



Considerations on Integrating Risk and Quality Management

Maria POPESCU*^a, Adina DASCĂLU^b

^{a, b}Transilvania University of Brasov, Romania

ARTICLE INFO

Article history:

Accepted 15 January 2011

Available online 31 March 2011

JEL Classification

G 32

Keywords:

Risk management, Quality management, Integrated systems

ABSTRACT

This paper aims to highlight the links between risk management and quality management and to study the possibility of their integrated approach. The study reviews the evolution of risk approach within organizations and stresses the need to increase the effectiveness of this approach by incorporating risk management methodology in the quality management system. Starting from this idea, the authors present the current state of risk approach into quality management, basic rules of integrated quality-risk management and major difficulties which may arise in the implementation of integrated quality-risk systems

© 2011 EAI. All rights reserved.

1. Introduction

Evolution of organizations in the current context, characterized by rough competition, rapid changes and uncertainty, enforce new concepts in management: quality and risk are considered key factors for a performant management, being approached in various ways in all areas.

Risk is a term used with different meanings: defines the uncertainty characterizing an activity; probability that something will happen, the effect of uncertainty on objectives [1]. The hazard occurrence and its adverse effects on human health, performance of organizations, society in general have brought to the forefront the management's concern for identifying risk factors and evaluating their effects.

Approaching risk in organization management requires setting objectives and activities that lead to goals, and simultaneously seeking to identify factors that may prevent it from achieving its objectives, to take timely necessary measures. Initially the focus was on risk assessment. In the present the approach is more complex and is called risk management; this expression defines the coordinated actions through which an organization plans and controls risks that could affect its ability to achieve its objectives. Such a preventive approach is characteristic for modern management systems, ensuring organizational performance improvement by managing threats and exploiting opportunities from the environment in which it operates [2, 23].

The dynamics of risk approach in organizations is related to the development of scientific instruments, methods and standards to address risk, that have sustained organizations in this approach. First were the methods, guidelines and standards specific on business fields, for example: the Monte Carlo simulation, the Value-at-Risk model (VaR) and other complex risk assessment models used in financial organizations [3], models such as SARA (Simply to Apply Risk Analysis), SPRINT (Simplified Process for Risk Identification) etc. [4] - for IT security, HACCP (Hazard Analysis and Critical Control Point) - for food safety [5] etc. The last one, chronologically, is the international standard ISO 31000 - Risk Management, revised in 2009, which introduce concepts and generally accepted international rules, creating a coherent framework for systematically approaching risk within organizations by implementing risk management systems.

Implementing risk management systems requires the organization to develop specific structures and processes by which to plan and to control risk in a systematic way and at all levels of management. According to the ISO 31000 addressing risk methodology, risk management process has three main sequences of activities: (1) establish the context, (2) risk assessment, (3) risk treatment. Also included are cross-cutting activities like communication and consultation, respectively monitoring and review.

Implementation of risk management in organizations has the effect of improving organization management, of means of control, by focusing on identifying opportunities (positive risks) and negative risks. As world practice shows the effectiveness of these actions depends on the organization's capability to integrate risk management methodologies in the management of the organization, in each process, contract or project [6]. This paper aims to explore the possibility of integrated approach of risk and quality management. The purpose of such an approach is to simplify management systems by reducing the number

* E-mail addresses: mariapopescu@unitbv.ro (M. Popescu) adina.dascalu@unitbv.ro (A. Dascalu)

of structures and processes, resources and documents used in organizations, while improving the performance of both systems through synergistic effects.

The underlying assumption of this study is that risk and quality are two sides of same coin: quality is the measure of satisfying the requirements, and risk measures the weight of unfavorable situations, deviations from the requirements. The two dimensions are not mutually exclusive but complement each other, being components of the indicators system that measure the performance of the organization.

The major problem of approaching risk and quality is that each is associated with a distinct system, with own goals, structures, processes and resources, which increase costs and complexity of the organization's management system. In addition, management effectiveness is reduced because problems are solved without taking into account the links between the two systems.

Based on these premises, the study developed in the paper has two specific objectives: the analysis of the current state of the approach of relationship quality-risk and to develop the methodological framework to integrate the risk management in quality management, with an illustrative example of application on a process. In the last part of the paper, the authors present the main sequences of the implementation process of integrated quality-risk systems, and stress the need for further investigations for developing guidelines and instructions to sustain the implementation of the methodology tailored to certain categories of QMS processes, project management and other management systems.

2. Risk approach in quality management, ISO 9000 standards

According to the definition given today, quality defines the degree to which a set of inherent characteristics fulfills requirements [7]: primarily counts customer's needs, but also of other stakeholders - employees and employers and society. Approach to quality has taken a systematic character since the 70s of last century when guidelines / rules concerning quality assurance, for specific industries / areas of activity appeared for the first time [8], [9]. In 1987 the international standards for quality systems have been developed, from ISO 9000 series, which introduced uniform principles and rules of action, generally applicable. ISO 9000 standards are now applied worldwide, helping organizations to implement management systems by which to be done planning, controlling and continuous quality improvement in a systematic way.

Knowing the current state of the risk approach in quality management is important in establishing ways to extend the integration of risk into quality at all levels. In this regard, it should be noted that the risk lies in the quality management systems (QMS), whose philosophy is based on the principle of risk prevention. Thus, effective implementation and operation of the ISO 9001 QMS model provides the opportunity for organizations to consistently make product and process to defined parameters, implicitly, the existence of mechanisms and tools to prevent and reduce risk. Most important levers of quality management through which are done the risk prevention and mitigation are:

- The organization's work is not performed at random, the quality objectives and processes upon which depends meeting the requirements are planned and controlled;
- Quality management systems include processes with key role in achieving quality. QMS configuration setting is based on international experience and best practices, which means that it provides risk control and prevention through the implementation of appropriate working and controlling methods, especially in critical areas, with potential risks;
- Operation of quality systems involves designing databases on quality and systematic analysis of deviations from the requirements - processes which allow risk identification and measurement;
- Quality management requires that in each process to be determined both corrective action - to prevent recurrence of errors / nonconformities and preventive action - to prevent potential problems;
- Data regarding quality in the organization are reviewed by management and are subject to underlying decisions concerning policy and objectives of the organization, and of change projects that will be taken to reduce or prevent nonconformities.

The items above are generally valid, but their application and effectiveness of QMS differ from one organization to another, influenced by objective and subjective factors. From the perspective of risk approach, one of the features of mature QMS is the using of rigorous methods of risk assessment and mitigation, such as FMEA (Failure Mode and Effective Analysis) - used in the design process for the analysis of actual and potential risks of failure and establish measures to mitigate or eliminate risk [10]; process capability analysis - based on statistical analysis of the likelihood that the results of a process meet the established objectives [11], Six Sigma - quality improvement method that focuses on reducing the dispersion of values that measure quality parameters of a product or process, which means reducing the risk of failing the established objectives / standards [12] etc.

Sporadic use of these methods is currently proved insufficient; the systematic application of risk management methodology and its extension to the entire organization can provide a significant competitive advantage in an increasingly uncertain world.

3. Methodology of integrating risk management in quality management

Risk approach in quality management in a systematic way is a component of an effective quality management system. Explicit formulation of the risk assessment requirements included in clauses relating to the quality management system through the latest edition of ISO 9000 - is part of that direction (Avanesov, E.

(2009), in particular ISO 9004: 2009 emphasizes the need to use risk management for organization development and sustainability. Concerns in this regard existed before as well, in various fields. More advanced applications are made in health and pharmaceutical industry sectors for which implementation guidelines were developed for integrated quality-risk systems [13], [14], [15], [16].

The core of the new approach is the consideration of risk management as key activity, associated to all decisions, the goal being to prevent negative risks and exploit opportunities at all levels - from strategic management and change projects, to support and basic processes. Such a system has proactive and systematic tools of identification, assessment and control of organization's quality problems and has as its purpose the continuous improvement of quality / performance. It can be said that the integration of risk management methodology contributes to increasing the effectiveness of quality management, by emphasizing on the preventive nature of the decisions regarding strategies and measures for improvement.

The integrated approach of quality and risk management is facilitated by the fact that ISO 9001 and ISO 31000 standards have elements and common principles, most important being the following:

- Quality and risk are associated to management, which involves conducting systematic planning and controlling processes;
- In both cases problems are treated from the perspective of the organization being integrated into specific management systems. Quality management system and risk management system ensure consistency of activities undertaken at the senior management level and at the key processes of the organization;
- Focus on continuous improvement in performance, which involves continuously repeating the cycle plan-do-check-act (Deming Wheel), both in terms of quality and risk;
- High-level coordination is essential in both cases. Leadership is the acknowledged term that summarizes the involvement of top management, establishing policies and objectives, communication and especially the concern for creating a culture that integrates the principles and requirements for quality and risk;
- The use of specific and measurable indicators regarding quality and risk, to allow the substantiation of business decisions of improvement and organizational performance.

Based on these elements and the applicative studies, conducted by the authors on improving the quality of services and processes in various areas through risk assessment and prevention [17], [18],[19] it has been identified several defining rules for the new approach, namely:

- a) Risk management is done at all levels of QMS, at the organization's level, of processes and of change projects;
- b) At the organization's level, responsibility for quality assurance and risk control is assigned to top management, but for each of the two areas must be created structures / distinct functions appropriate to the organization's particularity;
- c) Encouragement of teamwork is essential for solving complex problems of integrated quality-risk management; the teams include representatives of the processes analyzed and specialists in quality management and risk management;
- d) At all levels, addressing risk is based on risk management methodology, which includes the following sequences: Establish the context; Risk assessment - risk identification, analysis, evaluation and prioritization; Risk treatment;
- e) Applying the methodology is in connection with the activities' cycle of planning, execution, control and quality improvement (PDCA cycle or Deming's wheel), specific to quality management. Fig.1 shows this correspondence at a process level.

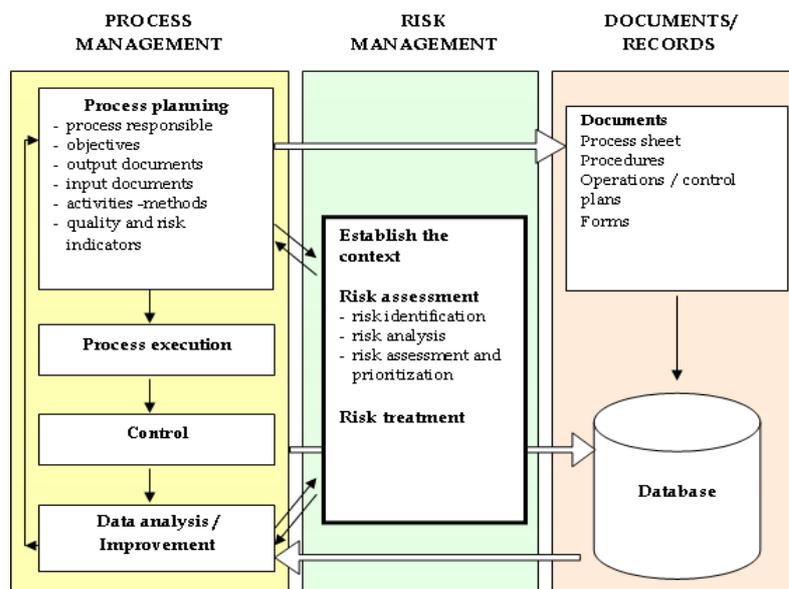


Figure 1. Integrated risk-process management approach

f) Results of risk management must be reported in documents and reports / records; should be considered the simplification of documents system by creating common quality-risk records, when possible.

Effectiveness of the created system depends on how the specific risk management activities, methods and tools are integrated into the processes' design, control and their performance improvement. It is essential to this the processing of historical data regarding processes, which makes it possible to improve risk measurement, the probability of risk event and its effects. Using these indicators in quality management ensures in the same time decisions' quality improvement as organizational performance. Access to information is done through specific communication quality management system, preferably with the same documents, emphasizing risk separately.

4. Case Study

Applying risk management methodology in the quality management will be exemplified on the purchasing process of a manufacturing firm. The study highlights the novelty items of the new methodology compared to the default approach of risk from the ISO 9001 QMS model.

ISO 9001:2008 standard, in cap.7.4 Purchasing, underlines the need for the organization to ensure that the supplied product complies with specifications. The general quality objectives of the purchasing process can be defined by the weight of deviations from the quantity, quality and deadlines established by the purchase contracts / orders. To these objectives are added the decrease / optimization of assets in production stocks, overall objective of any organization, with an economic effect.

ISO 9001 requires organizations to develop mechanisms for planning and control of the purchasing process, namely supply databases (internal customer's requirements / production facilities, suppliers, orders launched and their execution, stocks for production). One of the main requirements of ISO 9001 refers to the need for organizations to select their suppliers with regard to their capability to meet customer's requirements. The materialization of this requirement varies from one organization to another and involves the suppliers' assessment processes and tools.

Typically, for this purpose organizations use evaluation grids by scores, which allow classification of suppliers, for example, three-level hierarchy: accepted suppliers (requirements fully met), suppliers with special approval (requirements are met insufficiently, the lack of a technology license, etc.), unaccepted suppliers (requirements unmet, scoring below a certain point).

Analysis of suppliers as defined is a process of quality management system, but also represents a specific form of risk analysis in purchasing, ensuring the hierarchy of suppliers by their capability to meet requirements regarding quality and quantity of materials / products purchased, supply dates and other requirements. For example, acceptance on the list of suppliers with the higher scores corresponds to a low level of risk in terms of achieving quality. If organization also takes into account the lower scores suppliers, it means that it takes greater risks. In these cases it is important to establish action plans to prevent or reduce risk, such as scheduling audits at suppliers, the development of preventive and corrective measures etc. A factor of which the effectiveness of these processes depends on is the continuous monitoring of suppliers, which involves recording and analyzing data on the requirements achievement by the existing suppliers, establishing corrective and preventive actions and even reconsidering the accepted level of risk of the supplier, depending on the context.

Compared to these specific items of ISO 9001 QMS model, the integrated approach quality-risk in purchasing requires that in all relevant sequences of the supply process to apply a systematic risk management methodology which includes: identifying factors that may cause deviations from the requirements of quality, amounts and dates of supply, analysis, assessment and risk treatment.

Thus, since the design phase of the supply process should be identified external and internal factors which can cause quality problems in supply, in various sequences of the supply process, from defining customer requirements / production facilities to reception and storage of materials and supplied products. An example is summarized in Table 1, which presents the risk factors and their weight for the transport phase. For each risk factor is necessary to measure the impact on the organization, for example: the direct consequences of the deterioration of materials during transport can be measured by economic loss equal to the purchase and transportation price, less amounts recovered (through REMAT, penalties, downgrading); the impact of quantitative deviations are expressed by theft losses, and the deviations from the deadlines may result in losses by discontinuities in the manufacturing process or by increasing the stocks for production.

In Table 1, the consequences are given in col. 4 (impact), as a percentage of turnover. The product between risk probability and impact gives the risk level, whose values are listed in col.5. A fair assessment requires that risk measurement to be done distinctly on types of materials and products.

It must be said that quantitative assessment of risks by probability of occurrence is not always possible. The alternative is to express the risks by qualitative descriptors, such as: high, moderate, or low. Such an assessment makes it possible to combine multiple levels of severity and probability into an overall relative risk estimator [20]. Establishment of risk assessment scales is a problem of each enterprise, important for prioritize actions to mitigate or eliminate risk.

Table 1. Risk factors for transport phase

Objectives	Risk factors	Probability (%)	Impact (% from turnover)	Risk level (%)
1	2	3	4	5
Quality of materials/ goods purchased	- inadequate preparation / packaging and product placement into a transport vehicle;	1	0,05	0,05
Quantity requested	- inadvertently in cargo loading; - theft / burglary on the route;	0,5	0,2	0,1
Dates set	- transport planning; - delays due to traffic; - misbehaviors	10	0,25	2,5
TOTAL			0,50	2,65

In the example above, the risk-mitigation measures in the transport process may include:

- Development of specifications and instructions on packaging, loading and settling them in the transport vehicle;
- Special requirements regarding the micro-environment in the transport vehicle and its monitoring (where applicable);
- Training staff that makes loading and unloading, respectively, transport of materials;
- Introducing material responsibility of drivers for verifying cargo loading and carrying out special instructions and requirements for loading and unloading and during transport etc.

Applying these measures reduces the risk of misconduct, which means implicitly reduction of accepted / residual risk and it is circumscribed on concerns for improving process performance. It should be emphasized the importance of recording data on transportation, systematic analysis of deviations from the standards and specifications and determining their causes, which ensures continuity of the control and process improvement.

Similarly you can determine the risk factors and their occurrence probability and impact for all the sequences of supply process: planning supply, developing contracts, receiving and storing materials and products supplied. Establish assumed risk depends on the policies and quality objectives of supply. For example, if you want to apply the JIT (Just in Time) method, which involves minimizing inventory, the assumed risk is low and involves minimizing the deviations from the requirements on quality, quantity and timings of supply. In this case it is necessary to act preventively for: better communication with customers for an accurate definition of the required materials, creating an effective information system on procurement (stocks, prices, suppliers, durations of supply process etc.); implementing mechanisms and tools to optimize supply plans that take into account the risks and losses associated with each sequence of the supply process. A documented output from the above sections (risk identification, analysis, evaluation and controls) is necessary. Results of risk management must be listed in specific records/documents, for example: Risk register / List of risk factors, Residual risk level, Measures to prevent and mitigate risk. These documents are continually revised, given the evidence provided by controlling the supply process, on one hand, and adapting to new requirements, policies and objectives, on the other.

5. Implementing integrated quality-risk systems

Implementation of integrated quality-risk systems is a complex process that includes as main sequences, setting the organizational framework, staff training, processes definition, establishing the methods of analysis and risk assessment, and providing the necessary resources.

The key role in this approach is attributed to the superior management, coordinator of the change process of the methods to address the organization's issues. One change concerns the management style: approaching risk involves the shift from the reactive management to a new attitude, foresight and proactive. In other words, managers should not be limited to treating the consequences of events that occurred and their causes to mitigate risk events. Treating the risks, which have already occurred, points out the effectiveness of control systems, but proves to be insufficient for a performant management: management must look into the future and identify potential risks caused by environmental changes and the strategies promoted.

A systematic approach of risk involves describing the processes, setting the working rules, creating tools to support risk identification and assessment. The literature presents a number of methods and techniques of risk analysis and assessment [21], [22], many of them have wide application in quality analyzing and improving in companies with advanced management systems.

System configuration and its complexity should be correlated with organization's resources and particularities. One of the factors that make the systematic risk approach in quality management to be difficult is that the establishment and control of risks are evidenced throughout the organization, at the level of relevant processes. Moreover, each process can be approached more or less complex. For example, during the supply process should be taken into account the variability of process' requirements and characteristics on the categories of materials and products, according to destination, the amount and consumption level, the impact on production, market supply, etc. Such an approach, nuanced and analytical, is not possible without

an advanced computer system that can manage large volumes of data. Another factor of which the success of such an approach depends on is the development of guidelines, rules and other tools to sustain planning and controlling of the quality and risk on processes or their sequences. When the organization's resources are limited, it is important to establish the priority of the risk control and reduction actions.

The most difficult problem in a systematic risk-quality approach is related of staff skills, given that both quality management and risk management are based on specific concepts and methods and require special training. Professional approach of risk within the organization implies the presence of specialists, but it is also necessary to train in risk management managers, quality specialists and other staff in the organization, participating in planning, implementing and controlling of QMS processes.

6. Conclusion

The integrated quality-risk approach represents a development axis for organization management that responds simultaneously to improvement requirements in the performance of quality management systems and successful implementation of risk management.

The wide spread of ISO 9001 QMS model is an opportunity to expand risk management within organizations, given the common items of the two approaches presented in the paper. According to the authors, it is important that risk management methodology to be applied within the organization and the relevant quality processes. The general methodology proposed by the authors is applied to an example which highlights that the systematic approach to risk management within the organization involves emphasizing on the preventive character of management processes.

The considerations on the implementation process of integrated quality-risk systems highlight the critical success factors; in this regard the adequacy on the organization's particularities is essential. According to the authors, extending the risk approach in quality management can be supported, on one hand, by including in the ISO 9001 standard of explicit requirements on risk assessment on the organization level and on the QMS processes, and the development of methodological rules and guidelines of good practice on integrated quality-risk management on processes and business fields.

References

- [1]. *** ISO 31000 - Risk Management. Principles and Guidelines, 2009.
- [2]. *** Methodology of implementation of internal control standard „Risk Management”, Ministry of Public Finance, 2007.
- [3]. *** Basel Committee on Bank Supervision, „Credit Risk Modeling: Current Practices and Application”, Technical Report, Bank for International Settlement, 1999.
- [4]. Ramirez, D., Risk Management Standards: the Bigger Picture, Information Systems Controls Journal, Vol. 4, 2008.
- [5]. *** HACCP - Hazard Analysis and Critical Control Point.
- [6]. *** Serco's approach to: Risk Management. http://www.serco.com/Images/Approach%20to%20Risk%20Management_tcm3-13017.pdf
- [7]. *** ISO 9000 – Quality Management Systems- Requirements.
- [8]. Olaru, M., Quality Management, Economic Publishing House, Bucharest, 1999.
- [9]. Morariu, C.O., Quality Management Systems, Transilvania University of Brasov Publishing House, 2006.
- [10]. Tague's, N.R., The Quality Toolbox, Second Edition, ASQ Quality Press, 2004.
- [11]. Kurekova, E., Measurement Process Capability, Trends and Approaches, Measurement Science Review, Volume 1, Number 1, 2001.
- [12]. Brue, G., Six Sigma for Small Business, Entrepreneur Press Publishing House, 2006.
- [13]. Hutchins, G., – Risk Management – The Future of Quality, QualityDigest.
- [14]. Avanesov, E., Risk Management in ISO 9000 Series Standards, International Conference on Risk Assessment and Management, Geneva, November, 2009.
- [15]. Badreddine, A., Romdhane, T.B., Amor, N.B., A New Process –Based Approach for Implementing an Integrated Management System. Proceedings of the International MultiConference of Engineers and Computer Scientists 2009 Vol. 2, IMECS 2009, March 18 - 20, 2009, Hong Kong16.
- [16]. Donawa, M., Effectively Incorporating Risk Management into Quality System, Medical Device Technology, June 2006, pg.36/38.
- [17]. Dascălu, A. D., Research on Project Quality Management, PhD thesis, Transilvania University of Brasov, 2009.
- [18]. Runceanu A.I., Quality Management of Automotive Service, Dissertation paper, Transilvania University of Brasov, 2010.
- [19]. Timaru, O., Quality and Risk Management, Integrated Approach, Dissertation paper, Transilvania University of Brasov, 2010.
- [20]. *** GHTF/SG/N15R8, Final Document, Implementation of Risk Management Principles and Activities within a Quality Management System, The Global Harmonization Task Force, 2005.
- [21]. Berg, H-P., Risk Management: Procedures, Methods and Experiences, RT&A 2(17) (Vol.1) 2010, June.
- [22]. ***Risk Management - Common methods of risk assessment. <http://www.risk-management-basics.com/risk-management-methods-of-risk-assessment-overview.shtml>.
- [23]. Mazilescu V., Knowledge Management and Intelligent Economic Systems, EDP Bucuresti, 2009.