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The Need to Implement a Quality Management System in Manufacturing Enterprises

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ABSTRACT: In the process of research and analysis, various materials from leading experts in the field of quality were used. All possible reasons for the implementation of a quality management system (QMS) at enterprises are considered.

The sequence of the diagram, the main factors of success and the elements of the QMS, is disclosed. The principles of the quality management system are given, which is considered as the basis for the management of the organization[1].

The publication provides a thorough and detailed analysis of the process of constructing a QMS, a meaningful statement and a solution to the problem of the methodology for calculating the effectiveness of the QMS process.

KEYWORDS: product quality, product quality improvement, quality management system, business processes, resources, efficiency.

I.INTRODUCTION

In today's market, high quality products and / or services is one of the main factors for the success of any enterprise, as well as ensuring competitiveness and economic benefits[1].

Every enterprise should have a detailed plan for improving product quality and establish a sound quality management program.In the conditions of tough competition in the market, the manufacturer strives to achieve a stable quality of its products, using all the tools developed by world practice. One of these conditions is the quality management system (QMS), which comprehensively covers all aspects of the enterprise's activities and has received the widest distribution and recognition throughout the world [2].

The need for a quality management system in an enterprise is determined by several important reasons. Firstly, this is an increase in the confidence of potential consumers in the products manufactured by this enterprise.

Secondly, this is an opportunity to significantly strengthen its position in existing markets, as well as significantly expand the spheres of influence by entering new domestic and foreign markets.

And thirdly, this is a significant increase in the productivity of any industrial organization, which has implemented and operates a quality management system.

A quality management system is a set of systems, methods and tools that a company uses to meet the expectations of consumers regarding the products or services it produces, in order to make products competitive in the market and improve the company's performance as a whole[2-3].

QMS is an integral system, the purpose of which is not to control each unit of production, but to exclude possible errors in work, due to which defects may arise. To do this, you need to determine which actions are correct to create quality products, and develop instructions for performing the correct actions, and then control them.

The quality management system was formed based on the requirements of the international standards of the ISO 9000 series. Any enterprise can develop and implement a QMS, regardless of the field of activity, the size of the staff and the industry. In total, the system can be implemented not only by manufacturing companies, but also by organizations that provide services or work where there are business processes that need to be optimized [3].

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II. ANALYSIS OF LITERATURE ON THE TOPIC.

Currently, all over the world, research is being conducted in the following priority areas: improving the scientific-theoretical, methodological and practical base for determining the effectiveness and efficiency of the QMS.

The USA, Japan and the countries of Western Europe have made a great contribution to the scientific and theoretical development of the quality management system, studying the basic concepts and principles of the QMS. Among foreign experts who have deeply studied the field of quality, including the evolution of the QMS, one can single out such leading researchers as E. Deming, J. Juran, K. Ishikawa, F. Crosby, J. Sting, A. Feigenbaum, J. Harrington, W. Schuhart, E. Kondo, G. Niv, V. Lapidus, L. Sachsa, H. Kume, D. Murdoch, F. Taylor, G. Emerson, A. Fayol, V. Max, F. Ford, etc.

The founder of management as a science can be considered the American scientist F. Taylor, who used measurements, observations, timing and analysis of operational work to create the most efficient and rational model of the labor process and production operations. His scientific results are reflected in the books "Enterprise Management" (1903) and "Principles of Scientific Management" (1911). The concept of organization of machine production, developed by F. Taylor, G. Leland, G. Ford, became the foundation for the world's leading manufacturing companies [3].It can be argued that Taylor's designs, which significantly increased labor productivity, were aimed at managing product quality and improving the efficiency of the company as a whole.

III. QUALITY MANAGEMENT SYSTEM

The quality management system includes the following elements [4]:

1) Business processes.

2) A group of employees with distribution of powers, functions, relationships and responsibilities.

3) Documents - working information, which includes:

Orders and regulations for the enterprise related to the QMS (“On improving the quality system”, “On the representative of the management”, “On the project manager”, “On the service of the quality system”).

A project implementation program that discloses the responsibility of officials for procedures.

A quality plan is a document that defines which procedures and their corresponding resources, by whom and when, should be applied to a specific project, product, process or contract.

Work and control instructions.

4) Resources - human, financial, temporary.

Practice allows us to highlight the following main factors for the success of the implementation of the QMS, see Fig.

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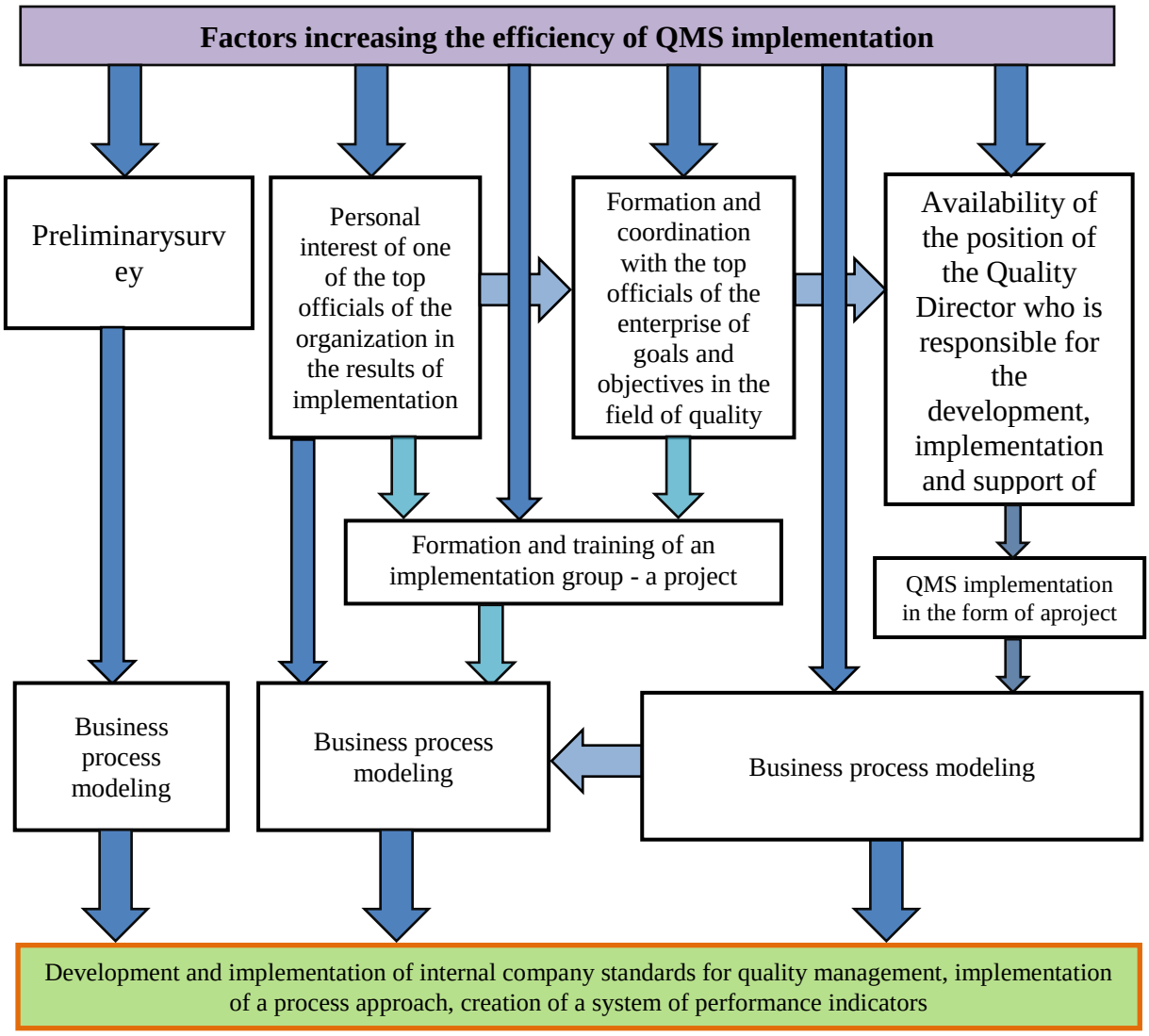

Fig. 1. The main factors for the success of the implementation of the QMS.

Any business consists of interconnected (correlated) actions. The implementation of these processes must be provided with resources (monetary, labor, material, information, etc.). Each process has its own cost. The set of enterprise processes makes it possible to calculate the actual actual cost of the business [5]. And then you can competently solve the problems of financial planning, analysis, pricing, product quality, etc.

Achieving business transparency by identifying business processes of an enterprise in accordance with the goals set is an urgent task for most enterprises, especially those that are actively developing [5].

IV.QMS PRINCIPLES

The principles of the quality management system are considered as the basis for the management of the organization. There are eight of them in total.

1. Customer orientation. This is an understanding of the needs of the target audience, compliance with their requirements, the ability to exceed their expectations.

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2. Leadership of leaders. Creation of common goals and directions of the organization's activities. Ability to create and maintain an internal environment in which employees will be motivated to achieve the goals of the organization.

3. Involvement of personnel. Revealing and using the talents of employees for the benefit of the organization. Engagement in work creates loyalty, which fosters innovation, a creative approach to work, and a sense of responsibility among employees.

4. A systematic approach to management. Allows you to focus efforts on key processes, integrate and chain those processes that will best allow you to achieve the desired results.

5. Continuous improvement of the company's activities.

6. Process approach. The resources and activities of the company must be managed as a process. This contributes to lower costs and shorter cycle times, and the end results are improved and more predictable.

7. Improvement of approaches to decision-making. When decision making is based on the analysis of data and information.

8. Improve relationships with suppliers.

V. BENEFITS OF QMS IMPLEMENTATION

The same companies that have carried out this process efficiently and fully have the following advantages and benefits [6]:

- due to quality improvement, product sales are increased;
- the management culture and the level of controllability are increasing
- costs for development, production, application are saved;
- risks and costs are reduced.

VI. QMS IMPLEMENTATION TASKS

Building an effective management system in accordance with the requirements of the international standard ISO 9001 is achieved by solving the following tasks:

1. Description of the company's business processes, interconnection, monitoring, development of performance criteria and assessment of business processes.

2. Development of the necessary documents for the management system.

3. Implementation of the developed documentation in the company.

4. Organization and conduct of internal audits of the management system on an ongoing basis to determine the strengths and weaknesses in order to continuously improve it.

5. Conducting an independent assessment by a certification body with the subsequent receipt of an independent certificate [7].

Let's consider the process of building a QMS in stages.

Stage 1. Management decision.

The manager must decide to start the project, notify the company's employees, and also create the prerequisites for the rapid implementation of all other stages.

You should also formulate the goals of building the QMS, highlight at the top level the QMS processes that need to be controlled, and the criteria for assessing their quality. Subsequently, the objectives of the QMS must be recorded in a document called“Quality Policy”, which also describes the principles for achieving them. This document is fundamental in the company's QMS regulatory documentation system.

Stage 2. Personnel training.

For the further successful work of the QMS, the company's personnel must study the theory of quality management, the ISO 9000 series standards, master the theory of the process approach, as well as the basic requirements for the implementation of the QMS. Training in using the system can be carried out both with the help of consultants and independently, if the company has an employee who has experience in setting up the QMS.

Stage 3. Formation of the QMS implementation program.

QMS implementation should be seen as a complex and lengthy project. Therefore, it is necessary to draw up a QMS implementation program, which should include [8]:

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⇨ description of the stages of implementation;

⇨ a list of those responsible for each stage of the project. As a rule, they are chosen from among top managers, as well as specialists who know the specifics of the work of their departments best of all;

⇨ budget for QMS implementation. It includes both the cost of certification and payment for the services of consultants, if they are involved, as well as the cost of further training of personnel and the cost of diverting management from the main work for the project;

⇨ the procedure for assessing the implementation of the QMS. Indicates the criteria by which management will be able to determine whether the goals set at the beginning of the project have been achieved.

After drawing up the program, you can proceed to the direct setting of the QMS.

Stage 4. Description and optimization of business processes.

The basis of the quality management system is the process approach. First of all, it is necessary to describe those business processes, the management of which the management considers the most important for the QMS. For example, for a manufacturing enterprise, this will be the process of manufacturing and selling a product, as well as service and purchasing.

The described business processes need to be optimized, that is, to eliminate all inconsistencies with the requirements of the standard and duplicate processes, as well as to develop new processes in accordance with the rules of the standard. Most often, companies do not have a "Customer Satisfaction Assessment" process, which is required by the standard.

Therefore, it is necessary to develop a system of indicators, as well as the procedures necessary for the implementation and monitoring of this process.

Stage 5. Development of the QMS normative documentation.

At this stage, normative documents, regulations and procedures are formed to ensure the operation of the quality management system. The basis for them is usually a set of documents already existing at the enterprise, which is modified and supplemented in accordance with the requirements of the standard.

First, on the basis of the Quality Policy, a document is prepared called the Quality Manual. It contains the main provisions governing activities within the framework of the QMS: delineation of areas of responsibility, requirements for the quality service, a description of quality assurance procedures, the procedure for maintaining the QMS document flow, a description of the complaints procedure, etc.

The next level of documents is called "System-wide documented procedures". According to ISO 9001, six procedures should be followed:

⇨ document management;

⇨ data management (records)

⇨ management of the QMS audit;

⇨ management of products that do not meet standards (the process of identifying defects and the procedure for their disposal);

⇨ management of actions to correct nonconformities;

⇨ management of measures to prevent the occurrence of nonconformities.

The next level documents describe the rules for the effective planning, implementation and management of processes. Such documents include working methods, job descriptions of employees, process flow charts[8].

The basis of the "pyramid" of documents is the data confirming that the requirements of the QMS are being implemented in practice. These are reports on the work done, entries in the operation logs, etc., that is, the documentary basis for the daily work of employees.

When drawing up regulatory documents, it is necessary to take into account the requirement of ISO 9001 on the competence of personnel performing work within the framework of the QMS. This means that the regulatory documents should describe the process of employees' access to regulatory documents, as well as the requirements for the competence of personnel (level of knowledge, work experience), a program for raising the level of employees, if necessary, a system of employee motivation, etc.

Stage 6. Testing of the QMS and internal audit.

After the development of all regulatory documents, the trial operation of the quality management system begins. It is possible to launch processes within the new system gradually, for example, first introduce control over the procurement process, then production, etc.

The trial operation is accompanied by an internal audit, special procedures for checking the work of the QMS. At the beginning of operation, they are carried out frequently (perhaps once a week), then less frequently (once a month or even a quarter).

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For internal audit purposes, it is necessary to record quantitative indicators of quality, for example, scrap rate, customer satisfaction rate, return rate, etc., which should be striven for. To determine the value of such indicators, similar indicators of industry leaders are usually used. Internal audit should identify inconsistencies between current work and the requirements of the standard. These deviations must be recorded. Then, based on the results of the audit, the work of employees, as well as regulatory documentation, is adjusted in order to avoid deviations in the future. All this work should also be documented in the appropriate QMS procedures [9].

The standardization of the QMS based on the requirements of ISO 9001 provides only the basis for stable customer satisfaction, but each industry has its own specific requirements and specifics. To more fully ensure customer satisfaction in industries, their own industry models of quality management systems are created in the form of separate standards or in the form of Recommendations for the implementation of ISO 9001. The most developed models of quality management systems in industries are:

- ISO / TS 16949 - Automotive component suppliers.
- ISO 13485 - Medical device manufacturers.
- AS 9100 - Aerospace component suppliers.
- ISO 29001 - Petrochemical and Gas Industry.
- TL 9100 - enterprises in the telecommunications industry.
- IRIS - the supply chain for the railway industry.
- ISO 22000 - food supply chain.
- ISO 20000 - Service Management.
- IWA 1 - healthcare institutions.
- IWA 2 - educational institutions.
- IWA 4 - local government bodies.

Internal audit of management systems.

Quality management systems, environmental management, occupational health and safety management, and risk management systems should be periodically audited internally. Internal audit is one of the management tools for monitoring and checking the effectiveness of the implementation and operation of the system [10-11].

Having implemented a management system, the management of the organization should be interested in how it functions, where failures occur in the system, and evaluate its effectiveness. The results of internal audits provide this kind of information for analysis by the management of the organization, which allows you to develop corrective actions and identify opportunities for improvement, both individual processes and the system as a whole [12].

The purpose of internal audits is to verify that the management system:

- complies with the planned activities, the requirements of the certification standard and QMS documentation;
- effectively implemented and maintained in working order.

Recommendations on the organization of the audit process are contained in IS ISO 19011 “Guidelines for the audit of management systems”.

Audits can be classified by type, by stage, by object and by method (Fig. 2).

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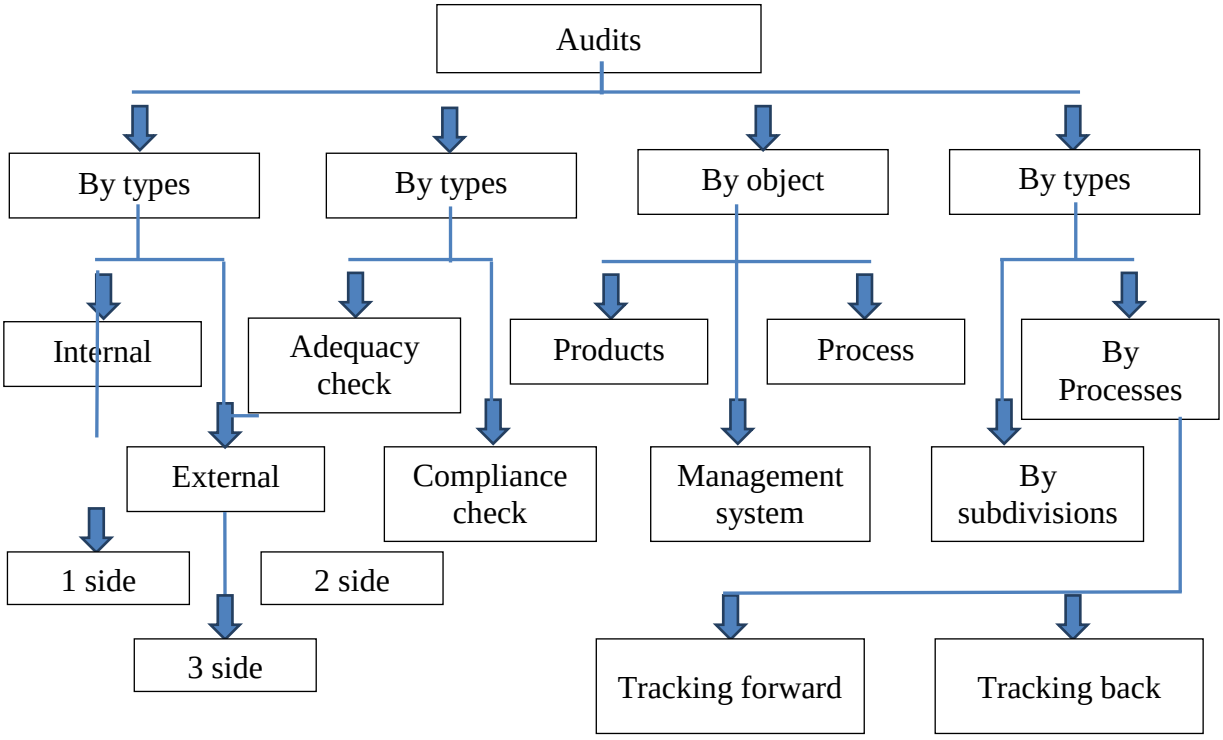

Fig. 2. Classification of audits.

Audits can be internal and external (Figure 3).

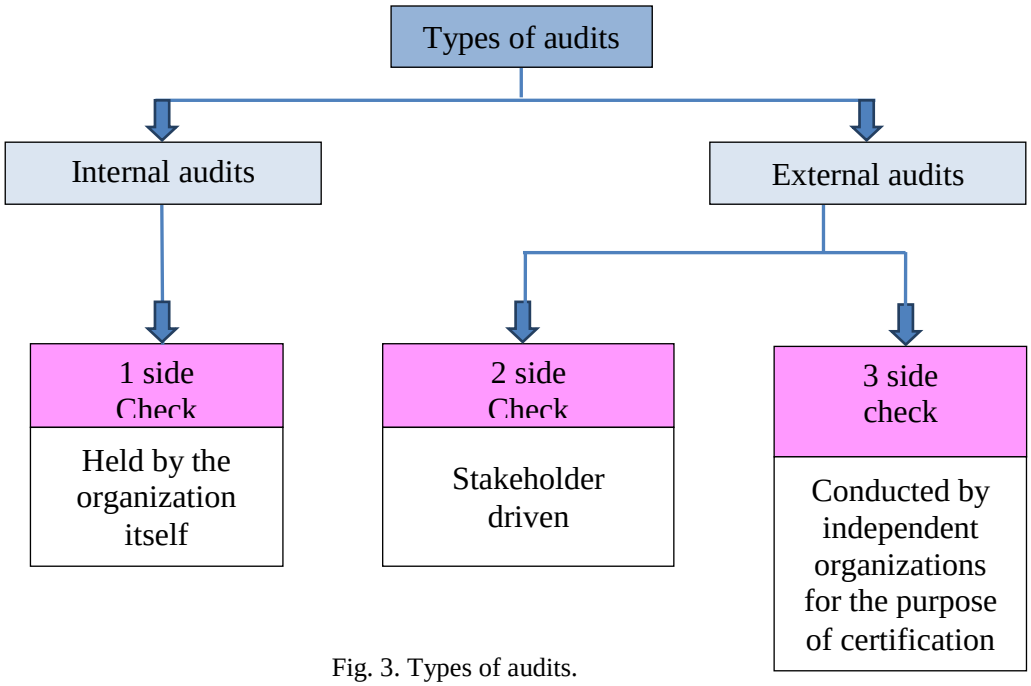

Fig. 3. Types of audits.

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A first party audit (internal audit) is an audit conducted by an organization in-house, i.e. an internal audit that requires an organization to review its own systems, procedures and operations to ensure that they are adequate and appropriate.

A second party audit is an audit of an organization on behalf of a customer or other interested party. The purpose of a second party audit is to obtain sufficient information about the organization's management system to provide customer confidence that its specific requirements will be met in a guaranteed and consistent manner [13].

A third party audit is an audit conducted by an external independent organization (third party). The most commonly used third party assessment is for certification purposes.

Internal audits, like external audits, usually have two stages: verification of adequacy and verification of compliance.

Adequacy Check - Determines the extent to which the documented system is adequate to the requirements of the applicable standard.

Conformity check - This check is recognized to establish the extent to which the documented system is understood, implemented and maintained by workers [14].

VII. METHODOLOGY FOR CALCULATING THE EFFECTIVENESS OF THE QMS PROCESS

Initially, when assessing the effectiveness of the QMS process the "cut-off" indicators of the QMS process (if any) are considered. If at least one of the "cut-off" indicators of the QMS process is not achieved, then the QMS process is recognized as "ineffective" and other indicators of the process are not considered.

If the "cut-off" indicators of the QMS process are achieved, then they are further considered as "estimated". In this case, the effectiveness of the process is determined by the formula:

$$E(PR_i)=(E(P_1PR_i)+E(P_2PR_i)+\ldots+E(P_nPR_i))/n, \quad (1)$$

The process is "effective" in assessing the QMS process $85\%<E(PR_i)<100\%$;

The process is "sufficiently effective" - when $75\%<E(PR_i)<85\%$;

The process is"insufficiently effective" - when $65\%<E(PR_i)<75\%$;

The process is "not effective" - when $E(PR_i)\leq 65\%$.

The procedure for calculating the effectiveness of the QMS

After calculating the effectiveness of all processes of the QMS, the effectiveness of the organization's QMS (E (QMS)) is calculated. The calculation of E (QMS) is carried out according to the formula (2):

$$E(\text{QMS})= (E(PR_1)+ E(PR_2)+\ldots+ E(PR_i))/i, \quad (2)$$

where i is the number of QMS processes.

After calculating the data, a conclusion is made about the effectiveness of E (QMS):

$E(\text{QMS})\geq 85\%$ – QMS «Effective»;

$75\%<E(\text{QMS})<85\%$ – QMS «Effective enough»;

$65\%<E(\text{QMS})<75\%$ – QMS «Insufficiently effective»;

$E(\text{QMS})\leq 65\%$ – QMS «Not effective».

VIII. DIFFICULTIES IN IMPLEMENTING THE QMS

The implementation of the QMS is a complex project for any company, for the successful implementation of which accurate knowledge and observance of all laws and documentation is required[14].

There are certain difficulties in a project of this scale:

- ⇨ failure of individual employees and managers to make a strategic decision to create the system;
- ⇨ powerful organizational structure, functional management;
- ⇨ internal barriers between departments, lack of understanding of the overall goals of the organization, a gap in trust between different levels of personnel;
- ⇨ imbalance of responsibility and authority;
- ⇨ low level of production culture;
- ⇨ lack of a clearly formulated vision, mission, common ideology, philosophy, development principles for the entire company;
- ⇨ processes are not described, key processes are not defined, quantitative and qualitative criteria are not defined and measured;

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⇨ quality is understood only as product quality, and not as the quality of processes, resources, management decisions;

⇨ lack of a system for measuring customer satisfaction and marketing.

To overcome these difficulties, ISO 9001 will help - a real tool for increasing the efficiency of activities, which brings the company to a fundamentally new level of development.

IX. CONCLUSION

The quality management system, built in accordance with the requirements of the international standard, can actually lead to an increase in the value of an enterprise by 5-10%, capitalization, attraction of investments, etc.

Specifying what has been said, let us emphasize the competitive advantages acquired as a result of the implementation of a quality management system that complies with ISO 9001:

- reduction of unforeseen expenses for marriage and product return;
- increasing the efficiency of work, and, consequently, net profit;
- the possibility of replicating the business;
- increase in the market value of the company;
- fulfillment of the conditions for joining an SRO;
- advantages in tenders, competitions;
- fulfillment of the conditions for obtaining the State order;
- increasing investment attractiveness;
- improving the company's image as a reliable supplier;
- optimization of internal business processes;
- freeing up senior management to make strategic decisions;
- increasing the likelihood of successful implementation of business plans, achievement of goals.

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