RISK-ORIENTED APPROACH IN QUALITY MANAGEMENT

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Abstract: *In free market conditions the successful operation of enterprises is impossible, if requirements to the product quality are not improved. The article describes the necessity in creation of Quality management system, and specifics of risk-oriented approach in quality management are considered. The selection of methods for assessment of risks is justified, and recommendations on application of these methods during organizational activities' monitoring are formulated. It is shown that the implementation of risk management is aimed on the achievement of qualitative results and the enhancement of enterprise' competitiveness.*

Keywords: QUALITY MANAGEMENT, RISK-ORIENTED APPROACH, MONITORING OF ACTIVITIES, METHODS FOR ASSESSMENT OF RISKS

1. Introduction

Risk-based thinking was announced in the 2015 edition of ISO 9000 series of international standards. According to ISO 9001 (6.1), this kind of thinking has to be represented in the requirements for development, implementation, maintenance and continual improvement of a Quality Management System (QMS). The standards users, especially those who are going to recertify their organization's QMS in accordance with the new edition of the standards, see it as an innovation and are puzzled. They have to develop the ways of risk addressing in line with the recommendations listed in the annex to 6.1.1 of ISO 9001:2015.

In QMS models, including a Business Excellence model applied in the organization of competitions for the Awards of the Government of Russian Federation in the field of quality, companies have to provide evidence of risk management in their activities when forming their self-assessment reports. Risks are not just financial ones. This notion includes practically all the aspects of the organization's activity under assessment. However, when documenting QMS, it is not required to present any calculation results, there is no a calculation method, and in most cases risk assessment and accounting are described verbally.

2. Rational

What is risk? In accordance with the international standard ISO 9000:2015 [1] (3.7.9), "risk is an effect of uncertainty", which is "a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding of an event, its consequences and likelihood", and an effect is a deviation from the expected result, both positive and negative. In this definition, the risk can be regarded as a deviation from the planned trajectory (scenario), and risk accounting reduces to an assessment of the possible outcomes of scenarios depending on variations in SWOT analysis components, a tool well known from strategic management. In this context, the following types of risks are usually analyzed: management risks, security risks, financial and commercial risks, industrial, environmental, social, political, etc., and risk refers to the discrepancy between the various possible outcomes of certain strategies. The main question that arises in this analysis is: how is this measure of discrepancy determined (measured, calculated)?

The definitions of the term "risk" in the standards directly related to this issue differ. So, ISO Guide 73:2009 Risk management - Vocabulary - Guidelines for use in standards [2] defines risk as a "combination of the probability of an event and its consequences", and the Large Economic Dictionary narrows the above definition by removing positive deviations: "Risk is the possibility of an event with negative consequences as a result of certain actions or decisions" [3]. Nevertheless, these definitions move the solution of the risk assessment problem into the field of the probabilistic approach, which is also widely used in practice.

The methodology of risk assessment is widely used in solving complex safety issues, while the risk is usually understood as a probabilistic measure of the occurrence of dangerous man-made or natural phenomena, as well as a description of the amount of damage and harm caused. The basis of this methodology is the definition of the consequences and likelihood of undesirable events, and analytically the risk is calculated as the ratio of the frequency of implementation of hazards to the possible number of them:

$$Risk = \frac{N(f)}{Q(f)},$$

where N is the quantitative measure of the frequency of undesired events in time *t; Q* is the number of risk objects subject to a certain risk factor f.

To solve such problems, it becomes necessary to determine the value of the acceptable level of risk under conditions of partial uncertainty associated with the inadequacy or inability to verify the information, then calculating the probability value of the risk and comparing it with the permissible value (it should be borne in mind that under conditions of total uncertainty, when the situation is not statistical, it is impossible to determine objective probabilities and to present the characteristics of a finite probabilistic scheme of variants of possible outcomes of the scenario, it is meaningless to calculate the risk value). In addition, risk analysis is a multicriterion problem, for which multidimensional statistics methods are applied.

Despite the thoroughness of this scheme, it is obvious that it is not reasonable to assess the risks in the organizations activities from the position of damage or harm. If benchmarking is involved, then the best practice, for sure, will be the methodology for assessing risks in the design and operation of complex technical facilities. Its conceptual focus is based on the scientific approaches of the theory of reliability, in which the main concept is a rejection. Failure is an event that causes the object in question to completely or partially stop performing the specified functions, and the total loss of the ability to perform functions is treated as a complete failure, partial loss is treated as a partial failure. The quantification of reliability for total and partial failures is different.

With reference to the activity of the organization, a variety of so-called initiated failures is identified, which include erroneous control actions and decisions. The human factor is at the forefront, since people who are prone to make mistakes are possible sources of secondary failures, if their actions lead to a malfunctioning system.

Reliability of a person's work is defined as the probability of successful fulfillment of a solution to the task at a given time interval under certain conditions of work performance, and a person's error is interpreted as a failure to perform the task (or performing an activity forbidden in the performance of the task), which can lead to equipment breakdowns, damage or disruption of the process. According to data available in different sources, from 20% to 30% of failures of complex technical systems are associated with initiated failures caused by human errors. When considering the processes of the organization's activities with a full production cycle, the following list of personnel-related errors can be identified:

- design errors, including the development of operational documentation;
- planning errors and mistakes made in the organization of production;
- marketing and logistics errors that lead to the wrong choice of suppliers;
- production errors, including deviation from the requirements of design and technological documentation;
- violation by the personnel of the requirements of operational documentation for the equipment used;
- improper organization of workplaces;
- technical maintenance errors of the technical system, resulting in improper adjustment or calibration of process equipment;
- errors at the stage of technical control caused by the use of inappropriate measuring instruments or violation of the prescribed procedure for monitoring and documenting the results;
- violation of the conditions for storage or transportation of finished products;
- management errors that lead to psychological incompatibility or lack of motivation for employees, etc.

In general, failures of any kind of systems are divided into two types: gradual and sudden, the risk, on the one hand, is a surprise, however, on the other hand, it becomes possible to predict the risk, analyze it and assess its impact over time, which may subsequently be used for scientifically substantiated choice of management decisions to prevent the risk factors or weaken the risk's effect.

To develop a methodology for assessing risks in organizations, the foundations of reliability theory can be applied. When calculating the reliability of complex systems represented as the connection of elements with an established linear structure, it is assumed that the failure flow of the system is the simplest, satisfying the stationarity conditions, the absence of consequences and the ordinary, so the failures of the elements of a complex system are random and independent events. Then the probability of failure-free operation $P_c(t)$ of a complex system during the time t will be equal to the product of the probabilities of failure-free operation of its elements in time:

$$P_c(t) = p_1(t) \cdot p_2(t) \cdot \ldots \cdot p_N(t) = \prod_{i=1}^{N} p_i(t),$$

where p_i is probability of failure-free operation of the i-th element, N is a number of elements of the system.

Accepting the condition of stationarity of the failure flow, then $p_i(t) = e^{-\lambda t}$, and

$$P_c(t) = \prod_{i=1}^{N} e^{-\lambda t} = e^{-t} \sum_{i=1}^{N} \lambda_i$$

where λ_i is an intensity of the failure of the i-th element.

Hence, in order to calculate the reliability of such a complex system, it is necessary to be able to determine the failure rate of each of its elements (the number of failures for the selected time interval is a statistical indicator calculated on the assumption that failure is a random event). The average statistical data on the failure rates can be obtained from the data on the operation of systems similar to the analyzed.

However, the most important characteristic of the reliability of the system is the time of its trouble-free operation. It is also the calculated probability characteristic, which shows that the failure of the system does not arise within the given operating time. For example, if one uses the hypothesis of the equidistance of the elements of the analyzed system, that means that all elements have the same average failure rate, the intensity of the system failures can be expressed as the sum of the failure rates of the elements: $\lambda_c = \sum_{i=1}^{N} \lambda_i$ In this case, the estimated time of the no-failure operation of the system is defined as:

$$T_c = \frac{1}{\sum_{i=1}^{N} \lambda_i}.$$

The problem becomes more complicated if the structure of the system is not linear, i.e. the interaction between the elements of the system takes place in pairs, crosswise, backward. In this case, the simplest formula for the probability of failure-free operation of the system $P_c(t)$, expressed in terms of the product of the partial probabilities of failure-free operation of its elements, turns out to be incorrect, and it is required to evaluate the probabilities in accordance with the structure of the system.

An important condition for calculating the probability and time of failure-free operation is the assumption that at the initial time (the beginning of the run-time calculation) the system was in an operable state. This makes it possible to involve in the calculation of reliability the theory of Markov processes, which is also called the probability dynamics. Of course, the scope of application of this theory is limited (in particular, with the above-mentioned condition for partial uncertainty), but it is necessary in such areas as queuing theory, reliability theory, optimal decision making theory, etc., which operate with the concepts of random processes reflecting random change of system states in time (or depending on another chosen argument), described by random functions.

The use of Markov processes in reliability analysis is recommended by IEC 60300-3-1 "Dependability management: Part 3-1 - Application guide - Analysis techniques for dependability - Guide on methodology", NEQ [4]. In particular, the standard suggests that "the presentation of the behavior of the system through the Markov model requires the determination of all possible states of the system, preferably depicted schematically in the state diagram and transitions. In addition, the intensity of transitions from one state to another (the intensity of failure and recovery of components, the intensity of events, etc.) should be determined. A typical result of applying the Markov model is the probability of finding a product in a given set of states ...". It also points to the main advantage of this method: "the ability to obtain a flexible probability model for analyzing the behavior of the system ..." (A.1.5.3).

The above assumption about the operable state of the system at the beginning of the calculation of the operating time in the theory of Markov processes will be interpreted as a random process without aftereffects, characterized by the so-called transition probability - when the probability of a system transition to each subsequent state depends only on the previous state and does not depend on how the system has come (or has been reduced) to the previous state: $P_{i/i+1} = f(S)$. The selection of reference points in the form of system states, which are determined, for example, by the frequency of monitoring by management or by corrective measures, leads to the partitioning of the random process into its discrete states, and such a random process is regarded as a random sequence. If a random sequence has a Markov property, then it is called a Markov chain, and in the case of discretization of system states with respect to time, a discrete Markov chain in which the system can jump from one state to another after a certain impact.

3. Conclusion

In a free market, the successful operation of enterprises is impossible without increasing the requirements for quality products. This justifies the relevance of the implementation of a quality management system [5-7] and the need to use a risk-based approach in its formation.

The effectiveness of the quality management system can be enhanced through risk management activities aimed at achieving better results and preventing adverse consequences. For this, the organization needs to identify the risks and opportunities to be considered, plan and implement actions to reduce them and assess the effectiveness of these actions. At the same time, it is necessary to use a systematic approach that includes organizational issues of risk management associated with identifying and assessing risks, taking measures to reduce the negative impact of risks, as well as the monitoring and analysis order [8]. In [9] developed risk management methodology is presented, which is a tool for improving the process of making and executing management decisions aimed at reducing the likelihood of an adverse result and minimizing possible losses. The methodology was tested, brought to practical use and applied in the documented procedure “Risk Management” in the documentation for the quality management system of the ITMO University (St. Petersburg, Russia).

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