

THE IMPROVEMENT OF A QUALITY MANAGEMENT SYSTEM BY APPLYING RISK MANAGEMENT

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Abstract: *In the 21st century, in order to survive in the market, all the organizations, regardless their filed of activity, must improve their business. For this purpose, different models have been developed that can be applied, such as TQM, SR EN ISO 9001:2015. Also, after implementation, they must be continuously improved in order to support organizations to cope with changes that occur in the market, thus the objective of this research is to improve the quality management system implemented in the largest porcelain manufacturer in Romania and in Southeast Europe by applying risk management. Methodology presented in this study is based on the following five steps: risk identification, risk analysis, risk assessment, risk treatment and risk monitoring and review. In conclusions, various risks have been identified that may affect the proper conduct of the quality management system. In order to avoid this, risk treatment actions have been implemented, thus contributing to the improvement of the considered quality management system.*

Keywords: *quality management system, risk management, improvement, porcelain factory*

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Introduction

The current period of economic development along with the market economy can be characterized on a global scale by the high pressure placed on organizations by customers and society itself, both of which have continuously increasing demands and requirements forcing the organization to achieve ever higher levels of efficiency within all business activities by finding new ways and resources to reinforce their position on the market. In order for an organization to satisfy the general and specific needs of its customers, it must continuously increase the level of quality of its own products and services due to the fact that quality is and will remain the decisive factor for stable economic growth going forward (Simanová și Gejdos, 2015).

Quality management system is a collection of business processes focused on achieving quality policy and quality objectives to meet customer's requirements (Kansal și Singhal, 2017). Regardless of its type and size, any organization faces risks that may affect the achievement of its objectives in terms of activities, strategic initiatives, operations, processes and projects with

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different consequences on strategic, operational, financial results and on the image and reputation (Moraru și Băbuț, 2010).

While the word risk applies to uncertain events, possible hazards or damages, or other undesirable consequences, which can be expressed by means of a probability, management denotes the organized actions or activities to control these occurrences (Oliveira și colab., 2017).

Therefore, risk management is indispensable for any business, because risk can affect the results of processes (Rosa și Toledo, 2015). It should be noted that risk management is not intended to completely eliminate the business risks of an organization, it is intended to minimize their possible impacts (Rampini și colab., 2019) through the following specific sub-processes: risk identification, risk analysis, risk assessment, risk treatment, risk monitoring and review (Shafqat și colab., 2019).

This paper consists of three chapters: first chapter presents a literature review regarding the importance of risk management on the quality management system, the second chapter consists in a case study, where by applying risk management are identified and treated various risks that may affect the proper conduct of the quality management system implemented in a porcelain factory and the last chapter presents the conclusions of the case study.

Literature review

In the scientific literature, the "risk concept" is always associated with a potential hazard. Risk management is considered a rational activity used in order to find solutions to reduce the likelihood of that potential danger and to take measures to mitigate it if it occurs (Bernstein, 1998). In the conditions of making decisions when the activities are not very clearly defined, we can define the concept of risk. "According to objective interpretations, the probabilities are real. We can discover them by logic or we can estimate them by statistical analysis. According to subjective interpretations, probabilities are human beliefs. They are not intrinsic to nature. Individuals specify them to characterize their uncertainly" (Holton, 2004). Ignorance or lack of information or knowledge generates uncertainly. Also, uncertainly can be given by our general state of knowledge only in a certain filed. It strongly influences managerial decision-making as a result of taking potential risks (Coleman and Casselman, 2016; Knight, 2006; Lindley, 2006). Organizational performance and sustainability are closely linked, being moderated by decision-making and strategic thinking.

Analyzing the specialized literature on risks in economic activities it is found that there is no single opinion on the notion of risk (Prunea, 2003). Moreover, risks are a complex phenomenon, which has a lot of contradictory principles, sometimes even incompatible. This offers the possibility of different treatments regarding the notion of risk in different aspects. The notion of risk is used in various sciences. In each of them, the risk study derives from the object of the research of the science in question and it is based on its own methods and treatments. In Webster's dictionary risk is defined as "the danger of material loss or damage". So, risk refers to the possibility of occurrence of a certain unfavorable situation (Webster dictionary).

Today, the risk management function usually involves, in addition to buying insurance, a number of other activities: assisting the organization in identifying and assessing risks; implementation of loss and damage prevention and control programs; checking and reviewing contracts and other documents for risk management purposes; organization of educational trainings and seminars on issues related to risk, security, labor protection, environmental protection etc.; ensuring compliance with the provisions of the legislation in the filed; the implementation of risk finance techniques that do not involve insurance; resolving complaints to the company; formulating and addressing complaints to third parties as well as negotiating litigation with the legal representatives of third parties; designing and coordinating insurance programs for employees. At the same time, there are three other fundamental "ingredients" that should be found in the risk

management strategy of any organization: organizational culture, procedures and information systems (Holton, 2004).

Thus, in his articles, Holton (2004) mentions that "organizational culture defines the behaviors that the organization approves and those that it rejects. Culture plays a critical role in risk management, because it defines the risks that an individual must take if he wants to get involved in the organizational risk management" and that "procedures systematize the risk management process and that information systems are essentials for organizational risk management".

Risk management is, currently, a key component of any quality management system. ISO 9001:2015 clarifies very well the concept of "risk-based thinking" and considers that risk management must extend to the "external supply of goods and services" and it must not stop only at the basic processes. Deysher (2015) considers that ISO 9001 has included the notion of risk management by default since previous versions, the 2015 version being clearer, because it incorporates this concept into the management system. Risk-based thinking within a company is a thinking based on a procedural approach, being an integral part of processes. Risk-based thinking has as its main objective the prevention of risks, but it can be said that by operationalizing it, the opportunities, the so-called positive risks, can be identified.

Research methodology

The methodology used in the case study presented in this paper consists of the following five steps:

- *Risk identification* involves finding, recognizing and describing risks that could help or prevent an organization from achieving its goals.
- *Risk analysis* provides a contribution to the risk assessment and decisions on how to treat risk, taking into account various factors, such as the probability of events and consequences, the nature and extent of the consequences, etc.
- *Risk assessment* involves comparing the results of risk analysis with the established risk criteria to identify the need for risk management actions (ISO 31000:2018).
- *Risk treatment* refers to the establishment of risk treatment actions that may have one or more of the following roles : elimination, reduction, transfer, distribution or acceptance of risks (Filipoiu and Rânea, 2009). The selection of these actions should be done in accordance with the organization's objectives, risk criteria and available resources (ISO 31000:2018).
- *Risk monitoring and review* involves the periodic review of both the risks identified, analyzed and evaluated, as well as the treatment actions implemented. The results of the reviews are reported to ensure continuous monitoring of the risk situation and to notice major changes that may occur.

Case study

Study area

The porcelain factory considered in the case study was founded in 1970 in the city of Alba Iulia; it is the largest porcelain manufacturer in Romania and in Southeast Europe and it is named S.C. APULUM S.A. It has a diversified production, including household and HoReCa articles on porcelain and decorative objects (Sârb și colab., 2018; Sârb și colab., 2019).

Application of the research methodology

Risk identification

By using the Brainstorming and Interview methods, 18 risks (table no.1) were identified in the considered factory, which may affect the proper functioning of the quality management system. It should be mentioned that in order to identify the risks, the specific requirements of the quality management have been taken into account, which can be found in ISO 9001:2015.

Table 1.

Identified risks on the considered quality management system within S.C. APULUM S.A.

Risk code	Possible risk of occurrence	Cause	Effect
Requirement: Context of the organization			
R1	Insufficient resources, unavailable for the processes of the quality management system	Inadequate management of resources within the organization	Impossibility to carry out all the processes necessary for the proper functioning of the quality management system
R2	Loss of documented information that supports the operation of the quality management system processes	Natural disasters (fires, floods)	Lack of documented information to give confidence that the processes are carried out as planned.
Requirement: Leadership			
R3	The customer's requirements are not known by all persons within the organization involved in satisfying these requirements.	Poor communication between different hierarchical levels existing within the organization	The customer's requirements are not consistently satisfied. Non-compliant products with customer requirements.
R4	The quality policy is not understood/ applied by all employees of the organization	Insufficiently aware personnel regarding the importance of the quality policy of the organization	Non-compliance with the quality policy by all employees
Requirement: Planning			
R5	Poor identification of possible risks	Untrained personnel regarding the possible applicable methods in risk management	Not all risks that may occur are taken into account; lack of measures to treat them
R6	Failure to comply with the monthly/weekly production plan	Out of stock regarding a certain pressing body	Postpone order
Requirement: Support			
R7	Decalibration of monitoring and measurement resources	Use of monitoring and measurement resources by unqualified personnel	Measurement errors
R8	Unqualified personnel	Lack of actions to acquire the necessary skills	Low performance and effectiveness of the quality management system
R9	Lack of personnel participation in increasing the effectiveness of the quality management system	Indifferent personnel regarding their contribution to the effectiveness of the quality management system, including the benefits of improved performance.	Ineffective quality management system.
Requirement: Operation			
R10	Loss of reference samples	There is no record of the reference samples	Impossibility to compare the products manufactured within the organization with the reference sample signed by the customer to prove the conformity of the products with the customer's requirements
R11	Insufficient data regarding the design process of the	Poor communication between the organization's	Design errors

	pressed product	departments	
R12	Lack of raw material control at the reception	Out of stock; the emergency of introducing raw materials into production	Non-compliant products
R13	Current shocks during the second firing of the products	Power outages due to problems with the electricity supplier	Non-compliant products
R14	Lack of identification of non-compliant products with customer requirements	Lack of knowledge of customer requirements by all the operators	Delivery of non-compliant products
Requirement: Performance evaluation			
R15	The subjectivity of the internal auditor in carrying out the audit process	Friendly relationship with the audited department	Incorrect audit findings in the audit report
R16	Non-compliance with the working procedures established regarding the monitoring and measurement of processes and products	The personnel with attributions regarding the monitoring of processes and products is not informed about the existence/ content of these procedures	Failure to comply with the established requirements (by customers or in specific standards) for the processes and products
Requirement: Improvement			
R17	Non-implementation of corrective actions resulting from an identified non-compliance	High costs	Untreated non-compliance
R18	Delivery of non-compliant product	The sorting operators do not know the customer's requirements	Customer complaints

Source: Own source

Risk analysis

Once identified, the risks were analyzed using the following three criteria : severity (S), detectability (D) and probability of occurrence (P). Therefore, each risk was assigned different values specific to the considered criteria (table no.2).

Table 2.

Severity, detectability and probability scales

SEVERITY* (S)	
High [10]	Obvious and serious effects
Medium [8]	Significant effects
Low [5]	Limited and difficult to notice effects.
Minor [3]	No effects or insignificant effects.
DETECTABILITY* (D)	
Undetectable[9]	Difficult to detect
Difficult to detect [7]	Probably detectable, but not always
Easy to detect [5]	Probably detectable, almost always
Obvious [3]	Easy to detect by anyone
PROBABILITY** (P)	
Very high [12]	The risk is certain
High [9]	The risk is almost certain
Medim [6]	The risk arises from time to time
Low [3]	The risk almost never occurs

Source: *S.C. APULUM S.A., PS-6.1-00, 2018; **Own source

Risk assessment

The risk assessment was performed using the Risk Matrix method (table no.3).

Table 3.

Risk Matrix

		DETECTABILITY (D)			
		3	5	7	9
SEVERITY (S)	3	27	90	189	324
	5	45	150	315	540
	8	72	175	504	864
	10	90	240	630	1 080
		3	6	9	12
PROBABILITY (P)					

Source: Own source

Thus, after calculating the risk value (RV) by multiplying the values of severity (S), detectability (D) and probability (P) assigned to each risks in the previous subprocess, the risks were assessed by placing them in one of the four considered categories (table no.4).

Table 4.

Risk categories		
Risk category	RV	Enunciation
Critical risk	361-1080	Critical risk, requires immediate attention.
High risk	181-360	High risk, requires immediate attention.
Medium risk	91-180	Medium risk, corrective action can be taken.
Low risk	27-90	Low risk, it can be ignored.

Source: Own source

Applying, the ones described above, the identified risks were analyzed and evaluated (table no. 5).

Table 5.

Analysis and assessment of the identified risks

Risk code	Possible risk of occurrence	Risk analysis			Risk assessment	
		S	D	P	RV	Risk category
Requirement: Context of the organization						
R1	Insufficient resources, unavailable for the processes of the quality management system	10	3	3	90	Low risk
R2	Loss of documented information that supports the operation of the quality management system processes	10	3	3	90	Low risk
Requirement: Leadership						
R3	The customer's requirements are not known by all persons within the organization involved in satisfying these requirements.	8	3	3	72	Low risk
R4	The quality policy is not understood / applied by all employees of the organization	3	5	6	90	Low risk
Requirement: Planning						
R5	Poor identification of possible risks	5	7	6	210	High risk
R6	Failure to comply with the monthly/weekly production plan	10	3	3	90	Low risk
Requirement: Support						
R7	Decalibration of monitoring and measurement resources	5	5	3	75	Low risk
R8	Unqualified personnel	8	5	3	120	Medium risk
R9	Lack of personnel participation in increasing the effectiveness of the quality management system	8	5	3	120	Medium risk
Requirement: Operation						
R10	Loss of reference samples	10	5	3	150	Medium risk
R11	Insufficient data regarding the design process of the pressed product	5	5	3	74	Low risk
R12	Lack of raw material control at the reception	8	3	3	72	Low risk
R13	Current shocks during the second firing of the products	10	3	6	180	Medium risk
R14	Lack of identification of non-compliant products with customer requirements	8	5	6	240	High risk
Requirement: Performance evaluation						
R15	The subjectivity of the internal auditor in carrying out the audit process	8	7	3	160	Medium risk
R16	Non-compliance with the working procedures established regarding the monitoring and measurement of processes and products	10	5	3	150	Medium risk
Requirement: Improvement						
R17	Non-implementation of corrective actions resulting from an identified non-compliance	8	3	3	72	Low risk
R18	Delivery of non-compliant product	10	3	6	180	Medium risk

Legend:
 High risk
 Medium risk
 Low risk

Source: Own source

Table 5 shows that identified risks were assessed as follows: 9 low risks, 7 medium risks and 2 high risks. Therefore, risk management actions will be formulated and applied for those risks classified as medium and high risks.

Risk treatment

The risk assessment indicates the need to treat 9 risks whose RV is ≥ 91 , which is why they were classified as medium risks (7) and high risks (2). In this regard, the risk management plan (table no. 6) was elaborated and implemented. It includes, in addition to the risk management actions and those responsible for the implementation of the actions and the deadlines.

The role of the risk management actions is to reduce the risk value specific to each considered risk, until it can be classified as a low risk, which can be ignored.

The evaluation of the efficiency of the implemented actions (table no.7) is performed by reanalyzing and re-evaluating the treated risks using the same criteria (severity, detectability, probability of occurrence).

Table 6.

Risk management plan

Risk code	Possible risk of occurrence	Risk treatment actions	Responsability	Deadline
Requirement: Planning				
R5	Poor identification of possible risks	Training personnel regarding the process of identification, assessment and treatment of risks.	Quality Manger	Permanent
Requirement: Support				
R8	Unqualified personnel	Assessment of personnel competence and, depending of the results obtained, the establishment of actions to acquire the necessary skills.	Human Resources department Responsabile department	Permanent
R9	Lack of personnel participation in increasing the effectiveness of the quality management system	Training personnel on the importance of the existing quality management system within the organization and the need to be involved in the increasing the effectiveness of this system.	Quality Manager	Permanent
Requirement: Operation				
R10	Loss of reference samples	Drawing up a Register of evidence of reference samples	Sales department	Permanent
R13	Current shocks during the second firing of the products	Installation of uninterruptible power suppliers (UPS)	Maintenance department	Permanent
R14	Lack of identification of non-compliant products with customer requirements	Testare tuturor sortatorilor conform cerințelor clienților, urmată de instruirea sortatorilor cu rezultate slabe Testing of all sorting operators according to customer requirements, followed by training of the personnel with poor results.	Quality assurance responsible Sorting responsible	Twice a year
Requirement: Performance evaluation				
R15	The subjectivity of the internal auditor în carrying out the audit process	Carrying out audits by rotation, so that each auditor audits each department within the organization	Audit team	Once every 2 years
R16	Non-compliance with the working procedures established regarding the monitoring and measurement of processes and products	Training of the personnel with responsibilities regarding monitoring and measuring of the processes and products about the existing of the working procedures and their content	Quality Manager	Permanent
Requirement: Improvement				
R18	Delivery of non-compliant product	Regular training of sorting personnel on correct sorting of the products in accordance to customer requirements.	Sorting responsible	Annual

Source: Own source

Table 7.

Reanalysis and reassessment of treated risks

Risk code	Possible risk of occurrence	Risk analysis			Risk assessment		Reanalyzed risk			Re-evaluated risk	
		S	D	P	RV	Risk category	S	D	P	RV	Risk category
Requirement: Planning											
R5	Poor identification of possible risks	5	7	6	210		3	7	3	63	
Requirement: Support											
R8	Unqualified personnel	8	5	3	120		5	3	3	75	
R9	Lack of personnel participation in increasing the effectiveness of the quality management system	8	5	3	120		5	5	3	75	
Requirement: Operation											
R10	Loss of reference samples	10	5	3	150		3	3	3	27	
R13	Current shocks during the second firing of the products	10	3	6	180		5	3	3	45	
R14	Lack of identification of non-compliant products with customer requirements	8	5	6	240		3	9	3	81	
Requirement: Performance evaluation											
15	The subjectivity of the internal auditor in carrying out the audit process	8	7	3	160		5	3	3	45	
R16	Non-compliance with the working procedures established regarding the monitoring and measurement of processes and products	10	5	3	150		5	5	3	75	
Requirement: Improvement											
R18	Delivery of non-compliant product	10	3	6	180		10	3	3	90	

Legend:
 High risk
 Medium risk
 Low risk

Source: Own source

As can be seen in Table 7, the treated risks registered values of the degree of risk ≤ 90 , being classified as low risks, which can be accepted. Therefore, the implemented risk management actions were 100% efficient. At the same time, they did not lead to the occurrence of new risks.

Risk monitoring and review

Continuous monitoring and periodic review of the risk management process and its results is carried out by drawing up a risk monitoring and review plan (table no.8), which includes all specific risk management requirements.

Table 8.

Risk monitoring and review plan

No.	Requirement	Risk identification	Analysis and assessment of the identified risks				Risk treatment				Monitoring and review of the identified risks			
							No. of treated risks	Reanalysis and re-evaluation of risks						
		No. of identified risks	Green	Yellow	Orange	Red		Green	Yellow	Orange	Red	Green	Yellow	Orange
1	Context of the organization	2	2	0	0	0	0	0	0	0	2	0	0	0
2	Leadership	2	2	0	0	0	0	0	0	0	2	0	0	0
3	Planning	2	1	0	1	0	1	0	0	2	0	0	0	0
4	Support	3	1	2	0	0	2	0	0	0	3	0	0	0
5	Operation	5	2	2	1	0	3	0	0	0	5	0	0	0
6	Performance evaluation	2	0	2	0	0	2	0	0	0	2	0	0	0
7	Improvement	2	1	1	0	0	1	0	0	0	2	0	0	0
TOTAL		18	9	7	2	0	9	0	0	0	18	0	0	0

Legend:

	Critical risk
	High risk
	Medium risk
	Low risk

Source: Own source

The risk monitoring and review plan provides an overview of the risk management on the quality management system within S.C. APULUM S.A.

Therefore, 18 risks were identified, which were classified as follow: 9 low risks, 7 medium risks and 2 high risks. All those risks included in other category than low risks were subject to risk management actions. Subsequently, the treated risks were reanalyzed and re-evaluated. All 9 treated risks were classified as low risks, which leads to the following conclusion: the risk management actions were 100% effective.

Conclusions

This paper illustrates an effective way to improve the existing quality management system within the considered porcelain factory, respectively S.C APULUM S.A. Therefore, in the case study a new approach of risk management was presented by applying it to the specific requirements of quality management, requirements presented in ISO 9001:2015.

Thus, in the first step specific to risk management, the risks that may affect the proper conduct of the quality management system were identified, by reference to the ISO 9001:2015 requirements. The identified risks were analyzed by applying three specific criteria: severity (S), detectability (D) and probability of occurrence (P) and assessed using the Risk Matrix method. This sub-process concluded the existence of medium and high risks that can have a negative impact on the considered quality management system, highlighting the need to implement risk management actions. The effectiveness of these actions was demonstrated when the risks were re-analyzed and re-evaluated, resulting that all identified risks were classified as low risks, which can be ignored, as illustrated in the Risk Monitoring and Review Plan presented in Table 8.

At the same time, for a continuous improvement of the quality management system belonging to S.C. APULUM S.A. it is recommended to continue the application of risk management on the requirements of ISO 9001:2015 implemented in the porcelain factory considered at least once a year, as well as to review and monitor the risks already identified at least once every 6 months.

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