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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 2

Abstract: *In message 2, the authors associate quality with life cycle analysis to ensure the production of priority and in-demand products, because "product quality" is one of the most important indicators that determine the efficiency and effectiveness of any organization in the conditions of market competition. "Quality of management" implies the personnel's mastery of methods and models for making management decisions, organizing their implementation within the required timeframes, and the effectiveness of work is determined by profit and the corresponding economic effect of using the organization's production assets. It should be noted that quality is inextricably linked with consumers, their needs, and the degree of their satisfaction. Therefore, competent definition and consideration of needs for manufacturers is the starting point for achieving complete consumer satisfaction and, as a result, securing stable positions in a competitive environment.*

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

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The intention to create a shoe cluster based on Dagestan, Rostov-on-Don and the Moscow region, which traditionally specialize in the production of

such products, is justified. Market participants are already preparing a concept for the project. Its main goal is to increase the share of domestic production to 30%. The document is being developed with the support of the Ministry of Industry and Trade,

The Ministry of Industry and Trade is ready to support industrial clusters both in these regions and in those with expertise in the light industry, and businesses are interested in attracting additional measures to implement new projects. The Ministry of Industry and Trade understands that, on the instructions of the President, the Ministry launched a preferential regime for industrial clusters from January 1, 2023. It includes various benefits, including: a loan rate of one-third of the key Central Bank rate plus 3%, a reduction in insurance premium rates to 7.6%, subsidies for reimbursement of a maximum of 50% of the costs of purchasing starting lots of components (up to 150 million rubles). In addition, companies from industrial clusters can participate in tax and customs monitoring procedures - this will exempt them from these checks. The Shoe Union knows about the concept being prepared, but it will not be easy to develop this project in the current conditions, as is the case with all businesses in the Russian Federation, shoe manufacturers are faced with sanctions restrictions, and many foreign markets are closed to them. The union emphasized that retail plays a key role in the development of the light industry: all the strong players in this industry in the world chose serious measures to support their trade and production. Thus, the Turkish authorities helped shoe retail develop in other countries. The government paid 100% of the rent for a year when opening retail outlets abroad, and also took on the costs of companies' participation in international exhibitions for several years - up to paying for business trips for company employees. All this together allowed the country to strengthen its position in the global shoe market.

This automatically spurred the development of production. Plus, their own shoe factories also received benefits: for example, in China, Vietnam, India and Turkey they gave negative interest rates on loans, zeroed out some taxes, provided free leasing of some equipment, and so on.

Russia can increase its share of domestic production to 50%, this is the figure that can ensure national security in this industry, Igor Surin, President of the Russian Union of Leather and Shoemakers and Chairman of the Board of Directors of the Russian Leather Group, told Izvestia. Today, the country produces 100 million pairs with consumption of 500 million pairs, meaning that the potential for import substitution is very good. Manufacturers can provide shoe production with the necessary materials to cover such needs, but businesses need tax breaks and the establishment of protective duties on imports. This became especially relevant after Russia joined the WTO, the country immediately weakened its "protection" from foreign products.

If we talk specifically about the regions that can get into the cluster, then, for example, Dagestan and Rostov-on-Don are already developing as shoe cities. True, there are small production facilities there that have potential for development. With the right support, they can increase their turnover many times over. Manufacturers need specific benefits in order to increase production, first of all, this is the fight against counterfeiting, the share of which today in some regions reaches more than 50%.

It is quite difficult to compete with counterfeit products bearing foreign brand names: buyers opt for cheaper goods. Mandatory shoe labeling has not yet proven its effectiveness, the share of counterfeit products remains the same - regulators are deprived of the opportunity to check sellers under the moratorium.

In addition, manufacturers need relief on social taxes and VAT - a reduction to 15% and 13%, respectively, as has already been done in the CIS countries. This can spur industry in the country as a whole, and not in a separate cluster. Business is also interested in the ban on self-employed people working with legal entities, otherwise the industry will continue to experience an outflow of personnel.

The fact is that in some areas, employers can save on insurance premiums and other taxes for the self-employed, while shoe manufacturing cannot hire such employees by law - enterprises need qualified and trained personnel who work on a schedule. Young people are more likely to choose non-manufacturing professions, just those that allow them to choose the self-employment mode: low social taxes allow employers to offer such employees higher salaries. The share of search queries for clothing and footwear of premium and mid-price brands in the first half of this year was 55%, an increase of 10 percentage points compared to the same period last year. In the first half of 2023, 55% of all brand queries in the "Clothing" category mentioned premium and mid-price brands. In the first half of 2022, this figure was 45%,

Therefore, the brand is important when buying shoes, jeans, sportswear and outerwear; the brand is least important when buying T-shirts, skirts, home and children's clothing, maternity clothes.

Overall, as shown by the data of an online survey among a thousand users in June of this year, online is increasingly becoming the key channel for choosing clothes and shoes. 76% of users start searching for wardrobe items online - this is a quarter more than a year earlier. At the same time, 60% of respondents buy clothes both online and offline. About 25% of users buy these goods only online: on a marketplace or in an online store... Almost a third of users noted that they looked for clothes or shoes on the store's website before visiting it.

Interestingly, the number of offline routes built to clothing stores increased by a quarter in the first

half of 2023 compared to the previous year. Russia is currently the second brand-dependent country in the world after Brazil.

Official inflation statistics are clearly deceitful, but even if we increase them by a factor of 0.5 and get a real average annual rate of 15–20%, we will have no choice but to state that the welfare of most citizens has increased in the context of a certain growth of the economy as a whole. The intensity of the dynamics is low, but the fact itself is obvious. The positive shift towards an increase in the purchasing power of Russians over the past 5 years is indisputable. But how fair is it to talk about "welfare"? Money is just an exchange equivalent. Having earned more money, you will not necessarily live better. Money should be exchanged for necessary goods. And here the problem of quality comes into full swing. Having earned money, you can easily spend it "unnoticed", i.e. buy not a product, but a "phantom product". "Phantom product" is a non-specific concept for a special system of knowledge. Nevertheless, it is necessary to get used to it as a theoretical expression of the realities of an underdeveloped commodity market. Speculating on the "white" and "gray" "spots" of the quality ideology, which is in an extremely "neglected" state, "black" manufacturers of low-quality consumer goods, together with sympathetic officials of the services responsible for the quality of products, have flooded the market with substandard products. The international quality control system "ISO 9000–2015" is more reminiscent of the latest phenomenon of the famous Potemkin villages. Only what is clearly spelled out can be effectively controlled. Any omission is a loophole for semi-legal penetration into the fields of hunting for consumers. "ISO 9000–2015" should be used not as a management tool, but as an instrument for preventing quality violations. The circle is thus closed, because a violation implies quality, and it is quality that we have not defined properly. In the system of special knowledge, which is the ideology of production, "quality" is replaced by "quality state", which, in turn, is reduced to quantitative parameters. Quantitative characteristics are given discrete expressions - this is how another derivative concept appears. Only this time not from the root concept of "quality", but from its concept of "quality state". The militant activity of the desire to describe quality with the help of quantity is surprising. Almost two hundred years have passed since the time of Hegel, who claimed that "quality is the main thing in defining a phenomenon, since quality is that, losing what, it ceases to be itself". It is time to learn a simple truth: quality is determined not through quantity, but through properties. With the help of quantitative measurements, we need to determine the "measure" - "qualitative" and "quality state" (the level of expression of quality). Practice rarely corrects errors in theory; on the contrary, it usually hides them until a certain point in development. The defects of the theory are clearly evident in difficult socio-economic circumstances, during times of political uncertainty.

It is no coincidence that such a peculiar time is "convenient" for the flourishing of theoretical uncertainty. The state, entangled in numerous problems, deviates from control of economic processes, counting on the market, which is called upon to put everything in its place. The market has its own laws of operation. The market adapts theory to its own interests. It does not obey the rules justified by theory, but strives to adjust these rules to a favorable way of relations with the consumer. The advertising statement: "the buyer is always right" is a lie! Only the legal order that determines the nature of relations in the goods market is always right. These relations themselves are built depending on the interpretation of the quality of goods and the correspondence of quality to price. Let us consider this statement using shoes as an example. Shoes, along with clothing, are goods dependent on national and historical characteristics. Can we recommend shoes for sale on the market that do not take into account the specifics of the geographical, climatic and national mentality of the regions of Russia? Apparently, such products can be allowed on the market, but only in limited quantities, for variety and to expand the consumer's choice. And it is not a matter of "kvass patriotism". Nature, nutrition, traditions affect the anthropometric characteristics of the population, namely, namely:

- configuration and proportions of the foot and lower leg;
- climatic features of the regions;
- national characteristics of territories;
- consumer differences in the regions for which the manufactured range of footwear is offered;
- distinctive features of the population of the territories of Russia in men, women and children;
- purchasing power of the population of the country's regions.

Main part

As shown by the experience of leading enterprises and others, as well as numerous materials from the journals "Methods of Quality Management" and "Standards and Quality" for the period 2001–2008, the following methods have confirmed their effectiveness in our conditions: the method of advanced product quality planning (Advanced Product Quality Planning — APQP), the method of analysis of types and consequences of failures (defects) (Failure Mode and Effects Analysis — FMEA), information technology ERP (Enterprise Resource Planning) — an enterprise management system (product deliveries, intra-plant movement, processing, warehouses, drawings, personnel, financial flows, etc.).

1. Develop and implement a system for accounting for quality costs, losses from poor quality, and income from quality improvement.

When developing and certifying a quality management system, such errors should be avoided (Table 1).

5.5 Responsibility, Authority and Information Sharing

5.5.1. Responsibility and Authority

Top management shall ensure that responsibilities and authorities are defined and communicated to the organization's personnel.

Table 2. Problems arising during development and certification of QMS and rules for overcoming them

	Problem	Rule
1	The organization's management does not understand that in order to implement a project to develop a QMS that meets the requirements of the ISO 9001:2000 standard, it is necessary to spend money not only on consulting and certification audit.	It is necessary to introduce a service into the organization's staff that will coordinate the activities for the implementation of the project for the development of the QMS. Moreover, the service must be created in a timely manner, i.e. immediately after the decision to begin work is made.
2	Wrong choice of consulting organization and consultant.	When choosing a consulting organization, do not focus only on price; take the time to collect information about the practical experience of the company and consultants.
3	Incorrect organization of the process of training personnel to implement the requirements of the ISO 9001:2000 standard.	Implementation of ISO standard requirements 9001:2000 requires training (managers absolutely must!), and proper organization of training is the key to success.
4	The organization's management and staff do not accept or implement the consultant's recommendations (or implement them, but with a great delay).	Listen to the consultant's recommendations and organize their timely implementation.
5	Incorrect planning of work on creating a QMS. The management decides that a QMS that meets the requirements of the ISO 9001:2000 standard must be created at the enterprise within three to five months, including its certification.	Set specific (real) deadlines for the implementation of the project to create a QMS in accordance with the requirements of ISO 9001:2000 after analyzing the current system and training managers and staff.
6	Failure of the organization's top management to understand their role and responsibilities in building the QMS. There are situations when top managers initiate a project to develop the QMS (issue an order) and then withdraw from participation in its implementation.	The organization's management should not limit itself to initiating a project to develop a QMS. Implement the PDCA methodology in practice.
7	The management decides on the need to develop a QMS that meets the requirements of the ISO 9001:2000 standard, creates a quality service and instructs it to develop QMS documentation without the participation of other departments and managers.	Creating a working QMS is a collective endeavor, so involve EVERYONE in developing QMS documentation and building the system, not just quality service employees.
8	The organization approaches the implementation of the project formally: attempts to build a system only on paper (a “Potemkin village”) continue.	Don't indulge in formalism. It's an expensive and pointless exercise. Health first (current QMS in accordance with ISO standard requirements 9001:2000), then a certificate (result).
9	The organization does not pay due attention to the stage of development (adjustment) of regulatory documentation: procedures, instructions, etc.	Assign the preparation of documents to competent specialists trained in the requirements of the ISO 9001:2000 standard and having sufficient

		production experience at the enterprise. And read them carefully when agreeing!
	Problem	**Rule**
10	When implementing a process approach in an organization, performance indicators that characterize the relationship between the achieved results and the resources used are not used to evaluate QMS processes.	Calculate costs (losses), use not only performance criteria (indicators) but also efficiency criteria to evaluate processes. In this case, you will see specific benefits from implementing the process approach.
11	Management of organizations often use the results of internal audit as a basis for punishment, and this can be applied to both those being audited and the auditors.	In order to get concrete benefits from internal audit, it must be organized in such a way that neither those being audited nor those auditing perceive it as a means of punishment. And do not try to turn the quality service into a riot police, a special rapid response unit, or something similar: it has a completely different purpose.
12	Not enough attention is paid to the selection of internal auditors, which leads to conflicts between those being audited and those auditing (auditors).	Pay attention to the selection and training of auditors. Follow the recommendations of the ISO 19011:2002 standard.
13	The organization pays little attention to carrying out preventive actions or does not carry them out at all.	Identify sources of information, collect and analyze it to take preventive actions.
14	Not enough attention is paid to the implementation stage following the development of QMS documentation (procedures, instructions, etc.)	Don't wait, but actively promote the dissemination of new rules (requirements of QMS documentation): train and check how they are understood and implemented by personnel.

Problem Rule

1. The organization's management does not understand that in order to implement a project to develop a QMS that meets the requirements of the ISO 9001:2000 standard, it is necessary to spend money not only on consulting and certification audit.

It is necessary to introduce a service into the organization's staff that will coordinate the activities for the implementation of the project for the development of the QMS. Moreover, the service must be created in a timely manner, i.e. immediately after the decision to begin work is made.

2. Wrong choice of consulting organization and consultant. When choosing a consulting organization, do not focus only on price, do not spare time to collect information about the practical experience of the company and consultants.

3. Incorrect organization of the process of training personnel in the implementation of the requirements of the ISO 9001:2000 standard. Implementation of the requirements of the ISO standard 9001:2000 requires training (managers absolutely must!), and proper organization of training is the key to success.

4. The management and staff of the organization do not perceive and do not implement the consultant's recommendations (or implement them, but with a great delay). Listen to the consultant's recommendations, organize their timely implementation.

5. Incorrect planning of work on creating a QMS. The management decides that a QMS that meets the requirements of the ISO 9001:2000 standard must be created at the enterprise in three to five months, including its certification. Specific (real) deadlines for implementing the project to create a QMS in accordance with the requirements of ISO 9001:2000 are established after analyzing the current system and training managers and personnel.

6. The top management of the organization does not understand its role and responsibilities in building the QMS. There are situations when the top managers initiate a project to develop the QMS (issue an order) and then withdraw from participation in its implementation. The organization's management should not limit itself to initiating a project to develop the QMS. Implement the PDCA methodology in practice.

7. The management decides on the need to develop a QMS,that meets the requirements of the ISO 9001:2000 standard, creates a quality service and instructs it to develop QMS documentation without the participation of other departments and managers. The creation of a functioning QMS is a collective effort, so involve EVERYONE in developing QMS documentation and building the system, not just the employees of the quality service.

8. The organization approaches the implementation of the project formally: attempts to build a system only on paper (a "Potemkin village") continue. Don't indulge in formalism. It is an expensive and pointless exercise. Health first (current QMS in accordance with the requirements of ISO 9001:2000), then a certificate (result).

9. The organization does not pay due attention to the stage of development (adjustment) of regulatory documentation: procedures, instructions, etc. Assign the preparation of documents to competent specialists trained in the requirements of the ISO 9001:2000 standard and having sufficient production experience at the enterprise. And read them carefully when agreeing!

Problem Rule 10 When implementing a process approach in an organization, performance indicators characterizing the relationship between the achieved results and the resources used are not used to evaluate QMS processes. Calculate costs (losses), use not only performance criteria (indicators) but also efficiency criteria to evaluate processes. In this case, you will see specific benefits from implementing a process approach.

11. Management of organizations often uses the results of internal audit as a basis for punishment, and this can be applied to both those being audited and those auditing. In order to obtain specific benefits from internal audit, it must be organized in such a way that neither those being audited nor those auditing perceive it as a means of punishment. And do not try to turn the quality service into a special police force, a special rapid response unit, or something similar: it has a completely different purpose.

12. Not enough attention is paid to the selection of internal auditors, which leads to conflicts between auditees and auditors(auditors). Pay attention to the selection and training of auditors. Follow the recommendations of the ISO 19011:2002 standard.

13. The organization pays little or no attention to preventive actions. Identify sources of information, collect and analyze it to implement preventive actions.

14. Not enough attention is paid to the implementation stage following the development of QMS documentation (procedures, instructions, etc.) Don't wait, but actively promote the spread of newrules (requirements of the QMS documentation): train and check how they are understood and implemented by personnel.

The responsibility and authority of the organization's personnel for quality activities must be defined in the relevant QMS documents. Each document describing processes defines a matrix of responsibility and authority for process actions. The matrix of responsibility and authority for top-level processes is given in the Quality Manual. An example of a matrix of responsibility and authority is presented in Table 3.

Table 3. Example of a responsibility and authority matrix

Functions (process actions)	**Job title 1**	**Job title 2**	**…**	**…**	**Job title 5**
1	2	3	4	5	6
Process planning	O *	I			U
1.		O	I	C	
2.		U	O	I	U
3.		O	I	I	U
4.		O	C	I	U
Control of process execution	O	I			
Process management	O	I			
Progress Report	O	U			I

*Legends:
O – responsible
I - the performer
C – co-executor
U – participates.

Evidence that responsibility and authority for certain actions and processes of the QMS have been established is the fact that employees have been familiarized with all original documents that they must use in their work. Management representative

Senior management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring the development, implementation and maintenance of processes required by the quality management system;

b) reporting to senior management on the functioning of the quality management system and the need for improvement;

c) facilitating the dissemination of understanding of customer requirements throughout the organization.

The management representative's responsibility may include liaison with external parties on matters relating to the quality management system.

In accordance with this clause, the head of the organization must appoint a management representative. The main responsibility for the functioning of the quality management system, its effectiveness and efficiency lies with the head of the organization. However, in order to manage the main work (project) of development, implementation and maintenance of the quality management system, a special representative must be appointed. The management representative for quality can perform these works only if he has sufficient authority. The assignment of the relevant responsibility and authority can be made by including in his job description or in the order on his appointment the requirements listed in this clause of the standard (a, b, c). Internal information exchange.

Top management shall ensure that appropriate communication processes are established within the organization, including those relating to the effectiveness of the quality management system.

Internal information exchange is the main problem area in modern Russian organizations. For the functioning of the quality management system, the internal information exchange system is of primary importance. Therefore, it is the responsibility of the top management of the organization to create such a system. The internal information exchange system can be described in the quality management system as a separate document (for example, the Regulation on the internal information exchange system) or in separate documents of the quality management system.

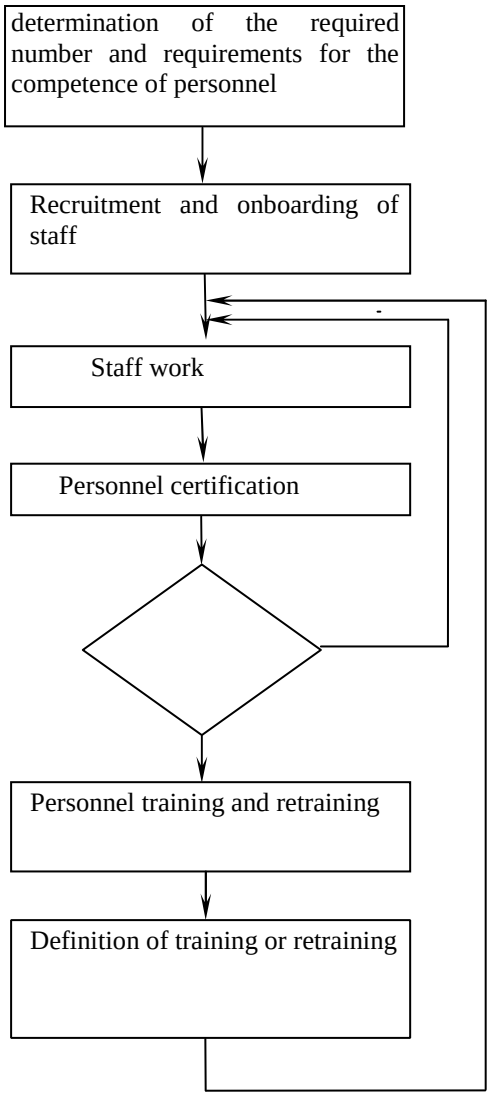
Management should ensure the exchange of information, encourage feedback from employees in order to improve the organization's performance. Information exchange usually includes:

- information provided by management at workplaces;
- meetings;
- use of the notice board;
- exchange of information via e-mail and specially designated network resources; - the organization’s website and other means of information.

Information about the organization's activities can also be made visual in the following ways:

- using notice boards adapted for displaying measurement results;
- creating special stands reflecting performance indicators based on the results of reporting periods;
- using replaceable sheets with current assessment of various indicators;
- distributing "improvement activity bulletins" containing improvement activity plans, performance measurement results, updates on progress, and a summary of how the company is doing in areas that are problematic.

Do you need staff training or retraining?



Management review. General provisions.

Top management shall review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include an assessment of opportunities for improvement and the need for changes to the organization's quality management system, including the quality policy and quality objectives. Records of management reviews shall be maintained.

Top management should periodically analyze the functioning of the quality management system based on data and reports submitted by structural units, owners of the organization's processes. The frequency of such analyses should be recorded in the relevant documents: the Quality Manual or a separate QMS document. Current analysis by the organization's management can be carried out monthly or quarterly. A large-scale analysis of the quality management system for the purpose of making changes to the quality policy and goals, changing the directions of the system's development can be carried out annually. The results of the analysis and the decisions taken are recorded in the relevant documents (e.g., minutes) and stored in the organization in accordance with the established rules and requirements of the standard for records. Input data for analysis Input data for analysis by management should include information on:

a) the results of audits (inspections);

b) feedback from consumers;

c) process indicators and product conformity;

d) the status of preventive and corrective actions;

d) subsequent actions arising from the previous analysis by management;

e) changes that could affect the quality management system;

g) recommendations for improvement.

Output from the review. The output from the management review should include all decisions and actions related to:

a) improving the effectiveness of the quality management system and its processes;

b) improving products in accordance with consumer requirements;

c) resource requirements.

According to the PDCA cycle, the quality management system must be regularly analyzed, both at the process and department level, and at the top management level. In order for the organization's management to be able to regularly analyze the effectiveness of the quality management system, it is necessary to collect data and information. After conducting the management analysis, it is necessary to draw up documents (records) that meet all the requirements

In addition to the input and output data listed in the paragraph of this subsection, the following characteristics of the manager himself significantly influence the analysis:

- knowledge, experience, intuition;
- analytical skills;
- methods of analysis and decision making used.

Although nothing is said about this in the requirements of the standard, the level of competence of the manager is a very important factor influencing the effectiveness and efficiency of the analysis of the quality management system and the decisions made.

The management review process with the input and output data of the review is shown in Figure 5. ISO 9001:2015 contains requirements for resource management in a quality management system. The following are considered as resources in Section 6 of ISO 9001:2015:

- human resources;
- infrastructure;
- production environment.

The ISO 9000:2015 standard does not define the term “resources”, but its content is given in the ISO 9004:2015 standard. It states that resources can be: people, infrastructure, production environment, information, suppliers, partners, natural or financial resources, i.e. everything that can be actually used to ensure the effectiveness and efficiency of the quality management system.

To improve the performance of an organization, it is necessary to consider issues related to resources, such as:

- effective, efficient and timely provision of resources taking into account capabilities and limitations;
- material resources, such as improved production and auxiliary equipment;
- intangible resources, such as intellectual property;
- resources and mechanisms that promote innovative continuous improvement;
- organizational structures, including services that meet the needs of project management and the matrix approach;
- information and technology management;
- improving competence through targeted training, education and learning;
- development of leadership skills and profiles for future managers of the organization;
- the use of natural resources and their impact on the environment;
- planning resource needs for the future.

6. Resource management. Provision of resources

The organization shall determine and provide the resources needed to:

a) implementation and maintenance of a quality management system, and

also continuously improving its effectiveness;

b) increasing customer satisfaction by meeting their requirements.

INPUT DATA

1. Audit results

2. Feedback from customers (audit records) and information on stakeholder satisfaction.

4. Status of corrective and (annual report of senior management, preventive actions before the shareholders' meeting, and actions after the previous customer feedback), management analysis (previous report-analysis of management, previous preventive plans of corrective actions and QMS processes. Market assessments of comparison and strategy with the best. Monitoring log of achievements. Changes in financial, social, environmental conditions, laws, regulations and other factors (annual report before the shareholders' meeting, reports of heads of departments and services).

Management review

OUTPUT DATA

3. Functioning of processes and product conformity. Management of nonconformities of processes and products (implementation of quality programs, monitoring log of QMS processes)

6. Recommendations for improvement (QMS process monitoring log, reports of department and service heads). Analysis of the quality service

Annual report of senior management to the shareholders' meeting

Strategic planning

Strategies and Initiatives

Reduction of losses and directions for marketing and satisfaction of stakeholders plans for reducing development risks and future needs

Management Analysis Reports

Strategic planning Strategic planning of development directions of development directions of development directions and future needs

Quality programs (new versions)

Improvement program

Quality program

Improvement program

QMS of resource management products

Corrective Action Plan

Preventive action plan

The definition and provision of necessary resources is implemented in the quality management system when implementing the allocation of auxiliary processes in the process model of the QMS. The order of their functioning is described, those responsible and executors for the implementation of process actions are determined. Maintenance in working order involves managing the processes of resource provision. When the quality management system is functioning, data is collected and analyzed for both primary and auxiliary processes, discrepancies are identified and decisions are made by management to bring the provision of resources to the required state.

Point b) indicates that not only data on internal processes influence the revision of existing resource provision, but also data on customer satisfaction.

Human Resource Management

Human resources. General provisions. Personnel performing work affecting product quality must be competent in accordance with their education, training, skills and experience.

This subclause states that the main requirement for personnel according to ISO 9001:2015 is their competence. Personnel competence is not just the necessary education and work experience (which is currently the main criterion for hiring personnel in organizations), but the ability of a person to perform all necessary types of work in accordance with the established quality requirements. The requirement to be competent "in accordance with the education, training, skills and experience received" means that the organization must calculate and justify the number of personnel, confirm the data on their qualifications, i.e. the data on the personnel listed in this clause are available, and comply with the regulatory documents of the organization defining its activities (e.g. the staffing table and/or job descriptions). ISO 9001:2015. Quality management systems. Requirements. Competence, awareness and training. The organization shall, namely:

a) determine the necessary competence for personnel performing work that affects product quality;

b) provide training or take other actions to meet these needs;

c) evaluate the effectiveness of the measures taken;

d) ensure that its personnel are aware of the relevance and importance of their activities and their contribution to the achievement of quality objectives;

d) maintain appropriate records of education, training, skills and experience.

Determining the required competence

The stated requirements mean that traditional methods of personnel selection, which involve hiring personnel based on education and work experience documents, are not sufficient in the quality management system. Employee assessment should also cease to be formal. This is especially true for personnel involved in the main processes of production of products (services). At present, there are no mandatory requirements to conduct personnel certification with a certain frequency, although the most advanced companies constantly assess their personnel. The first requirement of this subparagraph means that the organization must, in any way, assess the competence of personnel with a certain frequency.

ISO 9000:2015 defines competence as a demonstrated ability to apply knowledge and skills. Determining the level of competence to effectively perform work is an important tool for hiring personnel, identifying career advancement opportunities, and training needs. Knowing the level of personnel competence can also help an organization determine the required level of documentation for the quality management system. To do this, it is important not to ignore the hint provided by ISO 9001:2015, where clause 4.2.1 states: “the volume of quality management documentation in one organization may differ from that in another, depending on the size of the organization and type of activity, the complexity of the interaction processes, and the competence of the personnel.” Competence volumes should be established for each position, starting with performers, specialists of various categories, middle-level managers, and ending with top managers of the organization. At the same time, the organization should remember that competence volumes should be established for each specific workplace. This means that the same competence volumes can be defined for the same positions of similar work. Organizations usually already have descriptions of the relevant competencies in job descriptions. But analysis shows that most such instructions in traditional organizations are guilty of mixing up responsibilities, specific duties, and competency requirements. Often, the requirements for an employee are limited to listing the functions he or she performs and do not contain any competency requirements at all. Personnel training and documentation for training.

In accordance with the requirements of the first three subclauses of the standard, for the selection and implementation of training or other actions aimed at reducing the gap between the required and existing competence, management must continuously monitor the following stages:

- identification of training needs,
- planning and development of training programs,
- provision of training, - assessment of learning outcomes.

Identifying the need for competent personnel

Once the competency requirements have been established and communicated to the staff, the organization can increase the competency requirements of the relevant employees. This need can be determined using various sources of information: based on the results of the analysis of corrective

actions or non-conformity reports, from annual work reports, from the materials of current control and monitoring of activities, etc. One of the main sources of information on the competence of the staff should be the assessment and certification of the staff.

Further, the requirements of this paragraph formulate the need not only to determine competence, but also to plan events for training, personnel preparation and other actions in case of detection of insufficient level of personnel professionalism. Such decisions are documented – personnel training plans, activity plans, etc. are drawn up. Personnel training should not be carried out formally. Training programs should be drawn up in full compliance with the identified "gaps" in the knowledge and skills of personnel, and training groups should include those who need it.

Most often, organizations resort to additional training of personnel as a typical method of solving the problem of insufficient personnel competence. The standard requires meeting the requirements for personnel competence, but not only by additional training, but also by other actions, this may be: mentoring, self-training, personnel rotation, modification of processes, change of procedures, transfer of certain types of activities to third-party organizations, etc.

Training or retraining of personnel is required.

Definition of performance.

Another difference between ISO 9001:2015 and the old version is the organization's obligation to evaluate the effectiveness of the actions taken to meet the need for competent personnel. ISO 9000:2015 defines effectiveness as "the degree to which planned activities are implemented and planned results are achieved."

Therefore, if personnel retraining is considered as one of the ways to solve problems, the organization should be able to determine how effective it was. In this case, the evaluation depends on the methods chosen to measure the desired results. For example, one method can measure the impact of personnel training or other actions on the production indicators of an individual employee or the organization as a whole, another - on the cost-benefit ratio. Recommendations for organizing effective training and conducting effectiveness assessment are contained in the international standard ISO 10015:1999 "Quality management. Guidelines for training". This document is "a guide that can help an organization identify and analyze training needs, plan and draw up a training program, provide training, evaluate training results in order to fulfill its tasks. The standard emphasizes the contribution of training to continuous improvement, and its purpose is to help organizations make training more effective and efficient investment." Criteria for evaluating training results.

Clause 4.5.1 of ISO 10015:1999 states that the evaluation should be carried out based on the criteria set out in clause 4.3.4 of the standard.

1. Student satisfaction. After each course, block, module of training, a survey of students should be conducted to assess the material they have listened to, the relevance and novelty of the information received, the effectiveness of training, the quality of teaching, etc..

2. Acquisition of knowledge, skills and qualities by students. To assess employees according to this criterion, it is possible to conduct an exam, professional testing, perform case assignments, group and individual assignments.

Assessing skills and quality presents certain difficulties:

- it should be carried out, for example, one to two months after training (depending on the employee's position) and the type of training;

- to carry it out it is necessary to plan financial and time resources (it requires large expenditures).

3. Before assessing skills and qualities after training, it is necessary to assess their presence (level of development) before training and then compare the results. The widely used "360" method can be used as a measurement tool. Since assessment by this criterion is labor-intensive, it is recommended to use it to assess long-term training.

4. The trainee's performance (efficiency) on the job. After training, usually after a certain period of time (e.g., a month, a quarter, etc.), the performance (efficiency) on the job is assessed. It is important to correctly determine the period after which the assessment should be carried out in each specific case. The assessment can be carried out according to the following indicators:

- increasing production standards;
- reduction in the number of defective products;
- reduction of labor intensity;
- increased productivity;
- reduction of time for completing work, projects (for engineering and technical personnel), optimization of processes, etc.

5. Satisfaction of the management of the trainees. Just as in the previous criterion, the manager evaluates the results of the training of his employees after a certain period of time, established for this training. The results of the manager's assessment are then compared with the corresponding results of the employee's assessment of the training, and based on this analysis, conclusions are made about the effectiveness of the training received.

6. The impact of the trained employee on the organization. To meet this criterion, it is proposed to use the following methods:

- Conduct an assessment by the immediate supervisor of the practical value of the knowledge obtained by the employee who has undergone training for his/her structural unit. - The employee who has

undergone training submits proposals for improving the activities of the unit(s) taking into account the knowledge obtained. The proposal submitted by the employee is reviewed by management and its effectiveness is assessed.

− The HR department, together with the manager, develops a task to solve the problems of the department (enterprise) in accordance with the focus of the training. A specific deadline is set for completion, and then the completed task is assessed. Having analyzed the data obtained, conclusions can be drawn about the impact of the employee who has undergone training on the organization.

7. Methods for monitoring (controlling) the learning process. Assessment results

At the final stage, all data is analyzed and conclusions are made about the effectiveness of the training conducted. The following methodology can be used to conduct the results of the employee training assessment and the clarity of their presentation.

1. Conduct an assessment of the student for each criterion and obtain the effectiveness in percentage. Examples of criteria:

- satisfaction of the employee who has completed the training – based on the analysis of training evaluation questionnaires completed by the employees who have completed the training;

- acquisition of knowledge, skills and qualities by students (training participants submit reports and exams);

- the effectiveness (efficiency) of the trainee in the workplace - such indicators as the fulfillment of production standards, the reduction in the proportion of defects, the productivity of the trainee before and after training (in production) are measured;

- satisfaction of the trainee's management – based on the analysis of the questionnaire of the heads of departments of employees who have completed the training.

2. Assign weight to each criterion (weight is the degree of significance of the criterion for the enterprise). To determine the weight of the criterion, the paired comparison method can be used.

3. Calculate the overall performance obtained taking into account the weights.

4. Calculate the effectiveness of training for this employee:

Efficiency = overall employee performance / training costs.

Report on the assessment of the effectiveness of training and assessment of the quality of the training process.

The evaluation process shall include data collection and report preparation (ISO 10015:1999, 4.5.2). "The evaluation report may include the following:

- specification of training needs;

- evaluation criteria and description of sources, methods and evaluation schedule;

- analysis of collected data and interpretation of results;

- analysis of training costs;

- conclusions and recommendations for improvement."

It is also necessary to conduct an assessment of the quality of the training process. For this purpose, a detailed feedback questionnaire can be used, which would contain both an assessment of the quality of teaching and an assessment of the organization of training. Based on the results of the assessment, the HR department of the enterprise (organization) should develop corrective and preventive actions.

The organization must have the following documents:

A. Requirements for the qualifications of personnel performing work affecting product quality. They are set out in job and work instructions. Brief summary of the requirements:

- necessary education;

- work experience in the specialty or in a similar position in a related field;

- additional requirements (visual acuity, absence of certain diseases, medical indications, physical and psychological capabilities of a person, color perception, etc.);

- special requirements (knowledge of languages, computers, mathematics, access to electrical installation work, driver's license, etc.). B. Appointment orders:

- those responsible for the development and approval of training programs; - those responsible for conducting training;

- composition of certification and qualification commissions. Awareness of personnel.

The next requirement of clause 6.2.2 is mandatory awareness of personnel about the necessity and importance of their activities. In addition, personnel must know how they contribute to the achievement of quality objectives.

One possible way to meet this requirement is to detail quality objectives, starting from the strategic level and ending with the operational level. The top management develops the organization's strategic quality objectives, formalizes and approves them, indicating those responsible and other necessary information. Then, based on the strategic objectives, the structural divisions set tactical quality objectives that must be achieved in the course of their activities. In a similar manner, the objectives of specific employees at the operational level are developed, documented and approved.

Maintaining records of personnel competence

The organization must store records of education, training, skills and experience of personnel in a convenient form for quick access to information and in complete safety. The most convenient way to do this is to use the technology of maintaining

personal files of employees, which contain the following documents:

- copies of orders on the movement of the contingent of workers;
- copies of educational documents;
- copies of orders on incentives and penalties;
- copies of documents on basic education and all advanced training courses, internships; - documents on the certification of employees, etc.

The collection and storage of this data can also be organized differently: by creating the necessary databases, personal and accounting cards, etc.

2. Infrastructure and production environment

Definition of terms

As noted, the content of the term "resources" is given in ISO 9004:2015. As for the terms "infrastructure" and "production environment", they are disclosed in ISO 9000:2015 and mean the following:

infrastructure – a set of structures, equipment and support services necessary for the functioning of an organization;

production environment – a set of conditions under which activities are carried out.

Requirements for infrastructure and production environment are contained in clauses 6.3 and 6.4 of ISO 9001:2015. Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, where appropriate:

a) buildings, workspace and associated work equipment;

b) equipment for production processes (both hardware and software);

c) support services (e.g. transport or communications).

When developing a quality management system, the organization's management should determine the infrastructure required for the product life cycle processes, taking into account the needs and expectations of consumers and interested parties. Infrastructure includes resources such as production facilities, workspace, tools and equipment, support services, information and communication technologies, and transport vehicles. Also, all types of activities that can be attributed to auxiliary (supporting) processes can be considered as necessary resources, such as: planning and financial support, material and technical support, accounting and control processes, and others, depending on the specifics of the organization's activities.

To meet the infrastructure requirements of the standard, the organization must first determine what will be needed to achieve product compliance with the established requirements. Needs may include such resources as workspace (work location), equipment (including new technologies), communications (information support), and transport units. This may also include services that perform scheduled preventive maintenance and equipment servicing. In addition, the organization may consider environmental aspects that are important to its specific production, such as the need to organize the reuse of raw materials or waste disposal.

The organization, by analyzing corrective or preventive action information, nonconformity reports, and audit results, must determine exactly what resources are needed to successfully implement improvement actions.

In addition, it should also be customer-focused in determining the resources needed to handle complaints and claims, implement monitoring and testing, fulfill warranty obligations and analyze consumer opinions.

Customer perceptions (satisfaction or dissatisfaction) are considered as indicators of the functioning of the quality management system. Therefore, the organization must ensure that sufficient resources are available to carry out these activities. For example, if the required number of employees are not allocated to handle customer complaints and to take appropriate corrective actions, this may result in loss of customers.

3. Requirements for the production environment

Requirements for the production environment are set out in clause 6.4 of ISO 9001:2015.

Production environment

The organization shall create and manage the work environment needed to achieve conformity to product requirements.

The provisions of this subsection apply to both human and physical factors that may influence the conformity of products to requirements. As before, the organization must decide which of the factors listed are important for ensuring the conformity of the product or service to requirements and how these factors should be managed in terms of resources. Such factors may include: safety regulations, protective equipment (hearing and vision), ergonomic factors, location of workplaces, temperature, humidity, lighting, pollution, noise, gas emission, etc. They may also include intangible factors: methods for increasing the creative output and interest of employees in the company's affairs, personnel incentive programs.

ISO 9004:2015 states that “creating a suitable work environment – a combination of human and physical factors – includes considerations for:

- methods of creative work and opportunities for more complete involvement with safety regulations and guidelines, including ergonomics;
- placement of workplaces;
- social interaction;
- means of servicing personnel in the organization;
- heat, humidity, lighting, air extraction;
- sanitary conditions, cleanliness, noise, vibration and pollution."

When checking the functioning of the processes described in the organization according to the requirements

Clause 6.4 of ISO 9001:2015, employees of the organization must answer the following questions:

- Can the company provide examples of the preparation of the production environment necessary to ensure that the product meets the established requirements?

- What is required for the product creation process to ensure that the established requirements are achieved?

- Are these environmental conditions safe? Are they appropriate for the process you are going to perform?

- Does the organization pay attention to the requirements of this section of the standard?

- What methods does the organization use to increase staff participation in solving such problems as industrial safety, cleanliness, participation in various internal competitions, and in improving recognition mechanisms?

Although the requirements of subclause 6.4 do not directly indicate the involvement of top management in their implementation, subclause 4.1, paragraphs 5.4.2 and 5.6.3 require top management to take direct part in ensuring that the quality management system meets these requirements. In addition, it is desirable for management to ensure that the quality management system also adequately controls all those resources that are not directly specified in the text of the standard.

It should be noted that ISO 9004:2015 provides many recommendations on how to meet the requirements of ISO 9001:2015. However, it should be borne in mind that the purpose of ISO 9004:2015 is only to suggest directions for action, and it cannot be used as a guide for the application of ISO 9001:2015.

When implementing the requirements of Section 6 of ISO 9001:2015, the organization should:

- identify and define the resources needed to support the quality management system. Ensure that top management is involved in the discussion of this issue;

- include discussion of issues of resources required for customer satisfaction and continual improvement in quality planning activities and management review;

- when planning and allocating resources, take into account all the parameters of the types of activity (time, number of people, wages, skills, outsourcing of part of the work to third parties, equipment, materials, information, processes) to ensure the availability of all the resources necessary for their implementation. Proper planning will guarantee the implementation of the necessary work, both in the short term and in the long term;

- take into account the links with other sections of the standard, the implementation of the requirements of which also requires resources. This is necessary to ensure that adequate resources are available and used when implementing all the requirements of the standard;

- ensure that scheduled preventive maintenance and transport services are carried out at the proper level;

- think about resources in advance, taking into account the future, for example, what will be required to successfully deliver products to consumers in connection with the creation of a new production;

– be flexible. Since this section of ISO 9001:2015 does not contain rigid procedural requirements, an organization can be flexible in applying the requirements of section 6 within its quality management system.

The organization should have a clear resource planning process in place to ensure that adequate resources are allocated and managed effectively for improvements to customer satisfaction. The organization should be able to demonstrate that its quality management system meets the requirements of ISO 9001:2015 and provide objective evidence of resource planning activities, as well as process and customer satisfaction measurement reports. Because resource references are found throughout the standard, the organization should think about them from a business perspective rather than simply acting on the assumption that "we just need to satisfy requirements." By taking resource planning to a high level, the organization's management has the opportunity to significantly improve the benefits of its quality management system.

Table 4. Additional provisions of ISO 9001:2015 concerning resource management

Chapter MS ISO 9001:2015	Contents related to resource management
4.1	The organization shall ensure that the resources and information necessary for the implementation of processes and their monitoring are available (including the process monitoring activities specified in clause 8)

5.1	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness through … provision of resources
5.4.1	Top management shall ensure that quality objectives, including those needed to meet product requirements, are established for appropriate functions and levels of the organization. Subclause 6.2.2 requires that personnel are aware of how they contribute to the achievement of quality objectives.
5.4.2	Planning shall be undertaken to meet the requirements of Section 4.1 regarding the allocation of resources necessary to ensure the operation and monitoring of processes.
5.6.3	Outputs for management review should include all decisions and actions related to improvement, including… resource requirements
7.1	When planning the creation of a product, an organization must determine in a form convenient for it the resources that need to be allocated for a specific product.

Contents related to resource management

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5.4.2 Planning shall be undertaken to meet the requirements of Section 4.1 regarding the allocation of resources necessary to ensure the operation and monitoring of processes.

5.6.3 The output for management review should include all decisions and actions related toimprovement, including… resource needs

7.1 When planning the creation of a product, an organization must determine in a form convenient for it the resources that need to be allocated for a specific product..

5.7. Product life cycle processes

This clause contains the main requirement – to plan the processes of the product life cycle. Process planning assumes that they must comply with the established requirements, established goals of the organization. Also, when planning processes, it is necessary to organize the activities of verification and validation, monitoring, control and testing for specific products, as well as product acceptance criteria, and to maintain records confirming the fulfillment of requirements in manufactured products. The document defining the processes of the quality management system can be called a quality plan, a quality program, or have another name. In June 2005, the second edition of the ISO 10005:2005 standard “Quality management systems. Guidelines for quality plans” was published. This edition replaced and canceled the 1995 edition. This standard describes in detail the recommendations on the content of the quality plan, the input data for its preparation, etc.

7. Product life cycle processes

7.1. Planning of product life cycle processes

The organization shall plan and develop the processes needed to ensure the product life cycle. Planning of product life cycle processes shall be consistent with the requirements for other quality management system processes.

When planning product life cycle processes, the organization shall establish, as appropriate, the following:

a) quality objectives and product requirements;

b) the need to develop processes, documents, and provide resources for specific products;

c) the necessary activities for verification and validation, monitoring, control and

testing for specific products, as well as product acceptance criteria;

d) records necessary to provide evidence that product realization processes and manufactured products meet requirements.

The result of this planning should be in a form consistent with the practice of the organization.

Evidence that planning has been carried out and is aimed at conducting controlled execution of processes may include:

- defining the project objectives, as well as the measurements that need to be carried out within the project to track their implementation;
- identification and planning of activities for the development, manufacture and shipment of products;
- determination of the need for documented instructions;
- ensuring the required working conditions;
- formal approval and monitoring of processes;
- establishing acceptance criteria;
- determining the required quality records.

Implementation of the QMS involves the following actions:

1. Manage the process based on the quality plan.

2. Establish critical control points.
3. Identify factors influencing the management of key processes.
4. Identify product requirements (specifications, applicable standards, regulatory requirements, acceptance criteria).
5. Analyze existing monitoring technology.
6. Develop review and approval procedures.
7. Develop job and work instructions.
8. Develop procedures for calibration and maintenance of measuring and control equipment.
9. Identify special processes.
10. Establish a recording system to ensure that the results obtained are accurate.

7.2. Consumer-related processes

7.2.1. Determination of requirements related to the product The organization shall determine:

a) requirements established by customers, including requirements for delivery and post-delivery activities;

b) requirements not specified by the consumer, but necessary for a specific or

intended use, when known;

c) statutory and mandatory requirements relating to the product;

d) any additional requirements specified by the organization.

7.2.2 Analysis of product related requirements.

The organization shall review requirements related to the product. This review shall be carried out before the organization makes a commitment to supply the product to the customer (e.g. participation in tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements have been defined;

b) the requirements of the contract or order, which differ from those previously formulated, have been agreed upon;

c) the organization was able to meet certain requirements.

Records of the results of the analysis and subsequent actions resulting from the analysis shall be maintained.

Where customers do not provide documented requirements, the organization shall confirm these before acceptance.

When product requirements are changed, the organization shall ensure that relevant documents are corrected and that interested personnel are informed of the changed requirements.

In some situations, such as Internet sales, it is impractical to conduct a formal analysis of each order. Instead, the analysis may be extended to relevant product information, such as catalogs or advertising materials.

7.2.3 Communication with consumers

The organization shall determine and implement effective measures to maintain communication with customers regarding:

a) product information;

b) processing of requests, contracts or orders, including amendments;

c) feedback from consumers, including consumer complaints.

The organization must meet the consumer requirements for the product. To do this, the organization must meet all the requirements established in legislative and other regulatory acts (Laws of the Russian Federation, GOSTs, OSTs, etc.); consumer requirements (for this, their requirements should be studied); product requirements identified as a result of analyzing market development trends and future needs, as well as additional requirements that the organization can implement in its products.

Implementation of the QMS involves the following actions:

1. Documenting customer requirements.
2. Identification of pre-contractual activities.
3. Establishing a contract review procedure.
4. Checking the possibility of satisfying the stated requirements of consumers.
5. Understanding consumer requirements and resolving contradictions in their understanding.
6. Control of purchase orders within the framework of a single contract with a consumer.
7. Establishing a procedure for analyzing purchase orders.
8. Coordination of all issues with the consumer.
9. Implementation and improvement of procedures.
10. Evaluation of the results obtained.

All requirements must be documented. Documentation of requirements is necessary for:

- the ability to verify that all requirements are met;
- resolving issues of disagreement with the consumer;
- obtaining objective data on the degree of fulfillment of established consumer requirements;
- accumulation of information for analyzing the progress of work on fulfilling orders and making decisions on continuous improvement of the organization's activities.

The organization must describe the actions (procedures, instructions) for concluding a contract with the consumer and determine the form of the contract, which contains a list of the main requirements. This will allow fulfilling the condition of coordinating the requirements of consumers and resolving contradictions with the customer.

Before accepting contractual obligations, the organization must conduct an analysis of requirements related to the product. The organization must conduct an analysis of identified consumer requirements and other requirements, both previously established and

additionally defined, but in accordance with the capabilities of the organization. The conducted analysis of product requirements must be documented in the records of the quality management system. Work on the production of products must be carried out in the organization only after all requirements have been agreed upon, which is confirmed by signing a contract. Changes in product requirements must also be documented and agreed upon, and also communicated to personnel.

When analyzing a contract, you should pay attention to the following points:

- completeness of the initial data;
- fulfillment of accepted obligations;
- price and terms of delivery;
- volume of work;
- calendar plan;
- payment schedule for work;
- technical requirements;
- requirements for acceptance of work;
- guarantees and support;
- intellectual property rights;
- dispute resolution procedure;
- compliance with current legislation;
- links to specifications;
- delivery data (timeframes, methods of product transfer, product identification);
- responsibility for non-conforming products; - quality control;
- contract analysis;
- resolution of contradictions;
- a list of services, including cost and work criteria.

The organization should define procedures for maintaining communication with customers in order to identify requirements and meet them. This procedure should include actions to obtain initial information from customers, to rank these requirements, and to conduct an analysis to determine their importance. The following methods are used to identify initial information on customer requirements:

- direct survey,
- the technique of repertory grids,
- technique for extracting arbitrary (spontaneous) characteristics,
- group discussion (focus groups),
- "in-depth interview"
- "thinking out loud"
- monitoring the use of products by consumers,
- double poll.

The main methods of classification and assessment of the significance of consumer requirements:

- for the classification of qualitative features – the Kano model, “seven new quality tools”;
- direct methods for assessing the significance of characteristics – simple ranking, simple paired comparison, constant sum distribution method, rating assignment method;
- indirect methods for assessing the significance of characteristics – regression analysis, various forms of decomposition analysis, multidimensional scaling.

7.3. Design and development

7.3.1. Design and Development Planning

The organization shall plan and control the design and development of products.

During design and development planning, the organization shall establish:

a) design and development stages;

b) conducting analysis, verification and validation corresponding to each stage

design and development;

c) responsibility and authority in the field of design and development.

The organization must manage the interactions between the various groups involved in design and development to ensure effective communication and clear assignment of responsibilities.

The planning results should be updated, where appropriate, as the design and development progresses.

Usually, design and development are described in organizations as a separate process related to the product life cycle processes, especially since this is a requirement of this section of the standard. This means that the actions (stages, steps) of the process must be defined; resources and the necessary qualified personnel for its implementation must be allocated; responsibility and authority for the implementation of the process actions must be assigned; the relationships between the various groups of the development team and the specialists of the structural divisions (possibly external organizations) must be defined; communications between them must be established; plans must be updated as the project develops. Updating the design and development plans means that all changes must be properly formalized and approved.

This clause also requires analysis, verification and validation of each stage of development. These are new terms for Russian organizations, meaning the following (according to ISO 9000:2015):

Verification is confirmation through the provision of objective evidence that specified requirements have been met;

Validation is confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

7.3.2. Input data for design and development

Input data related to product requirements shall be defined and records maintained. These data shall include:

a) functional and operational requirements;

b) relevant statutory and mandatory requirements;

c) where appropriate, information taken from previous similar

projects;

d) other requirements important for design and development.

These inputs must be analyzed for adequacy. Requirements must be complete, unambiguous, and consistent.

Defining input data for design and development means:

- documents defining the work assignment have been drawn up;
- documents defining the requirements for the system have been drawn up;
- an analysis of the adequacy of the requirements was carried out;
- issues related to ambiguity, unrealistic or contradictory requirements have been resolved;
- product acceptance criteria have been established;
- the requirements of supervisory authorities have been taken into account;
- technical and operating characteristics are defined; safety requirements have been established.

7.3.3. Design and Development Outputs

Design and development outputs shall be presented in a form that allows verification against the design and development input requirements and shall be approved before release.

Design and development outputs must:

a) meet the input requirements for design and development;

b) provide relevant information on procurement, production and maintenance;

c) contain product acceptance criteria or references to them;

d) determine the characteristics of the product that are essential for its safe and correct use.

Defining design outputs means:

- all established requirements for the product correspond to the output data, which allows for their verification;
- the output data must contain everything necessary to provide information on procurement, production and maintenance, corresponding to the established requirements for the characteristics and quality of the products;
- product acceptance criteria have been formulated and established;
- the characteristics of the product that are essential for its safe and correct use have been determined.

This section of the standard sets requirements for conducting a systematic analysis of the design and development process. The analysis is conducted according to the planned project activities, as well as when any problems arise during the design and development or proposals arise. The project analysis is conducted to assess whether the results obtained during the design and development meet the established requirements and are suitable for their further application.

7.3.4. Project and development analysis

At appropriate stages, a systematic review of the design and development shall be carried out in accordance with the planned activities with the aim of:

a) assessing the ability of design and development results to meet requirements;

b) identifying any problems and making proposals for necessary actions.

Participants in such reviews shall include representatives of departments related to the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5. Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs meet the design and development input requirements. Records of verification results and any necessary actions shall be maintained.

7.3.6. Design and development validation

Design and development validation shall be carried out in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified use or for its intended use, where known. Where practicable, validation shall be completed before delivery or use of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7. Managing Design and Development Changes

Design and development changes shall be identified and records maintained. Changes shall be reviewed, verified and validated as appropriate, and agreed upon prior to implementation. Review of design and development changes shall include an assessment of the impact of the changes on constituent parts and on products already delivered.

Records of the results of the change analysis and any necessary actions shall be maintained.

Not only the project team members but also representatives of those structural units that are interested in the results of the decisions taken should participate in the analysis. The results of the analysis are documented and stored in the relevant units of the organization.

Conducting verification of design and development is a mandatory requirement of the standard. Verification is carried out on the basis of alternative calculations, comparison with similar projects, computer modeling, qualification tests of samples, and analysis of documents.

Validation is the process of analyzing sufficient evidence that the product is ready for use. Validation consists of two stages.

1 stage: the design team plans the time for design validation before starting workand also

develops regulations for actions to check the quality of the design solution in real conditions.

2 stage: specific tests (or other similar actions) are carried out with documentary confirmation of the test results. The second stage can take place with or without the direct participation of designers.

The results of analysis, verification and validation of design and development often lead to the need for changes in the project. All changes to the project must be documented and identified. Changes must be agreed upon and approved. Before approval, an analysis of the impact of changes on components or already delivered products must be carried out.

Procurement

7.4.1. Procurement process

The organization shall ensure that purchased product conforms to the requirements established for purchasing. The type and extent of control applied to the supplier and purchased product shall depend on its impact on subsequent stages of the product life cycle or the finished product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the evaluation results and any necessary actions resulting from the evaluation shall be maintained. 7.4.2. Purchasing information

Purchasing information should describe the products ordered, including, where appropriate:

a) requirements for approval of products, procedures, processes and equipment;

b) requirements for personnel qualifications;

c) requirements for the quality management system.

The organization shall ensure that the established purchasing requirements are adequate before they are communicated to the supplier.

7.4.3. Verification of purchased products

The organization shall establish and implement controls or other activities necessary to ensure that purchased products meet established purchasing requirements.

If the organization or its customer intends to carry out verification at the supplier's facility, the organization shall establish in the purchasing information the intended verification measures and the method of release of the product at the supplier's facility.

The organization should develop a procedure, the main purpose of which is to ensure confidence that the products and services of suppliers meet its requirements and the requirements established for purchases. The procedure should determine the importance of each of the purchased materials depending on the degree of their influence on the quality of the manufactured products. This means that the organization should develop evaluation criteria for each type of purchased product for the evaluation and selection of the supplier. The most important criteria should be those that affect the quality of the manufactured products and the ability to meet all the established requirements of the organization. The requirements of the standard establish that the organization should also conduct a repeated evaluation of the supplier, which is carried out after the beginning of the relationship for the supply of products. The results of the evaluation and selection of suppliers must be documented, stored in accordance with the rules established in the organization, and subsequently used for analysis and decision-making with respect to suppliers.

To carry out procurement, a supplier classification system should be established:

- create a list of real and potential suppliers;

- determine the required degree of supplier control, taking into account the type of product supplied, the impact on the quality of the final product, and the results of previous quality audits;

- include suppliers of raw materials, tools, equipment, services, etc. in the list of approved suppliers.

The organization should plan work with suppliers, coordinate incoming inspection, establish and maintain a system of records regarding the suppliers' quality assurance capabilities. The organization should also establish procedures for exchanging information with suppliers, create and store the results of periodic reviews of supplier performance, purchase contracts, and purchase data reviews and approvals.

7.5. Production and maintenance

7.5.1. Production and maintenance management

The organization shall plan and ensure production and service provision under controlled conditions. Controlled conditions shall include, as appropriate:

a) availability of information describing the characteristics of the product;

b) availability of work instructions if necessary;

c) use of suitable equipment;

d) the presence and use of devices for monitoring and measurements;

d) monitoring and measurements;

e) implementation of release, delivery and post-delivery activities of products.

The requirements of this section of the standard require the organization to plan production and service processes and control their implementation. Production processes must be described in the relevant documents (regulations, instructions). The processes are designed based on specific customer requirements describing the characteristics of the product. When planning production processes, the use of suitable equipment, requirements for the availability and use of monitoring and measurement devices, and

monitoring and measurement procedures must be determined.

It is also necessary to document the service requirements as a procedure and provide controls over the planned process to ensure that the customer's service requirements are met.

7.5.2. Validation of production and service processes

The organization shall validate all processes for production and service provision whose results cannot be verified through subsequent monitoring or measurement. This includes all processes in which deficiencies become apparent only after the product has been put into use or the service has been delivered.

Validation should demonstrate the ability of these processes to achieve their intended results.

The organization shall establish arrangements for these processes, including, as appropriate: a) defined criteria for review and approval of processes;

b) approval of relevant equipment and personnel qualifications;

c) the use of specific methods and procedures;

d) requirements for records;

d) re-validation.

The first paragraph of this clause deals with special processes whose results cannot be verified by control, but only by destruction of the product. The organization must establish all possible control methods for these processes, but the main emphasis should be on control of the process actions and the level of qualification of workers. When planning such processes, it is necessary to identify all process characteristics that can affect the ability of the product (service) to meet customer requirements; ensure that all equipment requirements are identified and the equipment and premises meet these requirements. In the process of execution, check that the requirements for the operation of each element of the product are verified.

7.5.3. Identification and traceability

Where appropriate, the organization shall identify the product by appropriate means at all stages of its life cycle.

The organization shall identify the status of product with respect to monitoring and measurement requirements.

If traceability is a requirement, the organization shall manage and record the unique identification of the product.

In a number of industries, configuration management is the means by which identification and traceability are maintained.

Identification is the ability to distinguish individual components or products, and traceability is the ability to trace the history of the development and assembly of a product (or its components) at any stage of the life cycle. Identification and traceability of design documents and products/systems developed during a project are implemented and supported by a project configuration management system.

Configuration management includes identification of development products, controlled changes to configuration items, building products/systems only from configuration items, maintaining the integrity of approved items and products, traceability of the current state and history of configuration item management.

The identification process within the configuration management system ensures that each configuration item (single configuration management element) is assigned unique identifiers and corresponding technical data. The product status is maintained up to date at all stages of the project life cycle, and change requests are traceable until they are closed.

The implementation of identification and traceability requirements depends on the specifics of the process being described. For the industrial sector, this is the assignment of numbers, symbols, and accompanying documentation for batches or individual units of products, both compliant and non-compliant, which must be separated from each other.

For the non-production sector, this can be implemented as:

- assignment of numbers or other symbols to documents containing information about the order, the service provided, as well as information transferred (sold) to the consumer;

- details of financial documents, projects, technical specifications for the development and transfer of scientific, technical, analytical, audit and other information;

- maintaining a nomenclature of cases, document archives, systematic transfer of the ordered service (product/document) to the client, creation of an electronic database, etc.;

- marks on documents or document details about their status – “current”, “draft document”, “control copy”, “unaccounted copy”, “accounted copy No.”, “draft”, “cancelled”, etc.

7.5.4. Consumer property

The organization shall exercise care with respect to customer property while it is under the organization's control or in use. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If customer property is lost, damaged or found to be unsuitable for use, the customer shall be notified and records shall be maintained. Customer property may include intellectual property. This clause addresses the identification, verification, protection and safeguarding of property, equipment, instruments and other customer property provided for use or incorporation into the product.

Examples of customer property include utility programs; customer logos or packaging provided for the product; printed instructions or accessories for

inclusion in the packaging; testing and measuring equipment provided for product inspection; service (delivery services), product manufactured by the organization on a tolling basis; provision by the customer to the supplier of intellectual property: license, patent, right to affix a trademark, etc. In order to manage customer property, the organization must:

- determine and identify the presence of property belonging to the consumer, including test equipment, intellectual property and confidential information;

- establish processes for checking, storing and maintaining this property; - audit and improve procedures; - evaluate the results of the audit.

7.5.5. Maintaining product conformity

The organization shall preserve the conformity of product during internal processing and during delivery to its destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the component parts of the product. During the manufacture of product, there are often transport operations between processing areas and to the point of delivery of finished product, intermediate storage of component parts of the product and final storage of finished product. The organization shall determine the critical points in the process, analyse the potential for damage to component parts or finished product during transport and storage and document the transport and storage procedures. Storage and transport may be a separate process or may be included as an integral part of the work performed in the manufacture of the product. 7.6. Control of monitoring and measuring devices. The organization shall determine the monitoring and measurement to be performed and the monitoring and measuring devices needed to provide evidence of conformity of product to specified requirements.

The organization shall establish processes to ensure that monitoring and measurement can be and are carried out in a manner consistent with the monitoring and measurement requirements.

Where it is necessary to ensure valid results, measuring equipment should be:

a) calibrated or verified at specified intervals or before its use according to

reference standards that convey the dimensions of units in comparison with international or national standards. In the absence of such standards, the basis used for calibration or verification must be registered;

b) adjusted or re-adjusted as necessary;

c) identified for the purpose of establishing calibration status;

d) protected against adjustments that would invalidate the measurement results;

d) protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall evaluate and record the validity of previous measurement results if equipment is found to be non-conforming to requirements. The organization shall take appropriate action with respect to such equipment and any product measured. Records of calibration and verification results shall be maintained. If computer software is used in monitoring and measuring specified requirements, its ability to satisfy the intended application shall be confirmed. This shall be done prior to use and reconfirmed as necessary.

This section of the standard provides for a set of actions to implement the requirements for managing monitoring and measurement devices. To do this, the organization must:

- determine the requirements for control and testing (what measurements need to be performed) and the requirements for measurement accuracy;

- identify the equipment and software products used to conduct inspections and tests: laboratory and testing equipment; production equipment; assembly fixtures, forms; test programs;

- establish requirements for calibration and verification procedures for each unit of equipment: measurement range, measurement error, calibration schedules;

− analyze and present in the form of flow charts the procedures and documentation for conducting the necessary measurements; performing calibration; determining the measurement error; identifying the calibration status; performing actions outside of calibration; handling and storing monitoring and measuring devices; determining intercalibration intervals; protecting against unauthorized interference.

ISO 10012 presents requirements for procedures for working with measuring and control equipment, while ISO 9001:2000 regulates actions with products released during the period when measuring instruments lose their metrological suitability.

Measurement, analysis and improvement

Subsection 8.1 provides a set of actions for defining, planning and applying monitoring and measurement. Implementation of the quality management system implies the following actions: defining, planning and implementing monitoring and measurement of customer satisfaction, quality management system processes and products, internal audits, control of nonconforming products, data analysis, continuous improvement, corrective actions, preventive actions.

8. Measurement, analysis and improvement

8.1 General Provisions

The organization shall plan and implement monitoring, measurement, analysis and improvement processes as necessary to:

a) demonstrate product conformity;

b) ensure compliance of the quality management system;

c) continuously improve the effectiveness of the quality management system.

This should include identification of applicable methods, including statistical ones, and the scope of their use.

The processes of measurement, analysis and improvement are included as a separate block in the process model of the quality management system. The main difference between the quality management system and traditional management systems is that the QMS implements a large number of different measurements and data collection, on the basis of which regular analysis is carried out at all management levels and then management decisions are made. The results obtained during the implementation of the processes of measurement, analysis and improvement should ensure: compliance of the product with the established requirements of consumers and interested parties; compliance of the quality management system with the requirements of this international standard and increased efficiency of the QMS.

Effectiveness of a quality management system is the degree to which the policy is implemented and quality objectives are achieved, including meeting customer needs and expectations, through planned activities and planned results.

In other words, a QMS is effective if the organization has implemented its quality policy and achieved its quality objectives, including those related to customer satisfaction, through planned and implemented activities and achieved planned results.

Increasing the effectiveness of the QMS means constantly setting higher and higher quality goals and creating the necessary conditions for achieving them. That is, if during the functioning of the QMS the management of the organization, based on the quality policy, constantly sets higher and higher goals for the team, and the QMS ensures the achievement of these goals, then this is proof that the effectiveness of the QMS has been constantly growing.

It is worth noting some inconsistencies contained in the standards. The definition of effectiveness requires ensuring a degree, but what degree is not specified. It is possible to ensure the achievement of only a given degree, and one set only by the enterprise. Thus, having ensured a given (by the enterprise) degree of achievement (implementation), and not necessarily 100%, but, for example, 10%, the enterprise can claim that the requirements for the effectiveness of processes and the effectiveness of the QMS have been met. Monitoring and measurement

Customer satisfaction. The organization shall monitor information concerning customer perception of the organization's compliance with customer requirements as one of the ways of measuring the functioning of the quality management system. Methods for obtaining and using this information shall be established. Clause 8.2.1 provides for a set of actions to ensure customer satisfaction and to search for and use information reflecting the degree of customer satisfaction. Implementation of these requirements of the standard implies the following actions:

1. Establish procedures for collecting, analyzing, and responding to consumer-related information.
2. Conduct customer satisfaction measurements and improve the organization's performance based on this.
3. Continuously search for additional sources of information on customer satisfaction.
4. Assess the feasibility of conducting consumer satisfaction analysis and interviews with consumers.

Evaluation of data allows the manager to make decisions based on facts. In this case, the object of the study is the opinion of consumers. The efficiency of the organization and its current position will depend on how the organization meets the needs and expectations of consumers. Evaluation of consumer satisfaction will allow to answer the question not only about the competitiveness of the product, but also the organization itself. Therefore, the purpose of consumer evaluation is to obtain and analyze information for making decisions aimed at satisfying the requirements and requests of consumers.

To achieve this goal, the developers of the procedure will have to solve the following tasks:

- identification of sources of information;
- determination of methods for obtaining information;
- definition of measurement criteria;
- collection of information;
- selection and use of information processing methods;
- analysis of measurement results;
- documenting and presenting research results to senior management.

In addition to conducting consumer satisfaction surveys, especially at Russian enterprises, there is another source of obtaining information on the level of satisfaction (or rather dissatisfaction). These are various types of complaints, letters of claim and, finally, consumer complaints. When working with consumer complaints, you can use the methodology contained in GOST R ISO 10002:2004 "Quality management. Customer satisfaction. Guidelines for handling complaints in organizations." This standard presents the best international practice of handling complaints. The approach set out in the standard creates conditions for improving interaction and its consumers by establishing feedback with consumers and ensuring confidence that complaints are studied and effective measures are taken on them.

According to GOST R ISO 10002:2004, a complaint is understood as an expression of dissatisfaction by a consumer with the actions of an organization, the products manufactured or the

services provided, as well as the process of handling a complaint.

In order to effectively handle complaints, GOST R ISO 10002:2004 recommends following the following principles:

- visibility – information about how and where to file a complaint should be communicated in a timely manner to consumers, staff and other interested parties;

- accessibility – the complaints process should be easily accessible to all complainants;

- availability of feedback – each complainant must be immediately informed of its receipt;

- objectivity - each complainant must be ensured fair, objective and impartial treatment during the complaint review process;

- expenses – no fee should be charged to the complainant for filing and reviewing the complaint;

- confidentiality - information about the complainant, provided if necessary, should be used only for the purpose of examining the complaint within the organization and should under no circumstances be disclosed unless the consumer or complainant consents to its disclosure;

- a customer-focused approach – the organization must be open to feedback, including complaints, and demonstrate its commitment to addressing complaints through its actions;

- responsibility - the organization must demonstrate clear responsibility for reviewing complaints and preparing reports on the results of the review and decisions taken;

- continuous improvement - the organization's ongoing goals should be to continuously improve the complaint handling process and improve product quality.

In accordance with the recommendations of the standard, a documented procedure is developed that establishes the procedure for handling consumer complaints.

Internal audits (inspections)

The organization shall conduct internal audits (checks) at planned intervals to determine whether the quality management system:

a) complies with planned activities, the requirements of this international standard and the requirements for the quality management system developed by the organization;

b) effectively implemented and maintained in working order.

The audit (check) program should be planned taking into account the status and importance of the processes and areas to be audited, as well as the results of previous audits. The criteria, scope, frequency and methods of audits should be defined. The selection of auditors and the conduct of audits should ensure the objectivity and impartiality of the audit process. Auditors should not audit their own work.

Responsibilities and requirements for planning and conducting audits, reporting results and maintaining records shall be defined in a documented procedure.

The management responsible for the areas of activity being audited shall ensure that actions are taken without undue delay to eliminate the detected nonconformities and their causes. Follow-up actions shall include verification of the actions taken and reporting of the verification results.

This clause of the standard provides for a set of actions to check and evaluate activities in the field of quality for compliance with the requirements of the standard, as well as the requirements developed by the organization itself, and to demonstrate the effectiveness and efficiency of the QMS.

Implementation of the QMS involves the following actions:

1. Identify the actions that need to be verified.
2. Establish qualification requirements for audit personnel, including education, practical experience, training in the field of auditing, and experience in conducting it.
3. Develop or update the internal audit procedure, including audit planning, assignment of responsibilities, establishment of requirements for audit personnel, and preparation of an audit report.
4. Conduct a pilot audit: assess the adequacy of procedures; determine their effectiveness; check the consistency of actions provided for by different procedures; determine the compliance of the surrounding working conditions with the requirements for the implementation of processes.

Conducting internal audits of the organization's QMS is a specific requirement of ISO 9000 series, these actions are set out in ISO 19011:2002.

Internal audits are conducted in the organization's divisions at planned intervals in accordance with an audit plan drawn up for a year or another period of time. The audit plan includes:

- structural divisions in which internal audit will be conducted;

- sections of the ISO 9001:2015 standard, the functioning of which is checked in this structural unit;
- audit deadlines.

During the internal audit, the following is established:

- does the QMS comply with the planned requirements;

- whether the QMS operates effectively and is maintained in working order.

In accordance with the requirements of this section of the standard, the organization must develop a documented procedure regulating the procedure for conducting internal audits. The documented procedure establishes the procedure for:

- training of expert auditors;
- planning internal audits;
- conducting internal audits;

- preparation of audit reports;
- control over the development and implementation of corrective actions based on the results of deviations identified during the internal audit.

Internal audits must be conducted by trained and certified auditors. Requirements for the qualifications, experience and personal qualities of auditors must be established in a documented procedure. Often, internal auditors in an organization work in the structural divisions of the organization and are involved in conducting internal audits during planned periods. The organization must ensure that the requirement of the standard is met that internal auditors do not audit their own divisions.

The annual internal audit plan for the following year is usually prepared by the QMS management representative no later than December of the current year and approved by the head of the organization. The approved annual internal audit plan is sent by the QMS management representative to the heads of structural divisions no later than December 20 of the current year.

During the audit, expert auditors fill out an internal audit protocol. After conducting internal audits, a report is drawn up, which usually contains the following information:

- audit deadlines;
- audit object (audited QMS processes);
- units being inspected;
- audit criteria (documents regulating the process);
- audit team (including team leader or chief auditor, technical experts, etc.);
- goals and objectives of the audit;
- audit schedule;
- notification of discrepancies, etc.

After the audit, the heads of the structural divisions analyze the deviations identified during the audit, develop and implement corrective actions on them. Corrective actions are drawn up in two copies and sent to the chief expert auditor for approval and control of the elimination of the identified deviations.

The chief expert auditor monitors the implementation of the developed corrective actions within the established timeframes and, in the event of their violation, immediately reports to the representative of the management for the QMS. After the implementation and verification of the effectiveness of the corrective actions, the head of the structural unit reports this to the chief expert auditor, who organizes a repeat inspection. In this case, only the elimination of the detected deviation is checked. The fact of elimination is recorded by the chief expert auditor in the report and submitted for approval to the representative of the management for the QMS. Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where appropriate, measuring the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. If planned results are not achieved, corrections and corrective actions shall be taken to ensure conformity of product, where appropriate.

Let us consider the essence of the terms “measure” and “monitor” used in the text of the ISO 9000 series of standards.

Measure – verb – to determine or establish a spatial magnitude or quantity (of something); to determine or establish (a spatial magnitude or quantity) by applying some object of known size or volume or by comparison with some fixed unit of measurement. Monitor – verb – to watch, supervise, keep under observation, measure or check periodically, especially for the purpose of regulation or control.

Translations of these concepts from English-Russian dictionaries contain the following:

Measuring – measurement, control, gauging, measuring.

Monitoring – control, observation, tracking, current control.

Comparing the definitions from the Guide and dictionaries, it is easy to see that the latter have hidden important features of measurements and monitoring:

- "measurement" can be done in two ways: in some cases, quantity is determined by recalculation or comparison with a certain value adopted as a unit of measurement, in others - by calculation (for example, calculating the average value, the value of the range, the median, the dispersion, etc.). The latter actions are not, of course, measurement in its pure form, but the goals of the actions in both cases are the same: to determine the numerical value of the characteristic of interest;
- monitoring can also have two options: tracking (supervision, etc.) without measuring anything and tracking (supervision, etc.) with measurement.

The most suitable methods for monitoring and measuring QMS processes are presented in Table 5.5.

A process-event is the direct use of some process, during which actions have begun and continue to be carried out to transform what was the “input” into some final result – the “output”.

A process phenomenon is a process that is fully developed for use with its own set of characteristics identified by the process owner, which:

- are inherent to it, i.e. are an integral part of the process;
- are considered unchanged if the established procedure for conducting the process does not change;
- necessarily manifest themselves in the “process-event” – either explicitly (for example, the duration of the production cycle), or indirectly (for example, in the form of a spread of values of the parameter being studied, on the basis of which such a

characteristic of interest to the process owner as the dispersion of this parameter is calculated);

- have a calculated nature of determining their numerical value based on data on actual direct or indirect indicators in previous implementations "process-events";

- are of an average or probabilistic nature;

- the more accurately they are determined, the greater the number of cases of the implementation of "event processes" in the past was used for their calculation.

This clause provides for a set of actions aimed at confirming the conformity of products or services with the requirements at each stage of the product life cycle and at carrying out corrective actions and continuous improvement.

Implementation of the QMS involves the following actions:

1. Establish a separate plan or procedure for each of the followingprocesses: incoming control and testing, current control and testing, outgoing control and testing.
2. List all product parameters and characteristics that must be inspected and tested.
3. Ensure that procedures for identifying requirements are available.
4. Ensure that a full set of procedures are in place at inspection and testing sites.
5. Ensure identification of products for urgent shipment.
6. Ensure delivery of products only if test results are positive.
7. Review and improve procedures.
8. Evaluate the results of the audit.

Table 5. Methods and objectives of monitoring

Method		Target
1	Monitoring (without measurements) compliance with the established sequence of operations during the course of a "process-event"	Obtaining confirmation of the implementation of a specific "process-event" in accordance with the established requirements for the process to ensure confidence in achieving the expected results
2	Measurement during the course of the "event process" of the established parameters of impact during the implementation of operations and, if necessary, monitoring of the parameters of those impacts that are carried out over a significant period of time	The same
3	Measurement of established characteristics of the results of certain operations during the course of a "process-event"	The same
4	Measurement during the course of a "process-event" of primary process parameters (including, possibly, some or all of the parameters and characteristics specified in paragraphs 2 and 3) at specified intervals or in connection with specified events	Accumulation of information to obtain numerical values of the characteristics of the "process-phenomenon" at the points of the process analysis
5	Calculation at the points of the process analysis of the established internal characteristics of the "process-phenomenon" based on the information obtained in paragraph 4	Determination of the values of the inherent characteristics of the "process-phenomenon" to predict the results of "process-events". Comparison of the characteristics of a "process phenomenon" with target values to determine the effectiveness of relevant management measures, including process improvement actions
6	Monitoring of the relevant primary parameters and calculated characteristics of the "process-phenomenon" at the points of process analysis	Obtaining evidence of the stability of characteristics or determining the direction and "speed" of their changes in order to predict their values in the future

1. Monitoring (without measurements) compliance with the established sequence of operations during the course of a "process-event"

Obtaining confirmation of the implementation of a specific "process-event" in accordance with the established requirements for the process to ensure confidence in achieving the expected results.

2. Measurement during the course of the “event process” of the established parameters of impact during the implementation of operations and, if necessary, monitoring of the parameters of those impacts that are carried out over a significant period of time. The same.

3. Measurement of established characteristics of the results of certain operations during the course of a “process-event”. The same.

4. Measurement of the primary parameters of the process (including, possibly, some or all of the parameters and characteristics specified in paragraphs 2 and 3) during the course of a “process-event” at specified intervals or in connection with established events Accumulation of information to obtain numerical values of the characteristics of the “process-phenomenon” at the points where the process analysis is carried out.

5. Calculation at the points of the process analysis of the established internal characteristics of the “process-phenomenon” based on the information obtained in paragraph.

Determination of the values of the inherent characteristics of a “process-phenomenon” to predict the results of “process-events”.

Comparison of the characteristics of a "process - phenomenon" with target values to determine the effectiveness of relevant management measures, including process improvement actions.

6. Monitoring of the relevant primary parameters and calculated characteristics of the “process-phenomenon” at the points of process analysis Obtaining evidence of the stability of characteristics or determining the direction and “speed” of their changes in order to predict their values in the future.

Monitoring and measuring products

The organization shall monitor and measure product characteristics to verify that product requirements are met. This shall be done at appropriate stages of the product life cycle process in accordance with planned arrangements.

Evidence of compliance with acceptance criteria shall be maintained. Records shall indicate the person(s) who authorized release of the product.

The release of products and provision of services shall not proceed until all planned arrangements have been satisfactorily completed, unless otherwise approved by the relevant authority or, where applicable, the customer.

Management of nonconforming products

The organization shall ensure that product that does not conform to product requirements is identified and controlled to prevent unintended use or delivery. The controls, associated responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product in one or more of the following ways:

a) take action to eliminate the identified non-conformity;

b) authorize its use, release or acceptance if permission is available

deviation from the relevant authority and the consumer, where applicable;

c) take action to prevent its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected, it shall be re-verified to confirm conformity to requirements.

When nonconforming product is detected after delivery or use has begun, the organization shall take action appropriate to the consequences (or potential consequences) of the nonconformity.

This clause provides for a set of actions aimed at preventing the use of non-conforming products and their supply.

Implementation of the requirements of the standard clause implies the following actions:

1. Review requirements and document a "Control of Nonconforming Product" procedure to identify nonconforming product, document it, segregate it from conforming product and prevent its unintended use and delivery.

2. Document a "Control of Nonconforming Product" procedure for reporting, classifying and disposing of nonconforming product and define responsibility for approving these actions.

3. Document the procedure for re-inspection, refurbishment or reprocessing.

4. Review and approve procedures.

5. Evaluate the results of the audit.

Actions with nonconforming product shall be defined in a documented procedure within the QMS.

The purpose of this documented procedure is to:

a) eliminate the unintentional use in the production and supply process of materials, raw materials and products that do not meet the established requirements;

b) analysis of nonconformities and obtaining quality data for the development of corrective and preventive actions;

c) development and implementation of procedures for reworking, restoration and downgrading of non-conforming products;

d) disposal of products recognized as non-compliant and unsuitable for reworking, restoration and downgrading;

d) material accounting of non-conforming products.

The procedure for dealing with non-conforming products includes:

- registration of deviations of product quality from documentation requirements;
- identification of non-conforming products;

- separation of such products from the corresponding ones;
- conducting an analysis of the causes and possible consequences of non-compliance;
- making a decision on the further use of the product;
- actions in case of detection of non-conformity after shipment of products to the customer;
- disposal and accounting of rejected products.

Deviations in product quality from the requirements of regulatory documentation (RD) occur during the production process (provision of services) and are discovered during control operations or at the customer's site.

All established cases of deviation of products from the requirements of ND must be registered. Deviations of product quality or conditions of its production, control, storage, transportation and delivery from the standards established in ND (including in the description of the process) are subject to registration. The method and place of registration of deviations are established in the working documentation for the process or individual operations of the process.

All products found to be non-compliant with ND standards must be identified. The identification method is selected based on the type of product and must exclude the possibility of unintentional use of non-compliant products. As a rule, inscriptions, stickers, tags, notes in accompanying documentation, assignment of additional indexes to file names with information, etc. are used for identification.

The identification method must provide a clear idea of the product status. The types of product status are as follows:

- The products are in the process of being controlled.

Status identification method:

- container with the inscription "For control" and the time of selection of samples for control;
- an unfilled incoming material inspection sheet until all incoming inspection procedures are completed or – another method;
- The product is found to be non-compliant. A decision must be made on further action.

Status identification method:

- a label attached to the container with samples of products recognized as non-compliant by the consumer. A decision on such products (for the entire delivery or part of it) is made after analyzing the consumer's complaint;
- designation of products (materials) that have been stored in a warehouse for longer than the period established by the regulatory document. A decision on the further use of such products or materials may be made after additional testing;
- a note in the accompanying documentation, placing the product in a container with an inscription or a specified color (for example, red), marking the product itself, if this does not cause additional damage to the product, or;
- another way;
- the product is considered defective and is subject to disposal. Status identification method:
- container for rejected products with the inscription "Defective";
- special marking of rejected products;
- moving the products to the "Defect Isolation Cell" for safekeeping by the Quality Control Department until the destruction procedure begins, or another method.

Products found to be non-compliant with regulatory requirements must be separated from those that comply to eliminate the possibility of their unintentional use.

Note. Separation of nonconforming products is essentially one of the identification methods. This means that nonconforming products must be placed in a specially designated place. In cases where the labor intensity of separating nonconforming products is too high, only identification of such products is allowed.

To decide on measures to eliminate the causes of the detected product non-conformity, the documentation regulating the process specifies typical types of non-conformity and those responsible for conducting the analysis for each of them. For example, product mix-ups, deviations in technical parameters of products, incompleteness of the supplied materials, etc.

The results of the analysis and the decision made on the further use of the product are documented by the person responsible for conducting the analysis in the form established in the organization.

Decisions about the continued use of the product may include:

- carrying out culling;
- conducting additional tests;
- obtaining consumer consent for the supply of products with deviations from regulatory standards;
- decision on disposal due to impossibility of further use;
- a decision to return to the supplier the material, the non-conformity of which was discovered during incoming inspection or in production;
- others.

In the event of detection of non-conformity after delivery of products to the customer (start of use of non-conforming incoming materials), actions must be described for immediate identification of such products, notification of the customer about the incident, analysis of the causes and consequences of the deviation and, if necessary, replacement of the products with appropriate ones.

Note. These actions are described for all cases of release of products of inadequate quality, including those tested on measuring instruments that have lost their metrological accuracy. In the event that the customer discovers a product non-conformity during

use and makes quality claims, the actions for immediately obtaining the necessary information from the customer must be described, an analysis must be carried out to establish the causes of the non-conformity. The customer is informed of the results of the analysis and the decision taken and, if necessary, the product is replaced with the corresponding one (or other actions are agreed with the customer).

Where appropriate, a system for recording the quantity and/or types of nonconforming products shall be described. The number of nonconforming events, volumes of nonconforming and rejected products shall be included in the process performance indicators and shall be involved in the work of the process owner when implementing the requirements of clause 8.4 "Data Analysis".

The organization shall identify, collect and analyze relevant data,

to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be achieved. They shall include information obtained from monitoring and measurement and other relevant sources.

Data analysis should provide information on:

a) customer satisfaction;

b) compliance with product requirements;

c) characteristics and trends of processes and products, including the possibilities of pro-

conducting preventive actions;

d) suppliers.

The requirements of this section of the standard provide for a set of actions to determine, collect and analyze the data necessary to demonstrate the suitability and effectiveness of the QMS, as well as identify areas for continuous improvement of the effectiveness of the QMS.

One of the key points is the collection and analysis of data and information about the process. In order to obtain a sufficiently complete picture of the process and the actions that need to be taken to control and improve it, it is recommended:

- understand the essence of the problem and focus only on what is really necessary;

- make sure that the data really characterizes the process, understand what specific data and information we have;

- realize that often the nature of the data dictates the use of certain methods and equipment;

- make forms for collecting and analyzing data as simple as possible;

- first of all, use historical information (from previously completed projects).

In accordance with the construction of the hierarchical management levels of the organization, data analysis is carried out at each level. In order to reduce the number of these levels and transfer the management and decision-making levels downwards, it is necessary to standardize the decisions made based on the results of deviations, i.e. to introduce standard decisions based on standard deviations.

All materials are formalized as certificates on the progress of the process, which are sent to the manager for analysis and decision-making. Based on the analysis, the manager, as well as the process owners, fills out a protocol for analyzing the progress of the processes and makes a decision on the advisability of changing resources and forming plans.

Subsection 8.5 "Improvement" provides for a set of actions to plan continuous improvement of the effectiveness and efficiency of the QMS, identify the causes of product nonconformity and eliminate possible causes of nonconforming products. Fulfilment of the requirements of this paragraph implies the implementation of ongoing actions in which planned activities are clearly visible, and obtaining results, as well as their assessment in terms of effectiveness and efficiency.

8.5. Improvement. Continuous improvement.

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy and quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.2. Corrective actions

The organization shall take corrective actions to eliminate the causes of nonconformities in order to prevent their recurrence. Corrective actions shall be consistent with the consequences of the nonconformities identified.

A documented procedure shall be developed to define requirements for: a) analysis of nonconformities (including customer complaints);

b) establishing the causes of non-conformities;

c) assessing the need for action to avoid recurrence of nonconformities;

d) determining and implementing the necessary actions;

d) records of the results of actions taken;

e) analysis of the corrective actions taken.

According to the requirements set out in clauses 8.5.2 and 8.5.3 of this standard, the organization must develop, implement and maintain documented procedures for “Corrective actions” (elimination of the causes of existing nonconformities or other undesirable situations) and “Preventive actions” (elimination of the causes of potential nonconformities or other undesirable potential situations).

As can be seen from the content of these points, the actions of the documented procedures are basically the same. Therefore, an organization can create one documented procedure "Corrective and preventive actions", specifying in the input data of the procedure nonconformities (for developing corrective actions) and potential nonconformities (for preventive actions).

Carrying out corrective actions involves the following:

- appoint those responsible;
- determine the number and significance of discrepancies;
- evaluate the effectiveness of the actions taken;
- provide the necessary resources (expertise, records, instructions, procedures, nonconforming products) for analysis;
- investigate the reasons for the discrepancy;
- determine the action plan;
- revise and improve procedures;
- apply new control methods;
- implement permanent changes;
- evaluate the audited procedures.

8.5.3. Preventive actions

The organization shall determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the impacts of potential problems.

A documented procedure shall be developed to define requirements for: a) identifying potential nonconformities and their causes;

b) assessing the need for action to prevent the occurrence of nonconformities;

c) determining and implementing the necessary actions;

d) records of the results of actions taken;

d) analysis of the preventive actions taken.

The implementation of corrective actions involves the following, namely:

- appoint those responsible;
- analyze the preventive actions taken;
- evaluate the effectiveness of the actions taken;
- identify sources of information (reports on the quality of purchased materials, process descriptions, audit results, quality records, consumer complaints);
- determine the need for preventive actions;
- modify and continuously improve procedures, applying new control methods, in order to identify potential non-conformities and take actions to prevent their occurrence;
- report on the preventive actions taken;
- evaluate the audited procedures;
- evaluate the effectiveness of the actions taken;
- present the results of the actions to the management for consideration.

Conclusion

The Doctrine of Information Security of the Russian Federation provides for a qualitative improvement in the efficiency of the public administration system. Defining the construction of an information society in the country as a priority, the state policy is aimed at increasing attention to the protection of state information resources. Digital transformation inevitably leads to the mass introduction of information and communication technologies into people's lives. Not so long ago, digital technologies were reduced to the use of bank plastic cards and communications of cellular operators. Russia is the leader in the number of cell phones and the number of bank cards per capita in the world. The development of the digital economy inevitably leads to an avalanche-like increase in the use of digital technologies by the population in everyday life. First of all, this will affect the use of biometric data of the population; storage of personal medical data in cloud storage; transport and logistics systems controlled by artificial intelligence; life safety systems; implementation of Smart City technologies; use of digital signatures in data transmission, etc., which will provoke a significant improvement in the socio-economic development of the regions of the Southern and North Caucasian Federal Districts.

According to the Doctrine, an information threat is a set of actions and factors that create a danger of harm to national interests in the information sphere. The advantages of the mass use of digital technologies also have a downside - first of all, the possibility of unauthorized access, illegal use of personal data, the ability to commit illegal and terrorist acts by interfering with technological and logistical processes. One of the most important threats is the mass use of imported software in the government, financial and industrial sectors, which creates threats to the development of our own software production and is fraught with unpredictability of behavior in the event of possible hostile actions by foreign government agencies. In 2020, the Government of the Russian Federation decided to establish the Russian Fund for the Development of Information Technology. Access to information resources using global networks can create potential threats for their unauthorized use by other states. Since 2007, the US National Security Agency has been implementing a state program for the covert collection and analysis of information in global networks. Modern information threats are directed against government bodies of the Russian Federation and regional government systems. The information systems of the authorities of the Southern Federal District store and process significant amounts of restricted information. There are hundreds of registered state information systems, several thousand IT systems process information on personal data of the district's population. Data arrays attract technical intelligence services of foreign countries. The development of ICT has led to the creation of a global network space. Reliable functioning of all information resources is necessary for the country's defense capability, stable functioning of technological processes, and life support systems for the population. To ensure information security in the Southern Federal District, there is an Information Security Council, which is attended by representatives of the highest executive bodies of the subjects of the Southern Federal District, the FSB Directorate of

Russia, the FSTEC Directorate of Russia for the Southern Federal District, federal inspectors of the subjects of the macroregion, etc. The doctrine of information security of the Russian Federation takes into account the construction of an information society, provides for strengthening the protection of information resources aimed at uninterrupted information support for the functioning of government bodies and the country's defense industry. The construction of powerful data processing centers capable of storing and processing significant amounts of information requires a systematic approach to the protection of information resources and data transmission lines, interdepartmental coordination of work on the safe use of information. Regional departments of the Federal Service for Technical and Export Control, in addition to implementing special functions for information protection, coordinate information security work at the interdepartmental level. A prerequisite for reducing information security risks is a correct risk analysis, their identification and development of adequate measures to reduce and prevent them. In December 2018, the Government of the Russian Federation approved an action plan in the Information Security direction of the Digital Economy of the Russian Federation program. The main goals of the program should ensure the unity, sustainability, security of the information and telecommunications infrastructure, legal protection of individuals, businesses, and state interests, and create conditions for the Russian Federation to achieve leading positions in the export of information technologies, taking into account national interests and information security. Based on the results of the implementation of regional digital programs, a comfortable environment should be created for interaction between government bodies, businesses, and the population in all areas, a unified system of communications and databases should be built, and the budget burden in the regions should be reduced. Thus, despite the existing problems, in general, quite positive trends in digital transformation are developing in the Southern Federal District, in particular, a system is being formed with a response to emerging or potential threats of information leakage, covering all government bodies of the macroregion. Society expects positive changes from digitalization... However, the informatization of society, in addition to the benefits for people, also creates a number of problems, uncertainties, risks, ignoring which creates threats to the lives of the population, and this must be addressed. Ignoring which creates threats to the lives of the population, and this must be addressed. ignoring which creates threats to the lives of the population, and this must be addressed.

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