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ZASTOSOWANIE PODEJŚCIA OPARTEGO NA RYZYKU W ANALIZIE KONTEKSTU ORGANIZACJI ZGODNIE Z NORMĄ ISO 9001:2015

Streszczenie: W artykule przedstawiono zagadnienie zarządzania ryzykiem w oparciu o analizę kontekstu organizacji. W wyniku czwartej nowelizacji normy ISO 9001 obowiązkiem organizacji jest wdrożenie podejścia opartego na ryzyku w całym przekroju swojej działalności. Zarządzanie ryzykiem w współczesnych czasach jest niezbędną do implementacji koncepcją w aspekcie utrzymania strategicznej pozycji rynkowej oraz stworzenia korzystnych warunków do dalszego rozwoju.

Słowa kluczowe: Zarządzanie ryzykiem, analiza w kontekście organizacji

APPLYING THE RISK-BASED APPROACH IN ORGANIZATION CONTEXT ANALYSIS IN ACCORDANCE WITH THE STANDARD ISO 9001:2015

Summary: The article presents the problem of risk management based on the analysis of the context of the organization. As a result of the fourth amendment of the ISO 9001 standard, the organization's responsibility is to implement a risk-based approach across its entire cross-section. Risk management in modern times is essential to implement the concept in terms of maintaining strategic market position and creating favorable conditions for further development.

Key words: Risk management, analysis of the context of organization

1. Introduction

ISO 9000 series quality management systems have been used in organizations around the world for more than 25 years. During this time, the standards of the ISO 9001 family have gained enormous popularity and have contributed to the standardization of business language around the world. There is no doubt that quality management is currently the most widespread approach to managing today's organization. Since the

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establishment of ISO 9001 standard several amendments have been made. The International Organization for Standardization is constantly on the lookout for standards to match the evolving market demands, management trends and needs of the organization. The new version of ISO 9001: 2015 encourages the organization to place more emphasis on analyzing the context of the organization and the business environment in which the business entity operates. The ISO 9001: 2015 standard was more flexible in terms of documentation requirements. The revision of the release ensures greater compatibility of the various elements of integrated management systems through a common structure and the direction of the organization to take a risk-based approach. [4]

Applied to ISO 9001: 2015, the wording has been modified to fit all types and sizes of organizations. The introduction of the term "products and services", taking into account all input options, highlights the differences in the application of certain requirements to services and products. A significant change in the new standard, with respect to predefined process approach requirements, is the need to define the required inputs and expected outputs, assign rights and responsibilities within processes, address identified risks and opportunities, and evaluate processes with the necessary changes.

The revision of the ISO 9001 standard introduced the need to define and maintain the organization's knowledge necessary for the functioning of the processes and for the conformity of products and services. The purpose of the treatment was to protect subjects against loss of know-how resulting from staff turnover or inadequate information distribution, and to assist the organization in the process of acquiring knowledge through experience, mentoring and benchmarking. It is not known today that the organizations build people together with their competences. Organization knowledge is based on internal and external sources. The knowledge of the organization should also be considered in terms of analyzing the context of the organization.

In the latest issue of ISO 9001, emphasis has been placed on the role of senior leadership in terms of leadership and commitment to the implementation, maintenance and improvement of an integrated management system. According to the norm, management should demonstrate compliance with Take responsibility for the effectiveness of the system, ensure the integration of goals and system requirements with the business processes of the organization and the strategic direction of development. This new edition also mentions the responsibilities of the management with regard to risk management. Top management should promote a risk-based approach and ensure that risks and opportunities are identified and taken into account that may have an impact on the integrated management system. The new release extends the scope of the management review to include aspects related to the change of external and internal factors relevant to the management system, feedback from the stakeholders, and the assessment of the effectiveness of the risk and opportunity analysis.

ISO 9001: 2015 has increased the requirements for the change management process at system level and operational level. Changes can be the result of Complaints, feedback, implementation of innovations, identified risks and opportunities, internal and external audits, management reviews and discrepancies. Changes can be made to any part of the system. To get the positive effects of the changes, the entity should

consider the risks and opportunities associated with the modification being implemented. [3, 8]

One of the most significant changes in ISO 9001 is adopting a systematic approach to risk in all areas of organization management. The risk-based approach assumes the identification, evaluation and risk monitoring of both the design and the operation of the management system. In ISO 9001:2015, preventive actions have been eliminated because the concept of these activities is embodied in a risk-based approach and forms an integral part of strategic planning. Risk management is the decision-making process whereby an entity has the opportunity to exploit the opportunity and influence the co-occurring risk by taking adequate action in the implementation of the organization's business strategy. According to PN ISO 31000 standard, risk management is a process in which systematic management policies, procedures and practices are systematically applied to the following: contextualization, communication and consultation, identification, analysis, evaluation, management, monitoring and risk management. Risk management should be aware of the decision-making and implementation of activities aimed at achieving acceptable levels of risk. Risk management is identified with risk management and diagnosis activities that aim to ensure a stable performance of the entity and to create conditions for further development. [3][9][10]

ISO 9001: 2015 is more flexible and less stringent than the previous version. This new release directs organizations to focus on the efficiency and effectiveness of the management system. The standard shows organizations the path to success by applying a combination of a process approach and a risk-based approach, and applying the PDCA cycle at all levels of the organization, taking into account the context in which the company operates. The purpose of the amendment was to orient the organization to meet the needs of customers and to integrate market needs. Contemporary companies operate in a dynamic environment, which brings new challenges to them. These conditions have been noticed not only by the committee working on the standard but also by the users themselves of the standard. That is why in the new ISO 9001 risk management, change and knowledge aspects play a significant role. [3][4]

2. Risk-based approach

According to ISO 9001, the risk refers to some degree of uncertainty in meeting the set objectives, is ensuring the organization's ability to consistently deliver products that meet the identified requirements and to continuously improve customer satisfaction. ISO 9001 points out that despite the general view that risk is a negative thing, adopting a risk-based approach makes it possible to identify opportunities for an organization. To summarize, we can understand all potential internal and external consequences that may negatively or positively affect the achievement of the company's goals. The essence of risk-based thinking, popularized by ISO 9001: 2015, is to support the organization in identifying opportunities for higher-than-expected outcomes and addressing existing or potential risks. Opportunities and risks are an extremely important part of the organization's business strategy planning process. The new ISO standards have introduced a new approach to stakeholders, which is considered one of the most important corporate governance principles. At present, most entities are already aware that it is impossible to build a long-term business

success without taking into account the requirements and expectations of the stakeholders. Keep in mind that this process should be a continuous process based on constant monitoring and review of stakeholders' data and needs. The table no. 1 presents sample expectations of interested parties. [8][2][1]

Table 1. Sample expectations of interested parties

Interested parties	Expectations of interested parties
Unions	• Ensuring compliance with legal requirements, • Guaranteeing the proper working environment, • Minimizing occupational risk,
Management	• Minimizing energy costs, • Building the expected level of quality awareness of employees, • Ensuring the organization's compliance with legal requirements, • Obtaining additional funds for investments,
Customers	• Ensuring high-quality products, • 36-month warranty on offered products, • An annual reduction in product prices, • Use of returnable packaging, • High production customization, • Delivery on time rate of 98%,
Certification bodies	• Compliance with the contract terms with the certification body,
Environmental organizations	• Meeting legal requirements, • Action to reduce the negative impact on the environment, • Compliance with the provisions contained in the permits,
Local community	• Providing adequate protection measures against emergency situations, • Action to reduce the negative impact on the environment, • Implementation of the Corporate Responsibility Policy,
Employees	• Increase in pay and creation of an incentive system, • Investing in human capital through training, courses and funding subsidies, • Minimizing occupational risk,
Banks	• Timely repayment of liabilities and fulfillment of other terms of contracts,

One of the major changes resulting from the revision of ISO standards is the need for businesses to focus on analyzing the context of the organization. The intention of the authors was to show that organizations function in a dynamic environment and participate in numerous interactions occurring in both the proximate and distant environments. The standard requires the understanding of the context of the organization, the identification of relevant stakeholders, their expectations and requirements for the management system, and the resulting opportunities and risks to which the entity should refer. The context of the organization is a relatively new concept, reflecting the need to adapt management systems to the factors affecting organizations. Context is a combination of external and internal factors that can

potentially influence an organization's ability to achieve its goals. External factors may include aspects such as cultural, social, legal, political, economic, technological and competitive conditions at international, national, regional or local level. Internal factors typically include culture, values, organizational knowledge, and internal business performance requirements. Understanding the context of an organization is a determinant of a company's success in achieving sustainable development through mission, policy, and organizational goals. [9] [5] [3] [10]

An integrated approach to risk management increases the ability of the subject to flexibly adapt to changes in the external and internal environment. The functioning management system must be a living creature that flexibly adapts to the changes that arise from the entity's living environment. To be able to effectively minimize the uncertainty inherent in your organization, you should:

- gather and collect data on potential risks and opportunities and their impact on organizations,
- analyze and evaluate the information obtained,
- develop effective procedures and
- monitor and update as needed.

In order to effectively manage the risk management process, it is necessary to specialize in accurately predicting the effects of possible future events on organizations, by analyzing the potential effects and the likelihood of their occurrence on the basis of risk analysis. The effect of using a risk-based approach is to implement planned actions in an organization's processes in an integrated manner and evaluate their effectiveness through monitoring. Considering the dynamics of the environment, monitoring and updating risks and opportunities must be a continuous process. The effectiveness of the implemented actions should be one of the topics covered by the management reviews. The scale of actions should be proportionately matched to the potential impact of risk on the functioning of the organization. Defined risk management should be described and disseminated in detail for effective control and the ability to review established risks. When setting up plans of action, one should strive to impose a clear responsibility for the implementation of individual actions and cover all aspects identified at the identification stage. The purpose of monitoring is to record changes in the business environment and to provide reliable information. Risk monitoring is the basis for implementing action plans and controlling risks. The environment is so dynamic that only continuous monitoring gives guarantees of the effectiveness of the risk management process. [6, 7, 10]

As most authors of management work predicts, current trends will remain unchanged and will deepen. In the future, companies will be forced to operate in an increasingly turbulent environment where factors continue to determine the possibility of economic success. The risk management process in modern times has a profound impact on the existence of economic operators in the context of market competition, so it is important to understand the context of the organization together with the needs and expectations of stakeholders. Adopting a systematic approach to risk management in the organization enables organizations to meet the needs and expectations of stakeholders. Given the fact that at present the risk is a permanent element in the functioning of the organization, its management should be a natural reflex of companies at every operational level. This is important in terms of even the effectiveness of managing the entire organization in the context of achieving the

set goals. The risk management process should be tailored to the existing organizational culture that is understandable to participants and stakeholders and is conducted in accordance with established methodology and legal regulations. The responsibility and expected competence of the people involved in the implementation of the process should be strictly defined and the entire risk management process planned. By working in a dynamic environment, it is important to be aware of the importance of adopting a risk-based management style and supporting mechanisms to effectively respond to the impact of the environment. [2, 6]

3. Risk management methods in organizations

Entrepreneurship approach to the aspect of risk management is characterized by constant evolution, which is a direct consequence of the development of a risk-based approach. There are now a wealth of tools and methods to support the risk management process based on statistics, experience, and expertise. Many of them are included in national and international standards or guides and recommendations from international organizations and associations and even regulated by law. The ISO 31000 standard describing 31 methods for risk assessment is helpful. In spite of the multiplicity of existing methods, one can see that there is a constant pattern of risk management that is depicted in Figure no. 1.

All methods dedicated to risk assessment contain common elements. These include: hazard identification, risk assessment, or probability of potential risks and losses that an entity may incur and risk assessment. The purpose of the identification step is to collect as much data as possible about the potential risk consequences for the entity along with the identification of risk factors. The result of the identification step should be the compilation of a complete list of risks arising from potential events that, depending on the determinant, can create, prevent, accelerate, delay, or prevent the goal from being achieved. In the further part of the process, the collected materials are subjected to a risk analysis, based on which decisions are made regarding the way of dealing with risk. The greatest stress at this stage lies in determining the consequences of the risk and the probability of its occurrence. Risk assessment involves assessing the relevance and acceptability of the risk from the perspective of the entity. Risk cannot be overestimated or underestimated. The established risk levels are compared with the criteria. The comparison requires high accuracy and reliability. It is estimated whether the anticipated risk falls within the acceptable limits of the organization. Risk evaluation determines how risk is dealt with. [1, 10, 9]

Depending on the severity of the effects associated with the defined risk and the probability of its occurrence, we use various activities to reduce its level to acceptance level. Risk management may take into account PN ISO 31000:

- risk avoidance performs a preventive function, by the decision not to start or continue to carry out risk-taking activities. To avoid risk, we can eliminate assets or processes that have certain vulnerabilities and thus put us at risk,
- take or increase risk to take advantage of the opportunity,
- risk reduction consisting of changing the consequences, probability of occurrence of a risk or removal of a source of risk,
- risk sharing with other parties,

- risk acceptance on the basis of informed decision, provided that they meet the requirements of the organization's policies and risk acceptance criteria. [10]

The expected outcome of a risk assessment is to plan for effective responses to potential risks. Risk assessment is the starting point for developing options for actions and actions aimed at reducing risks from possible risks on the one hand, and, on the other, increasing the potential benefits of achieving the goals. It is important for the planned actions to be proportionate to the consequences of adverse events, to neutralize the impact of the threat in an economically viable manner and to be implemented in accordance with the schedule. [10] [3] [7]

The standards applicable to risk management primarily recommend using available tools to consolidate and build the organization's knowledge of risk management, is identified risks, and the decisions and actions taken in the management process. This enables companies to learn and improve their methods and to support decision-making through the use of stored historical data.

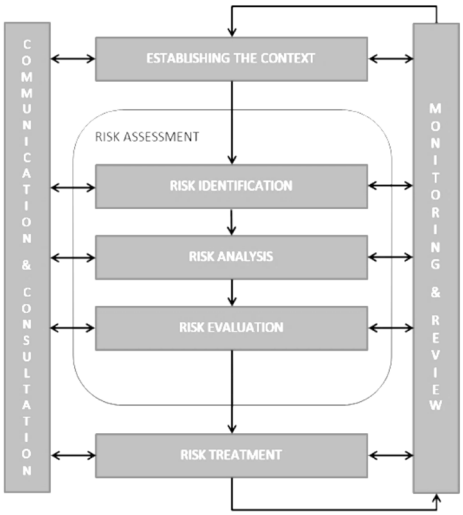
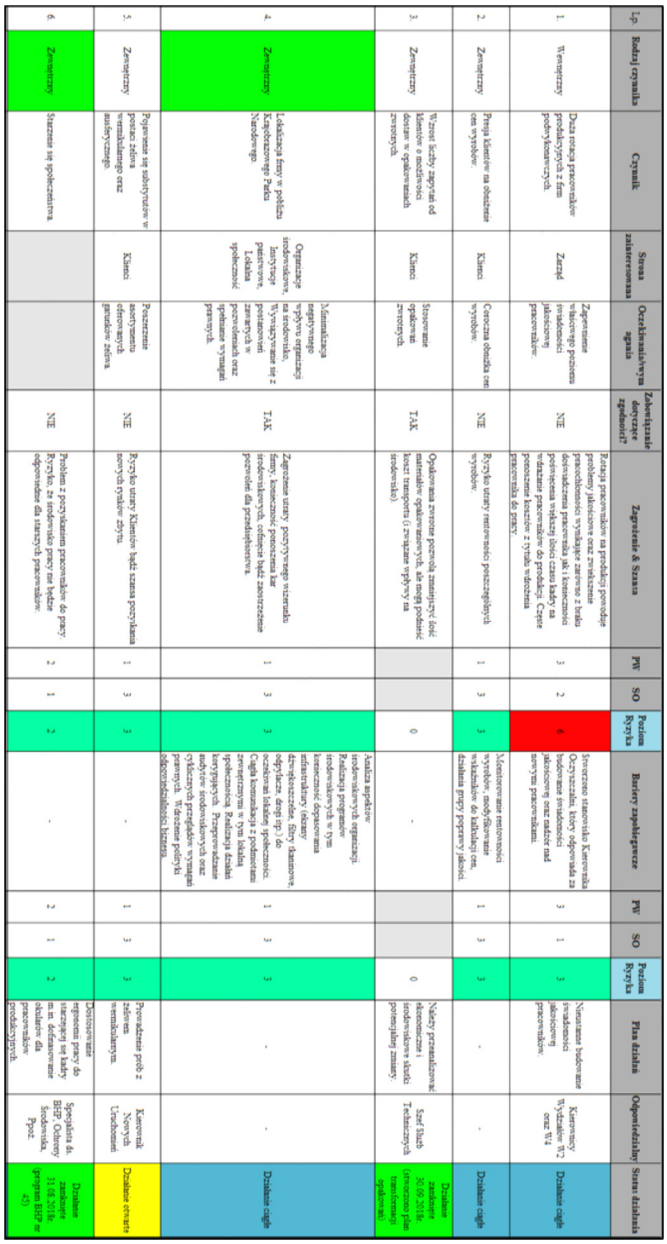


Figure1. Risk management scheme according to PN ISO 31000

No organization operates in a vacuum only within the network of internal and external connections, so it is important to examine these relationships in terms of their impact on the functioning of the organization. Understanding the context is a prerequisite for determining the key elements of the system, is risk and opportunity, the scope of the management system, processes, quality policy and quality objectives. When defining the context of an organization, it is necessary to refer to the defined goals, responsibilities, scope and scale of activities undertaken. To identify the context of the organization, a variety of methods have emerged that are dedicated to the organization, depending on their size and activity profile. In small organizations, context identification can be accomplished using the popular SWOT analysis. In larger organizations, it is advisable to use a method to address specific organizational environment factors. The most common methods of environmental analysis dedicated to larger companies are based on the PEST or STEP method. On the other hand, for organizations with integrated systems or those that use a large number of diverse resources in their operations, it is recommended to expand

the categorization and to treat individually the legal and environmental aspects of the PESTEL method. In practice, companies use systematic analysis of competition and market development, which can also provide information about the context of the organization. The following is an example of a fragment of the risk analysis of the organization's context (Table no. 2). [6, 5, 8]

Table 2. An example of a fragment of the organization context analysis



4. Summary

ISO 9001 standards have played a significant role in spreading the concept of quality management worldwide. They have helped to build a platform and a common management language for over a million organizations. Standards are constantly evolving to match their changing realities and user needs. ISO 9001 revision marks a new direction for the organization. The new requirements focus on understanding the context of your organization to fully meet the needs and expectations of the relevant stakeholders.

To effectively manage risk in an organization, you must implement risk-based thinking into your organization's business management systems and decision-making processes. So that all the components of the risk management process are inextricably linked to the organization's management process. Entities operating on the market, regardless of their size, have contact with internal and external factors. These factors generate uncertainty, resulting in the risk of belonging to the business profile. Factors affecting organizations are constantly changing, so they should be regularly monitored and reviewed. Risks reflect the impact of the various threats and involve the possibility of loss. [5] [4]

Taking into account the incredible dynamics of the environment, which depends on the efficiency of the operations of organizations, theories of risk management are increasingly popular. Many qualitative and quantitative methods have been developed to assess risk, but all are based on the same elements, is hazard identification, analysis and estimation of the effects and probability of occurrence of risk. Risk management is not limited to the hazard area, but also to opportunities for the organization. Risk management helps to create and protect a value that translates into efficiency and effectiveness in reaching organizational goals including: By supporting decision-making. A risk-based approach assumes the planning and implementation of integrated risk prevention and risk-taking measures. The scale of activities should be closely aligned with the potential impact of the risk on achieving the objectives of the entity. Companies to stay in a turbulent environment must implement appropriate action strategies based on the building of monitoring and early warning systems, setting up scenarios and rapid response plans. Risk management can lead to new risks or modifications to existing ones, so it is important to continually monitor and update the data processed in the risk management process.

The introduction of a risk-based approach in the new ISO 9001: 2015 standard can certainly be seen as significant from the point of view of adapting businesses to the new economic reality. Everybody striving to achieve their goals must face ubiquitous risk. Implementing risk management components into management systems makes organizations make informed decisions. The risk management process should be characterized by continuity and logically sequential sequence of successive events, decisions, actions that result in creating an acceptable level of risk for the organization. In order to meet ever higher market demands and to ensure stable growth in a troubled environment, it is imperative to incorporate a risk-based approach into the corporate culture. [6, 4, 10, 9]

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