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RISK MANAGEMENT - AN IMPORTANT ISSUE IN QUALITY MANAGEMENT SYSTEMS

Abstract: *In the current economic conditions and increasing competition on the market, the risk undertaking is normal and necessary phenomenon for the dynamic development of companies. Risk management provides appropriate responses to identified threats and hazards in different areas of the organization. This article will discuss the importance of identifying and assessing business risks in relation to the requirements of standardized management systems.*
Keywords: *risk management, ISO9001, quality, management systems,*

1. INTRODUCTION

An essential element in the strategy of any organization is to minimize business risk to a level that ensures the security market. To ensure efficiency and competitiveness, it is required from the organization to implement a system and a comprehensive approach to risk management, and therefore to identify effective methods for identifying, analyzing, monitoring and mitigation of risk. System management and its improvement should lead to a comprehensive minimizing of the risk of adverse events. A number of rules and standards supports this objective of minimizing risk. Universally known solutions relates to corporate risk management, environmental risk, the risk for accidents, sickness, biological risk or loss of reputation due to the poor quality of the product [1, 2].

Risk is defined in the ISO 31000 standardas "the effect of uncertainty on objectives" [3]. At the same time it is shown that the uncertainty causes a deviation from the expectations - positive and/or negative. Risk is often expressed as a combination of the consequences of an event (including changes in circumstances) and the associated probability of occurrence. Combining the effects of the events of the likelihood of its occurrence is the most common component of the definition of risk. Risk management is defined as the coordinated efforts of directing and supervising the organization's risk. This definition is similar to the definition of the management of the different standards but a different element is always a major problem for the standard. In the ISO 31000 standard this applies to risk, and in the ISO 9001 it relates to quality [4].

2. THE RISK IN THE STANDARDIZED MANAGEMENT SYSTEMS

The objective of each standardized management system is a systematic approach to supervise activities in the organizations, focusing on the prevention of non-compliance [5]. Standardized management systems meet the

requirements of different standards, and are a tools of profiled risk management within the organization. The most commonly certified system in the world is the quality management system based on ISO 9001 standard [6]. It can be indicated that the company implementing and certifying this system is focused on risk management in the area of quality.

Another widely used management system is the environmental one, relating to the requirements contained in ISO 14001 standard [7]. Organizations that certify this management system, systemically manage the risk in the area of influence of the organization and its products on the environment. This standard sets requirements for the identification of environmental aspects that have or can have significant impacts on the environment and incorporate these aspects in planning action to minimize adverse impacts on the environment. The environmental aspect is defined there as part of the organization, its products or services that can interact with the environment. There will be no non-compliance, if the environmental aspect will associate with the threat and risk situation adversely interact the environment.

Organizations, for whom activities connected to risks in relation to employees are significant, implement a systematic approach to occupational health and safety of employees system based on OHSAS 18001 standard [8]. In the case of such organizations it can be indicated that the risk of loss of life and health of the employees are essential and therefore they implement such a management system. It is worth emphasizing that in its idea, the system is based on risk assessment as an issue arising from legal requirements. This standard focuses on the occupational risk (accident, sickness, biological) and adverse events related to the work performed, especially those which have an impact on human health. The standard sets requirements for:

- systematic identification of hazards and assessment of occupational risks at workplaces in the organization, occurring in its activities and products or services, and in relation to all stakeholders,
- taking into account the results of the identification of the purpose of planning improving in the organization based on risk analysis and assessment.

In the food industry, the ISO 22000 standard is becoming increasingly popular. This standard supports organizations that are a part of the food chain directly and indirectly by helping to identify and manage significant risks and effectively manage the organization in relation to the risks in the production and handling of food [9].

As a result of the development of IT systems and their role in managing and competing, information security management system according to ISO/IEC 27001 [10] gained on the importance. This system is based on a formal approach to risk management through the analysis of risks for loss of individual features of information - confidentiality, availability and integrity.

The ability to obtain supplies in a timely manner and to provide products and services to the customer at the agreed time is important for any organization. Various risks affect their ability to interrupt the supply chain but a systematic approach to its security can be monitored through the implementation of a system that meets the requirements of ISO 28000 standard [11]. It can be pointed out that above mentioned standardized management systems are contained in a widely understood term of quality. A practical approach to the implementation of standardized management systems have been taken into account for the most common quality management system, so in the newest edition of the ISO 9004 [12] standard

indicates the usage of quality management in order to the sustainable success of the organization.

Besides the standardized management systems mentioned above, there are also quite popular different kinds of quality awards and selfassessment models. In those models risk assessment is taken into consideration by ewaluation team [13].

3. ISO 9001:2008 VS RISK MANAGEMENT

ISO 9001:2008 standard and proposed in it quality management model is the most popular and is one of the most important systems, because it concerns on business processes. However tnit present version there is no relation to riska assessment and risk managemet. From the information gained form ISO, the following edition of ISO 9001 stadard will include th reisk assessment approach. So far, it can be stated that this is an oversight, the fact of the lack of presence of the requirements for risk management in the ISO 9001 standard in comparision to many other standards [14]. But it can not be assumed that the managers do not analyze the inherent risks associated to business and its development. However, a systematic process of implementation and certification of the management system and its maintenance, ensures organizing of operations and continuity of management. The implementation of the process approach must be accompanied by a more or less formalized risk analysis of changes in customer satisfaction, developments, processes and the use of products. System approach allows to include the risk management to the business practice as part of quality management. The introduction for the general provisions of the standard, contains a recommendation that the adoption of a quality management system is a strategic decision for the organization to focus on the "organizational conditions, their changes and the associated risks" [15]. However, we do not find in the standard specific risk management requirements, but in many of its sections, the indirect references to this issue can be found. This are presented in Table 1.

Table 1. ISO 9001 standars requirements related to risk management [16].

ISO 9001:2008	Risk references
4.1 General reqiurements	Specifying processes, we define the criteria and methods needed to ensure the effectiveness of the course and monitor the process, which may not make sense without taking into account hazards and the associated risks
5.6 Management review	The review should include an assessment of opportunities for improvement and the need for changes in quality management. Proposed amendments should be evaluated for effects on quality. Evaluation of the effectiveness and efficiency of processes must take into account the risks in each of the processes.
6.2 Human resources	Implementing this requirement we provide the required expertise, thus managing the risks associated with people, taking into account all stakeholders.
6.3 Infrastructure	Taking into account characteristics of the infrastructure, which affects the requirements of the product can deliver risk management related to infrastructure.
7.2.2 Review of requirements related to the product	The requirement to review the contract before signing, indicating the possibility of realization, significantly reduces the risk of failure to comply with contract requirements (including legal entities).
7.3.7 Control of design and development changes	It is necessary to evaluate the effects of changes in the already delivered product.

7.4 Purchasing	Criteria for selection and a systematic evaluation of suppliers reduces the risk sensitivity of the organization to suppliers and partners activities.
7.5 Production and service provision	Providing of controlled production conditions reduces the risk of non-compliant product release.
8.2.1 Customer satisfaction	Monitoring of customer perception is an important element in identifying the risks associated with customer dissatisfaction, loss of reputation, image of the organization, loss of market share.
8.2.2. Internal audit	Internal audit shoud identify the operational risk.
8.5.3 Preventive action	The elimination of the causes of potential non-compliance is the result of a risk assessment.

It can not be expected to find any detailed interpretation of the requirements of the standard and having a direct application to the organization. This best interpretation is the averaged sum of solutions that have passed the examination in the developing and ongoing business organizations. Practical solutions strictly depend on the nature of the organization, its size, industry, number and size of risks. Some organizations appoint risk management departments, others define the tasks, responsibilities and authorities for the single positions while some others include the issue of risk to management systems. This last solution may be a practical guidance for companies with quality management system in accordance to ISO 9001 standard. Practical approach in the quality management system should take into account the suggestions contained in Table 1.

Considering above, there can be suggested some practical, universal solutions [16]:

- Realizing requirements of ISO 9001, organizations define processes, their sequence and relationships. Often, they use of so-called processes map and associated to this processes cards or other form of description. Inputs, outputs, methods of measuring and monitoring the flow of process, indicators of performance of the process and etc. are typically described. This description can be added to the hazard identification and risk assessment, indicating the essential points of inspection, preventive measures and etc. In this way, there has been designed risk management actions, that keep risks at an acceptable level and indication of actions to reduce probability or impact of adverse events.
- Discussing by the process owners, of current threats and assessment of the risks to their categorization as part of preparation and discussion of input data to the management review and propose remedial actions, providing a team perceptions of threats.
- Awareness campaign for process owners to the possibility of the emergence of new risks or increase the risk after introduction of process changes and changes in the external environment of processes.
- Monitoring and periodic auditing of critical risk areas taking into account their importance.
- Decision making (preferably as formal corrective action or preventive) to continue dealing with the risk, such as defining the necessary preventive measures to reduce probability and/or consequences of adverse events and considering the proposed action in the context of legal requirements. Typical preventive action can be written also in the form of operational quality objectives.
- Establishment of management control on the basis of which decisions are prepared and changes are made such as change of plans or objectives priorities. There may be considered

the inclusion of the audit process and internal auditors to control specific areas of significant risk.

- Evaluation of the effectiveness of realization of corrective actions.

4. CONCLUSION

Risk management is a term and practice that has been known for a long time. In conclusion it is important to underline that risk management in the context of profiled management systems is not substitutable but complementary in the idea of minimizing risks for business operation. Elements that influence the decision of choosing a management system include type of business, size of the organization and market conditions.

The application of effective mechanisms of risk management allows an organization to identify threats quickly and respond to them better than the competition, use appearing opportunities faster and better than the competition which translates into achieving more than the average income and will maintain a relatively high rate of development, which is one of the conditions for lasting competitive advantage.

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