Risk Management as Part of the Quality Management System According to ISO 9001

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Abstract. The top management staff of a company which applies a quality management system are interested in ensuring that the system safeguards a proper functioning of processes, achieves the objectives of these processes, and triggers perfecting mechanisms in a proper manner. Application of risk management in this system may provide some contribution to the fulfilling of the expectations of the management.

Keywords: risk, quality management system.

1 Introduction

Standard ISO 9001 specifies requirements for a quality management system. This system are the policies, procedures and rules of conduct that are carried out by employees of the organization on its behalf and its customers. It is therefore important to ensure that the risks which may render the established system ineffective and inefficient have been identified. The quality management system is important not only to ensure the quality of products but also the quality of the activities of each of the processes.

2 Quality Management System

2.1 The Notion of Management

In the literature, management is defined as [4]:

- a set of functionally discrete activities characteristic of organized projects involving more than one subject of action;
- a clear understanding of what is expected of people, and then ensuring that they do that in the best and cheapest way possible;
- a process of bringing certain things to a completion, efficiently and effectively;
- a process of planning, organizing, leading and controlling the work of the members of an organization and using all the available resources of the organization to achieve its objectives in an efficient and effective manner.

Due to the complexity of the issue of management, it must be considered in a multidimensional way, through the prism of management itself (the management function), the scope of objectives and through the organisation in which management is conducted (management of units, processes/actions, and resources).

Fig. 1. Multidimensionality of management [4]

2.2 Quality Management

Quality management includes all management actions which determine the shape of the quality policy, the objectives and responsibilities as well as their implementation within a quality system, by such means as:

- quality planning,
- quality assurance,
- quality control (meeting the requirements)
- quality improvement [4].

Quality planning includes activities related to the establishment of quality objectives as well as all the resources, processes and responsibilities associated with the achievement of the quality objectives. Quality assurance is to ensure that quality requirements are met. Quality control is to prevent defects, shortcomings and incompatibilities, and to maintain an appropriate level of compliance while retaining an optimal level of costs. Quality improvement is to continuously improve the ability and capacity to maintain an appropriate level of the fulfilment of the requirements [4, 5,8].

A quality management system which complies with ISO 9001 is very popular these days and this is due in large part to the desire to streamline the operations related to the division of responsibilities, the flow of information within the company and the stimulation of an awareness of the quality of products or services among all employees [1,3]. A quality management system, although built on the same ISO 9001 standard, will function and look different from enterprise to enterprise. To a large extent it depends on their specificity, experience and qualifications of employees as well as on how the requirements are documented [1].

The underlying idea of ISO 9001 is the process approach, whose aim is to identify the processes taking place in the company and to manage the relationships between those processes. A model of a quality management system which is based on a process is shown in Figure 2.1.

Fig. 2. A model of the quality management system based on a process [13]

3 Risk Management

Risk in management may be defined as the risk of making wrong decisions which prevent the achievement of objectives [11].

Implementation of the management system based on ISO 9001 is the first step to improve the functioning of an organization and to improve its management methods,

which is evident in research on the causes of the implementation of quality management systems [6].

The main reasons for the implementation of risk management at the level of an organization include:

- it facilitates the monitoring of the company and the management and supervision over the key risks of the organization,
- it allows lower level managers to take risks in a controlled manner and in compliance with the objectives of the company,
- there will be common, transparent criteria for evaluation, comparison and procedures when handling risks relating to completely different areas of activity and functions of the company (e.g. the risk of losing the customer, the risk of an IT system failure),
- full awareness of all the risks facing the company, their consequences and possible scenarios leading to the realization of risks,
- the company will be prepared for the occurrence (materialization) of the risks, because everything has been done to minimize the likelihood of the occurrence of threats and also preparations have been made to deal with the impact of a potential occurrence [14].

In 2012 a translation of ISO 31000 “Risk management. Rules and guidelines” appeared on the Polish market. A diagram of the risk management process based on the above mentioned standard is shown in Figure 3.1.

Fig. 3. The risk management process [12]

4 Risk Management in the Quality Management System

Table 1 shows the concept of the management system built on the basis of the ISO 9001 standard integrated with risk management for an organization [2,3,5,7,9,10].

Table 1. Risk management as an element of the management system according to ISO 9001

Elements of the management system according to ISO 9001	Risk management according to ISO 31000 integrated with ISO 9001
Management system	Determining the context of risk management Risk assessment for processes Handling of processes risk
Management responsibility	Business risk assessment Handling of business risk Strategy risk assessment Handling of strategy risk Policy of integrated management of risk and quality
Resources management	Personal risk assessment Handling of personal risk Assessment of infrastructure related risk Handling of infrastructure related risk Assessment of working environment risk Handling of working environment risk
Product implementation	Assessment of the client related process risk Handling of the client related process risk Assessment of the design process risk Handling of the design process risk Assessment of the purchases process risk Handling of the purchases process risk Assessment of the manufacturing process risk Handling of the manufacturing process risk Assessment of the measurement process risk Handling of the measurement process risk
Measurement, analysis and improvement	Monitoring and review of risks Communication and consultation in assessing and dealing with risks Identification and assessment of improvement actions

As one may see, the management system must take risk into account in order to ensure continuity of operations and achievement of its objectives.

5 Conclusions

Application of a systemic approach to risk management in such a way that each of the elements of the systemic approach to quality management is enriched by elements of risk assessment and management can contribute to a more efficient achievement of goals.

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