IDENTIFICATION OF POTENTIAL RISKS IN PRODUCT QUALITY PLANNING

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Abstract

The new edition of ISO 9001 standard, which defines the requirements for quality management systems, emphasizes the necessity of the risk-based thinking. Organizations that have implemented a quality management system according to this standard, which include practically all metallurgical companies, will have incorporate risk management techniques to their processes. Metallurgical companies that are suppliers to the automotive industry, already apply some approaches to risk management mandatorily (e.g. FMEA), but these do not cover all existing risks. In doing so, a thorough analysis of the processes and the use of appropriate risk management tools can minimize existing risks and maximize effectiveness of processes. The paper deals with the risk management and its application in the quality management processes. In detail it focuses on product quality planning process. On the basis of analysis of the expected results of individual sub-processes of the product quality planning, they are identified potential risks, which are further analysed. Methodology of affinity diagram is used for potential risks identification.

Keywords: Risk identification, quality management, product quality planning

1. INTRODUCTION

Quality is in today's rapidly evolving world perceived as one of the main means to promote in the competitive environment. Quality management is an important part of developing and improving the quality of not only the final products but the organization as a whole. During managing, respectively planning of quality it is very important that the emphasis is on preventing errors that may occur and on the correct evaluation of already existing faults. If we are able to detect possible errors already in preproduction stages, preferably already in the design and development of the product and the process, we do not need to spend so many resources, how much they were needed to incur in removing these errors during production, or by the means of complaints from the customer. The risk-based thinking is an integral part of the process approach in quality assurance of products in order to minimize undesirable results. The term “risk” is defined in many different ways, depending on sector or results that may occur. According to standard ISO 31000: 2010 risk is defined as "the effect of uncertainty on achieving objectives". The effect is a kind of deviation from the expected state, whether positive or negative [1]. Objectives may focus on different areas, e.g. financial, health, safety, environmental and accordingly different types of risks may exist. Minimizing these risks is therefore in the process control and product quality assurance necessary step. More information can be seen in [2], [3], [4]. New inputs for improving access to risk management has brought new edition of ISO 9001 defining the requirements for quality management systems, which emphasizes the necessity of risk-based thinking. Organizations that have implemented a quality management system according to this standard, which include practically all metallurgical companies, will have incorporate risk management techniques to their processes.

2. STANDARDS IN RISK MANAGEMENT

The issue of risk management is also increasingly getting into the requirements, not only customers, but also legislation. Risk management is a part not only of certain laws, attention is paid to this issue in some standards. Major standards dealing with risk analysis include: ISO 31000 Risk Management - Principles and guidelines, IEC/ISO 31010: 2010 Risk Management - Techniques of risk assessment, ISO Guide 73: 2009 Risk

management - Vocabulary, and other. Risk-based thinking is also one of the important topics in the current version of the standard ISO 9001: 2015. In previous editions of this standard it was included only in certain clauses, e.g. in the form of requirements for the planning, review and improvement. Newly risk-based thinking should be used in planning and implementing processes of the quality management system and should be also a kind of another helpful tool in determining the documented information in the organization. Organizations can decide which methodology of risk management will use. Each process of quality management system can be associated with varying degrees of risk. According to the requirements of this standard the organization is responsible for risk-based thinking and for the measures used in dealing with risks and should retain documented information as evidence identifying potential risks. Requirements relating to risk-based thinking in standard ISO 9001: 2015 occurr primarily in the following chapters:*5.1.1 Leadership and commitment*, *6.1 Actions to address risks and opportunities, 9.3.2 Management review inputs*, *Appendix A. 4 Risk-based thinking,* where the term "risk-based thinking" is not defined in this standard, it can be understood as a process of creating initial impetus for the implementation of risk management [5].

Also new edition of ISO 9000: 2016 refers to the concept of risk, which is defined in section 3.7.9 as the effect of uncertainty. Uncertainty is defined as kind of status and lack of information related to the event, its consequence or possibility of occurrence and its understanding or knowledge.

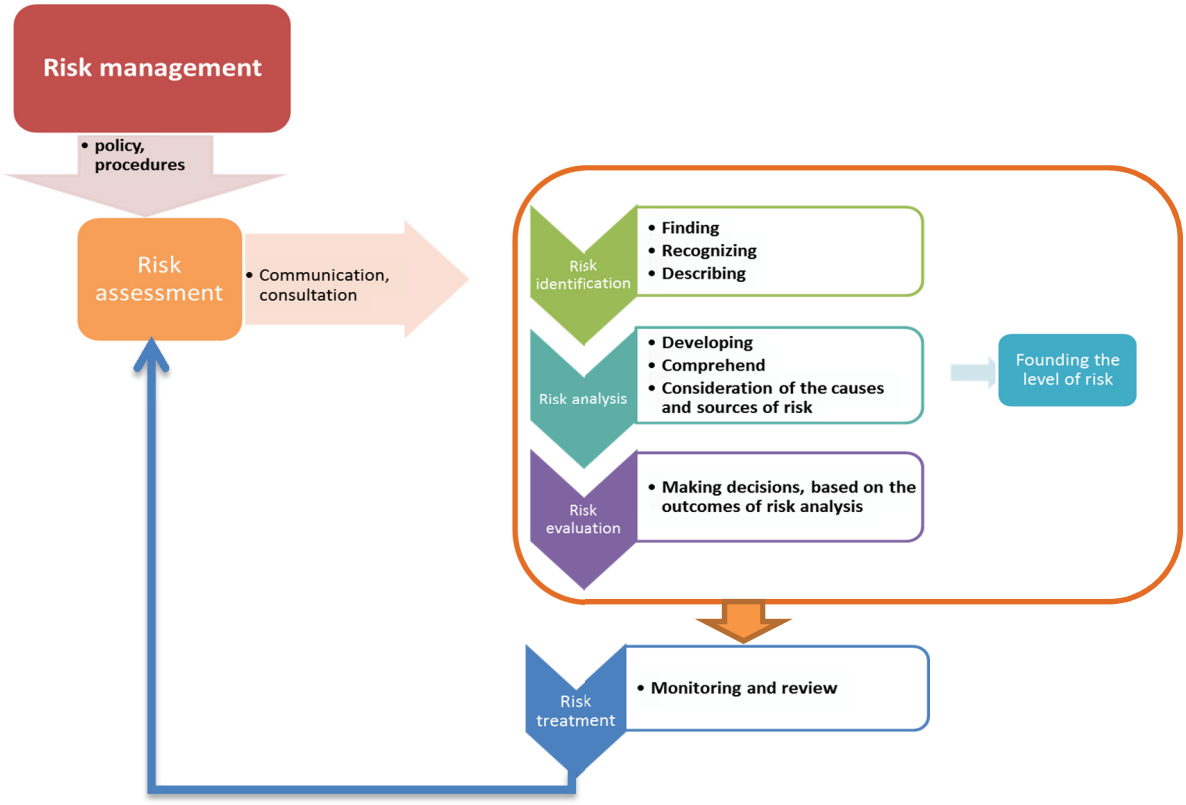

Figure 1 Risk management scheme

One main function of risk management is to find appropriate methods for the treatment of risk on the basis of the results of the risk assessment. Selecting an appropriate approach and appropriate methods depends on the purpose of the assessment, the nature of the data that are available, funding and often on the social and political context. The main obstacle of risk assessment is usually a lack of data. Risk management is a set of coordinated activities for the management and control an organization with regard to the area of risk [6]. For better orientation in concepts relating to risk management scheme was proposed, which also includes a brief description of each activity. The proposed scheme can be seen in **Figure 1**.

3. RISK MANAGEMENT

Risk management is a set of coordinated activities for the leadership and management of organization with regard to risk. The process of risk management is the systematic application of management policies, procedures, and other activities such as practical implementation, monitoring, etc. This process consists of a number of sub-processes, which will be described later. The key process of risk management is the risk assessment. Risks can be assessed both organization-wide and on various levels of the organization, individual processes or activities [7].

3.1 Risk assessment

Risk assessment is carried out mainly for understanding the risks themselves, their causes, consequences and probabilities. With this is then possible to determine how to deal with the process to minimize the adverse conditions. This process consists of the following sub-processes: risk identification, risk analysis and risk evaluation.

Risk identification

Risk identification is the process through which we find, recognize and record risk. Its purpose is to identify situations that might arise, and that could affect the achievement of the desired objectives. Part of this process is to determine possible causes and their sources. Risks can also arise in the context of external influences, both at the very beginning or already during the implementation process, e.g. changing customer requirements, failure of suppliers.

Risk analysis

Risk analysis is the process of providing input for risk evaluation and decision about risk treatment and about suitable strategies and methods. There are many methods to support these activities, and their choice depends on the objectives of the analysis, and the nature of the system. Risks cannot be completely eliminated, but can be controlled by using appropriate tools. More about the methods can be found in [8], [9], [10], [11].

Risk evaluation

The risk evaluation process includes comparing the respective levels of risk with the established criteria. This process uses an understanding of risk obtained by analyzing risks and compares them with just given risk criteria. Risk evaluation is also in deciding how to deal with that risk.

3.2. Risk treatment

Risk treatment is the process of modifying risk, which may include: removal of sources of risk, change the possibilities of risk occurrence, sharing risk with other parties, risk retention, and other. The treatment itself can cause new risks or modify existing risks [7].

4. IDENTIFICATION OF RISKS IN PRODUCTS QUALITY PLANNING

One of the critical processes affecting the quality of the final products is product quality planning. It is a set of activities carried out in the pre-production stages, which result is design of product that meets requirements of customers, legislation and other interested parties, and design of process, which under normal conditions will be able to produce this product in required quality. At present it is generally accepted that the processes of quality planning decide about resulting product quality by about 80 percent. Certainly it is desirable to deal with the risks that may occurr during these processes.

For a more detailed definition of sub-processes of product quality planning sub-steps of methodology by J.M. Juran were used [12]. For these activities there were defined expected objectives and identified possible risks. Risks identification ran with the team through brainstorming and the results were processed by the affinity diagram. Processed affinity diagram is shown in **Figure 2**.

Customers identification
- Incorrect determination of potential customers (e.g. including those, which never will be customers) - Not recovering all potential customer groups (age, lifestyle, residence, ..)
Customer needs identification
- Including requirements that are not important for the customer - Wrong understanding of the requirements formulations - Absence of information about the importance of individual requirements - Disregarding the requirements of other stakeholders - The requirements do not cover all requirements of the legislation *- Customers did not introduce some requirements* *- The requirements of different customers are different or inconsistent* *- Customer requirements are in conflict with legislation* *- Identified requirements do not correspond to a representative sample of customers (unbalanced structure)* *- The response from the small number of respondents*
Translation of customer needs to producer language
- Wrong understanding of some requirements during translation - The producer is not able to provide defined target values of quality characteristics - Some important requirements are not met due to ensuring acceptable price - Omission of some requirements during translation - Some declared product quality characteristics cannot be measured - Absence of some quality characteristics affecting fulfilment of requirements - Faulty proposal of the quality characteristics target values - The target values do not reflect the competitive environment - Inaccurate (insufficient) defining the target values of some quality characteristics *- Some requirements are not achievable*
Product development
- Designed product is not competitive - Designed product puts very high demands for the user - Designed product does not provide the required functionality for all anticipated conditions of use - An increased risk of possible failures in the product use - Some of the risks of possible failures were not taken into consideration - The risk of some possible failures of the product during use was undervalued *- Customer requirements or legislation are changed during product development* *- Customer will have certain reservations to the proposed product* - Difficult maintainability of the product ("cannot be repaired") - Designed product is hardly to produce - Product development takes too long time *- Different parts of the product will have different durability* *- The product meets the requirements of the desired quality, but is too expensive*
Process development
- The proposed process is not stable - The proposed process is not capable to produce products of required quality - The proposed process will be difficult to implement on existing equipment - The proposed process cannot be implemented due to lack of competence of personnel - Some risks of potential nonconformities during manufacturing were underestimated - Some risks of potential nonconformities were not included in the process FMEA - The proposed process is too costly - The proposed method of process control does not assure required process parameters - The producer is not able to achieve required capacity of production - The course of pilot production is not identical with the conditions of series production - The proposed control plan does not provide sufficient efficiency of product quality monitoring *- Product quality can be adversely affected by the instability of supply / subcontracting*
Transfer to manufacturing instructions
- Processed manufacturing instructions are not clearly formulated or not understandable - Deadline of the planned start of production is not met

Figure 2 Afinity diagram of risks in products quality planning

They were identified 49 risks which may occur during product quality planning. From the supplier's perspective these risks can be divided into controllable and uncontrollable ones. Controllable risks can be treated with appropriate interventions at the supplier, uncontrollable ones are e.g. related to customer behavior or market development. Uncontrollable risks are in the affinity diagram written in italics (see **Figure 2**).

Identified risks are related to the more general case when producer on the basis of customer requirements is developing both product and process. A number of identified risks are touching to objective identification of customer requirements and their transfer to product quality characteristics and process parameters. In terms of products quality, these risks are very significant, because if the product design does not meet the customers requirements, it doesn´t find its customers, even if no matter how well is made. For these reasons, metallurgical companies and other manufacturing organizations should pay sufficient attention to correct converting customer requirements into product quality characteristics and process parameters. An example of a suitable approach to this converting is to use QFD method. For example in [8] QFD was used for transfer customer requirements for the welding wire to the target values of quality characteristics of the wire.

Risks identification is only the first step of their assessment and after it risks analysis and risks evaluation should follow. On the basis of risks evaluation suitable actions for risks treatment are proposed. Yet mere identification of risks is very important step, because it leads to awareness of the risks. On the basis of identified risks they were proposed checklists of questions, which will serve for preventing these risks in individual sub-processes of product quality planning in the conditions of particular organization.

Analysis of identified risks and their evaluation can be performed only on the basis of knowledge of the conditions in a particular organization. Here it is possible to use various methods. Sophisticated approach offers FMEA, which in practice proved to be a very efficient tool for minimizing the risks of possible failures of product during its use or for minimizing risks of possible failures that may occur during the proposed process [9]. In addition, metallurgical companies that are in the supply chain of the automotive industry, this method has been applied mandatorily. FMEA is fully applicable also for non-production processes, such as for the product quality planning process.

5. CONCLUSION

Risk management should be an essential part of any business management. The goal of risk management is mainly to analyze current and future risks and by appropriate measures to decrease probability of their occurrence and severity of possible effects. This state could be changed by the means of suitable description of risk management processes and by implementintg suitable procedures and methods. The appropriate impulse for the implementation of risk management in organization can be the requirements of the new edition of ISO 9001.The article deals with terminology of risk management and in detail analyses the possible risks during the product quality planning. Risks identification is only first step of risks assessment. Risks analysis, risks evaluation and risks treatment for concrete company conditions must follow.

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