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**RISK-ORIENTED THINKING IN THE QUALITY MANAGEMENT SYSTEM
OF AN ORGANIZATION**

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Abstract

High dynamics of modern production development lead to many new tasks and, at the same time, an increased level of risk and its diversity. This makes enterprises not only periodically, but constantly identify new risks, analyze them and develop appropriate methods for their management based on risk-oriented thinking, the basic principles of which are formulated in ISO 31000 and ISO 9001. The article presents risk-oriented thinking models in quality management system and risk management in quality management system, allowing one to carry out management activities in a situation of uncertainty and make decisions aimed at preventing mistakes in the management of organization and ensuring proper quality.

Keywords

Quality management system – Risk – Risk-oriented thinking

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Introduction

The characteristic features of the modern world include competition for resources and markets and, since recently, struggle in the field of science and technology. In addition, the modern world is characterized by rapid changes and high development dynamics, which leads to many new tasks, and, at the same time, to an increased level of risk and its diversity. Standards in risk management are regularly updated, reflecting the latest trends and identifying new approaches to risk management. All this makes enterprises not only periodically, but constantly identify new risks, analyze them and develop appropriate methods for their management. However, as studies show, not all enterprises cope with this task successfully.

In 2017, the international consulting company “Deloitte”, together with the Institute for Strategic Risk Analysis, conducted studies to assess the level of risk management maturity of 50 large Russian enterprises in engineering, metallurgy, transport, communication and energy industries Rezultaty issledovaniya kompanii “Deloit”¹.

The study revealed that 68% of the enterprises considered results of risk analysis in strategic planning. Only 8% had this procedure regulated. In one-third of the enterprises, the documented procedure “Risk management” did not comply with GOST R ISO 31000-2010 or was completely absent. The remaining 32% did not analyze risks at all. Moreover,

- 72% did not associate risk management with key performance indicators;
- 81% did not calculate risk appetite;
- 84% did not integrate risk management with business decisions;
- 45% did not inform their personnel about risks associated with the decision-making process.

According to the results of the study, the overall maturity level of risk management of the Russian enterprises amounted to 1.77 points on a three-point scale. For most enterprises, it is rated low (40%) and medium (42%); only 18% received a high assessment of their risk management culture. The main factors preventing the effectiveness included the low interest of leaders in risk management and analysis, as well as the use of only qualitative assessment methods and the lack of skills for quantitative assessment of risks impact Rezultaty issledovaniya kompanii “Deloit”².

The following main trends in risk management development in the quality management system (QMS) of Russian enterprises are observed:

- 1) development of a risk management culture;
- 2) integration of risk management elements in the processes of setting goals and formation of key risk indicators;

¹ Rezultaty issledovaniya kompanii Deloit, “Upravlenie riskami v Rossii: uroven zrelosti”, Business Excellence num 6 (2017): 28-32.

² Rezultaty issledovaniya kompanii Deloit, Upravlenie riskami v Rossii...

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- 3) integration of risk management elements in key production processes;
- 4) introduction of quantitative assessment tools.

These promising areas should be taken into account by leaders of organizations when developing a risk management system.

Recently, risk management specialists and experts have noted that the classic approach used by organizations, namely, timely identification, risk assessment and management, is insufficient. In their opinion, a new approach to risk management should be aimed at making management decisions considering risks, which requires the use of new tools A. Sidorenko³, M. A. Rodionova⁴, Yu. M. Golubinskii, A. G. Elistratova, V. A. Piskunova.⁵

This approach is required by the latest revisions of the standards GOST R ISO 9001-2015, GOST R ISO 31000-2010, ISO 31000: 2018, which are concerned not with risk management, but risk-oriented management and thinking GOST R ISO 9001-2015, 2015⁶, GOST R ISO 31000 – 2010 , 2010⁷, ISO 31000:2018⁸ . “Risk management is not an individual activity, which is separated from the main activities and processes in the organization. Risk management is a part of obligatory management and an integral part of all organizational processes, including strategic planning and all processes of project and change management. In addition, today, quality management is no longer considered a narrow specific activity limited by the production process, but the administration and management of the entire organization, which considers risks and capabilities, allowing one to constantly improve the organization’s activities based on the strategy aimed at using capabilities and counteracting various constantly changing negative factors both in the internal and external environments of the organization S. A. Zaitsev, O. F. Vyacheslavova, I. E. Parfeneva, T. Lartseva⁹. One of the principles of quality management is evidence-based decision-making associated with the fact that decisions, relying on the analysis and assessment of data and information, are more likely to produce desired results GOST R ISO 9000-2015¹⁰. However, decision-making processes in QMS of organizations occur, as a rule, in uncertainty, which, in its turn, arises as a result of a number of factors, such as I. I. Mazur, V. D. Shapiro, N. G. Olderogge¹¹.

³ A. Sidorenko, “Mirovoi risk-menedzhment menyaetsya”, Business Excellence num 6 (2017): 23-27.

⁴ M. A. Rodionova, Proektirovanie i vnedrenie protsessa menedzhmenta riska v sisteme kachestva predpriyatiya (Moscow: INFRA-M, 2017).

⁵ Yu. M. Golubinskii; A. G. Elistratova; V. A. Piskunova and E. S. Chernova, “Primenenie risk-orientirovannogo myshleniya v novoi versii standarta ISO 9001:2015”, Izmerenie. Monitoring. Upravlenie. Kontrol num 2 Vol: 16: 201-274.

⁶ GOST R ISO 9001-2015 Sistemy menedzhmenta kachestva, Trebovaniya (Moscow: Standartinform, 2015).

⁷ GOST R ISO 31000 – 2010 Menedzhment riska, Printsipy i rukovodstvo (Moscow: Standartinform, 2010).

⁸ ISO 31000:2018 Menedzhment riska, Rukovodstvo (russkii perevod).

⁹ S. A. Zaitsev; O. F. Vyacheslavova; I. E. Parfeneva and T. A. Lartseva, Sistemy menedzhmenta kachestva: razrabotka, vnedrenie, uluchshenie: uchebnoe posobie (Moscow: RUSAINS, 2019), 206.

¹⁰ GOST R ISO 9000-2015 Sistemy menedzhmenta kachestva, Osnovnye polozheniya i slovar (Moscow: Standartinform, 2015), 49.

¹¹ I. I. Mazur; V. D. Shapiro and N. G. Olderogge, Upravlenie proektami: uchebnoe posobie. Edited by I. I. Mazura. 2-e issue (Moscow: Omega-L, 2004), 664.

- insufficient knowledge of all parameters, circumstances and situations for choosing the optimal decision, as well as impossibility of adequate and accurate accounting of all information and probability characteristics of environment behavior;
- random factor, that is, implementation of factors that cannot be foreseen and predicted even in a probability implementation;
- subjective factors of opposition, when a decision is made in the situation of partners dealing with opposite or conflicting interests.

Methods of assessment, analysis and risk treatment

There are numerous capabilities and various methods of risk assessment, analysis and treatment GOST R ISO/MEK 31010-2011¹², the lack of a structured approach to the choice of which makes leaders at different levels of management rely only on their experience, knowledge and intuition. This often leads to loss of invested time and money.

Risks have traditionally been assessed and managed in various informal ways (empirical and/or internal procedures) based on, for example, a compilation of observations, trends and other information. These approaches continue to provide information that may be useful in areas such as processing of complaints, quality defects, error and resource allocation.

From our point of view, risk management in QMS should be based on a scientific and practical approach to decision-making, which is documented and uses transparent and reproducible methods for performing all steps of the process, based on current knowledge on assessing the probability, severity and detectability of risk and turning into a systematic process of determining the situation, planning, assessment, monitoring, control and analysis throughout the entire life cycle of objects.

Results

Based on the analysis of current changes in the world and domestic risk and quality management, the following definition can be formulated: "Risk-oriented thinking in QMS is an approach to the administration and management of an organization relying on management decisions taking into account risks with regard to quality, in which the emphasis from identification, analysis, assessment and risk management is shifted to the assessment of business decisions and factors affecting the deviations from goals, as well as to the assessment and use of favorable opportunities, retention, acceptance or avoidance of risk".

Based on the above, it is reasonable to consider the concept of "risk in QMS" as a characteristic of management activities carried out in a situation of uncertainty due to insufficient information, when a leader chooses an alternative decision, the effectiveness criterion of which is associated with the probability of financial loss caused by low quality. The risk-oriented thinking model in QMS is presented in (Figure 1).

¹² GOST R ISO/MEK 31010-2011, Menedzhment riska. Metody otsenki riska (Moscow: Standartinform, 2012), 74.

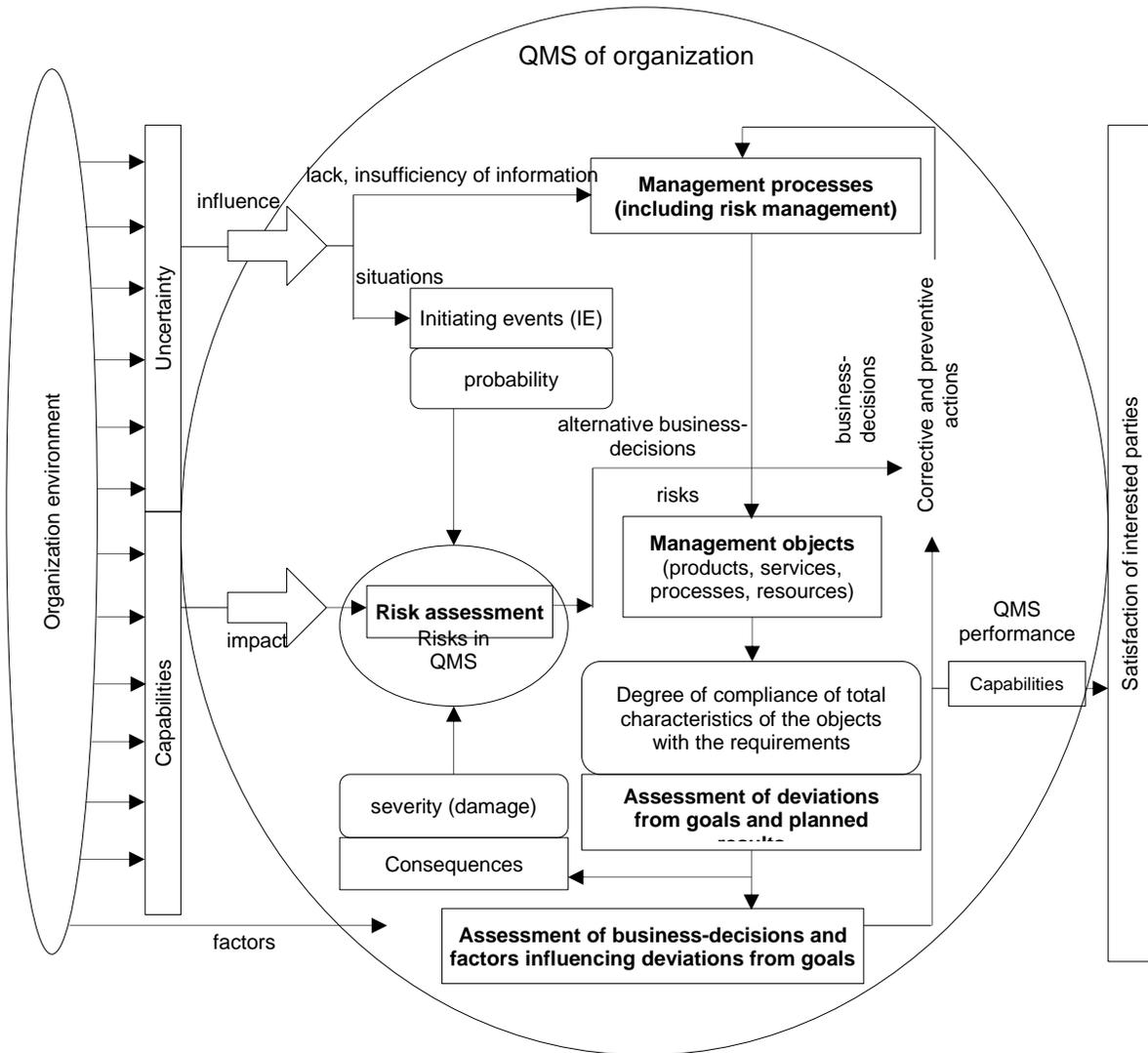


Figure 1
Model of risk-oriented thinking in QMS

Within the proposed risk-oriented thinking model in QMS, a risk management model is developed (Figure 2). According to this model, the decision-making takes place at any point of each of the presented processes. If necessary, these decisions can be a return to the previous step and the search for additional information or even the termination of the risk management process based on the information that supports this decision. Each component of the structure can differ, but in any case, the process involves the consideration of all elements at the level of detalization commensurate with the specific risk.

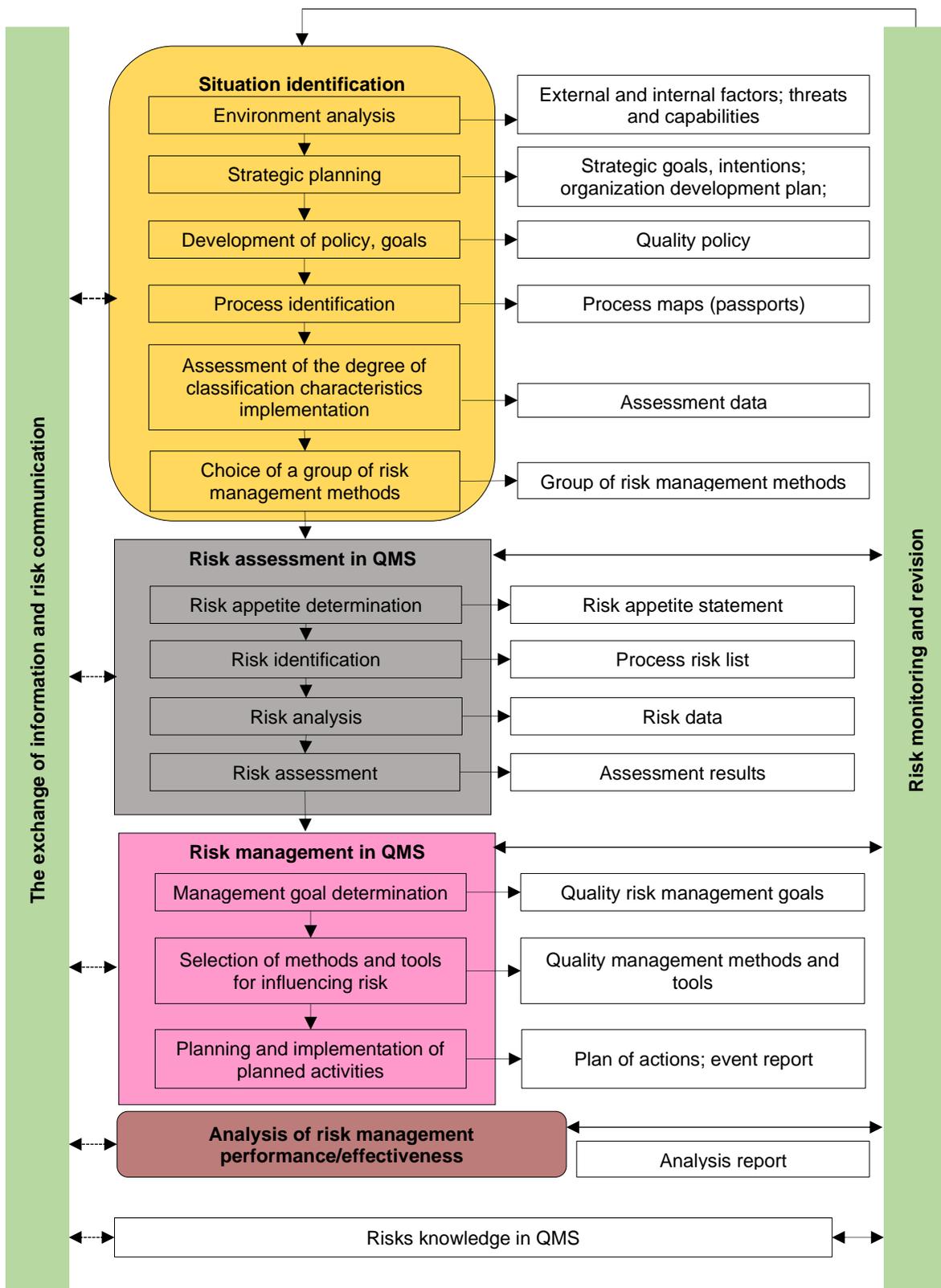


Figure 2
Model of risk management in QMS (mechanism)

Discussion

The main function of risk-oriented thinking in QMS is to prevent mistakes in the management system of the organization to minimize the impact of uncertainty on the degree, to which total characteristics of the management object meet the requirements. Moreover, products, services, processes and resources are understood as the object. The proposed risk management mechanism in QMS is based on the concept of risk-oriented thinking, enshrined in the standards ISO 9001 and ISO 31000. Risk management in QMS should start with an analysis of the organization environment, based on which the organization strategy (articles 4.1 and 4.2 of GOST R ISO 9001-2015) and quality policy (article 5.2 of GOST R ISO 9001-2015) should be developed and the goals in terms of quality (article 6.2 GOST R ISO 9001-2015) should be determined. The analysis of goals will allow the organization to identify the processes necessary for effective quality management, achievement of the planned results and determination of their sequence and interaction (article 4.4.1 of GOST R ISO 9001-2015). Next, at the step of situation determination, it is reasonable to select risk management methods. This selection will depend on the features of the organization, its products, as well as the nature of the risks and their consequences.

Risk assessment in QMS includes identification, analysis and assessment, which should become a part of management decision-making process at different levels of organization management. Based on the results of the first two steps, management goals should be determined that are interconnected with management methods, including risk avoidance, risk localization (risk identification and control), risk diversification (minimization of possible losses) and risk compensation (risk prevention). The effectiveness and efficiency of the measures taken to manage risks in QMS can be determined by one or more indicators established at the step of situation determination, taking into account the attributes of the identified processes. Performance/effectiveness criteria should be associated with such indicators as quality, time and costs.

In addition, the standard GOST R ISO 9001-2015 has significantly changed the approach to the competence of the organization, putting forward the concept of “organization knowledge” and “knowledge management” (article 7.1.6 of GOST R ISO 9001-2015), which is also taken into account in the developed model. With this approach, not only the experience of individual specialists is important, but also the joint competencies of the whole personnel, including risk management, which is ensured by the accumulation of knowledge in the organization information funds, proper formation of teams, working groups, etc. The degree of formalization and documentation of risk management procedures in QMS should reflect the existing knowledge and commensurate with the complexity and/or importance of the issue under consideration.

Conclusion

Thus, the increasing competition in the Russian and world markets requires organizations to be flexible and dynamic and to respond quickly to changes in the internal and external environment, as well as the transition of goal-setting from profit priority to quality priority, which is possible only by creating and functioning “through the prism of risks and capabilities” of own effective management systems. The concept of risk-oriented thinking consists in making management decisions taking into account risks; therefore, risk management in QMS should not be a goal of the organization in itself, but should be considered as a tool to achieve goals.

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