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Implementation of ISO 9000 Series International Standards "QUALITY SYSTEMS" At the Enterprise

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ABSTRACT:. This article discusses the implementation of the quality system is a set of works that affects various aspects of the organization and its subsystem - the strategic management subsystem, the production subsystem, the logistics subsystem, personnel management, internal communications, document management, etc. Inthisregard, the implementation of the quality system is a rather difficult, lengthy and time-consuming task.

KEY WORDS: quality, quality management systems, standard, international standards, enterprises, implementations, documentation structure.

I.INTRODUCTION

A quality management system is a combination of organizational structure, methodologies, processes and resources necessary for general quality management. QMS is part of the organization's overall management system and is intended to continuously improve the enterprise's activities, to increase the organization's competitiveness in the domestic and world markets.

The adoption (choice for implementation) of a quality management system should be a strategic decision of the organization. As a rule, the development and implementation of an organization's quality management system is influenced by: the environment of its business, changes in this environment or risks associated with this environment; her changing needs; its specific goals; manufactured products; processes used by her; its size and organizational structure.

The implementation of the quality system is a set of works that affects various aspects of the organization and its subsystems - the strategic management subsystem, the production subsystem, the logistics subsystem, personnel management, internal communications, document management, etc. In this regard, the implementation of the quality system is quite difficult, a long and laborious task. The solution to this problem, as a rule, occurs in several stages.

The structure of the documentation of the quality management system, built according to the ISO 9001 standard, is a hierarchical model of interrelated documents. A part of these documents is clearly stipulated in the standard, another part is implied. Therefore, the structure of the quality system has a "permanent" component defined by the standard, and a "variable" component depending on the particular organization.

The "permanent" component of the QMS documentation structure: quality policy; quality goals; quality manual; six mandatory procedures; quality records.

The "variable" component includes, as a rule, various plans, maps or process diagrams, work instructions, reporting forms, contracts, regulatory documents, invoices, etc. Those. we can assume that almost all the documentation of the enterprise falls under this "variable".

In accordance with the requirements of ISO 9001, the organization's quality system must be documented. As a rule, the documentation of the quality system is carried out in the procedures of the quality system. The minimum set of procedures that should be developed in the organization in accordance with the requirements of the standard includes a quality manual and six basic procedures: document management; management of quality records; management of non-conforming products; conducting internal audits; carrying out corrective actions; conducting preventive actions .

ISO 9001 defines quality records as a special type of quality system documentation. The peculiarity of this type of documentation consists only in the fact that these documents confirm the fact of the performance of an action and

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change their status at the time of registration of this fact. For example, a blank form for monitoring results is a common quality system document. As soon as the control results are entered into the form (the form is filled out), this form becomes quality records.

The main stages of the implementation of the QMS are as follows:

The first stage is the analysis of the existing situation in the organization and staff training; The second stage is the development of documentation and changes in the work of employees; The third stage is the internal audit of the quality system. The fourth stage is QMS certification.

Each of these stages consists of a certain, rather large set of works. The second stage is the most difficult and time-consuming stage, but the first one is the most critical for the entire QMS implementation project. Consider what needs to be done to develop and implement a quality system.

The development and implementation of a quality system must be formalized as a project that has its own goals, its own deadlines, its own resources. Therefore, before starting an analysis of the existing situation, it is necessary to organize work on a project to introduce a quality system. For this, firstly, the organization's management must want and be able to administratively support the quality system project, and secondly, it must allocate resources for this project.

The work of the first stage consists of the following main steps:

Step 1. An order is issued for the enterprise to begin work on the quality system.

The order shall indicate: the purpose of the commencement of work; the person responsible for the quality system from the management of the organization (a person with a rank not lower than the deputy general director); the composition of the working group on the implementation of the quality system.

When performing this step, you must pay attention to the following points:

1. When choosing a person responsible for the quality system from the organization's management, it is necessary to take into account that this person has real authority, sufficient to influence the heads of any organization's departments and have free time to monitor the progress of the project.

2. The composition of the working group directly involved in the quality system should be no more than 5-7 people.

For a small business (up to 100 people), a group may look like this:

The head of the group is the head of the organization's quality service (should devote at least 50% of the working time to building a quality system, it is better when everything is 100%). He may also be the only employee of this service;

The participants in the working group are key employees of the departments who know how the department works (should devote at least 5-10% of their working time to building a quality system in addition to the main work).

For a large enterprise:

The head of the group is the head of the organization's quality service, who devotes 100% of his working time to issues of the quality system;

The members of the group are quality service employees who devote 100% of their time to building a quality system.

Representatives of the quality system - are not part of the working group, but carry out the tasks of the leader and members of the working group. Representatives of the quality system are employees of organizational units. For the normal organization of work, one employee from each unit is required. In addition to the main work, they should devote 5-10% of their working time to issues of building a quality system in their unit.

Step 2. Since the analysis of the existing situation in the organization is carried out with a view to constructing a quality system, the next step will be training of the working group participants in quality management and the requirements of ISO 9000 series standards. The leader of the working group and its participants must be trained, as analysis of the current state of affairs and the development of a quality system will be their main task.

Step 3. In order to understand how much the existing activity in the organization differs from the requirements of the ISO 9001 standard, it is necessary to analyze the current situation. Baseline data collection is carried out mainly by two methods - questionnaires and interviews. It is most effective to use both methods, first conduct a survey, and then clarify the necessary information during conversations with employees. Responsible for questioning and conducting interviews are members of the working group.

You can certainly not do all of this, but in this case, the participants in the working group should, based on their knowledge of the work of the units, conduct such an analysis.

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The result of the analysis can be a report or another document in which, for each requirement of the standard, it will be indicated how it is implemented and what is the depth of implementation of this requirement in various departments of the organization.

An analysis of the current situation should reveal:

main production processes of the organization;

supporting processes and support processes;

the most critical business processes in terms of quality system;

the availability and relevance of regulatory documentation (enterprise standards, instructions, regulations on units, job descriptions, etc.);

the existing distribution of responsibility, authority and resources across the organization's processes.

II. DEVELOPMENT OF DOCUMENTATION AND CHANGES IN THE WORK OF EMPLOYEES

This stage is the most time-consuming and lengthy.

During this stage, the design, development and implementation of quality system documentation is carried out, as well as the introduction of changes in the work order of employees.

The work of the second stage consists of the following main steps:

Step 1. At this step, it is necessary to plan how the quality system will be built, what will be the scope of its application, what processes will be included in the quality system, how it will expand. For example, an organization provides its customers with several types of various services. These services are provided by various departments. Then at this stage it may be decided to initially include in the scope of the quality system all the processes and units involved in the provision of a single service, and the processes and units involved in the provision of other services may be involved later, after the quality system will fully work when managing the quality of the first service. In this case, the construction of a quality system will take place on the principle of increasing the scope of its distribution.

Step 2. The main principle of the ISO 9001: 2008 standard is the process approach. In order to be able to implement a process approach, the standard requires the definition and documentation of organization processes. To fulfill this requirement, the working group must first formalize the processes that were included in the scope of the quality system in the form as they are, and then make changes to these processes in accordance with the requirements specified in the standard.

When performing this step, you must pay attention to the following points:

The implementation of the quality system is associated with changes in the organization. Making any changes always affects the interests of the employees to whom these changes relate. As a result, people either resist change or support it; a neutral attitude is rare. In order to be able to effectively carry out process changes at the level of performers, administrative support from the organization's leadership is required (to reduce the level of resistance) and obtaining sufficiently fast results from changes (to maintain support from those who accept the changes). To implement this principle, it is necessary to correctly determine the procedure for documenting and changing processes. First of all, it is recommended to formalize and adjust the most important processes.

Step 3. Documentation and implementation of quality management system procedures.

The ISO 9001: 2008 standard requires that organization processes be defined and documented. Documentation of processes can be performed in the form of process maps, which indicate the sequence of operations of the process, the input and output data (information, resources) of each operation and those responsible for the operation. Documenting processes in the form of maps significantly reduces the amount of documentation. In addition, when documenting processes, it is important to balance the details of the process presentation. The process should be presented with such a level of detail so that the personnel involved in the process can understand the process flow of the process and determine its "place" in this process.

In accordance with the requirements of the standard, 6 mandatory procedures and a quality manual should be developed, as well as documents necessary for the organization to ensure effective planning, implementation and management of processes (process maps, regulations, instructions).

Implementation of process system cards and quality system procedures is best done in parallel with their development, i.e. Having developed a process map and making changes to the process, it is necessary to put it into effect.

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The introduction of procedures and new process maps must be accompanied by staff training and control over the procedure (process map).

After you have developed all the necessary process maps and quality system procedures, it is necessary for the organization to work on these maps and procedures for a period of time. This time is necessary for "refinement" of the quality system. During this period, minor changes to the quality system documentation are usually made.

Certification of the quality system is an independent verification of the organization's quality system by a third party (Certification Body) and the issuance of a certificate based on the positive results of the audit.

Certification is a short time process. Certification is carried out by an already built and functioning quality system, in which all the requirements of the ISO 9001 standard are implemented.

Preparation for certification is a lengthy process. during this process, the organization determines and implements methods for implementing the requirements of the ISO 9001 standard, i.e. preparation for certification includes all stages of the implementation of the quality system.

Certification of the quality system is voluntary, therefore, the organization has the right to decide on the need for such certification, as well as the choice of certification body.

Quality system certification is carried out in three stages:

1 - analysis of the organization's quality system documentation. At this stage, the certification body checks the organization's documentation to reflect the implementation of all requirements of the standard.

2 - audit of the quality system. At this stage, the auditors of the certification body come to the enterprise and check on site the compliance of the documentation with the actual practice of the organization, as well as the effectiveness and efficiency of the quality system.

3 - making an audit decision and issuing a certificate. At this stage, the certification body analyzes the audit results and, in case of positive results, makes a decision on the issuance of the certificate.

After the organization successfully passes certification and receives a certificate of compliance with the requirements of ISO 9001, work on the quality system does not end there, although of course their volume may already be less. The quality system must be maintained and must be continuously improved. This means that any changes in the products (services) of the organization, processes or in the system itself must be promptly analyzed and recorded in the documentation of the quality system. In addition, to confirm the effectiveness and efficiency of the quality system, the organization should conduct periodic internal audits. Such audits should be carried out in the organization at least as long as the audit will be conducted by the certification body. As a rule, supervisory audits by the certification body are carried out once a year.

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