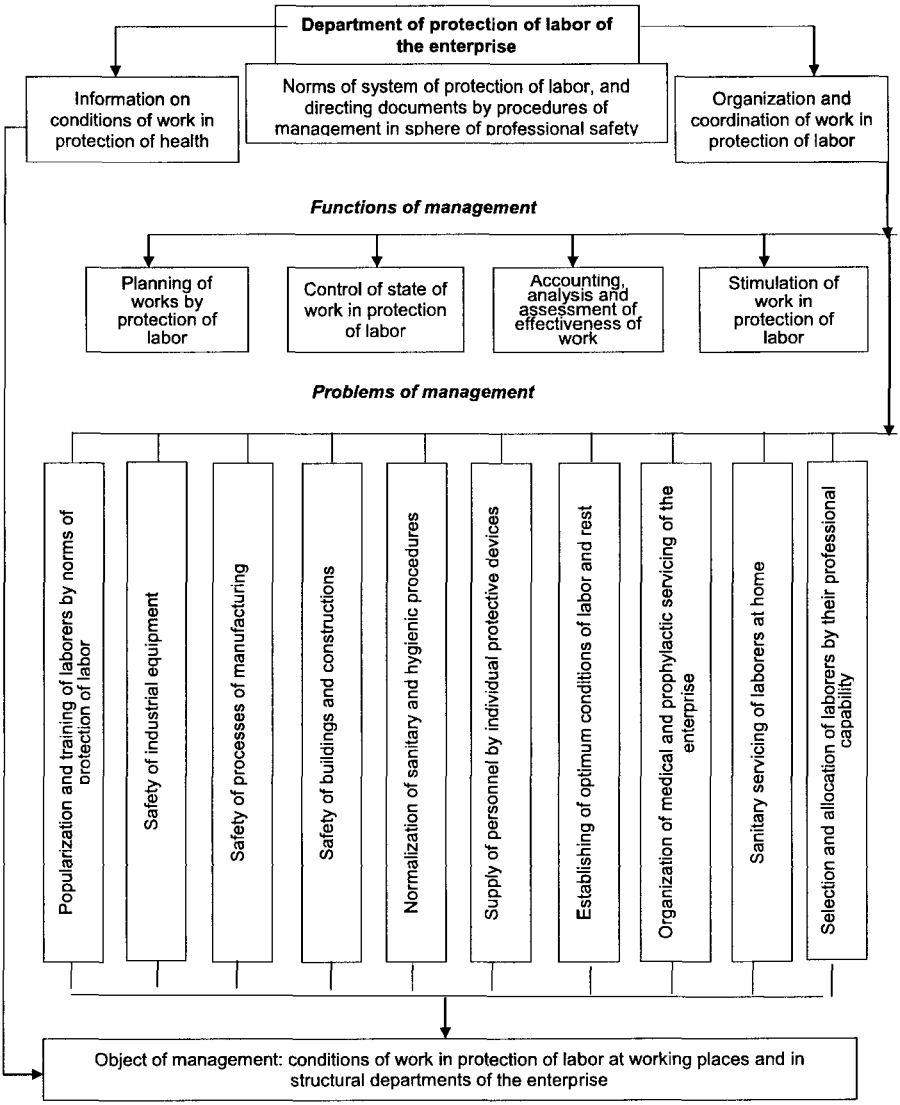


Fig. 4.6 Scheme of work in protection of labor at the enterprise

The specialized third party bodies attest the systems of protection of labor and issue the certificates of their conformity to norms of standard OHSAS 18001, what means that the attested business persons accomplish

the comprehensive work on control and prevention of origination of industrial and professional risks, as well as cares for hygienic conditions and safety of work of its personnel at workplaces. The term of such certification is up to three years on condition of carrying out of annual inspection control (audit) of the introduced BiGP system. Observance of norms of standards of OHSAS of 18000 series and certification of systems of BiGP on compliance to their norms is voluntary, but this fact may be the decisive in accomplishing of tenders and obtaining of investments because the attested enterprise decreases the level of riskiness of its fining and prosecution in origination of any kind accidents, industrial injuries or professional diseases.

4.6 Certification as the Base of System of State Regulation of Safety of Goods and Services

The principal forms of attestation of conformity used in Ukraine normalize provisions of the State law *"On Assessment of Conformity"*. There exist two types of certification: the *obligatory* used in sphere of legal regulation and the *voluntary* one used out of it. These type activities are character by differences listed in Table 4.3:

Table 4.3

Types and features of voluntary and voluntary certification

Features	Types of certification	
	obligatory	**voluntary**
Purpose of certification	Prevention of marketing of production of poor quality and products dangerous for life, health, property of citizens and conditions of environment	Assisting consumers in competent choose of qualitative production and promoting business persons in rising of competitiveness of goods they produce and put on markets
Executors	State certification bodies	Persons of all forms of property authorized on this job by the State
Applicants	Manufacturers and suppliers of production	Manufacturers, suppliers, sellers, consumers of production, bodies of State executive power, public organizations and individuals
Objects	Products to be certified obligatorily (see Table 4.4)	Objects chosen by the applicant
Persons, which determine the procedures of certification	Certifying bodies	Applicants by agreeing with the certifying body
Parameters of inspection	Parameters of the attested items identified as the obligatory for observance	Parameters of the attested items not chosen by applicants

The objects of obligatory certification are (Table 4.4):

Table 4.4

List of production certified in Ukraine in obligatory manner

##	Name of group of commodities
1	**2**
1	Special means of self-defense: • gas weapon (pistols, gas cans etc.), • means of individual protection (body armor etc.), • special means of not-mortal actionї (devices for shooting of cartridges etc.)
2	Medical technique: • measuring and control instruments and devices for diagnostics, • apparatus and devices for roentgenology, • instruments and apparatus for cure, high-frequency and quantum apparatus for curing, • endoscopic apparatus, • apparatus for ultrasonic therapy, • stomatological equipment, • syringes, • entry needles, • cotton wool, bandages, gauze, and articles made of these.
3	Detergents: • foaming means, • shampoos, • means for painting of hair, • liquid soaps (means of hygiene), • means for placing of hair.
4	Small-size tractors
5	Welding equipment: • machines, apparatus, devices for gas welding.
6	Bicycles, baby carriages: • bicycles for teenagers, minor students, sporting, childish, • baby carriages.
7	Means of protective destination: • protective informers, informers on fire, control of access, • instruments receiving and control, protective, fire-preventive, of access, • instruments for guidance, sanctioned access, warning and triggering, • systems of information on hazard situations, • receiving control protective instruments for cars.

1	2
8	Means of communication: • telephone sets, • attachments for telephone sets, • facsimile apparatus.
9	Crockery made of ferrous and non-ferrous metals, porcelain, faience and glass: • steel made enameled crockery, • crockery made of corrosion-proof steel, household crockery, • household aluminum crockery, • porcelain crockery, • faience crockery, • ceramic, majolica, potter crockery.
10	Fire-preventive equipment: • fire-extinguishers, mixes and cartridges for these, • fire-protective coverings and impregnating substances for wood, • fire-protective coverings for cables, • informers on fire, • systems informing on conflagration.
11	Travelling transport means, their spare parts and equipment: • passenger cars with number of places excluding driver more of 8, • new cars, • used cars.

Because the given list includes the negligibly small part of products present in the market, the applicants for certification ask for this work in most cases voluntarily. The list of attested indices of quality of products may include in this case also the norms not regulated by domestic normative documents but set by national standards of foreign countries and regional and international standards not harmonized in Ukraine, what is especially important for domestic enterprises of exporting orientation. To simplify such exportation in absence of interstate treaties on mutual recognition of results of certification, most procedures of certification may accomplish the specialized domestic authorities, but the final stage of this work has to be done by the authorized foreign executor, which issues the certificate of conformity to be recognized in country of destination of the attested item.

4.7 National System of Certification of Ukraine

The predecessor of Ukrainian system of certification is the former Soviet Union system of attestation of conformity normalized by the documents of GOST 16504-81 *"The state system of testing products. Products test and quality inspection. General terms and definitions"* and the *"Temporary Procedures of Certification of Production of Mechanical Engineering"* introduced in mid-80-s by the respective Decree of Council of Ministers of the USSR. The Ukrainian system of certification adopted most of its basic norms, as well as introduced the procedures of international systems of certification of electrical goods (IECEE), electronic components (IECEC), motor and tractor vehicles meant for exportation by rules of UNECE, as well as procedures of attestation of safety of electric instruments by the IEC norms.

The leading institute, which operates in structure of the State Committee of Ukraine by problems of technical regulation in development of scientific, methodological and organizational problems of certification is the *Ukrainian R&D Institute of Standardization, Certification and Informatics (UkrNDISSI)*, and the functions of the Central national body by problems of certification executes the *Department of Technical Regulation of Ministry of Economy of Ukraine* that authorizes the certifying bodies on accomplishing of functions they manifest.

The system of certification used in Ukraine the most often is the in the *Ukrainian State System of Certification of Production (UkrSEPRO)*. Its norms regulate the set of national standards as follows:

- DSTU 3410-2004 "System of certification of UkrSEPRO. Basic principles",
- DSTU 3411-2004 "System of certification of UkrSEPRO. Requirements attributed to [competence of] certification bodies and procedures of their accreditation",
- DSTU 3412-96 "System of certification of UkrSEPRO. Requirements attributed to [competence of] testing laboratories and procedures of their accreditation",

- DSTU 3413-96 "System of certification of UkrSEPRO. Procedures of certification of production",
- DSTU 3414-96 "System of certification of UkrSEPRO. [Procedures of] attestation of manufacture. Sequence of their execution",
- DSTU 3415-96 "System of certification of UkrSEPRO. Register of the system",
- DSTU 3417-96 "System of certification of UkrSEPRO. Procedures of recognition of results of certification of production meant for exportation",
- DSTU 3418-96 "System of certification of UkrSEPRO. Requirements attributed to qualification of auditors and procedures of their attestation",
- DSTU 3419-96 "System of certification of UkrSEPRO. [Procedures of] certification of quality systems. Sequence of their execution",
- DSTU 3498-96 "System of certification of UkrSEPRO. Forms and content of documents",
- DSTU 2296-93 "National sign of conformity. Form, dimensions, technical characteristics and procedures of use".

The concrete procedures of certification in Ukraine regulate the documents listed below:

- "Norms of obligatory certification of tobacco products" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 13 of September 1996 # 378,
- "Norms of obligatory certification of alcoholic beverages" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 13 of September 1996 # 379,
- "Norms of obligatory certification of petroleum and oil products" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy 16 of January 1997 # 19,

- "Norms of obligatory certification of farm machines for cultivation of plants, breeding of cattle and poultry and manufacturing of forages" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 17 of January 1997 # 24,
- "Norms of obligatory certification of crane production" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 24 of January 1997 # 37,
- "Norms of obligatory certification of metal- and woodworking production" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 7 of April 1997 # 186,
- "Norms of obligatory certification of technical means of intruder and fire alarm systems" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 10 of April 1997 # 191,
- "Norms of obligatory certification of materials and items for construction" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 12 of April 1997 # 192,
- "Norms of obligatory certification of means of computing machinery" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 25 of June 1997 # 366,
- "Norms of obligatory certification of production of fire-prevention destination of use" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 27 of June 1997 # 374,
- "Norms of obligatory certification of services in maintenance and servicing of vehicles and their constituents" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 28 of August 1997 # 520,
- "Norms of obligatory certification of electrical and analogous equipment and their auxiliaries" approved by order of State

Committee of Ukraine by problems of technical regulation and consumer' policy of 12 of September 1997 # 567,

- "Norms of obligatory certification of pipes and balloons" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 12 of December 1997 # 777,
- "Norms of obligatory certification of services of nourishment" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 27 of January 1999 # 37,
- "Norms of obligatory certification of hotel services" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 27 of January 1999 # 37,
- "Norms of obligatory certification of motor transport" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 19 of March 1999 # 119/156,
- "Norms of obligatory certification of individual protective devices" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 14 of June 1999 # 322,
- "Norms of obligatory certification of road transport machinery and their components and accessories" approved by order of State Committee of Ukraine by problems of technical regulation and consumer' policy of 25 of January 2002 # 48.

The *basic rules of carrying out of works* in attestation of conformity in Ukraine are:

- coordination of activities and avoiding of doubling of functions of State bodies of executive power, which attest conformity,
- perfecting of methods of certification used domestically, rapprochement of basic norms of Ukrainian and European schemes of certification,
- accrediting of Ukrainian certifying centers and testing, measuring and calibration laboratories done preferably by norms of international standards,

- mutual recognition of certificates issued by the domestic and foreign certifying bodies and measuring and testing laboratories,
- objectivity, transparency and availability of procedures of assessment and attestation of conformity,
- identity of procedures of attestation of production of domestic and foreign origin,
- comprehensive informing of all interested parties of results of works in certification.

Ukraine joined to numerous influential organizations operating metrology, standardization and certification of goods and services in signing in March 1998 of the *"Treaty on Partnership of Ukraine and European Union"*, which clauses presume convergence of basic norms of Ukrainian system of technical regulation with the European one.

The functions of certification in Ukraine may be executed by any accredited juridical person, which compiles to criteria of third party. To carry out the imposed works, this one has to develop the constituent documents as follows: *"Regulations ..."*, *"Passport ..."*, *"Directions on Quality"* and *"Range of Accreditation"* that shall describe all aspects of its activities in declared sphere of operation. The information obtained by the commission in process of certification and technical inspections is confidential; therefore the certifying bodies and organizations operating by their orders are responsible for its divulging. After the work in certification would have been finished, the manufacturer obtains the license on right of issuing of certificates of conformity of items of attested quality, and their marking by the sign of conformity of established design. The term of validity of such license is maximum five years and cannot be prolonged. To continue the work in witnessing of conformity, the enterprise must give to the authorized body it chooses freely the application on repeated certification of the object (not less of three months before certificate issued previously will lose its validity).

The Ukrainian base of certification presumes distribution of responsibilities of its participants in processes of attestation and certification of conformity by spheres of activity as follows:

- *certifying body* is responsible for observance of norms and procedures used in certification, as well as for control of correctness and legitimacy of work in witnessing of proper quality of products of the attested quality by their owners during the period of validity of documents the applicant gave for certification,
- *testing laboratory (center)* is responsible for authenticity of results and impartiality of its work in testing of items applied to certification,
- *manufacturer (supplier)* of items of the attested quality produced serially is responsible for observance of their certified parameters during the whole term of validity of the license they obtained,
- *seller* is responsible for realization of products, which quality has to conform to the certified norms.

Meantime, validity of the license obtained the attested person may be postponed or even cancelled in finding of infringements of conditions of certification, which the most significant are:

- systematical non-conformity of indices of quality of production to their certified values,
- absence of conditions of steady fabrication of production of declared quality,
- violation of rules of issuing of declarations of conformity and/or marking of produced products by the sign of conformity.

The decision on postponing (termination) of validity of license agreement may be taken also in cases as follows:

- numerous reclamations and complaints on quality of certified products,
- non-observance by the certified person of provisions specified in the license agreement,
- non-fulfillment by the owner of the license of recommendations of inspecting bodies issued by results of inspecting control,
- postponing of fabrication of the certified production for the term of more than 6 months.

The validity of the document, which witnesses the fact on certification, may be recommenced on condition of elimination by the applicant of found infringements and positive results of extraordinary inspection of the object of certification.

The one more mode of witnessing of proper quality of each type product produced by the businessperson to avoid certification by third party is its self-certification permitting to cut expenses on assessment of conformity of items produced serially, and decrease the quantity of exterior audits. To obtain right on its accomplishing, the manufacturer has to introduce and attest its quality system on compliance to norms of international standard of ISO 9001 (see Chapter 6.6).

4.8 Members of Process of Certification in Ukraine

The members of process of attestation of conformity in Ukraine are:

National certification body is the State Service of Technical Regulation and Consumer' Policy of Ukraine, which forms the strategy of development and establishes basic principles, rules of operation and structure of national systems of certification, approves the list of production to be certified obligatorily, co-ordinates activities in this sphere and registers the products of attested quality and signs of their conformity in the State catalogue of certified products.

Scientific and technical commission by certification develops projects of norms of certification based on provisions of Law of Ukraine *"On Protection of Interests of Consumers"*. The Commission:

- establishes norms of uniform policy in certification and develops directions of international cooperation in this sphere,
- develops programs of joining of Ukraine to international treaties by certification,
- works out mechanisms of mutual recognition of results of testing and certificates and signs of conformity issued (placed on products of certified quality) domestically and abroad,
- develops projects of specialized organizational and methodological documents used in process of certification.

Territorial centers of standardization, certification and metrology of the State Service of Technical Regulation and Consumer' Policy of Ukraine:

- certify the proper quality of production and services, qualification of personnel, systems of quality management, systems of environmental management etc.,
- control stability of indices of quality of certified production in its serial manufacturing and sale,
- disseminate information and documents to be used in certification.

Other persons, which operate certification and conform to criteria of third party carry out the functions of:

- reception and examining of applications on certification,
- expertise of normative documents by the problem,
- attestation of conformity and carrying out of certification,
- control objectivity and trustworthiness of results of testing and correctness of issuing of certificates of conformity of objects of certified quality,
- drawing up of resolutions on postponing or cancellation of licenses on right of declaring of conformity issued in earlier time,
- informing of interested parties on planned amendments of norms of documents, which normalize indices of its quality of products they produce (sell, distribute etc.),
- control of observance of conditions of certification,
- consideration of appeals and expertise of pretensions of consumers to quality of products of certified quality.

Testing laboratories (centers) are the juridical persons of any form of property, which have the registered juridical status and organizational structure and accredited on right of carrying out of works in control of quality of production including these that has be certified.

Auditors. These ones are the juridical and natural persons authorized by the State Service of Technical Regulation and Consumer' Policy of Ukraine or the body it authorized on right of inspection of quality of the certified production, processes, services, quality systems etc.

Manufacturers (sellers) of production accomplish the functions as follows:

- give applications to the authorized bodies on certification of their products,
- produce documentation necessary for carrying out of assessment of conformity of their production to established criteria and assist in control of observance of attested indices of its quality during the whole term of validity of the certificate of their certification,
- assist in carrying out of scheduled and extraordinary control of work of their certified departments.
- issue certificates of conformity of products of the attested quality and mark them by the national sign of conformity,
- fix the registered number of certificate of conformity in advertising materials and documents, which supplement products of certified quality.

4.9 Procedures of Certification

There are used two principal mechanisms of witnessing of conformity in Ukraine (Fig. 4.7):

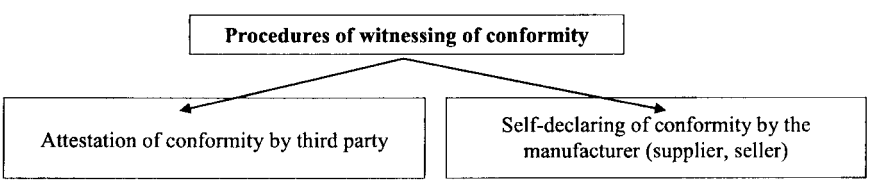


Fig. 4.7 Procedures of witnessing of conformity

Ukrainian legislation interpreted the terms above in meanings as follows:

> *Declaring of conformity means the documented confirmation given by manufacturer (supplier, seller) or his authorized person on full responsibility for compliance of indices of quality of production (technological processes, services) of attested quality to norms of documents he declares*

Attestation of conformity means the process of identification by third party of the fact of observance by the attested person of established norms of normative documents by profile of certification

The factors taken into consideration in carrying out of these processes identify the Figure 4.8:

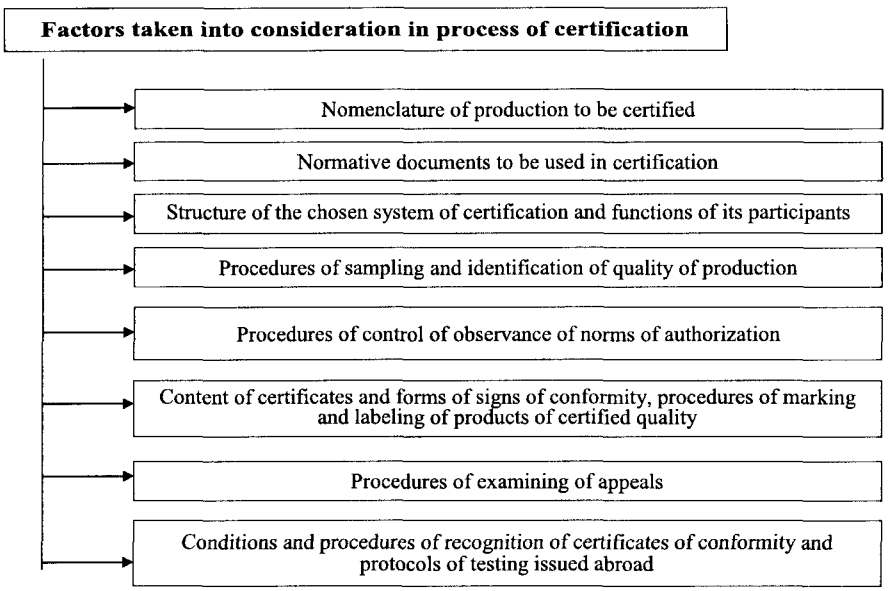


Fig. 4.8 Factors taken into consideration in process of certification and post-certification control

Choosing the system of certification, one has to observe the rules and factors as follows:

- expedience of simultaneous attestation of manufacture,
- size of series of products (individual or serial production), number of items in batches, their mass, dimensions to be certified etc.

The obligatory stages of certification in the system of UkrSEPRO are (Figure 4.9):

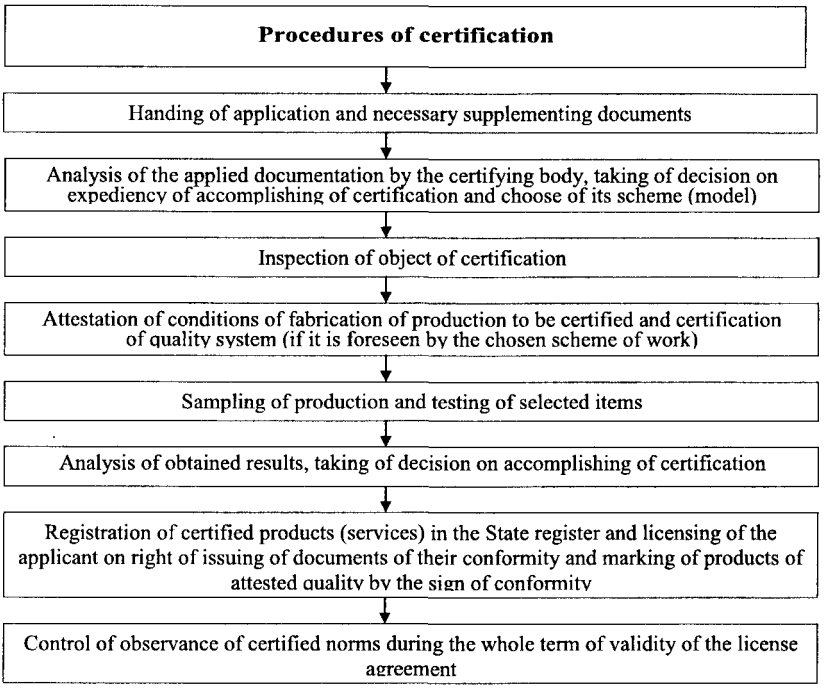


Fig. 4.9 Typical procedures of certification in the system of UkrSEPRO

The routine of carrying out of works in certification is as follows:

Stage 1: handing of application. The businessperson chooses freely the authorized certification body and hands it the application on certification of his production (process, services, personnel, quality system etc.) together with the set of documents to be used in it.

Stage 2: analysis of documentation consists of examining during the prescribed term (not more of one month) of completeness of applied documents and their compliance to norms to be observed in certification. It is controlled also if necessary validity of permissions of directing organizations (Ministry of Protection of Health of Ukraine, State Veterinary Inspection etc.) on carrying out of declared activities.

Stage 3: inspection of manufacture. The commission of the certifying body visits the facilities of the applicant and identifies its

capability to produce goods (give services), which comply to norms of declared normative documents.

Stage 4: attestation of manufacturing facilities (if it is specified by the chart of certification) consists of control of observance of stable conditions of manufacturing of production or giving of services to be certified.

Stage 5: sampling, identification and testing of samples. Samples of products, which quality has be certified take in most cases the representatives of specialized testing laboratories. This work may accomplish in certain cases laborers of the person of certification in presence of inspectors of the certifying body. Some of taken samples are kept as the reference and stored safely during the term defined by rules of certification. The work in testing of taken samples carries out the authorized accredited laboratory, which has to give its results to the inspecting commission.

Stage 6: analysis of results of work. The commission of the certifying body analyzes the report on testing of taken samples and makes the resolve on conformity (nonconformity) of quality of the product (activities) to be certified and existence of conditions of its stable producing.

Stage 7: giving of license on right of issuing certificates of conformity of production of attested quality and its registration in the State Register. In positive conclusion of the inspecting commission, the certifying body grants the applicant the license on right of issuing of documents on conformity of the product of certified quality and/or its marking by national sign(s) of conformity. The certifying body keeps the register of issued licenses and sends its copy to the State Service of Technical Regulation and Consumer' Policy of Ukraine. Using information of regional centers, the latter publishes the catalogues of production certified in Ukraine.

Stage 8: technical control of operation of certified manufacture is carried out during the whole term of validity of issued license by the schedule plan approved by the certifying center.

The schemes (modules) used in authorization and typical procedures used in it are (Table 4.5):

Table 4.5

Schemes (modules) of certification used in system of UkrSEPRO

Object of control	Used procedures				Issued documents
	attestation of manufacture	certification of quality system	testing of production	technical control of manufacture	
1	2	3	4	5	6
Single item	Not accomplished	Not accomplished	Each item	Not accomplished	Certificates of conformity of each item
Batch of production	Accomplished by consent of the applicant and the certifying body	Not accomplished	Samples taken by procedures and in quantities established by the certifying body	Accomplished by consent of the applicant and the certifying body	Certificate of conformity of the batch, which identifies the quantity of articles in it
Serial production, which each item has to be controlled on conformity to the established norms	Not accomplished	Accomplished by consent of the applicant and the certifying body	Each item	Accomplished by procedures established by the certifying body	Certificate of conformity of each item issued during the term of validity of the license agreement and the document on certification of quality system (if certified)
Parameters of serial manufacture	Accomplished	Not accomplished	Primary testing of production with use of samples taken by procedures and in quantities established by the certifying body	Periodical scheduled control accomplished by procedures established by the certifying body	Certificate of conformity issued during the term of validity of the license agreement

1	2	3	4	5	6
Quality system	Accomplished	Accomplished	Primary testing of production sampled by procedures and in quantity established by the certifying body	Periodical scheduled control accomplished by procedures established by the certifying body	Certificate of conformity valid during the term established in authorization

4.10 Methods of Witnessing of Fact of Certification

There exist two methods of confirmation of compliance of indices of items of the attested quality to certified norms: certifying/declaring of their conformity and marking of items by the sign of conformity of established design.

Certificate of conformity is the document, which witnesses the conformity of attested indices of quality of objects to norms of documents used in certification. One should note, that the licenses on right of issuing of documents, which establish the special requirements of safety (e.g. of sanitary, veterinary character etc.) may be given applicant only on condition of existence of hygienic, sanitary, veterinary, phytosanitary and/or other documents that show their harmlessness. The conformity of production of foreign origin to Ukrainian norms may be recognized if there exist the bilateral and/or multilateral treaties on mutual recognition of validity of certificates issued by foreign partners.

Sign of conformity is the sign of established design (combination of letters, ciphers, graphical symbols etc.), which presence witnesses compliance of certified indices of quality of marked production to norms of documents declared in process of certification. To have right to mark products of attested quality, the enterprise has to obtain the related license of third party. However, marking of items, which certify the third party, may be done by this one only. The designs of signs of conformity used in Ukraine regulate the related normative documents. The one of their possible variants is the sign used in UkrSEPRO system, which design normalizes the standard of DSTU 2296-93 *"National sign of conformity"* (Figure 4.10):

Fig. 4.10 Signs of conformity used in UkrSEPRO system

The sign ***"a"*** witnesses conformity of production certified in *obligatory* manner and the law *"On Protection of Interests of Consumers"* prohibits sale of goods (including those of foreign origin) non-marked by this sign, if they are subordinated to obligatory certification. The sign ***"b"*** is used voluntarily in marking of products not subjected to obligatory certification of attested quality. The reasons of such marking are:

- simplifying of procedures of obtaining of permission of State regulative bodies on their realization (if necessary),
- raising of competitiveness of items because of strengthening of confidence of consumers in their proper quality,
- the insurance companies consider presence of sign of conformity as one of guarantees of safety of production, reducing so their actuarial fees.

The provisions of law of Ukraine of *"On Protection of Rights of Consumers"* set the following rules of marking of goods by the sign of conformity:

- the enterprise (organization) obtains the right on marking of goods only after receiving of the registered certificate of conformity of conditions of their fabrication,
- the sign has to be placed on the non-removable part of the article of the attested quality and its package. In impossibility of marking of the item directly, this one has to be placed on its smallest packing,
- the sign of conformity of the certified service (process) has to be printed (stamped) in its supplementary documents and advertising materials.

However, one has to take in mind that the fact of self-marking of goods of serial production by the sign of conformity does not mean that

each one its peace was attested on its proper quality. In reality it is realization of right of the person, which certified the product, to do this job on its own responsibility and the fact of marking evidences that the marked goods are *the most probably* qualitative.

Test Questions

1. Sphere of responsibility of certification activities
2. Reasons of origin of certification
3. Main directions of works in sphere of certification
4. Basic constituents of structure of certification system
5. Normative documents being the base of national system of certification
6. Participants of processes of certification
7. Conditions, which observance is obligatory before starting of certification works
8. Common features and differences in works in certification and verifying of conformity
9. Basic principles of system of certification of UkrSEPRO
10. Distribution of spheres of responsibility of participants of certification in accordance with regulations of UkrSEPRO system
11. Normative documents regulating procedures of work in evaluation of conformity
12. Basic principles of system of obligatory certification
13. Objectives of work on obligatory certification
14. Peculiarities of procedures of obligatory certification
15. Basic principles of system of voluntary certification
16. Principal objective of work on voluntary certification
17. Parameters being evaluated in process of voluntary certification
18. Factors being taken into consideration in process of certification
19. Succession of actions on certification established by system of UkrSEPRO
20. Schemes of certification established by UkrSEPRO system
21. Methods of witnessing of fact of certification

22. Ukrainian sign of conformity established by normative documents
23. Signs of environmental safety of commodities
24. Procedures and requirements regulating process of obligatory certification of foodstuffs
25. Procedures of evaluation of conformity valid in Ukraine and abroad
26. Procedures of declaring of conformity
27. Regional certification
28. Modules of evaluation of conformity valid in EU countries
29. Conditions of recognition of foreign certificate of conformity
30. State control and State supervision – common features and differences
31. Procedures of inspection
32. Environmental certification

5. Accreditation of the Assessment Conformity Bodies

5.1. Meaning of Accreditation in Modern World

The increasing number of highly tailored technical regulations and standards results in need of founding of the specialized third party bodies specialized in assessment of capability of businesspersons to operate in observance of provisions of normative and technical documents used in process of their authorization. However, norms of such documents differ in different countries, what leads to origination in international trade of barriers of purely technical character. The one more complication in such barter is absence in certain countries of legal norms of recognition of results of attestation of conformity done abroad. Therefore, it became necessary to introduce in global practice the uniform procedures of attesting of proper competence of applicants in spheres of activity they declare, as well as norms of mutual recognition of results of work of persons specialized in the same jobs. The method used in it is *accreditation* carried out in observance of international norms, which appellation origins of Latin *accredo* ("*to confide*"). Accreditation is the process of formal recognition by third party of competence of the party it authorizes to perform the specific tasks listed in the document of *"Sphere of authorization"*. The fact of accreditation of the businessperson permits interested parties to identify and choose the competent executor (e. g. the specialized laboratory, inspection or certification body) of the work in question.

The term of accreditation used in viewing of this type activities was stated finally in process of harmonization of Ukrainian legislation with the European one (Law of Ukraine of 17.05.2001 # 2407-III *"On Accreditation of Bodies Attesting Conformity"*) is:

> *Accreditation means the procedure of documented witnessing by the authorized national body of proper competence of juridical person or the body specialized in attestation of conformity in carrying out of certain types of works (testing, calibration, certification, control)*

Use of practice of accreditation gives clients the confidence in proper competence of accredited persons and quality of production they propose, what have to assist in protection of interested parties against doubtfulness in trueness of information of certificates they issue. The Ukrainian legislation interprets the basic notions used in these works as:

- *accreditation of bodies by attestation of conformity* means carrying out of work in control of correctness of procedures of execution of activities of applicants in sphere of their authorization,
- *range of accreditation* means the official document, which lists the attested works, which carries out by the applicant on base of license he received,
- *accrediting personnel* means the qualified auditors and experts invited by the specialized national agency of Ukraine to carry out works in accreditation,
- *national sign of accreditation* means the symbol, which witnesses the fact of accrediting of the organization on right of execution of works it declares.
- *assessment of conformity* means the process of identification of the fact of observance by the applicant of attested procedures of its business operation,
- *conformity assessment bodies* mean the enterprises, institutions, organizations, or their specialized structural departments authorized on work in attestation of conformity,
- *authorized organization* means the metrological center, territorial body, enterprise, organization, verification, calibration or measuring laboratory, authorized on carrying out of declared metrological works,
- *criteria of authorization* mean the complex of norms to be observed by the authorized persons of economy in carrying out of their attested works,
- *certificate of authorization* means the document, which witnesses observance by the attested person of economy of criteria of its authorization.

The developed countries finished their work in legalization of basic principles of authorization in 1970-s, especially the criteria, which state that *"Accreditation is the most influential factor in assuring of stable functioning of system of attestation of quality of production. It is especially important in industry, which persons operate in conditions of strong competition. It is necessary for bodies of public administration in process of mutual recognition of validity of documents and certificates issued in different European regions. It is urgent for most bodies that attest conformity in wish to demonstrate their technical competence, honesty and objectivity in this work."*

There exist presently the accrediting bodies of State subordination (Austria, Russia, Sweden and Ukraine), commercial organizations (Kazakhstan) and organizations, which represent interests of the State and private institutions simultaneously (Germany). To avoid differences in interpreting of details of accreditation, establish the uniform criteria of attestation of businesspersons, prevent commercialization and competition in this work, the national organizations of EU countries specialized in this sphere concluded the *"Multilateral Treaty of Recognition of Equivalence of Results of Accreditation"* valid since January 1, 2010. The document declares that the right on issuing of permissions on carrying out of works in accreditation in each country obtains the only body of any form of legal status and subordination. The bodies they authorize obtain the legal right on carrying out of accreditation of applicants on right of execution of self-maintained metrological works, but not accrediting of other applicants. To avoid any kind conflicts of interests, accredited bodies must not superpose this work with activities in spheres of measurement, testing, inspecting, calibration etc.

The modern process of accreditation is accomplished in two steps. The first one is attestation of competence of the person of authorization in carrying out of works it declares, and the second stage is its licensing on right of carrying out of works in sphere of authorization and issuing of related documents marked by the logo of the accrediting person (if exists).

The persons of authorization are organizations specialized in work in attestation of conformity, namely:

- testing and calibration laboratories,
- bodies, which attest quality of production, processes, services, personnel, quality systems, quality management systems and environmental management systems,
- inspecting bodies,
- metrological services of juridical persons, which verify means of measurement,
- organizations, which train specialists of persons listed above.

The document, which summarizes results of work in authorization, should contain the following data:

- information on the attested person,
- list of activities of the declarant,
- list of normative documents used in process of authorization,
- parameters of inspection,
- methods, which have be used in work in sphere of authorization.

The fact of accreditation of the person of economy or its department specialized in work in sphere of authorization permits the interested counteragents to take the grounded decision in choose of qualified partner. Accreditation becomes in some cases the obligatory condition of licensing of the applicant on right of carrying out of work in sphere of obligatory certification. Therefore, accreditation becomes in modern society one of the most significant factors of influence on the state of business activities of persons, which obtain in accrediting of its measuring (testing) department by international procedures the guarantees of global recognition of proper quality of their work.

5.2 International Norms Used in Accreditation

5.2.1 Accreditation of Bodies Accrediting Conformity Assessment Bodies (ISO/IEC 17011)

The structures, which govern the routine of State regulation procedures, establish the legal norms of operation, which observance guarantees safety of production in use by destination and absence of its

harmful influence on health of men, animals, plants and conditions of environment. The first known document used in control of trueness of results obtained in testing (analysis) of the marketed production was the ISO/IEC Guide 58 *"Calibration and testing laboratory accreditation systems -- General requirements for operation and recognition"*. The ISO CASCO Committee detailed in later time its provisions, so the International Organization for Standardization approved the amended version of this document in category of international standard ISO/IEC 17011:2004 *"Conformity assessment – General requirements for accrediting bodies accrediting conformity assessment bodies"*. These organizations service in confirmation of correctness of carrying out of profile activities for clients, which specialize in work in testing of products, calibration of measuring equipment and secondary standards of measurement, inspection, certification of personnel, production and systems of management and operate by principle of independence of influences of persons of economy they authorize. The Figure 5.1 below gives the general chart of activities normalized by this standard:

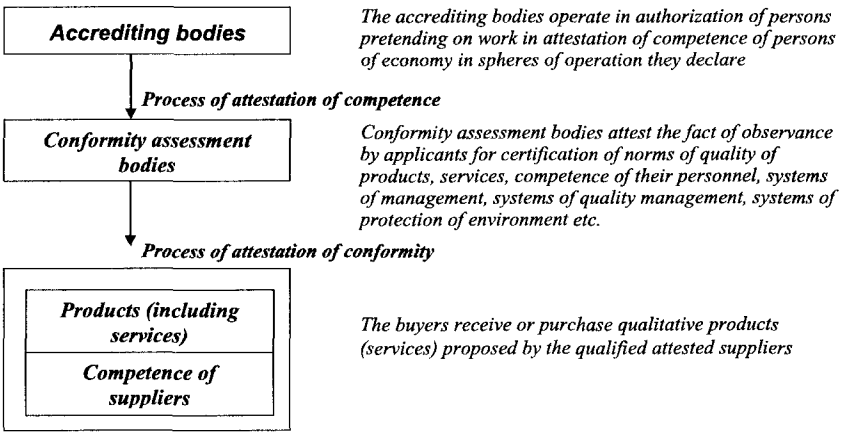


Fig. 5.1 Block-diagram of processes of accreditation and attestation

5.2.2 Accreditation of Inspecting Bodies (ISO/IEC 17020)

The norms of accreditation of inspecting bodies were approved initially as provisions of the CEN/CENELEC standard EN 45004 and

acquired finally the category of international standard ISO/IEC 17020:2012 *"Conformity assessment – General criteria for the operation of various types of bodies performing inspection"*. Its structure is closely similar with this one of standards of operation of certifying bodies but has some specific features, especially those that are attributed to criteria of classification of inspecting bodies to be accredited:
Inspecting bodies of "A" type are those that propose the third party services and operate by indiscriminative principles of independence of pressing of parties interested in results of inspection, as well as of financial and other factors of their influence.
Inspecting bodies of "B" type are those that give the first party servicing departments of organizations, which operate in development, fabrication, supply, tuning, exploitation and servicing of items they produce. The principal structural and functional characteristics of "B-type" services are:

- status of independence of structural department detached functionally of other structural units of its parent organization,
- nonparticipation of inspecting personnel in activities, which may influence on independence and objectivity of their conclusions,
- delimitation of spheres of responsibility of inspecting personnel and persons engaged in accomplishing of other functions of the organization.

Inspecting bodies of "C" type are the persons that execute functions of first parties in control of productive work of their own organizations. The difference of this kind structure of "B-type" services is that they may propose their services for off-site persons.

The administrative and operative characteristics and spheres of responsibility of inspecting organizations of all three categories are:

- *administration*: clear structure, documented functions and norms of business operation, separated accounting,
- *independence* of operation of other legal persons (departments of the parent organization) and absence of interests in results of inspections,
- *confidentiality* of information got in process of work in inspection,

- *management*: documenting of structure of operation and norms of responsibility, effective self-control of work; control of sufficiency of skill of personnel in carrying out of profile work and its systematical training,
- *quality system*: documenting of policy and objectives in profile work, regular carrying out of inner audits,
- *personnel*: completeness of the staff, non-dependence of value of remuneration of quantity of inspections and their results,
- *reports on results of inspections*: in-time issuing of reports and/or other documents on results of inspections,
- *complaints and appeals*: registration of complaints and appeals, documenting of results of their examination and corrective actions carried out by their results (if exist),
- *collaboration and interchange by experience* with other inspecting bodies.

5.2.3 Accreditation of Bodies Providing Audit and Certification of Management Systems (ISO/IEC 17021)

The standard ISO/IEC 17021:2011 *"Conformity assessment — Requirements for bodies providing audit and certification of management systems"* establishes norms of functioning of bodies operating audit and certification of systems of management. The authorized bodies use in the same purposes in some cases also the norms of documents of category of *"specifications"*, e.g. the standard ISO/TS 22003:2007 *"Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems"*.

The principal points of activities taken into consideration in such work are:

- *general norms of operation*: documented form of legal responsibility; validity of taken decisions on certification and absence of interest in its results; financial responsibility for violation of norms of accuracy and trueness of results work,

- *structure*: existence of established organizational structure and normalized procedures of operation,
- *personnel*: sufficiency of competence of personnel and invited off-site auditors in control work, technical experts and specialists,
- *procedures of informing*: openness and accessibility of information; storing of documents on certification and directing of register of certified clients; approval of norms of quoting of information on certificates and procedures of use of signs of conformity; guaranteeing of norms of confidentiality,
- *norms of certification*: normalizing of procedures of registration of applicants for initial certification; establishing of norms of inspection, repeated certification, audit and examining of appeals and complaints; approval of procedures of expanding and narrowing of sphere of certification, postponing or recall of documents on accreditation,
- *norms of management*: accreditation of clients by norms of international standards of quality or specific variants of authorization agreed with applicants.

The full-value procedure of introduction of norms of standard ISO/IEC 17021 presupposes use by the attesting body of norms of the whole set of standards of authorization, namely:

- ISO 9001:2008 "Quality management. Requirements",
- ISO 14001:2004 "Environment management systems – Requirements with guidance for use",
- OHSAS 18001:2007 "Occupational health and safety management systems – Requirements".
- ISO 19011:2002 "Guidelines for auditing management systems",
- ISO 22000:2005 "Food safety management systems. Requirements for any organizations in the food chain",
- ISO/TS 22004:2005 "Food safety management systems – Guidance on the application of ISO 22000:2005".

5.2.4 *Accreditation of Bodies Operating Certification of Personnel (ISO/IEC 17024)*

The norms of operation of bodies accredited on work in certification of personnel establish the international standard of ISO/IEC 17024:2012 *"Conformity assessment – General requirements for bodies operating certification of persons"*. Its basic clauses are:

- *organizational structure*: ensuring of confidence of clients in proper competence of the attesting party and absence of its own interests in certification; responsibility of administrative personnel for all aspects of operation of the organization; documented structure; delimiting of work in certification and other type activities; confidentiality of information obtained in accreditation,
- *development and maintaining of schemes of authorization*: choose of the most appropriate methods of attestation of competence of candidates, development of advanced schemes of accreditation and informing of interested persons n amendments in existing schemes of authorization,
- *system of management*: documenting of the existing system of management; regular inner auditing and control of activities of administration of the enterprise; continuous upgrading of style of operation; correcting of drawbacks and carrying out of preventive actions,
- *documentation*: compliance of provisions of used documents to legal norms; identification of documents and procedures of paperwork, dissemination, storage, withdrawal and assuring of confidentiality of documents,
- *norms of operation of regular and engaged specialists*: identification of criteria of their qualification and competence; documented duties and norms of responsibility of the staff members,
- *procedures of inspection*: control of conformity of routine of work of personnel to their attested norms of operation; absence of interests of the staff members in results of accreditation.

Standard ISO/IEC 17024 contains also the informative addendums, which describe procedures of development and validation of schemes of attestation of applicants and examining of skill of their personnel.

5.2.5 *Accreditation of testing and calibration laboratories (ISO/IEC 17025)*

The international standard ISO/IEC 17025:2005 *"General requirements for the competence of testing and calibration laboratories"* is the basic document in accreditation of laboratories on the right of carrying out of works they declare in observance of norms of their profile operation to the established norms.

> *Accredited laboratory means the laboratory of any form of property authorized by the authorized accrediting body by norms of specialized national standards and/or the international standard ISO/IEC 17025*

The preceding normative document used in accreditation of laboratories was the ISO/IEC Guide 25 developed in mid-1970-s, which norms were taken in later time as the base in development of the European standard of EN 45001:1989 *"General Criteria for the Operation of Testing Laboratories"*. Because such problems became the more significant in progress of globalization of economical relations, the International Organization for Standardization refined its norms and validated the revised document in 1999 in category of international standard of accreditation of laboratories. It was declared that the fact of use of norms of standard ISO/IEC 17025 *"... gives benefits for the business and governmental structures in assuring of their confidence in competence of laboratories, which services they use"*.

This standard contains many norms closely similar to those of standard ISO 9001, therefore may be used in development and accreditation of quality systems specific for operation of laboratories. The document consists of five chapters. The initial three, *"Range of use"*, *"Normative references"* and *"Terms and definitions"*, are of pure technical character. The following two chapters, namely *"Norms of operation"* and *"Technical norms"* classify and normalize criteria of

competence of laboratories and fix conditions of reaching of correctness of norms of their profile operation. Taking these factors into consideration, many countries introduced in their technical legislation the condition of obligatory accreditation of laboratories by norms of this document.

However, ISO revised the norms of standard ISO 9001 in a year after validation of standard 17025 in version of 1999, what resulted in need of correction of its provisions to ensure compatibility of these two documents. The most significant of made alterations relate to rising of level of responsibility of administration for trueness of results of work of the laboratory and introduction of the norm of permanent perfecting of norms of management, especially of norms of interrelations of the accredited laboratory with clients it services. Hence, the *International Laboratory Accreditation Cooperation (ILAC)* specialized in this work guarantees global recognition of results given by laboratories accredited by norms of this standard. Its last version is ISO/IEC 17025:2005 published 12th of May 2005 and it was authorized presently by its norms more of 25,000 laboratories worldwide. Ukraine harmonized this version document as DSTU ISO/IEC 17025:2006. The advantages of accreditation of the laboratory are:

- documented confirmation of sufficiency of technical competence of accredited laboratories and guarantees of reliability and trueness of results of their profile work,
- unconditional guaranteeing of uniformity of measurements and identification of level of uncertainty of results they produce.

5.2.6 *Accreditation of bodies providing proficiency testing and rounds of interlaboratory tests (ISO/IEC 17043)*

The problems, which arise typically in process of operation of accredited laboratories are:

- need of continuous perfecting and confirmation of effectiveness of methods of measurement they use,
- identification of causes of differing of results obtained by different laboratories in measuring of the same property (if exist);

- evaluation of level of proficiency of laboratories in use of attested methods of measurement.

The procedure used in their solving is carrying out of international interlaboratory rounds of testing of materials of standardized composition. To normalize conditions of doing of this work, the ISO/CASCO committee developed its ISO/IEC Guide 43 replaced in later time by standard of ISO/IEC 17043:2010 *"Conformity assessment — General requirements for proficiency testing"* used as the instrument of control of capability of the laboratory to be sure in correctness of its work, identifying of unconformities in its work (if arose) and use of necessary corrective measures to be done in purposes of:

- correction of results of measurements done in use of materials of standardized composition in calibration of measuring equipment it uses,
- modernization of standardized methods of testing,
- raising of level of confidence of clients to results they produce.

Therefore, the organization specialized in development of norms of operation of measuring, testing and calibration laboratories, the *International Laboratory Accreditation Cooperation (ILAC)*, guarantees in turn that results of work of laboratories, which take part in rounds of interlaboratory testing and show the correctness and trueness of results they produce, would be recognized by all interested parties worldwide.

5.2.7 Accreditation of Bodies Operating Product Certification Systems (ISO/IEC 17065)

The central idea of standard ISO/IEC 17065:2012 *"General requirements for bodies operating product certification systems"* is fixing of norms, which have to demonstrate the competence and reliability of results of work of bodies, which operate certification. The provisions of this document regulate the following aspects:

- *general norms*: absence of discrimination in management; work in assessment of conformity of quality of production to criteria of attributed normative documents,

- *procedures of work*: absence of own interests, objectivity of conclusions and responsibility for trueness of taken decisions; existence of legal status and approved structure of distribution of authorities; completeness of staff of personnel qualified in work in accreditation; in-time examination of complaints and appeals,
- *operations*: competence of persons operating sampling and testing. Use of services of organizations specialized in this work,
- *quality system*: clear identification of policy and purposes of operation; existence of guide by quality and other necessary documents of used system of quality,
- *conditions and procedures of accreditation*: clear identification of norms of operation and procedures of issuing of documents on accreditation and license agreements; clear procedures of keeping of actuality, prolongation, postponing and cancellation of validity of issued documents on accreditation,
- *inner audits and control of administration*: periodical inner audit and documenting of results of inspections; in-time execution of corrective actions; continuous analysis of practice of operation by the administrative personnel,
- *documentation*: normalization of procedures of identification, distribution and storage of documents, assuring of their confidentiality,
- *personnel*: competence in execution of set functions; normalization of criteria of attestation of its qualification; appropriate level of education and operational experience of laborers by specialty,
- *accreditation*: use of appropriate normative documents and criteria of authorization,
- *decisions*: drawing up of necessary documents; assignment of date of coming into force of decisions on accreditation; identification of range of authorization and procedures of its amending and cancellation,
- *inspecting control:* documenting of procedures of control of operation and applying of charges for improper work; periodical

assessment of quality of production of the accredited persons on compliance to norms of authorization.

5.3 International Organizations Operating Accreditation

The persons, which operate accreditation, co-work with their colleagues in foreign countries using in it norms of standards of international and regional category, as well as provisions of guiding documents developed by competent national bodies and international organizations and institutions specialized in accreditation. The basic principles used in it are:

1) *voluntariness*,
2) *independence* of any business relations with the persons and clients, which apply for accreditation,
3) *competence* (independent control of competence of accrediting bodies in spheres of activities they operate),
4) *availability* (use in accreditation of simple and accessible procedures),
5) *equality* (use of uniform procedures in accreditation of all applicants independently of places of their location, subordination and form of property).

The typical procedure of accreditation used internationally normalizes the standard of ISO/IEC 17011:2004 "*Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*", which basic norm is use of procedure of reciprocal accreditation expressed by Ukrainian legislation as:

> *Reciprocal accreditation means the process of mutual accreditation of National body of Ukraine by Accreditation and national accrediting bodies of foreign countries by norms of documents recommended by the specialized in accreditation international organizations, which member Ukraine is*

Historically, the first national agencies specialized in accreditation were NATA in Australia (1947) and TELARC in New Zealand (1973). The models of their work introduced later other countries too, and the first

of these ones were the accrediting services of UKAS (United Kingdom), FINAS (Finland) and DANAK (Denmark). The most influential international organizations operating accreditation presently are the *International Accreditation Forum*, *International Laboratory Accreditation Cooperation*, and *European Organization for Accreditation*. The principles of authorization they use form the base in development of specialized guides and international standards of ISO/IEC 17000 series.

5.3.1 International Accreditation Forum (IAF)

IAF is the global federation of State bodies, which authorize its members on accreditation by international norms of businesspersons, specialized in work spheres of management, servicing, attesting of personnel, and other similar programs. There exist the following categories of IAF membership:

- *full members*. Membership is open for all national organizations, which develop and use programs of accreditation of bodies operating certification/registration of works listed above. The condition of its full membership is recognition of all IAF agreements in force and joining to treaties signed in its structure,
- *associated members*. These ones are the authorized by the State national organizations, which take part in work in development and introduction of norms of accreditation used universally,
- *organizations of special recognition*. These ones are the member-organizations of regional unions and national agencies specialized in accreditation,
- *observers*. These ones are the Forum partners and organizations of special missing that have the right of deliberative vote in discussion and taking of IAF decisions.

The Forum full members are presently the specialized bodies of 47 countries. IAF lists also 14 associated members, 4 regional unions and 2 partner organizations. The first grade persons in its hierarchy have the right of full membership in its General Assembly, therefore the right of casting vote in regulation of IAF policy. Its operative structure is the

Council of Directors, which carries responsibilities for development of generalized directions of IAF activities and control of observance of established norms of operation by its member-organizations.

The IAF Statute and Memorandum of Understanding (MoU) signed 27.10.2008 with ISO and ILAC establish norms of competence and define tasks and obligations of IAF members and its regulatory structures. There exist two principal objectives of IAF activities. The prime task of the Forum is development of the unified global program of assessment and attestation of conformity put in progress by the competent accrediting bodies, control of sufficiency of competence of the Forum members by profile problems and prevention of origination of conflicts of their interests. Secondly, it is unification of norms of work of bodies that operate in the IAF structure and assisting in concluding of treaties of its members based on provisions of the document known as *"Multilateral Treaty on Mutual Recognition"*. IAF actively collaborates with international and regional organizations of the same profile of work, especially:

- Asian-Pacific Association of Collaboration (APEC),
- European Organization by Collaboration in Accreditation (EA),
- Inter-American Association by Collaboration in Accreditation (IAAC),
- Pacific Accreditation Commission (PAC),
- Pan-American Organization of Standardization (COPANT),
- International Trade Center (ITC).

5.3.2 ***International Organization by Cooperation in Accreditation of Laboratories and Inspecting Bodies (ILAC)***

The process of intensifying of international collaboration in the sphere of attestation of conformity caused the need of organization of global net of accredited testing, measuring and calibration laboratories. Following this tendency, many countries began to found since 1970-s the specialized systems of authorization of persons, which operate in this sphere, and organized in 1977 the international unprofitable organization by cooperation of national bodies, which

operate accreditation (ILAC) recognized in 1996 as the official global forum, which principal task is development of norms of accreditation of laboratories to be used universally. Following this task, 36 accrediting bodies of 28 countries signed in Washington 2nd of November 2000 the *ILAC Treaty of Mutual Recognition* put into force 31th of January 2001. There exist three categories of membership in ILAC:

1. *Full members*. These ones are the parties of the ILAC Treaty on Mutual Recognition accredited by international norms. Each one takes liability to operate in observance of provisions of the ILAC Statute and directing documents based on use of criteria of accreditation of interested parties by norms of international standardi of ISO/IEC 17011 and ISO/IEC 17025.

2. *Associated members*. These ones are the accredited bodies officially recognized in their own countries as the organizations, which operate accreditation of laboratories but did not signed the *ILAC Treaty on Mutual Recognition* yet. The functions they accomplish are:
   - accreditation of 1) testing, measuring and calibration laboratories, 2) control and supervision bodies and 3) other institutions, which operate in sphere of responsibility of ILAC,
   - operation in observance of norms of ILAC guiding documents and related standards of international category.

3. *Partners*. These are the accrediting bodies of ILAC partner-countries, which:
   - Accredit in observance of ILAC regulations or plan to begin in near future works in accreditation of 1) national testing, measuring and calibration laboratories, and 2) control and supervision bodies specialized in this sphere of activities,
   - declare their intentions to carry out works by accreditation in observance of norms of ILAC directing documents and specialized international standards by accreditation.

ILAC lists presently 52 full, 16 associated, and 19 affiliated members, 5 regional associations by accreditation and 18 organizations interested in

collaboration with the Organization. To accomplish its practical tasks, ILAC organized the following working committees:

- Committee by conducting of conferences under the ILAC aegis,
- Committee by practice of accreditation in trade,
- Committee by practical problems of accreditation,
- Committee by practice of work of laboratories,
- Editorial committee.

The basic directions of work of ILAC structures are development of typical regulations of accrediting bodies and basic principles of their collaboration in spheres of:

- exchange by information on practice of authorization of bodies, which accredit laboratories,
- collaboration with organizations interested in accreditation of their testing/measuring/calibration laboratories,
- global harmonization of criteria and practice of authorization of businesspersons on right of carrying out of metrological works.

ILAC conducts the annual sessions to discuss its current problems and disseminate information on experience of practical work. The Organization assists its members in concluding of treaties on mutual recognition of national norms of accreditation of laboratories and results they produce, what permits to realize one of the main purposes of free trade – *"tested once – recognized everywhere"*. Working in this direction, ILAC closely collaborates with the ISO/CASCO committee and other international and national organizations by problems of assessment and attestation of conformity. The fundamental elements of reaching of confidence in this work of national accrediting bodies are:

- participation in work of ILAC General assemblies,
- work in observance of recommendations of the ILAC working committees,
- accrediting of competent metrological institutions, which control and supervise practice of operation of measuring, testing and calibration laboratories,
- accreditation of bodies, which evaluate and attest conformity and control of their operation,

- dissemination of information on international norms and practice of accreditation,
- conducting of international interlaboratory comparative rounds of testing of materials of standardized composition.

ILAC closely collaborates in its work with international and regional organizations, especially:

- European Accreditation Organization (EA),
- Asian-Pacific Organization by Collaboration in Accreditation Sphere (APEC),
- Inter-American Organization by Collaboration in Accreditation (IAAC),
- Pacific Organization by Collaboration (PAC),
- Pan-American Organization by Standardization (COPANT),
- International Trade Center (ITC).

5.3.3 European Organization for Accreditation (EA)

The European model of accreditation presumes execution of profile works in absence of competition of members of EA, which represents itself the non-profitable regional association of bodies specialized in this work. The Organization was founded in 1997 in Netherlands has its headquarters in Paris and began its activities 26.06.2000. The EA members are presently the specialized agencies of 27 European countries (Austria, Belgium, Bulgaria, Germany, Greece, Czechia, Denmark, Estonia, Finland, France, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey, United Kingdom, and Sweden).The status of membership in it have organizations, which operate in conditions of full accounting, collegial direction and absence of corporative interests. EA signed treaties on collaboration with 25 non-EU member-countries including Ukraine, Russian Federation and the European Free Trade Association members. The main goals of their operation are:

- development of effective structure of European accreditation,

- development of norms of mutual recognition by EA member-countries of equivalence of results of accreditation,
- development of criteria and procedures of attestation of competence of persons, which operate metrological problems,
- coordination of works on accreditation of bodies, which certify quality of production, quality systems, systems of protection of environment and qualification of personnel.

The principal duties of EA members are:

- work in observance of norms of standards of EN 45000 series and other specialized international documents by accreditation,
- recognition of equivalence of schemes of accreditation used by the specialized accrediting services of other EA member-countries.

The EA structure shows Figure 5.2:

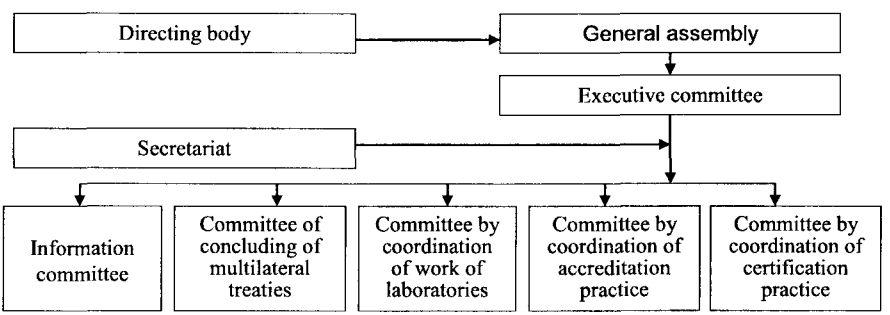


Fig. 5.2 EA structure

The activities of the Organization have to assist the European accrediting bodies in introduction and use of norms of specialized profile standards and dissemination of information, which assists in global recognition of results of work in accreditation they do. Therefore, the EA members may be and are at the same time members of other global organizations operating accreditation, especially ILAC and IAF, hence recognize validity of certificates issued in structure of such associations as equivalent with those that were produced in framework of EA operation.

5.3.4 *System of Accreditation of Analytical Laboratories (SAAL)*

SAAL is the Russian national organization operating accreditation of laboratories. Its principal problems are analogous with those that exist in other CIS countries including Ukraine, and its basic tasks are:

- accreditation of testing, measuring and calibration laboratories by norms of RF national standards. If the laboratory operates at the same time on international market, SAAL may accredit it by norms of standard ISO 17025 as well,
- identification of possessing by the person of accreditation of all necessary normative and technical documents to be used in sphere of its competence,
- documented confirmation of trueness of information of applicant on its capability to carry out the activities declared in its constituent documents,
- control of technical competence of the applicant.

The sphere of SAAL activities includes the principal directions of work as follows:

- development of normative and technical documents by profile problems,
- concluding of two- and multilateral treaties on cooperation with accrediting structures of foreign countries and international profile organizations,
- betterment of organizational and methodological procedures of attestation of applicants and methods of control of their competence,
- training of experts by all directions of SAAL activities.

The system permits to attest skill of persons that determine composition, properties and structure of substances and materials used in metallurgy, geology, food, chemical and pharmaceutical industries, mechanical engineering, agriculture, medical sphere etc. The validity of certificates of accreditation issued by the Russian Accreditation Service recognize on base of mutuality all CIS countries.

5.4 Members of Process of Accreditation in Ukraine. Their Principal Functions

The basic principle of work in accreditation in Ukraine is operation in observance of norms established by laws of 17.05.2001 # 2407-III *"On Accreditation of Conformity Assessment Bodies"*, of 11.02.1998 # 113-98-VR *"On Metrology and Metrological Activities"* and provisions of normative and regulatory documents by accreditation including those that are harmonized with international norms.

> *Accreditation of bodies, which attest conformity, means the process of official recognition by the State Central national accreditation body of competence of juridical person (or its specialized structural department) in carrying out of works by attestation of conformity of products (services) it declares*

The main players, which carry out the work in accreditation in Ukraine, and their principal functions are:

1. *National Body of Ukraine by Accreditation*. The Central body, which governs activities in accreditation in Ukraine is the *National Accreditation Agency of Ukraine (NAAU)* founded by the Ministry of Economy of Ukraine in 2002 in purposes of coordination of works in control of competence and raising of level of confidence of interested parties to results of operation of bodies, which attest conformity. Its principal functions are:

- organization of work in harmonization of national legal and normative deeds and other documents by accreditation with the international and European norms,
- carrying out of:
  - accreditation of the following persons, which operate attesting of conformity:
    - bodies, which certify quality of production, processes and services (by norms of standards of DSTU EN 45011-2001),
    - inspecting bodies (DSTU ISO/IEC 17020-2001),
    - bodies, which certify systems of quality management (DSTU ISO/IEC 17021:2006),

- bodies, which certify personnel (DSTU ISO/IEC 17024:2003),
- testing and calibration laboratories (DSTU ISO/IEC 17025:2006),

- taking of decisions on accreditation and refusing in it; widening and contracting of sphere of accreditation; postponing, recommencement and cancellation of validity of certificates of accreditation issued in earlier time,
- control of observance of criteria of accreditation by the authorized persons.

➢ approval of:

- national programs of work and procedures of accreditation in Ukraine,
- procedures of registration and monitoring of activities of accredited persons,
- procedures of consideration of appeals on decisions taken by the accrediting bodies,
- procedures of training, raising of qualification and attestation of personnel engaged in work in accreditation.

The International Accreditation Forum (*IAF*) recognized NAAU as the Central Ukrainian body by accreditation in Ukraine. NAAU signed also with the European Organization by Accreditation in 2009 the *Memorandum of Understanding* and the *Treaty on Mutual Recognition of Results of Accreditation* and in 2011 – the *Treaty on Associated Membership*. To assure the proper conditions of international collaboration in accreditation, the Agency:

➢ represents Ukrainian interests and participates on her behalf in work of international, European and other regional organizations specialized in accreditation,

➢ concludes treaties with its foreign counteragents on collaboration and mutual recognition of results of accreditation of conformity assessment bodies,

- participates in mutual evaluative tests of competence of persons accredited in structure of international, European and other regional organizations by accreditation which member it is,
- asks foreign accreditation bodies on details of their profile works,
- takes part by consent of its foreign counteragents in accreditation and control of operation of persons of foreign countries.

The persons accredited by NAAU have the right to mark the documents they issue by the national sign of accreditation, which design coincides with logo of this Agency (Fig. 5.3):

Figure 5.3 Ukrainian national sign of accreditation

2. *Council by Accreditation*. Its staff is formed by principle of parity, and includes representatives of central State bodies of executive power, scientific institutions, associations of business persons, public organizations etc. The Council carries out the principal works as follows:

- develops procedures of accreditation and consideration of appeals,
- approves criteria of competence of members of accrediting bodies and procedures of attestation of their professional skill,
- agrees regulations of appeal commissions, and amendments thereof,
- develops norms of collaboration with foreign bodies, which operate accreditation, and develops procedures of recognition of results of their profile works,
- considers annual reports on activities of NAAU.

3. *Territorial bodies authorized on work in accreditation* accredit competence and periodically control activities of bodies specialized in assessment and attestation of conformity and issue certificates of accreditation legalized on base of rights delegated them by NAAU.

4. *Technical committees by accreditation* develop the methodological recommendations by problems of accreditation and the specific norms valid in various branches of economy.

5. *Accrediting committee* takes decisions on authorization of persons of economy or their specialized structural departments, postponing of their validity or refusing in accreditation.

6. *Testing, measuring, calibration laboratories* give the interested parties the testing and calibration services, which results are used in process of their accreditation.

7. *Inspection bodies* control observance by persons of economy of criteria of their accreditation.

8. *Appeal commission*: considers themselves or in law-courts the appeals on actions and/or inactivity of NAAU and its subordinated bodies.

Appeal means the application on revision of unfavorable decision taken by the accrediting body

5.5 Procedures of Accreditation of Persons of Economy in Ukraine

Each kind activity subordinated to accreditation reflects specificity of concrete work carried out in concrete conditions. Therefore, various countries establish differing procedures of accreditation but all of these ones presume observance of uniform criteria of authorization as follows:

a) accreditation of applicants, which have status of legal persons only,
b) existence in the Statute of the organization to be accredited of clause of *"... carrying out of accreditation..."* as one of the main kinds of its activity,
c) existence of non-living premises used in operation of the applicant, which are in own property of the applicant or are leased for this work for a long term,
d) existence of not less of 10 specialists, who have the higher professional education in declared sphere of accreditation and work by this specialty at least 3 years,

e) existence of managing documents developed in observance of norms of documents used in process of authorization,
f) existence in own structure of laboratory accredited on right of carrying out of declared analytical works, otherwise use in this purpose of services of accredited laboratories of other persons of economy,
g) existence of necessary literature and reference base (including the electronic one) of officially edited deeds by profile of activity,
h) existence of system of accounting and documenting of results of works by authorization carried out in sphere of authorization of the applicant.

There exist three types of accreditation – the initial one carried out in cases of authorization of applicants not subjected to this procedure before, the periodical carried out in cases of prolongation of term of validity of certificate issued in earlier time, and the extraordinary authorization carried out in cases of expanding of sphere of operation of the businessperson authorized before. The basic steps of carrying out of such works are:

1. Giving by the person of economy of application on accreditation or expanding of sphere of its responsibility to NAAU or the body it authorized.
2. Appointing by the accrediting body of group of auditors.
3. Analysis of the applied documents by the auditing group.
4. Drawing up of program of authorization and informing of applicant on its terms and content of works to be done.
5. On-site attestation of conditions of operation of the person of authorization.
6. Analysis of collected information and drawing up of statement on results of inspection, which contains recommendations on expedience of accreditation of the applicant (expanding of sphere of his accreditation) or refusing in it.
7. Analysis by the accredited person of given statement, taking of related decision and issuing in positive results of inspection of certificate of accreditation or expanding of its range for the term

of up to five years and giving the applicant of license on right of marking of documents it issues by the sign of accreditation (if exist).

8. If the accrediting person takes decision on refusing in accreditation (expanding its sphere) it sends the applicant the related written motivated message.

The proper competence of the organization in its operation in the declared sphere of activities witnesses the certificate of accreditation of established form. The obligatory addendum to this document is the *"Range of Accreditation"*, which every sheet signs the Chief of the authorizing body and stamps it by the registered seal. The applicant, which is not the juridical person, may be recognized as an independent one if it specializes in work in attestation of conformity and is the separated structural department of the enterprise (organization) registered by the State. The accrediting bodies and organizations they appoint systematically control activities of the authorized persons on observance of criteria of their authorization. The inspection control may be of *periodical (scheduled)* and *extraordinary* type. The minimal term between the planned successive inspections must not be less of one year, and the extraordinary inspections may be carried out by decision of accrediting body in receiving of negative information on operation of the accredited person.

The applicant must use in its work the attested methods of measurement, practice the continuous inner control of operation and have in its disposal:

- premises, which conditions satisfy to sanitary norms and regulations in force necessary for carrying out of metrological works declared in its constitutive documents,
- verified standards of properties and composition used in calibration, graduation and control of workability of means of measurement,
- attested and verified testing equipment and the necessary auxiliary means of calibration and measurement,

- list of exploited means of measuring technique subjected to periodical verification and schedule plan of periodical control of their metrological characteristics,
- normative, organizational, methodological documents, and necessary scientific and technical literature used in carrying out of declared metrological works.

The accrediting body periodically inspects and/or repeatedly attests activities of persons it authorized. In existence of grounded doubt in sufficiency of competence of the audited person, it has to carry out the extraordinary inspection. If NAAU or the body it appointed on this task will find that the accredited body loosed its competence in carrying out of works listed in the Range of Accreditation or roughly violated the taken obligations, it uses the necessary measures by contracting of sphere of accreditation, or postponing of its validity, or annulment of the certificate.

The persons responsible for carrying out of work in authorization and spheres of their control are:

- metrological centers, territorial bodies, enterprises and organizations: State accepting testing, verification (calibration) of means of measuring technique, metrological attestation of methods of measurement,
- metrological services of central bodies of executive power and their leading and basic organizations: control of correctness of use of norms of measurement.

Control questions

1. What is accreditation ?
2. Who are the persons of accreditation ?
3. What sense has the notion of accreditation of conformity assessment bodies ?
4. What is the essence of accreditation of person of economy ?
5. Who is the person of accreditation ?
6. List the principal tasks set in execution of accreditation of persons of economy

7. What are functions of accrediting bodies ?
8. How many types of control bodies establishes the standard ISO/IEC 17020:2012 ?
9. What are conditions of recognition of control bodies of "A" category ?
10. What are conditions of recognition of control bodies of "B" category ?
11. What are conditions of recognition of control bodies of "C" category ?
12. What international standard is used in accreditation of measuring and calibration laboratories ?
13. What is the name and what are authorities of Global Federation by accreditation of specialized State bodies operating in accreditation of persons pretending to work on assessment of conformity ?
14. What is the purpose of operation of European Association by Collaboration in Sphere of Accreditation ?
15. What Ukrainian organization carries responsibility for development of norms of accreditation of measuring and calibration laboratories on compliance to norms of international standards ?

6 Quality and Methods of its Ensuring

6.1 Concept of Quality

The one of serious problems of public economy, which exists since the earliest stages of its development is perfecting of quality of marketed production and resulted finally in clearer understanding of need of continuous revision and perfecting of principles of work, the thought expressed by ancient thinker Zaratustra in form of axiom: *"The snake not capable to change its skin is doomed to die"*. Therefore, up to 25 % of expenses of typical industrial manufacture were spent on identification and removing of defects of produced products. This need became the more understandable in intensification of global competition and quick change of demand of consumers in conditions of oversaturated market.

The quality of products of men's activities depends of influence of numerous accidental, local and subjective factors. To decrease the grade of their influence on conditions of business operation, persons of economy use complex of measures directed on the continuous control of process of fabrication of the product (giving of services). Being in competitive conditions, each enterprise must reconsider periodically style of its operation reckoning *a priori* that the principal norm of reaching of effectiveness of operation is *"satisfying of needs of consumers in receiving of qualitative production"*. To satisfy needs of men, the consumable has to have certain properties and the grade of their compliance to the existing demands of consumers may be correlated as the ratio of its cost and value:

Quality = Satisfying of needs of consumers = Value / Cost

Quality means the grade of satisfying of needs and expectations of consumers by the complex of character properties of production

However, most persons of economy and consumers have no clear understanding of the sense of *"proper level of quality"* yet, what requires of concretization of quantitative parameters of its evaluation. Initially, at first stages of serial producing, the main criterion in evaluation of quality of products taken into consideration was grade of observance

of the complex of their normalized properties. However, rising of complexity of construction and composition of produced items resulted in augmentation of quantity of criteria to be controlled, and the principal question to be cleared in this work became what group of properties is crucial in evaluation of quality of production, and the main accents in its quality control were shifted on comprehensive inspection of *functional characteristics* of consumables in conditions of their mass production. The principal object of control became the entire set of character properties of totality of produced items, but not the parameters of each one. The way used in it was introduction of modern principles of quality management, i.e. organization of coordinated operation of administration, managers, engineers and laborers of the enterprise to be carried out in minimum spending of used materials, energy and live work. The measures used to reach this goal were rising of qualification of engaged laborers, optimization of structure of spending of finances, betterment of quality of products, introduction of innovative projects of business operation and intensification of activities in marketing of finished products.

> *Quality management means the activity in setting of objectives to be reached in operation of the enterprise, clear distribution of responsibilities of executors of basic works and optimization of principles of general guidance directed on continuous betterment of quality of its production*

Planning quality of products (services, procedures of operation etc.), one has to take into consideration the fundamental principles of business activities as follows:

- normalizing and steady improvement of regulated indices of quality of production,
- centering of work in betterment of parameters of quality of production on, which define its goodness,
- observance of established norms of operation and steady elimination of found unconformities and drawbacks,
- improvement of conditions of labor as one of the main priorities in work.

Guaranteeing of high quality of production is the crucial factor of operation in conditions of international competition, what influences sufficiently on the state of national safety, forming of foreign policy of the State and assuring of satisfactory conditions of life of population. The basic parameters of quality are formed mainly under the influence of factors as follows: 1) use of advances reached in scientific and technical progress, 2) use of creative potential of personnel realized in its training, and systematical raising of qualification, 3) extensive use of material and moral methods of motivation, psychological compatibility of laborers, 4) analysis and consideration of needs of domestic and international markets. Despite their variety, they have the common features. *First*, it is consolidation of staff of the enterprise in functional groups. *Second* is mobilization of laborers of the enterprise on solving of concrete tasks and reaching of common goals. *Third*, mutual work of members of labor collectives permits to coordinate and unify their activities, what assists in forming of the staff as the integrated unit, which totalized capability exceeds greatly the sum of capabilities of its individuals. All these features were unified in realization of the central idea of advanced Japanese concept of quality (Figure 6.1), which declares that the *"WAY TO QUALITY IS ENDLESS"*.

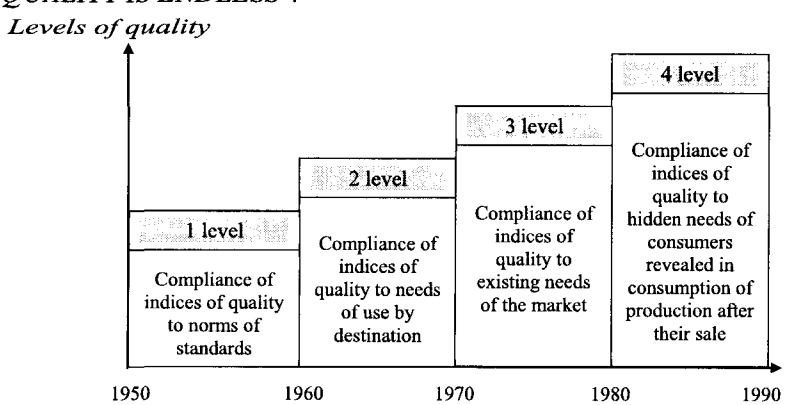


Fig. 6.1 Progress of principles of ensuring of quality accordingly to Japanese concept

6.2 Legal Norms of Quality

USA was the pioneer State in organizing of national leagues of quality organized first in 1899. The analogous trend found its continuation after WW II, when the consumer's cooperative organizations of Australia, Belgium, Netherlands, United Kingdom and USA unified their activities and founded in 1960 the *International Organization of Unions of Consumers (IOCU)*, which lists now more of 200 organizations worldwide. The basic principles of its policy is development of norms of observance of right of persons on safety and information, right to be heard on their needs, right on satisfying of their basic interests and compensation of losses, right on education and life in healthy environment. Using said norms as a model, the UN General Assembly approved (April 9 1985) the document of *"Guiding Principles of Protection of Interests of Consumers"*, which gave the priority level for the rights of consumers in regulation of conditions of functioning of the society. Shortly, their content is as follows:

Right on safety – protection of consumers against marketing of production and giving of services hazardous for their health and life.

Right on information – acquainting of consumers with their basic rights and obligations, introduction of norms of protection of citizens against dishonest advertising, marking and labeling of products (services) they use.

Right on satisfaction of basic needs – right on access to goods and services necessary for normal vital activity.

Right to inform on needs – right on driving of information on interests of consumers in development of market policy of the State.

Right on compensation of losses – right on fair policy in solving of substantiated claims of men for replacing of falsified goods (services of improper quality) for the qualitative ones.

Right on education – right on obtaining of knowledge and skill necessary for the informed behavior in vital situations.

Right on healthy environment – right of present and future generations of mento live in the environment safe for their life and health.

Observance by the State of rights of consumers is the constituent part of freedom of individuals, and the UN Organization recognized this principle as the fundamental criterion in evaluation of quality of life. The basic elements in its realization are the rules and norms of contracts, which normalize typically procedures of establishing, amending or cancellation of material and other kind duties of businesspersons in assuring of proper quality of products (services) they propose at all stages of their life-cycle. The event of concluding of contract gives its parties juridical guarantees of observance by contracting parties of taken obligations and permits to take into consideration the peculiarities of their interrelations. If the contracting party would violate any provision of the contract, it has to pay the suffered party all financial losses and compensate its missed profit.

To detail norms of observance of provisions of quality standards, the EU governing structures developed directives, which establish norms of responsibility of persons of economy for supply of poor-quality production on European markets, namely:

- decreasing of prices of sale,
- elimination of found unconformities of quality of defective production in established term at expense of supplier,
- free replacing for the suffering parties of defective production for the qualitative one,
- forced annulling of validity of contract on sale and compensation of committed harm.

6.3 Factors of Forming of Quality

The work in quality management includes the basic stages as follows:

- *planning of quality* centered on formulation of objectives to be reached,
- *guaranteeing of quality* centered on ensuring of conditions of reaching of set objectives,
- *control of quality* centered on control of routine of carrying out of work in observance of the planed procedures and analysis of finished products,

- *continuous improvement of quality* centered on perfecting of conditions of manufacturing and optimization of quality of finished products.

The factors, which influence considerably on quality of produced products may be grouped as follows:

Technical and technological. These are the factors dependent of specificities and grade of observance of details of existing technologies of operation, technical state of means of manufacture etc. In relation to agricultural sphere, these ones are the chemical, zooveterinary, engineering and technical factors of influence, e.g. the used sorts of agricultural products, periodicity of their planting and ripening; grade of mechanization, automation and metrological support of processes of manufacturing; conditions of means of measuring technique etc. Observance of norms of their use assists in solving of engineering problems of fabrication, safe storage and use (consumption) of produced products, guaranteeing of stability of used technologies and minimizing of their negative influence on health of men and conditions of environment.

The *organizational* factors comprise style of operation of the businessperson and observance of terms in execution of their planned works. The work in planning of policy of operation of persons of economy in sphere of quality has to substantiate foresee the basic directions of development of manufacture, marketing of their production and utilization of generated wastes. The necessary factor of decreasing of economical losses and improving of quality of products of agriculture and cattle breeding is founding of farms of rational size and allocation, optimum distance between the enterprise and places of processing of its production, as well as proper equipping of bases of safe storage of finished products.

The list of *economical* factors varies dependently of structure of manufacture, interrelations of producers of primary products with suppliers of raw and auxiliary materials and consumers of finished products. The principal ones are the system of financing of enterprise, prime cost and price of its production.

Environmental factors, prime the grade of pollution of environment by wastes of manufacture, are of especial necessity in producing of agricultural production, for its quality depends greatly of conditions of surrounding nature (geographical location, climate, state of fertile soils etc.). The specific feature of this group factors are this, that interests of entrepreneurs may differ of interests of the society, hence results of their activities can worse conditions of surrounding nature.

Social factors, such as rising of qualification of laborers and system of remuneration of their labor, acquire in modern conditions the great significance and affect appreciably on quality of production through the specific strains of laborers.

6.4 Methods of Control of Quality

The notion of *"control of quality"* may be defined as the complex of works in measurement, inspection, and comparison of one or more indices of quality of production with their normalized values. The quantitative characteristic of the measured property is named as the *index of quality*, and the whole totality of such indices may be classified:

- in quantitative expression (single, complex and integral ones),
- by category (reliability, manufacturability, ergonomics),
- by stage of life cycle of products (projecting, fabrication, exploitation),
- by methods of identification (calculated, statistical, experimental, evaluative),
- by method of expression (dimensional, non-dimensional, expressed in numbers and/or percents etc.).

Use of the system of generalized indices is crucially necessary in planning of style of work of the enterprise and quality of individual items it produces. Its principal indications are:

- coefficient of renovation of assortment of output,
- quota of production of attested quality,
- quota of production to be exported,
- quota of goods sold by depressed prices,
- quota of defective items.

The methods used in evaluation of quality may be subdivided by procedures of obtaining of necessary data as:

- *method of measuring* carried out by attested methods of measurement with use of verified technical means of control and,
- *method of registration* based on counting of quantity of abnormal items (cases of defective operation) in total output,
- *organoleptic method* based on perception of experts in evaluation of tasty properties of products,
- *method of calculation* based on comparison of useful effect of use (exploitation) of an item with the amount and/or cost of means spent in periods of development, construction and adjusting of manufacturing facilities and production of products of marketable quality.

The normative documents establish *11 groups of indices of quality* of production:

1. *Indices of destination* characterize useful effect of use of production and classify the principal functions to be used in it by categories as follows:
   a) *classification* indices identify belonging of articles to certain category (class of automobile, certified precision of instrument etc.),
   b) *functional (exploitation)* indices of articles define the grade of their usefulness in exploitation (speed of operation of computer, productivity of machine etc.),
   c) *constructional* indices specify the basic projecting and constructional solutions used in development of design of items,
   d) *composition and structure indices* specify masses of elements, formulas of compounds the product consists of, dimensional and structural characteristics of articles etc.
2. *Indices of reliability* identify characteristics of products as follows:
   - *ultimate term of use*, i.e. appropriateness of unused item for operation during the period of given guarantees,
   - *absence of failures*, i.e. their property to keep workability during the guaranteed term of use,

- *durability (longevity)*, i.e. duration of the term of preservation of operable state of an item (on condition of observance of terms of its scheduled maintenance,
- *maintainability*, i.e. appropriateness of an item for technical servicing and repair.

The grade of reliability of production may be characterized by the whole set of listed four indices, or by each one separately of other ones, which values are determined experimentally, calculated and/or evaluated by expert methods. The related index of keeping by the object of evaluation of its consuming properties specifies the norm of natural losses of mass or worsening of certain indices of quality of production in its storage, transporting etc., which may be calculated as:

$$K_D = Q_U / Q_L$$

where K_D – percentage of production, which keeps its normalized quality indices in permissible limits after its storage/transporting/unloading,

Q_U – quota of production, which keeps its normalized quality indices in permissible limits after its storage/transporting/unloading,

Q_L – total quantity of production in the batch.

3. *Ergonomic indices* such as hygienic (intensity of illumination, temperature, atmospheric pressure, humidity), anthropometric (need in clothing, footwear, furniture), psychical and physiological (thresholds of hearing and vision), as well as some others that take into consideration the whole complex characteristics of this category displayed in process of use of an item.

4. *Aesthetic indices* characterize expressiveness, rationality of shape, integrity of configuration (e.g. characteristics of artistic styles, tints, smells, harmonicity) of object of evaluation etc.

5. *Technological indices* characterize effectiveness of constructional and exploitative solutions put in base of processes of manufacturing and repair. These ones are indices of laboriousness, material capacity, stock reserves etc. used in characterization of production as the criteria of

guarantees of productiveness of introduced technologies of manufacturing, optimal distribution of expenses of consumables and observance of planned terms of their fabrication.

6. *Indices of standardization and unification* characterize the grade of unification of details and assemblies used in production of goods with those that are used in other articles of the same destination, as well as their richness by details subdivided by groups of standardized, unified and original ones. The main indices of unification are the specific part of standardized components of products, coefficients of their selectivity, reiteration and interchangeability, as well as the index of original details used in constructions of goods.

7. *Indices of portability* express the grade of suitability of production to its transportation, and characterize kinetics of variation of properties of goods in process of their move from place of production to place of use (safe storage).

8. *Patent indices* characterize the grade of renovation of technical tricks in technologies of manufacturing and designs and composition of finished goods, as well as the level of their protection by patents. Such characters play a great role in evaluation of competitiveness of produced items, for existence of patents is the crucial factor in determining of possibility of free realization of production whether domestically or abroad. Identifying such indices, one has to take into consideration also the existence of registered industrial patterns and trademarks for the same items.

9. *Environmental indices* are used in defining of grade of harmful influence of products on health of men and conditions of environment in process of their exploitation and/or use. These may be, for example, the ratio of real content of harmful admixtures to their maximum permissible concentrations, composition of local gas atmosphere, necessity of irradiation of products in their storage and use etc.

10. *Safety indices* characterize the specific properties of production and actions, which may influence on its safety in process of fabrication, storage, exploitation and use.

11. *Economical indices* characterize amount of expenses to be spent in development, fabrication, exploitation and use of production (its prime cost, price etc.) as compared with the analogous ones spent production of items of analogous destination of use.

There exist different methods of evaluation of level of quality. Their principal variants are the differential and complex ones. Using the differential method, one compares values of individual indices of quality of any object with the identical basic ones, and in use of the complex method – the values of properties of the totality of factual and basic quality indices. The index, which characterizes one of specific properties of production in quantitative expression, is named as the *individual index of quality* (for example, power, calorie content etc.). The one more category of indices of quality of production is *relative* ones calculated as the ratio of value of certain current index of quality of production to its basic value expressed in non-dimensional numbers or percents:

$$K_i = Q_{prod} / Q_{basic}$$

where K_i – relative index of quality,

Q_{prod} – value of current index of quality,

Q_{basic} – value of respective basic index of quality.

The relative indices of quality of production characterize any of its individual properties as compared with the normalized one, and the totality of such indices (*complex index of quality*) expresses the real level of quality of production overall.

Complex index of quality brings together the whole set of individual values of indices of quality multiplied by coefficient of ponderability of each one:

$$K_{comp} = k_1 b_1 + k_2 b_2 + \ldots\ldots + k_n b_n$$

where K_{comp} – complex index of quality,

n – quantity of indices taken into consideration,

k_i – coefficient of ponderability of respective index of quality (individual or relative),

b_i – normalized value of respective index of quality.

All valuables to consume may be classified conditionally by criterions of *basic, permanent, temporary, attendant, introduced,* and *universal* categories of quality understood in meanings as follows.

Basic criteria are attributed to exploitation properties of production chosen as early as at the stage of its projecting and include such their categories as:

- range of use (functions to register),
- reliability (stability of the product in process of storage, absence of brakes and failures during the guaranteed term of exploitation, as well as its maintainability in process of operation),
- technical aesthetics (integrity of composition, perfection of marketable appearance),
- environmental indices (physical, chemical, microbiological),
- ergonomic characteristics (correspondence to ergonomic norms),
- patent purity (novelty, protection of patent rights),
- safety,
- portability.

This category properties are character and attributed to any product during all its life cycle. Their nomenclature is determinative from viewpoint of their basic consuming values evaluated in comparison with production of competitors. The other kind indices of this category do not change the essence of basic properties of products but expand or emphasize the prospective sphere of their use, what results in rising of their attractiveness and usefulness for consumers.

Permanent values add some criteria to be taken into consideration in evaluation of quality of production and are character by mediate relation to basic values. These ones are image of its manufacturer, attractiveness of items he produces, existence of certificate of their quality etc. Such kind values influence some on buyer's preferences and permit to increase competitiveness of proposed goods, therefore quantity of sold items. The influence of these factors assists sometimes in additional liquidity of goods even in cases of their worse basic properties as compared with the analogous products produced by competitors.

Temporary values do not relate to appearance and quality of goods but serve as the additional factors of temporary influence, what assists in introduction of extra charge in period of their action, sometimes as long as one season. Their examples are novelty, prestige, fashion etc.

Attendant values mean the auxiliary characteristics not attributed to basic parameters of marketed production directly but influencing on conditions of its sale. These are the seasonal demand for production, rate of inflation (in international trade) and so on.

Introduced values relate mainly to the information category but not to quality of production directly: these ones are the advertising companies, placing of goods on expositions etc. This category values have no direct relation to their attractiveness but may raise it in announcement of new or repeating many times of known information capable to interest potential consumers.

Universal values, e.g. price of production, permit consumers to compare goods of differing levels of quality in parameters of their cost.

6.5 Principles of Quality Management

The work in solving of existing problems of manufacturing (servicing) presumes the systematical audit and valuation of routine of operation of the enterprise, as well as the continuous improvement of practices of manufacturing (quality management), which influence on quality of its products the most. The basic ideas used in introduction of such practices are:

- ensuring of quality is not the individualized function of specialized departments of the enterprise but the universal demand to be taken into consideration in operation of all its structures,
- work on betterment of quality of fabricated products is obligatory at all stages of their life cycle including the stage of post-manufacturing servicing,
- continuous perfecting of practice of operation in introduction of advanced technologies,

- introduction of system of quality management as the only way of guaranteeing of stability of quality of production.

The essence of work in introduction of quality system lies in unconditional observance of norms of complex of regulative documents of three levels, which exemplary model to be used by the enterprise, the so-called *"Pyramid of Quality"*, shows the Figure 6.2 below:

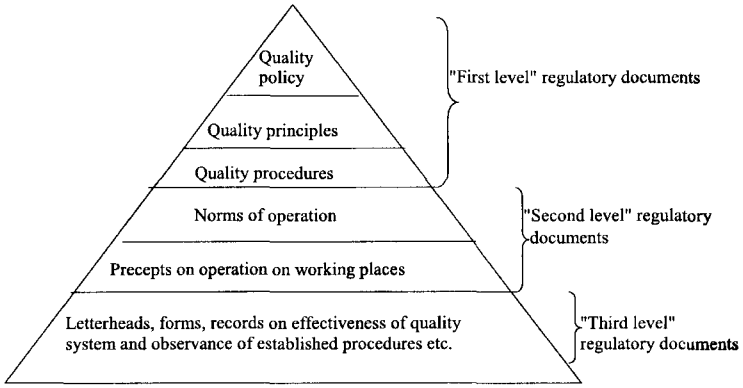


Fig. 6.2 Traditional pyramidal model of documentation of quality system

The main users of documents of the "first level" are the upper rank managers of the enterprise and its clients. The document of supreme level of importance in this structure is the *Guide by Quality*, which describes policy of the businessperson in observance of norms used in certification of activities of the enterprise, perfecting of norms of operation of its structural departments and system of distribution of authorities and responsibilities of engaged laborers. The typical structure of this document includes the following chapters:

a. policy in sphere of quality,
b. brief description of juridical status of the enterprise, its organizational structure and information on structure of distribution of authorities and responsibilities of administration and engaged laborers,
c. identification of level of education, competence and professional experience of employees,

d. administrative procedures, including norms of work with documents of regulative character,
e. functional charge and procedures of training and rising of qualification of laborers,
f. list of subcontractors of the enterprise and procedures of control of their competence,
g. procedures of identification of unconformities (if would arise), control of effectiveness of carrying out of necessary corrective measures and work in avoiding of their repeated origination,
h. procedures of evaluation and attestation of quality of production,
i. policy and procedures of examination of appeals and complaints and description of methods of resolution of controversies if would arise,
j. procedures of inner audit of routine of operation of the enterprise.

The second-level documents used mainly by personnel of the "middle level of management" include methodological instructions, which administer procedures of operation at working places and personal obligations of employees.

The norms of carrying out of individual operations detail documents of the "third level" category. These ones are instructive manuals, methods of analysis of production, passports of quality of finished products and reference materials used in current operation etc.

To survive on the market and be competitive, the enterprise must periodically reconsider the existing practice of its functioning and introduce the advanced principles of work to be carried out in observance of rigorously documented procedures of business operation. P. Druker, one of the most known ideologists of contemporary principles of management, formulated such objectives some strangely: *"Management is the specific kind of operation, which transforms the non-organized crowd into the effective purposeful and organized group"*. This term is used usually in meaning of complex of actions the enterprise carries out in control of quality of its production and correctness of procedures of operation at all stages of manufacture, which starts in obtaining of raw materials and finishes in dispatching of finished products to their

consumers. Henceforth, the key problem of management is development, introduction and certification of system of guaranteed producing of qualitative production (*"quality management system"*, the modern term used instead of earlier *"system of managing of quality"*).

The methodology of standards, which specify conditions of such work, regards the notion of *"quality system"* as the complex of activities, which ensure the capability of the manufacturing person to optimize the structure of its expenses and satisfy at the same time the existing and predictable demands of consumers, which lists and formulates the international standard of ISO 8402 *"Quality management and quality assurance – Vocabulary"* as *"... the complex of organizational structure of the object and procedures and processes it carries out to satisfy the existing and prospective needs of consumers"*. The Ukrainian normative documents define this notion some differently:

> *Quality system means the complex of interrelated and interacting elements of organizational structure, mechanisms of responsibility, distribution of authorities and procedures of operation of the organization*

The work in structure of such system guarantees manufacturer the stable and profitable fabrication of qualitative production produced in observance of norms of protection of environment, which conforms to requirements of used normative documents and satisfies the clearly defined needs of consumers. The main priority in this work is the effective use of human resources and the principal instrument to be used in it is regular training of employers in purposes of rising of their professional skill. To optimize conditions of operation of the enterprise, its upper managing personnel have to learn fundamentals of modern principles of assuring of quality the first, and do it even before the beginning of training of other members of the staff. The Japanese specialists even formulated the thesis that *"nobody must not be taught by principles of quality management earlier of his chief"*. To be successful, the administration of the enterprise may use in it services of consultants or train its laborers at outer seminars or courses. The persons, who passed training, obtain, in

turn, the right to train other staff members and do it just at their working places.

There exist two differing approaches to establishing of effective system of quality management: the synergic and traditional ones, and the undoubted success of Japanese firms is based on principles of the first of named systems of management, what may be explained by use of more effective system of governing by their manpower (Table 6.1):

Table 6.1

Comparative characteristics of systems of managing by manpower

Aspects	Philosophy	
	Synergetic (Japan)	**Traditional (United Kingdom)**
1	**2**	**3**
Cultural and national peculiarities	Big quota of men, who have the university degree Lifelong engagement Successful career in accumulation of experience in the same company	Smaller quota of persons, who have the university degree Engagement by contracts for the set term Independence of success in business operation of principle of loyalty to the same company
Philosophy of the work in management	Ordinary laborers share the responsibility for reaching of set goals in operation of the enterprise with the upper management Ordinary laborers are the biggest value of the enterprise Operators have right to solve the arising problems of manufacture themselves	Ordinary laborers carry responsibilities for integrity of means of manufacturing and not more Ordinary laborers are valued only by values of expenses for their salary The arising problems of manufacture are solved by the authorized specialists only

1	2	3
System of managing	Systems are simple and viable Chiefs of structural departments participate in planning of perspectives of development of the enterprise together with other staff members Laborers are free of continuous commands and control of managing personnel Operators have the sufficient level of education and may be used as experts	The systems are not understandable for ordinary laborers The most attention is given to operation in existing conditions of manufacture Governing by processes of manufacture by chiefs of the enterprise only The level of education of operators is the minor factor
Variants of synergetic effect	The positive style of interrelations in work of specialists of all departments of the enterprise	Insufficiency of useful collaboration among laborers of different structural departments

6.6 International Quality Standards

The businesspersons used initially the notion of *"quality"* in relation to products they produce only, but in change of priorities of operation the center of interests was shifted to satisfying of vital interests of own laborers and raising of level of exactingness of consumers to quality of products they fabricate. To ensure traceability in operation and guarantee reaching of characteristics of objects capable to satisfy the existing and predictable needs of their consumers (users), the administration specifies norms of use of energy, procedures of work and indices of quality of raw materials to be used in operation of the enterprise. Fulfillment of such doings ensures stable operation of the enterprise during the certain period of time (term of validity of contract, term of producing of certain type of products etc.), and the basic criteria of proper quality of works carries out the businessperson are:

- compliance of indices of quality of production to set requirements or its destination,
- satisfying of needs of consumers,
- conformity of parameters of operation to provisions of used normative documents,
- observance of norms of protection of environment.

The objects of attestation in this kind work are production (goods and services) and processes of their manufacturing (giving). The basic norms of operation, otherwise procedures of *quality management*, use the businesspersons are:

- cooperation of administration and laborers in introduction of scientific principles of organization of work and norms of operation based on their use,
- use of scientific criteria in engagement of laborers and attestation of their qualification and professional skill,
- continuous rising of levels of qualification and education of personnel,
- assuring of atmosphere of psychological compatibility and friendly relations of employees.

The spheres of responsibility in execution of productive works are: 1) optimization of procedures of activities and structure of spending of finances, 2) introduction of innovative processes and 3) betterment of indices of quality and methods of marketing of finished production based on use of four groups of methods of operation as follows:

1. *economical* – development of new and betterment of existing designs and norms of manufacturing. This group methods include procedures of pricing, giving of credits, imposing of sanctions for nonobservance of established norms etc.,
2. *initiative* – inducing of work in development and fabrication of qualitative production and imposing of sanctions for losses resulted of marketing and use of poor quality products,
3. *organizational* – administrative methods, which character depends of grade of observance of norms of documents of regulative character (directives, guides etc.),

4. *educational* – measures, which result in improvement of methods of manufacturing and introduction of advanced techniques and technologies.

In progress of processes of globalization of economy, there arose the urgent problem of unification of norms of quality management worldwide. The result was development in 1980-s of group of international quality standards known as standards of ISO 9000 series. These documents establish norms of carrying out and documenting of processes, which influence on quality of production. Use of norms they established permits persons of economy to detail procedures of productive work and improve the style of operation of the enterprise. The essence of this series standards is guaranteeing of reaching of three basic objectives as follows:

- fabrication of production and giving of services, which quality would meet the norm of steady satisfying of existing and prospective aspirations of consumers,
- steady confidence of upper managing persons in proper quality of production of their enterprise,
- steady confidence of consumers in proper quality of production they buy.

The essence of quality standards may be formulated as follows: all processes that can influence on quality of finished products must be documented. The normalized norms have to be carried out under the systematical control of specially appointed persons who carry the personal responsibility for their observance. The principal problems to be solved in introduction of norms of quality standards are:

- reaching of mutual understanding and confidence of suppliers and consumers in their contracting,
- reaching of mutual recognition of validity of certificates on quality systems issued in observance of international norms by the specialized accredited bodies of different countries,
- assistance and methodological servicing of enterprises of various size, forms of property and spheres of activities in development and introduction of effective quality systems.

Use of canons of these documents cannot guarantee elimination of all existing discrepancies of used technologies, but permits to reckon, that the way chosen by the attested person in solving of problems listed above is the optimal.

The ideology of structuring of ISO 9000 standards consists conditionally of four constituents of activities in assuring of quality: its planning, managing, guaranteeing and steady betterment.

The stage of *planning of quality* includes the work in setting of purposes, constituents and basic principles of system of quality to be developed. Its essence is identification, classifying and establishing of norms of quality of production and services put in the base of the system to develop. This work includes also the constituents of development and steady betterment of program of quality.

The essence of stage of *managing of quality* consists in choose of procedures of operational character to be carried out in observance of the standardized norms of operation, which presume the condition of carrying out of work in steady control of quality and accomplishing of necessary corrective measures. The principal goal of their execution are finding of causes of origination of deviations of indices of quality of production of their normalized values, identifying of possibility of repeated fabrication of defective production and realization of corrective measures to prevent the possibility of their repeated origination in future.

The work in *ensuring of quality* consists in execution of planned actions, which are necessary for assuring of confidence of interested parties in compliance of quality of production to established norms. Such work includes two type activities: the *internal work* in assuring of conformity of administrative procedures to established norms of operation, and the *external* one carried out by third parties in control of observance of said norms to convince consumers and other interested persons (e.g. auditors of quality systems and State inspectors) in proper operation of the inspected party.

The work in *control and betterment of quality* is the fundamental norm of the ISO 9000 series standards, which establish the practice of carrying out of all actions done in purposes of rising of effectiveness of

work of the enterprise, what has to give benefits for it itself, as well as for consumers of its production and the society in whole. The typical structure and norms of accomplishing of such kind works are shown in Figure 6.4.

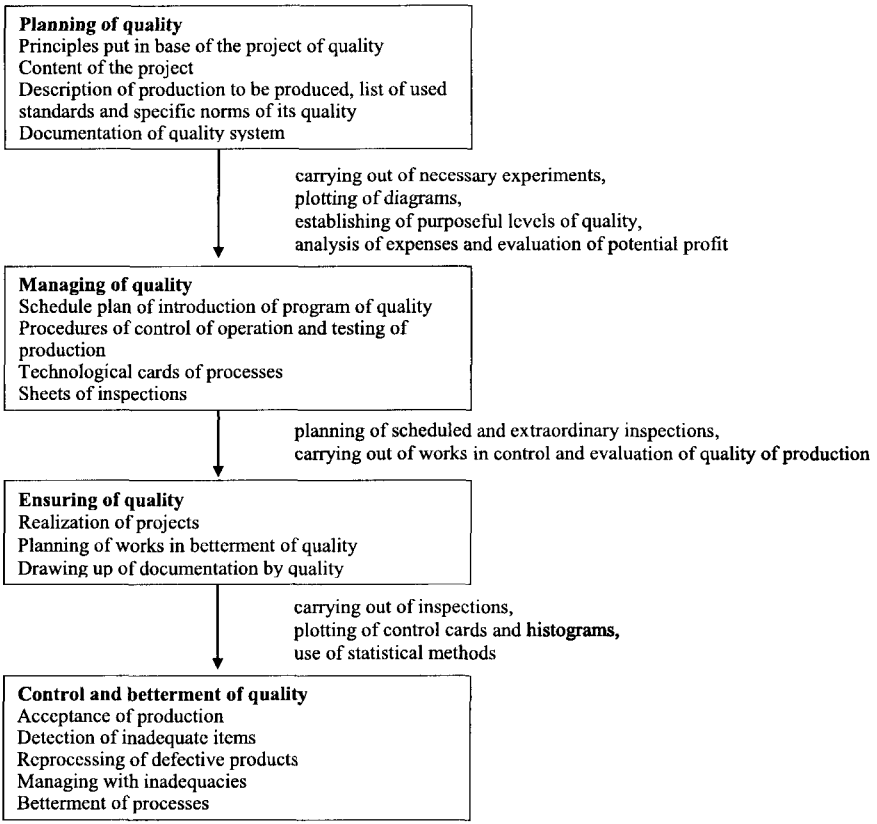


Fig. 6.4 Structure of system of management of quality

The first document, which established norms of assuring of quality, was the US military standard of MIL-Q 9858 developed in the end of 1950-s and taken as a base in development of British standards of BSI 5750 series approved in 1979 that were replicated in later time in observance of international norms. Now they are known as the international standards of ISO 9000 series in version of 1987:

- ISO 9000 "Quality management systems – Fundamentals and vocabulary",

- ISO 9001 "Quality management systems – Requirements",
- ISO 9003 "Quality system. Model for quality assurance in final inspection and test",

The following revision of norms of international quality standards accomplishes the ISO Technical committee 176. This series standards were amended many times, and presently there are known their versions as follows:

- the initial versions approved in 1987,
- the second one validated in 1994 as the edited versions of standards of 1987 series,
- the third revision of standards in 2000 is the result of thorough editing of provisions of documents of 1994 versions,
- the fourth version of standard of ISO 9001 was published in 2008 and standard of ISO 9004, which normalizes procedures of this document, was developed and validated in 2009. These ones represent itself the coordinated pair of normative documents, which detail norms of operation of enterprises in observance of modern trends of progress of global economy.

The basic normative document used in identifying of capability of the enterprise to operate effectively in global markets and certification of quality systems is the standard of ISO 9001. It consists textually, of eight chapters. The first three: *"Sphere of use", "Normative references"* and *"Terms and definitions"* are of "auxiliary" character and do not contain any regulative norm. The real procedures recommended for observances by businesspersons list its chapters 4 ÷ 8 addressed to the following concrete groups of their laborers:

Chapter 4 *"System of quality management"* is addressed to the whole staff of the enterprise and contains the generalized norms of its operation and procedures of their documenting.

Chapter 5 *"Responsibility of administration"* details procedures of work of upper managing personnel.

Chapter 6 *"Management of resources"* regulates procedures of operation of managers of "second level" of responsibility and methods of

optimization of infrastructure of the enterprise and rising of skill of its personnel.

Chapter 7 *"Producing of production"* contains provisions of unconditional observance of the standardized norms of manufacture and/or servicing, registration of their results and methods of control of quality of production understood as succession of actions carried out in observance of norms of used technologies. Such recommendations have the addressees of the "second rank" administrative persons and concrete executors of productive works.

Chapter 8 *"Measurement, analysis and improvement"* relates to the following works:

- continuous monitoring of operation of the enterprise and carrying out of necessary corrections,
- procedures of identification of unconformities, their unconditional elimination and identification of probable causes of their origination to prevent their repeated occurrence.

The addressees of this regulation are all laborers of enterprise and the last subclause represents, in fact, the central idea of the document and was the main cause of its development.

The strict observance of norms of standard ISO 9001 guarantees goodness of operation of businesspersons at all stages of their work, what would witness the goodness of production of their enterprises independently of their size, form of property and sphere of responsibility. Seeing advantages of operable management, this series standards harmonized presently more of 190 countries.

The developers of these standards took into consideration initially the existing norms of contracting, conditions of purchasing and sale of marketed products, procedures of documenting and carrying out of corrective actions, as well as periodicity and norms of audit. However, clauses of documents of 1987 version did not reflected all specificities of operation in fabrication of many kinds of products, first of all norms of use of software to be included into the revised versions of standards, as well as the key problem, which arose in progress of global economy – the need of satisfying of demands of consumers on technical servicing of

products they bought during their whole life cycle. The second versions of standards published in 1994 normalized also the concept of permanent improvement [*of quality of production*]. The following versions of standards approved in 2000 put in practice the concepts of *control of quality* (oriented on product) and *attesting of quality* (oriented on process), which main idea was avoiding of ineffective operations and causes of origination of inner conflicts. However, it became clear soon that norms of standard ISO 9001 in version of 2000 require of detailing, what was taken into consideration in the next revision of standards in relation to actions to be done in perfecting of procedures of quality management. To close this gap, the International Organization for Standardization make in the text of standard of ISO 9001 the necessary corrections (2008) and developed also the standard of ISO 9004 *"Managing for the sustained success of an organization — A quality management approach"*, which concretizes the procedures of management oriented of solving of own problems of the enterprise, which are out of sphere of regulation by norms of standard ISO 9001. This standard foresees the synchronous consideration of potency and effectiveness of functioning of system of quality management realized at the enterprise hence point on methods of optimization of its procedures.

In Europe, standards of ISO 9000 series were adapted to local conditions and are known as standards of EN 29000 series, namely:

- EN 29000 "General management of quality, and standards of quality. Directions on choose and use",
- EN 29001 "Systems of quality. Model of ensuring of quality in projecting and/or development, manufacturing, assembling, and servicing activities",
- EN 29002 "Systems of quality. Model of ensuring of quality in outgoing inspection and testing",
- EN 29003 "General management of quality, and elements of quality systems. Directions",
- EN 29004 "General management of quality and elements of quality systems. Guides".

The process of modernization of methods of management in change of priorities of international quality standards is illustrated characterizes on example of standard ISO 9000 (Table 6.2):

Table 6.2

Transformation of priorities of standards of ISO 9000 series

# #	Principal purposes of management	Basic idea of normalization
1	2	3
1	Structuring of activities of enterprise. Indentifying of processes in form of "trees of functions" in allotting of spheres of responsibility of their executors	ISO 9000:1987 Functional management by principle of allotting of responsibility of persons responsible for its accomplishing
2	Normalization of "crucial" processes of manufacturing and basic contours of management in ranks of standardized techniques of operation	ISO 9000:1994 Establishing of 20 processes, which have the crucial influence on quality
3	Transition from principle of managing of current processes of operation to practice of realization of strategy of development of the manufacture in whole	ISO 9000:2000 Identifying of eight principles of quality management and *"3p"* ideas ("process of permanent perfecting")
4	Refinement of norms of standards of 2000 version	ISO 9000:2008 Bringing of norms of operation of quality system in line with the modern conditions of productive work

The principal purpose of revision of the standard of ISO 9001 to be done in future is equalizing of norms of standards ISO 9001 (quality) and ISO 14001 (environment).

6.7 History of Development of Quality Systems

The philosophy of material production varied many times from the early time of existence of systems of quality. The principal phases of progress of such systems in the modern *"community of consumption"* are: 1) screening of products of proper quality, 2) control of quality of serial products, 3) control of quality of operation of the enterprise,

4) introduction of systems of quality management in operation of the enterprise, 5) introduction of norms of quality management in their operation in conditions of environmental friendliness. Respectively, their history includes conditionally five stages as follows:

The *first* stage was begun in introduction in beginning of XX century of the system of Taylor character by conditional subdividing of processes of manufacturing of machines for the simplest operations. There were normalized dimensions of their assemblies (details) in form of fields of tolerances and stencils, as well as formalized their permissible limits. Because of use of work of non-qualified laborers, the managing personnel of the enterprise had to control observance of the established norms of their operation at each stage of work. To assure the successful work, administration of enterprises were forced to introduce positions of controllers of quality, who became the first professional functionaries, who operate in this sphere. The main points of their activities was control of quality of serial products and screening of items not conforming to normalized indices of quality, which had be sent to rework, but not identification of causes of origination of their defects.

The system of motivation of personnel included the practice of fining and dismissal of workers who committed the repeated drawbacks and defects, which resulted of their guilt. Meantime, such practice needed services of numerous qualified checkers, whose stuff had grown sufficiently in parallel with rising of level of complexity of fabricated products. Finally, the number of checkers in big companies became comparable with the number of productive personnel, what induced the need of development of new methods of assuring of quality.

The *second* stage was began conditionally in 1924, when businesspersons introduced the practice of analyzing of information on found unconformities obtained in use of statistical methods of control of quality and organized in this purpose departments specialized in assuring of quality of operation of the enterprise. The pioneer in this work was the *"Bell Telephone Laboratories"* company (now *AT & T*), which organized the specialized group, which task was to develop the fundamental principles of statistical system of managing of quality. The

novelties they introduced were use of control cards proposed by V. Shukhart and founding of new specialty – the engineer by quality, whose main job was to control observance of normalized parameters of quality of production directly in process in its manufacturing, plot respective diagrams, find causes of origination of defects and unconformities and the optimum ways of optimization of manufacture.

The character peculiarity of progress of industry at this stage was those that consumers began to take into consideration not only the factors of cost, but indices of quality of proposed production too, what lead to complications of manufacturers in its selling. As the result, producers began to project the prospective properties of products, detail processes of their fabrication, organized the specialized departments responsible for purchasing of qualitative raw materials, auxiliaries and consumables, as well as services responsible for selling of finished products. Therefore, inspectors of quality of production began to execute also the functions of control of quality of processes of projecting and manufacturing, incoming control of quality of raw materials, evaluation of reliability of finished products in their after-sale use and analysis of committed failures.

The advantages of this system were recognized worldwide, especially in Japan, what assisted greatly in success of economical revolution in this country in the after-WW II period.

The ***third*** stage. The American scientist A. Feigenbaum proposed in 1950-s the concept of *Total Quality Control (TQC)* to be used in conditions of severe competition of persons of economy and oversaturation of global markets by goods of similar destination of use. The essence of this technology is the detailed analysis of state of global markets and demands of consumers to quality of production they buy, what forced manufacturers to tough their demands to quality of auxiliaries and materials supplied by their counteragents.

Introduction of systems of quality permitted their users to foresee the events of occurrence of potential unconformities of production at all stages of its projecting and manufacturing up to stage of its post-manufacture servicing. The novel scheme of quality management sufficiently changed the practice of operation of businesspersons, who

founded central departments of *"managing of quality"* and gave their chiefs the highest possible rank of vice-presidents by quality. This stage of progress of quality systems is character by the detailed distribution of authorities and responsibilities of laborers, and encouraging of close intercommunication of quality managers with the administration of the enterprise.

This system was perfected in later time in Japan, where professor Ishikawa proposed to take into consideration the relations of businesspersons with consumers of production they produce. The main idea of this system he proposed is that the principle of ensuring of quality is the central in management. Its realization requires of participation of all employees of the enterprise and decreasing of role of material factors in favor of measures of moral stimulation. Since 1950-s, Japan began founding of so-called *"groups of quality"*, what had the purpose to raise effectiveness of manufacturing in use of services of the specially trained laborers and introduction of three basic principles of work as follows:

- to engage laborers in work in optimizing of structure of manufacture,
- to create the joyful working environment based on mutual respect to each laborer and content of works they execute,
- to assist in development of maturity of men.

The *fourth* stage. It was 1980-s, when principles of the novel system of *Total Quality Management* (*TQM*) replaced norms of concept of TQC. The new system was based on the idea of continuous optimization of structure and principles of manufacture but not on its final result (*"3P"* concept: *"the process of permanent perfecting"*). The new concept presumed carrying the continuous control of observance of conditions of purposeful and coordinated processes of productive work and unconditional elimination of committed deficiencies, drawbacks and causes of their origination. To manage quality, enterprises founded the specialized departments of quality management, which principal functions are:

- development of effective systems of quality management and introduction of standards of enterprises on elements of management they use,
- steady inspection control of conditions of manufacture,
- distribution of information on current level of quality and state of acceptance of finished products,
- continuous metrological control of state and scheduled verification of means of measurement.

The persons responsible for ensuring of proper quality of processes of operation had to explain laborers the content of work they will execute and trace correctness of works they carry out. The new form of attestation of quality introduced at this stage became certification of *systems of quality management* by norms of international standard of ISO 9001.

The *fifth* stage began conditionally in 1990-s is character by intensive introduction of principles of TQM in all spheres of functioning of persons of economy including their activities in administration, logistics, operation and marketing. The practice of carrying out of works they execute have the prime purpose of *prevention of errors*, but not their identification and correction after they would have been committed. Assurance of quality became the task of not the department of quality only, but the priority in work of all structural units of the enterprise and each its laborer is accounted now for guaranteeing of proper quality of his work and the items he produces. This stage of development of the system of material production is character by intensifying of influence of community on routine of operation of businesspersons in producing of qualitative healthy production in conditions friendly for environment. This resulted in development and publishing in 1996 of first five ISO standards of 14000 series, which extended norms of management on sphere of protection of nature and permitted to raise attractiveness of enterprises, which certified conditions of their work by norms of standard ISO 14001 ISO 14001 *"Systems of environmental management. List and description of documents, and directions on their use"*.

The persons of economy give in parallel more attention to solving of problems of rising of safety of work and betterment of conditions of life

of laborers, hence introduce norms of specialized standards OHSAS of 18000 series (normalization of methods of protection of health and assurance of safety of productive work) and SA 8000 (use of norms of social accountability), what permitted to decrease levels of traumatism and sickness of laborers and the population in whole. The enterprises became interested, in turn, in introduction of norms of said standards too because this event assists in cutting of nonmanufacturing expenses, therefore rising of competitiveness of their operation.

6.8 Certification of Systems of Quality Management

The modern principles of managing of quality are based on postulate that such activities are effective in regulation of processes of productive operation and have to be done also at stages, which precede its beginning. The one of vital conditions of successful work of enterprises is certification of existing quality systems because neglecting of this work worse conditions of marketing of production or even makes it in certain cases impossible. The collected experience shows also that putting in force of quality systems, effective correcting of found drawbacks and prevention of their repeated origination, as well as monitoring of stability of operation in process of manufacturing permits to declare the manufacturer compliance to established norms of all kinds of items produced by the enterprise, what is more effective as compared with use of practice of outgoing inspection of quality of each type of finished products it produces. The desire of businesspersons to obtain such advantage leads to strengthening of tendency of certification of systems of quality and narrowing of sphere of attestation of conformity of each type of individual products produced by the enterprise. The purposes of their development, introduction and certification have typically the goal of improvement of norms of operation, effective analysis of current activities and making of in-time corrections of used technologies in observance of factors as follows:

- taking into consideration of present and future needs of users (consumers) of finished production,
- continuous control and analysis of business processes,

- clearing of causes of variation of current indices of quality of production and in-time elimination of found unconformities,
- evaluation (benchmarking) of results of own works and activities of competitors and making of necessary corrections.

The typical stages of execution of this work establish the norms of standard of DSTU 3419-96 *"System of certification of UkrSEPRO. Certification of quality systems. Procedures"*. The example of their use is the typical succession of work in development and introduction of quality system used by the servicing enterprises:

1. *Organizational stage*. Appointing of the person responsible for coordination of works in development and validation of quality system to be done in close contact with laborers of all departments of the enterprise.

2. *Identification of needs of consumers*. Identification and detailing of used procedures of servicing, methods of inspection of processes of their giving, identification of probable unconformities in this work and setting of necessary corrective actions and forms of registration of results of operation in prospective sphere of authorization.

3. *First stage of development*. Examining of existing structure of system of servicing and identifying of grade of compliance of its procedures to norms of quality standards. Identification of structure of processes of servicing and establishing of quantitative characteristics by each index of operation of the enterprise (if possible). Classification of works by groups of:

- processes of management (on-line planning and development of strategy of evolution of the enterprise, procedures of monitoring and analysis of results of its activities, periodicity of audits etc.),
- processes, which occur during the life cycle of given services (analysis of needs and expectations of consumers, development and introduction of new type services etc.),
- control of processes of management and betterment of conditions of servicing.

The finishing work to be done at this stage is development of working documents. Doing so, one has to take into consideration that the more complicated and detailed document is, the more chances exist on its

amending and modernization in future. Therefore, to decrease probability of faulty use of their obsolete versions, it is strongly recommended to introduce the *"cascade"* of short and interrelated documents, as well as to decrease their quantity, what is necessary for more effective and univocal understanding of content of the work to do. The principal norms to be observed in managing of documentation are:

- actualization of new versions of documents and abolition and clear identification of those that lose their urgency,
- optimizing of schemes of withdrawal of invalid documents and distribution of actual ones instead,
- establishing of the uniform format of records on business operation and clear indentifying of places and terms of their storage.

4. *Perfecting of system of planning and analysis* is the principal direction of work in optimization of norms of quality managing systems to be revised at least annually. To observe the established principles of declared policy, the administration identifies purposes and generalized indices to be used in evaluation of results of work of the enterprise and schemes of their monitoring.

5. *Training and motivation of personnel*. Participation of all employees in realization of planned policy of progress of the enterprise is the principal condition of successful operation of the system of management. To assist in involving of laborers in this work, the authorized persons give them the necessary information materials and taught employees themselves directly on workplaces and/or invite in this purpose the exterior tutors and lecturers. The one more method used in rising of level of education is training of employees at the outside courses of rising of level of their professional skill. To stimulate them to raise their qualification, the administration introduced such methods of motivation as material stimulation, granting of gratitude and valuable presents etc.

6. *Introduction of procedures of documentation, carrying out of internal audits*. After approval of new documents to be used in optimization of structure of administration, the upper level managing persons discuss with the staff the expediency of introduction of

amendments in existing system of operation, issues orders on validation of the optimized norms, and organize the inner audit of compliance of activities of enterprise to the newly approved procedures. By results of inspection, auditors draw up the report on its results and give proposals on carrying out of actions by elimination of identified nonconformities. The possible variants of conclusions to be taken by results of inspection of the existing system of management are:

- the quality system wholly complies to the normalized criteria of operation,
- the system complies to the normalized conditions of operation in most criteria but there exist some unconformities, which may be eliminated in term of up to six months,
- the system is character by serious unconformities, which elimination needs the prolonged time, hence presently its certification is impossible.

7. *Successive perfecting of the system*. The administration has to carry out the periodical thorough analysis of activities of the enterprise and find the directions of amending or revising of the existing structure of management.

After the recommended work in optimization of structure of management would have been finished, administration of the enterprise applies for certification of quality system, and the certifying body gives the applicant in positive conclusion the certificate of its conformity and registers it in the Register of the System.

To normalize the recommended routine of operation of business persons, ISO develops more of 10 normative and technical documents, the so-called *"auxiliary"* standards and guides, which detail the basic procedures of use of standards of ISO 9000 series in concrete conditions of manufacturing, servicing and trade. The set of these standards is formed in certain sequence, i.e. each its next document narrows the sphere of regulation normalized by the previous standard.

Initially, at early stages of development of procedures of certification, the authorized persons attested processes of fabrication of individual products, what gave applicants the right on issuing of certificates and

marking of goods of certified quality by sign of their conformity. However, it became apparent in progress of public economy the sufficient disadvantages of such method in view of necessity of multiple certification of each unit of the whole spectrum of products fabricated by the enterprise. Hence, there arose the need in founding of methods of simultaneous confirmation of proper quality of the whole totality of products it produces. This problem was solved finally in development of quality standards of ISO 9000 series, which normalize procedures of proper operation of all department of enterprise as the whole one in structure of its *quality system*, which certification by norms of standard of ISO 9001 serves as the proof of conformity to valid norms of all *processes of operation* realized at the enterprise for the moment of attestation, hence proper quality of all its products produced during the period of its validity. As the result, the enterprise obtains the right to mark all its products by the sign of conformity of its quality systems to norms of the international quality standard of ISO 9001 (Figure 6.3):

Fig. 6.3 Sign of conformity of quality system to norms of standard ISO 9001

However, presence of this sign does not mean that the third party persons inspected and attested quality of each type of marked products. It is rather the corroboration of positive results of work in control of existence of proper conditions of their producing. Therefore the event of marking of products by this sign cannot be reckoned as the proof of their goodness, but witnesses that these ones are qualitative the most probable.

Ukraine introduced the same principles of authorization, and the list of regulative normative documents, which harmonized in our country the related procedures, includes the standards as follows.

1. DSTU ISO 9000-2001 Systems of quality management. Basic concepts and vocabulary
2. DSTU ISO 9001-2001 Systems of quality management. Requirements

3. DSTU ISO 9004-2001 Systems of quality management. Procedures of perfecting of activities
4. DSTU ISO 10011-1-97 Guidelines for auditing quality systems. Part 1. Auditing
5. DSTU ISO 10011-2-97 Guidelines for auditing quality systems. Part 2. Qualification criteria for quality system auditors
6. DSTU ISO 10011-3-97 Guidelines for auditing quality systems – Part 3: Management of audit programmes
7. ISO 10012:2002 Measurement management systems. Requirements for measurement processes and measuring equipment
8. DSTU ISO/TR 10013-2002 Guidelines for quality management system documentation
9. DSTU 3921.1-1999 (ISO 10012-1:1992) Procedures of ensuring of quality of measuring technique. Part 1. System of metrological servicing of means of measuring technique
10. DSTU 3921-2-2000 (ISO 10012-2:1997) Procedures of ensuring of quality of measuring technique. Part 2. Methods of control of measurement

Certification of quality systems raises the level of confidence of consumers to quality of products produces the enterprise and investors in correctness of its operation. Carrying out of this action is also the crucial requirement in obtaining of the State order on purchasing of production of the enterprise, its shipping for military, space and related purposes of use, as well as guarantees partners the certitude in stability of work of the enterprise and confirmation of its possessing by the necessary technical base and qualified personnel. The *objects of control* in process of certification of quality system are:

a) documentation,
b) procedures of operation,
c) quality of production produced in the sphere of validity of the certified quality system.

To certify the quality system by norms of standard ISO 9001, the enterprise must not develop the wholly new style of operation but to

normalize procedures of management used by the time of its attestation. After finishing of this work, the enterprise has to keep the attested system in actuality during the whole term of certification. To control observance of established norms by the certified person, the certifying body carries out the scheduled audits of its operation and, depending of its results, confirms validity of conditions of certification, or postpones, or even nullifies the certificate it issued.

Introducing the system of quality, the enterprise takes in it also the obligations of *observance of interests of consumers*, which basic norms are the continuous betterment of quality of its production. There exist two principal ways of continuous perfecting of the system:

a) realization of *"breakthrough"* projects, what leads to reconsideration and dramatic amending of norms of existing technologies or introduction of the bettered ones instead,
b) *step-by-step optimization* of procedures of carrying out of existing processes of operation.

The businesspersons, who have intentions to optimize the existing structure of manufacture by any of these methods, shall take into consideration the following factors:

- *current situation*: evaluation of effectiveness of existing technologies and identification of problems to be solved,
- *analyzing*: identifying of principal causes of origination of nonconformities,
- *possible decisions*: studying of alternate variants of solution of existing problems,
- *perfecting*: choose of optimum methods of solving of existing problems, what would permit to prevent their repeated origination,
- *introduction and standardization of new methods of operation*: replacing of existing processes by the perfected ones and their normalization,
- *evaluation of influences*: analysis of processes of functioning of the enterprise in optimized conditions and confirming of effectiveness of its work in elimination or diminishing of

probability of repeated occurrence of the found type nonconformities,

- *evaluation of effectiveness of perfected processes*: evaluation of effectiveness of new-style works and taking of decision on expedience of their use in other structural departments of the enterprise.

All works carried out in structural departments of the enterprise must be documented, what permits to inform the interested persons on their content and assists in:

- reaching of level of work, which permits to satisfy expectations of consumers,
- raising of qualification of personnel,
- reaching of traceability of works,
- obtaining of objective information on real conditions of the manufacture,
- evaluation of effectiveness of the existing system of quality management.

To raise the culture of operation, the persons, who obtained such certificate, may demand, in turn, of their counteragents to introduce systems of quality management, which comply to norms of international standards.

The one more important aspect of operation of modern enterprise as the integrated unit is introduction of norms of standards, which permit to regulate the conditions of life and work of their laborers and quality of production they fabricate. Table 6.3 gives the brief characteristic of norms used in it:

Table 6.3

Standards used in sphere of ensuring of quality

Number of standard	Sphere of use of standard	Objectives of use of standard
1	2	3
SA 8000	Social accountability of employers	Improving of conditions of labor of employees, observance of ethical norms of the civilized society
DSTU ISO 14001	Systems of environmental management. Recommended norms and procedures of operation of the enterprise	Protection of environment and decreasing of quantities of natural resources used in process of business operation
DSTU ISO 15161	Norms of producing of safe foods and drinks	Reaching of high level of quality and safety of foodstuffs
DSTU ISO/IEC 17021-1	Criteria of competence of bodies, which accomplish certification and audit of quality systems	Establishing of norms of competence of bodies operating attestation of quality systems
DSTU ISO 17025	General norms of competence of testing and calibration laboratories	Establishing of norms of technical competence of laboratories
DSTU OHSAS 18001	General norms of management of work in assuring of professional safety and protection of health of laborers	Decreasing of negative influence of harmful and hard works on health of men, prevention of danger for laborers in process of their operation, improving of image of labor
DSTU ISO 22000	Managing of safety of foods and procedures of their fabrication	Guaranteeing of safety of foodstuffs in processes of their producing, storage, reprocessing and distribution

The principal purpose of introduction of norms of listed standards is protection of interests of individuals in obtaining of maximum guarantees of goodness of products they buy. The character peculiarity of works in realization of these rights is *certification of quality system used by the enterprise* on conformity to provisions of quality standards but not attestation of quality of individual products the enterprise produces. The

fact of certification of system of quality management to norms of standard ISO 9001 means that the system of its operation *permits* to produce products, which quality indices would conform to norms established by the normative document he declares in their producing and *minimizes but not excludes* risks of consumers in purchasing of poor-quality items he proposes, because such standards establish the strictly fixed norms, characteristics and rules observed by the attested enterprise by the enterprise in its operation, but not give any information on quality products it produces in sphere of attestation.

6.9 Concept of Total Quality Management

The modern systems of assuring of quality are of predominantly organizational type character by normalization of some nuances of social and psychological character. The procedures of operation of persons of economy in modern conditions differ of those that were used traditionally because of difference in their structures because norms of standards of ISO 9000 series identify *what* to do, but not fix *how* to do it. To answer on the last question, there was developed the system of *Total Quality Management (TQM)* – the effective and comprehensive system, which permits to guarantee the proper quality of products produced by the enterprise in free choose by the operators of methods of reaching of set goals. Use of term *"total"* in the latter expression means involvement in business processes of all laborers of the enterprise, the term *"quality"* denotes care for satisfying of needs and interests of consumers in their realization, and the term *"management"* means use of modern principles of operation in reaching of planned level of quality of processes of operation and their products.

The term of *"management"* (governing, organization of work) is now in extensive use, but each person understands it with respect of own mind. Therefore, unification of understanding of its essence requires of establishing of certain norms of interpretation of this notion. Generally, the term of management is understood as the effective and rational coordination of work of laborers in observance of five basic functions as follows:

- *Planning* of activities in reaching of goals to be realized.
- *Organization* of work in distributing of men's and material resources and ascertaining in its correctness.
- *Guidance*. Identification of works to be done and appointing of their executors.
- *Coordination*. Development of structure of operation, which permits to realize the set goals.
- *Control*. Control of obtaining of planned results.

The central point of management in reaching of desirable quality of products of manufacture as the indivisible element of business operation is the end-to-end guidance by each stage of work, what presumes realization of system of effective communications of all productive structures of the enterprise and proper operation in proper use of all its equipment and belongings, as well as creation of the effective system of motivating of personnel on reaching of set goals. The successful operation of businesspersons is possible only in their continuous work in betterment of *quality of organizational work*, regular analysis of achieved results, aspiration to minimization of quantity and grade of significance of defects, decreasing of non-manufacturing expenses, rising of competitiveness of production and winning of recognition of interested parties. Fairly, planning of work has certain democratic elements: to reach the planned results, managers have to take into consideration the long-term interests of most of employees and introduce the practice of their material and moral stimulation (e.g. participation of laborers in distribution of profit of the enterprise, granting them awards etc.).

The basic principles of modern management are:

- organization of the department responsible for planning of administrative and organizational work,
- agreeing with the labor collective of goals to reach in operation of the enterprise and clear distribution of planned works among its structural units,
- noting the managers of medium level of administration on tasks they have to realize in their everyday work and the planned terms of their execution,

- creation in the labor collective of atmosphere of mutual confidence and respect,
- regular analysis of results of operation and correcting of plans of work,
- use of elements of forecasting in change of structure of manufacture resulting of amendments in content of works to be executed,
- adequate reorganization of style of work in violent changing of conditions of operation.

The processes put in base of systems of management used in most enterprises are administrated by structures formed by principle of pyramid, as a rule. Their typical structure and functions are:

1. *Upper managers.* These ones are the administrative persons and managers of upper rank responsible for coordination of operation of all structures of the enterprise and planning of directions of its progress. Upper managers play the determinative role in attracting of outside resources and carry responsibility for realization of goals set by its stockholders, control and coordinate everyday activities of structural departments of the enterprise, fix budgets and define specificities of their operation, develop schedule plans of carrying out of planned works, appoint the medium level managers, as well as coordinate interrelations of the enterprise with its counteragents, bodies of local administration, mass media sources, stockholders and other interested parties.

2. *Managers of medium level of administration.* These ones are represented typically by chiefs of structural departments of the enterprise. Their principal business is organization of works set by upper managing structures and development in collaboration with managers of upper and lower levels of administration of prospective plans of work of their departments. Their principal functions are:

- assisting the upper managing structures in rising of effectiveness of operation of their departments and the enterprise as the whole one,
- development of criteria of successfulness of works they execute,

- identification of existing problems and development of methods of their mastering,
- development and agreeing with managers of upper rank of systems of stimulation of laborers by results of their work.

3. *Chiefs of groups, which are the non-formal units of structural departments of the enterprise (third-level managers)* concentrate their efforts on control and managing of current activities of subordinated laborers, give them the necessary methodological assistance in execution of everyday tasks, control quality of their work and quantity of production they fabricate and develop recommendations on methods of solving of problems arising in carrying out of current work,.

The *principal norms* of work of the enterprise in planning of its current activities are:

a) *Attention to interests of customers*. The principal norm used in it is fabrication of products, which quality would satisfy and even surpass expectations of customers.

b) Leading role of upper management. Administration of the enterprise collects opinions and desires of staff members and develops principal procedures of their satisfying.

c) Maximum involvement of employees as the "basement" of the organization in realization of set policy.

d) Processual approach presumes carrying out of all works centered on fabrication of qualitative products. The processual model of operation includes the work in development and introduction of the optimized business-processes, which executors are all structural departments and functionaries of the enterprise. The fundamental points of control in these activities are quality of used processes and terms of execution of planned works. The processual approach to practical realization of norms of quality systems presumes carrying out of actions as follows:

- identification of resources to be used in the chosen system of management,
- identification of sequence and details of interdependence of processes,

- identification of criteria to be used in work in evaluation of conformity,
- identification of methods of guaranteeing of effectiveness of functioning of introduced processes and control of their realization,
- use of sufficient informative resources in monitoring of processes o operation,
- control and analysis of adequacy of used procedures of management,
- use of corrective and preventive measures.

e) Systemic approach to management. To raise effectiveness of work, the enterprise develops the system of coordination of interrelated processes of its operation.

f) Permanent perfecting of operation. The enterprise traces events of occurrence of problems in its functioning and develops measures, which use would permit to prevent causes of their repeated origination in future.

g) Taking of decisions based on analysis of trustworthy facts obtained in process of inner audits of functioning of quality system.

h) Interrelations with suppliers. The enterprise and its suppliers are the mutually dependent parties. Therefore, their favorable relations assist in rising of capabilities of the manufacturer in fabrication of items of improved quality.

The principal advantage of this work is the permanent control of linkage and coupling of individual processes of manufacturing. The basic points of concept of ***TQM*** are 14 principles formulated the internationally known scientist E. Deming in his book *"Quality, productivity, competitiveness"* published in USA in 1982:

1. *The changeless purpose of the enterprise* should be improving of quality of production it produces because existence of severe competition of producers of analogous products requires of continuous perfecting of style of operation. This work presumes such mode of dispensing of resources, which, the most probable, will not give quick

profit but would guarantee reaching of the long-term advantages in stable producing of qualitative production.

2. *To improve quality of production and services*. It is necessary to introduce the philosophy of inadmissibility of mismatching. The administration must understand the need of continuous introduction of innovations and take leadership in realization of such style of management, which excludes delays, layups, errors, and defects.

3. *To exclude dependence of total control of quality*. It is necessary to demand of suppliers of continuous confirmation of proper quality of materials and component parts used in manufacture and collaborate with them in atmosphere of long-term confidence and mutual understanding, what would result in improvement of quality of operation. To cut expenses coupled with control of quality of each unit of finished production, manufacturers have to introduce statistical methods of its control.

4. *To cease practice of purchasing of the cheapest component parts and raw materials*. The low price must not be the sole criterion in choose of products used in manufacturing, because negative consequences of such practice may reveal later, when their purchaser will be forced to cull defective materials and replace buyers of products produced with their use incongruous articles.

5. *To improve each process*. The administration must continuously improve each aspect of work of the enterprise at each stage of process of manufacturing and post-manufacturing servicing, as well as forecast probability of origination of problems dependent of practice of producing of products of improper quality and make in-time corrective actions but not wait of their origination.

6. *To train all laborers including the administrative persons*. It is necessary to use new methods of training and guarantee acquainting of laborers with all novelties in manufacturing of items of the same destination of use.

7. *To introduce new methods of managing*. The foremen and inspectors must center their attention on helping employees in use of existing equipment the best.

8. *To drive the fear away.* It is necessary to encourage the close bilateral relations of ordinary laborers with their managers in effective collaboration in interests of the enterprise.

9. *To destroy the unnatural barriers between structural units of the enterprise,* which result of aspiring of managers to hide the existing problems.

10. *To cancel use of slogans and appeals.* Some managers do not analyze their own actions and specific conditions of manufacturing and reckon that productivity of labor and quality of production depend of orders they give, hence ignore the fact that the main causes of fabrication of poor-quality production are disadvantages of style of management but not deficiency of qualification and lack of industriousness of their subordinates.

11. *To exclude quantitative norms of output as the sole criterion* of productivity of labor, because results of work of each laborer depend not only of his personal abilities, but mainly of structure of manufacture, working conditions of equipment, quality of used materials etc.

12. *To eliminate barriers, which impede men to be proud of their qualification.* The existence of barriers insuperable for laborers finally leads to extinguishing of their creative abilities. It is necessary therefore to give anyone the possibility to make his own deposit in general business and be proud of personal qualification.

13. *To stimulate interest to education and self-perfection.* The primordial property of men is aspiration to make their work better, and managers must help laborers in realization of their productive abilities.

14. *Clearly identify duties of administration in sphere of assuring of quality.* The routine of work in steady optimization of conditions of operation of the enterprise and betterment of quality of its production depends mainly of decisions taken in the manager's room, therefore, planning of related works cannot be entrusted to subordinates.

The listed postulates compose the interrelated complex, and rejecting of any one will influence negatively on realization of all other constituents of successful operation. It was Deming, who first pointed that *"maximum 6 % of problems of operation are in sphere of responsibility of*

laborers. Instead, 94 % of problems are caused by imperfection of system of management".

Summarizing, one should note that, contrary to the standardized norms of operation, the TQM approaches are flexible and have no elements obligatory for execution. Managers set only principal concepts and ideas put in the base of operation of enterprise, what gives executors freedom in choosing of concrete methods of their realization. The principal TQM concepts differ of those of systems used before, and their comparison is given in Table 6.4:

Table 6.4

Differences in principal concepts of traditional and TQM systems of management

Traditional principles of management	Principles of system of TQM
1	2
Satisfying of current needs of the manufacturer in process of his operation	Satisfying of needs of consumers and the society in whole
Planning and control of quality of production	Planning and control of quality of processes and systems of business operation
Use of correcting actions	Use of preventive measures
Control of quality of production exclusively by the stuff of the department specialized in it	Use of norms of ensuring of quality of production by all laborers of the enterprise
Placing of responsibility for putting on sale of products of proper quality on the personnel of the control department only	Placing of responsibility for putting on sale of products of proper quality on all laborers of the productive and control departments of the businessperson
Elimination of problems of deterioration of quality after they would have been occurred	Regular identifying of reasons of occurrence of chronic problems of production of goods of poor quality and their elimination
Solving of existing problems of operation by each laborer autonomously	Co-ordination of actions of all laborers in solving of current and prospective problems of operation

The TQM principles are character by dynamicity and their use permits to solve the problems of:

1. Achieving of level of quality of production, which guarantees satisfying of demands of both manufacturers and consumers and minimizing of risks in conditions of spending of reasonable expenses.
2. Creation of base of mutual confidence of all persons interested in proper quality of works they execute.
3. Assuring of positive image of the enterprise and recognition of proper quality of its production on markets of goods and services.

6.10 Norms of Protection of Interests of Consumers in Ukraine

The first Soviet public organization, which operated problems of protection of interests of consumers was the *"Club of Consumers"* founded in 1988 incorporated in 1989 in the *Federation of Associations of Consumers of the USSR*, the independent voluntary public community of associations located in different regions of the country. After collapsing of the Soviet Union, each new independent country including Ukraine founded their own national associations by protection of interests of consumers, which principal goal is forcing of manufacturers and suppliers to compensate losses resulted of use of their production (traumas, damage of property etc.). This event brings the serious drive for manufacturers to raise the level of quality of production they propose, and the principal instruments used in it are:

- introduction of effective quality systems,
- normalization of procedures of testing that have the purpose to demonstrate interested parties the guiltlessness of manufacturer (supplier) in cases of worsening of quality of production they sold,
- development of norms of identification and sending back of poor-quality production,
- refuse in unfair advertising of production, which may mislead consumers in expectations on its quality.

The State protects rights of consumers legally and regulates their relations with manufacturers. For instance, Article 42 of the Constitution

of Ukraine declares: *"The State protects rights of consumers, controls quality and safety of production and all types of services and works, as well as assists in operation of public organizations of consumers"*, and its Article 50 proclaims: *"Everybody has the right on life in environment safe for his life and health, as well as on compensation of damages resulted of violation of its normal conditions. Everybody has the right of free access to of information on conditions of environment, quality of foods and everyday-use goods and its dissemination"*. The practice of protection of interests of consumers is understood as placing of responsibility for poor quality of goods (services) on their manufacturers (suppliers, sellers). To implement said norms, Ukraine approves the laws as follows:

- Law of Ukraine of 24.02.1994 4005-XII "On sanitary and epidemiological welfare of population",
- Law of Ukraine of 17.05.2001 # 2406-III "On attestation of conformity",
- Law of Ukraine of 17.05.2001 # 2407-III "On accreditation of conformity assessment bodies",
- Law of Ukraine of 23.12.1997 # 771/97-VR "On safety and quality of foodstuffs",
- Law of Ukraine of 15.05.2014 # 1315-VII "On standardization",
- Law of Ukraine of 01.12.2005 # 3161-IV "On protection of interests of consumers" and others.

The brief content of rights, which residents of Ukraine get by these norms in purchasing, ordering and use of production for their own needs is:

Right of guaranteed protection of interests. The State gives her citizens the possibilities of obtaining of knowledge and qualification necessary for taking of independent decisions in purchasing of qualitative production or receiving it by any other legal method.

Right on safety of production bought in net of licensed trade institutions is realized as follows:

- the products (works, services) bought by citizens must be safe for their life, health, property and conditions of environment in use in usual norms of consumption,
- the manufacturer (supplier, seller) has to inform consumers on possible risks and recommend procedures of safe use of his products during the guaranteed term of their goodness at the normalized conditions and mark them by related symbols of established design,
- the consumables, which require of special treatment must be safe in use, storage, transporting and utilization by the recommended procedures,
- it is prohibited to sell goods (carry out works, give services) to be certified in Ukraine in obligatory manner but not certified yet,
- the manufacturer (executor, seller) must cease fabrication (realization) of his products in existence of risks of pollution of environment and ascertaining of their dangerousness for life, health and property of men till the causes of origination of identified hazards would be eliminated. If necessary, he has to withdraw the items in question from circulation, take them aside of consumers and reimburse the suffered persons losses caused in their use,
- developing the novel item, the developer has to apply the attributed documentation to the specialized body to carry out the State expertise of its safety.

Right on information on consumables (works, services) is realized in use of norms as follows:

- information on goods (works, services) must be accessible, reliable and referred to the attributed normative documents. If the object of regulation is the foodstuff, the supplementing and advertizing materials has to contain information on its normalized composition, caloricity and factual content of compounds harmful for health (if present), as well as the list of ingredients present in the product, date of its producing; guarantees of manufacturer; procedures of effective use of goods and the guaranteed terms of

their appropriateness; recommended actions to be done after expiring of the guaranteed term of their storage and probable consequences of nonobservance of given recommendations. In potential danger of the product, the supplementing materials have to contain information on contra-indications of their use. The supplementing documents must contain also information on juridical address of the manufacturer and factual place of location of place of fabrication of sold items, as well as information on persons responsible for taking of complaints and carrying out of their after-sales service and maintenance,

- the goods (works, services) certified in obligatory manner have to be supplemented by the certificate of their quality,
- the businessmen have to inform users of their products on numbers of licenses on right of their fabrication and names of bodies, which authorized them on this kind work,
- if the proposed goods (works, services) may cause any damage for life, health and property of consumers, they have the right to return the defective products and demand of compensation of losses caused by the guilt party.

Right on obtaining of production of proper quality: The consumer has rights:

- to demand of seller (manufacturer, executor) of truthful information on quality of purchased commodities (executed works, given services) and conformance of their properties to norms of related documents, clauses of contracts etc.,
- to demand of seller (manufacturer, executor) of elimination of defects found during the period of six months after purchasing of products they proposed (or during three years in relation to immovables, which have no the guaranteed terms of usefulness),
- to demand of seller or manufacturer of free removal of found defects and/or falsifications of consumables they bought, or compensation of means spent on their elimination, or replacement of defective goods on qualitative ones, or abating of prices of bought goods, or breaking of contract and compensation of losses,

- to take part in development of normative documents on consumables (works, services) he is interested to obtain,
- to take part in work in control of quality of goods personally or use in it services of his personal representative(s),
- to demand breaking of contract and compensation of losses in founding of essential differing of terms of execution of works conditioned in signing of contracts or identifying of weaknesses of proposed goods (services),
- to change the nonfood goods of poor quality for the analogous ones at the place of their buying during 14 days after the date of their purchasing on condition of their nonuse, preservation of initial image and consumer' properties, presence of noninjured seals, labels, as well as in presenting of the cash bill and/or other documents received in purchasing together with the items in question. The exceptions are goods named by Council of Ministers in Ukraine in the special list of consumables as such that cannot be exchanged,
- in absence of the same goods for the moment of application, the buyer has the right to take any other accessible goods instead in making of related re-calculation, or return the spent means, or replace the defective good on the suitable analogous one just after its first receiving by their seller.

Material responsibility for damage caused by goods (works, services) of poor quality:

- the manufacturer (executor) carries responsibility for damage caused for the life, health and property of consumers who used materials, equipment, tools and other means used in producing of goods (carrying out of works, giving of services), and has to compensate him the losses caused by the sold production, which has any defects, if the legislation in force does not foresees more severe punishment,
- the grade of compensation of caused damage defines the suffered consumer themselves, whether he had or not the contractual relations with the manufacturer (executor, seller). He preserves

this right during the normalized term of usefulness of good(s) he bought. In absence of such term, this one is ten years after fabrication of the defective item.

The judicial protection of consumers: Satisfying claims of the consumer, the court solves by his choose (in cases foreseen by legislation) also the problems of compensation of moral (nonmaterial) damage by suits given at place of his habitation, or place of registration of manufacturer, or place of causing of damage, or place of carrying out of contractual works that presuppose use of the sold item(s). In cases of identification of violation of his rights, the suffered person should not pay the State fee for work of bodies of legal power.

Right of consumer on association in public organizations. To protect their rights and interests, consumers may associate voluntarily in public organizations, which work should support the State.

6.11 Ukrainian Public Quality Organizations

The main Ukrainian players in sphere of protection of rights of consumers listed in Chapter 6.10 are the public organizations as follows: *Ukrainian Quality Association (UQA – Українська асоціація якості, УАЯ)*, *Ukrainian Company by Quality (UCQ – Українське товариство з якості, УТЯ)*, *Academy of Quality (AQ – Академія якості, АЯ)*, *Ukrainian International Fund of Quality (UIFQ – Український міжнародний фонд якості, УМФЯ)* and other specialized associations and individual enterprises. The most influential of these ones are:

Ukrainian Quality Association founded in 1989 unifies professionals by quality that work in all regions of the country and represents interests of Ukraine in the European Quality Association (EQA) since March 1996, when Ukraine was recognized at 90th session of EQA General Assembly as its full member. The UQA structure includes more of 260 collective and 1000 individual members. The UQA structure includes also such collective members as the Association of Testing Centers of Ukraine, Association of Auditors of Quality, Association of Directors by Quality and its regional branch offices

founded in provincial centers located in all regions of Ukraine. Its collective members are such organizations as the Ukrainian Union of Industrialists and Businessmen, institutes of National Academy of Sciences, leading enterprises and organizations, which represent practically all branches of industry. The individual UQA members are scientists, directors of enterprises, presidents of associations and specialists in quality management who reside in Ukraine and abroad.

The basic structures, which operate under the UQA aegis are technical committees of:

- quality of environment and conditions of health of men,
- quality of foodstuffs and tap water,
- quality in metallurgy,
- quality and certification in chemical engineering,
- quality and certification in chemical and petrochemical industries,
- quality in modern material science,
- quality in instrument-making industry,
- quality and certification in aviation engineering,
- quality of projecting.

The leading UQA structure is its Intersectoral center of quality of *"Prirost" ("Increment")* founded in 1991 on base of the Institute of Cybernetics of National Academy of Sciences of Ukraine. Its basic structural departments are:

- center of accreditation and organization of work in certification of production,
- center of certification of quality systems,
- training center,
- center of informative services,
- center of development of principles of assuring of quality.

The principal purpose of the UQA operation is forming of public opinion and development of fundamental principles and methods of guaranteeing and betterment of quality of production and services in Ukraine. Doing so, the UQA summarizes the advanced global experience in sphere of assurance of quality, disseminates the collected information among interested parties and gives them the necessary scientific and

technical assistance in rising of their competitiveness in domestic and foreign markets.

Taking into consideration the especial importance of problems of quality, the European Commission convenes since 1995 the annual European week of quality, which principal goal is rising of level of understanding by citizens of importance of work in quality management. Following this practice, UQA carries out the analogous seminars in Ukraine. The principal problems to study are novel methods of renewal and integration of Ukrainian industry in European and global economical structures and improvement of conditions of living in Ukraine.

Ukrainian International Quality Fund located in Lviv is the independent public organization founded in 1993 by the Ukrainian Quality Association, Ukrainian Confederacy of Industrialists and Businessmen, Ukrainian Association of Consumers and others. The leading Ukrainian persons who take part in its work are chiefs of State institutions and public and commercial structures and qualified scientists and industrialists of various profiles of activity. The Fund assists in cooperation and collaboration of Ukrainian enterprises and organizations of businessmen with international organizations and firms and State and public organizations of various countries operating standardization, certification and quality assurance. The principal UIQF task is assisting in integration of Ukrainian business structures in global economy, creation of mutually beneficial conditions of foreign investments in Ukrainian economy, and assisting foreign businessmen in their operation in Ukraine.

Ukrainian Company by Quality founded in 2000 works on consolidation of activities in assuring of quality of operation of industrial, advice, training and other profile organizations of all forms of property. UCQ has more of 20 regional branch offices in regions and cities of Ukraine, which goal is introduction of advanced principles of assurance of quality in Ukraine realized in processes of consulting, carrying out of contests by quality and giving of scientific, technical, methodological, informational and financial assistance the interested parties in wish to

improve quality of their operation. The UCQ working structures are its technical commissions, which operate by directions as follows:

- general problems of quality,
- processes and procedures of certification,
- dissemination of profile information and interconnection with organizations specialized in quality assurance ,
- legal and normative activities,
- training of specialists,
- consultative assistance,
- development of norms of quality in projecting of objects of town-planning, electric and nuclear power engineering etc.

6.12 Systems of Environmental Management

The human society understands in progress of industry the more that rising of level of culture of manufacturing and ensuring of safety of business activities are insufficient for creation of healthy state of sphere of habitat, including the bioproductive soils, water, minerals and sources of energy (oil, gas, coal, turf and uranium).

> *Natural environment means the complex of natural objects minimally altered under the influence of anthropogenic factors but existing under their continuous direct or mediate pressure*

To guarantee the comfortable conditions of living, the humanity has to preserve the environmentally favorable conditions of nature, what became the constituent element of policy of ensuring of national safety. The work in solving of this problem requires of persons of economy to minimize the probability of origination of delayed effects of worsening of state of health of living and future generations. To prevent origination of risks and hazards specific to degradation of environment, the society has to operate in observance of two basic principles of management as follows:

- *principle of steady development*: optimization of conditions of living in process of industrial progress of the society has to guarantee satisfying of needs of men the most, but must not threat

to capability of future generations to use natural resources because of their exhausting,

- *principle of raising of purity of manufacture* consists in use of complex of prophylactic measures in spheres of material production and servicing.

The constituent principle of this system should be:

- understanding of those that mankind is the integral part of nature, therefore the conditions of life of men depend greatly of state of environment,
- understanding of impossibility of existence of living beings in absence of adequate conditions of natural systems,
- understanding of finiteness of natural resources of the planet,
- voluntary limitation of amount of used resources of nature to avoid their irreversible degradation,
- limiting (if possible) of count of mankind, therefore, decreasing of its negative pressure on conditions of environment at local, regional and global levels,
- use of environmentally friendly technologies,
- recognition of norm of deliberate sufficiency in limiting of variety of goods necessary for vital activities.

It became clear soon the necessity of expanding of practice of development and certification of environmentally friendly technologies, hence introduction of principles of so-called *"environmental management"* character by minimum influence of men on conditions of nature and continuous control of hazards and risks arising in their business operation.

> *Risk in use of natural resources means the probability of emerge of unfavorable changes of conditions of environment (intentional or accidental, gradual or catastrophic), which result of anthropogenic factors of influence*

Observance of norms of protection of nature in business operation is in many cases the crucial condition of contracting of persons of economy with their partners. Operating in this sphere, the EU countries legalized practices of *"ecologized"* and *"environmental"* management.

The *ecologized* type of management does not require of serious amendments in used systems of manufacture and other type business activities and presumes adaptation of norms of their operation to conditions of modern policy of rational use and saving of natural resources. This kind activity may be considered as the conservative type of management, otherwise, operation on the first level of environmental safety, which main principles are:

- economy in use of natural resources and minimization of quantity of generated wastes,
- systematical evaluation of grade of environmental risks and guaranteeing of safe conditions of living,
- regular informing of neighboring population on character of activities of the enterprise and their influence on conditions of surrounding nature.

The *environmental* management is the more advanced system, which introduction presumes participation of local businesspersons in forming by the State of territorial economical complexes character by optimum proportion of environmental and economical interests of local persons of economy and inhabitants of neighboring region. Meantime, there exist two concepts of environmental operation, which have some different senses but used often incongruously. These are the notions of environmental administration and environmental management, which are used in meanings as follows:

- *Environmental administration* means operation of the State administration bodies and persons of economy in observance of obligatory norms of environmental legislation, development and realization of projects and programs directed on protection of natural conditions.
- *Environmental management* means the economic activities of persons of economy, which has the purpose of solving of existing problems in conditions of work in protection of environment accomplished by principle of *"three P" – permanent perfecting of processes.*

It is reckoned presently that activities in environmental management are the indivisible part of work of businesspersons in ensuring of proper quality of production and favorable conditions of labor, which character criterions are:

- close interrelationship of economical interests of manufacturing and ecological constituents of productive work,
- systemic revision and optimization of norms of economic policy,
- involvement of all employees in work in protection of environment,
- primacy of taking into consideration of ecological problems in everyday operation,
- charge for committing of damage for environment, which results of improper business operation.

The principal tasks to be observed in it are:

- steady decreasing of quantity of used materials and consumed energy,
- use of raw materials and auxiliaries minimally harmful for health of live beings and conditions of nature,
- stimulation of activities of the enterprise in protection of environment and creation of its "green" image,
- assuring of environmental friendliness of the enterprise,
- minimizing of negative anthropogenic influence on environment in processes of fabrication, processing and utilization of production.

Both type activities are the constituent parts of general system of management having to assist in stable progress of the enterprise in reaching of environmental parameters of its operation favorable for life. For the present, there were developed some concepts of environmental management, and the principal ones are:

- prevention of events of catastrophic character including the work in refusing of fabrication of hazardous items and/or closing of manufactures, which operation may worse conditions of surrounding nature,

- minimizing of influence of prospective effects on natural conditions of probable extraordinary situations (construction of protective erections, underground infrastructures and dams, timely evacuation of population etc.),
- alleviation of consequences of catastrophes and use of stabilizing compensative measures.

The procedures used in Europe in work in protection of nature and pinning of responsibility on guilt parties for infringement of its normal conditions regulate norms of the EU Council Directive of 21.04.2004 # 2004/35/CE *"On environmental liability with regard to the prevention and remedying of environmental damage"*. Under its terms, the environmental damage is:

- direct or indirect damage to aquatic environment covered by norms of the Community *water management legislation,*
- direct or indirect damage to species and natural habitats protected at the Community level by the 1979 *"Birds"* Directive or by the 1992 *"Habitats"* Directive;
- direct or indirect contamination of the land, which creates the significant risk to human health.

The criterion taken into consideration in evaluation of grade of inflicted damage is also the level of blowout of wastes into the atmosphere because this event leads inevitably to pollution of waters, earth and the natural surrounding as a whole.

There exist two principal schemes of putting of liability on persons of economy for the environmental damage they cause. The first scheme to be licensed by norms of *integrated pollution prevention and control* is applied to the really or potentially dangerous occupational activities accomplished mainly in agricultural or industrial spheres. The hazards to be controlled are discharge of heavy metals into water and air environments, emission of wastes from installations, which produce dangerous and poisonous chemical substances, genetically modified organisms and micro-organisms, as well as the waste management activities (including landfills and incinerators). The operator may be held responsible under this scheme, even if he was not at fault.

The second liability scheme is applied to all occupational activities other than the works listed above. The punishing measures for violation of these norms may be implemented in cases as follows: 1) in existence of damage or existence of the imminent threat of damage for species and/or natural habitats protected by the Community legislation, 2) in cases of causing of damage or in existence of threat of inflicting of damage resulting of armed conflict, natural disaster etc., 3) in accomplishing of activities covered by norms of the Treaty on establishing of the European Atomic Energy Community, 4) in realization of national defense or international security preventive measures, 5) in carrying out of works listed in related international conventions, 6) in occurrence of natural phenomenon of extraordinary, unavoidable and insuperable character. The norms of Directive of 2004/35/CE do not presume covering of losses of natural persons, which result of damage of environmental conditions because its fundamental principle is putting of financial responsibility on operators, whose activities caused or may cause the damage for environment and health of the community as a whole but not its individuals. The basic notions used in evaluation of grade of such kind risks are:

Damage for environment:

a) damage for conditions of nature and its protected beings, which threatens to the state of maintaining or the process conservation of normal conditions of their existence

б) damage for waters means any perturbation, which has the considerable influence on ecological, chemical and/or other status and/or ecological potential of nature

Status of conservation:

a) in relation of conditions of environment means minimizing of grade of sum of the long-term influences of unfavorable factors on conditions of surrounding nature,

б) in relation to living beings means the sum of influences on conditions of their long-term existence and reproduction

Preventive actions means any activities in prevention or minimization of grade of influence carried out in response on the

event or action, which cause the imminent threat of inflicting of damage to conditions of environment

In existence of the imminent threat of environmental damage, the competent authority of each EU member-country may demand of potential polluter to take the necessary preventive actions.

Preventive actions means any activities in prevention or minimization of grade of negative influence of unfavorable factors carried out in response on the event or action, which cause the imminent threat of inflicting of damage to conditions of environment

In case of inflicting of environmental damage, the competent authority may demand of the guilt businessperson to take the necessary restorative actions, or organize carrying out of necessary restorative actions by other persons of economy and demand of him of recovering of spent costs, as well as assign priorities in succession of their execution. Dependently of its type, the environmental damage may be remedied in different ways:

- in damaging of state of land, the damaged soils must be decontaminated until there it would be absent any serious risk of their negative influence on human health,
- in damage for water, or protected species, or natural habitats, the damaged objects must be restored to the state, which existed before its inflicting, otherwise replaced by identical, similar or equivalent natural resources either at the site of the incident or at an alternative place.

If the market operator causes any type damage for the environment, he has to inform on this event the competent bodies of his country immediately and take all necessary measures by control, restriction, elimination and other type works by diminishing of spreading of its consequences. In expansion of such negative influences on territories of other countries, the suffering states have to combine their efforts with the State, which inflicted the damage and organize exchange by related information, as well as inform third countries on hazards, which may influence on conditions of nature in their territories.

The enterprises, which introduced systems of environmental management, obtain the advantages in their business operation as follows:

- betterment of conditions of collaboration with suppliers of raw and auxiliary materials and consumers of their production,
- obtaining of right on concluding of cheaper insurance agreements,
- reaching of favorable taxation,
- decreasing of quantity of incidents in manufacture, which may cause their juridical responsibility.

As a result, the more organizations show their interest in refinement of systems of their operation and introduction of systems of environmental management.

6.13 International Standards of Environmental Management

The work in protection of environment and optimization of structure of use of natural resources is one of crucial tasks of global economy because atmospheric air, water of rivers and oceans, animals and birds, do not know state borders. The intense interest to this problem was initiated at 1972 UN Stockholm conference by protection of natural conditions, which accepted the document of *"The UN Program of Work by Problems of Protection of Environment"*. To harmonize the routine of mutual work in it, the Organization of United Nations gathered in Rio-de-Janeiro in June 1992 the Conference by problems of protection of environment, where representatives of 179 countries approved the document of *"Program of work in XXI century"*, which principal purpose is development of healthy economies that operate in all countries in conditions of preservation of high quality of environment. Approval of these documents progressed greatly the work in development of norms of environmental management and optimization of quantitative parameters of such activities (quantity of generated wastes, permissible concentrations of hazardous compounds etc.).

System of environmental management is the constituent part of the system of management, which includes

work of the enterprise in introduction in practice of its operation of elements of environmental policy

The first known normative document of such kind specialization was the British standard BS 7750 *"British Standard on Environmental Management Systems"* published in 1992. The initiator of its development was not the British State, but the group of industrialists doing so in response on introduction of severe requirements of legislation to norms of protection of nature. The specialized organizations of various countries developed their own systems of environmental management as well, but their basic provisions and norms of realization differed of one other, as a rule. This event became the main cause of origination of need in development of document of universal character, and the party responsible for this work became the ISO Technical committee TC 207 *"Environmental management"*.

The first such documents coded as the ISO standards of 14000 series validated in 1996 and did not contain any norm of "absolute character" in limiting of grade of influence of activities of the enterprise on natural conditions. However, use of their norms permitted to modernize principles of its environmental policy. The fundamental criteria taken into consideration in introduction of norms of said standards are not the permissible quantitative criteria of pollution of nature (capacity of wastes, volumes of sewage, maximum permissible concentrations of pollutants), and not criteria of ecological compatibility of existing technologies with the newly developed regulative norms, but procedures of operation in conditions of steady decreasing of pressure of results of activities of the enterprise on natural conditions. The list of the most significant of this series standards lists the Table 6.5:

Table 6.5

International environmental standards

Standards establishing principles of environmental management	
ISO 14001	Environmental management systems – Specifications with guidance for use
ISO 14004	Environmental management systems – General guidelines on principles, systems and support techniques
ISO 14014	Environmental management systems – Initial Reviews
Instruments of environmental control	
ISO 14010	Environmental auditing – General principles of environmental auditing
ISO 14011	Environmental auditing – Auditing of environmental management systems
ISO 14012	Environmental auditing – Qualification criteria for environmental auditors
ISO 14015	Environmental site assessments
Standards oriented on environmental methods of manufacture	
ISO 14020	Environmental labeling – Basic principles of environmental labeling
ISO 14021	Environmental labeling – Self-declaration – Environmental claims – Terms and definitions
ISO 14024	Environmental labeling – Practitioner programs – Guiding principles, practices and certification procedures of multiple criteria (type 1)
ISO/TR 14025	Environmental labeling and declarations – Environmental declarations of 3rd type
Evaluation of environmental effectiveness	
ISO 14031	Environmental Performance Evaluation
ISO/TR 14032	Environmental management – Examples of environmental performance evaluation
Environmental assessment of life cycle of production and services	
ISO 14040	Life-cycle assessment – General principles and practices
ISO 14041	Life-cycle assessment – Goal and definition/scope and inventory assessment

ISO 14042	Life-cycle assessment – Impact assessment
ISO 14043	Life-cycle assessment – Improvement assessment
ISO/TR 14047	Environmental management – Life-cycle assessment – Illustrative examples on how to apply ISO 14044 to impact assessment situations
ISO 14048	Environmental management – Life-cycle assessment – Data documentation format statue
ISO/TR 14049	Environmental management – Life-cycle assessment – Management of environment – Examples of use of standard of ISO 14041 in determining of objectives, sphere of investigation, and inventory analysis
ISO 14050	Terms and definitions
ISO 14060	Guide for the inclusion of environmental aspects in product standards
ISO/TR 14062	Environmental management – Integral environmental aspects into product design and development
ISO 14063	Environmental management – Environmental communication – Guidelines and examples

The basic standard of this series documents is ISO 14001, the only normative document used in certification of systems of environmental management. The principal advantages the enterprise obtains in introduction of its norms are:

- decreasing of quantities of used energy and materials
- minimization of negative influence of results of its activities on conditions of nature,
- cutting of expenses spent on processing and utilization of wastes,
- improving of its image as the certified party among the State regulation bodies, other persons of economy and consumers,
- simplifying of procedures of contracting with foreign partners.

The standard ISO 14001 contains many norms similar or even identical with those of standard ISO 9001. Therefore, norms of both ones may be introduced in parallel as instruments of demonstration of capability of the enterprise to operate properly in conditions of friendliness for the surrounding nature. Introduction of norms of ISO

14000 standards in EU countries permitted to legalize norms of "green" operations the constitutive instruments of tender procurements. Ukraine is the competent participant of global processes of protection of environment as well. To raise effectiveness of this work and optimize structure of national system of standardization, the Ministry of Ecology and Natural Resources of Ukraine initiated founding in 1993 of the Technical committee of Derzhstandart of Ukraine TK 82 *"Protection of conditions of nature"*.

Observance on environmental norms becomes one of the most significant factors of "survival" of the enterprise in the unified European market, because work in development, introduction and certification of systems of protection of nature is now one of the most important criteria of goodness of its business operation.

6.14 Environmental Certification and Labeling

The essence of standards of ISO 14000 series is normalizing of procedures of work of enterprises in sphere of environmental management and the basic doings in it are:

- establishing of norms of work in protection of environment. The interested party has to develop the special document of *"Environmental policy"*, which should declare the basic principles of its activities in preservation and continual betterment of conditions of nature,
- development of program of environmental management and procedures of work in extreme situations. Identification of methods and terms of realization of set purposes,
- steady work in identification of actions potentially harmful for environment and development of procedures of liquidation of their consequences. Taking into consideration of interests of legal persons and individuals, whose interests fall under their influence,
- continuous monitoring or control of parameters of operations, which might influence sufficiently on the surrounding conditions. Introduction of norms of audit of used system of protection of nature,

- periodical analysis of functioning of system of environmental management by administration of the enterprise and introduction of necessary amendments in its environmental policy.

As provide norms of standard ISO 14001, the process of development and introduction of procedures of environmental management includes the work by stages as follows:

1. *Preliminary analysis of conditions of manufacture.* Identification of existing environmental conditions of operation of the enterprise and analysis of elements of its operation in spheres, which may influence on conditions of surrounding nature.

2. *Formulation of principles of environmental policy.*

3. *Establishing of duties and development of structure of responsibilities* of persons engaged in work in development of principles of environmental policy of the enterprise. Appointing of person(s) responsible for supervision on processes of realization of newly established norms.

4. *Evaluation of grade of influence of results of economical activities on environmental conditions.* Characterization of quantity of emitted gases and solid and liquid wastes. Planning of methods of their disposal, treating (if possible) and utilization.

5. *Identification of processes, which influence on environmental conditions the most, development of system of their control.*

6. *Development of system of environmental management.*

7. *Introduction of system of registration* of environmental doings and use of procedures of identification and minimization of influence of consequences of found infringements and violations of established norms of operation on conditions of nature.

8. *Betterment of environmental conditions* in observance of grade of potential influence of manufactured production on conditions of nature during the whole term of its producing and staying at the enterprise.

9. *Introduction of system of inner audit,* which foresees among others the possibility of control of third party.

The work in environmental certification based on norms of EU Directive 92/880/EU *"On environmental signs"* and British standard BS

7750 *"System of environmental management"* was began in 1992. However, just after validation of standard ISO 14001, the bodies specialized in environmental certification began to use its norms as the only base and certified for this time more of 110,000 enterprises and organizations worldwide. The global leaders in this sphere are Japan, China, Spain, United Kingdom, Italy, USA and Germany. In Eastern Europe, the biggest quantity of systems of environmental management certified Czech Republic, Hungary, Poland, Romania, and Slovenia.

The persons of economy obtain in introduction of norms of environmental standards the number of economical benefits. For the first, they decrease the kevel of risks of applying of fines because they cut quantities of used consumables, hence quantity of wastes generates in their operation. For the second, enterprises may certify their environmental systems domestically and need not attest them repeatedly in any other country for the standard ISO 14001 used in formal certification is the norm of category recognized worldwide. For the third, they normalize their relations with the local natural persons, who raise the level of their consciousness continuously and may demand of introduction of environment management systems in practice of work of neighboring enterprises.

Despite voluntariness of use of provisions of this standard, almost all big foreign companies have the intention to certify their systems of environmental management by its norms and do it in 10 years. The predominant motive in it is that this became the one of obligatory norms of marketing, especially for companies that have intentions to operate in the unified European market.

The right on carrying out of this work obtain the third-party bodies accredited by norms of the document of ISO/IEC Guide 66:2003 *"General Requirements for Bodies Operating Assessment and Certification/Registration of Environmental Management Systems"*. To attest the environmental friendliness of work of the applicant, the accrediting person appoints the specialized group of auditors, whose work includes two stages:

- works by stage 1 are centered on planning of process of auditing and analysis of documents, which describe environmental conditions at place of location of the enterprise and the business-processes it realized,
- works by stage 2 are carried out directly at the enterprise and represent in fact the certification proper.

The *objects of environmental certification in Ukraine are:*

- systems of environmental management,
- technologies potentially harmful for conditions of environment,
- exported and imported production harmful for environment and industrial wastes generated in their fabrication,
- procedures of treatment and reprocessing of wastes.

As to Ukraine, the three principal directions of this work in our country are:

1. *In sphere of functioning of national economic complex:*
   - control of observance of norms of protection of environment in processes of operation of native businesspersons,
   - introduction of environmentally friendly technologies,
   - creation of conditions of assurance of environmental safety during the whole life cycle of production used in the country,
   - observance of norms of environmental safety and prevention of pollution of nature in placing, processing, transporting, disposal and annihilation of wastes,
   - prevention of importation in Ukraine of environmentally dangerous products and wastes.
2. *In sphere of integration of Ukraine in the European Union:*
   - rising of competitiveness of "green" production of domestic origin,
   - granting the certificate of environmental conformity of status of document, which indicates observance by its owner of norms of environmental legislation in force.
3. *In sphere of international collaboration in sphere of protection of nature:*

- cooperation in work with foreign associates in forming of global mechanisms of protection of environment,
- unambiguous guaranteeing of observance of provisions of international treaties, conventions and agreements of environmental profile,
- steady control of trans-boundary movement of pollutants and dangerous wastes.

The International Organization for Standardization and the World Trade Organization introduced also the program of voluntary environmental certification and labeling. Its principal purpose is identification of items character by minimum negative influence on conditions of nature. The used methods of witnessing of environmental friendliness of object of certification have the sole purpose: *"to assist in stimulation of demand for goods and services character by minimal negative influence on environment"*. Their basic norms are giving of respective information in textual documents, technical bulletins, circulars etc. and placing of sign of established form onto the certified item or its packing. The signs used in marking of packs are of three types:

- signs, which appeal to protect conditions of environment,
- signs used in witnessing of environmental friendliness of items of certified quality,
- signs, which indicate the potential hazard of marked items for conditions of nature.

The International Organization for Standardization and World Trade Organization state that all types of environmental marking are of voluntary character. Therefore, its principal purpose is identification of items among the whole set of similar products that are character by minimum negative influence on state of environment.

The concrete criteria of environmental friendliness and rules of use of symbols of environmental purity develops the *Global Ecolabelling Network (GEN)* – the unprofitable association of independent specialized bodies operating certification of activities of legal persons, which work on improvement of conditions of environment. In 2013, the GEN members were Australia, Brazil, Canada, Croatia, Czechia, Denmark,

Finland, Germany, Hong Kong, India, Indonesia, New Zealand, Norway, People's Republic of China, Philippines, Republic of China, Republic of Korea, Russian Federation, Singapore, Sweden, Thailand, Ukraine, USA, Japan and European Union (as her collective member). The principal directions of GEN operation are:

- assisting in development of programs of environmental labeling to be used universally,
- informational assistance in introduction of programs of ecolabelling and harmonization of criteria of work in evaluation of conditions of environment,
- participation in programs of profile international organizations,
- conducting of international seminars and trainings of GEN members.

The Network member-countries developed for the present, about of 1,400 documents, which established the environmental criteria of quality of more of 200 types of goods used in certification of more of 120,000 kinds of products.

Ukraine joined GEN in 2004 and is represented in it by her national public organization of *"Live Planet"*, which operates under the aegis of Ministry of Ecology and Natural Resources of Ukraine. In 2011, Ukraine legalized the CEN program of confidence, which foresees recognition by the Network member-countries of results of attestation of its programs of ecolabelling by the mutually recognized norms and obtained the certificate of recognition of operation by the program of "GENICES". Therefore, Ukrainian manufacturers may sell on global markets by the simplified procedures their products attested by the "Live Planet" functionaries.

To identify items, which quality conforms to criteria of ecological purity, Ukraine registered 8th of October 2004 at the official annual meeting of GEN member-countries in Tokyo her National Program of Ecolabelling and the national ecolabel of *"Environmentally pure and safe"* (*"Green crane"* – Figure 6.4*)* to be used in marking of goods attested by norms of standard of ISO 14001 *"Environmental management systems – Specifications with guidance for use":*

Fig. 6.4 Ukrainian national ecolabel

Attesting the environmental purity of products, the Ukrainian business persons use the norms of the set of international standards of ISO 14000 series, especially of the standard of ISO 14020 *"Environmental labeling – Basic principles of environmental labeling"* and a number of normative documents, which specify norms of work in observance of criteria of environmental purity, which basic concepts are:

> *Environmental declaration means the statement, which indicates the environmental characteristics of products of attested quality*
>
> *Environmentally pure product means the certified product of uppermost quality supplemented by the respective environmental declaration*

The ISO 14000 series standards do not fix any restriction in choose of category of products, goods and services, which may be marked by ecological marks, which are of three basic types.

The norms of *environmental declaring and labeling of the first type* regulate the provisions of standard of ISO 14024 *"Environmental labeling – Practitioner programs – Guiding principles, practices and certification procedures of multiple criteria (type 1)"*. This type marking witnesses the fact of minimal influence on conditions of environment of production marked by the sign of the established design placed on base of the right given by the license issued by the third party bodies specialized in environmental certification. Some of generally known signs of this category ecolabelling are (Figure 6.5):

E

F

G

H

Fig. 6.5 Signs of environmental purity of some countries
A – "Daisy" – sign used by EU countries, B – "Scandinavian swan" – sign used by Scandinavian countries (Sweden, Norway, Finland, Iceland), C – "Blue angel" – sign of environmental purity used in Germany, D – "Ecosign" of Japan, E – "Green seal" (USA), F – sign of environmental purity used in People's republic of China, G – sign used in Republic of Korea, H – environmental sign of Czech republic

The conditions of placing of such kind marks are:

- proving of environmentally friendly norms of business operation,
- carrying out of environmental certification of processes of fabrication of products to be labeled.

The certifying body carries responsibility for objectivity of its work in control of observance by the certified party of criteria used in process of its attestation.

The procedures of *environmental declaring and marking of the second type* regulate the norms of standard ISO 14021 *"Environmental labeling – Self-declaration – Environmental claims – Terms and definitions"*:

> *Environmental self-declaration – means the assertion of the manufacturer, importer, distributor, retail trader or any other legal person on environmental purity of the marked product they propose issued in absence of environmental certification by the third party person of process of its fabrication*

The inscriptions normalized by the standard of ISO 14021 used the most often are: *"capable to decomposition", "product of prolonged term of use", "recuperated energy", "suitable for reprocessing", "contains reprocessed materials", "decreased use of energy", "decreased use of water", "low-wasted"* and some other. The declarations of type of *"free of ..."* the person may use only if the content

of indicated harmful substance(s) is less of the threshold level of sensitivity of the attested method(s) of its (their) determination.

The Figure 6.6 below shows the graphical symbols used usually together with documents, which declare the possibility of reprocessing of the marked item or the fact of use in its fabrication of reprocessed materials:

A *B*

Fig. 6.6 ***Signs that indicate the possibility of reprocessing of material of the item or presence of reprocessed components in it: A – the product may be reprocessed, B – the product contains the reprocessed materials***

The applicant carries the full responsibility for correctness of his environmental declaration and giving the interested parties of data necessary for control of its trustworthiness. The character peculiarities of this type marking are:

- voluntary use of symbols in process of environmental self-declaration,
- simplicity and intelligibility of symbols of environmental purity,
- differing of environmental symbols of other type marks.

The rules of environmental labeling of the second type restrain also the range of use of certain declarations, which have the illegible sense and indicate some criterions of environmental purity and/or environmental safety of products. The manufacturers/sellers/suppliers have to avoid of using of such formulations as *"favorable for ozone", "green", "favorable for nature", "environmentally favorable", "non-polluting"* etc.

Both type marking relate to processes of indication of environmental purity of products but not of processes of their fabrication, and do not witness the fact of certification of systems of environmental management by parties that propose the marked product. Moreover, some of signs of this category are sometimes illusory and may mislead consumers in their

believing of reality of certification of environmental purity of marked products (Figure 6.7):

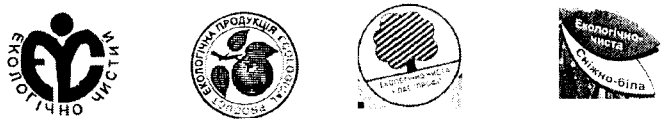


Fig. 6.7 Examples of improper use of signs of environmental marking of second type

Such kind declarations are given usually in absence of certification of ecological purity of marked products, therefore use of expressions of type of *"environmentally pure"* is ungrounded in most cases. Rather they witness the wish of manufacturers to raise competitiveness of their production.

Taking into consideration the collected experience of use of environmental marking of the second type, CEN and ISO established the rules of use of such kind signs, and allotted three aspects of regulation normalized by provisions of standards of ISO 14021 (rules of use of terms of type of *"may be recycled"* on labels/supplementing documents), ISO 14022 (rules of use of symbols of recycling on labels and in advertising materials), and ISO 14023 (procedures of identification and verification of legitimacy of use of environmental signs).

The process of the *environmental declaring of the III type* is carried out in accordance with norms of standard of ISO 14025 and does not supposes marking of products by signs of environmental purity. Such work has the purpose of giving of environmental information on processes occurred during the whole life cycle of production, what has to give the possibility of comparing of characteristics of products of the same destination of use. This type documents may issue one or more organizations and use in this work the data obtained in process of independent evaluation of details of life cycle of production (LCA), data of inventory analysis of the life cycle of production (LCI) or the information, related to the data named above and:

- developed in use of information obtained in earlier time,
- comply to requirements set by the operator of the program, e.g. by the company or group of companies, branch of industry or the

trading association, State regulation bodies of agencies, independent scientific or other type organizations.

As provided norms of standard ISO 14025, the environmental declarations of type III are issued in purposes of dissemination of information among the businesspersons but may also be used in purposes of passing of information from business structures to consumers. The developer of the environmental declaration of type III is not capable to identify users of his information in advance but he has to take into consideration needs of various groups of buyers or groups of consumers, such as large business structures, enterprises of small and average size, State organizations specialized in purchases and individuals. The specialists who issue the environmental declarations of type III and develop programs of operation in observance of norms of standard of ISO 14025, have to notice the awareness of consumers who are the addressees of the issued information.

The businesspersons have to develop their environmental declarations in observance of legalized norms and guarantee that the given data was controlled by experts of third party or persons of their own subordination.

After the Chernobyl catastrophe had occurred, the domestic manufacturers began to declare extensively the medicinal properties of their products and use in it the special type marks in absence of the specialized standards that may give them right of such marking. The one of possible designs of signs, which witnesses the radioprotective properties of the product is shown on Figure 6.8:

Fig. 6.8 Sign used for marking of products, which have the radioprotective properties

However, the concept of ecological safety is of more general character and relates also to norms of operation in protection of environment, as well as guaranteeing of minimal negative influence on nature of marked products and their packing at all stages of their life cycle. The one more norm to observe in progress of industrial society is assuring of minimal harmless of conditions of their utilization and possibility of reprocessing of wastes of manufacture. The signs used usually in indication of recommended methods of carrying out of these works are:

Group # 1: signs, which inform on possibility of reprocessing of the product and its packing (Figure 6.9):

A *B* *B* *B*

Fig. 6.9 Signs that indicate the possibility of use of materials of the marked items as the secondary raw materials: A – "Recycle for the better tomorrow"; B – signs recommending throwing of used items into the garbage tanks differentiated by types of wastes: paper, glass, plastics, rags etc. These signs may be used together with the inscriptions of "Keep your country tidy", "Gracias" (Thank you) etc.

In need of identifying of substance used in producing of the packing material, the latter may be marked by numerical or literal symbols placed inside the recirculation loop or below it:

- $1 \div 19$ plastics,
- $20 \div 39$ paper and cardboard,
- $40 \div 49$ metals,
- $50 \div 59$ wood,
- $60 \div 69$ textile,
- $70 \div 79$ glass.

Group # 2: *"Re-treating of plastics"*. These signs are coded by numbers and used in marking of plastic items, which may be re-treated industrially. The letters put down the sign indicate the acronym of used plastic (Figure 6.11):

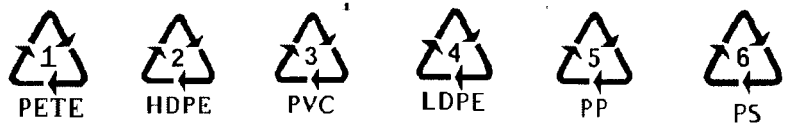


Fig. 6.11 Samples of coding of plastics

Group # 3. Signs used in EU countries in indication of possibility of repeated use of labeled materials (Figure 6.12):

Fig. 6.12 Signs indicating possibility of the repeated use of the item (material it was made):
A – the material used in fabrication of the item may be reprocessed, or the product was made of secondary raw materials partly or in whole, B – "Green point" – German sign, which witnesses the guarantee of acceptance of packing in places of collecting of secondary materials, C – packs of multiple use, D – packs made of secondary raw materials

Collecting of wastes means the work in their accumulation and disposal at places or objects specially assigned for these purposes

Treating (reprocessing) of wastes means carrying out of any operation associated with modifying of their physical, chemical or biological state done in purposes of their preparing for environmentally safe storage, transporting, utilization or annihilation

Neutralization of wastes means decreasing or abolition of harmfulness of wastes done by mechanical, physical, chemical and/or biological method(s)

Disposal of wastes means their final placement at specially assigned places done by mode(s), which exclude their long-term

harmful influence on conditions of environment and state of health of men

The environmental marking has to inform on environmental safety of the marked item and minimum level of risk for health of men in its use (consumption). Contrary, presence of the sign shown below or the similar ones has to attract attention of consumers to probable danger of the marked product (Fig. 6.13):

Fig. 6.13 Sign of environmental danger

To protect consumers against risks, the State Service of Technical Regulation and Consumer Policy of Ukraine demands that the supplementing informative materials on imported commodities have to be written in Ukrainian. They may have also the additional inscriptions written in foreign languages, e.g. *"best before", "a consommer de preference", "avant le Mind", "haeybar bis (Ende)", "consumir preferemente antes de"*, which inform on terms of suitability of products for consumption. Such inscriptions as *"expiry date", "term of validity"*, inform on permissible term of storage of the item before its use and *"production date"* about date of its producing.

Test Questions

1. What is the sense of term "quality" ?
2. What is quality management ?
3. What are the basic evidences of compliance of products with established norms of quality ?
4. What are the basic methods of attestation of quality of production ?
5. What are the main tasks of persons in sphere of assuring of quality ?
6. What are principles of concept of total quality control ?
7. What are principles of total quality management ?
8. What is the system of quality ?

9. What documents normalize the fundamental parameters of work in assuring of quality ?
10. What are cases of certification of quality systems ?
11. What are mechanisms of introduction of principle of refusal of total quality control ?
12. What are the principal norms of modern system of management ?
13. What sense has the concept of environmental safety ?
14. What is the system of environmental management ?
15. What are motives of environmental certification ?
16. What organizations develop the environmental criteria and norms of use of signs of environmental purity ?
17. What is the name of the Ukrainian national sign of environmental purity ?
18. What is the environmentally pure product ?
19. What is environmental marking of first type ?
20. What is environmental marking of second type ?
21. What is the sense of notion of "environmental safety" ?

7. State Regulation of Quality and Safety of Foodstuffs

7.1 Concept of Safety of Foods

Reports of FAO/WHO experts show that preservation of proper state of health of population depends of conditions of its nutrition by factor of 50÷70 %. The consumed foods and drinking water bring in organism up to 90 % of harmful compounds, therefore ensuring of safety and absence of harmfulness of foodstuffs and drinks is one of crucial problems in guaranteeing of retention of healthy conditions of living and preservation of healthy genofond of mankind, what is one of the most important functions of State regulation in introduction of norms of protection of environment against negative consequences of technical progress.

Recognition of this fact leads to revision of basic principles and strategy of development of food and agricultural industries, which milestone became transition from not the only practice of quantitative rise of output of foods to introduction in parallel of the norm of improvement of their nutritional value. Producers of foods introduce in its realization effective manufacturing processes and develop the fundamentally new trends in organization of low-wasted and energy saving technologies, what permits to reduce dramatically use of chemical compounds not occurring in nature. The US Academy of Sciences, for example, recommended the government to postpone the practice of funding of farms, which use chemical means of protection of plants, and support instead the projects, which assist in progress of environmentally safe agriculture.

The European Union approved in 1996, in turn, the Directive of 93/43/CEE *"On Hygiene of Foodstuffs"*, which establishes norms of production of foods in hygienic conditions and criteria of their safety, which are the crucial in assuring of health of future generations. Use of provisions of this Directive became the obligatory norm of work of all EU member-states since the date of its validation (14th of December 1995) and the notions mentioned above have to be understood in meanings as follows:

Foodstuffs mean all treated, partly treated or non-treated commodities produced in purposes of consuming by people. The category of foodstuffs includes also drinks, chewing gum and substances, particularly water, added to foodstuffs in process of their fabrication, processing or treatment. The term of "foodstuff" does not include:

- *forages,*
- *live animals, if they are not assigned for consumption by men,*
- *plants (before they would have been harvested),*
- *drugs,*
- *cosmetics,*
- *tobacco and tobacco goods,*
- *narcotic and psychotropic substances understood in interpretation of the UN Convention on narcotics of 1961 and the UN Convention on psychotropic substances of 1971,*
- *polluting substances.*

Foodstuff of animal origin means milk, mean the products assigned for consumption by men including fish, mollusks and crustaceous organisms in fresh, cooled and frozen state, as well as eggs, honey, their derivatives and other products produced of their solitary organs and/ or tissues

Safety of foodstuff means the state of the eatable product, which guarantees that it may be consumed without harm for health produced and realized in observance of sanitary norms and/or provisions of related technical regulations

Safe foodstuff means the eatable product character by absence of direct or indirect negative influence on health of men f it was produced and distributed in observance of established sanitary and veterinary norms and consumed by prescription

Hazardous foodstuff means the alimentary product hazardous for health and/or unfit for consumption. In identification of its hazard there have to be taken into consideration the factors as follows:

- *usual conditions of its producing, reprocessing and circulation,*
- *information for the consumer on the recommended conditions of consumption, especially the data on date of its fitness for consumption given in marking and other understandable for all data on modes of avoiding of negative effects of its consumption.*

Identifying hazards of the foodstuff, one has to consider the factors as follows:

- *its probable short- of long-term influence on health of consumers and future generations of men,*
- *probable accumulative effect of toxicity of the product,*
- *individual sensitivity of organisms of certain categories of consumers.*

Food hygiene means the complex of measures used in ensuring of safety and wholesomeness of foodstuffs at all stages, which follow their primary production (e.g. processes of harvesting, slaughtering and milking), including the work in reprocessing of raw materials, producing of finished products, their packaging, storing, transportation, distribution, handling and offering for sale or supply to consumers

Usefulness of the food means fitness of the foodstuff for human consumption as far as hygiene is concerned

Safety means absence of risks, which harmful influence exceeds the level acceptable for consumers

Safety of production means absence of its any harmful influence on conditions of life and health of consumers and state of neighboring nature in use of usual procedures of its producing, storage, transporting, use and utilization

The EU countries established in 2002 five basic principles of safe work in the food industry:

- continuity of all stages of nutrition raw,
- analysis of conditions of producing of foodstuffs and prevention of origination of risks as the basic norm of work,

- responsibility of operators of food market for assuring of safety of foods they propose,
- control of quality of products at any stage of nutrition raw,
- guaranteeing of right of citizens on obtaining of accurate and trustworthy information on quality of foods they consume.

Basing on these principles, the state regulating bodies of EU member-states developed the system of laws, by-laws and normative deeds, which establish the norms of safety of foods. The latter category documents includes technical regulations, national, interstate, regional and international standards, specifications of persons of economy, norms of technologies, State sanitary and veterinary norms and rules and other documents of regulatory character. The document, which normalized in Ukraine such kind activities is the law of 23.12.1997 # 771/97-VR *"On Safety and Quality of Foodstuffs"* and the Law of Ukraine of 22.07.2014 *"On Amending of Provisions of Certain Legal Deeds of Ukraine Related to Foodstuffs"*.

The State regulates safety and certain indices of quality of foodstuffs by way of:

- establishing of sanitary measures,
- normalizing of certain indices of quality of foodstuffs,
- State registration of objects of sanitary measures listed in the State laws,
- issuing, postponing, annulment and renovation of permissions on exploitation of objects subordinated to the sanitary regulation,
- information and rising of level of education of operators of the market and consumers by problems of safety of foodstuffs,
- establishing of requirements to conditions of health of persons who work at enterprises of food industry,
- participation in work of specialized international organizations,
- carrying out of State control of safety and quality of foodstuffs,
- punishing of operators of the market for violation of norms of legislation on safety of foodstuffs.

At the same time, if the international treaty signed by Ukraine and approved the Supreme Soviet of Ukraine establishes norms of safety of

foods, which differ of national ones, the concerned businesspersons must observe its provisions but not norms of any other document of national category. In absence in normative and legal deeds of Ukraine on norms of safety of foodstuffs planned to production, it is necessary to observe parameters of safety set by documents of related international organizations. If the latter were not normalized by such documents too, the businessperson has to observe parameters of safety of foods established by legal deeds of the European Union. The compliance of said parameters to EU norms is supposed in this case as assurance of their safety in conditions equal to those that are set by Ukrainian legal norms.

Safety of any food depends directly of grade of their contamination by compounds hazardous for health. Because occurrence of danger is equally probable at any stage of nutrition raw, the operator of the market has to develop the adequate procedures of management at all its stages, normalize methods of processing and safely storage of foods and substantiate the maximum permissible concentrations of their pollutants. The principal measures used in it are:

- establishing of minimum specifications of quality of foodstuffs in normative and technical documents,
- establishing of veterinary and sanitary conditions of operation at stages of fabrication, safe storage and sale of foods,
- carrying out of the steady State sanitary and veterinary control of objects and products used in manufacturing and reprocessing of foodstuffs,
- guaranteeing of safety of consumption of new types of foodstuffs before they would have been introduced in circulation,
- raising of level of knowledge of manufacturers and sellers (suppliers) on problems of assuring of safety of foodstuffs they propose and principles of good practices to be observed n their fabrication,
- establishing of obligatory criteria of skill and conditions of health of employees of businesspersons, which produce and sell (supply) foods,

- participation in work of regional and international organizations in development of sanitary norms to be observed in fabrication and circulation of foodstuffs.

Nutrition raw means the sequence of stages of producing, processing, distribution and storage of foodstuffs and ingredients thereof up to stage of their consumption

Pollutants means any biological and/or chemical substances of inorganic and organic nature (including pesticides and toxins), as well as radioactive substances and products of their decomposition, microorganisms, residuals of veterinary preparations (including hormones, sedatives and tyreostatic substances) and other substances present in foods, forage and products of animal origin potentionally dangerous for health of men and animals

Low-grade and hazardous production means:

- *production, which indices of quality do not comply to norms of Ukrainian legal and normative documents in force,*
- *production marked in foreign language, and/or having the incomplete information to be given in obligatory manner,*
- *production does not supplemented by documents on its quality and safety*

Generally, the state of *Food Safety* means absence of toxic, carcinogenic, teratogenic, mutagenic and/or other negative influence of foods on human organism in their consumption in conventional quantities. Its assuring is the problem of avoiding of conditions capable to lead to origination of sicknesses of food origin in treating, storage and preparing of foods for consumption. Following this logic, the work in assuring of food safety includes the constituents of protection of health of domestic animals and their proper feeding, as well as care on health of eatable plants. The principal norms set forth in EU regulatory documents by problems of food safety to be observed in Ukraine as its associated member are:

I General requirements for food premises

1. Food premises must be kept clean and maintained in good repair and condition.

2. The layout, design, construction and size of food premises shall:
   - permit adequate cleaning and/or disinfection,
   - be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces,
   - permit good food hygiene practices, including protection against cross contamination between and during operations by foodstuffs, equipment, materials, water, air supply or personnel and external sources of contamination such as pests,
   - provide, where necessary, suitable temperature conditions for the hygienic processing and storage of products.

3. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. An adequate number of flush lavatories must be available and connected to an effective drainage system. Lavatories must not lead directly into rooms in which food is handled.

4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. When necessary, the provisions for washing food must be separate from the hand-washing facility.

5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical air flow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. All sanitary conveniences within food premises shall be provided with adequate natural or mechanical ventilation.

7. Food premises must have adequate natural and/or artificial lighting.

8. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of foodstuffs.

9. Adequate changing facilities for personnel must be provided where necessary.

II Specific requirements in rooms where foodstuffs are prepared, treated or processed

1. In rooms where food is prepared, treated or processed (excluding dining areas):

- floor surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors must allow adequate surface drainage,
- wall surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
- ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles,
- windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must where necessary be fitted with insect proof screens which can be easily removed for cleaning. Where open windows would result in contamination of foodstuffs, windows must remain closed and fixed during production,
- doors must be easy to clean and, where necessary, disinfect. This will require the use of smooth and non-absorbent surfaces

unless food business operators can satisfy the competent authority that other materials used are appropriate,

- surfaces (including surfaces of equipment) in contact with food must be maintained in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Where necessary, adequate facilities must be provided for the cleaning and disinfecting of work tools and equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.

3. When appropriate, adequate provision must be made for any necessary washing of the food. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

III Requirements for movable and/or temporary premises (such as Marquees, market stalls, mobile sales vehicles) premises used primarily as a private dwelling house, premises used occasionally for catering purposes, and vending machines

1. Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contaminating foodstuffs and harboring pests, so far as is reasonably practicable.

2. In particular and where necessary:

- appropriate facilities must be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities),
- surfaces in contact with food must be in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate,

- adequate provision must be made for the cleaning and, where necessary, disinfecting of work utensils and equipment,
- adequate provision must be made for the cleaning of foodstuffs,
- an adequate supply of hot and/or cold potable water must be available,
- adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) must be available,
- adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available,
- foodstuffs must be so placed as to avoid, so far as is reasonably practicable, the risk of contamination.

IV Transport

1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs. Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or must be marked *'for foodstuffs only'*.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there must be effective separation of products, where necessary, to protect against the risk of contamination.

4. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different

foodstuffs, there must be effective cleaning between loads to avoid the risk of contamination.

5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimize the risk of contamination.

6. Where necessary, conveyances and/or containers used for transporting foodstuffs, must be capable of maintaining foodstuffs at appropriate temperatures and, where necessary, designed to allow those temperatures to be monitored.

V Equipment requirements

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

- be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food,
- with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned and, where necessary, disinfected, sufficient for the purposes intended,
- be installed in such a manner as to allow adequate cleaning of the surrounding area.

VI Food waste

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.

2. Food waste and other refuse must be deposited in closable containers unless food business operators can satisfy the competent authority that other types of containers used are appropriate. These containers must be of an appropriate construction, kept in sound condition and where necessary be easy to clean and disinfect.

3. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and to protect against

access by pests and against contamination of food, drinking water, equipment or premises.

VII Water supply

1. There must be an adequate supply of potable water intended for human consumption. This potable water must be used whenever necessary to ensure foodstuffs are not contamined.

2. When appropriate, ice must be made from water which meets the specifications referred to water intended for human consumption. This ice must be used whenever necessary to ensure foodstuffs are not contamined. It must be made, handled and stored under conditions which protect it from all contamination.

3. Steam used directly in contact with food must not contain any substance which presents a hazard to health or is likely to contaminate the product.

4. Water unfit for drinking used for the generation of steam, refrigeration, fire control and other similar purposes not relating to food, must be conducted in separate systems, readily identifiable and having no connection with, nor any possibility of reflux into, the potable water systems.

VIII Personal hygiene

1. Every person working in a food handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where appropriate, protective clothing.

2. No person, known or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted through food or while afflicted, for example with infected wounds, skin infections, sores or with diarrhea, shall be permitted to work in any food handling area in any capacity in which there is any likelihood of directly or indirectly contaminating food with pathogenic microorganisms.

IX Provisions applicable to foodstuffs

1. No raw materials or ingredients shall be accepted by a food business if they are known to be, or might reasonably be expected to be, so contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or

preparatory or processing procedures hygienically applied by food businesses, they would still be unfit for human consumption.

2. Raw materials and ingredients stored in the establishment shall be kept in appropriate conditions designed to prevent harmful deterioration and to protect them from contamination.

3. All food which is handled, stored, packaged, displayed and transported shall be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state. In particular, food must be so placed and/or protected as to minimize any risk of contamination. Adequate procedures must be in place to ensure pests are controlled.

4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health. Consistent with food safety, limited periods outside temperature control are permitted where necessary to accommodate the practicalities of handling during preparation, transport, storage, display and service of food.

5. When foodstuffs are to be held or served at chilled temperatures they must be cooled as quickly as possible following the final heat processing stage, or final preparation stage if no heat process is applied, to a temperature which would not result in a risk to health.

6. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labeled and stored in separate and secure containers.

X *Training*

Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

To trace probable hazards and take the in-time measures by their elimination, the businessperson has to control passing of production through all stages of nutrition raw up to its placing on shelves of

supermarkets, and trace the content in foods of residues of pesticides, antibiotics and radionuclides.

Hazard means the potential source of harm for life and health

Hazardous factor (in the foodstuff) means any biological, chemical and/or physical factor, substance, material or product present in foodstuffs, which influences or may influence negatively on health of men

Deficiency means any deviation of indices of quality and/or properties of production of norms established by normative and technical documents, legal deeds and terms of contracts, as well as incorrectness of information on quality of products given by their manufacturer (executor, seller)

Considerable deficiency means the deficiency, which results of impossibility of use of the consumable by its destination. This one has at least one of the following attributes:

- *it cannot be eliminated,*
- *the term of its elimination is more of 14 days,*
- *its existence sufficiently amends properties of the consumable as compared with the established norms and or provisions of regulatory documents*

The risks of occurrence of incidents in normal functioning of society may be classified by their extent as the negligible, acceptable, ultimately permissible and excessive ones. The values of the first group risks are such small that their level is in limits of variation of natural noises. The acceptable risk is such that the society apprehends as the tolerable in existing technical and economical level of its development. The value of the ultimately permissible risk is such that must not be exceeded in reaching of desirable result of business operation, and the excessive one has the extremely high level of harmful influence, which results in most cases in occurrence of negative consequences.

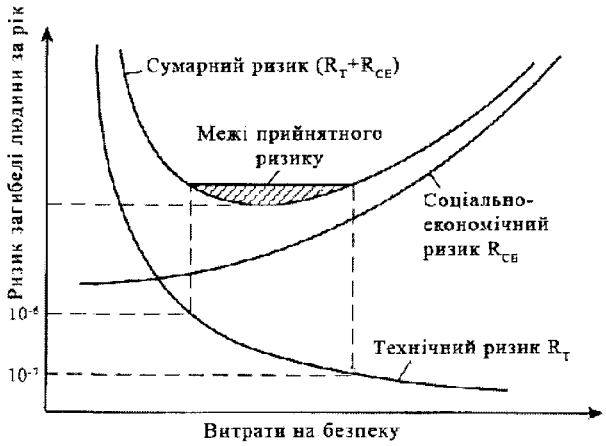
The generally used base of system of safety of foods, which existed till now was the concept of "*absolute safety*". The community introduced gradually the more sophisticated systems of operation, which use permitted to eliminate almost all danger for health and life of citizens.

Meantime, the means of manufacturing and technologies used in process of serial manufacturing became the more complicated and the society understood finally the inadequacy of such trend in view of too big expenses and impossibility of guaranteeing of conditions of absolute safety, and the modern norm in business operation is reaching of *"acceptable"* level of risk, what results in compromising of levels of safety and probability of origination of accidents well-grounded from the social and economical viewpoints. Naturally, this requires of establishing of quantitative criteria of evaluation of the permissible grade of risks (***R***), which may be expressed as the ratio of quantity of accidents (***n***) occurred during the certain period to general quantity of men, who work in sphere in question (***N***):

$$R = n / N$$

Most of developed countries use presently just this trend and level of individual risk recognized as the maximally permissible one in any sphere of activity, branch of industry and individual enterprise, is now of 10^{-6} per year, and the negligible one is 10^{-8} (Fig. 7.1):

Figure 7.1 Identification of level of acceptable (permissible) level of risk



The one of crucial problems of guaranteeing of safety of the society is the food safety of the State. Its basic norm is capability to provide the community by the enough quantity of foodstuffs of own fabrication and assure their import in minimal complications in case of their purchasing abroad. Unfortunately, the specialized scientific literature and official international documents had not interpreted uniformly the content of the term of *"food safety"* because of dependence of its content of the whole set of specific problems of nourishment. However, the latest publications permit to interpret this notion as the social, economical and productive category to be understood as the condition of observance of one of fundamental rights of men – the right on maintaining of their existence in consumption of high-quality and safe foods. Therefore, the problem of food safety has to be studied from the viewpoints as follows:

International level. This is a problem of finding of the compromise in establishing of ratio of quantities of foods produced domestically and bought abroad.

State level. This is a problem of balancing of quantities of produced and consumed products prompting to intensify the progress in structures of agricultural manufacturing, food industries, and conjugated branches of economy. The safety and quality of foodstuffs on the State level have to be guaranteed in use of methods of: ***1)*** observance of obligatory parameters of safety at all stages of nutrition raw, ***2)*** observance of hygienic, sanitary and veterinary norms by manufacturers, distributors, sellers and importers of foodstuffs, ***3)*** organization of steady State control of operation of manufacturers, ***4)*** establishing of norms of work, which observance guarantees good conditions of health of laborers.

Level of manufacturing and reprocessing of agricultural production. These are problems of evaluation of weightiness of hazardous factors identified in process of business operation. The principal problems of food safety at the level of fabrication and distribution of foodstuffs are maintenance of interests of individuals in operation of business persons in strict observance of provisions of normative and technical documents and legal deeds as follows:

- Law of Ukraine of 24.02.1994 # 4004-XII "On Sanitary and Epidemiological Well-being of Population",
- Law of Ukraine of 23.12.1997 # 771/97-BP "On Safety and Quality of Foodstuffs",
- Law of Ukraine of 14.01.2000 # 1393-XIV "On Requisitioning from Circulation, Reprocessing, Utilization, Annihilation or Following Use of Low-grade and Dangerous Production",
- Law of Ukraine of 16.11.2006 # 361-V "On Veterinary Medicine".

Sanitary and epidemiological well-being of population means the existence of good conditions of health of population, which result of maintenance of threshold of sickness in restricted limits, observance of acceptable conditions of living of population and ensuring of compliance of parameters of vital functions of men to the established sanitary norms of living

Harmful influence on health means the negative influence of dangerous factors of the biotope on health and conditions of life or working capacity of men, as well as existence of threat of their influence on state of health of future generations

7.2 Global Problems of Guaranteeing of Safety of Foodstuffs

The objectives of reaching of competitiveness of agricultural production and rising of export potential of Ukraine became the problems of prime interest in the light of expanding of deficit of foodstuffs worldwide. However, differences in provisions of national systems of sanitary and hygienic normalization impede to create the stable base of international barter by foods. To unify the practices used in this kind trade, the developed countries took the norm of ensuring of safety of foodstuffs as the priority and found in this purpose the State agencies specialized in regulation of activities in producing and processing of foods. For instance, the Canadian authority responsible for development of norms of assuring of safety of foods is the *Federal Service of Protection of Health of Canada (HC)*, and observance of norms in this work controls in this

country the *Canadian Inspection by Control of Quality of Foodstuffs (CFIA)*. The work on evaluation of grade of risks, which occur in consumption of foods in France executes the *French Agency by Safety of Foodstuffs (AFSSA)*, and control and supervision of set norms – the *Central Bureau by Foods (DGAL)*. The related authorities in USA are the *Federal Department of Alimentary Products and Drugs (FDA)* and the *Federal Inspection of Safety of Foods (FSIS)*. To solve the same problems at the European regional level, the Eurocommission developed in 1997 the *"Green Book of General Principles of Legislation on Foodstuffs"*. The generalized principles of policy of food safety in Europe details the *"White Book on Safety of Foodstuffs"* published in 2000. Its basic norms are:

- tracing of processes of treating and use of forage, foodstuffs and their ingredients,
- complex analysis of indices of quality of production at all stages of nutrition raw,
- clear identification of functions of operators and clients of food market (profile authorities, farmers, producers, distributors and sellers of foodstuffs, consumers),
- analysis and managing of risks,
- informing on possibility and probable consequences of origination of risks and hazards.

The basic norms of hygiene of foodstuffs and forage in Europe establishes the *Regulation of European Parliament and EU Council # 178/2002 of 28 January 2002* on introduction of norms of newly developed *Food Codex*, founding of the *European Food Safety Authority* and laying down of procedures of guaranteeing of food safety, which the most significant are:

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
   (a) injurious to health;
   (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:
   (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
   (b) to the probable cumulative toxic effects;
   (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.
5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
8 Conformity of a food to specific norms applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market

or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there is no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty.

Batch means any quantity of foodstuff, which have the same appellation and properties produced by the operator of the market at the same productive facility in identical conditions in certain period of time

It was 2003, when the next fundamental document, the *"EU Blue Book"*, was developed in Europe as the complement to the complex concept of control of safety of foods (including those ones, which were produced abroad). The work in observance of provisions of this document permits to evaluate the grade of adequacy of norms of safety of foods at all stages of nutrition raw and classify and standardize methods of identification of their quality. The Ukrainian system of guaranteeing of safety of foodstuffs is based on use of the same principles of regulation by structural units of four ministries (*Ministry of Protection of Health, Ministry of Agricultural Policy and Food, Ministry of Economical Progress and Trade*, and *Ministry of Ecology and Natural Resources*), and seven committees and services (*State Sanitary and Epidemiological Service, State Service of Quarantine of Plants, State Service of Veterinary Medicine, State Service of Technical Regulation and Consumer' Policy, State Custom' Service, State Environmental Inspection*, and *National Agency of Accreditation of Ukraine*).

Unfortunately, there still exist numerous events of deviation of practices of operation of businesspersons of established norms of producing, storage, transporting and realization of foods, as well as emerging in their operation of other negative consequences of intensification of processes of agricultural manufacturing. To improve the

current situation, the administrative personnel of business operators introduce the principles of *SUBKhP (System of Management of Safety of foods – Системи управління безпечністю харчової продукції)* as follows:

- putting of responsibility for guaranteeing of safety of produced foodstuffs on the managing personnel of the enterprise,
- appointing of persons responsible for ensuring of safety of produced foods,
- dissemination of comprehensive information among suppliers, subcontractors, consumers and local authorities on conditions of manufacturing, storage and distribution of their products,
- development and introduction of steady control of quality of used raw materials, ingredients, substances and materials,
- identifying of the existing biological, chemical and physical hazards, and development of procedures of their elimination.

The procedures of operation by norms of the system of SUBKhP regulate in Ukraine the norms of law of 23.12.1997 # 771/97-BP *"On safety and quality of foodstuffs"*, and the routine of identification, evaluation of grade of influence and control of hazards in process of manufacturing and safe storage of foodstuffs – provisions of national standards of Ukraine of DSTU 4161:2003 *"Systems of management of safety of foodstuffs"*, and DSTU ISO 15161:2004 *"Guidelines on the application of DSTU ISO 9001:2000 in the food and drink industry"*. The fundamental principles of the System of management of safety of foodstuffs are:

- identification of hazards (biological, physical and chemical), which exist in process of manufacturing and may be the cause of production of products dangerous for health of their consumers,
- identification of critical control points, which exist in processes of manufacturing and circulation of products. The business processes occurred in these points have to be controlled continuously, what has to prevent or minimize the possibility of origination of hazards, or eliminate their occurrence during all time of business operation,

- establishing of limiting values of indices of quality, which must be controlled in the identified critical control points,
- effective monitoring of observance of indices of quality of products to be controlled in critical control points,
- assigning of procedures of operation that have to guarantee prevention of cases of deviation of indices of quality of products of their normalized values,
- assigning of actions to be done in occurrence of deviations of indices of quality of products of their normalized values (corrective actions),
- establishing of the system of traceability at all stages of circulation of products, which participant is their producer,
- establishing of system of documenting and registration of decisions taken in purposes of guaranteeing of safety of foodstuffs in processes of its producing and circulation,
- planned auditing of effectiveness of use of procedures of control, and corrective and preventive measures. The manufacturer have to carry out the extraordinary audit if there would be amended any parameter of technological processes, norm of system of management or any other procedure of operation that influences on safety of products,
- continuous control of effectiveness of functioning of the system.

To solve the problems listed above, the Council of Ministers of Ukraine issued the Decree of 10.09.2014 # 442 on establishing of the State Service of Ukraine by Problems of Safety of Foodstuffs and Protection of Consumers (Derzhprodspozhivsluzhba). The Service was founded by way of reorganization of the State Veterinary and Phytosanitary Service and incorporation into the new formed structure of the State Inspection by Problems of Protection of Interests of Consumers and the State Sanitary and Epidemiological Service. The Service works under the guidance and supervision of the Council of Ministers of Ukraine and solves the functions as follows:

- realization of the State policy in spheres of responsibility of the liquidated State bodies (except of functions of pedigree farming

of stock) and hygiene of labor, as well as dosimetric control of working places and conditions of raying of laborers),

- carrying out of State control (supervision) of observance of the State controllable prices.

The laborers responsible for guaranteeing of safety of foods (working group of system of management of quality, persons who work at places of critical control) and the auditing personnel must have certificates, which witness their professional skill, as well as raise their qualification by problems of their responsibility at least once per three years.

The operators, who work with foodstuffs, must introduce the system of management, which use would permit consumers to identify the level of professional skill of any supplier of foods, food additives, forages and animals to be used in producing of foodstuffs, as well as trace the routine of carrying out of processes of manufacturing, especially the data of two kinds as follows:

1. Information accessible to competent bodies every time:
   - name and address of supplier and type of the product he proposes,
   - name and address of requester and type of the product he receives,
   - date of sending/receiving of each batch of the product.
2. If possible, the following information should be given in addition and in terms established by the attributed normative and legislative documents as follows:
   - volume or quantity of produced foodstuff or forage,
   - number of the batch,
   - detailed description of packed goods, type of supplied fruits/vegetables/raw materials/treated products etc.

7.3 Procedures and Means of Guaranteeing of Safety of Foodstuffs

Ensuring of food safety in conditions of global pollution of environment is the crucial problem of food markets, because there exists the danger for health of consumers resulted of illnesses in consumption of foodstuffs contaminated by various pollutants. Therefore, to avoid any hazard in production of foods, manufacturers have to use the qualitative raw materials and ingredients only. Particularly, the Law of Ukraine of 23.12.1997 # 771/97-BP *"On Safety and Quality of Foodstuffs"* declares:

The sanitary measures have to be developed, revised and amended by the authorized State regulation bodies and approved by the Central body of executive power in sphere of protection of health, Chief State Sanitary Doctor of Ukraine, and/or Chief State Inspector of Veterinary Medicine (in spheres of their responsibility) in observance of norms as follows:

1. *all sanitary measures have to be properly substantiated and correspond to norms of modern scientific base (excluding the cases listed in Clause 4 of this Article),*
2. *in existence of related international standards, instructions, and recommendations, said sanitary norms have to be developed in observance of their requirements (except of cases of their insufficiency for guaranteeing of level of protection of health normalized in Ukraine),*
3. *in absence or insufficiency of norms of specialized international standards, instructions or recommendations, the necessary sanitary measures have to be developed in conditions of avoiding of consequences of negative influence of risks identified by norms used internationally,*
4. *in insufficiency of substantiation necessary for evaluation of grade of influence of probable risks or origination of extraordinary conditions, which threat to health of men, the*

necessary measures have to be developed in use of recommendations of international organizations specialized in this work or sanitary measures used by Ukrainian trade partners.

Accordingly to norms of this Law, the natural persons have rights on:

- consumption of foods and drinking water, as well as to work, rest and living in conditions of environment safe for their health,
- compensation for harm committed to their health in result of violation of norms of sanitary legislation by parties, which ,sold them defective products,
- participation in development, discussion and public expertise of programs of ensuring of sanitary and epidemiological well-being of population,
- obtaining of trustworthy and timely information on existing and probable risks and their influence on state of their health.

The basic norms used in work in protection of conditions of life of consumers against the negative influence of harmful factors potentially present in foods are:

- establishing of minimum obligatory parameters of quality of foodstuffs, as well as observance of sanitary norms by sellers (suppliers) of consumables they distribute,
- establishing of basic obligatory parameters of safety of foods, especially of products of special dietetic consumption and functional food additives to be used by persons, who have the specific dietetic needs,
- establishing of minimal norms of state of health of laborers of manufacturers and sellers (suppliers) of foodstuffs who contact with foods, consumables, raw and packing materials etc.,
- accomplishing of steady State control and supervision on activities of manufactures, which produce foods potentially dangerous for life and health of men,
- control of safety of new types of foodstuffs for health of men before they would have been put in circulation in Ukraine.

Use of listed actions stimulate the minimal use by manufacturers in production of foods of agricultural chemicals and medical preparations. However they cover at the same time the much bigger quantity of problems, e.g. normalization of healthy conditions of labor and state of environment, establishing of norms of well-being of animals etc. The factors, which can influence negatively on safety of foodstuffs and taken into consideration in organization of producing facilities, are:

- *Physical* factors, which result of inactivity of operators, and/or ingress of exterior pollutants in products, what may cause physical injuries of internals.
- *Chemical* factors, which result of ingress of hazardous chemical substances in foodstuffs, therefore intoxication of their consumers.
- *Biological* factors, which result of germination in foods of microorganisms, which presence and/or presence of products of their vital activities results in pollution of foods and intoxication of their consumers.

To protest consumers of dangers resulting of influence of said factors, it is necessary to guarantee the compliance of norms of quality of foodstuffs to requirements of standards and other normative and technical documents of national, regional and international categories. The complication in it is frequently absence of uniform criteria of identification of their quality or ambiguity of related formulations. It is problematically therefore to testify identity of parties of wheat flower of extra class produced by the same mill in different shifts and/or this one made of grain of the same class but delivered by different suppliers. So, to strengthen the confidence of consumers to declarations of suppliers, which declare the proper quality of their products, the foreign manufacturers practice introducing in their labeling of certain elements of information on belonging of products to certain batches of output.

Ukraine introduced the same norms, but limited range of their use by canned products only. However, this problem requires the rapt attention, for the Ukrainian National Committee by Protection of Interests of Consumers informs that more of 80 % of Ukrainian foods are falsified at

least by one of indices of their quality. The most often it is the result of substitution of all or some of ingredients of foodstuffs in preservation of similarity of one or more of its remaining components. These ones may be the cheaper or lower quality ingredients and substitutes, imitators of natural components, or even excessive quantities of water. The most expressive examples are concentrated products, syrups, juices, wines and drinks, where tasters do not see their falsification in adding of 10 % water. In adding of 20% water about 1/3 of experts express their doubt in proper quality of the product, and most of them are confident in its watery taste in 50% dilution only.

To decrease losses of valuable products, raw materials, food additives etc. and unify norms of safety of foodstuffs in conditions of globalization of processes of their distribution, the community worked out the normative documents of regulatory character, which principal norms are:

- avoiding of diseases resulted of consumption of poor quality foods,
- avoiding of intoxications of nutritional character in public catering establishments.

7.3.1 Good Agriculture Practice

Avoiding of misunderstandings and ensuring of proper quality of foods are the principal instruments used in the so-called *"good agriculture practice" (GAP)*, which norms presume use of normalized methods of maintaining of productive, ecological and social viability of foods at all stages of nutrition raw. The basement of this kind practice is observance of such basic elements used in work as *"pure soils", "clean water", "clean hands, "clean surfaces"*. As such, the constituents of GAP practice are the good manufacture and good hygiene practices:

- *Good manufacture practice (GMP)* in agriculture relates to activities executed in fabrication and reprocessing of foods, which set includes also the work in their treatment at final stages of distribution. The fact of observance of principles of GMP witnesses the high culture of operation and guarantees producing

of qualitative and safe foods, as well as international recognition of proper qualification of the enterprise.

- *Good hygiene practice (GHP)* means the kind of activities of the businessperson in regulation of hygienic conditions of fabrication, storage, transporting and distribution of foodstuffs, as well as ensuring of proper hygienic conditions of productive and accommodation premises and equipment used in it.

The person, who intends to develop norms of good practices of general use, has to take the measures as follows:

- to commit their development to qualified specialists of food business sector and skilled representatives of other interested parties, e.g. the competent authorities and consumer groups,
- to ensure the compliance of content of newly developed norms to provisions of the *Recommended International Code of Work in Development of Norms of Good Practices* and the *General Code of the Codex Alimentarius Principles of Food Hygiene*,
- to assure the applicability of norms of such guides in sectors of food industry to which they refer,
- to ensure that all interests of parties, which will introduce the norms in development, are substantially affected by such guides.

The most efforts in process of producing of finished products have to be given to prevention of their microbial, weed-killing and pesticidal contamination. Observance of GAP principles obliges farmers to control not the quality of raw materials, semi-manufactured and finished products only, but also the content of microorganisms, compounds of heavy metals and radio nuclides in water, which contacts with the semi-manufactured and finished products, as well as neutralize the existing sewage and domestic outflows. Moreover, if the hygienic or other problem that poses the serious risk to human health arises in the EU boundaries or spreads in territories of third countries, the EU Commission, either by its own initiative or at the request of the concerned EU Member State has the right to take the following measures:

- suspend imports from all or part of the this country and, where necessary, from the transit country as well, and/or

- lay down special conditions of circulation of foodstuffs descendent from the whole or the part of the country concerned.

Next, the subsidiary elements used in realization of principles of Good Agriculture Practice are good practices of work in laboratories and distribution of finished production:

- *Good laboratory practice (GLP)* is the instrument of control of quality of production and founding of so-called "narrow places" in technological raw of its fabrication. The measuring/testing laboratory, which declares its intentions to work in observance of *GLP* principles, has to be accredited by criteria of international standard ISO 17025, therefore be recognized by all ILAC member-countries as the competent one in the sphere of its authorization.
- *Good distribution practice (GDP)* is one of key elements of circulation of foods and preservation of their safety at all stages of nutrition raw.

The GAP norms have also the purpose of establishing of norms of work in conditions of protection of surrounding nature and assurance of rational use of its resources. Therefore, this system includes also the constituents of good practices of storage, transporting, accounting and use of chemicals. The result of introduction of complex of norms of listed practices is:

- production of safe foodstuffs,
- production of useful foodstuffs, and
- production of safe nonfood products of agriculture.

The UN Food and Agriculture Organization developed in it the frame guidance, which execution presumes introduction of such ten basic GAP constituents as normalization of conditions of use of soils; water and energetic management; cultivation of cultural plants; protection of plants; breeding of domestic animals; cropping, treating and storing of harvest; processing of wastes; assuring of healthy conditions of work; protection of environment and natural lands. As such, the instrument used in proof of good quality of foods and witnessing of their compliance to norms of

documents used in realization of good practices is certification, which objects are:

- products produced in Ukraine,
- products imported in Ukraine and marked by their manufacturers as such that comply to requirements of normative documents valid in Ukraine,
- products imported in Ukraine and does not marked by their manufacturers as complying to requirements of Ukrainian normative documents but identified by the supplementing documents as such,
- products imported in Ukraine and does not marked by manufacturer as conforming to requirements of Ukrainian normative documents and did not identified as such, but supplemented by the positive finding of the State sanitary and hygienic expertise carried out in Ukraine.

Depending of scheme of certification there may be used the methods of control of observance of the attested parameters of quality of items to sold as follows:

- periodical technical control of conditions of manufacture in whole or of its separated attested section(s), which produces the products of certified quality,
- periodical audit of effectiveness of observance of norms of certification.

The authorized accredited certifying body has the right to postpone or even cease validity of certificate of conformity it issued and demand of execution of corrective actions in cases of:

- unconformity of quality of serial production of the enterprise to its certified norms,
- infringements of norms of certified technologies and/or procedures of acceptance of finished products, rules of their marking, use of non-attested methods of testing and so on,
- uncontrolled amending by the certified person of conditions of manufacturing, which may influence sufficiently on compliance of indices of quality of its serial production to the certified norms,

- violation by the attested person of provisions of the license agreement with the certifying body.

The necessary corrective actions have to be carried out just after receiving of the order of the inspecting body. These ones are considered as the successful ones:

- if the attested quality indices of serial production after carrying out of necessary corrections would comply to their normalized values,
- if the attested methods of manufacturing would exclude after their correction the possibility of the following fabrication of production of poor quality, and
- if the poor-quality production was withdrawn from storehouses, wholesale bases, trade organizations, taken aside from buyers, and then reprocessed or annihilated.

7.3.2 Global Standard of Safety of Products of Agriculture GlobalGAP

The large European traders founded in progress of globalization of economy and intensifying of processes of integration of business structures the *Association of European Retail Traders of Agricultural Production (EUREP)*. Its basic norms forced its members to introduce productive schemes, which use would guarantee reaching of proper quality and safety of products of agriculture and decrease quantities of agrochemical means and medicinal preparations in their cultivation, and reprocessing. The EUREP structures incorporated also manufacturers of agricultural chemicals, consultative and certification bodies. The main result of functioning of this structure was development in the end of XX century of norms of practice of producing of safe agricultural production known as *EurepGAP*. Its principal difference of practices existed before is not the control of quality of produced products, but tracing of processes of their cultivation and reprocessing based on the concept of good agriculture practice.

As provide the EurepGAP norms, the foodstuff may be considered as safe, if it was produced in conditions of avoiding of contaminating of

foods and semi-manufactured products by potentially harmful substances used in their fabrication. The guaranteed safety of products produced by EurepGAP norms, and sufficient democracy and rationality of norms of operation in this system assisted in its successful introduction worldwide. As such, it was revised in observance of global norms and renamed in 1997 in *GlobalGAP* – the code of good practices used in processes of producing, storage, transporting and sale of production of agriculture.

The first farms certified by norms of GlobalGAP emerged in 2003. This event became the mass in Europe since 2004 and began to spread worldwide since 2006. The norms of this system are used presently in attestation of productive activities of manufactures of agricultural production of more of 90 countries, and the total quantity of persons, which certified their economies by norms of this system, exceeds now 100,000. Particularly, the European countries, which farmers certified their economies by norms of, are Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom. Its norms use also the farmers of eight countries of former USSR: Armenia, Azerbaijan, Georgia, Latvia, Lithuania, Moldova, Tajikistan and Ukraine.

The principal forms of operation in this system are:

- steady observance of details of normalized technologies of operation,
- guaranteeing of safe conditions of labor and observance of sanitary and hygienic norms of operation,
- observance of well-grounded norms of fertilizing and protection of health of objects of attestation,
- transparency in work in processing, utilization and annihilation of wastes,
- careful documenting of all details of business operation.

The significant advantage of GlobalGAP is the wide spectrum of objects of certification: its provisions permit to attest quality of work of producers of almost all types of agricultural production, e.g. the number

of persons, who certified by its norms their work in cultivation of plants amounted to 74 %, products of breeding of cattle – 17% and aquaculture – 9% of total quantity of attested persons. The parties interested in progress of this type certification the most are the public catering and trading networks and establishments, because one of conditions of taking for sale of products of agriculture by the net of European supermarkets is their production in observance of norms of GlobalGAP.

Certification of manufacturing facilities by the GlobalGAP norms includes the clearly defined stages: the preparatory one and the following work in inspection and attestation of the enterprise (its certified department). The principal condition in it is carrying out of operations of inspection and attestation by different organizations, what permits to avoid the biliousness and partiality in this work. The typical sequence of works to be done in it is:

1. *Preparatory work and introduction of norms of conformity.* The activities of the enterprise are analyzed in details. The identified unconformities, if found, have to be eliminated in the possibly short time. Identifying of existing risks in manufacture and introducing of necessary elements of analysis of products on content of residual quantities of fertilizers, herbicides, pesticides and other harmful compounds, introducing of procedures of tracing of improper actions and returning of products of poor quality. Development of systems of documenting and registration of procedures of operation of the enterprise.

2. *Registration.* After the processes of operation of the enterprise would have been brought in compliance to the established norms, the applicant draws up the comprehensive register of procedures of its operating and methods used in their control and apply it together with the set of necessary documents to the organization, which will inspect the object.

3. *Initial auditing by the specialized third party.* The commission of the inspecting person specially appointed by the certifying body carries out the initial audit of the enterprise to acquaint with its leading specialists and used technologies of manufacturing. There are taken into consideration usually the specialization of the farm and specificity of

planting of cultures (breeding of cattle etc.) to be certified, technical state of used equipment, conditions of protection of labor and environment and so on. The commission carries out the initial audit just before the beginning of work in certification, repeats it during the whole term of validity of the GloblGAP certificate issued by the third-party body and places the related information on its web-site open to general use. This site may be used also for commentaries and conclusions the person of certification made by result of its self-control.

4. *Final audit carried out by the certifying body* consists in inspection of used processes of operation, technical state of manufacturing areas and places of processing of products of manufacture up to stage of packing of finished products. It is permitted also to invite for this job the exterior specialists, who have right to give the applicant the consultations and explanations (if necessary) even at this stage of work.

5. *Registration of unconformities.* If the process of inspection revealed the significant unconformities, the owner of the farm has to eliminate them in term of up to 28 days and send to the certifying body documents, which would confirm this fact. Otherwise the repeated certification may be done only in later terms and on condition of carrying out of the repeated inspection of activities of the applicant.

6. *Taking of decision on certification.* If the inspectors would not found any serious unconformity, the owner of the farm receives the certificate of GlobalGAP in term of 2–4 weeks after finishing of the final audit. At that, the body, which carried out certification, deposits the respective information on its site free for access of all interested parties.

The principles of system of GlobalGAP may be introduced both in the individual manufacture and in the group of enterprises. In the latter case, nonconformities found in process of audit of work of each its certified participant may result in postponing of validity or even ceasing of certificate given to the whole group but not only to the person committed the found violation of the established norms.

7.4 System of Safety of Foodstuffs HACCP

The modern norms of guaranteeing of safety of foodstuffs are based on the concept of *"From afield to meal"*, which crucial norm is identification and elimination of risks and food safety hazards, which may arise in processes of producing and consumption of foods. Therefore, there exists the necessity of development of the related procedures of operation, and the most known of such ones is the *Concept of HACCP (Hazard Analysis in Critical Control Points)* recognized universally.

The idea of HACCP was expressed first in 1959 in process of development of the program of prolonged staying of astronauts in open space. Working on this problem, the laboratories of US National Aeronautics and Space Agency (NASA), and "Pillsbury" company (USA) began to develop in details modes of producing of foodstuffs, which would be free of pathogenic organisms. The purpose of this work was development of conditions of prevention of contaminating and deterioration in conditions of durational storage of foods used in ration of astronauts, therefore, excluding of risks of their poisoning in space.

The first information about this system was announced in 1971 at the First American National Conference on safety of foodstuffs. Just after publishing of its basic principles, the US Department of Control of Foodstuffs and Drugs (FDA) approved the directive on obligatory use of norms of this system in processes of fabrication of canned products, and the US Department of Agriculture (USDA) introduced the same norm in work in treating of meat and poultry. After learning of the collected experience of use of this system, the US National Academy of Science recommended in 1985 to oblige all US producers of foods to work in observance of principles of HACCP.

The same was recommended by WHO and the International Commission by Microbiological Norms of Safety of Foodstuffs. In view of importance of system of HACCP for normalization of procedures of control of quality and safety of foods, the Commission "Codex Alimentarius" adopted at her XX session (June 28 – July 7 1993) the *Guide on Procedures of Use of Norms of HACCP* and approved in 1997 at its XXII session the set of documents of *"Recommended*

International Code of General Principles of Hygiene of Foodstuffs", and *"The System of Hazard Analysis and Critical Control Points (HACCP), and Directions on its Use"*. The system presumes the conditional division of technological process of producing (reprocessing, safe storage etc.) of any food by separate blocks and introduction of norms of control of potential risks in each one.

Use of principles of HACCP is the obligatory norm introduced now in legislations of USA, Canada, Japan, and other developed countries. Introduction of norms of HACCP in Europe was began in 1993 (*EU Directive # 93/43/EEC on Hygiene of Foodstuffs*), and its use became obligatory in EU member-countries since 2006. As provided the norms of HACCP, the food business operators shall document each step of their work potentially critical in ensuring of food safety and guarantee that the adequate procedures of operation are identified, implemented and maintained on the basis of the following seven basic principles of HACCP:

- identification of potentially hazardous factors, which may occur in processes of producing and circulation of foodstuffs,
- identification of nominal values of critical parameters recommended for observance and control,
- identification of critical control points (CCP) character for technologies of manufacturing,
- development of system of control in CCP,
- development of correcting procedures directed on elimination of risks or minimization of probability of their occurrence,
- development of norms of functioning of HACCP system,
- detailed documenting of all type activities.

Analysis of global markets witnesses that to compete with foreign businesspersons native manufacturers of foods must observe the norms of operation of their enterprises used internationally. Therefore, introduction of norms of HACCP in structure of quality management helps them in rising of effectiveness of operation, improving of image and increasing of level of satisfaction of interests of consumers by quality of their production. Taking into consideration the information above, one should

recognize that to sell products abroad, native manufacturers of agricultural production have to operate in observance of principles of system of HACCP, what gives them the numerous advantages over operators that work in observance of norms of other systems of ensuring of safety of foods as follows:

- guaranteeing of prevention, elimination or minimization of influence of hazardous factors on conditions of manufacturing, therefore increases safety of foods,
- raising of level of responsibility of personnel for observance of normalized procedures of producing of safe production,
- guaranteeing of compliance of indices of quality of produced products to established norms, what permits to decrease the number of third party audits and inspections,
- increasing of level of confidence of consumers and market operators to safety and quality of production, rising so the investing attractiveness of the enterprise,
- augmenting of possibility of export of products, which were produced in observance of norms of the System.

The Ukrainian business persons, which produce foodstuffs are obliged to *"... use the measures by stage-by-stage introduction of norms of HACCP"*, as well as operate in observance of norms of documents as follows:

- Law of Ukraine of 23.12.1997 # 771/97-BP "On quality and safety of foodstuffs",
- Law of Ukraine of 24.10.2002 # 191—IV-2002 "On amendment of Law of Ukraine of "On quality and safety of foodstuffs",
- Law of Ukraine of 22.07.2014 № 1602-VII "On amendment of norms of certain legal deeds of Ukraine concerning of foodstuffs",
- Decree of President of Ukraine of 07.08.2001 # 601/2001 "On measures on development of food market and assisting in export of agricultural production and food raw materials",
- DSTU ISO 9001:2008 "Systems of quality management. Requirements",

- DSTU 4161:2003 "Systems of Safely Operation with Foodstuffs. Requirements",
- DSTU ISO 15161:2004 "Guidelines on the application of ISO 9001:2001 for the food and drink industry",
- DSTU ISO 22000:2007 "Food safety management systems – Requirements to any organization in the nutrition raw".

As provided the Law of Ukraine of 22.07.2014 # 1602-VII *"On amendment of norms of certain legal deeds of Ukraine concerning of foodstuffs"*, operators of the market are obliged to introduce procedures of operation based on principles of this System. The exclusions are:

- activities of operators of the market, which produce primary products and carry out the related works, especially their transporting and processing at places of production on condition of excluding of sufficient change of their state,
- work in transporting of live animals to be consumed by men, products of fishery and hunting and products of vegetative origin from places of producing of primary production to places of its reprocessing.

7.5 International Systems of Managing of Quality of Foods

The modern enterprises operate in conditions of establishing by the State of the more tough norms of quality of foods. Because risks for health of consumers may arise at any stage of nutrition raw, the norm of adequate management of processes of their manufacturing became invariant since the earliest times of men's civilization. Really, the historical data witness the existence of systems of control of quality of foods already in ancient states of Assyria, Egypt, Ancient Greece and Rome. Nevertheless, the first laws, which regulated norms of quality of foodstuffs, were approved in XIX century only, when the condition of analysis of foods became the constitutive norm. The first known set of documents, which regulated the procedures of work based on scientific principles of control of quality of foods was the codex of standards of *"Codex Alimentarius Austriacus"* developed in Austria-Hungary during the period of 1897 ÷ 1911. The next step in progress of global system of guaranteeing of quality of foods was

made in the end of 1950-s, when Austria agreed with the EU and EFTA member-countries the decision on development of European regional codex of standards on foods of *"Codex Alimentarius Europeaus"*. This idea was favored at the first FAO regional conference of 1960 when the Council of Codex Alimentarius Europeaus took in 1961 the resolution on subordination of its activities to FAO and WHO. The initial idea was finally transformed in founding of new global organization operating safety of foods – the *Commission "Codex Alimentarius" (CAC)*.

The modern norms of its work in control of safety of foods developed the British Consortium of Retail Traders (BRC) on base of the document of *"The technical standard on foods"* and put them in force in 1998. The main idea of this work was development of basic principles of attestation of quality of foods to be sold in the net of supermarkets under brands of their manufacturers. The norms of the standard are based on principles of HACCP, and its basic points are:

- description of procedures of HACCP recommended for introduction,
- recommended procedures of quality management,
- standardized climatic conditions of manufacturing premises,
- standardized procedures of control of quality of production,
- recommended means of control and procedures of their use,
- requirements to personnel.

The BRC developed in addition the series of standards used internationally, e.g. the *"BRC Global Standard – Food Storage and Distribution"*, *"BRC Global Standard – Consumer products"*, *"BRC Global Standard – Food Packaging and other Packing Materials"* etc. The one more standard of safety of safety of foods used worldwide is the *"International Food Standard" (IFS)* developed in 2002 by the German *HDE (Hauptverband des Deutschen Einzelhandels) Association* together with the *French Association of Traders and Distributors (FCD)*. Same as BRC, the IFS standard has the goal of normalization of conditions of guaranteeing of safety of foods and assigned for use by the manufacturers, which sell their products under

brands of supermarkets. The basic norms of guaranteeing of safety of foodstuffs established by this standard are:

- responsibility of upper management for organization of proper operation of the enterprise,
- introduction of system of HACCP,
- observance of norms of individual hygiene by personnel,
- use of raw materials, which are supplemented by the due form specification only,
- supplementing of finished production by certificate of its quality,
- identification of potential sources of pollution of foods and use of measures by prevention of their contamination,
- introduction of system of traceability in processes of producing, safe storage and distribution of foods,
- carrying out of regular inner audits and elimination of found unconformities,
- indisputable use of corrective actions.

Traceability means the possibility of identification of personality of operator of the market, time, place, commodity and other factors sufficient for identifying of source of origination of food rows, animals that would be used in production of foodstuffs, materials that may contact with foodstuffs or substances which would be or may be used as their ingredients at any stage of work in their production, reprocessing and circulation

However, the universally recognized norm of progress of modern society is introduction by persons of economy of systems of quality management by norms of standard ISO 9001. This is especially significant for those ones, which produce, treat and pack foodstuffs and drinks. Therefore, it is the standard of ISO 15161:2001 *"Guide on use of standard of ISO 9001:2000 in processes of manufacturing of foodstuffs and drinks"*, which norms assist in regulation of procedures used in its use in Ukraine as the sole document that normalizes conditions of operation of manufacturers of foods. The normative document used in Ukraine in solving of these and analogous problems initially was the

national standard of DSTU 4161-2003 *"Systems of management of safety of foodstuffs. Norms"* applicable in the food industry, public catering and other spheres of circulation of foodstuffs. The document was developed in observance of most of provisions of the European Directive of 14.06.1993 # 93/43 *"On Hygiene of foodstuffs"* and the document of *"Codex Alimentarius and UN Food and Agriculture Organization Basic Texts on Food Hygiene"*. For the present, this document becomes, however, antiquated and needs actualization or replacement by norms of national standard of DSTU ISO 22000 *"Food safety management systems – Requirements to any organization in the nutrition raw"* introduced in practical use 01.08.2007. However, there exist some complications in it (for instance, the norms of standard DSTU 4161 permit manufacturers to use the rented premises, what is prohibited by norms of standard 22000). Therefore, presently both these documents are in parallel use. The one more argument in favor of continuing of use of norms of standard DSTU 4161 is that this document, same as standard ISO 15161, is based on the norms of use of concept of HACCP and attributed programs-preconditions. So, the enterprises, which operated already in observance of norms of standard DSTU 4161, may simplify their work in introduction of norms of standard DSTU ISO 22000 as compared with those ones that begin this work from nothing.

> *Program-precondition means the complex of basic norms of maintaining of proper hygienic conditions of the working environments at all stages of nutrition raw, which use permits to produce and supply foods safe for consumption*

Use of programs-preconditions is the basic norm of the Order of Ministry of Agricultural Policy of 01.10.2012 *"On Approval of Norms of Development, Introduction and Steady Use of Procedures of System of Management of Safety of Foodstuffs (HACCP)"*, which sets that manufacturers *"... have to develop and introduce effective systems of HACCP, what would permit them to control all hazardous factors potentially present in foodstuffs"*. The principal practices to be used in it are *GMP*, *GHP* and *SOP* (standardized operative procedures), which basic principles are:

- configuring of productive, auxiliary and accommodation spaces in conditions, which would permit to avoid the cross-pollution of foods by exterior admixtures,
- normalization of sanitary conditions of premises and development of norms of safety in works in repair, maintenance and calibration of used equipment,
- assuring of safety of water, ice, vapor and auxiliary materials used in producing (reprocessing), storage and transporting of foodstuffs,
- regular cleaning (washing, disinfection) of auxiliary and common use premises,
- assuring of norms of hygiene of personnel,
- steady control of observance of norms of used technologies.

Doing so, businesspersons must take into consideration that some groups of people (babies, children, pregnant women, aged persons, diabetic etc.) are especially sensitive to probable negative consequences of consumption of certain kinds of foods they produce. Therefore, suppliers of foods have to devote the especial attention to their needs and put into the parcels with the finished products they propose the clear instructions on recommended methods of their treating and consumption.

Introducing the HACCP norms, enterprises must observe the following norms of Ukrainian legislation:

- *The organization has to introduce, maintain and document the effective system of management of safety of foodstuffs.*
- *The organization has to identify the range of use of introduced system of operation and guarantee safety of products to be operated with.*
- *The organization has to carry out the actions as follows:*
  a) identify, evaluate grade of influence and eliminate the probability of occurrence of direct or indirect harm for consumers of the food safety hazards, which may arise with the sufficient grade of probability in products, which are in sphere of its management,

b) give the unbiased information by problems of safety of their products to all participants of work in structure of nutrition raw;

c) give interested persons the comprehensive information on existence and norms of assuring of safety of foodstuffs.

The standard ISO 22000 normalizes procedures of detection of risks, methods of their elimination and norms of evaluation of grade of hazard in use of newly developed foodstuffs and/or their ingredients, as well as the grade of compatibility of procedures of their production with norms of good practices (Table 7.1):

Table 7.1

Procedures of control used in development of new products

Stage of work	Procedure to use	Note
Inspection	Control of accuracy of observance of carrying out established norms of planned works	Predicting of probability of reaching of the desired result
Control	Continuous process, which includes the work in steady control of correctness of operation at all stages of manufacture and/or comparison of quality of the exemplary and pilot samples of production	Convincing in compliance of controlled indices of products to their normalized values
Approval	Attestation of compliance of indices of the product to established norms	The condition of approval is assurance in admissibility of consumption of the product by certain groups of population (e.g. by infants) in absence of harm for their health

The objects of control in process of manufacturing are:

- procedures of producing of primary products of agriculture (fattening of cattle, initial treatment of grain etc.),
- hygienic state of manufacture, especially conditions of equipment, packing and other materials, particularly properties of chemicals, which may contact with foods,

- grade of contamination of finished products and pollution of environment,
- quality of water and ingredients of foods used in process of business operation,
- observance of norms of processes of manufacturing,
- auxiliary operations (e.g. the specified methods of their packing),
- criteria of operation of testing laboratories,
- procedures of storing of raw materials, semi-manufactured products and finished products,
- procedures of safe storage, transporting and distribution of finished products.

Planning his work, the businessperson has to introduce the necessary preventive measures to decrease the grade of ingress in foods of biological, chemical and physical pollutants, what would permit to raise quality of his products and decrease quantity of inspections of off-site parties. As early as before beginning of planned works, the chairman of the enterprise has to appoint the group of experts experienced in managing of safety of foodstuffs, which has to describe the characters as follows:

a) biological, chemical and physical properties of substances/materials contacting with foods,
b) specifications of purchased materials and ingredients,
c) methods of preparation and/or treatment of raw and auxiliary materials,
d) composition of multicomponent ingredients (including the used additives and auxiliary materials),
e) technologies used in process of business operation,
f) methods of packing and supply of finished production, as well as term of their fitness for consumption.

The enterprise has to introduce the system of traceability, which would permit to identify causes of origination of deficiencies and drawbacks in its work, as well as to clear the grade of dependence of quality of finished products of composition of used raw materials, methods of their treating and history of supply. It is necessary to develop

also the block-diagram of processes of producing of safe foods and fix the information as follows:

a) succession and interrelationship of processes of manufacturing,
b) details of processes of manufacturing, information on used raw materials, ingredients and semi-manufactured products, methods of their treating and procedures of removal of wastes,
c) methods of reprocessing of production incongruous to established norms, and recommended methods of repeated use of reprocessed products,
d) works executed out of manufacturing premises, including those that are carried out by subcontractors.

The persons, who have the sufficient skill in profile works have to analyze the data obtained in monitoring of processes of manufacturing, trace conditions of operation in critical control points and issue recommendations on corrective actions to be done (if necessary). The enterprise, in turn, has to document procedures used in identification and elimination of found unconformities, particularly:

a) identify the found unconformities and causes of their origination,
b) analyze tendencies of variation of results of work of the enterprise and identify probable risks of loss of managing and recommend procedures of work directed on exclusion of probability of their origination,
c) fix results of corrective actions.

The finishing stages of manufacturing have to be executed in the following sequence:

a) packing of products by the contractual methods,
b) control of placing on packs of necessary marks,
c) safe storage of finished products till the moment of their shipping in observance of the normalized climatic conditions, especially of parameters of temperature and humidity,
d) informing of interested parties on guaranteed terms of storage of finished products and use of measures by prevention of risks of their contamination,

e) carrying out of hygienic and invasive control up to stage of packing of finished foods.

The documents, which supplement parcels with finished products, have to contain the following information:

a) name of the product, its composition, normalized term of fitness and recommended conditions of storage,
b) biological, chemical and physical factors, which may influence on its safety,
c) characteristic of packing,
d) potential harmfulness of foodstuffs and/or instructions on their preliminary treatment, preparation to use and conditions of consumption.

The enterprise has to carry out regular inner audits, what would permit to control the fact of observance of norms of quality system it uses, and identify and reprocess batches of poor-quality production (if exist) by methods as follows:

a) reprocessing of production by consent of its owner,
b) utilization of production, or
c) its alternative use.

To make the in-time withdrawal of poor-quality products taken from batches prepared for shipping, administration of the enterprise has to appoint persons responsible for this work and establish the following rules of operation:

- introduction of norms of informing of interested parties and/or consumers on existence of products of improper quality,
- establishing of procedures norms of reprocessing of withdrawn products still stored in warehouses, and
- documenting of methods of reprocessing of poor-quality products.

The culled products must be stored under the strict control up to stage of their annihilation or alternate use, or be recognized as safe for use by destination, or be reprocessed by methods, which would guarantee safety in their following use. The procedures used in such cases normalize the international standards as follows:

- DSTU-P ISO/TS 22003:2009 "Food safety management systems – Requirements for the bodies providing audit and certification of food safety management systems",
- DSTU-N ISO/TS 22004:2009 "Food safety management systems – Guidance on the application of ISO 22000:2005",
- DSTU ISO 22005:2009 "Traceability in the feed and food chain – General principles and basic requirements for system design and Implementation".

The ISO technical committees continued this work and developed the next documents, which principal goal is detailing of mechanisms of guaranteeing of food safety:

- ISO/DTS 22002-2:2013 "Prerequisite programmes on food safety — Part 2: Catering",
- ISO/AWI TS 22002-6:2014 "Prerequisite programmes on food safety — Part 6: Transport and storage",
- ISO/AWI TS 22002-7:2014 "Prerequisite programmes on food safety — Part 7: Food packaging manufacturing".

The designations used in coding of these documents are: DTS – *Draft Technical Specification*, and AWI – *Approved Work Item*.

Because hazardous factors may exist at any stage of nutrition raw, the crucial factor of management is the adequate securing of procedures of operation against risks, which may occur in process of manufacturing, transporting and storage of finished foodstuffs, as well as in producing and supply of forage and primary products. this work has to be done not by producers and suppliers of listed products only, but also by persons specialized in retail trade and public catering (together with the adjoining organizations, such as manufacturers of equipment, packing materials, cleaning agents, additives and food ingredients). The important factors in identification and elimination of risks and hazards in consumption of products they propose are informing of all interested persons on probable after-effects of their use. One of possible variants of structure of channels of exchange by such information normalized by this standard illustrates Figure 7.2:

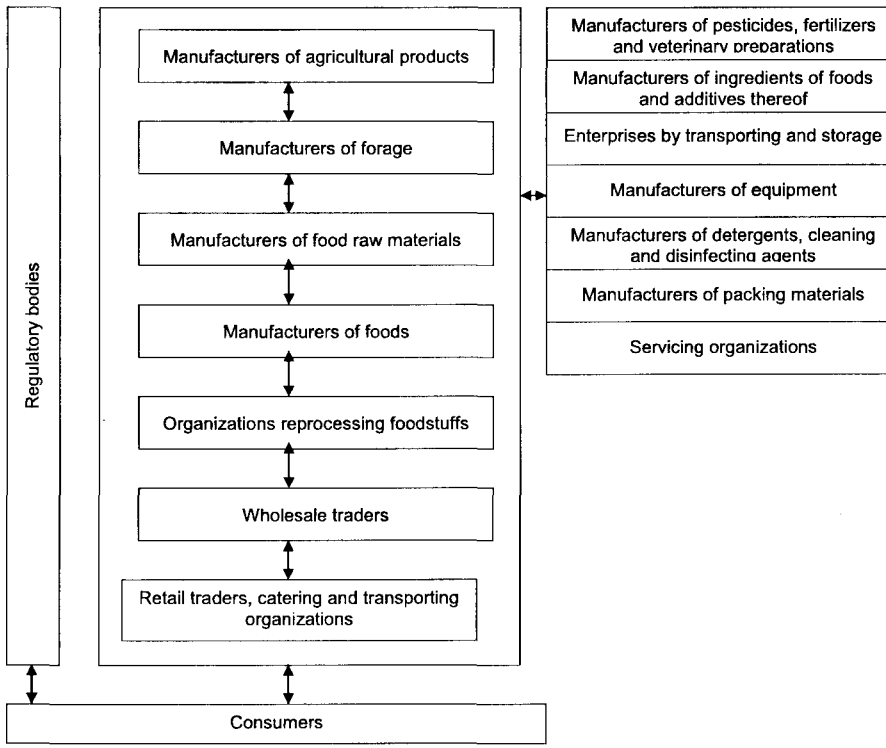


Fig. 7.2 The exemplary scheme of exchange by information in structure of nutrition raw

All requirements normalized by standard ISO 22000 are of general character and may be used by producers of forage, harvesters, farmers, manufacturers of foodstuffs and their ingredients, retailers, catering organizations, suppliers of production, as well as organizations, which operate transporting, storage and distribution of foods. The best results may be achieved if the organization operates in observance of norms of standard ISO 9001, which use permits:

a) to guarantee safety of produced foodstuffs,
b) to observe interests of customers,
c) to plan, introduce, maintain and renovate systems of management of safety of foods,

d) to demonstrate the compliance of parameters of safety of their production to norms of legal, regulatory and normative documents in force,
e) to take into consideration the messages of customers, suppliers and other interested parties on hazards non-identified before,
f) to certify the proper quality of foods, or certify the norms of used system of quality management.

The successful introduction of system of management of safety of foodstuffs gives the enterprise the advantages as follows:

- possibility of certification of system of management of safety of foodstuffs on conformity to international norms, therefore their free sale in international markets,
- decreasing or even excluding of probability of origination of nonconformities,
- documental approval of safety of conditions of manufacture and its production,
- getting of advantages in tender competition,
- raising of level of confidence of consumers to its production.

7.6 World Trade Organization as a Guarantor of Quality of Production, Goods and Services

The idea of liberalization of conditions of global trade, hence founding of international organization operating this problem, arose just after ending of World War I. Thus, negotiations on realization of principle of free trade were carried by participants of 30 countries in Brussels under the aegis of the League of Nations since 1920. Following this idea, delegates of 50 countries took at the Third Global Economical Conference in Geneva (1927) the obligation to derestrict during six months all limitations and prohibitions on import and export of goods of common use. However, such resolution was not ratified by most of participating countries and the problem was considered again only after the WW II was ended. 1945 was the year of beginning of work on forming of new principles of global financial and trade systems. To solve these problems, there was founded the *UN Economical and Social Council (ECOSOC)*,

which had to concentrate its efforts on development of methods of elimination of financial controversies among its members by problem of *"... assisting in progress of works in global barter by commodities, as well as raising of level of their consumption by people"*. To start this work, it was convoked the Conference held in Cuba in period of 21.11.1947 – 28.03.1948. Its principal results were development of the so-called *"Habana Charter"* by problems of fair trade and the project of the Statute of the Organization, which principal task would be operation the problems of global trade. This document had to establish not only the problems of regulation of conditions of global barter, but normalize also principles of engagement of laborers, delimiting of conditions of trade by goods and services and procedures of international investments.

The first step in settling of global economic relations was the event of signing in 1947 of *GATT (General Agreement on Tariffs and Trade)*, which principal purpose was introduction of "*temporary regime of regulation of trade to be used in purposes of renewal of structure of global economy demolished in wartime*" by governments of 23 countries: Australia, Belgium, Brazil, Burma, Canada, Ceylon, Chile, China, Cuba, Czechoslovakia, France, India, Lebanon, Luxembourg, Netherlands, New Zealand, Norway, Pakistan, South-African Union, South Rhodesia, Syria, United Kingdom and USA. However, it became apparent soon that the Habana Charter will be never ratified, and GATT, which was founded as the *instrument* of arrangement of trade relations, acquired finally the functions of *organization* responsible for carrying out of work in harmonization of norms of global trade, which basic principles were:

- elimination of trade barriers, what meant, each GATT member-country had to grant in introducing of any technical regulation the regime of the most-favored conditions of sale for production of any other GATT member-country,
- absence of discrimination in trade as the result of mutual granting of the most-favored conditions of circulation of production in carrying out of export, import and transit operations,
- progressive decreasing of custom duties,

- priority of use of tariff methods of protection of national markets over actions centered on quantitative limiting of import of goods,
- solving of trade controversies in negotiations and consultations. In impossibility of reaching of mutually acceptable solution, these ones have to be solved by the specially organized arbitration court, which decisions should be of obligatory character.

Meantime, the agreements concluded in the GATT structure did not impede its members to use the norms of national standards and methods of inspection, what became the serious barrier of pure technical character in progress of international trade. Nevertheless GATT, though did not justified expectations on full settling of all existing problems, became the relatively efficient structure, which work permitted to reduce the rate of custom duties from about 40 % for the time of its founding to approximately 4 % for the time of mid-1990-s. This phenomenon resulted in annual growth of volumes of trade operations of 8 % in period of 1950-s – 1960-s, what was sufficiently more of rate of growth of global volumes of manufacturing and remained too big in later years being of about 6% till the end of 1990-s. As a result, the volume of international dealings exceeded in 2000 the respective level of 1950 by factor of 22. However, GATT was not capable to solve all problems existed in global trade, especially the problems of settlement of level of export subventions, because of invalidity of that time provisions of Anti-Dumping and Investment codes by problems of assuring of conditions of fair competition.

However, in progress of global economy, there arose in 1970-1980-s the negative tendencies of use of unfair methods of protection of national economies, which suffered of systemic crisis. Therefore, GATT became invalid in successful solving of problems it had to solve, what lead to need of its reorganization and the finishing event in its activities as an independent structure became approving in Montevideo (15^{th} of April 1994) of 28 treaties on minimization of values of tariff and non-tariff limitations in global trade. The talks on their discussion known as the *"Uruguay round"* of negotiations continued in period of 1986 ÷ 1994 and resulted finally in juridical fixing of new system of trade. There was

taken also the decision on transformation of GATT, which is the ***treaty*** by its form, in the new global ***structure*** – the *World Trade Organization (WTO)*.

The prerequisites of taking of decision on its founding were:

- necessity of elimination of differences of national norms of quality of objects of trade,
- necessity of founding of organization, which principal goal would be assisting in concluding of mutually favorable treaties of WTO member-states on reducing of values of custom duties and liquidation of discrimination in global trade,
- necessity of intensification of international economic and trade relations, raising of welfare of peoples, reaching of maximum employment and effective use of human resources.

The Declaration on founding WTO was signed in the city of Marrakesh (Morocco) at the April 1994 conference of profile ministers of 124 countries. As provided the WTO Treaty, its founders are the GATT member-countries, which had ratified the pack of its constitutive treaties till the end of 1997. By the state on 30.04.2012 WTO listed 153 countries and separated custom territories including some of CIS member-countries: Armenia, Georgia, Kyrgyzstan, Moldova, Russian Federation and Ukraine. Besides, statuses of observer in WTO have more of 50 international organizations: the International Monetary Fund, World Bank, Organization of Economical Collaboration and Development, some of UN structural units, regional associations and others.

The WTO members took also the decision that the work in its structure would relate to trade by both goods (what in fact was the only subject of GATT activities since the time of its founding) and services (which cost for the time of beginning of XXI century reached about of 20% of total value of global trade). WTO does not form any supranational structure and all countries, which participate in its functioning, preserve full sovereignty in their own territories in foreign trade relations and introduce norms of WTO treaties same as it is done in signing of other kind international treaties.

WTO assists also in solving of many supplementary problems, e.g. in protection of rights on intellectual property, as well as has the authority in taking of decisions obligatory for execution by its members. The *principles* used WTO in its functioning are:

- trade without borders and discrimination,
- assistance in fair and conscientious competition,
- establishing of well-grounded custom tariffs,
- development of details of economical reforms and assistance in their introduction.

The principal *WTO functions* are:

- assistance in regulation, liberalization and raising of level of predictability of trade relations of its member-countries,
- development of mechanisms of settlement of controversies in trade,
- control of observance of established norms of global trade and giving of necessary consultations.

Contrary to the sequence used in GATT, the WTO participants have to harmonize their national bases of normative documents with international norms, hence use the uniform procedures of evaluation and attestation of quality of production of same destination of use. To realize this principle, the Treaty on founding of WTO foresaw creation of the Standing Forum of its members, which principal function is control of observance of provisions of treaties taken in Uruguay Round and settlement of problems, which influence on trade relations of the WTO members.

The supreme WTO body convened biennially is the Conference of profile ministers of its member-countries. The one more constitutive body of the Organization is its Secretariat headed by Managing Director, whose main functions are working up of decisions to be executed by WTO structures and giving the interested parties of necessary information and consultative services. The WTO structure includes also its working committees subordinated to the WTO General Council. Their principal function is exploring and generalizing of experience of use of norms of State regulation used in WTO member-countries, studying of practices of

trade policies of its members and settling of appeals of parties of trade relations. However, if the complaining party would not be satisfied by proposed method of settling of dispute, it may apply to WTO General Director for mediation and if his efforts would be ineffective too, there has to be started the procedure of arbitration by the commission that should consist of experts by the problem to be solved, which resolution must be fulfilled by the guilt party obligatorily.

Each WTO member-country founded the information center, which has to answer on the well-grounded inquiries of interested parties about norms standards she uses in trade. To avoid origination of ungrounded barriers in international barter, such documents must not be of more limiting character that it is necessary for guaranteeing of the following conditions: 1) assuring of national safety, 2) prevention of dishonest actions of trade partners, 3) guaranteeing of proper state of work in protection of life and health of men, animals, plants and preservation of normal conditions of environment.

The bank of documents used in the everyday operation of WTO signed in the Uruguay Round of negotiations contains more of 50 multilateral treaties and documents of legal and normative character, which the most significant are:

1. In sphere of trade by commodities:
   - General Treaty on Tariffs and Trade (GATT-94),
   - Treaty on Technical Barriers in Trade,
   - Treaty on Use of Sanitary and Phytosanitary Measures,
   - Treaty on Agriculture,
   - Treaty on Investments in Trade,
   - Treaty on Procedures of Use of Article 6 of GATT-1994 (anti-damping procedures).
2. In sphere of use of Article 7 of GATT-94 (Evaluation of custom system):
   - Treaty on Inspecting Before Shipping,
   - Treaty on Procedures of Identification of Origination,
   - Treaty on Procedures of Licensing of Import,
   - Treaty of Subventions and Compensating Measures,

- Treaty on Safeguards.

3. General Treaty on Trade by Services.
4. Treaty on Trade by Rights of Intellectual Property.
5. Treaty on Rules and Procedures of Solution of Controversies.

The basic agreements used in regulation of norms of trade by agricultural production are:

7.6.1 WTO Treaty on Agriculture

The barter of agricultural production is one of the most sensitive sectors of international trade; therefore operation in observance of norms of this Treaty permits the WTO member-countries to normalize procedures of granting for native producers of agricultural products of budget subventions in manufacturing, realization and export of their production. Following its norms, each WTO member guarantees free access of agricultural production of foreign origin in its domestic market and establishes in it the well-grounded custom duties and fair export quotes. The norms of their realization of such practices are:

Access to markets: prohibition of use of non-tariff measures of limiting of volume of import and their recalculation in the *"tariff equivalent"* (custom duties), if necessary.

Protective measures: each WTO member has the right to introduce the extra-duties of protective character in import of products of agriculture designated in tariff lists of WTO members by mark of *"SSG" (special safeguard)*. The conditions of their introduction are:

- exceeding of volumes of import of norms of this Treaty,
- smaller price of imported products as compared with the level, which exists in the importing country.

There has to be fixed also the maximum amount of State budget financing of export and the rate of its annual decreasing in form of: 1) cutting of volume of financing, and/or 2) cutting of physical volume of export. At the same time, clauses of this Treaty establish three basic permissible directions of spending of budget means to be used in it as:

"Green Basket" Measures used by each WTO member-country without any limitation:

- financing of R&D works in agricultural sphere,
- control of germination of pests and level of spreading of diseases,
- training of specialists and personnel of inspection services,
- servicing in marketing of agricultural production and assistance in its progression on the global market,
- giving of infrastructural services (including the procedures of spending of means on transport servicing and supply of energy and water to places of their use),
- accumulation of State reserves of food,
- upkeep of certain level of income of manufacturers guaranteed by the State,
- compensation of well-grounded losses occurred in cases of natural disasters,
- paying by programs of protection of environment,
- paying by programs of aid for regions, which are in unfavorable conditions of nature,
- assistance in restructuring of structure of agricultural sector of economy.

"Blue Basket" measures done without any limitation: the direct budget subventions by programs of cutting of volumes of producing of agricultural products.

"Yellow Basket" measures comprise all other aspects of interrelations of native businesspersons with domestic manufacturers of agricultural production. Each country, which joins WTO, agrees with the Organization the initial maximum permissible rate of the State financing of programs of this "basket", which, in turn, has to be gradually decreased by certain percent accordingly to the agreed schedule.

As seen, Ukraine, being the WTO-member, retained the right of effective subsiding of persons, which operate in the agricultural sector of economy by programs of development of branches of breeding of cattle, growing plants, as well as forming of the State reserves of food. Besides, she can introduce the rate of special taxation of agricultural manufacturers by the Value Added Tax and obtaining of means from local budgets, what

is the weighty mechanism of indirect support of agricultural manufacturers.

7.6.2 WTO Treaty of Safeguards

Accordingly to norms of this Treaty, each WTO member-country has the right to limit temporarily the uncontrolled raising of volume of importation of any consumable if it threatens by serious harm for domestic manufacturers of goods of analogues destination of use, as well as to postpone partly of in full observance of obligations taken by signatories of international contracts. The protective measures are introduced typically in form of custom duties, which act temporarily during the term sufficient for restructuring of respective branch of national economy (up to four years). In extreme cases their action may be prolonged for the period of up to eight years, but not more.

The suffering country has to send in this case the respective written application to all interested countries and accomplish the necessary consultations before such measures would have been introduced. In critical cases, when the delay in their introduction may result in irreparable harm for the State, said actions may be introduced immediately for the period of up to 200 days on condition of informing of all interested WTO member-countries *just after their introduction*. At the same time, the country, which introduces such measures, has to give the adequate compensation to the WTO member-country, which produces goods that are the object of protective measures. These ones are given typically in form of adequate decreasing of value of custom duties levied in import of other goods from the country, which suffers of said actions. If some WTO member-countries are unified in any customs union, they may introduce the protective measure valid on the territory of one of its members only but not on the whole territory of this union.

If any goods that are potentially the object of protective measures are produced in the developing WTO member-country, the respective actions must not be introduced till the quota of their import is less of 3 % of total value of commodities of analogous destination used (consumed) in

importing country and in case of import of said goods from some developing countries, the protective measures cannot be introduced till the integrated quota of their export will be less of 9 %.

7.6.3 WTO Treaty on Technical Barriers in Trade

The one of fundamental documents put in base of WTO activities is the Treaty on Technical Barriers in Trade (TBT). Some of their types are:

- differences in national legal bases and norms of national standards used in work by assessment and attestation of conformity of objects of barter,
- differences in norms used in some national systems of certification,
- existence of stringent procedures of recognition of validity of foreign certificates of conformity issued abroad.

The main cause of validation of this Treaty was the need in introduction of uniform parameters of quality of objects of normalization and elimination of differences of methods of their identification and control. The principal conditions of barter set by the TBT treaty are:

- all operations concerning of import and export of consumables,
- all taxes and other duties applied to consumables of foreign origin,
- all norms of selling, purchasing, transportation, distribution and use of goods of foreign origin,
- all duties, rules and formalities used in transit of goods of foreign fabrication through the national custom territory.

To avoid the dishonest trade actions and protect life and health of men, animals, plants and preserve good conditions of nature, each country is free in use of measures necessary for limiting of access on domestic market of any product of foreign fabrication. So, the constitutive TB Treaty clauses declare:

- observance of most-favored-nation conditions in trade,
- establishing of obligatory norms of import of objects in question by technical regulations of international category, but not by national standards,

- attestation of quality of goods to be exported by norms of international standards,
- transparency and predictability of procedures of export-import operations,
- adequacy of limitations in trade introduced dependently of grade of hazard of objects of barter,
- accessibility of information of all WTO member-countries on details of their national systems of technical regulation for all interested parties,
- possibility of participation of foreign assessment conformity bodies in carrying out of works by profile of their specialization in other WTO member-countries.

Accordingly to provisions of the Treaty, the basic norms of international trade are:

1. *Non-discrimination and use of national procedures*. The same cost of works carried out by orders of native and foreign businesspersons and procedures of attestation of conformity of production imported from any WTO member-country and analogous products of domestic manufacture (use of national mode). The same norm is applied also to products exported from not WTO member-countries, which concluded the respective treaties with the WTO members that import their goods (mode of most-favored-nation in trade).

2. *Harmonization*. Observance by the WTO member-countries of provisions of international and regional normative documents (preferably ISO standards) in development of national technical regulations and norms of regulative character. However, the participants of international trade are free of obligation of use of norms of said standards if this is justified by fundamental climatic and other geographical factors, and/or existing of risks of inflicting of considerable harm for national economy because of inequality of existing state of domestic infrastructure to norms of business operation in modern conditions.

3. *Equivalence*. The process of development, approval and harmonization of international (regional) standard may be too durational and expensive. So, the members of intercommunications may operate also

by the norm of technical harmonization known as equivalence. Following this principle, the national document of normative and/or technical character may be recognized as the equivalent to the norm used by his trade partner, if the regulative documents they use permit to reach the same results even in differing of their basic norms.

4. *Mutual recognition of results of testing*. Manufacturers may have problems in confirmation of proper quality of their production abroad because of differences of methods of its analysis in different countries, what may be eliminated, if the attestation of its quality will be done once by the third-party person authorized on carrying out of this job by international norms of accreditation.

5. *Transparency*. Each WTO member-country has to found the national information center responsible for answering on all substantiated inquiries of interested parties and disseminating of documents, which inform on content of national procedures used in work in assessment and attestation of conformity.

7.6.4 WTO Treaty on Sanitary and Phytosanitary Measures

This treaty is one of the most significant treaties signed by results of the Uruguay round. As provide its provisions, the WTO member-countries have to recognize the sanitary and phytosanitary norms and measures carried out by other WTO members as equivalent with the domestic ones, if they permit to reach the level of protection of health of consumers, which they normalized in their countries.

> *Sanitary or phytosanitary measure means any action, which is carried out in purposes of:*
>
> - *protection of life and/or health of animals and plants against risks, which emerge in result of penetration, rooting or spreading of harmful organisms and sicknesses, as well as organisms, which are carriers of sicknesses and pathogenic organisms,*
> - *protection of life and/or health of men and/or animals against risks, which emerge in consumption of additives,*

pollutants, toxins or pathogenic organisms present in foodstuffs and/or forages,

- *protection of life and health of men and/or animals against risks, which emerge as the result of sicknesses that are transferred by animals, plants or products produced with their use, as well as those hazards that result of penetration, rooting or spreading of harmful organisms and sicknesses, as well as organisms, which are carriers of sicknesses and pathogenic organisms,*
- *avoiding or limiting of grade of other kind harm, which results in penetration, rooting or spreading of harmful organisms and sicknesses, as well as organisms, which are carriers of sicknesses and pathogenic organisms.*

The category of documents that regulate the extent of use of sanitary and phytosanitary measures include all legal and normative deeds by problems of assuring of safety of foodstuffs and health of animals; manufacturing processes and methods of manufacturing; procedures of sampling, testing, inspection and approval of proper quality; quarantine procedures including those ones that regulate norms of transporting of animals or plants or materials necessary for their persistence in processes of transporting; methods of analysis of risks; norms of packing and marking of finished products

The one of obligatory norms of this Treaty is the condition of attestation of good quality of foodstuffs (if there are not used in this purpose documents of upper level of regulation, e.g. the European directives).

The sphere of use of this Treaty spreads on: 1) actions conditioned by the specialized legal and normative deeds and regulations, 2) methods of producing of foodstuffs, 3) procedures of testing, inspecting and attestation of quality of objects of sanitary and veterinary control, 4) quarantine procedures, 5) methods of selective inspection of quality of foods and evaluation of grade of risks, which arise in their consumption, 6) conditions of packing and marking of foods. The sanitary and

phytosanitary norms are recognized as such that cannot be contested if they are based on scientific principles and used in extent necessary and sufficient for protection of life and health of men, plants and animals. Using norms of this Treaty, the WTO members:

- have the right to introduce in relation to products of international barter the sanitary and phytosanitary measures established by its clauses on condition of non-use of unauthorized or unjustified discriminative measures against any WTO member-country, which operates in similar conditions,
- guarantee that each used measure is properly substantiated and effects only in extent necessary and sufficient for protection of life and health of men, animals and plants,
- guarantee that the used measures would conform to those that are normalized by international standards, guides and recommendations in force,
- have the right to introduce the temporary preventive sanitary and/or phytosanitary restrictions in relation to subjected products in cases of expansion of disease, vermin and pests even in insufficiency of the adequate scientific substantiation.

The WTO members have to guarantee the possibility of reaching of satisfactory level of sanitary and/or phytosanitary safety of exported products in countries of destination. At that, the importing WTO member-country has to recognize reasonableness of measures taken in relation to production in question and give her partners the possibility of free inspection of objects of interest, testing of products subjected to inspection and carrying out of other necessary procedures by problems covered by provisions of this Treaty.

7.7 Environmental Constituent of Safety of Foodstuffs

The conditions of living in modern world are character by swift growth of count of population, what requires of sufficient increase of quantity of produced foods, hence rising of productivity of products of agriculture. However, any economic activity is potentially hazardous and generates risks of technogeneous character. To nourish mankind, farmers

are forced to intensify technologies of planting, hence bring in soils annually up to 500 million ton of mineral fertilizers and 4 million ton pesticides showing in it the raise since 1960-s in spending of nitrogen fertilizers tenfold, phosphorus fertilizers – by factor of 7.5, pesticides – sixfold etc. Therefore, there increased quantities of waste products potentially dangerous for health thrown down in result of economic activities in basins, atmospheric air, and soils, which migrate into foodstuffs and drinking water. For example, analysis of 30,000 specimen of water carried out in UK showed pollution of about of 30% of samples of drinking water, 7 % groundwater and 62 % tap water taken for control. Next, the World Health Organization reported on chronic poisoning till the end of 1990-s of about of 500,000 persons (5,000 of them died), as well as the US National Academy of Sciences published in 2000-s the report, which predicted that about of one million of Americans will have within the next 70 years the risk of cancer affected by presence in food of 28 types of carcinogenic pesticides.

The modern tendencies of progress in practices of agriculture show the sufficient increase of use of energy per unit of manufactured production, deterioration of conditions of environmental balance in agricultural ecosystems and landscapes and their bigger genetic similarity, hence raising of sensitivity to exterior influences, as well as growth of grade of dependence of conditions of business operations of non-regulated variations of conditions of nature. Therefore, there arouse the necessity of identification of the most serious environmental risks, which the most significant are:

- global alteration of climate,
- de-enrichment by ozone of stratosphere,
- alteration of conditions of habitat,
- loss of populations and impoverishment of biological diversity.

So, the main tasks of modern society are introduction of technologies of economical spending of natural resources and decreasing of grade of pollution of the habitat. To improve the existing situation, the EU institutions promulgated the Directive of 2010/75/EU *"On industrial emissions (integrated pollution prevention and control)"*, which

principal purpose is to establish norms and conditions of throwing away of substances hazardous for environment into the air, soils, superficial and underground waters, as well as to normalize the measures of integrated control of pollution of environment.

> *Substance means any chemical element and its compounds except of radioactive isotopes and genetically modified organisms*
>
> *Pollution means the direct or mediate throwing of substances into the air, earth and water environments, as well as generation of vibrations, emissions of heat power or noises capable to influence unfavorably on conditions of health of men and quality of nature, what results in material losses and/or worsening of comfort in use of natural resources*
>
> *Emission means the direct or indirect release of substances, vibrations, heat or noise from individual or diffuse sources into the surrounding nature*

The events of deterioration of environmental conditions produced the more attention of governments and global community to problems of pollution of nature, hence need of development of strategy of protection of nature and introduction of technologies of *"environmentally pure manufacturing"* character by minimal expending of materials and energy. The *UNIDO (United Nations Industrial Development Organization)*, the organization specially founded in these purposes, interpreted (1992) the latter notion as the kind of activities, which presumes carrying out of continuous work in protection of environment, and gave at its 1996 Oxford conference the conjugated formulations of:

> *Environmentally pure manufacturing means the producing activity character by steady contraction of use of material and energetic resources, minimizing of use of toxic materials and substances and continuous decreasing of quantity of toxic outbursts*
>
> *Environmentally pure product means the product character by minimal negative influence on conditions of environment during all its life cycle*

Environmentally pure services means the services given in observance of established norms of protection of environment
Wastes mean any substances, materials and items, which were formed in result of men's activity and have no following use
Hazardous wastes mean the wastes, which physical, chemical, biological or other properties are or may be sufficiently dangerous for health of men and conditions of nature
Environmental risk means existence of probability of coming of event caused by the business activity, which may influence unfavorably on conditions of nature in occurrence of extraordinary situations of natural and/or technogeneous character

To decrease the negative influences of results of business operation on conditions of nature at rural regions, there are used extensively since 1970-s the methods of *organic agriculture* (otherwise *"organic farming"*) based mostly on use of norms of standards set by the *International Federation of Organic Agriculture Movements (IFOAM)*. The term of "organic agriculture" is used usually in relation to activities centered on optimization of conditions of functioning of interrelated communities of productive plants, domestic animals and inhabitants of soil in conditions of preservation of healthy state of nature:

Organic agriculture is the productive system centered on sustaining of health of soils, ecosystems and people, conservation of biodiversity and use of environmentally friendly processes and cycles adapted to local conditions of nature. Organic agriculture combines traditions, innovations and achievements of science in betterment of environmental conditions and promoting of good quality of life of all parties involved. Organic farming unifies all systems of environmentally, socially and economically rational methods of agricultural manufacturing based on use of natural potential of plants, animals and landscapes, as well as harmonization of conditions of operation in

observance of established norms of protection of environment

Because principles of organic farming are based on norms of nourishing of plants through the soil ecosystem, the hydroponic method of cultivation should not be recognized as such because plants grow in this case in the inert medium and are fed by soluble minerals and nutrients but not the components of soils. In progress of processes of organic agriculture the European Union members accepted the Regulation # 834/2007 concerned of methods of organic production (including the processes of producing of products of aquaculture) and norms of labeling of organic products to be placed on the market, as well as the Regulation # 889/2008, which details norms of its implementation. The one of possible designs of EU logos detailed by these documents and used in marking of organic products (its English version) shows the Figure 7.3 below:

Figure 7.3 The EU model logo used in marking of organic products

The Eurocommission approved the restricted list of the auxiliary products and substances that may be used in organic farming and ranked by categories as follows:

a) plant protection products,
b) fertilizers and soil conditioners,
c) non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition,
d) feed additives and processing aids,
e) products used in cleaning and disinfection of ponds, cages, buildings and installations for animal production,
f) products used in cleaning and disinfection of buildings and producing installations.

As provided the practice of organic farming, the products, which may be recognized as "green" ones are:

a) live or unprocessed agricultural products,
b) processed agricultural products to be used as food,
c) feeds,
d) vegetative propagating materials and seeds for cultivation.

The products of hunting and fishing of wild animals shall not be considered as organic production. This Regulation shall also apply to yeasts used as food or feed.

Organic farming shall be based on use of the following norms:

a) the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:
   (i) use living organisms and mechanical production methods,
   (ii) practice land-related crop cultivation and livestock production or practice aquaculture, which complies with the principle of sustainable exploitation of fisheries,
   (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products,
   (iv) are based on risk assessment, and the use of precautionary and preventive measures, when appropriate,
b) the restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in paragraph (a) do not exist, these shall be limited to:
   (i) inputs from organic production,
   (ii) natural or naturally-derived substances,
   (iii) low solubility mineral fertilizers,
c) the strict limitation of the use of chemically synthesized inputs to exceptional cases these being:
   (i) where the appropriate management practices do not exist,
   (ii) the external inputs referred to in paragraph (b) are not available on the market, or
   (iii) where the use of external inputs referred to in paragraph (b) contributes to unacceptable environmental impacts,

d) the adaptation, where necessary, of the rules of organic production taking account of sanitary status, regional differences in climate and local conditions, stages of development and specific husbandry practices.

Organic farming shall be based on the following specific principles:

a) the maintenance and enhancement of soil life and natural soil fertility, soil stability and soil biodiversity preventing and combating soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem,

b) the minimization of the use of non-renewable resources and off-farm inputs,

c) the recycling of wastes and by-products of plant and animal origin as input in plant and livestock production,

d) taking account of the local or regional ecological balance when taking production decisions,

e) the maintenance of animal health by encouraging the natural immunological defense of the animal, as well as the selection of appropriate breeds and husbandry practices,

f) the maintenance of plant health by preventative measures, such as the choice of appropriate species and varieties resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and the protection of natural enemies of pests,

g) the practice of site-adapted and land-related livestock production,

h) the observance of a high level of animal welfare respecting species-specific needs,

i) the production of products of organic livestock from animals that have been raised on organic holdings since birth or hatching and throughout their life,

j) the choice of breeds having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems,

k) the feeding of livestock with organic feed composed of agricultural ingredients from organic farming and of natural non-agricultural substances,

l) the application of animal husbandry practices, which enhance the immune system and strengthen the natural defense against diseases, in particular including regular exercise and access to open air areas and pastureland where appropriate,

m) the exclusion of rearing artificially induced polyploidy animals,

n) the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems in aquaculture production.

Introduction of principles of organic agriculture assists in considerable decrease of use of external resources. Running of its norms presumes satisfying of present-day needs of population without harm for interests of future generations, especially:

- prohibition of use of industrial chemicals,
- decreasing of level of use of energy,
- reaching of environmental advantages:
  - minimization of negative influence on environment,
  - prevention of degradation of soils (erosion, raising of their acidity and salinity) and restoration of their natural productivity,
  - decreasing of level of pollution of superficial and ground waters,
  - decreasing of quantities of greenhouse gases emitted in atmosphere,
- producing of environmentally pure foods,
- preservation of biological diversity and genetic fund of plants and animals, refusing of domination of monocultures, keeping of wild animals in conditions close to the natural ones.

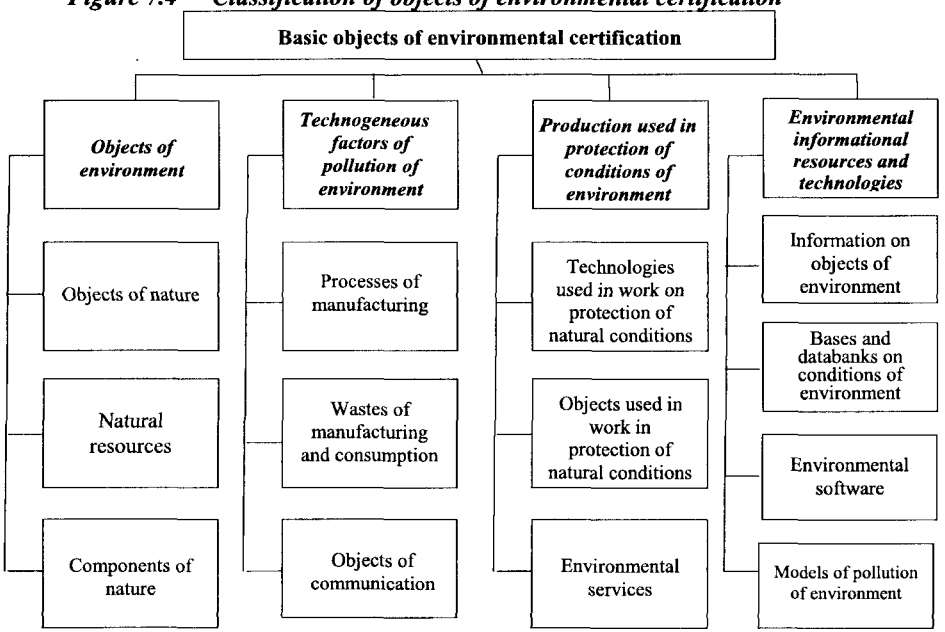
The most important characters of organic farming are:

- encouraging of preferable use of natural means of control of vermin and pests,

- encouraging of farmers to preferable use in curing of ill animals of medical and homeopathic preparations of natural origin,
- prohibiting of planting and breeding of genetically modified organisms,
- planting of organic products in use of exclusively small quantities of synthetic additives (fertilizers, means of protection of plants etc.).

The most effective instrument of demonstration of environmentally friendly conditions of organic farming is environmental certification by norms of standard of ISO 14001. Its typical objects are (Fig. 7.4):

Figure 7.4 Classification of objects of environmental certification



The most influential international organization, which operates the organic agriculture processes is the *"International Organization by Accreditation in Sphere of Environmental Management" (IOAS)* coordinated by IFOAM, which is the IOAS parent organization. For the present, IOAS accredited or works on accreditation of 29 juridical persons specialized in certification of environmental management systems by

norms of the document of *"Principles of Organic Agriculture"* approved by IFOAM in 2005 located in USA, Europe, Japan, Australia, China and countries of Latin America.

The practice of organic farming permits to use means of protection of plants in principle, but excludes or strictly limits using of pesticides, herbicides, insecticides, fungicides, highly soluble synthetic fertilizers, and plant growth regulators (hormones, livestock antibiotics, food additives, genetically modified organisms, human sewage sludge and nanomaterials). This form planting presumes the preferable use of fertilizers of natural origin, e.g. the bone and blood powders, composts and powdered natural minerals (phosphates, carbonates). The farmers specialized in producing of organic products use also in these purposes animal manure and seed meal. In necessity of amending of ***pH*** of soils, they use components of natural origin, such as lime and sulfur.

Meantime, principles of organic agriculture introduced in various countries may differ and be character by some specific details. Its European variants permit to use composts, bone meals, "raw" rocks. The U.S. farmers use for these purposes some chemical compounds, such as iron sulfate, aluminum sulfate, magnesium sulfate and soluble boron products. Sweden and Switzerland introduced systems of increasing of fertility of soils, which allow using of microbiological preparations and some mineral fertilizers of prolonged action (rock phosphate, greensand, some natural forms of potassium). Frenchmen, in turn, developed the *"Lemiere-Bouchet"* system of use of organic fertilizers.

The five main types of pesticides permitted for use in "organic" planting often complementing other pest control strategies and applied the most often are *Bt* (bacterial toxin), pyrethrum, rotenone, elemental sulfur and compounds of copper. To limit expansion of weed and vermin, there are used biological methods of protection of plants: importation of natural enemies and specific pathogens of undesirable greenery and insects, deep ploughing of seed of weed, use of successions of planting developed in observance of cycles of evolution of vermin etc.

To normalize conditions of operation in producing and distribution of organic production in Europe, the governments of EU countries began

to develop the related recommendations since mid-1980-s. The final result of this work became approval in 1991 of the fundamental document of *"EU Eco-Regulation"*. Japan accepted later (2001) the analogous program, and the USA approved in 2002 the *"National program of organic manufacturing"*.

The market of organic products has grown dramatically since 1990, and reached now the value of about $55. This resulted in increasing of area of organically managed farmland over the past decade at a rate of 8.9% per annum. Thus, in 2007 principles of organic agriculture were used on area of 30.5 million hectares worldwide and for the year of 2009 it was enlarged to 37,000,000 hectares, what represented approximately 0.9 percent of global farmland area. The European manufacturers of organic products farm 23 percent of global organic farmland seconded by Latin America (19 %), Asia (9.5 %), North America (7.2 %) and Africa – 3 %. The countries, which have the biggest organic farmlands are Argentina (3.1 million hectares), China (2.3 million hectares), the United States (1.6 million hectares) and Australia (1,180,000 hectares), followed by Spain, Germany, Brazil, Uruguay, and the UK. Appraisals show that quota of organic production in global output of products of agriculture would reach 20 ÷ 25 % by the mid-XXI century, and their total cost will be of about 200 ÷ 250 billion US dollars per annum.

The area of organic farming In Ukraine was of 270,320 hectares for the beginning of 2011, what exceeded twice the respective index for the period of 6-7 years before. Ukraine is ranked in it now as the 21st worldwide and has all preconditions to take one of leading positions in producing and supply of environmentally safe foods to Europe. The practice of development, propagation and use of principles of environmentally pure agriculture is based in Ukraine on use of norms of such documents as *"UN Convention on Environment and Development"* (1992), *"UN Declaration of Millennium"* (2000), documents of Universal Summit by Sustainable Development (Johannesburg, 2002), State laws *"On priorities in progress of science and technique"*, *"On priorities in progress of innovative activities in Ukraine"*, *"On organic agriculture"*, *"On Saving of Energy"*, *"On*

Protection of Environment", "On Environmental Audit", "On Wastes", and Decrees of Supreme Soviet of Ukraine. At the same time, most of organic foods produced here are not consumed domestically, but exported in view of continuous rising of demand for the environmentally pure food in EU countries.

However, norms of organic agriculture are not free of certain disadvantages and risks: to reach the equal effectiveness of use of fertilizers as compared with the modern industrial methods, one has to use the sufficiently bigger quantities of compounds of purely organic origin, for instance, up to 4 tons of manure per hectare instead of one ton of chemical fertilizers. Besides, such fertilizers contain practically one of three basic nutritional components, namely nitrogen and practically no potassium and phosphorus, whereas it is necessary to keep their balance because uncontrolled introduction of nitrogen leads to accumulation in planted products of nitrates. Moreover, investigations of Minnesota University (USA) showed that probability of infecting of vegetables planted on the organic farmland by salmonella is three-five times bigger of the same in use of methods of modern agriculture. So, the practice of organic farming needs of the more detailed investigations and perfecting of existing technologies.

7.8 Genetically Modified Organisms and their Advantages over the Traditional Products

The considerable broadening of areas used for planting of organic products in future is problematic, for estimations show that the planet Earth is capable to feed in use of "green" technologies not more of 4 billion people, what is greatly less of number of global inhabitants even now. Therefore, it is necessary to search for alternate ways of augmentation of quantity of food. The one of possible variants is introduction in the ration of novel types of foodstuffs and it is reckoned now that the most expedient its method is extensive planting of genetically modified organisms, which represent itself biological beings character by new combination of genes – the tracts of molecules of deoxyribonucleic

acid responsible for preservation and transferring to successors of parent organisms of certain character features. These ones may be quicker ripening and bigger productivity, lesser content of harmful compounds, increased resistance to pathogenesis (events of occurrence and progress of wide spectra diseases– starting out of molecular abnormalities and up to alteration of organs and systems of organisms) and other positive effects.

The possibility of hatching of organisms, which have the considerably altered genic structure, was identified as early as in 1946, but the first real GMO was produced almost 40 years later, in 1983. It was the kind of tobacco stable to negative influence of antibiotics, but this plant was not marketed, and the first commercialized GMO was the tomato *FlavrSavr* (1994). However, it did not contain any introduced foreign gene. Instead, its genic apparatus was modified by extraction from it of gene of polygalacturonasa responsible for dissolution of walls of cells of vegetables in storage resulting in shorting of terms of keeping of capacity of non-modified vegetables.

In the beginning of work in genic engineering, the formations character by new combination of genetic material were named as the *"live altered organisms"*, but the Directive of European parliament and EU Council 2001/18/EU of 12th of March 2001 renamed them in later time as the *"genetically modified organisms"*, the appellation used now everywhere. The basic terms used in sphere of circulation of GMO are:

> *Organism means any biological entity capable to replicate or transmit its genic material to other organisms*
>
> *Genetically modified organism means any organism except of hominal one, which genetic material was modified by mode unnatural and/or not occurring in nature*
>
> *Intentional passage [of genic material] means any mode of introduction of GMO or combination of GMO in nature character by absence of strict limiting of their direct contact with natural populations*
>
> *Placement on market [of GMO] means giving third parties of free and payable possibility to contact with GMO*

To harmonize terms used in this sphere with those that are used worldwide, Ukraine introduced just the same term (Law of Ukraine of 31.05.2007 # 1103-V *"On State System of Biological Safety in Creation, Testing, Transporting and Use of Genetically Modified Organisms"*) and classifies GMO by categories as follows.

> *Genetically modified organism means the live being, which has genetic apparatus not occurring in nature and produced by artificial transfer of genes by methods of:*
>
> - *recombination, i.e. forming of new combinations of genetic material in placing of outside molecules of nucleon acids inside any virus, bacterial plasmoid or other vector system and their following introduction into the host organism capable for long reproduction,*
> - *direct introduction of hereditary material, i.e. forming of the modified object by methods of macro injection, micro injection and microencapsulation of genic material in it,*
> - *cell fusion, i.e. hybridization of genic material of live organisms in new combinations, when the altered cells are formed by unnatural fusion of two or more cells or their fragments (including the cases of fusion of their protoplasm)*

At the same time, one should note that practically all cultural sorts of plants and breeds of domestic animals (e.g. mules) the mankind used since the earliest time are in fact genetically modified organisms, which represent itself the products of intervention of men in their genome in process of purposeful selection of stochastic variations of genic apparatus. In progress of science and technique, bioengineers began to use since the beginning of XX century also such methods of modification of genic structures as irradiation and treating of objects of modification by chemical substances capable to provoke mutagenic effects. This work permitted to speed up dramatically processes of mutations of genic structures and screen organisms that have the desired properties. Thus, the modern methods of creation of genetically modified organisms are not new in principle, and the only difference is that results of work in variation

of genome are *purposeful* and appreciably more precise and predictable as compared with the traditional methods of mutagenesis.

> *Mutagenesis means the process of purposeful modification of structure of genic apparatus of organisms exhibited through the complex of their inherited individual morphological, biochemical and physiological characteristics*

The genetically modified organisms known for this time may be classified by three basic groups as follows.

1. *Genetically modified plants*. This is the biggest group of organisms by criteria of their diversity and sphere of use. The stimulating motive of their generation was the desire to solve the problem of elimination of starvation of mankind that originates in conditions of quick growth of numbers of global population especially actual for the countries of *"Third World"*. Therefore, the most of efforts of biotechnologists were centered on development of kinds of plants capable to vegetate in almost all climatic conditions (in conditions of permafrost, saline, arid steppes, and even in deserts). The one more condition was their resistivity to attacks of vermin and influence of herbicides and pesticides in process of planting and capability for storing during the prolonged time after their harvesting. The desirable characteristics of new types of GMO plants were also their bettered tasty and nourishing values. The one more direction of investigations was creation of plants, which may be used as sources of medicinal preparations.

2. *Genetically modified animals*. Such category organisms include first mice created especially for testing of various preparations and identification of potentially dangerous effects resulted of use (consumption) of plants. Said modifications of animals were created preferably by methods of "extraction" from biotope of certain genes. There exist already modified cows capable to give milk, which composition is in close conformity with the men's one, modified salmon character by bigger size and speeded evolution, modified hogs, which manure minimally damages structure of soils, flies does not capable to reproduction and so on.

3. *Genetically modified microorganisms*. This is the smallest group of modified organisms created in purposes of use in medicine, as a rule, and information on their existence and properties is minimal because pharmaceutical companies wish to keep it in secret.

The genetically modified organisms may be grouped also by various categories and the most often used criteria in their subdivision are spheres of using, grade of effectiveness and so on. Here is given one of variants of such grading based on criteria of their prevailing use.

a) *Resistant to attacks of insects*. Attacks of insects damage plants and decrease their productivity increasing so their prime cost. The typical measure used by manufacturers to decrease such kind losses is application of pesticides into the cultivated farmlands. In certain cases this measure is effective, but most of used chemicals are toxic for the useful types of insects including those that are not vermin. Moreover, these chemicals are toxic for men and animals.

To decrease quantities of applied pesticides or even avoid their use, some plants were purposeful modified by such mode that the albumens they produce became harmful for the undesirable forms of insects. The examples are plants, which genome obtains the gene of bacteria of *Bacillus Thuringiensis*, which annihilate caterpillars.

b) *Resistant to action of herbicides*. Herbicides are chemical compounds that annihilate weed, which compete with cultural plants for use of water, nutritive substances, solar energy and space. If the planter would not control their reproduction, his harvests would be sufficiently less. Because most of weeds are in close biological similarity with cultural plants, there exists the crucial problem of finding of herbicide character by selective influence on weed and not causing of damage for the purposeful culture. To solve this problem, bioengineers use technologies that permit to produce organisms, which have the acceptable prime cost and are not sensitive to influence of herbicides used in quantities sufficient for annihilation of undesirable plants. The example is the transgenic kind of soy GTS_40-3-2 resistant to influence of herbicide "Roundup" sold under the trademark of Roundup Ready (RR).

c) *Character by the bettered nutritional properties*. Men are not capable to produce most of vitamins essential for normal passing of metabolic processes. At the same time, basic cereal crops used in rations of men, such as rice, do not contain vitamins at all. The problem cannot be solved by consumption of fruits and vegetables because of their high prices. Therefore the task of improvement of nutritional value of grain was solved in some cases by way of modification of its genic apparatus, e.g. in rearing of "golden rice" enriched by vitamin *"A"*. This culture is not planted extensively yet, but is promising in view of possibility of decreasing in its consumption of level of sicknesses caused by deficit of this vitamin. There exists also tomatoes character by bettered tasty and nutritional properties, e.g. the sweet tomato, as well as the violet tomatoes character by increased content of antioxidants capable so to protect their consumers against falling in cancer as their developers manifest.

d) *Resistant to affections*. Plants, same as animals, are exposed to diseases, which may sometimes progress uncontrollably. This is especially inherent for modern agricultural systems character for crops character by low genic diversity of cultures planted on large areas. Because traditional methods of selection are character by the long-term duration, services of genic engineers permit to decrease terms of introduction of necessary elements in genic apparatus of plants to give them resistivity to influence of certain illnesses. The examples are the modified manioc and papaya.

e) *Character by the bettered characteristics the after-harvesting time*. The main problem of some cultures is the need of preservation of their integrity in transporting and guaranteeing of prolonged term storage during the after-harvesting period. The usual methods of cooling, thorough treating and/or use of chemical agents assist in their retardation and protect products in process of their storage and transporting. However these techniques deteriorate in many cases quality of products and increase considerably their prime cost. Meantime, methods of genic engineering permit to amend genic apparatus of such crops to avoid such disadvantages. The examples are the tomato "Flavr

Savr", arctic apples and potato "Innate", which enzymes assist in afterripening and preserving of properties in storage.

e) *Resistant to climatic and weather influences*. These ones are the modified cultures, as a rule, which are capable to survive in arid areas, saline soils, regions character by big quantity of precipitations and low temperatures (frost-resistant cultures).

f) *Medicinal agents*. The most known drugs and vaccines created with use of GMO are insulin, hormones of thyroid gland and vaccines used in treatment of hepatitis. They are cheaper in production, therefore more available for their users.

g) *Food additives*. The most known representatives of this class compounds are aspartame and yeast. Moreover, numerous ingredients of foods contain the ingredients produced with use of GMO as well.

h) *Modified animals and men*. This category organisms include both domestic and many wild animals, especially those that have the improved visual characteristics (color of fur, scale, capable to shine in dark etc.), as well as animals character by the bettered tasty and nutritional characteristics (e.g. those that have bigger size, therefore contain more nutritive materials). Such GMO include also animals breed for laboratory investigations, which are character by the specially given "deviations" to simplify interpretation of results obtain in this work.

As to men, the United Kingdom became the first country, which officially legalized technologies of amending of the embryonic line of men (if the child has genes of three parents: two women and one man) and there already exist the first modified men who finished secondary schools in 2015. This is one of the most problematic themes of discussion in modern science because such works open the way to creation of "eugenic children".

7.9 Risks of Use of GMO in Agricultural Production

The principal advantages of use of genetically modified organisms and foods, which contain GMO, are:

- chance to solve the problem of hunger, for they give bigger

harvests,

- speeding of processes of ripening of products of agriculture,
- rehabilitation of environment owing to planting of cultures, which are not sensible to attacks of vermin, hence may be grown in use of decreased quantities of toxic chemicals,
- retardation of processes of deterioration of products, hence decreasing of losses in their producing, transporting and storage,
- expanding of areal of planting of cultures, which are planted usually in hot climate and medium latitudes (e.g. strawberries in conditions of frosts),
- enrichment of foods by minerals and vitamins (the most expressive example is the "golden rice" enriched with vitamin "A").

To realize such possibilities, the human society accomplishes the extensive R&D works, but the accessible information on probable negative influence of genetically modified organisms on health of men is too contradictory and not detailed yet.

At the same time, the published results of works in studying of influence of GMO on conditions of nature and state of live organisms, which consume GMO, are doubtful till now because researchers use usually the dubious methods of studying of aftermath of feeding of some dozens of rats, mice or rabbits but not the alternative of studying of effects of consumption of GMO by the men-volunteers. Besides, most attempts of identifying of grade of safety of GM-products were mediate, so, even the induced effects they revealed are thoughtful. Thus, in 2002 scientists published the information of results of comparative analysis of rate of sickness caused by consumption of foods in USA and Sweden. It was stated, that conditions of living of population of these two countries are character by relatively high standards of life, the closely similar ration and use of the same level medical services. However, *"... the US doctors fixed that during some years after beginning of intense use of GMO as foods, the 3-5 times bigger quantity of intoxications of US consumers as compared with the Swedish statistics"*. The discussions by problems of safety of transgenic cultures were intensified since the end

of 1998, when the *Institute of Nourishment of the Russian Academy of Sciences* published the information that *"... rats, which ate transgenic potato had after passing of six months of experiment the unconditionally less mass, anemia and dystrophic changes of cells of liver"*. At the same time, conclusions of some scientific teams are the diametrically opposite, what does not permit to make the unambiguous decision on recognition of safety of extensive introduction of GMO in practice of alimentation.

Generally, scientists reckon that the principal risks in consumption of genetically modified organisms as foods are:

1. Inhibiting of immunity and occurrence of allergic reactions and metabolic disorders as the direct result of consumption of transgenic albumens. The mechanisms of influence of albumens, which contain specially introduced foreign genes on conditions of health, are still unknown because men never consumed them before in big quantities. Moreover, it is not known in advance, whether they are allergens or not. The representative example is the attempt of interbreeding of genes of Brazil nut into the genic apparatus of soybeans to rise the content of protein. However the resulted combination became the powerful allergen and the modified soy was extracted from circulation.

2. Potential sterility of hybrid generation of transgenic plants in transmission of new genes, so impossibility to use their seeds in their reproduction in future.

3. Various dysfunctions in conditions of health resulted of consumption of GMO-modified albumens or influence of toxic products synthesized in their metabolism. The example is development in USA in the end of 1980-s of technology of producing of food additive *tryptophan* with use of the genetically modified bacterium created specially for this purpose. However this one began to synthesize simultaneously with the purposeful product of by-product of ethylene-bis-tryptophan. Consumption of such mix produced chronic aches of 5,000 men, which 37 persons died and 1,500 became invalid.

4. Emergence of resistance of men's pathogenic microflora to attacks of antibiotics. Developing new types of GMO, breeders introduce in many cases in their genic structure fragments, which produce resistance of microflora of bowels to action of antibiotic, what results in medical problems in cure of some illnesses shown in experiments.

5. Deterioration of health because of accumulation of herbicides and other dangerous substances in man's organism. Most of known transgenic plants are capable to accumulate sufficient quantities of agricultural chemicals used in their planting, e.g. the GMO-modified sugar-beet resistant to action of herbicide glyphosat accumulates its toxic metabolites.

6. The ultimate carcinogenic and mutagenic effects. Each case of inserting of foreign gene into the live organism is in fact its mutation that may cause undesirable consequences.

7. Uncontrolled influence of altered genic structures of certain live organisms on conditions of living of other organisms, for instance their toxicity for other biological forms. It was published in 1999 the information on intoxication of rats, which ate potato that contained in its genic apparatus the gene of snowdrop *Glantus nivalis* introduced in purposes of giving it of capability to resist to attacks of nematode. The one more example may be occurrence of indirect threat in result of generation by the plant of albumen, which is not toxic for certain kinds of insects but poisonous for birds, which ate them together with eaten GMO and products of their metabolism they accumulated.

8. Advantages in capability of GM-plants to accommodate to influence of abiotic factors, what may result in suppressing of growth of traditional cultures. Alteration of climatic conditions, presence of certain specific salts in places of planting and so on may result in giving the hybrid plants, e.g. the plant, which received the gene of resistivity to influence of pesticide in cross-pollination with the genetically modified plant, enough advantages as compared with the usual kinds of local plants and transform it in aggressive weed.

To minimize the probability of negative influence of listed factors on conditions of nature, each country gives permissions on access of GMO on her national market after use of preventive measures as follows:

a) creation of structure of guarded objects or regions, which conditions of functioning preserve the structure of existing biological diversity,
b) development of guiding principles of choose and creation of guarded objects,
c) assisting in conservation of conditions of ecosystems and natural places of existence and living of viable populations,
d) assuring of integrity of biological resources at guarded territories and outside and introduces the necessary measures of regulation of their rational functioning,
e) maintaining of environmentally friendly evolution of populations in guarded and neighboring regions,
f) rehabilitation and restoration of degraded ecosystems to their normal conditions and assisting in saving of beings, which are under threat of disappearance,
g) establishing of norms of work in minimization of grade of risks, which may arise in introduction in nature of GMO capable to influence negatively on health of men and existing conditions of ecosystems,
h) maintains innovations necessary for preservation and stable use of biological resources.

7.10 UN Convention of Preservation of Biological Diversity. Cartagena Protocol of Biological Safety

The considerable interest of the community to problems of protection of environment and rising of effectiveness of use of natural resources, as well as need in improving of ecological parameters of operation of enterprises, induce occurrence of tendencies of *"ecologization"* of almost all branches of economy because quick changes in conditions of nature lead to mass extinction of live organisms. Appraisals show that the variety

of beings, which live on the planet Earth, continuously narrows and now is less of 1 % of total number of their types existing and existed whenever. This phenomenon results in quick loss of variety of gene structures and speeding of changes of conditions of health of global inhabitants, mostly negative. The one of causes of worsening of conditions of living is loss of biological diversity because live organisms are the major source of compounds used in pharmaceutics: the World Health Organization reported that the state of health of approximately 65 % of global population depends directly of consumption of plants, which components have medicinal effect, and more of 25 % of existing medicinal preparations contain at least one active substance extracted from raw materials of vegetative and animal origin. So, there becomes clear in conditions of quick rise of population and increasing of technogeneous pressure on environment, the necessity of preservation of *biological diversity* understood as *"... the diversity of live organisms, (including the variety of types of live organisms in limits of certain biological form and/or biological type), which exist in terrestrial and marine ecosystems and environmental complexes"*. Therefore, the EU institutions adopted the Directive of 92/43/EEC *"On the conservation of natural habitats of wild fauna and flora"* centered on idea of assuring of conditions of stable development of the community in conditions of preservation of biological diversity.

> *Conservation means the complex of measures by preservation and/or rehabilitation of biological diversity centered on idea of reaching of conditions of friendliness of nature for residing and functioning of inhabitants of biotypes of wild flora and fauna*
>
> *Conditions of conservation of natural environment means the complex of influences on state of nature and biological diversity of biosystem, which have the goal of assurance of existence of adequate conditions of long-term existence and functioning of its typical inhabitants*

The significance of work in preservation and development of biological diversity may be illustrated by the simple example of the event of cultivation of potato in Ireland in XIX century: its sickness occurred in 1846 lead to death of about one million people and emigration of another one as the result of planting of only two of its kinds, both sensitive to the occurred illness.

The necessity of betterment of conditions of living in existing biosystems became clear soon, because it was understood that technologies used till the mid-XX century could not satisfy the prospective need of mankind in food. Hence the community was forced to find ways of augmenting of productivity of cultivated plants. The method used in it the most often is application in soils of mineral fertilizers, phytogormones and chemical means of protection of plants. However, use of such substances not character for processes of metabolism of live organisms results inevitably in their accumulation in eatable products and chronic poisoning of population. The way to improve such situation some researchers see in intense use of GMO as foods. However, mechanisms and effects of influence of their metabolites on health of big groups of consumers, animals, plants and conditions of environment are still unknown.

Direct effects of use of GMO mean the events, which influence directly on state of environment and conditions of men's health

Indirect effects of use of GMO mean the events, which influence on state of environment and conditions of men's health and reveal through the sequence of accidental incidents occurred in their interreaction with other live beings accompanied by transmission them of genic material of genetically modified organisms

Immediate effects of use of GMO on state of environment and men's health (whether of direct or indirect character) are classified as such that occurred just in process of circulation and marketing of genetically modified organisms

Delayed effects of use of GMO on state of environment and men's health, including the after-effects of their consumption (whether of direct or indirect character) are classified as such that were not identified in process of circulation and marketing of GMO but became noticeable in later time

Evaluation of grade of risk of use of GMO for the state of environment means the work in evaluation of grade of hazard of intentional transfer of genetically modified organisms to open systems, whether of direct, indirect, immediate or delayed character

The work in confirming of safety of novel products and minimization of probability of emerging of delayed effects of negative character became the prime task in putting of GMO in circulation since the moment of their origination as such, and it was the decision of international community to hold the 1992 World Summit in Rio-de-Janeiro by problems of conservation of biological diversity. Its basic decision was to recommend governments to prevent release of genetically modified organisms to open systems till all effects of their influence on conditions of health of live beings and state of nature would have been studied in details. The delegates of the Summit approved also the document known as the *Convention on Preservation of Biological Diversity* opened for signing 5th of June 1992. The Convention entered into force 29th of December 1993 and ratified for the present by 192 countries (plus EU as its solidary member). Its principal goal is to preserve the existing biological diversity of ecosystems for the sake of receiving of mutual and equitable benefits of use of preserved genic resources. It was pointed, that the main directions of genic engineering to be carried out in guaranteeing of conditions of biological safety are:

- operation with GMO in closed systems in avoiding of their contact with population and objects of environment, and
- prevention of release of GMO in environment (excluding cases of State testing and studying of their "behavior" in open systems).

Biological safety means the condition of safety of men character by absence of negative influence of exterior biological, chemical and physical factors on biological structure and vital functions of present and future generations, as well as absence of nonreversible negative influence of conditions of nature (biosphere) on vital functions of other biological objects

Genetic safety means existence of conditions of environment character by absence of any unnatural and uncontrolled influences on genomes of objects of biosphere, men, agricultures, domestic animals and microorganisms cultivated in industry, which may affect negatively on conditions of their vital activity

Closed system means the space organized for work character by modification of genic apparatus of living beings, their cultivation, treating, storage, use, transporting, annihilation and burial in avoiding of contact with the outside population and objects of environment

Open system means the space of work in genic engineering where genetically modified organisms may contact freely with the outside population and objects of environment in their planned use in agricultural practice, industry, medicine and other spheres of business operation

Because the problem of influence of GMO on state of nature was not studied properly, 600 participants of 60 countries met as early as 19th of October 1998 at the XII Scientific conference in Mar-del-Plata (Argentina) and approved the norm of prophylactics in prevention of introduction of GMO in open systems and *"... basing on principle of preservation of biological diversity and adequate conditions of health of global population"* took unanimously the Declaration on avoiding of use of genetically modified organisms and products, which contain GMO:

We, the undersigned participants at the 12th Scientific Conference of the International Federation of Organic Agriculture Movements (IFOAM) at Mar del Plata, Argentina,

call on governments and regulatory agencies throughout the world to immediately ban the use of genetic engineering in agriculture and food production since it involves:

- *Unacceptable threats to human health*
- *Negative and irreversible environmental impacts*
- *Release of organisms of an unrecallable nature*
- *Removal of the right of choice, both for farmers and consumers*
- *Violation of farmers' fundamental property rights and endangerment of their economic independence*
- *Practices, which are incompatible with the principles of sustainable agriculture as defined by IFOAM*

In accordance with the Charter on founding of the United Nations and principles of international law, the parties of the Convention have the sovereign right to exploit freely the resources pursuant to their own environmental policies in their territories, but must not cause any damage to environmental conditions of areas beyond the limits of their national jurisdiction. The norms of the Convention regulate also the procedures of safely move of products of modern biotechnology through the national borders, and one of its principal conditions is normalization of procedures of reprocessing and use of GMO in avoiding of probability of emergence in ecosystems of uncharacteristic types of life, which may cause potentially the undesirable changes in their stable functioning. Following this principle, the GMO and products of their reprocessing are considered as the potentially hazardous objects till their safety will be confirmed by all normalized methods, and to avoid the irremediable harm for health of men and biological diversity, the genetically modified organisms have to be treated in absence of reliable information in observance of all precautionary measures of their uncontrollable release into the open systems.

To minimize influence of GMO on environmental conditions, each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity,

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity,

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use,

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings,

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas,

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia,* through the development and implementation of plans or other management strategies,

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health,

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species,

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components,

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices,

(k) Develop or use the necessary legislative and/or other regulatory norms in force in protection of species and populations existing under threat of disappearance, and

(l) Regulate or manage the relevant processes and categories of activities in identification of significant adverse effect of natural conditions on biological diversity.

Despite the taken Resolution prohibits unambiguously release of GMO into open systems, such norm is applicable now in the organic agriculture only, and genetically modified products are used extensively in global economical processes and spheres of their circulation were delimited by clauses of the *Protocol on Biological Safety*, the document known as the *Cartagena protocol* signed 1999 in Colombian city Cartagena-de-Indias and put in force in Montreal in 2000 as the supplement to the *Convention on Biological Diversity*. The main goal of its taking was normalization of conditions of accomplishing of actions declared by Principle 15 of the Preventive approach approved at the Rio-de-Janeiro World Summit as *"... assisting in assuring of adequate level of protection of biological diversity and guaranteeing of its safely development in observance of existing risks for health of men and peculiarities of safe transboundary move, reprocessing and use of live organisms modified by methods of modern biotechnology"*. The document declares:

> *"... Nothing stated in this Protocol must not cause damage for sovereignty of States in their territories, exclusive territorial zones and shelves ...*
>
> *... The Party, which takes the decision to use in own territory the live modified organism, which may be the object of cross-border movement as a foodstuff or forage, has to inform on it all Parties in fifteen days term and give the written copies of related information materials to their National information centers."*

7.11 Procedures of Admittance of GMO on Global Markets

The fact of joining of the country to the Cartagena protocol does not put her any hindrance in commercialization of new types of genetically modified products domestically. The parties are free in cultivation in their territories of genetically modified plants and breeding of domestic animals character by modified genic apparatus. The signatories of the Convention on Biological Diversity and the Cartagena Protocol are free at the same time in normalizing of maximum permissible norms of content of GMO in foodstuffs consumed in their countries (see Table 7.2), which observance permits domestic manufacturers to declare, that their products are *"free of GMO"*. Table 7.2

Permissible contaminations of GMO in foodstuffs in some countries

Country	Permissible level, %	Mode of marking
USA	5	Voluntary
Canada	5	Voluntary
Japan	5	Obligatory
Brazil	4	Depends of province
Norway	2	Obligatory
Switzerland	1	Obligatory
EU	1	Obligatory
Ukraine	0.9	Obligatory

The only condition is that each signatory of the Protocol has, as far as possible, to *"...establish and maintain workability of means of regulation, control and limitation of grade of risks of use and release of GMO in open systems. The parties have to take into consideration the risks of consumption of live organisms modified by methods of modern biotechnology and their undesirable influence on conditions of preservation and sustainable development of biological diversity"*. The typical sequence of marketing of GMO that are permitted for commercialization normalized the provisions of the European directive of 2001/18/EU *"On the deliberate release into the environment of genetically modified organisms"*, which states that any businessperson,

which intends to put the new type of GMO on the native market of his country has to give its authorized State body the data as follows:

- information on GMO to be marketed,
- information of general character (including the data on the engaged personnel and its qualification in sphere in question),
- information on conditions of marketing of the organism and probable mechanisms of its influence on conditions of nature,
- technical specification of risks that may occur in marketing of new type GMO,
- plan of monitoring of influence of GMO on health of men and state of nature,
- information on procedures of control and methods of elimination of undesirable effects, methods of treating of wastes and plan of operation in extreme situations,
- brief information on content of the applied dossier.

Obtaining this information, the authorized State body has to send to the Eurocommission during 30 days the brief description of notification it received. The Commission disseminates, in turn, this information in period up to 30 days among all EU countries, which may return during 30 days their remarks and inquiries directly to the country of potential naturalization of GMO and/or send them to the Eurocommission.

To issue permission on marketing of GMO and/or the product, which contains its combination with other ingredients, the authorized State body of country, where these objects would be marketed for the first time, has to identify the comprehensiveness, correctness and compliance of content of information it obtained to established norms and inform on it other EU countries by topics as follows:

1. *Information of general character:* the name and juridical address of person of economy, which intends to market the GMO, as well as the information on qualification and professional experience of its specialists responsible for this work.
2. *Information on recipient of new genes and/or mother plants:*
   - name, type, kind, subspecies, mode of cultivation,

- mode of breeding: mode and specific factors of reproduction, term of generation, capability to interbreed with other plants,
- information on vitality: data on structures capable to survive or fall into hibernation and the data on specific factors of influence on these events,
- information on potential expansion of GMO in nature: ways and intensity of expansion (e.g. grade of spreading of pollen or seed dependently of distance out of the mother plant), and specific factors, which influence on their spreading (if exist),
- predictable areal of existence of the plant, information on its predators, parasites, competitors and symbiotic plants,
- possible interreactions of GMO with inhabitants of ecosystems of its probable vegetation, including data on its toxic influence on health of men, animals and other live organisms.

3. *Information on variation of genic apparatus:*
   - description of used method(s) of modification of genic apparatus,
   - nature and source of used vector of variation,
   - dimensions, source of origination (name) of the donor organism and foreseen vital functions of fragments to insert.
4. *Information on the genetically modified organism:*
   - specific features and characteristics planned to modification,
   - data on inserted/deleted fragments of genic apparatus, information on constituent parts of vector of modification or carriers of foreign DNA, dimensions and structure of fragments of modification, methods of their characterization and identification,
   - if the work in modification presumes extraction of genic fragments out of structure of DNA, the dossier has to contain information on presumable functions of the modified plant and place of deletion of such fragments,
   - data on inserted fragment: information on its functions during the life cycle of the GM-plant and list of its parts, where the expression occurs (roots, stem, pollen etc.),

- data on difference of vital functions of genic apparatus of the modified plant and the recipient, mode and speed of reproduction and dissemination,
- genic stability of the insert,
- capability of the modified plant to transfer its genic material to other organisms,
- toxic or other unfavorable influences on health of men resulting of genic modification,
- safety of the modified organism for health of animals in their use as forages,
- mechanisms of interrelation of fragments, which modify genic structure of the plant, with the target cells,
- potential influence of modified organisms on abiotic objects of their surrounding,
- data on preliminary events of release of genetically modified organisms in environment, if existed.

Besides, the notification must contain the following information:

- predictable risk of release of GMO into open systems,
- conditions of marketing of product, information on specific conditions of its handling and use,
- proposed term of validity of permission on marketing of GMO (not more of 10 years),
- schedule plan of control actions,
- proposed method of marking and informing of consumers on presence of GMO in it,
- proposals on methods of packing,
- brief content of the dossier.

After obtaining of the notification, the authorized competent body of the interested country has to prepare the report on assessment of its content and send it in term of 90 days to its sender and the Eurocommission, which, in turn, has to inform the authorized bodies of all EU member-countries on information thereof.

If the authorized competent body, which prepared said report, would not obtain from the Eurocommission her motivated objections on

marketing of the declared product in term of 60 days (which may be prolonged in extreme cases to 105 days), it issues the permission on use of GMO in open systems. The next step in its commercialization is informing on its content, of applicant, Eurocommission and other EU countries to be done in the term of 30 days.

In existence of information on potential negative influence of the product to be marketed on men's health and/or conditions of environment, the country, which had such intentions, has to limit or prohibit its use and/or sale in her own territory and inform on it her citizens, Eurocommission and other EU countries. The information to be sent in it must inform on causes of taking of this decision and content of works she had done in evaluation of risks of marketing of GMO in question.

7.12 Basic Principles of Modern Biotechnology

As it was stated in Chapter 7.11, the alimentary resources of mankind are the more dependent of presence on the market of genetically modified ingredients, what is the crucial problem of mankind in liquidation of deficit of food, energy and mineral resources. This phenomenon causes the need in intensification of R&D works in sphere of science of biotechnology centered on solving of problem of raising of harvests of planted cultures and selection of new kinds of plants character by bigger productivity of their eatable parts. The term of *biotechnology* (*Βιοτεχνολογία)* origins of Greek *bios* — life, *techne* — art, skill, and *logos* — training and relates to sphere of men's activities in development of new kinds of products used in public economy and live organisms to be used in food, as well as new processes of their fabrication. Such appellation relates not to any unique technological process, but to the whole family of technologies integrated by the feature of work with live cells and molecules, which are their parts. The biotechnology as such is the practice of *"... use of live organisms and products of their vital activity in commercial purposes"*. If so, mankind uses traditional biotechnological methods since the earliest stages of progress of civilization, and the eldest known processes are baking of bread with use

of yeast and producing of wine, cheese and products of sour milk, kvass, beer etc.

Biotechnology is the interdisciplinary branch of industry, which unifies principles of operation used in biological, chemical and technical processes. Use of biotechnologies permits to alter procedures of many processes used in practice and decrease quantities of used energy and generated undesirable by-products of manufacture, e.g. hydrogen chloride. Use of biocatalysts permits to produce the same products with smaller expenses and improve some of consuming properties of purposeful products. For instance, the cotton modified by methods of advanced bioengineering is warmer, more durable and absorbs bigger quantities of moisture as compared with the usual cotton fiber. Some plants used in agriculture, e.g. corn, are used in chemical engineering in oxidation of sugar it contains to acetic acid directly, but not to ethanol as it is realized in traditional methods of synthesis, what permits to avoid the stage of its oxidation and simplify so the existing chemical technologies. It is forecasted also, that the global need in motor oil and chemicals would be satisfied by products of biotechnologies up to 30 % till the mid-XXI century. The basic directions of progress of biotechnological science are: development of methods of producing of foodstuffs, preparations and products used in agriculture, industry and everyday life, synthesis of drugs, means of diagnostics and chemicals, betterment of technologies of leaching and concentrating of metals and technologies of protection of nature against pollution.

The modern biotechnological science progresses mainly by two following directions: development of technologies of producing of substances and compounds produced by methods of biotechnology (organic acids, amino acids, vitamins) and rising of productivity of processes of producing of foodstuffs and food additives including those that are produced in use of microorganisms. The last class of compounds includes enzyme preparations, sweeteners, aromatic additives, stiffeners etc. (Table 7.3):

Table 7.3

Use of products of biotechnology in food industry

Products of biotechnology	**Sphere of use in food industry**
1	**2**
Amino acids:	
➢ Cisteine, methionine, lysine	Raising of food (biological) value of products, which contain albumens
➢ Glutamine acid (sodium glutamate)	Intensifying of flavor of meat, fish and other products
➢ Glycine, aspartat	Adding of sweet and acidic taste for confectionery and soft drinks
Vitamins:	
• A, B1 , B2 , B6 , B12 , C, D, E, β-carotene	Increasing of food value of products
• C, E, B2, β-carotene	Antioxidants, dyers, intensifiers of color
Organic acids	
➢ Acetic, lemon, benzoic, lactic, gluconic, malic acid	Preservatives, flavoring agents, acidifiers
Terpenes and their compounds	
➢ Geranyl, nerol	Flavoring agents
Polysaccarides	
➢ Xantanes	Stiffeners and stabilizers of creams and jams

1	2
Olygopeptides:	
➢ Aspartam, taumatine	Producing of low-calorie sweet products
➢ Enzymes	
• α-amilase	Producing of ethyl alcohol, wines, beer, bread, sweets and foods for babies
• Glucoamilase	Producing of glucose, removal of dextrines from beer
• Invertase	Producing of confectionery
• Pullulanase	Producing of maltazic (together with β-amilaze) or gluconic (together with glukoamilaze) fruit syrups made of starch
• β-galactozidase	Removal of lactose from milk serum, producing of ice-cream etc.
• Cellulases	Producing of soluble coffee, carrot jam, betterment of consistency of mushrooms and vegetables, treatment of citrus fruits
• Pectinase	Clarification of wines and fruit juices, treatment of citrus fruits
• Microbial proteinase	Producing of cheese, speeding of process of afterripening of pastry, producing of cracker, betterment of quality of meat
• Rennine	Setting of milk
• Pepsin, papaine	Clarification of beer
• Ficine, tripsine, bromelaine	Speeding of process of pickling of fish, separation of meat and bones
• Lipases	Imparting of specific flavor for cheese, chocolate, milky products, betterment of quality of beaten egg albumens
• Glucooxidase, catalase	Removal of oxygen from dried milk, coffee, beer, mayonnaise, fruit juices done in purposes of betterment of their quality and increasing of term of their storage

The live organisms consist of cells all programmed by the same genetic material – DNA (deoxyribonucleic acid). The segments of DNA known as genes carry the information used by individual cells in producing of albumens constituted by combination of nucleotides

adenine (A), *guanine (G)*, *thymine (T)*, and *cytosine (D)*, the same for all live organisms but forming the biological structures specific for each one. So, the one of basic directions of progress of biotechnology is genic engineering, which essence is transfer of certain genes of one organism to another one, or extraction of some ones out of existing biological structures to give the object of modification the desired feature or characteristic. Because all organisms are constituted of the same genetic structural units, biotechnologists use in their work organic catalysts, the so-called enzymes, which play the role of agents capable to extract certain DNA fragments and move them inside the molecular structures of other organism(s) what permits to upgrade the consuming and/or other properties of resultant products.

Methods of modern biotechnology, contrary to those of traditional technologies of hybridization and selection, permit to overcome the physiological barriers in selection of organisms, which would possess after finishing of work in their modification by desired characters. Many of developed countries work actively in sphere of biotechnological research and the most prospective direction of progress of biotechnological science is producing of nutritious foods, which have the bettered taste, bigger productivity and higher resistance to sicknesses and attacks of vermin. The great progress in it reaches China (some appraisals show that Chinese breeders registered for the present more of 120 kinds of genetically modified cultures). There was developed the technique of rehabilitation of plants against infections, what is especially necessary for cultures reproduced asexually (e.g. potato), investigated modes of optimization of composition of amino acids of proteins contained in vegetables, commercialization of new kinds of regulators of growth and microbiological means of protection of plants and advanced bacterial fertilizers. The vaccines and serum produced by methods of genic engineering are used in prophylactics, diagnostics and therapy of illnesses of domestic animals.

Methods of modern biotechnology is capable now to replace in many cases traditional technologies (e.g. those that are used in purposes of prolongation of term of storage of products in production of foodstuffs,

polymers, and raw materials used in textile industry, processes of producing of methanol, ethanol, biogas and hydrogen, as well as in technologies of extraction of metals from some ores). Some branches of industry show the significant rise of specific part of products of biotechnologies in total output (Table 7.4). These ones are first of all technologies of producing of foodstuffs (wide-ranging use of microorganisms in production of albumens, producing of amino acids, organic acids, vitamins, enzymes), raising of productivity of agricultures (cloning and selection of kinds of plants based on use of cellular technologies *in vitro*, use of bioinsecticides), pharmaceutical industry (producing of vaccines, biological synthesis of antibiotics, hormones and other substances), decreasing of level of pollution of environment (purifying of wastewaters, reprocessing of wastes and co-products of agriculture and industry) and many others.

Table 7.4

The principal directions of progress of biotechnology in various spheres of public economy

Branch of industry	**Sphere of use**
1	**2**
Agriculture	Selection of new types of microorganisms, which produce the biological masses used as the albuminous and vitaminous concentrates. New methods of selection of plants and animals, getting of genetically modified raw materials and cloning. Use of antibiotics (including those that were produced by processes of biotechnology) in purposes of prophylactics and cure of sicknesses of animals and poultry, production of vaccines. Use of hormones and other promoters of growth.

1	2
Producing of chemical substances and compounds	Production of organic acids (citric and others). Production of vitamins, antibiotics and other substances. Use of enzymes as components of decolorants and detergents.
Control of conditions of environment	Betterment of methods of testing and monitoring of pollution of environment. Forecasting of transformations of xenobiotics as the result of the better understanding of biochemistry of microorganisms. Betterment of methods of reprocessing of the everyday and industrial wastes in use of microorganisms, which decompose plastics and other compounds.
Medicine	Use of enzymes in purposes of betterment of methods of diagnostics and development of sensors, which operate with use of enzymes. Use of microorganisms and enzymes in development of the complicated medicinal compositions (e.g. steroids). Synthesis of new types of antibiotics. Use of enzymes in therapy (festal, mezyme) and preparations of microorganisms (lactic bacterium, bifidobacterium etc.).
Power engineering	Increase of use of biogases – products of vital activity of microorganisms. Mass production of ethanol to be used as the liquid fuel.
Material science	Leaching of metals from ores. Intensification of R&D work by problems of biological decomposition.
Food industry	Development of novel methods of reprocessing and storage of foodstuffs. Use of food additives produced by microorganisms (amino acids, organic acids, polymers etc.). Use of albumen produced by the monocelled microorganisms. Use of albumen in processes of reprocessing of food raw materials. Use of microorganisms in fermentative manufactures. Use of microorganisms as starters.

Naturally, these processes may be realized on condition of existence of permission of authorized governmental structures only. In Ukraine, particularly, the conditions of execution of such works regulate norms of

Law of 31.05.2007 #1103-V *"On State System of Biological Safety in Development, Testing, Transporting and Use of Genetically Modified Organisms"*. It is stated that products of genic engineering have to pass before their commercialization of the preventive comprehensive testing in closed systems to confirm absence of their harmful influence on state of neighboring nature. The products, which passed said testing with the positive result, may be released into open systems on condition of their preliminary registration. The one more obligatory condition to be observed in use of GMO in open systems is existence of methods of their identification based on norms of international standards harmonized in Ukraine. The only exclusion of such procedure is carrying out of works in their State approbation (testing) to be done by permission of the Council of Ministers of Ukraine issued by application of Ministry of Education and Science of Ukraine. To do this work, Ukraine founded the specialized *Commission by Biological and Genetic Safety*, and the products to be registered are:

- kinds of genetically modified agricultural plants,
- races of cattle breed with use of GMO,
- means of protection of plants produced with use of GMO,
- foods, cosmetics and drugs, which contain GMO or were produced with their use,
- forages, food additives and veterinary preparations, which contain GMO or were produced with their use.

After expiring of term of five years, the validity of the permission issued earlier has to be confirmed repeatedly by the same procedure. The accountable material of GMO unfit for following use, or prohibited for use, or obtained in process of their testing and packing, have to be utilized, annihilated or neutralized by procedures normalized by the Ministry of Education and Science of Ukraine and the Ministry of Ecology and Natural Resources of Ukraine.

7.13 Principal Documents Used in Organization of Industrial Manufacturing

The next step to do after the GMO would have been permitted to marketing, is its serial production and commercialization. To normalize procedures used in development and organization of facilities for their producing, Ukraine developed and systemized the set of regulative and normative documents, which may be subdivided conditionally by four big classes:

1. Unified system of technological documentation (YeSTD – Єдина система технологічної документації, ЄСТД).
2. Unified system of constructional documentation (YeSKD – Єдина система конструкторської документації, ЄСКД).
3. System of documentation by development of technology and commercialization of serial production (SRPV – Система документації з розроблення та постановлення продукції на виробництво, СРПВ).
4. Unified system of documentation by technological preparation to manufacturing (YeSTPV – Єдина система документації з технологічної підготовки до виробництва, ЄСТПВ).

7.13.1 Unified system of technological documentation (YeSTD)

YeSTD is the complex of standards of interstate category, recommendations and other normative and technical documents, which normalize *the interrelated rules and procedures of development, systematization, legalization and dissemination of technological documentation* used in processes of manufacturing and repair of products (including the work in collecting and handing over of wastes of manufacture to services specialized in their reprocessing and/or burial). The set of YeSTD documents is used in realization of functions as follows:

- assuring of compatibility of all systems of information (whether they use any means of mechanization and automation or not),
- forming of unified information base of documents, which legalize means of mechanization and automation used in manufacture,

- establishing of norms of drawing up of documents, which regulate procedures of development and normalizing of details of individual, typical and grouped technological processes (operations) of manufacturing,
- creation of preconditions of decreasing of laboriousness of engineering and technical works carried out in process of preparation to manufacturing,
- assuring of interconnection of YeSTD documents with systems of national standards of general, organizational and methodological character.

The standard of GOST 3.1102-81 *"Unified system of technological documentation. Stages of development and types of documents"* classifies the YeSTD norms by categories of basic and auxiliary documents. The *basic documents* are attributed as such that normalize the data of summarizing character used in solving of principal engineering, technical, planning, economical and organizational problems of prospective manufacture. The *auxiliary documents* detail norms of development, introduction and functioning of technological processes, e.g. orders on detailing of auxiliary technological operations and statements that detail the procedures of introduction of technologies. The basic stages of development of this system documentation are:

- stage of *"Technical proposal"*,
- stage of *"Draft design"*,
- stage of *"Technical (preliminary) project"*.

Some institutions practice working up of the set of norms known as *"Directorial technological documentation"* used in carrying out of various works, which precede the constructional stage of development (calculation of engineering, technical, economical organizational and other aspects of prospective manufacture), which have the purpose of evaluation of the possibility and expediency of its allocation at certain place. Because variety of this category documents is too big, they are classified by specialization, destination of use, structure, type of information, type of carrier of information, and so on.

7.13.2 Unified system of constructional documentation (YeSKD)

YeSKD is the complex of State standards, which normalizes the interrelation of procedures and norms of *development, legalization and dissemination of constructional documentation* among the interested parties at all stages of life cycle of production to produce and establishing of values of regulated indices of its quality. The *constructional documentation* represents itself the set of graphical and textual documents, which normalize the composition and construction of object of normalization and contains the data necessary for development of methods of its fabrication and control of quality, as well as norms of exploitation, repair and utilization of finished products. The typical categories of YeSKD standards are:

1. general norms,
2. basic norms,
3. classification of articles to be fabricated and systems of their indication,
4. general norms of drawing and exploitation of concrete groups of articles,
5. norms of accounting and storage of finished products,
6. conditional and graphical symbols used in diagrams,
7. breadboard design.

The principal spheres of use of such documents are:

- development of modern methods of operation,
- efficient preparation of documentation to be used in speedy changeover of manufacturing facilities,
- unification and standardization of procedures of development of documents used in projecting of products of prospective manufacture,
- simplifying of forms of constructional and graphical materials,
- establishing of rules of interchange by the constructional documentation with other parties, what excludes the need of its repeated development and legalization,
- shortening of terms and decreasing of laboriousness of work at stages, which precede the serial manufacturing,

- normalization of procedures of use of projected items,
- organizing and maintaining of the unified informative base.

7.13.3 System of documentation by development of technology of serial production (SRPV)

SRPV is the system of standards, which normalize procedures of erection of manufacturing premises and mounting of technological equipment to be used in functioning of serial manufacture. Its predestination is mastering and shortening of terms of development of technologies of producing of qualitative products, establishing of organizational and technical principles of their fabrication, assisting in in-time renovation of assortment of produced items, prevention of making of obsolete and ineffective products and avoiding of producing of products, which technology of fabrication was not worked-out in details. The SRPV standards regulate:

- procedures of analysis of bases of patents by problems of interest and carrying out of R&D, experimental and constructional works related to the prospective plant, as well as working out of procedures of fabrication of its production,
- agreeing and approval of indices of quality and methods of control of products in development,
- procedures of mastering of technologies of manufacturing (including the technologies used by licenses of foreign firms), accomplishing of author's control in process of introduction of novel technologies, in-time discontinuing of producing of obsolete products and assisting in beginning of manufacturing of advanced items of the same destination instead.

As to the problem of supply of population by the sufficient quantity of foods, there were developed the relative numerous normative and technical documents. The one of such regulative documents is the national standard of DSTU 3946-2000 *"System of development and beginning of fabrication of production. Foodstuffs. Basic norms"*, which states that the new type foodstuff is such that was produced by newly developed or sufficiently altered technology and/or with use of raw materials,

bulking agents and food additives not used before, as well as the product character by altered composition and nutritional value, organoleptic properties and/or variation of physical, chemical and microbiological indices of quality.

The work in development of composition of new products and technologies of their producing may be subdivided conditionally by stages as follows:

1) development of preliminary specifications,
2) producing of experimental specimen of new product and formulation of prospective norms of its quality,
3) development of technology of its fabrication,
4) producing of pilot parties of the product, their testing and work in refinement of parameters of its quality,
5) attestation of quality of the product by the specialized tasting commission(s),
6) development, approval and registration of the attributed normative and technical documentation,
7) editing of technological documentation and final adjusting of technologies used in manufacturing,
8) beginning of serial production.

Some of listed stages may be unified in one. It is possible also to vary their succession. However, carrying out of comprehensive R&D works and drawing up of preliminary specifications of quality of the product in development are the obligatory stages of work in preparation to serial amnufacturing. The permission on beginning of new types of serial foods issue the authorized juridical persons by recommendations of the licensed commissions, which may be:

- central sectoral tasting commissions of committees and associations subordinated to the Ministry of Agricultural Policy of Ukraine,
- central tasting commission of the Ukoopspilka (except of products, which approval may be done by decision of respective body of executive power only, products of special destination of use, alcoholic beverages, tobacco goods, biologically active substances

used as food additives and products produced with use of untraditional raw materials),

- tasting commissions of regional State administrations of executive power, which control quality of products produced and consumed in boundaries of regions of their responsibility (except of products of special destination of use, canned products, alcoholic beverages, tobacco goods and products produced with use of untraditional raw materials),
- special tasting commissions of associations of enterprises of food industry, which have the right of issuing of permissions for interested parties on producing of new foods of their own fabrication (except of products subordinated to control of the specialized body of executive power, products of special destination of use, alcoholic beverages, tobacco goods, biologically active substances used as food additives and products produced with use of untraditional raw materials).

The regulations, which normalize procedures of operation of central tasting commissions develop and approve the specialized committees of the Ministry of Agricultural Policy of Ukraine and Ukoopspilka; regulations of regional tasting commissions develop and approve the respective higher State regulative bodies; regulations of special tasting commissions develop and approve the associations of enterprises, which operate by profile of specialization of applicants. The documents of the second and third listed categories must be agreed also by the Ministry of Agricultural Policy of Ukraine and the State Service of Technical Regulation and Consumer' Policy of Ukraine.

To obtain permission on beginning of serial manufacturing, the developer applies to the tasting commission the documents as follows:

- samples of new products, and protocols of their testing,
- projects of normative and technical documents on products in question,
- projects of documentation (formulations, technological instructions etc.) on technology of their producing,
- executive summary.

If the product should be used in special destination, the applicant must add to these documents the permission of the Ministry of Protection of Health of Ukraine. By results of expertise of applied materials and tasting of the product, the commission takes one of the following decisions:

- issues permission on serial producing of declared product,
- recommends to continue work on betterment of quality and/or detailing of technology of its fabrication,
- rejects the applicant in his claim and explains causes of taken decision.

In need of completing of technology of fabrication of the product, the applicant carries out the necessary work and applies the augmented set of necessary documents and materials to the tasting commission repeatedly.

7.13.4 Unified system of documentation by the technological preparation to manufacturing (YeSTPV)

The modern biotechnologies have typically the multi-stage character. Technologists operate in most cases in too diluted solutions of reagents, what requires of using of highly complicated technologies of extraction and purification of purposeful products at highly specialized enterprises, and the five basic stages of their operation are:

- the first and the second stages include operations on preparation to reprocessing of raw materials and biologically active substances,
- the third stage is fermentation of raw materials, i.e. the biotechnological process proper, where the purposeful product is formed,
- the fourth stage is extraction of the purposeful product from cultural liquids and its purification,
- the finishing stage of biotechnological process, is producing of commercial forms of products.

To normalize conditions of operation of such enterprises, Ukraine introduced the series of documents known as *"Norms of technological preparation to manufacturing"* representing itself the code of norms of

carrying out of technological operations, which observance guarantees reaching of the prescribed quality and output of purposeful products. The YeSTPV is in fact the series of interstate standards, which use assures shortening of terms of preparation to fabrication of products of set quality in conditions of ensuring of flexibility of manufacturing facilities and sufficient saving of resources of labor, consumed materials and spent finances. The basic stages of works in realization of this plan are:

- development of technological processes in details,
- purchasing of technological equipment, projecting and fabrication of technological accessories and non-standardized equipment,
- checkout and regulation of processes of operation of the installation, carrying out of starting and adjusting works in final alignment of the manufacture.

The one of the most significant principles put in base of YeSTPV norms is typification of technological processes based of use of standardized billets and materials, methods of reprocessing of raw materials and semi-manufactured products, exploiting of standardized technological equipment, introduction of unified forms of organization of manufacturing. Respectively, the set of State standards of YeSTPV category may be subdivided conditionally by five groups as follows:

- Group 0 — general norms,
- Group 1 — rules of organization and management by the process of TPV,
- Group 2 — rules of assuring of manufacturability of items,
- Group 3 — procedures of realization of technological processes, which permit to reach the planned characters of products of manufacture,
- Group 4 — procedures of use of technical means of mechanization and automation of the engineering and technological works.

Use of this system standards permits to obtain by producer the guarantees of reaching of advanced level of manufacturability of purposeful products as early as at the stage of projecting of prospective plant for their production.

7.14 Problems of Introduction of GMO in Public Economy

The main problem, which arises in extensive introduction of products of bioengineering, especially of GMO, as foods and/or their ingredients, is their probable hazard for health and life of live organisms. That is why the problem of use in economy of GM-products, prime forages, is the subject of systematical investigations. The principal factor to be revealed in this work is tracing of variations of state of health of domestic animals in systematical consumption of GMO, for this may be the index, which will permit to predict their probable influence on vital functions of men. However, at present stage of development of analytical chemistry, it is not still possible to identify in many cases the fact of presence of GMO in foods. Moreover, despite the increasing sensitivity and precision of methods of investigation, there was not found yet any difference in quality of eggs and meat of animals fed by forages, which contained GMO as one of their ingredients, and their traditional analogues. The root of the problem is that almost all works in studying of safety of GMO finance big corporations, such as "Monsanto", "Bayer", which produce genetically modified products and are interested in positive results of their testing.

At the same time, the European Department of Safety of Foods reported on results of independent investigations, which witness safety of consumption by men of meat and milk of genetically modified animals. Similarly, the General Directorate of European Commission by Science and Technology reported: *"The principal conclusion of more of 130 R&D works carried out by more of 500 research groups during 25 years is that the GMO-products are not more dangerous as compared with products of traditional technologies of planting"*. The WHO made therefore the conclusion that *"... the genetically modified organisms present in international market were comprehensively tested, and probability of their harmful influence on health of men is too small as compared with their traditional analogues"*. So, there were eliminated the principal objections for use GMO in public economies, and countries became free in their development and

commercialization. One should note, however, that said works were carried out in the short-time series of investigation and were done in absence of studying of delayed effects of their consumption.

Despite this notice and taking into consideration the fact that the infrastructure of agriculture in underdeveloped countries is too poor, the UN Food and Agriculture Organization recognized expedience of introduction of technologies of production and use of genetically modified organisms in these regions as foods. The reason of taking of this decision is that it may be the key factor in ensuring of the reasonable level of healthy nourishment of their growing population. It is reckoned, for example, that consumption of the *"golden rice" (Oryza sativa)*, which grains contain big quantity of vitamin "A", would permit to improve the quality of feeding of people, who live in countries of "third world", what is critically necessary, because deficit of this component in foods they consume results in losing of sight of up to half million people each year in Africa only.

Meantime the sizeable part of livestock and poultry is fed now by forage, which contains residues of GMO, mostly of the modified rape and soybean seed, which contain the modified albuminous component (e.g. the fraction of meat produced EU countries from the livestock fed by such forages constitutes roughly 40 %). The country leading in commercialization of GM-products is the USA, which permitted since 1995 planting of rape resistant to action of herbicide bromoxynile, soybean resistant to herbicide gliphosate, tomatoes resistant to rotting and other genetically modified cultures. For the state of 2013, USA planted 25 kinds of agricultural products subjected to genic modification, e.g. fraction of modified corn in total area of its cultivation in this country was of 85 %, and soybeans – of 91 %. As informs the National Center of problems of alimentation and agrarian policy in Washington (district Columbia), the American farmers got benefits in introduction of:

- Genetically modified soy (decrease of quantity of herbicides used annually by 28.7 million pounds = 13,018.3 ton, and reducing of prime cost of the total output of production on 1.1 billion US dollars),

- BT-cotton (decrease of annual use of insecticides by 1.9 million pounds = 861.8 ton, an increase of harvests on 185 million pounds = 83,916 ton),
- BT-sorts of corn (decrease of annual use of insecticides by 16 million pounds = 7,257.6 ton, an increase of harvests of grain on 3.5 billion pounds = 1,587,600 ton),
- BT-papaya resistant to affect of virus of annular blotch. The decrease of expenses on planting of this kind plant in Hawaii in 1998 only was of 17 million dollars).

It is recognized now that introduction of GMO have certain advantages, and one of the most expressive examples is the cotton seed that contains up to 20 % oil, which may be, in theory, the significant source of feeding of more of half billion people. However, its regular consumption is limited now because of richness by terpenes poisonous for heart, liver and reproductive system of men. Use of methods of conventional agriculture permits to select the kinds of this plant free of harmful compounds, but they will be sensitive to attacks of vermin. At the same time, methods of genic engineering permitted to select plants character by unchanged content of terpenes in all their parts except of seed, where this one was decreased to level of less of 1 % of its content in traditional kinds of the plant. The one more example of positive effect of cultivation of genetically modified cotton is reaching of resistance of the plant to attacks of cotton borer, the vermin the most dangerous for this culture. The agrotechnical practice used usually in control of its population is intense, up to 8 times per season, treating of sowing by insecticides. Meantime, introduction of gene of *Bt*-toxin inside the genome of cotton permits to decrease the periodicity of such treating fourfold. The same phenomenon is character for other plants too, so the areas used for cultivation of herbicide-resistant cultures reached 79 million hectares as early as in 2008. For the state of 2009, there was permitted the commercial cultivation of 33 kinds of transgenic plants: soy – 1, corn – 9, rape – 4, cotton – 12, sugar-beet – 1, papaya – 2, pumpkin – 1, paprika – 1, tomato – 1, rice – 1, and more of 90 kinds of potato, plum, lucerne, haricot, wheat, peanut, mustard, cauliflower, pepper chilly

etc. are on stage of commercialization. The information on GMO-cultures cultivated in some countries and areas of their planting shows Table 7.5:

Table 7.5

Areas of cultivation of genetically modified plants in some countries

№ №	Country	Area, *million hectares*	Culture	Part in total area, %
1	USA	64.0	Soy, corn, cotton, rape, squash, papaya, sugar-beet, lucerne	38
2	Brazil	21.4	Soy, corn, cotton	36
3	Argentina	21.3	Soy, corn, cotton	66
4	India	8.4	Cotton	5
5	Canada	8.2	Rape, corn, soy, sugar-beet	18
6	China	3.7	Cotton, papaya, paprika	3
7	Paraguay	2.2	Soy	51
8	Republic of South Africa	2.1	Soy, corn, cotton	14
9	Uruguay	0.8	Soy, corn	57
10	Bolivia	0.8	Soy	22

The GM-plants were officially cultivated in 2013 in 25 countries, including Australia, Burkina-Faso, Chile, Colombia, Costa-Rika, Czechia, Egypt, Honduras, Mexico, New Zealand, Philippines, Poland, Portugal, Romania, Russian Federation, Slovakia, South Korea, Spain, and some other EU countries. The total area of their planting reached 134 million hectares (about of 9% of the cultivated fertile soils, what is 1.7 times more as compared with 2009).

The USA produces presently more of 150 GMO-cultures. The most often it is the modified soy, which is used in producing more of 3,000 types of foodstuffs including soups, potato chips, sauces for salads, canned fish etc. the genetically modified cotton and rape are used in producing of vegetable oils, genetically modified potato – in producing of French fries, tomatoes of prolonged afterripening – in producing of ketchup etc. it is expected that most of foods consumed in USA would contain GMO during the nearest 10 years.

However, despite the wide consensus on relative safety of consumption of GMO products, there exists the opposition to their use conditioned mostly by reasons of environmental character. The opponents of practical use of GMO, such as *Greenpeace* and the *World Wildlife Fund* suppose, that probable risks of their commercialization are not identified properly yet because in some cases composition of foods of animal origin differs of those of traditional products. For instance, the US Supreme Appellation Court pronounced 30th of September 2010 the "differences in composition" of milk of cows fed by GM-forage and the usual one. It was informed, that at certain periods of lactation their milk is fatter and contains less albumen and bigger quantity of somatic cells, what may result in variation of processes of metabolism in its consumption.

7.15 Practice of Introduction of GMO in Public Economy

Our country joined to the Cartagena Protocol in 2002 witnessing so her support of practice of carrying out of coordinated protective actions in creation, testing, processing, circulation, trans-boundary move and use of GMO. The basic principles of the State policy used in Ukraine in this sphere are:

- observance of norms of biological and genetic safety in creation, investigation and practical use of genetically modified organisms,
- priority in care for protection of health of men and preservation of existing conditions of nature over the desire to obtain economical advantages,
- State support of investigations by problems of practical use of GMO,
- control of circulation of GMO-products in borders of the Ukrainian custom territory.

Procedures of circulation of GMO in Ukraine regulate norms of documents as follows:

- Law of Ukraine of 31.05.2007 # 1103-V "On State System of Biological Safety in Development, Testing, Transporting and Use of Genetically Modified Organisms",

- Decree of Council of Ministers of Ukraine of 18.02.2009 # 114 "On Procedures of State Registration of Genetically Modified Organisms and Sources of Foods, Foodstuffs, Cosmetics and Drugs, which Contain such Organisms or were Made with their Use".

The norms of Ukrainian legislation state that works in genic engineering must be licensed and carried out initially in closed systems. To ensure the maximum level of biological safety, the State founded the *Commission by Biological and Genetic Safety* responsible for preliminary evaluation of probable risks, which may arise in their commercialization. The accountable GMO material unsuitable or prohibited for use, as well as the GMO material obtained in process of testing, have to be utilized, annihilated or neutralized by procedures established by the Ministry of Education and Science of Ukraine and the Ministry of Ecology and Natural Resources of Ukraine.

After finishing of the laboratory stage of work, novel kinds of GMO have to be undergone to expanded State testing, which purpose is identifying of possibility and expediency of their commercialization. The essence of this work consists in studying of interconnection of new organisms with wild plants at places of their probable vegetation, exploring of dynamics of infestation of crops in conditions of uncontrolled reproduction of GMO and identification of probability of generation in their vegetative and generative organs of specific substances, which can stimulate breeding of pests and produce conditions of occurrence of epizooties. The investigations specific for each kind of GMO have to be carried out by procedures agreed with the Ministry of Ecology of Ukraine and Ministry of Protection of Health of Ukraine, and approved by the Ministry of Agricultural Policy of Ukraine. Such norms have to take into consideration the specificity of tested GMO and their differing of traditional sorts of plants, establish mechanisms of passing of materials to be tested to persons who would do this work and settle terms of their approbation. The obligatory condition of introduction of GMO in open systems in Ukraine is existence of the attested methods of their identification and analysis by norms of international standards. To

approbate GMO in open systems, the authorized person has to obtain the respective license of the Ministry of Ecology and Natural Resources of Ukraine and permission of the Ministry of Agriculture of Ukraine. The full set of documents to apply to obtain such permission includes:

- comprehensive technical characteristic of the genetically modified organism to test and its predecessor,
- recommended procedures of monitoring and control,
- conclusions of the State ecological and the State sanitary and epidemiological expertise of grade of biological and genetic safety of GMO,
- report on results of testing of safety of the object of expertise in closed systems.

After they would have been received by the Ministry of Agricultural Policy of Ukraine, the latter issues the Conclusion on level of safety of the organism in question and gives it to the applicant. This document has to contain also the information on probable changes, which may occur in emerging of GMO in areal of vegetation of wild plants, risks of infestation of crops of cultural plants with it and other undesirable effects of uncontrolled reproduction of GMO.

The next stage of introduction of genetically modified plant in circulation is its State approbation and registration to be done by the Ministry of Agricultural Policy of Ukraine. The objects subordinated to the State registration are:

- kinds of GMO-plants and domestic animals produced with their use,
- means of protection of plants produced with use of GMO,
- GMO-sources of foods, cosmetics, drugs and products produced with their use,
- GMO-sources of forages, food additives, veterinary preparations and products produced with their use.

The State registration of GMO may be cancelled and products made with their use withhold in case of obtaining in later time of scientifically substantiated information on their probable hazard for health of men or danger for conditions of environment.

If the product or any its ingredient contains GMO in quantities more of 0.9 % or was produced out of genetically modified organisms, its marking must contain the mark of "Contains GMO". The operator of the market has also the right to mark his product by the sign "Without GMO". The condition of such marking is the documented proof of its absence issued in observance of norms of Ukrainian legislation in force.

7.16 Principles of State Control of Quality and Safety of Foodstuffs

The norms of quality of production of agriculture have to comply to certain aesthetic, physiological and technological norms, and the principal properties to be observed in their fabrication are:

- *physical* (shape, coloring, density etc.),
- *chemical* (content of fat, albumen, carbohydrates, vitamins etc.),
- *biological* (capability to be stored without sufficient loss of mass, resistivity to worsening of marketable and nutrition properties and so on).

The structure of bodies of State executive power responsible for control of procedures of work in ensuring of safety and observance by businesspersons of set norms of quality of foodstuffs includes the persons as follows:

- Council of Ministers of Ukraine,
- Central body of executive power, which forms and accounts for realization of State policy in protection of health,
- Central body of executive power, which forms and accounts for realization of State policy in ensuring of conditions of safety and correspondence to established norms of quality of foodstuffs,
- Central body of executive power, which forms and accounts for realization of State policy in assuring of the sanitary and epidemiological welfare of population.

The Central body of executive power, which forms and carries responsibility for realization of State policy in protection of health:

- establishes norms of protection of health of men,

- establishes procedures of informing of the community on cases of food poisoning,
- accomplishes the State registration and running of State registers of novel foodstuffs, food additives, flavoring additives, enzymes and mineral drinking waters,
- establishes indices of safety and quality of foodstuffs,
- approves hygienic norms of objects of sanitary measures,
- draws up the list of reference methods of analysis of foods recommended for use,
- approves documents of guiding character and presents the respective information on its official web-site.

The Central body of executive power, which forms and accounts for realization of State policy in ensuring of safety and observance of certain indices of quality of foodstuffs:

- approves the list of enterprises, which export their products abroad and puts and excludes them out of their official register,
- accomplishes continuous consultations with the specialized bodies of other countries by problems of recognition of equivalency of all or certain measures used in assuring of safety and proper quality of foods to be used in signing of intergovernmental treaties,
- organizes and accomplishes work in State control of safety and quality of foodstuffs including this work at food markets and on the State border,
- approves the long-term plan of State control and supervision and establishes forms of documents used by the State inspectors in process of carrying out of their professional activities,
- approves the procedures and criteria of accreditation of testing, measuring, calibration and reference laboratories.
- develops and validates the annual and long-term plan of State control and supervision,
- carries out inspections of animals before and after their slaughtering at enterprises specialized in this work, as well as inspects the bulks of animals killed at hunt,

- accomplishes the State control of work in introduction of procedures of operation of businesspersons based on principles of HACCP,
- authorizes testing and reference laboratories on carrying out of work in searching (testing) of objects of sanitary measures in process of the State control in spheres of their responsibility,
- carries out the epizootic search and identifies causes and conditions of marketing of hazardous and unfit foodstuffs,
- takes part in development of sanitary measures, certain norms, technical regulations and standards of quality of foodstuffs.

Reference laboratory means the accredited laboratory authorized by the competent body by norms of Law of Ukraine of 22.07.2014 # 1602-VII "On amendment of certain legal deeds of Ukraine concerning of foodstuffs" on carrying out of works defined by this Law

The reference laboratories are founded in accordance with norms of the Law of *"On Amendment of Certain Legal Deeds of Ukraine Concerned of Safety of Foodstuffs"*. The functions of reference laboratories execute the persons as follows:

- accredited laboratories authorized by the competent legal person,
- reference laboratories recognized in this status as such that conform to requirements of international organizations and/or European Union specialized in this job.

The reference laboratory must comply to criteria as follows:

- be accredited on right of carrying out of investigations (tests) to be done with use of reference methods,
- have the personnel, which possesses by the necessary experience in work in development of methods of investigation (testing) of quality of foodstuffs and training of personnel of other laboratories specialized in analysis of foods,
- possesses by databases of national, international and European standards on methods of control of safety of objects of sanitary measures and their investigation (testing) in sphere of their authorization.

The principal functions of reference laboratories are:

- development of methods of investigation (testing),
- organization of courses of training of their personnel by profile of its authorization,
- carrying out of interlaboratory rounds of identification of professional skill of laboratories,
- participation in development of legal and normative deeds by problems of safety and control of certain indices of quality of foods,
- carrying out of R&D works to be used in work in State control and supervision,
- carrying out of arbitrary tests.

The typical procedure of expertise of quality and safety of foods shows the Figure 7.5 below:

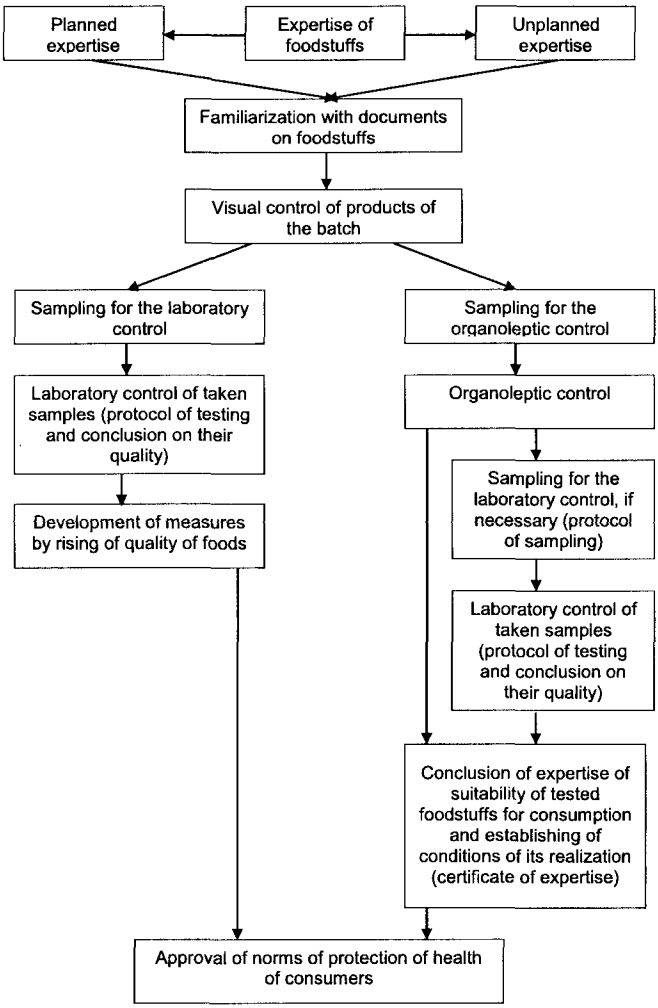


Figure 7.5 Typical procedure of expertise of quality of foods

As provide the norms of Law of Ukraine of 22.07.2014 # 1602-VII, the only body, which has the power on carrying out of work in control of state of safety of foodstuffs in Ukraine, is the *State Service by Problems of Safety of Foodstuffs* founded in way of unification of related structures of the State Veterinary Service of Ukraine, State Phytosanitary

Inspection, Sanitary and Epidemiological Service of Ukraine and State Inspection by Problems of Protection of Interests of Consumers. The principal sphere of its responsibility is development and approval of norms as follows:

- procedures of introduction of principles of HACCP and/or other analogous systems of assuring of safety and quality of foodstuffs subordinated to its control,
- methods and procedures of State control of quality of foodstuffs subordinated to control of services listed above,
- maximum allowable concentrations of pesticides, veterinary preparations, inclusions, polluting substances, food additives and auxiliary materials in foods and food raw materials used in their production.

The objects of the State expertise are:

- enterprises that produce foods intended for exporting (in purposes of their registration),
- enterprises that produce and sell foodstuffs on the inner market (in purposes of issuing of permissions on their exploitation or restoration of productive activities after postponing of operation).

The State Service by Problems of Safety of Foodstuffs control conditions of operation of businesspersons in producing and distribution of products of meat- fish- and milk-processing industries, controls routine of operation of enterprises of wholesale storage of not-processes foods of animal origin, and supervises on operation of all objects of sanitary control. Besides, this Service accomplishes the functions of issuing of permissions on circulation of foods as follows:

1) foodstuffs and additives of special dietetic use,
2) functional foodstuffs,
3) all types of foodstuffs excluding those, that are in sphere of responsibility of the State Service of Veterinary Medicine of Ukraine.

The departments of the Service make the expertise of:

- technologies of production of foods not used in Ukraine before,
- quality of foodstuffs produced in Ukraine for the first time,

- safety of foodstuffs imported in Ukraine the first in absence of valid resolution of the State Sanitary and Epidemiological Service or the substantiated declaration on their safety issued by their producer (importer),
- foodstuffs for special dietetic consumption, functional foodstuffs, dietetic additives, food additives, flavoring substances and auxiliary materials used as their ingredients and not registered in Ukraine yet,
- projects of plants, which will produce and reprocess foodstuffs.

The terms mentioned above are used here in meanings as follows:

Foodstuffs for special dietetic consumption mean foods, including the products to be consumed by children and aged persons, which are not the medical preparations but were specially treated in purposes of satisfying of concrete dietetic needs, which result of specific physical or physiological conditions of men and/or their specific illnesses or disorders

Foodstuff consumed in special medical purposes means the product developed and produced specially in purposes of curing and consumed under control of physician. Such product is assigned for partial or total substitution of ingredients of usual ration of patients, who have the limited, broken or inadequate capability to eat, digest and assimilate usual foods, or their certain nourishing ingredients, or their metabolites. The foodstuffs assigned for consumption in special medical purposes may be prescribed for the partial or full-scale alimentation of patients in impossibility of satisfying of their needs in modifying of usual ration identified by physicians

Functional foodstuff means the food, which contains medical preparation(s) as the constituents added in purposes of prophylaxis and/or softening of consequences of illness

Useless foodstuff means the foodstuff, which contains the outside inclusions and/or pieces or was damaged in result of influence of mechanical, and/or chemical, and/or microbial

factors. In case of its consumption in usual conditions, the useless product is not harmful for health of men

Food additive – means the substance, which is not the foodstuff or its ingredient in usual conditions, but was added to the foodstuff in technological purposes in process of its production becoming so the integral component of the product (this term does not includes substances, which were added into the foodstuff to improve its nutritious properties)

Dietetic additive means the vitaminous, mineral, or grassy component consumed with foods perorally in form of tablets, powders or mixes

Auxiliary material for remaking of foods means any material does not consumed as a food but used in technological purposes in process of producing or processing of foodstuffs or their ingredients

Flavoring substances mean all products not consumed separately of other foods but added into foodstuffs to give them the flavor and/or taste, or modify their scent. This class ingredients includes aromatic substances, aromatic preparations, aromatic substances treated thermally, smoking flavoring substances, aromatic precursors, as well as other flavoring agents and their mixtures that cannot be classified by categories listed above

The State control and State supervision services control the grade of safety of foodstuffs by approved programs of inspection. If the inspector would have any suspicions on improper quality, and/or incorrect marking, and/or labeling of any object of sanitary control, he has to demand of its owner to do the necessary laboratory investigations by methods normalized by national standards of Ukraine. In impossibility of use or absence of such norms, there have to be used the methods established by the respective specialized international organizations. If such methods would be absent too, there have to be used the special methods of analysis developed in observance of norms of national standards of Ukraine, or

documents of respective international organizations, or documents used in the European Union.

If any foreign substance must not be present in the foodstuff, the related normative and legal deeds establish the minimum level of sensitivity of methods of its identification. If result of analysis by this method would not show its presence, one may consider that this substance is absent in the analyzed food.

The persons, which produce, reprocess, transport and realize foodstuffs with violation of norms of Law of Ukraine of 22.07.2014 # 1602-VII *"On Introduction of Amendments in Certain Legal Deeds Concerned of Foodstuffs"*, are subjected to fining in cases as follows:

1. admitting to processes of production and/or circulation of foodstuffs of persons, who have counterindication to this work,
2. producing and storage of foodstuffs in premises, which are not registered in accordance with norms of said Law,
3. producing and storage of foodstuffs in absence of the related permission,
4. nonobservance of obligation on introduction of principles of system HACCP at the continuously working enterprises,
5. realization of products marked improperly,
6. violation of norms of traceability at all stages of being at the enterprise of finished products and ingredients used in their producing,
7. nonobservance of obligation on returning or withdrawal of hazardous products,
8. use of non-registered auxiliary materials, which contact with foodstuffs in process of their fabrication,
9. realization of non-registered objects of sanitary measures, if such registration is specified by this Law,
10. putting in circulation of unfit foodstuffs,
11. infringement of parameters of safety of objects of sanitary measures set by legislation,
12. non-fulfillment of substantiated claims of functionaries on elimination of violations of safety and causes of non-observance

of certain indices of quality of foodstuffs to be done during the term agreed with the competent body,

13. non-fulfillment of legal claims of functionaries of competent bodies on annihilation of foodstuffs and materials used in their reprocessing, which are hazardous for health of men and/or dangerous in other type uses,
14. concealment (non-presentation), refusal in giving of necessary data and giving of inauthentic information in answering on claims of competent persons,
15. refusal in admission to the enterprise of functionaries, who are authorized on carrying out of planned control actions.

Withdrawal of the foodstuff means the measures directed on prevention of distribution, demonstration and proposing for consumers of dangerous foods

Recall of the foodstuff means the measures directed on returning of the dangerous foodstuff, which was sold, or given for use, or is available for the consumer

As provided the normative and regulatory documents, each manufacturing enterprise is subjected to State registration and regular State sanitary and epidemiological expertise. The procedures of State registration of the manufacture of the foodstuff presuppose the stage of identification of absence in it of hazardous chemicals and biological factors named in the State Register of Hazards, which lists their appellations, properties, methods of identification, mechanisms of probable negative influence, biological effects, grade of danger for health of men, character of behavior in environment, recommended hygienic procedures etc. The norms of safety of foods for life and health of inhabitants have to be fixed in national standards and other normative and technical documents, and the conditions of their commercialization are:

To start serial production of the foodstuff, the manufacturer has to receive, dependently of its type, the permission of the Chief Sanitary Doctor of Ukraine or the Chief State Inspector of Veterinary Medicine.

- compliance of characteristics of objects of expertise to sanitary norms,

- safety in carrying out of operations, which influence on state of health and conditions of life of men,
- completeness and effectiveness of sanitary, anti-epidemic and prophylactic measures to be taken by businesspersons in their work.

The content of information on medicinal properties of foodstuffs (if exist) to be put in their labels, explanatory and advertising materials, has to be agreed with the Ministry of Protection of Health of Ukraine in obligatory manner. The head body, which main subject of work is rising of level of safety of foods in Ukraine, is the National Commission by Codex Alimentarius subordinated to the Council of Ministers of Ukraine. Its principal functions are:

- establishing of parameters of safety of foodstuffs, which have to comply to international norms, as a rule,
- coordination of activities in harmonization of domestic norms of quality of foodstuffs with the international ones,
- coordination of works in harmonization of international standards, technical regulations, and sanitary norms used in producing and analysis of foodstuffs,
- development of projects of advanced sanitary measures and proposals on amending of the valid ones,
- organization of scientific and expert investigations by problems of its competence,
- informative and reference servicing in dissemination of information on activities of supreme bodies of the Commission "Codex Alimentarius".

7.17 Procedures of Import of Agricultural Production in Ukraine

The Council of Ministers of Ukraine publishes regularly the list of foods, additives, preservatives and products, which contain substances that must not be imported in Ukraine, especially the foods potentially dangerous for health, unfit for consumption, incorrectly marked and not

conforming to provisions of technical regulations and/or sanitary measures of national category.

Unfit (adulterated) foodstuff means the product useless for consumption by men in cases as follows:

- *if it contains toxic or harmful substance(s), which presence make it dangerous for health of men (excluding substances, which are present in quantities not harmful for health),*
- *if it contains toxic or harmful substance(s) added intentionally (excluding pesticides, food additives, colorants or medical preparations for animals) in quantities, which do not exceed their maximum permissible levels,*
- *if it does not conforms to minimum specifications of quality,*
- *if it is fully or partly produced out of ill animal(s) or animal(s) slaughtered outside of supervised slaughter-house(s),*
- *if it is placed into the container or packing, which fully or partly consists of substances toxic or harmful for health,*
- *if it was specially irradiated (excluding the cases of use of irradiation done in observance of international norms of its safe use),*
- *if it contains food additives not permitted for use in foods, and/or substances that are permitted for use but present in quantities, which exceed their maximum allowable concentrations in foods,*
- *if it contains pesticides, veterinary preparations or their residues, which presence in foodstuffs is prohibited, and/or compounds, which are permitted for use but present in quantities, which exceed their maximum permissible concentrations in foods,*
- *if there were fully or partly removed and/or substituted any useful ingredient(s) of the product, or if its composition was knowingly altered in purposes of increasing of its volume or mass, or was amended in purposes of raising of its attractiveness or worth*

Product marked incorrectly means the foodstuff, which marking is made incorrectly in use of methods as follows:

- *its label is counterfeited or contains deceiving information,*
- *the foodstuff is sold under the trade mark of other product,*
- *information on the label is written in foreign language,*
- *the foodstuff was packed, placed in pack or prepared for realization by deceiving mode,*
- *the label placed on the product contains words and/or combinations of words read with difficulties or problematic for understanding by ordinary consumers,*
- *the foodstuff was treated or irradiated by the permitted mode but information on name and address of irradiator is not given in its label properly. The exclusion is the non-packed commodity, which was irradiated and not supplemented by the documents but supplemented by documents that inform on such treatment*

Besides, there is prohibited importing in Ukraine of products as follows:

1) *inedible products of animal origin*,
2) *live pathogenic microorganisms* and materials, which contain pathogens of diseases of animals (excluding cases of their import in Ukrainian territory for research or other permitted use),
3) *veterinary preparations, premixes, forage and forage additives* not complying to norms of the Law of Ukraine *"On Veterinary Medicine"*.

   Premixes mean mixes of feed additives not intended for direct feeding of animals, which contain vitamins, amino acids, minerals and other substances mixed with water and/or forages of animal or vegetative origin used as their carriers

The reasons of refusing in issuing of permissions on importing in Ukraine of clinically healthy animals, or cancellation of validity of resolving documents issued in earlier time, are: a) probability of bringing of pathogenic organisms, b) delivery of commodities prohibited for use in Ukraine, c) riskiness of import of commodities potentially harmful for health of men and animals.

The live animals have to be subjected before their importing in Ukraine to thermometry and inspection of State veterinary services on absence of brucellosis, paratuberculosis, leucosis, leptospirosis, as well as to prophylactic dehelmintation and treating against parasites done in terms sufficient for liberation of organism out of residues of used preparations. The transport means to be used for their delivering have to be treated and prepared by the norms used in these purposes in Ukraine.

The fact of carrying out of work in inspection and veterinary treating of animals witnessed by documents, which indicate used methods of control and witness the fact diagnostics, vaccinations and inform on their results, have to be registered in veterinary and sanitary certificates of international form written in Ukrainian and the language of the country of exportation and signed by the State Veterinary Doctor of the country of origination of the freight. If the Ukrainian State inspector will find its invalidity or discrepancy of given information, he has to inform on it the Chief State Sanitary Doctor, or the Chief State Inspector of Veterinary Medicine, or their deputies, and issue the prescription on sending of suspicious parcel on storage at specially appointed veterinary inspection post(s) on the State border.

Control of conformity on the State border means the form of State control, which represents itself visual inspecting of the freight carried out in purpose of examination of compliance of its real content to data contained in certificates and/or documents, which supplement the parcel

Physical control on the State border means the control of content of objects of sanitary measures to be done in purposes of correctness of supplementing documents and identification of its safety. This work may include the control of some indices of quality of foodstuffs and state of means of transporting, correctness of packing, marking, sampling, measuring of temperature, as well as other type control actions, which would be necessary in identification of conformity of content of state of freights to legal norms

In revealing of evident discrepancies of state of the freight to be transported through the Ukrainian territory in transit to established norms, there have to be done the actions as follows:

- the inspector of veterinary medicine on the State border must inform on it the Chief State Inspector of Veterinary Medicine as soon as possible and the latter has, in turn, to inform on it the importer and/or owner of the freight and functionaries of countries of origin and destination,
- in finding of the especially dangerous illnesses, ill animals must be slaughtered and their bulks utilized by methods, which exclude expanding of found illness(es),
- the suspicious freights have to be isolated in questionable cases in quarantine stations. In existence of such necessity, the inspector has to take the representative samples of commodities and send them to the authorized accredited laboratory.

The foodstuffs recognized as dangerous, unsuitable for consumption, incorrectly marked or not complying with requirements of domestic technical regulations and sanitary norms, are not permitted for importation and must be returned to their owner. The exclusions are cases, when the importer or his authorized representative agrees on reprocessing of condemned commodities or their use by changed destination. At that, each pack of such products has to be marked by notification *"Not for consumption by men"*. In absence of packs, the problematical commodities have to be packed by method, which would permit to put such marking on the packing.

In existence in countries of origin of illnesses of animals listed by the International Epizootic Bureau as dangerous, the Chief State Inspector of Veterinary Medicine of Ukraine has the right to terminate or even prohibit importing of cattle from regions of their occurrence. This restriction is applied to all freights, including those that were sent in transit through the country (zone) of prohibition. The term of prohibition is set in observance of duration of the incubation period of the respective illness calculated since the last date of its appearance in the quarantine zone. All condemned freights of foodstuffs, which were already imported in Ukraine and

reckoned as risky for health of men and animals, as well as those that are recognized as such that cannot be reprocessed, have to be annihilated by procedures established by the Council of Ministers of Ukraine.

Annihilation of production withdrawn from circulation means the mechanical, physical, chemical, biological or other type procession and/or disposal (burial) of products or their residues in specially assigned places

Processing of production withdrawn from circulation means the complex of technological operations in changing of physical, chemical or biological state of production withdrawn from circulation done in purposes of its preparing for utilization or following use in another destination

The enterprises, which reprocess, utilize and/or annihilate the dangerous and poor quality production, have to observe the following terms:

- keep the manufacturing facilities in conditions safe for health of men and state of environment,
- keep books of receipt, procession, utilization and annihilation of obtained products,
- regularly train and attest the level of proficiency of their personnel,
- inform bodies of executive power, local corporate bodies and population on accidents and extreme situations occurred in process of their operation and skillfully liquidate their consequences,
- prevent the possibility of storage of products withdrawn from circulation in unforeseen places and cases of unauthorized treating.

The products of agriculture subordinated to the State control and supervision actions, as well as the products imported, to be imported, exported or transported through the Ukrainian custom territory, have to be subjected to obligatory selective veterinary and sanitary control at the boundary quarantine stations of the State Department of Veterinary

Medicine on transport. The conditions to be observed in import of objects of sanitary control in Ukraine are as follows:

- *foodstuffs* must be supplemented by originals of international veterinary (sanitary) certificates and/or marked by the mode, which witnesses their suitability for consumption,
- *other objects of sanitary control* must be supplemented by documents and/or be marked by mode that indicates the place of their fabrication.

The work of the State veterinary and sanitary frontier control bodies includes the actions as follows:

1) control of validity of permission on import,
2) phytosanitary, veterinary and sanitary control of foods subjected to custom procedures,
3) control of completeness and authenticity of international certificates, as well as trueness of information on content of the parcel,
4) control of animals on presence of symptoms of dangerous diseases,
5) control of existence of marking placed in country of origin onto bulks of animals, or on parts thereof, or on their packing, which witnesses their suitability for consumption,
6) selective control of accuracy of marking and fullness of information on quality of foodstuffs given in their labels, as well as proof of their compliance to norms of technical regulations of national category,
7) control of integrity of packs of foodstuffs and their opening (if necessary) in purposes of identification of their pollution by exterior substances.

The posts of the State Department of Veterinary Medicine authorized on control of production to be imported (exported) accomplish the *scheduled* actions as follows:

- taking of samples out of animals or other commodities for diagnostics, clinical examination and laboratory testing,

- selecting on quarantine of ill animals and animals, which show signs of illnesses,
- control of disinfecting of means used in transporting of freights.

The *expanded* veterinary and sanitary control of freights or their extraordinary *selective* sanitary inspection is carried out in the following cases:

- if the product was considered as dangerous at least once during the last five cases of its importing,
- if the product is useless, incorrectly marked or does not complies to established technical and/or sanitary norms,
- if the visual inspecting of the product carried out in earlier inspections showed evident infringements of sanitary norms,
- if the foodstuff is imported into the Ukrainian custom territory for the first time and is not supplemented by declaration of conformity of the form recognized in Ukraine,
- if the State inspector of veterinary medicine on the Ukrainian border suspects the probability of risk for health of men and animals in consumption of products, which are in the parcel.

International sanitary certificate means the document issued by the competent authorized body of country of origin, which witnesses suitability of the product for consumption by men (excluding the products subordinated to control of the State veterinary service)

International veterinary certificate means the document issued by the State Doctor of Veterinary Medicine of country of origin, which witnesses that the established norms of work in protection of health of animals were observed in their fattening wholly, and/or indices of quality and safety of foodstuffs subordinated to control of the State Veterinary Service conform to the established norms

Inadmissible international certificate means the certificate, which contains at least one of features listed below:

- *it was issued by the non-authorized person,*

- *it was not ratified or was issued with infringement(s) of the form approved by the competent body of country of origination,*
- *it was formalized illegibly,*
- *it contains the incomplete or inauthentic information,*
- *the term of validity of the certificate was expired,*
- *it contains the non-notarized corrections or erasures,*
- *it contains the contradictory information,*
- *it was set forth in the language not conforming to the legalized standards of registration,*
- *it was issued on products, which import and/or export (transporting in transit through the national custom territory) is prohibited*

The label on the product has to contain the additional information on its properties and may be considered as the one more instrument of control of quality of the product. The legends on the label have to be written in the official State language. The operator of the market, if wish, may double such information in other languages too. Some categories of information to be given in such kind label are given in Table 7.6:

Table 7.6

Typical information contained in labels of foods

Category of information	Content of label
Content	Appellation of the foodstuff and/or its ingredients
Characteristics	For example "Conforms to norms of European directive # ... "
Conditions of exploitation	For example: "Fill only by distilled water"
Quality	For example: "First grade of quality"
Safety	For example: "Sigh CE"
Warning	For example: "Safe for children"
Health	For example: "Allergic"
Environment	For example: "Environmental label"
Guarantees	For example: "Not rusting"

The results of environmental, veterinary and sanitary operations carried out in other countries may be recognized as equivalent with the Ukrainian ones only on condition of concluding of bilateral or multilateral treaties on recognition of their equivalence The foodstuffs and forages may be exported or re-exported in third countries only on condition of concluding with these states of special treaties and in existence of permissions issued by the competent State bodies of country of destination. The validity of certificates of conformity issued abroad may be recognized in Ukraine only on condition of absence of commercial or other interests of the authorized competent foreign body, which issued the document, and trustworthiness of results of attestation of quality of foods carried out in observance of criteria as follows:

- existence of qualified personnel and means necessary for attestation of quality of products to be exported, and
- possibility of inspection of appropriateness of equipment used in testing of said products in the country of origin.

The criteria to be observed to recognize the necessary level of competence of foreign administration in work in attestation of quality and safety of foods are:

1. Membership of country of export in the profile international organizations.
2. Observance of procedures of veterinary and sanitary control recognized internationally.
3. Transparency in making of resolves on quality and safety of objects of export.
4. Existence of independent organization, which controls observance of procedures used in international sanitary and veterinary certification.

The results of work done in assessment of conformity of foodstuffs abroad may be recognized in Ukraine in absence of respective international treaties in cases as follows:

- if Ukraine and the Party, which persons issued certificates are both members of the same international and/or regional specialized

organization(s) and use the same norms of attestation of conformity,

- if this work was carried out by the specialized foreign agency accredited by the international or regional organization, which member Ukraine is.

The products of agriculture imported into the Ukrainian custom territory must be certified in obligatory manner (excluding the raw materials imported in purposes of producing in Ukraine of commodities to be certified independently) and subjected to sanitary, veterinary, epidemiological and radiological control. The enterprises, institutions, organizations and entrepreneurs can import in Ukraine raw materials, production (articles, equipment, technological lines, etc.) on condition that they are safe for life and health of men and named in the listing approved by the Chief State Sanitary Doctor of Ukraine.

The products imported in Ukraine in purposes of trade may be marketed only on condition of their origination from countries free of quarantine and in existence of: 1) certificate of origin and marking of package (boxes, packs, packaging), which informs on appellation of the product, 2) information on mass (volume) and composition of the commodity, 3) list of ingredients, additives, preservatives, colorants etc. used in process of producing of the foodstuff and/or possibly present in it, 4) information on content in products of foreign chemical substances or compounds. There also has to be given the information on energy of the product, limiting term of its use, probability of secondary effects of consumption, place of manufacturing, name and address of manufacturer, information on owner of the trade mark (if exist) written in Ukrainian (excluding the trade marks, logos or original names of companies and/or products, which may be given in original spelling). Importing in Ukraine of foodstuffs by natural persons for own consumption may be done on condition of declaring of type and quantity of all products of animal origin and fresh vegetative products.

Importing of food products is prohibited if they are potentially danger for health of men, and/or may bring in Ukrainian territory organisms and/or infections harmful for men and animals.

Test Questions

1. What is the foodstuff ?
2. Give the notion of safety of foods
3. What is the hazardous factor present in foodstuff ?
4. What normative documents normalize the notions of identification, evaluation and control of hazardous factors in foods in process of their manufacturing ?
5. What if GlobalGAP and what is its principal mission ?
6. What foods have to be certified in Ukraine ?
7. What is the system of HACCP ?
8. What are principal results of execution of decisions of Havana Chart ?
9. What was the purpose of founding of GATT ?
10. What is the national mode of trade ?
11. What organization became the successor of GATT ?
12. What were preconditions of reorganization of GATT ?
13. What were the year of founding and principles of activities of WTO ?
14. What are technical barriers in trade, and what are the principal decisions in their elimination ?
15. What are norms of regulation provided by the WTO Treaty on Sanitary and Phytosanitary Measures ?
16. What is the environmentally pure manufacture ?
17. What is the genetically modified organism and what are causes of limiting of their spreading ?
18. What document regulates norms of work with GMO ?
19. What production is in sphere of State veterinary control ?
20. What production is in sphere of sanitary and epidemiological control ?
21. What shall be actions of the Chief Sanitary Doctor of veterinary medicine in case of poor quality of the foodstuff ?

LITERATURE

1. Law of Ukraine of 24.02.1994 # 4005-XII "Про забезпечення санітарного та епідемічного благополуччя населення" /// http.www.zakon.rada.gov.ua
2. Law of Ukraine of 23.12.1997 # 771/97-ВР "Про безпечність та якість харчових продуктів" /// http.www.zakon.rada.gov.ua
3. Law of Ukraine of 11.02.1998 # 113-98-ВР "Про метрологію та метрологічну діяльність" /// http.www.zakon.rada.gov.ua
4. Law of Ukraine of 05.03.1998 # 187/98-ВР "Про відходи" /// http.www.zakon.rada.gov.ua
5. Law of Ukraine of 14.01.2000 # 1393-XIV "Про вилучення з обігу, переробку, утилізацію, знищення або подальше використання неякісної та небезпечної продукції" /// http.www.zakon.rada.gov.ua
6. Law of Ukraine of 17.05.2001 # 2406-III "Про підтвердження відповідності" /// http.www.zakon.rada.gov.ua
7. Law of Ukraine of 17.05.2001 # 2407-III "Про акредитацію органів з оцінки відповідності" /// http.www.zakon.rada.gov.ua
8. Law of Ukraine of 17.05.2001 # 2408-III "Про стандартизацію" /// http.www.zakon.rada.gov.ua
9. Law of Ukraine of 24.10.2002 № 191—IV-2002 "Про внесення змін у Закон України "Про безпечність та якість харчових продуктів"/// http.www.zakon.rada.gov.ua,
10. Law of Ukraine of 01.12.2005 # 3161-IV "Про захист прав споживачів" /// http.www.zakon.rada.gov.ua
11. Law of Ukraine of 15.01.2015 "Про технічні регламенти та оцінку відповідності" /// http.www.zakon.rada.gov.ua
12. 1.12.2005 # 3164-IV "Про стандарти, технічні регламенти та процедури оцінки відповідності" /// http.www.zakon.rada.gov.ua
13. Law of Ukraine of 16.11.2006 # 361-V "Про ветеринарну медицину" /// http.www.zakon.rada.gov.ua
14. Law of Ukraine of 31.05.2007 # 1103-V "Про державну систему біобезпеки при створенні, випробуванні, транспортуванні та

використанні генетично модифікованих організмів" /// http.www.zakon.rada.gov.ua
15. Law of Ukraine of 02.12.2010 # 2735-VI "Про державний ринковий нагляд і контроль нехарчової продукції" /// http.www.zakon.rada.gov.ua
16. Law of Ukraine of 22.07.2014. # 1602-VII "Про внесення змін до деяких законодавчих актів України щодо харчових продуктів" /// http.www.zakon.rada.gov.ua
17. Decree of Council of Ministers of Ukraine of 08.04.1993 # 113/98-ВР "Про державний нагляд за додержанням стандартів, норм і правил та відповідальність за їх порушення" /// http.www.zakon.rada.gov.ua
18. Декрет Кабінету Міністрів України від26.04.1993 р. № 40-93 "Про забезпечення єдності вимірювань" /// http.www.zakon.rada.gov.ua
19. Decree of Council of Ministers of Ukraine of 10.05.1993 p. # 46-93 "Про стандартизацію та сертифікацію" /// http.www.zakon.rada.gov.ua
20. Decree of President of Ukraine of 13.07.2005 "Про заходи щодо вдосконалення діяльності у сфері технічного регулювання та споживчої політики" /// http.www.zakon.rada.gov.ua
21. Order of State Committee of Ukraine by standardization, metrology and certification of 02.06.1997 # 322 "Правила обов'язкової сертифікації харчових продуктів" /// http.www.zakon.rada.gov.ua
22. Order of State Committee of Veterinary medicine of 17.12.2009 # 535 "Порядок видачі міжнародних ветеринарних сертифікатів для експорту м'яса птиці в країни ЄС" /// http.www.zakon.rada.gov.ua
23. Order of State Committee of Ukraine by standardization, metrology and certification # 321 of 03.06.2002 including amendments dome in accordance with Order Of State Service of technical regulation # 107 of 21.03.2011 /// http.www.zakon.rada.gov.ua
24. Order of Ministry of agricultural police of 01.10.2012 590 "Про затвердження вимог щодо розробки, впровадження та застосування постійно діючих процедур, заснованих на

принципах Системи управління безпечністю харчових продуктів (НАССР)" /// http.www.zakon.rada.gov.ua
25. Энциклопедический словарь Брокгауза и Ефрона в 82 тт. и 4 доп. тт. — М.: Терра, 2001. — 40 726 стр.
26. Абрамов А.В. Аккредитация и взаимное признание результатов оценки соответствия / Абрамов А.В., Новиков В.Н., Никитюк А.А // Науково-технічний вісник УкрНДНЦ, Вип. 4, – К., 2007. – Р. 100
27. Адлер Ю.П. Восемь принципов, которые меняют мир / Адлер Ю.П. // Стандарты и качество, № 5/6 – К., 2001. – Р. 49
28. Бичківський Р.П. Управління якістю / Бичківський Р.П. – Львів: "Львівська політехніка", 2000. – 329 р.
29. Бичківський Р.П. Метрологія, стандартизація, управління якістю і сертифікація / Бичківський Р.П., Столярчук П.Г., Гамула П.Р. – Львів: "Львівська політехніка", 2002. – 506 р.
30. Боженко І.Л. Метрологія, стандартизація, сертифікація та акредитація / Боженко І.Л. – Львів: Львівська політехніка, 2004. – 315 р.
31. Болотніков А.О. Стандартизація та сертифікація товарів і послуг / Болотніков А.О. – К.: МАУП, 2005. – 144 р.
32. Бугай М. Харчування і здоров'я нації. Для нормальної життєдіяльності людини потрібні екологічно чисті і безпечні продукти / Бугай М.П.// Виробництво і економіка, №2 – К., 2006. – Р. 8.
33. Ванько В.М. Вимірювальні перетворювачі (сенсори) / Ванько В.М., Поліщук Є.С., Дорожовець М.М., Яцук В.О., Яцук Ю.В – Львів, Видавництво Львівської політехніки, 2015. – 580 с.
34. Варріс Енн-Марі Наступне покоління стандарту ISO 14001: три запитання і правило "трьох С" / Варріс Енн-Марі // Стандартизація, сертифікація, якість, № 2 – К., 2010. – Р. 15-
35. Величко О.М. Основи метрології та метрологічна діяльність / Величко О.М., Коцюба А.М., Новиков В.М – К.: 2000. – 228 р.
36. Величко О.М. Основи стандартизації, та сертифікації / О.М. Величко, В.Ю. Кучерук, Т.Б. Гордієнко, В.М. Севастьянов //

режим доступу: http://ignatenko.vk.vntu.edu.ua/file/d5192139eb3dfb0597e7cda841630056.pdf
37. Вербицький П.І. Довідник лікаря ветеринарної медицини / Вербицький П.І., Достоєвський П.П. – К., 1991. – 351 р.
38. Віткін Л.М. Сучасна система технічного регулювання України: теорія та практика / Віткін Л.М., Хімічева Г.І., Зенкін А.С. - К.: МАУП, 2011. – 546 р.
39. Віткін Л. Європейська стандартизація. Погляд у майбутнє / Віткін Л., Сирота О. // Стандартизація, сертифікація, якість, № 3 – К., 2010. – Р. 8
40. Захожай В.Б. Статистика якості /, Захожай В.Б., Чорний А.Ю. – К., МАУП, 2005. – 576 р.
41. Кириченко Л.С. Сертифікація та якість продукції в сучасних умовах господарювання / Кириченко Л.С., Чернухіна Н.М. – Львів: Державний університет "Львівська політехніка", 1995. – 227 р.
42. Кириченко Л.С. Основи стандартизації, метрології, управління якістю / Кириченко Л.С., Мережко Н.В. – К., Київський національний торгівельно-економічний університет, 2001. – 446 р.
43. Коваленко С.М. Концептуальні основи систем управління якістю. Основні принципи міжнародних стандартів / Коваленко С.М., Лебединець В.О., Коваленко С.М. – Харків: Нац. Фарм. Університет, "Золоті сторінки", 2003. – 96 р.
44. Коваленко І.І. Методи аналізу якості / Коваленко І.І., Дубовий О.М., Бідюк П.І. – Миколаїв: НУК, 2004. – 208 р.
45. Кузьміна Т.О. Міжнародна система стандартизації та сертифікації / Кузьміна Т.О. – К.: Кондор, 2011. – 426 с.
46. Melnychuk S.D. Fundamentals of the System of State Technical Regulation / Melnychuk S.D., Borovykov O.Ya., Bal-Prylypko L.V. – Kyiv, NUBiP of Ukraine, 2013. – 254 p.

47. Мухаровський М. Система безпеки харчових продуктів / Мухаровський М. // Держстандарт України, № 4 – Харків, 2001. – Р. 55
48. Нечипоренко Н. Діяльність CENELEC / Нечипоренко Н. // Стандартизація, сертифікація, якість, №1 – К. 2007. – Р. 17
49. Окрепилов В.В. Всеобщее управление качеством, ч. 1,/ Окрепилов В.В. – СПб: 1996. – 198 р.
50. Панасюк В.М. Проблеми стандартизації та сертифікації в Україні / Панасюк В.М., Друзюк В.М. // Міжвідомчий науково-технічний збірник "Вимірювальна техніка та метрологія" № 55 – Львів, Державний університет "Львівська політехніка", 2001. – Р. 147
51. Перля З.Н. Путь к микрону / Перля Н.Н. – М.-Л.: ОНТИ, 1936. – 107 с.
52. Радкевич Я.М. Метрология, стандартизация и сертификация / Радкевич Я.М., Схиртладзе А.Г., Лактионов Б.И. – М.: Высшая школа, 2004. – 767р.
53. Рамазанова-Стьопкіна О.А. Основи стандартизації, сертифікації та контролю якості / Рамазанова-Стьопкіна О.А. – К.: НАУ, 2004. – 112 р.
54. Ришняк Н.М. Удосконалення принципів оцінки результативності праці / Ришняк Н.М. // Вид. ДНУ Вип. 240, т. 3, – Дніпропетровськ, 2008. – Р.722
55. Ровенчак Т.Г. Стандартизація, управління якістю і сертифікація продукції / Ровенчак Т.Г., Христич О.В. – Вінниця: ВНТУ, 2005. – 120 р.
56. Салухіна Н.Г. Стандартизація та сертифікація товарів і послуг / Салухіна Н.Г., Язвінська О.М. - К.: Центр учбової літератури, 2010. – 335 р.
57. Сергеєв А.Г. Сертифікація / Сергеєв А.Г., Латишев В. М. – М.: Логос, 1999. – 248 р.
58. Саранча Г.А. Метрологія, стандартизація, відповідність, акредитація та управління якістю – К.: Центр навчальної літератури, 2006. – 668 с.

59. Тарасова В.В. Метрологія, стандартизація і сертифікація / Тарасова В.В., Малиновський А.С., Рибак М.Ф. – К.:, 2006. – 262 р.
60. Хоменко В.І. Ветеринарно-санітарна експертиза з основами технології і стандартизації продуктів тваринництва, т. 1 / Хоменко В.І. – К.: Фірма "ІНКОС", 2005. – 416 р.
61. Цициліано О. Креативність та стандартизація як основа конкурентоспроможності організації / Цициліано О // Стандартизація, сертифікація, якість, № 1 – К., 2007. – Р. 38
62. Шаповал М.І. Менеджмент якості / Шаповал М.І. – К.: Знання, 2003. – 415 р.
63. Melnychuk D.O., Pidlisnyuk V.V., Stefanivska T.R., Key questions about sustainable development: what everyone needs to know – К.: ТОВ "ЦНТ "Гопак", 2003. – 60 р.
64. Національна стандартизація. Основні положення. ДСТУ 1.0:2003. – К. Derzhspozhivstandart of Ukraine, 2003. – (National standard of Ukraine)
65. Національна стандартизація. Правила розроблення національних нормативних документів. ДСТУ 1.2:2003. – К. Derzhspozhivstandart of Ukraine, 2003. – (National standard of Ukraine)
66. Національна стандартизація. Правила і методи прийняття та застосування міжнародних і регіональних документів. ДСТУ 1.7:2001. – К.: Derzhspozhivstandart of Ukraine, 2002 (National standard of Ukraine)
67. Національна стандартизація. Правила розроблення та застосування міждержавних стандартів. ДСТУ 1.9:2008. – К. Derzhspozhivstandart of Ukraine, 2008. – (National standard of Ukraine)
68. Національний знак відповідності. Форма, розміри, технічні вимоги та правила застосування. ДСТУ 2296-93. – К.: Derzhstandart of Ukraine, 1993. – (National standard of Ukraine)

69. Сертифікація. Основні поняття. Терміни та визначення. ДСТУ 2462-94. – К.: Derzhstandart of Ukraine, 1994. – (National standard of Ukraine)
70. Метрологія. Терміни та визначення. ДСТУ 2681-94. – К.: Derzhstandart of Ukraine, 1994. – (National standard of Ukraine)
71. Система сертифікації УкрСЕПРО. Основні положення. ДСТУ 3410-2004 . – К.: Derzhspozhivstandart of Ukraine, 2004. – (National standard of Ukraine)
72. Система сертифікації УкрСЕПРО. Вимоги до випробувальних лабораторій та порядок їх акредитації. ДСТУ 3412-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
73. Система сертифікації УкрСЕПРО. Порядок проведення сертифікації продукції. ДСТУ 3413-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
74. Система сертифікації УкрСЕПРО. Атестація виробництва. Порядок здійснення. ДСТУ 3414-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
75. Система сертифікації УкрСЕПРО. Реєстр системи. ДСТУ 3415-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
76. Система сертифікації УкрСЕПРО. Порядок реєстрації об'єктів добровільної сертифікації. ДСТУ 3416-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
77. Система сертифікації УкрСЕПРО. Процедура визнання результатів сертифікації продукції, що імпортується. ДСТУ 3417-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
78. Система сертифікації УкрСЕПРО. Вимоги до аудиторів та порядок їх атестації. ДСТУ 3418-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
79. Система сертифікації УкрСЕПРО. Сертифікація систем якості. Порядок проведення. ДСТУ 3419-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)

80. Система сертифікації УкрСЕПРО. Бланки документів. Форма та опис. ДСТУ 3498-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
81. Система розроблення і поставлення продукції на виробництво. Продукція харчова. Основні положення. ДСТУ 3946-2000. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
82. Системи управління безпечністю харчових продуктів. Вимоги. ДСТУ 4161-2003. – К.: Derzhspozhivstandart of Ukraine, 2003. – (National standard of Ukraine)
83. Системи управління якістю. Основні положення та словник термінів. (ISO 9000:2004) ДСТУ ISO 9000:2007. – К.: Derzhspozhivstandart of Ukraine, 2007. – (National standard of Ukraine)
84. Системи управління якістю. Вимоги. (ISO 9001:2004) ДСТУ ISO 9001-2008. – К.: Derzhspozhivstandart of Ukraine, 2008. – (National standard of Ukraine)
85. Системи управління якістю. Настанови щодо поліпшення діяльності. (ISO 9004-1:2000.). ДСТУ ISO 9004-2001. – К.: Derzhstandart of Ukraine, 2001. – (National standard of Ukraine)
86. Управління якістю та елементи системи якості. Частина 2. Настанови щодо послуг. (ISO 9004-2:1994). ДСТУ ISO 9004-2-96. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
87. Управління якістю та елементи системи якості. Частина 3. Настанови щодо перероблюваних матеріалів. (ISO 9004-3:1994). ДСТУ ISO 9004-3-98. – К.: Derzhstandart of Ukraine, 1998. – (National standard of Ukraine)
88. Управління якістю та елементи системи якості. Частина 4. Настанови щодо поліпшення якості. (ISO 9004-4:1994). ДСТУ ISO 9004-4-98. – К.: Derzhstandart of Ukraine, 1998. – (National standard of Ukraine)
89. Системи управління якістю. Настанови щодо програм якості. (ISO 10005:2004). ДСТУ ISO 10005:2007. – К.:

Derzhspozhivstandart of Ukraine, 2007. – (National standard of Ukraine)

90. Системи керування вимірюванням. Вимоги до процесів вимірювання та вимірювального обладнання. (ISO 10012:2002). ДСТУ ISO 10012:2005. – К.: Derzhspozhivstandart of Ukraine, 2005. – (National standard of Ukraine)
91. Настанови з розроблення документації системи управління якістю. (ISO TR 10013:2002). ДСТУ ISO/TR 10013-2003. – К.: Derzhspozhivstandart of Ukraine, 2003. – (National standard of Ukraine)
92. Системи екологічного керування. Вимоги та настанови щодо застосування (ISO 14001:1994). ДСТУ ISO 14001-97. – К.: Derzhstandart of Ukraine, 1997. – (National standard of Ukraine)
93. Настанови щодо застосування ДСТУ ISO 9001-2001 у виробництві харчових продуктів та напоїв. (ISO 15161:2000). ДСТУ ISO 15161:2004. – К.: Derzhspozhivstandart of Ukraine, 1993. – (National standard of Ukraine)
94. Оцінювання відповідності. Словник термінів і загальні принципи. (ISO/IEC 17000:2004, IDT). ДСТУ ISO/IEC 17000:2007. – К.: Держспоживстандарт України, 2008. – (Національний стандарт України)
95. Оцінювання відповідності. Загальні вимоги до органів акредитації, що акредитують органи оцінювання відповідності. (ISO/IEC 17011:2001). ДСТУ ISO/IEC 17011:2005. – К.: Derzhspozhivstandart of Ukraine, 2005. – (National standard of Ukraine)
96. Загальні критерії щодо діяльності органів різного типу, що здійснюють діяльність з інспектування. (ISO/IEC TR 17020:1998). ДСТУ ISO/IEC TR 17020-2001. – К.: Derzhstandart of Ukraine, 2001. – (National standard of Ukraine)
97. Оцінювання відповідності. Вимоги до органів, які провадять аудит і сертифікацію систем управління (ISO/IEC 17021:2011) ДСТУ ISO/IEC 17021-1:2008. К.: Держспоживстандарт України, 2009. – (Національний стандарт України)

98. Загальні вимоги до компетентності випробувальних та калібрувальних лабораторій. (ISO/IEC 17025:2004). ДСТУ ISO/IEC 17025-2006. – К.: Derzhspozhivstandart of Ukraine, 2006. – (National standard of Ukraine)
99. Оцінювання відповідності. Загальні вимоги до знаку відповідності третьої сторони. (ISO/IEC 17030:2000). ДСТУ ISO/IEC 17030:2005. – К.: Derzhspozhivstandart of Ukraine, 2005. – (National standard of Ukraine)
100. Оцінювання відповідності. Декларація постачальника про відповідність. Частина 1. Загальні вимоги. (ISO/IEC 17050-1:2001). ДСТУ ISO/IEC 17050-1:2006. – К.: Derzhspozhivstandart of Ukraine, 2006. – (National standard of Ukraine)
101. Оцінювання відповідності. Декларація постачальника про відповідність. Частина 2. Підтверджувальна документація. (ISO/IEC 17050-2:2001). ДСТУ ISO/IEC 17050-2:2006. – К.: Derzhspozhivstandart of Ukraine, 2006. – (National standard of Ukraine)
102. Система управління безпекою та гігієною праці. Вимоги. (OHSAS 18001:2002). ДСТУ-П OHSAS 18001:2006. – К.: Derzhspozhivstandart of Ukraine, 2006. – (National standard of Ukraine)
103. Система управління безпекою праці. Основні принципи виконання вимог. (OHSAS 18002:2002) ДСТУ-П OHSAS 18002:2006. – К.: Derzhspozhivstandart of Ukraine, 2006. – (National standard of Ukraine)
104. Настанови щодо здійснення аудитів систем управління якістю і (або) екологічного управління. (ISO 19011:1998). ДСТУ ISO 19011:2003. – К.: Derzhspozhivstandart of Ukraine, 2003. – (National standard of Ukraine)
105. Системи управління безпечністю харчових продуктів. Вимоги до будь-яких організацій харчового ланцюга. (ISO 22000:2002). ДСТУ ISO 22000:2007. – К.: Derzhspozhivstandart of Ukraine, 2007. – (National standard of Ukraine)

106. Загальні вимоги до органів, які керують системами сертифікації продукції (EN . 45011:1998). ДСТУ EN 45011-2001. – К. Derzhstandart of Ukraine, 2007. – (National standard of Ukraine)
107. Настанова щодо розробки стандартів, придатних для оцінювання відповідності. (ISO/IEC Guide 7:1989). ДСТУ ISO/IEC Guide 7:1994. – К.: Derzhstandart of Ukraine, 1994. – (National standard of Ukraine)
108. Способи зазначення відповідності для систем сертифікації третьою стороною. (ISO/IEC Guide 23:1979). ДСТУ ISO/IEC Guide 23:1982. – К.: Derzhstandart of Ukraine, 1982. – (National standard of Ukraine)
109. Настанови щодо коригувальних дій, здійснюваних органом сертифікації у разі втрати знаку відповідності. (ISO/IEC Guide 27:1978). ДСТУ ISO/IEC Guide27:1983. – К.: Derzhstandart of Ukraine, 1983. – (National standard of Ukraine)
110. Оцінювання відповідності – Настанова щодо системи сертифікації продукції третьою стороною. (ISO/IEC Guide 28:2000). ДСТУ ISO/IEC Guide28:2004. – К.: Derzhspozhivstandart of Ukraine, 2004. – (National standard of Ukraine)
111. Тестування на професійність шляхом міжлабораторних порівнянь – Частина 1: Розроблення та дія схем випробування на професійність. (ISO/IEC Guide 43-1:1994). "ДСТУ ISO/IEC Guide43-1:1997. – К.: Derzhstandart of Ukraine, 1997. – (National standard of Ukraine)
112. Тестування на професійність шляхом міжлабораторних порівнянь – Частина 2: Вибір та використання схем тестування на професійність органами, що акредитують лабораторію. (ISO/IEC Guide 43-2:1994). ДСТУ ISO/IEC Guide43-2:1997. – К.: Derzhstandart of Ukraine, 1997. – (National standard of Ukraine)
113. Оцінювання відповідності – Настанова щодо використання систем управління якістю організації під час сертифікації продукції. (ISO/IEC Guide 53:2001). ДСТУ ISO/IEC Guide

53:2005. – К.: Derzhspozhivstandart of Ukraine, 2005. – (National standard of Ukraine)
114. Оцінювання відповідності – Кодекс доброчинної практики. (ISO/IEC Guide 60:1999). ДСТУ ISO/IEC Guide 60:2004. – К.: Derzhspozhivstandart of Ukraine, 2004. – (National standard of Ukraine)
115. Загальні вимоги до органів, які керують системами сертифікації продукції. (ISO/IEC Guide 65:1991). ДСТУ ISO/IEC Guide 65:1996. – К.: Derzhstandart of Ukraine, 1996. – (National standard of Ukraine)
116. Загальні вимоги до органів, які здійснюють оцінювання і сертифікацію/реєстрацію систем екологічного управління (ISO/IEC Guide 66:1999). ДСТУ ISO/IEC Guide 66:1996. – .: Derzhstandart of Ukraine, 2000. – (National standard of Ukraine)
117. Оцінювання відповідності – Основні принципи сертифікації продукції. (ISO/IEC Guide 67:2000). ДСТУ ISO/IEC Guide 67:2004. – К.: Derzhspozhivstandart of Ukraine, 2004. – (National standard of Ukraine)
118. Угоди про визнання і прийняття результатів оцінювання відповідності. (ISO/IEC Guide 68:1998). ДСТУ ISO/IEC Guide 68:2002. – К.: Derzhspozhivstandart of Ukraine, 2002. – (National standard of Ukraine)
119. Загальні вимоги до органів, які керують системами сертифікації продукції. (EN 45011:1998). ДСТУ EN 45011-2001. – К.: Derzhstandart of Ukraine, 2001. – (National standard of Ukraine)
120. Системи менеджменту якості. Керівництво по застосуванню ISO 9001 в органах місцевого самоврядування (IWA 4:2005) ДСТУ IWA 4:2009 . – К.: Derzhspozhivstandart of Ukraine, 2009. – (National standard of Ukraine)
121. Directive 92/43/EEC "On the conservation of natural habitats and of wild fauna and flora"
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123. Directive 98/34/EU "On procedure for the provision of information in the field of technical standards and regulations"

124. Directive 2001/18/EC "On the deliberate release into the environment of genetically modified organisms"
125. Directive 2001/95/EC "On general product safety"
126. Directive 2004/95/EC "On environmental liability with regard to prevention and remedying of environmental damage"
127. EU Directive 2008/1/EC concerning integrated pollution prevention and control
128. EU Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards
129. EU Council Resolution 834/2007 (EC) of 28 June 2001 on organic production and labeling of organic products and repealing of Regulation (EEC) N0 2092/91
130. Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products with regard to organic production, labeling and control
131. International vocabulary of metrology — Basic and general concepts and associated terms, ISBN 978-5-91259-057-3
132. Quality management and quality assurance – Vocabulary, Standard ISO 8402:1994. Geneva – International Standardization Organization, 1994. – (International standard)
133. Conformity assessment - General requirements for bodies operating certification of persons, Standard ISO/IEC 17024:2012. – Geneva – International Standardization Organization, 2012. – (International standard)
134. Conformity assessment — General requirements for proficiency testing. Standard ISO/IEC 17043:2010. – Geneva – International Standardization Organization, 2012. – (International standard)
135. General requirements for bodies operating product certification systems, Standard ISO/IEC 17065:2012, Geneva – International Standardization Organization, 2012. – (International standard)
136. Standardization and related activities — General vocabulary (ISO/IEC Guide 2:2004)

137. ISO/IEC Guide 2: Standardization and related activities — General vocabulary
138. ISO/IEC Guide 21-1:2005: Regional or national adoption of International Standards and other International Deliverables -- Part 1: Adoption of International Standards
139. Guidelines on assessment and reporting of compliance with specification (ILAC Guide 8:1996)
140. "The ISO Survey of Certification 2008" / ISO Central Secretariat, Geneva – 2008. – 71 p.

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