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Issue Article

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ON THE SPECIFICS OF FORMING A LIFE CYCLE TO ENSURE THE PRODUCTION OF PRIORITY PRODUCTS. MESSAGE 1

Abstract: *In message 1, the authors consider quality as a philosophical category, the genesis of the category of "quality" that determines various stages of its understanding, as well as the points of view of various philosophers on the definition of this category. The essence of such aspects of the category of "quality" as "social quality", "product quality", "service quality", "management quality" is revealed. The approaches of various researchers to the study of such multifaceted concepts as "need", "value", "satisfaction" are presented and the relationship between quality, needs and satisfaction of consumers is revealed. Quality covers all aspects of our life and is one of the main factors in the development of society. The origins of its study go back far to ancient times. In the works of Aristotle, the concept of "quality" acquired a categorical status and for many subsequent centuries determined the development of thought in this direction. Russian philosophers of the XIX-XX centuries also paid much attention to the problems of quality, emphasizing its value significance and systemic nature. Essential in this approach was the connection of quality with spirituality, development of personality, formation of the "new economic man", quantity, and the fate of Russia. This shows that the category of "quality" is a multifaceted concept and includes many aspects. Thus, "social quality" is of fundamental importance for the study of social processes and includes such components as the quality of society; quality of communities; quality of culture; mentality, spirituality, quality of man, way of life, quality of life, quality of economy.*

Key words: *competitiveness, demand, quality, accessibility, innovation, digital technology, economic policy, industrial policy, union of federal, regional and municipal branches of government; profitability, profit, financial sustainability, stability, purchasing power.*

Language: *English*

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Introduction

UDC 658.56:101.04.

Agreeing that today manufacturers do not produce what they can, but mainly what is especially profitable, because in the market, needs are not determined by buyers. In the markets, the seller rules in all persons and as the organizer - the owner of the market. And, of course, the owner of the market in turn knows very well about the importance of cooperation with the manufacturer for his well-being. Such a vicious circle provokes a situation in which the concept of "quality" has become a bargaining chip, dependent on the understanding and taste of the seller, who, unfortunately, does not have such criteria, he simply does not have them. In this regard, the status of "Priority of the product" is a litmus test for the consumer, if the manufacturer again turns to face him through an alliance with a designer, producing fancy products, that is, original, ultra-fashionable and modern, guaranteeing their priority and demand, and the seller - his role in the demand market should change significantly and he, and only he, should bear both material and legal responsibility for the non-sale of this very product, and the buyer needs to return his rightful status of "market deity". Marketing experts agree that consumers give their main preferences to product quality. Market monitoring confirms the stable traditions of demand for quality goods. But not everything is so simple and obvious. The essence of the matter is that statistics is a pure operator and statistical data, therefore, are absolutely dependent on the chosen conceptual description of the process. Statistical results are always correct, since they are obtained by using a proven mathematical apparatus, but correctness and truth are "two big differences". In order for the “correct” to be “true”, it is necessary to verify the entire chain of logical and mathematical actions for correctness. Certification is required not only for a material and software product. The premise knowledge must also be certified, otherwise the defects of the initial judgments will migrate to the inferred knowledge. And no technology will correct the inherent defect. In the ideology of production, especially the production of goods for direct consumption, the concept of “quality” must be a system-forming factor. We anticipate the objection: “What is the use of quality if the quality criteria limit the quantity and the range of goods will suffer from the priority of quality characteristics, the price will increase?”, and we have an answer to opponents. If the quality of the product is not ensured, then no quantity will improve the situation. It will be necessary either to agree with the obvious (for professionals) deception of the consumer, or to sacrifice professional competence and consciously lower the quality requirements, allowing a product of essentially low quality to enter the market. As for the range, its dependence on the quality requirements of the products is relatively conditional and indirect. The range is “tied” to the technical condition of production, technology and professionalism of developers. The more visible the features of a civilized market, the more relevant the issue of quality is. Moreover, the problem of quality has moved from the sphere of theoretical relevance to the level of practical relevance. Let's try to justify this shift in relation to the results of the domestic shoe industry. A shoe cluster may appear in Russia: market participants have begun to develop a concept for this project. It is proposed to include Dagestan, Rostov-on-Don and the Moscow region. The goal is to increase the share of domestic production to 30%. The Ministry of Industry and Trade is ready to support these initiatives - companies working in clusters will be able to receive significant benefits, the department clarified. Currently, the share of Russian products on the market is only 20%, taking into account government orders, market participants estimated.

Main part

ISO 9001 was developed by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC2, Quality systems. ISO 9001:2000 cancels and replaces the second edition (ISO 9001:1994), along with ISO 9002:1994 and ISO 9003:1994. It is a technical revision of these documents. Organizations that previously used ISO 9002-2015 and ISO 9003:2015 for system development and certification can use ISO 9001:2015 by excluding certain requirements in accordance with subclause 1.2 of the updated standard.

The establishment of a quality management system requires a strategic decision by the organization. The development and implementation of an organization's quality management system is influenced by changing needs, specific objectives, products, processes, and the size and structure of the organization. This International Standard does not imply uniformity in the structure of quality management systems or documentation.

The quality management system requirements specified in this International Standard are complementary to the product requirements. Information marked "NOTE" provides guidance on understanding or clarification of the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to evaluate an organization's ability to meet customer, regulatory and its own requirements.

When developing this international standard, the quality management principles established in ISO 9000 and ISO 9004 were taken into account.

The strategic decision of the organization on the development and implementation of the quality management system at the enterprise (in the organization) can be reflected in the administrative document (order, decision). As a rule, such an order contains:

- declaration of work on the commencement of a project for the development and implementation of a quality management system, and its completion dates;
- appointment of those responsible for the project as a whole and its provision;
- a plan for implementing project activities, indicating deadlines for implementation and those responsible for their implementation;
- the total amount of financial resources allocated for the project, as well as an estimate of expenses.

The needs and goals of the organization may include the following:

- the need to improve the organization's activities to increase competitive advantages;
- requirement for the presence of a certificate or an implemented quality management system of consumer or client enterprises;
- requirement for a certificate or quality management system from government agencies (for example, in higher education institutions), etc.

The development and implementation of a system at different enterprises (organizations) may differ greatly in the scope and scale of work performed, documentation created, and implementation timeframes. This depends not only on the needs and goals of the organization, but also on specific factors characteristic of the enterprise (organization): industry affiliation, complexity and number of processes, requirements for the quality of manufactured products, form of ownership, number of employees, level of complexity of the organizational structure, and existing corporate culture. According to the requirements of this standard, it can be used by internal and external parties. ISO 9000:2015 defines internal and external parties for using the standard (conducting an audit) to meet the requirements of ISO 9001:2015 as follows:

- audits (inspections) carried out by the first party (the organization itself) or on its behalf for internal purposes may serve as the basis for the organization's declaration of compliance;
- audits (inspections) conducted by the second party may be carried out by the organization's consumers or by other persons on behalf of the consumers;
- third party audits are carried out by external independent organisations. Such organisations, usually accredited, provide certification for compliance with requirements such as ISO 9001.

This International Standard promotes the application of a "process approach" to the development, implementation and improvement of the effectiveness of a quality management system in order to enhance customer satisfaction by meeting customer requirements.

To function successfully, an organization must define and manage numerous interrelated activities. An activity that uses resources and is managed to transform inputs into outputs can be considered a process. Often, the output of one process directly forms the input of the next. The use of a system of processes in an organization, along with their identification and interaction, and the management of processes can be considered a "process approach."

The advantage of the process approach is the continuity of management that it provides at the junction of individual processes within the system, as well as during their combination and interaction. When applied in a quality management system, this approach emphasizes the importance of, namely:

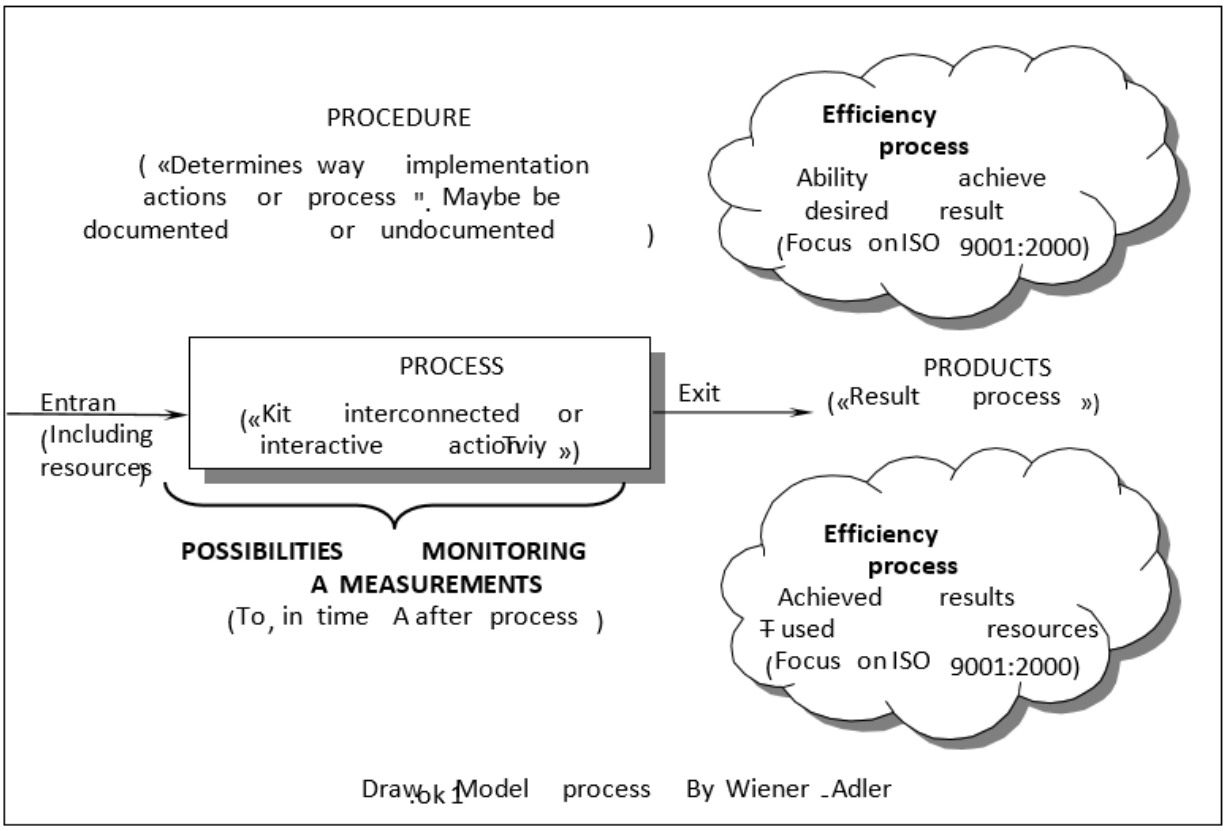
a) understanding and fulfilling the requirements;

b) the need and consideration of processes from the point of view of added value;

c) achieving results of process implementation and their effectiveness;

d) continuous improvement of processes based on objective measurement

The model of a quality management system based on the process approach shown in Figure 1 illustrates the links between the processes presented in Clauses 4–8. This model shows that customers play a significant role in determining input data. Monitoring customer satisfaction requires evaluating information on customer perceptions of the fulfillment of their requirements. The model shown in Figure 1 covers all the essential requirements of this International Standard without going into detail.



Picture 1.

In addition, the Plan-DoCheck-Act (PDCA) cycle can be applied to all processes. The PDCA cycle can be briefly described as follows:

Planning (Plan): Develop the objectives and processes needed to achieve results in accordance with customer requirements and organizational policies.

Do: Implement the processes.

Check: Fully monitor and measure processes and products against policies, objectives and product requirements and report the results.

Action (Act): Take action to continually improve process performance.

The international standard ISO 9001 version 2000 differs significantly from the previous version of 1994 by introducing the core basis of the quality management system concept of "process approach". For the first time, it is proposed to move away from the principles of managing an organization by functions and manage interrelated processes. This approach reflects the modern realities of doing business - customer orientation. During its existence, functional management has exhausted its reserves and has been replaced by a more progressive one - process management, which currently occupies a dominant position in the world. Using it, the organization is considered as a set of functional processes connected across the organization, which corresponds to the actual order of work. The development of policy and the choice of strategic direction of activity remains with the top management, but responsibility and authority in studying, critically analyzing and changing work methods are delegated between functional work teams (Figure 2).

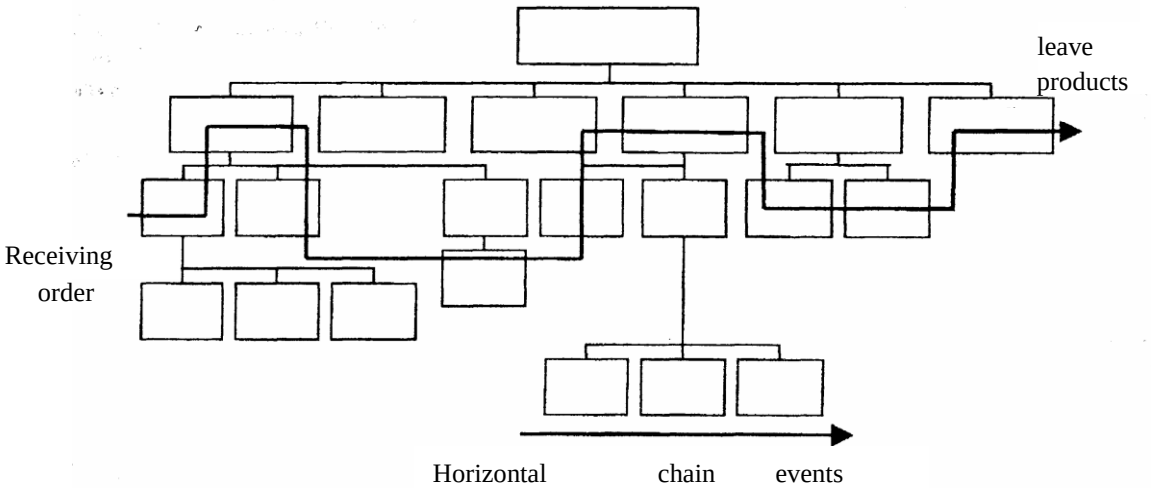


Figure 2. Modern management structure using business process management

The ISO 9001 standard defines the PDCA cycle, also known as the Shewhart-Deming continuous improvement cycle, as the basis for quality system management. The continuous process improvement cycle underlies the management of not only individual processes of the organization, but also the entire activity of the organization as a whole. The implementation of the process approach in the organization provides the following opportunities, namely:

1. The process approach allows us to optimize the corporate governance system, make it transparent for management and capable of flexibly responding to changes in the external environment.
2. The process approach allows us to obtain and use a system of indicators and criteria for assessing management effectiveness at each stage of the production/management chain.
3. The process approach provides confidence to the founders of the organization that the existing management system is aimed at continuously improving efficiency and taking into account the interests of stakeholders as much as possible.
4. The implementation of a process approach to management and the construction of a quality management system guarantees a clearly defined order and responsibility for the development, coordination, approval and maintenance of documentation.
5. The basis of the process approach to management is fact-based decision-making, so the presence of an information system in the organization is of great importance.

The present editions of ISO 9001 and ISO 9004 have been developed as a coordinated pair of quality management system standards to complement each other, but they can also be used independently. Although these International Standards have different scopes, they have a similar structure to enable them to be used as a coordinated pair. ISO 9001 specifies requirements for a quality management system that can be used for internal use by organizations, for certification or contractual purposes. It addresses the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 provides guidance on a broader range of quality management system objectives than ISO 9001, particularly on continual improvement of an organization's performance and its effectiveness and efficiency. ISO 9001 is recommended for organizations whose top management, in pursuing the objective of continual improvement, wishes to go beyond the requirements of ISO 9001. However, it is not intended for certification or contractual purposes.

This subsection of the Introduction of the international standard establishes the degree of importance of the harmonized standards of the ISO 9000 series and the difference between them. ISO 9001:2015 is intended for certification purposes, in other words, when creating and implementing a quality management system, an organization must be guided by and fully comply with its requirements. ISO 9004:2015 is a methodological standard, designed to improve activities in the development of a quality management system. On the other hand, ISO 9004 describes the content of all parts of the quality management system in more detail than ISO 9001. Therefore, it is recommended to use ISO 9004 already at the stage of creating and implementing a quality management system.

This International Standard is aligned with ISO 14001:2015 to improve compatibility between the two standards for the benefit of the user community.

This International Standard does not include specific requirements for other management systems, such as environmental management, occupational

health and safety management, financial management or risk management. However, it enables an organization to align or integrate its own quality management system with other management systems with corresponding requirements. It is possible for an organization to adapt its existing management system(s) to establish a quality management system that complies with the requirements of this International Standard.

The main provision of this paragraph of the standard speaks about the compatibility of the ISO 9000:2015 series standard with modern standards of special areas of activity. This standard is compatible not only with management systems such as: environmental protection management, occupational health and safety management, financial management, information management, risk management, but also serves as a basis for building such systems as the excellence model, balanced scorecard, universal performance indicator system and other models and awards in the field of quality.

Scope, normative references, terms and definitions.

Scope of application

The first section of the standard is devoted to establishing provisions for the application of the requirements of the standard.

The main goal of creating international standards of the ISO 9000 series was to help organizations build a quality management system to improve their competitiveness. Therefore, organizations can use the ISO 9001:2015 standard both for creating and implementing a quality management system and for its further certification. Currently, the ISO 9001:2015 certificate is a pass to the world of big business and gaining customer and partner loyalty not only abroad, but also in Russia. This international standard sets requirements for a quality management system in cases where the organization:

a) needs to demonstrate its ability to supply products that meet

consumer requirements and relevant mandatory requirements;

b) aims to increase customer satisfaction through the effective application of the system, including processes for its continual improvement and ensuring conformity with customer and mandatory requirements.

The requirements of this international standard are intended for all organizations regardless of the type, size and products supplied.

If any requirement(s) of this international standard cannot be applied due to the specific nature of the organization and its products, its (their) exclusion is permitted.

With exceptions made, claims of conformity to this International Standard are acceptable if these exceptions fall within the requirements of the relevant clause and do not affect the organization's ability or responsibility to provide products. It should be noted that this clause defines the boundaries of the scope of the QMS. The ISO 9001 Auditing Practice Group Guidelines of 24.11.2014 "Scope of ISO 9001:2015, scope of the quality management system and scope of registration/certification" explain the differences between three similar concepts:

1) scope of ISO 9001:2015;
2) area of distribution of the QMS;
3) scope of QMS certification.

The scope of ISO 9001:2015 is established in this clause of the standard.

The scope of the QMS is used to describe the processes, products and/or services, as well as the associated sites, departments, divisions, etc., to which the organization applies a formally documented QMS. In this case:

- the scope of the QMS should be described based on the nature of the organization's products and processes for their creation, the results of risk assessment, commercial considerations, as well as contractual, statutory and regulatory requirements;

− this list does not necessarily include all processes, types of products, production areas, departments, divisions or other types of divisions of the organization. The scope of QMS certification is the area of QMS distribution with an indication of all excluded requirements of the ISO 9001:2015 standard. For an unambiguous understanding of this term, the Guide additionally explains that the scope of certification should define:

- the range of manufactured products and/or services provided, covered by the QMS;

- production sites, departments, divisions and other types of subdivisions associated with this nomenclature;

- the main processes or activities (such as design, manufacturing, supply, after-sales service) related to the specified range of products and/or services;

- all requirements of the ISO 9001:2015 standard that were excluded due to the specifics of the certified activity.

The requirements of the ISO 9001:2015 standard apply to all organizations, regardless of their type, size and supplied products. This means that when creating a quality management system in a small enterprise, a large plant, a holding company in any industry, all the requirements of the standard must be met. However, not all the requirements of the standard can be implemented in the QMS of organizations that have certain specifics. Requirements that can be excluded are marked in the sections of the standard with the phrase "if appropriate". The content of this clause of the standard allows for exclusion of entire subsections of the standard, but only from the section "Product life cycle processes". This is done when the organization does not implement one or more product life cycle processes specified in the section:

- processes related to the consumer;

- design and development;
- purchases;
- production and maintenance.

However, any exceptions listed shall be made on condition that they do not affect the ability or responsibility of the organization to provide product that meets customer or applicable regulatory requirements. The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent standards and revisions of any of these publications are not applicable. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. For undated references, the most recent edition of the standard applies. Member bodies of ISO and IEC maintain inventories of currently valid International Standards. This clause indicates that the most current (current) standard shall be applied to the creation, implementation and certification of a quality management system. If this International Standard is revised, its provisions will not apply to the creation and implementation of a quality management system.

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. The following terms used in this edition of ISO 9001 to describe the supply chain have been modified to reflect the currently applicable vocabulary.

Supplier customer organization The term "organization" replaces the term "supplier" used in ISO 9001:2015 and refers to the entity to which this International Standard applies. In addition, the term "supplier" replaces the term "subcontractor". In the text of this International Standard, the term "product" may also mean "service".

Since the release of the ISO 9000 series of international standards, the ISO 9000:2000 standard "Quality management systems. Fundamentals and vocabulary" has been in effect. Currently, another version of this standard is in effect - ISO 9000:2015 "Quality management systems. Requirements for quality management systems". Explanations regarding the relationship between the terms "supplier" and "organization" are given for organizations implementing a quality management system according to the requirements of ISO 9000:2015. In the previous version of the standards, the term "supplier" was applied to the object to which the 1994 version of the standard was applied. Since the 2015 version of ISO is universal, all the requirements of the standards can be applied to both organizations that manufacture products and provide services. However, during an in-depth analysis of the ISO 9000:2015 series of international standards, the following was revealed:

1) there is no definition of the term “services (provision of services)”;

2) the definition of the term “product” is disclosed, which includes “services (rendering of services)”, but the explanations contained in Annex 2 of ISO 9000:2015 are ambiguous;

3) Based on the above explanation, only "face-to-face service (rendering of services)" can actually be attributed to "products". At the same time, "face-to-face service" initially has features that determine the specifics of applying the requirements of the ISO 9001:2015 standard to it. This contradicts the ideology of the standard, which provides for the possibility of universally replacing the term "products" in the text with the term "service (rendering of services)".

This means that in the current edition of the ISO 9001:2015 standard there is ambiguity in the application of the requirements of this standard to the activity of "servicing (provision of services)". The first main section of this international standard is devoted to the definition of general requirements for the quality management system.

The organization shall establish, document, implement, maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization must:

a) define the processes needed for the quality management system and their application throughout the organization;

b) determine the sequence and interaction of these processes;

c) determine the criteria and methods necessary to ensure the effectiveness of both

both in the implementation and in the management of these processes;

(d) ensure the availability of resources and information necessary to support these

processes and their monitoring;

d) monitor, measure and analyze these processes; and

e) take measures necessary to achieve planned results and continually improve these processes.

The organization shall manage these processes in accordance with the requirements of this International Standard,

If an organization decides to outsource any process that affects product conformity, it shall ensure that it has control over that process. Its control shall be defined in the quality management system.

Developers of a quality management system in an organization should first understand what improvement or increase in the effectiveness of the QMS is. ISO 9000:2005 provides the following definitions: effectiveness is the degree of implementation of planned work and achievement of planned results; quality management system is a management system that allows for the management and control of an organization with respect to quality.

Combining these terms, we can obtain the following: QMS effectiveness is the degree to which the organization has implemented the planned activities and achieved the planned results in implementing the quality policy and achieving the quality objectives. Thus, continuous improvement of effectiveness means periodic revision of the quality policy and objectives based on the results of the quality management system operation and the nonconformities identified in it, changes in consumer requirements and other mandatory requirements. Before submitting the quality management system for certification, the organization must:

- develop,
− document,
- implement,
- maintain in working order.

The quality management system of the organization must be fully described in documents. Then it is necessary to implement new activities of the organization based on the process approach and in accordance with the described documents. Maintaining the quality management system in working order means that the organization's activities are constantly carried out in accordance with the described documents, analyzed and improved on the basis of the obtained analysis data at all management levels.

The development of a quality management system begins with defining the processes required for it and applying them throughout the organization. The introduction and this section of this standard define the main groups of processes required for inclusion in the QMS processes. The main groups of QMS processes and an approximate list of them are given below.

1. Processes of management activities of the leadership.

- Determination of consumer requirements, legislative and mandatory requirements, bringing them to the attention of the organization.
- Development of quality policy and objectives.
- Planning quality goals for the organization’s divisions and checking their achievement.
- Planning the creation and development of the QMS.
- Distribution of responsibilities, powers, exchange of information.
- Analysis of the QMS by management.
- Evaluation of customer satisfaction.
- Documentation management.
- Records management.

2. Resource provision processes. - Personnel management.

- Financial management.
- Management of funds (buildings, structures, etc.).
- Management of equipment and tooling for processes.
- Energy resources management.
- Transport management and communications.
- Management of the production environment. Compliance with environmental and occupational safety requirements.
- Management of information support and computing technology.
- Product marketing.

3. Product life cycle processes.

- Planning of product life cycle processes.
- Determination of product requirements based on consumer requirements and other mandatory requirements.
- Product design.
- Design of production processes.
- Selection of suppliers, procurement.
- Production of products.
- Packaging, storage of products.
- Delivery of products.
- After-sales service and product disposal. - Management of monitoring and measuring devices.

4. Measurement, analysis and improvement processes.

- Planning, conducting and recording internal audits.
- Self-esteem.
- Monitoring and measuring processes.
- Monitoring and measurement of products.
- Management of nonconforming products.
- Analysis of data on processes, products, customer satisfaction, suppliers.
- Planning, implementation, recording and analysis of the results of corrective actions in order to improve the QMS.
- Planning, implementation, recording and analysis of the results of preventive actions in order to improve the QMS.
- Statistical methods of analysis, control and regulation of product quality. - Verification and validation of projects.
- Product testing.

Next, it is necessary to determine the sequence and interrelations between the processes. In essence, at this stage, a graphical process model of the organization's quality management system is built. It is best to begin building a process model with the product life cycle processes. This is an activity that exists in any organization, and it is quite easy to connect the life cycle processes into a single chain. It should be noted that building a chain of product life cycle processes and identifying processes facilitates the need to build the beginning of the chain from consumer requirements to the end - consumer satisfaction.

Next, auxiliary (supporting) processes, or so-called resource provision processes, are defined. Then, management and measurement, analysis and improvement processes are built into the model. The interaction of processes is determined not only by

arrows on the graphical model of processes, but also by the coordination of inputs and outputs. The coordination of processes can be clearly defined using a matrix diagram. An example of constructing such a diagram is shown in Figure 3.

Номер процесса		Вход процесса						
		1	2	3	4	5	6	7
Выход процесса	1		○	●		Δ		
	2						●	
	3					○		
	4			Δ				
	5				○			
	6			●		○		
	7		○				●	

Conventional designations of the degree of influence of processes in a process network:

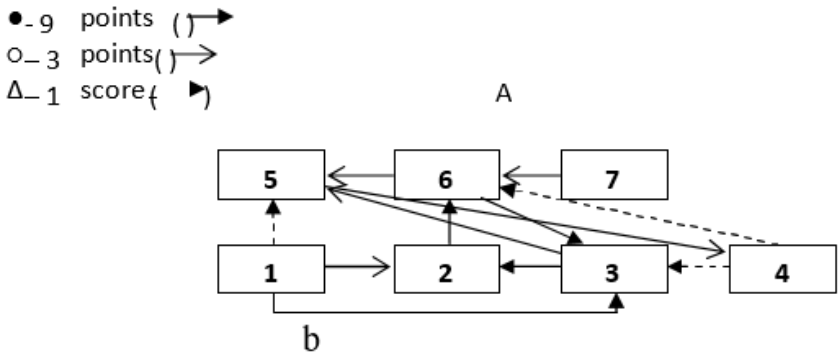


Figure 3. Method for determining the interaction of processes: a – matrix diagram of the interaction of processes; b – graphic diagram of the interaction of processes

The processes of the quality management system should not only function, but also ensure effectiveness, therefore the processes need to be measured. It is necessary to measure how well the processes fulfill the planned goals and programs. To measure them, the organization needs to define the indicators of the effectiveness of the processes and the methods for their measurement.

It is also necessary to determine the resources and information needed to support these processes. The resources should be defined quite clearly in relation to the process requirements: personnel of a certain qualification, premises, equipment necessary to achieve quality goals. According to the conditions of functioning of the process approach based on the PDCA cycle, it is necessary to regularly monitor, measure and analyze all QMS processes in order to improve the activity. Thus, after defining and determining the relationships between QMS processes, it is advisable to determine the following characteristics of each process:

- the full name of the process (it should be short and, if possible, expressed by a verbal noun; the name defines the boundaries of the process);
- process code (process identification number);
- definition of the process (formulation that reveals the essence, main content of the process);
- the purpose of the process (the necessary or desired result of the process);
- process owner (the person responsible for long-term planning, resource provision and process efficiency);
- process manager (the person responsible for the ongoing planning and management of the process in order to achieve the planned results);
- process standards (documentation containing the standard indicators in accordance with which the process is carried out);
- process inputs (material and information flows entering the process from outside and subject to transformation);

- process outputs (results of transformation that add value (cost), any process must have at least one output);

- resources (financial, technological, material, labor and informational, through which the transformation of inputs into outputs is carried out);

- supplier processes (internal or external suppliers – sources of inputs for the processes under consideration);

- consumer processes (processes of internal or external origin that are users of the results of the process under consideration);

- measured process parameters (its characteristics subject to measurement and control);

- process performance indicators (reflecting the degree to which the actual results of the process correspond to the planned ones);

- process efficiency indicators (reflecting the relationship between the achieved result and the resources used).

The order of execution of the process, i.e. the sequence of actions, is described on the basis of its graphical representation in the form of a flow chart or algorithm. The main steps of implementing the process approach in an organization are presented in Figure 5.3.

The requirement to implement process management in accordance with the requirements of this standard means that all subsequent sections of the standard describe in detail the requirements for all processes of the quality management system.

In recent years, organizations have increasingly resorted to transferring their processes to third-party organizations (outsourcing). If an organization implementing a quality management system transfers its processes to a third party, then the management of these processes should be defined in the relevant QMS documents, for example, in the Quality Manual. In turn, special relations in terms of the organization's management of such a process should be stipulated in the contract. In addition to this, based on the practice of conducting control, it can be stated that control is ensured when:

- the need for control and the procedure for its implementation are established in one way or another (the organization, determining how to ensure control, correlates them with the ultimate goal - preventing discrepancies, defects, and marriage);

- the results of control are recorded, analyzed and evaluated in one way or another, and based on the evaluation, decisions are made on compliance or corrective actions (if necessary).

What processes does your company have? What are the goals of this process, why is this process needed?

Where does the process begin and end, and how is it related to other processes?

Who is responsible for the process, who for a specific part of it?

How does the process proceed?

What tools and resources are required to implement it?

What are the stages of the process? Who does what, when, why and how?

What indicators are used to manage process and evaluate the result?

What control operations are built into the process so that it is predictable? ?

Where we see opportunities for improvement and how do we implement them?

Define your management processes, business processes and supporting processes

Define the purpose and purpose of each process

Define the scope. Establish relationships with other processes.

Identify process owners, involve relevant collaborators

Define responsibility and competence

Analyze the flow and content. Describe the chain of processes

Identify significant input quantities (materials, information)

Define the framework conditions. Describe the process.

Know your staff and train them Provide the means and resources to implement

Find out the information flows.

Determine adequate indicators (preferably fewer, but which are purposefully monitored)

Manage processes proactively.

Keep records. Use process monitoring as needed. Conduct process audits to assist when needed.

Analyze the causes of deviations. Identify improvement activities, monitor and evaluate their implementation. Optimize your processes regularly

Quality Management System. Requirements for Documentation

General provisions for documenting a quality management system are set out in ISO 9000:2005 and ISO/TR 10013. ISO 9000:2015 The Importance of Documentation. Documentation enables the conveying of the meaning and sequence of actions. Its use contributes to, namely:

a) achieving compliance with consumer requirements and improving quality;

b) ensuring appropriate training of personnel;

c) repeatability and traceability;

(d) ensuring objective evidence; and

d) evaluating the effectiveness and continuing suitability of the quality management system.

Documentation development should not be an end in itself, but should add value.

Documentation in the quality management system is created so that planned optimal and rational actions, combined into processes, are described and used by employees in order to perform homogeneous work in the same way, with predictable efficiency and effectiveness. Each employee has the necessary

documentation at his/her workplace, uses it in the process of performing work. It should be noted that the presence of documentation describing processes significantly reduces the adaptation period of new employees.

The QMS documentation consists of two large groups of documents – documents describing the system's activities, and records – documents that record data on the process and the fulfillment of established quality requirements. Documents describing the activities are initially developed taking into account the requirements of consumers and the quality requirements of both the system and the product.

Working according to developed documents describing the activity allows all employees to master the most optimal and rational methods of work, as well as to perform actions efficiently.

The availability of documents makes it easy to control the actions of employees, and the availability of records makes it possible to collect and store data on the progress of the processes being implemented, and compare results from previous periods. Among other things, important goals in revising the ISO 9000 series of standards were:

- develop a simplified set of standards that would equally meet the needs of all types and sizes of enterprises – small, medium and large, as well as service sector organizations;

- ensure that the volume and nature of the necessary documentation to a greater extent corresponds to the goals and results of the organization's work to improve its processes.

ISO 9001:2015 significantly relaxes the documentation requirements and is not as prescriptive as its previous version from 1994. This allows an organization to have more flexibility in choosing the way it can document its quality management system (QMS). Now, every organization can develop the minimum amount of documentation necessary to demonstrate the effectiveness of planning, control, management, implementation and continual improvement of its QMS. The systematization of the quality management system documentation is usually based either on the organization's processes or on the structure of the applied quality standard, or on a combination of both. Any systematization that meets the needs of the organization can also be used. The structure of the documentation used in the quality management system can be described as a hierarchy. Such a structure facilitates the distribution, maintenance and understanding of the documentation. The quality management system documentation can include definitions of terms. The vocabulary used should correspond to the standard terms and definitions that are mentioned in ISO 9000 or in commonly used dictionaries. The main purposes of the documentation that each organization maintains, regardless of whether it has implemented a documented QMS or not, are the following, namely:

- Transfer of information. As a means of transferring information, as well as a method of communication. The type of documentation and the degree of documentation of an organization depend on the nature of the products and services, the nature of the organization's processes, the degree of formalization of the communication system, the level of communication skills within the organization, as well as its organizational culture.

- Confirmation of compliance. As evidence that what was planned was actually accomplished.

- Knowledge dissemination. To properly disseminate and preserve the organization's experience. A typical example is a technical specification that can be used to develop and design new products. Also, orders, instructions, and protocols containing materials on identified problems and proposed solutions can be used as accumulation of the organization's experience.

Requirements for documentation: General provisions. The documentation of the quality management system should include, namely:

a) documented statements of quality policy and objectives;

b) quality manual;

c) documented procedures required by this International Standard;

d) documents necessary for the organization to ensure effective planning, implementation of processes and their management;

e) records required by this International Standard.

The degree of documentation of a quality management system may differ from one organization to another depending on:

a) the size of the organization and type of activity;

b) complexity and interaction of processes;

c) staff competencies.

Documentation may be in any form and on any medium.

ISO/TS 10013 expands the proposed list. Quality management system documentation typically includes:

- quality policy and its objectives;
- quality manual;
- documented procedures;
- work instructions;
- forms;
- quality plans;
- specifications;
- external documentation;
- records.

A quality manual is a document that provides agreed information about an organization's quality management system for both internal and external use.

Documented procedures, work instructions – documents containing information on how to consistently perform actions and processes.

Quality plans are documents that describe how the quality management system is applied to a specific product, project or contract.

Forms are various documents that regulate a uniform approach to design and content in specific types of activities.

Specifications are documents that set out requirements.

External documentation – regulatory, administrative, methodological and other documents received by the organization from outside.

Records are a large group of different types of documents containing achieved results or evidence of activities carried out.

Provides guidance to users of ISO 9001:2015 on understanding the intent and purpose of the general documentation requirements of this standard. Documented quality policy statements.

The requirements for the quality policy are defined in Article 5.3 of ISO 9001:2015. The quality policy must be documented in accordance with the requirements of Article 4.2.3. Some organizations considering the quality policy for the first time in order to meet the requirements of ISO 9001:2015 should pay special attention to Article 4.2.3 (c, d, g). These requirements mean that the quality policy and objectives must ensure the identification of changes and revision status (documents must necessarily contain the date and approval stamp of the document), distribution of the document to all structural divisions of the organization and timely withdrawal of the outdated quality policy and replacement of these documents with updated ones.

The requirements for quality objectives are defined in Clause 5.4.1 of ISO 9001:2000. These documented quality objectives shall also meet the requirements for document control in Clause 4.2.3. Quality manual.

Article 4.2.2 of ISO 9001:2015 defines the minimum requirements for the content of a quality manual. Each organization decides on the format and structure of a quality manual independently, depending on its size, level of culture and complexity. Some organizations may use a quality manual for other purposes, and not only for documenting the QMS. Recommendations for the structure and content of a quality manual are defined in ISO/TR 10013.

− Small organizations may choose to combine the description of the entire QMS into one manual, including all documented procedures required by the standard.

- Large multinational organizations may have multiple global, national and regional guidelines and more complex documentation.

- The quality manual is a document that must be managed in accordance with the requirements of Article 4.2.3.

Documented procedures.

− ISO 9001:2015 specifically requires an organization to have documented procedures for the following six activities:

4.2.3. Document management;

4.2.4. Records management;

8.2.2. Internal audit;

8.3. Control of nonconforming products;

8.5.2. Corrective actions; 8.5.3. Preventive actions.

- These documented procedures shall be managed in accordance with the requirements of Article 4.2.3.

− Some organizations may, for convenience, combine procedures for several activities into a single documented procedure (e.g., corrective and preventive actions, since the two procedures contain most of the same steps). Others may document an activity using more than one documented procedure (e.g., internal audits). Either is acceptable.

− Some organizations (especially larger organizations or those with more complex processes) may require additional documented procedures (especially those related to product creation processes) to implement an effective QMS.

− Other organizations may also require additional procedures, although the size and/or culture of the organization allows for the implementation of such procedures without mandatory documentation. However, in order to demonstrate compliance with the requirements of ISO 9001:2015, such an organization must provide objective evidence that the QMS has been effectively implemented.

Documents required by an organization to ensure effective planning, control and management of processes.

− In order to demonstrate effective implementation of the QMS, an organization may need to develop not only documented procedures, but also other documents. However, the ISO 9001:2015 standard specifically mentions only the quality policy (Article 4.2.1 a), quality objectives (Article 4.2.1 a), and quality manual (4.2.1 b).

− There are several requirements of ISO 9001:2015 that an organization could use to add value to its QMS and demonstrate compliance with the standard by developing other documents, even if the standard does not specifically provide for them. Examples include:

process diagrams and/or descriptions; organizational structure; specifications; work and/or test instructions; documents containing internal communication diagrams; production schedules; lists of approved suppliers; test and inspection plans; quality plans.

− Management of all listed documents must be carried out in accordance with the requirements of Art. 4.2.3 and/or 4.2.4.

Recordings.

− Examples of records required by ISO 9001:2015 are presented in Table 1.

− Organizations may develop other records that may be necessary to demonstrate conformity of their processes, products and QMS.

- Records management requirements differ from other document management requirements. All records must be managed in accordance with the requirements of ISO 9001:2000.

The extent of documentation of a quality management system may vary from one organization to another, due to - the size of the organization and the type of activity; - the complexity of processes and their interaction, as well as - the competence of the personnel.

Table 1 Records required by ISO 9001:2015.

Article Required Entry.

5.6.1 Management Review.

6.2.2.d Education, training, skills and experience.

7.1g Evidence that product creation processes and manufactured products comply with requirements.

7.2.2 Results of the analysis of requirements related to the product and actions resulting from the analysis.

7.3.2 Developing input data for design and development.

7.3.4 Results of design and development analysis and any necessary actions.

7.3.5 Results of design and development verification and any necessary actions.

7.3.6 Results of design and development validation and any necessary actions.

7.3.7 Project and development change management results and any necessary actions.

7.4.1 The results of the supplier assessment and any necessary actions arising from the assessment.

7.5.2 g In accordance with the organization's requirements for validation (confirmation) of conformity of those processes whose results cannot be verified through consistent monitoring or measurement.

7.5.3 Identification of products for which traceability is a requirement.

7.5.4 Consumer property that has been lost, damaged or otherwise rendered unusable.

7.6a Basic data used for calibration and verification of measuring equipment for which there are no international or national measurement standards.

7.6 Validation (confirmation) of previous measurement results in case of non-compliance of measuring equipment with the necessary requirements.

7.6 Results of calibration and verification of measuring equipment.

8.2.2 Internal audit findings and follow-up actions.

8.2.4 Certificate of persons who authorized the release of products.

8.3 The nature of the product nonconformity and any actions taken, including concessions received.

8.5.2 Results of corrective actions.

8.5.3 Results of preventive actions.

All QMS documents shall be controlled in accordance with the requirements of clause 4.2.3 of ISO 9001:2015 or, in the case of special records, clause 4.2.4.

Each organization determines the volume of documentation required and its carriers. This depends on factors such as: the type and size of the organization; the complexity and interaction of processes; the complexity of the product; customer requirements; relevant mandatory requirements; demonstrated; personnel capabilities; and the depth to which it is necessary to confirm the fulfillment of the quality management system requirements.

The definition in Article 3.7.2 of ISO 9000:2015 gives the following examples:

- paper medium;

- magnetic media;

- electronic or optical computer disk; - photograph; - reference sample.

The advantages of documents on electronic media include the following:

- the relevant personnel always have access to the latest information;

- access and changes are easy to implement and control;

- distribution is immediate and controlled using the hard copy printing option;

- there is the possibility of remote access to documentation; - deletion of obsolete documentation is simple and effective.

4.2.2. Quality Manual

The organization shall develop and maintain a quality manual that includes:

a) the scope of the quality management system, including details and justification for any exclusions;

b) documented procedures developed for the quality management system,

or links to them;

c) description of the interaction of quality management system processes.

The purpose of the Quality Manual is to help the success of an enterprise (department, workshop, laboratory) by concentrating recommendations and descriptions of measures to optimize all its activities. This is a conceptual document, creative adherence to which should significantly increase the effectiveness

of the quality management system (QMS) operating at the enterprise.

The main idea of the Quality Manual is that the enterprise must create a documentary basis for optimizing the enterprise's activities, systematizing the planning, coordination and control of organizational and production processes, constantly adapting to rapidly changing external conditions, maintaining and strengthening its image in the occupied market sector.

The structure and content of the Quality Manual should make it as easy as possible to conduct internal and external quality audits by providing references to sections of regulatory documents and, first and foremost, the international standard ISO 9001. Therefore, most often, sections of ISO 9001 are repeated in the Quality Manual.

The Quality Manual can be understood and formed in different ways. Depending on the documentation procedure adopted at the enterprise (organization), it can be:

1) a single document submitted in electronic or paper form (preferably in both, as required by standards);

2) a set of documented procedures and guidelines, united by a single purpose, covering all elements of the ISO 9001:20 standard15.

The volume of the Quality Manual, which has the form of a single document, should be as small as possible. Experience shows that documents whose volume exceeds 40-50 pages often do not meet their purpose, are overloaded with quotations from regulatory documents, which would be sufficient to refer to. And, as practice shows, they contain too many repetitions. The Quality Manual should be developed based on the following characteristics:

- the effectiveness of the sections and formulations included in it,
- the effectiveness of the procedures and processes described in it,
- ease of perception of its text,
- limited in volume to what is actually necessary.

The content of the Quality Manual should provide an idea of the structure of the enterprise and the organization of its production, based on the principle of managing the sequence of operations. It should present the processes, but not describe in too much detail the distribution of responsibility, as well as the production and technological steps. If their description is contained in job descriptions or process charts, references to them are sufficient. Most often, the Quality Manual contains references to the regulatory documents of the system. The main thing is that the sections of the Quality Manual should provide references to the regulatory documents in which the requirements of ISO 9001 are implemented. The order of fulfilling the requirements can be reflected both in individual documents and in the Quality Manual itself.

The Quality Manual is a strategic document of a lower level in relation to the quality management strategy, but more detailed. The Quality Manual should present the strategy of relations with the external environment (current and potential consumers, suppliers, regulatory, administrative and public bodies), the internal organization of the enterprise and its operational activities, comparing it with all the elements of ISO 9001:2015. It is in this form that it will be able to fulfill its other purpose: to familiarize external auditors representing the interests of customers and end users, and auditors of certification bodies and companies with the quality system. Let us recall once again that the ISO 9001:2015 standard contains three dominants:

1) consumer (customer) orientation;

2) focus on process management:

3) assessment (self-assessment) of the enterprise's quality level.

The Quality Manual has a conceptual meaning. Some authorities believe that only about 15% of product quality nonconformities arise directly during production activities, while the rest appear due to shortcomings in administrative, i.e. managerial activities. In order for the Quality Manual to meet this purpose and comply with the ISO 9001:2015 standard, it must reflect the following points, namely:

1. Strategic and tactical goals and means of achieving them.
2. Methods of supporting and improving organizational and production processes, identifying and eliminating unproductive processes, i.e. those that interfere with production or unreasonably increase its cost.
3. Measures to stimulate continuous improvement of qualifications and professionalism of employees.
4. A strategy for achieving the required level of quality of products, services and processes, maintaining and further improving it, protecting the safety and health of employees and end consumers.
5. Criteria for assessing the adequacy of the performance of work, processes and activities of the enterprise as a whole to the requirements imposed.
6. A set of measures to ensure that all employees understand their role in achieving the specified quality.
7. Distribution of powers and responsibilities of enterprise employees.
8. Key conditions of quality management:

- a statement of the basic principles of the enterprise's activities;
- documentary acts and rules for performing work; - structure and content (model) of the quality system;
- regulatory framework for quality management.

What sections should a Quality Manual contain, whether it is a single or composite document? If we follow ISO 9001:2015, the elemental basis of which is

close to the TQM model, then the main part of the Quality Manual should be combined into five blocks:

- quality (management) system;
- responsibility of the Management;
- resource management;
- product life cycle processes;
- measurements, analysis and improvements.

4.2.3. Documentation management

The documents required by the quality management system must be controlled. Records are a special type of document and must be controlled according to the requirements given in 4.2.4.

To determine the necessary controls, a documented procedure shall be developed that provides for:

a) checking documents for adequacy before their release:

b) analysis and updating as necessary and re-approval of documents;

c) ensuring identification of changes and revision status of documents;

d) ensuring the availability of relevant versions of documents at the points of their application;

d) ensuring that documents are kept clear and easily identifiable;

e) ensuring the identification of documents of external origin and managing their distribution;

g) preventing the unintended use of obsolete documents and applying appropriate identification of such documents retained for any purpose.

Before commenting on this section of the standard, the content of the definitions used in it should be provided.

Adequacy – compliance with the requirements of ISO 9000 series standards.

Identifiability – each sheet of documentation must be clearly assigned to a specific document.

Up-to-dateness – all changes must be reflected in each document in a timely manner.

According to the definition of adequacy, this means that the documents must comply with the requirements of ISO 9001:2015. The basis for the development and revision of QMS documents are the conclusions of officials when changing policies and goals, reengineering QMS processes, analyzing QMS records, as well as proposals for improving documentation and identified inconsistencies.

In addition, when developing and revising documents, the following are taken into account:

- decisions on the release of new types of products; - customer requirements (records, oral statements, etc.).

All this means that before any quality management system document is agreed upon and approved, it must be checked for compliance with the requirements of ISO 9001:2015.

Analysis, updating and re-approval of documents are performed:

- when changing the strategy, policies and goals of the organization;
- when releasing new types of products;
- during process reengineering and changes to the product life cycle model; - when non-conformities are detected by process owners or during internal (external) audit.

Updating and making changes are carried out on the instructions of senior management and in agreement with the quality representative.

When changes are made to a document by the quality representative or another person authorized to make changes, a record of the version change is made in the document revision table. In this case, the revision table indicates the reason for making the changes and their brief content, and the document is assigned a different version number in the order of succession.

Ensuring document identification is expressed in the presence of certain mandatory requisites on documents. Such as:

- name of the organization,
- name of the document type,
- document code,
- the document's relation to a specific section of the ISO 901:2000 standard,
- developers who agreed and approved the document,
- date of document approval,
- document version number (confirms the revision status of the document),
- numbering of all pages of the document and the content of the main details on each page of the document.

This list pertains to QMS documentation (quality manual, documented procedures, documents describing processes, regulations on structural divisions, job descriptions, work instructions). Records contain details in accordance with the design of a specific type of document to which the records pertain. For ease of use, both records and QMS documentation are generally assigned unique identification codes of the document or document form (for records).

The availability of versions of the document at the places of their application is ensured by:

- corporate information system;
- printed versions of documents in the required quantity;
- sending documents to remote departments using MS Outlook, etc.

Ensuring the availability of documents at the places of their use is confirmed in the distribution list of each QMS document. The distribution list must contain a list of structural divisions to which the document must be sent, each copy of the document must be assigned a unique number corresponding to the serial number in the document distribution list, receipt of the document must be confirmed by the

signature of the division representative in the distribution list of the original document.

Responsibility for the availability of current versions of documents at workplaces rests with the heads of departments. The availability of versions of documents at workplaces is monitored by the quality representative.

External documents are updated continuously - according to contracts, subscriptions, etc., and periodically - according to one-time requests from process owners throughout the year.

The responsible executor shall execute the applications on the organization's letterhead or in the form adopted by the organization distributing (selling) the documents. At the same time, the employee shall register the application in the Table of control over the execution of applications for external documents. The formation of orders for the acquisition of documents shall be carried out on the basis of the submitted applications.

Received external documents are sorted and identified, registered in the external document control log, and then distributed among applicants in accordance with their requests.

The relevance of external documents is monitored by the quality representative.

The "Document Management" procedure must provide a mechanism for removing cancelled documents from their places of use. If there is a need to leave old versions of documents at workstations, then a storage location for the cancelled document must be determined, different from the storage location of the current document of the same name. Also, the cancelled document must be marked with some inscription informing about this, for example, "cancelled, cancellation date".

4.2.4. Records Management

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. They shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls required for the identification, storage, protection, retrieval, retention period and disposition of records.

A documented procedure establishes the order of records management in the quality management system. The procedure is performed by process owners, department heads and project managers during the production of products and the management of QMS processes.

The procedure can be performed using a corporate information system and an automated document management system.

Identification of records is the assignment of a specific code to each record form, which may contain: the name of the document type, the relationship of the document form to a specific document of the quality management system and/or the relationship to the section of the Quality Manual, as well as the serial number in the registration log.

Records in the quality management system shall be stored in the relevant departments in identified files. Clause 4.2.4 of ISO 9001:2015 contains requirements for the retrieval of records, so electronic (or paper) copies of records must be retained. Catalogue structures are developed to store records in electronic form that confirm the execution of processes.

When using an automated document management system, protection of records from unauthorized access and changes is ensured by:

- personal password of employees for access to the CIS;

− restrictions at the system level by means of Windows NT/2000;

− a password for opening the file in MS Word. The safety of records is ensured by:

− regular copying;

- protection from physical damage;

- antivirus protection.

Ensuring the recovery of records in case of emergency and force majeure situations occurs due to their multiple backup storage and execution of the backup procedure. In addition, it is necessary to restrict access by unauthorized persons to servers, hubs, switches, network cables and other equipment, use means of protection against power failures (uninterruptible power supplies and network filters) on each server.

The records management procedure includes the determination of:

- the process of creating a recording form;

- rules and procedures for filling out the form, including the procedure for dating entries and their identification (formalization of the entry by entering details specific to this entry);

- responsible persons;

- the procedure for coordinating and approving the record (if necessary); - the period and place of storage of the record;

- protection against changes that violate the authenticity of the recording;

- the procedure for obtaining information from the record;

- a list of officials who have access to it;

- the procedure for restoring the recording; - the procedure for disposing of the recording or transferring it to an archive.

The procedure must reflect:

- who develops the recording forms;

- a list of required groups of records according to sections of the ISO 9001:2000 standard;

- a list of specific types (groups) of records of a specific organization;

- those responsible for the records management process;

- who establishes the forms of records, the procedure for filling them out and responsibility for filling them out;

- an algorithm for managing records and assigning specific officials to perform certain actions in each specific organization.

5.5. Management Responsibility

In the family of international standards ISO 9000:2000, more significant attention is paid to the responsibility of management. Leadership of the manager is highlighted as one of the fundamental principles of the quality management system in the standard ISO 9000:2015. ISO 9001:2015 contains a separate section devoted to the responsibility of management and, in addition, the responsibility of management is detailed and specified in other sections of the standard and is allocated to separate processes in the process model of the QMS.

The responsibility of the head of the organization, according to ISO 9001:2000, includes:

- making a decision on the development and implementation of the QMS, planning its creation and development (introduction 0.1);

- continuous improvement of the QMS activities (clause 5.1);

- formulation of the Policy and objectives in the field of quality, communicating them to the organization's personnel (clause 5.3);

- orientation of personnel to the importance of identifying and fulfilling consumer requirements (clause 5.2);

- communicating to the organization's personnel their responsibilities and powers in the area of quality, as well as the responsibilities of management (clause 5 1);

- analysis of the created QMS, assessment of the possibilities for changes and improvement of the organization's activities (clause 5.6);

- ranking of the general goal in the area of quality at the appropriate levels of management of the organization and by departments (development of a tree of goals) (clause 5.4);

- appointment of a representative from the management team with the assignment of responsibilities for the development and operation of the QMS, submission of a report on the results of the work

QMS and the need to improve the organization's activities (clause 5.5);

- creation of an internal information system that ensures the functioning of the QMS (clause 5.5).

In other words, "managers must ensure unity of purpose and direction for the organization; they should create and maintain an internal environment in which employees can be fully involved in achieving the organization's goals – primarily, advancing toward business excellence."

It should be noted that the ISO 9000:2005 standard does not contain a definition of the term "responsibility", therefore the concept of this term is discussed in the specialized press and one of the articles attempted to define this term: "Responsibility means that the person who performed the "action", i.e. the "actor", assumes the responsibility to answer the question "Who did it?"

In this definition, the term "responsibility" is understood as the need to answer for one's actions and deeds. However, at present, this term is interpreted in different ways:

- responsibility as a synonym for duties;

- responsibility as the need to answer for one's actions and deeds;

- responsibility as a punishment for failure to fulfill one's obligations;

- responsibility as awareness of the importance of one's activities, the ability to voluntarily take on some obligations.

As can be seen from the above interpretations, all of them, to one degree or another, reflect the meaning of the term "responsibility". The task of the developers of the new version of the ISO 9000 series is to provide, if possible, a more precise definition of this term.

5. Management responsibility. 5.1. Management commitment. Top management shall provide evidence of commitment to the development and implementation of the quality management system and to continually improve its effectiveness, as follows:

a) communicating to the organization the importance of meeting customer requirements, as well as statutory and mandatory requirements;

b) development of quality policy;

c) ensuring the development of quality objectives;

d) conducting an analysis by management;

d) provision of necessary resources.

As stated in the introduction to the standard, "creating a quality management system requires a strategic decision by the organization", which is expressed in issuing an order to begin work on creating and implementing the QMS. The organization's management must realize that such a decision will entail serious changes in the organization and a fairly large-scale implementation of additional work on the project. Therefore, when making such a decision, the organization's management must take into account not only the requirements of consumers, but also the specifics of the organization's corporate culture, its internal capabilities and needs.

The QMS cannot be borrowed from another organization or built according to a template offered by consultants. It must develop on the basis of the existing structure and management system in the organization, its specific features (industry, regional) and the level of personnel readiness for change.

Before making a decision to create and implement a QMS, the organization's management

should thoroughly study the possibilities of both the process approach and the prospects for creating a quality management system in accordance with the requirements of ISO 9001:2015.

The top management, in accordance with the requirements of the standard, should bring to the attention of the organization's personnel the importance of meeting customer requirements and other mandatory requirements for the products they manufacture. This is a fairly large-scale work, which, of course, is not carried out by the top management personally. Fulfillment of customer requirements in the quality management system should be carried out at all stages of the product life cycle. This does not mean that each employee of the organization should be aware of all the requirements that consumers make. It means that customer requirements should be formulated in a certain way for the output data of each process, starting from product sales and ending with marketing (pull process) according to the "internal supplier - internal consumer" system. The requirements formulated for each process in turn determine the actions that must be performed, the requirements for the resources that provide each process, the distribution of responsibilities and authorities, in other words, a large-scale revision of the management documentation is required. The final result of the distribution and authority should be the organizational structure of the QMS, which, according to the definition, is "the distribution of responsibilities, authorities and relationships between employees."

Requirements for the need to ensure the development of a quality policy, the development of quality objectives, management review and the provision of necessary resources are discussed below.

To meet the requirements of management responsibility, a Quality Council may be created in the organization, which is the highest coordinating and advisory body under the top manager. The Quality Council may include heads of structural divisions, representatives of the Quality Service, specialists, and representatives of external organizations. The Quality Council:

- develops forecasts, policies and strategic goals relevant to the organization;
- communicates to personnel the organization's areas of activity, values related to the quality of processes and products and the quality management system;
- plans and implements projects to improve the QMS, develop new areas of activity;
- defines the product life cycle processes that add value to the organization, as well as supporting processes that affect the effectiveness and efficiency of the life cycle processes;
- creates an environment that promotes the involvement and development of the organization's employees and the receipt of feedback directly on the effectiveness and efficiency of the quality management system;
- provides the organizational structure and resources necessary to support strategic plans and achieve the planned goals of the organization.

5.2. Consumer focus

Top management shall ensure that customer requirements are determined and met to enhance customer satisfaction.

The ISO 9000 series of standards places a central place on defining customer requirements and meeting them to improve their satisfaction. This principle reflects the modern realities of doing business and changes the purpose of manufacturing products. It should be noted that at present, an organization should focus not only on customer requirements, but also on the requirements of interested parties. It should also be noted that not only the current needs of consumers and interested parties should be implemented by the organization in its products, but also take into account their future needs and strive to exceed their expectations.

A possible list of consumers and interested parties is offered by the ISO 9004:2015 standard. According to the authors of the standard, the organization's interested parties include:

- consumers and end users;
- employees of the organization;
- owners/investors (such as shareholders, individuals or groups, including the public sector, with a specific interest in the organisation);
- suppliers and partners;
- society in the form of various associations and government structures that are influenced by the organization or its products.

Each specific organization should identify its customer and interested party groups from the list provided in ISO 9004:2000.

Next, it is necessary to determine the requirements of each of the identified groups of consumers and stakeholders. Defining these requirements will help identify their current needs. Consumer requirements should be identified as a list of characteristics for a product or service. To make it easier for consumers to choose, the organization should independently determine this list and offer consumers to evaluate it. In this case, it is necessary to take into account the following:

− the list includes precisely those characteristics that are most important for the consumer and influence his satisfaction;

- it is necessary to determine the content and level of detail of the characteristics of a product or service, which is necessary for development and planning.

To determine the future needs of the organization, it is necessary to conduct large-scale marketing research of the market: to determine and evaluate the competitive situation in the market, to

determine the market opportunities and features of the competitive struggle, forecasts of the development of society, the development of the economic and political situation, trends in the development of products or services. Such research will help the organization to identify future needs.

At the next stage, it is necessary to establish by what indicators the consumer will evaluate the degree of his satisfaction with the established characteristics of the product or service.

The established characteristics of the product or service are used by the organization as input data for the development stage. Also, a mechanism for assessing customer satisfaction must be developed and applied in the quality management system.

5.3. Quality Policy

Top management shall ensure that the quality policy: a) is consistent with the objectives of the organization;

b) included a commitment to meet requirements and continually improve performance

effectiveness of the quality management system;

c) created a basis for setting and analyzing quality goals;

d) was communicated to the organization's personnel and was understood by them;

d) analyzed for continued suitability.

The quality policy contains the main directions of the organization's development. Further, in paragraph 5.4 it is established that the quality policy and objectives must be consistent with each other. In essence, the quality policy demonstrates how, in what way, the organization will achieve the established quality objectives. It should be noted that the organization should very carefully analyze both its internal capabilities and the situation developing in the product market and the forecast estimates made. Therefore, most often, on the basis of a large-scale analysis, the organization's mission is drawn up and, in accordance with it, the objectives and quality policy are determined.

An organization's quality policy is usually a short, concise document that enables customers, suppliers, other interested parties, and the organization's staff to form their own understanding of the top management's attitude toward quality, to understand what obligations it undertakes to ensure the quality of manufactured products, and what principles and beliefs it adheres to.

The first requirement for the content of the policy is compliance with the organization's goals. Therefore, after a thorough analysis of the internal and external environment of the organization, determining forecasts for the possible development of its activities based on the identified current performance indicators, quality goals are first established and defined, and then the quality policy is developed. This requirement means that for all established quality goals, the directions for their provision in the quality policy must be determined. In fact, the formulated directions in the policy are obligations assumed by the top management of the organization. The standard actually requires that all declared intentions be translated into goals set for the relevant officials and departments at the relevant management levels.

The second requirement is the commitment to meet the requirements and continually improve the effectiveness of the quality management system. Therefore, the organization must necessarily reflect in the quality policy the extent to which it meets this requirement.

The third requirement is to create a basis for setting and analyzing quality objectives. This requirement can be reflected in the policy both explicitly and implicitly. It is possible to reflect in the policy that the organization will, for example, annually analyze and adjust quality. However, given that the quality policy is a long-term document, quality objectives may not be specified in numerical form. Then it is possible to measure the numerical indicators of the objectives annually and confirm the effectiveness of the quality management system through the improvement of these indicators.

The next requirement is the requirement to communicate the policy to the organization's personnel and to make it understandable to them. It is usually not difficult to fulfill this requirement. In the practice of Russian enterprises and organizations, it is already common for each employee of the organization to be familiar with the policy and for the policy to be posted in each structural unit. This condition can also be fulfilled by mini-training in the basic provisions of the quality policy in structural units and its discussion. Some organizations, when preparing for a certification audit, issue methodological materials for their employees that explain the basic principles of the implemented QMS.

The final requirement is to review the quality policy for continued suitability and compliance with the organization's objectives. The organization must provide for the procedure and frequency of reviewing the quality policy. This requirement can be implemented in two ways:

1) create a separate document with the conventional name Regulation on the QMS, or Quality Policy, describing in it the status of the Policy and the procedure for revision, as well as those responsible for its regular revision. This method is often used in "old" enterprises when implementing the ISO 9001(2) MS, (3):1994. At the same time, the number of documents increases and work with them becomes more complicated;

2) include the Quality Policy in the Quality Manual. In this case, in accordance with the procedure for making changes established in the Quality Manual, it is necessary to regulate the regular revision of the Manual and Policy.

Development of a meaningful quality policy

One way to link quality policy to quality objectives is to use the Ishikawa cause-and-effect diagram. The following five steps will help any company's management develop a meaningful quality policy (Figure 5.4).

Step one: Use the diagram to generate quality goals, such as:

1. Human Resources. To ensure that our people achieve and maintain the high level of professionalism necessary for the company to occupy leading positions, to create and maintain business processes at the world level and to continuously improve them. To reduce staff turnover to a level that is 25% lower than the turnover in our industry and region.

2. Materials: Create, maintain and improve relationships with suppliers to reduce the cost of purchased materials by 5%, delivery times by 10%, and work in progress by 40% while continually improving quality.

3. Equipment. Ensure the creation, maintenance and continuous improvement of the technological capabilities of the equipment. Increase the equipment utilization rate to 95% due to its effective scheduled preventive maintenance.

4. Methods: To establish and maintain a quality management system that will enable management to apply the PDCA (plan-do-check-act) cycle to key management and production processes, providing increased value for internal and external customers.

5. Measurements. Create, maintain and improve key management and production processes, ensuring their reproducibility index Cp at a level of at least 1.33, which will allow satisfying the requirements of internal and external consumers.

6. Work environment. To continuously improve our knowledge and ensure compliance with environmental, health and safety requirements, which will ensure the safety of our employees and the future existence of our company.

All goals were measurable. However, some goals may have several criteria for achieving them.

- Methods Objectives Equipment Objectives Personnel Objectives implementation SM K in accordance increase the utilization ratenaming reduce staff turnover to meet requirements ISO standard equipment utilization up to 95% level, which is 25% lower9001;
- his planned account the level of employee turnover in the industry ISO 9001 QMS certification for preventive maintenance and regionthroughout the year. Quality Policy. Continuously increase the value of manufactured products or services provided to the consumer and increase their satisfaction through achieving leadership positions in its business, continuous improvement, personnel development and corporate social responsibility. Materials objectives. Measurement Goals Goals in the area of production environment reduction of delivery times reach the level of Cp = 1.33 for ensure understanding and implementation of 10%;
- all key characteristics all employees requirements for reduction prices by 5%;
- processes environmental protection, health protection health and safety at work;
- reduction of unfinished production by 40%;

Step two. Next, the "Five Whys" technique is used to analyze the connection of each goal with the company's key values and the commitments of its management. If the connection is established, then the next "bones" of the diagram are considered. If not, this step is repeated. Let's look at an example.

The goal is to ensure that our employees achieve and maintain a high level of professionalism, which is necessary for the company to occupy leading positions, create and maintain business processes at the world level and continuously improve them.

1. Why? So that business processes are developed, explained to staff and applied correctly.

2. Why? So that management can clearly understand the management of business activities and allocate the necessary resources in a timely manner.

3. Why? So that managers can manage effectively business activities of the company.

4. Why? To create the necessary value for our customers and satisfy their expressed and unexpressed expectations.

5. Why? To add value to society through sustainable income for our employees and tax revenues.

This approach applies to all goals.

Step Three: Use the final “why?” question to develop a quality policy that will cover the six goals listed above. For example, “to continually improve the value of products or services to customers and enhance customer satisfaction through business leadership, continuous improvement, personnel development, and corporate social responsibility.”

Step Four: Select the methods that will be used to monitor and evaluate the extent to which each objective is being achieved. Management should be encouraged to use simple methods such as the Pareto chart to conduct trend analysis and identify potential for continuous improvement.

Step Five: Use the data obtained as feedback and input for analysis by senior management.

Creating a meaningful quality policy is never a finished process. Successful management and leadership begin with clearly expressed and targeted intentions.

5.4. Planning

5.4.1. Quality objectives

Top management shall ensure that quality objectives, including those needed to fulfil product requirements, are established in the relevant units and at the appropriate levels in the organization. Quality objectives shall be measurable and consistent with the quality policy.

Any activity, including quality activities, must be planned. Planning begins with setting goals. According to the requirements of this clause of the standard, goals in the quality management system are set not only at the level of the organization, but also at the level of structural divisions according to the organizational structure. First, goals are developed at the level of the organization in accordance with the conducted analysis of the internal and external environment, as well as the established requirements of consumers and interested parties; then each management level, each structural division details the organization's quality goals, projecting them onto their specific activities. In addition, quality goals can be divided into long-term (three to five years), medium-term (one to three years), short-term (from three months to one year).

The main requirements that the goals must meet are:

- achievable – you cannot plan unrealistic goals, they must correspond to real current performance indicators and the possibilities of upcoming changes for improvement;

- measurable - otherwise it is impossible to determine whether the organization is approaching them or moving away from them, all defined quality goals must have indicators for their measurement;

- specific – in full compliance with the previous requirement;

- flexible – excessive specificity of goals can lead the organization to a dead end (unforeseen circumstances may arise during the future period that will not allow them to be achieved);

- compatible – goals should not contradict the mission and development strategy of the organization, as well as the quality policy.

5.4.2. Planning the creation and development of a quality management system

Top management shall ensure that:

a) planning for the creation and development of a quality management system was carried out to meet the requirements specified in clause 4.1, as well as to achieve quality objectives;

b) the integrity of the quality management system is maintained when planning and implementing changes to it.

The creation of a quality management system is planned in the development and implementation project. Planning involves determining:

- working group and project manager;
- project activities;
- general and intermediate deadlines;
- those responsible for the implementation of project activities;
- results (intermediate products) of the project.

To maintain the integrity of the quality management system, input and output data should be defined during its establishment and in accordance with the process approach.

In the development of the quality management system in the organization, an annual Quality Plan can be created, which will be formed on the basis of identified nonconformities, the results of internal audits, changes in the requirements of consumers and other interested parties, etc.

ISO TC 176 proposed a Procedure for the implementation of a quality management system in an organization. The procedure includes the following stages:

1. Identify the goals you want to achieve. Typical goals might include:

- improve efficiency and profitability;
- produce products and provide services that fully meet consumer requirements;
- achieve customer satisfaction;
- increase market share;
- maintain market share;
- improve relationships and morale within the organization; • reduce costs and reduce debt;
- strengthen confidence in the production system.

2. Determine what others expect from you.

Examples of people and organizations interested in the results of your work:

- customers and end consumers;
- company staff;
- suppliers;
- shareholders;
- society as a whole.

3. Find the information you need about the ISO 9000 series of standards:

- general information;
- For more detailed information, see ISO 9000:2015. MS ISO 9001:2015 and MS ISO 9004:2015;
- For additional information, please visit the ISO website;
- experience of applying ISO 9000 series standards worldwide – read the publications of the ISO Management Systems magazine.

4. Apply ISO 9000 series standards in your quality management system.

Decide whether you are going to obtain a certificate of conformity of your quality management system to the requirements of the ISO 9001:2015 standard or want to nominate (register) your quality management system for a national quality award:

- use the requirements of ISO 9001:2015 as a basis for obtaining a certificate;
- use the requirements of ISO 9004:2015 together with the criteria of the national quality award for nominating a quality management system for this award.

5. Obtain a manual on individual sections of the quality management system.

Such special subject standards are:

ISO 10006:1997 "Quality management - Guidelines for quality assurance in project management" - on project management;

ISO 10007:1995 "Quality management - Guidelines for configuration management" - on configuration management;

ISO 10012-1:1992 "Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment" and ISO 10012-2:1997 "Quality assurance of measuring equipment - Part 2: Guidelines for the control of measurement processes" - for measuring systems;

ISO/TR 10013:2001 "Guidelines for developing quality management system documentation" - on quality documentation;

ISO/TR 10014:1998 "Guidelines for quality economic management" - on quality economic management;

ISO 10015:1999 “Quality management – Guidelines for training” – on training;

ISO/TU 16949:2002 “Quality management systems. Particular requirements for the application of ISO 9001:2015 to the production of motor vehicles and spare parts for them” – for vehicle suppliers;

ISO 19011-A “Guidelines for quality and/or environmental management systems auditing. – Part A: Document identified as Part A and B to facilitate voting by both ISOAC 176/SC 3 and ISO/TC 207/SC 2/" and ISO 19011-B "Guidelines for quality and/or environmental management systems auditing. – Part B: Document identified as Part A and B to facilitate voting by both ISOAC 176/SC 3 and ISO/TC 207/SC 2/” – no audit.

6. Establish your status, identify non-conformities of your quality management system with the requirements of ISO 9001:2015.

You can carry out:

- self-esteem;
- assessment by an external organization.

7. Identify the processes needed to provide your customer with products and services.

Review the requirements of the ISO 9001:2000 section on product creation processes and determine whether your quality management system, including the processes:

- consumer related;
- design and/or development:
- procurement;
- production and maintenance;
- control of monitoring and measuring equipment.

8. Develop a plan to eliminate the nonconformities (item 6) and improve the processes identified in item 7.

Determine the actions to eliminate the identified nonconformities, allocate the resources needed to implement them, distribute responsibility and authority, establish relationships between performers and draw up a schedule for implementing these actions. Clauses 4.1 and 7.1 of ISO 9001:2000 contain information that you need to consider when developing a plan.

9. Carry out your plan.

Carry out planned actions and mark their progress according to the schedule.

10. Conduct periodic internal assessments.

Use ISO 19011 as an auditing guide, for assessing auditor qualifications and managing audit programs.

11. Does your quality management system require verification of compliance?

If yes, go to step 12.

If not, go to step 13.

You may need or want to confirm compliance (obtain a certificate/registration) with the requirements of the standard in order to:

- satisfaction of contract requirements;
- meeting market demands or consumer preferences;
- meeting the requirements of regulatory organizations;
- ensuring risk management;
- defining the development objectives of your organization in the area of quality.

12. Conduct an independent audit.

Engage an accredited registration/certification body to audit and certify your quality management system to ISO 9001:2015.

13. Continue to improve your business.

Analyze the effectiveness and suitability of your quality management system. ISO 9004:2015 provides a methodology for improving it.

Point 7 should include cascading training of personnel, starting with senior management and ending with the organization’s rank-and-file employees.

ISO 9000 series standards have been developed taking into account the business experience of developed countries, therefore, CIS organizations face significant difficulties when creating a QMS. Historical restructuring in Russia and the CIS countries has had a significant negative impact on the current state of the economy and management systems of enterprises and organizations. The following main reasons can be identified for the lag of the CIS countries behind developed countries in the pace and volume of implementation of ISO 9000 series standards.

The consequences of the sharp decline in production after the collapse of the USSR and mass privatization have still not been overcome.

The processes of forming a free market and market relations, saturating it with goods and services, intensifying the competitive struggle of enterprises, and the emergence of an urgent need for them to improve the quality of their products in order to

increase their competitiveness have not been completed.

Insufficient quantity, low quality and little experience of professional managers. Most managers in the CIS countries are still technical specialists or economists. The training of professional managers in the field of quality in the CIS countries began in the late 1990s, and yet they are in little demand.

The skills of applying scientific methods of analysis and decision-making have been lost, and methods of statistical control and regulation of product quality are practically not used.

Conclusion

The poor condition of fixed assets of many enterprises, the use of outdated technologies and methods of organizing and managing enterprises, including administrative-command management methods, a functional approach to organizing an enterprise. These and other factors lead to the fact that the main quality problems at CIS enterprises are mainly associated with the processes of manufacturing products, their material base, and not with management and information processes, the improvement of which is primarily aimed at the ISO 9000 series standards.

Lack or insufficient use of information technology in organizations.

The development of a QMS is not for increasing the efficiency of production, competitiveness of products and services, but for certification of the QMS for the purpose of formal expansion of business opportunities. The presence of a certificate of conformity, according to the management of such organizations, will allow them to strengthen their positions, and often increase prices for products and services in the domestic and foreign markets.

The listed reasons lead to the fact that QMS created without their elimination are ineffective, and the funds spent on them do not justify themselves. As the analysis showed, 80% of enterprises of the Russian Federation that implemented MS ISO series 9000:2015 did not receive the expected effect from their QMS. Many enterprises and organizations do not even strive to build a system, but are focused on obtaining a certificate.

At those enterprises (organizations) of the CIS, for which the above-mentioned problems are typical, before the stages of creating a QMS recommended by TC 176 ISO, it is necessary to perform the following work.

1. Conduct marketing research of your products and services, assess their competitiveness prospects, and choose a strategy for your development.
2. Conduct training of senior and middle management personnel in basic methodsgeneral management and quality management, lower-level managers and performers in key operations - the principles of QMS in accordance with ISO 9000 series, their role in this system, statistical methods of analysis, quality control and regulation.
3. Assess the quality of your products, establish the reasons for violations of the requirements of the current NTD, eliminate these reasons by replacing or training personnel, replacing or repairing equipment and tooling, changing the technology, methods of organizing and managing production (if necessary).
4. Develop and implement statistical methods of analysis, control and regulation of product quality at the maindefective production facilities.
5. Select and apply the most appropriate methods and information technologies for quality management and enterprise management.

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