AN ANALYSIS OF TWO NEW PROCESS APPROACH-RELATED TERMS IN ISO 9001:2015: RISK-BASED THINKING AND CONTEXT OF THE ORGANIZATION

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Abstract: *This paper is focused on understanding "risk-based thinking" and "context of the organization" in the process approach according to the requirements of the updated norm, ISO 9001: 2015 Quality Management Systems – Requirements. These new trends should increase the effectivity of the quality management system, should improve company results, and should prevent negative effects of processes. This article explains how to understand the context of the organization in order to make correct strategic decisions. The author describes the integration procedure of risk-based thinking into several organizations in the Czech Republic. This article can support organizations in the implementation of the best practice of new requirements of ISO 9001: 2015. This paper is focused on several production organisations from the different industrial area in the Czech Republic. This research is based on the up to date research data of world´s databases. The author used the qualitative method in the form a structured interview.*

Keywords: *Risk-based Thinking, Context of the Organization, ISO 9001: 2015, Quality Management System, Actions to Address Risks and Opportunities*

JEL Classification: *G32, L15, O31*

Introduction

One of the external factors influencing the continuous improvement of business processes are the new trends published by the International Organization for Standardization (hereinafter referred to as ISO), based in Geneva. In September 2015, ISO published an update EN ISO 9001: 2015 Quality Management System – Requirements. ISO Secretary Kevin McKinley justifies updating the ISO 9001 standard as an opportunity to organizations to adapt to the changing world (ISO 2015). The survey of IRCA QMS registered Auditors of all industry and services sectors worldwide claims that ISO 9001: 2015 is in line with modern business and quality management concepts and will be a useful tool for the companies (Fonseca et al., 2016).

The Principal Auditor of the International Register of Certificated Auditors (Trčka, 2015) states that two significant changes regarding the updating of standards EN 9001: 2015 are the implementation of the context of the organization, and risk-based thinking. According to the type of the organization, the different industries in which it operates, legal requirements, the context and objectives of the organization face various risks (EN 31010: 2011). Standard EN 31000: 2010 defines the context of determining a definition of external and internal parameters to be taken into consideration in risk management and setting the scope and risk criteria for risk management policy.

ISO 9001: 2015 argues that the organization is responsible for the introduction of risk-based thinking and identification of actions to address risks, including documenting the actions as an evidence of addressing the risks. (ISO 9001: 2015). Ionașcu et al. (2016) suggest that the financial performance of Romanian companies implementing and certifying multiple management systems (ISO 9001, ISO 14001 and OHSAS 18001) is higher and directly proportional to the complexity of the management systems implemented and certified. Řeháček (2017) states that the effectiveness of a QMS is to a great degree related to whether quality costs are introduced into the frameworks of the company's strategies and supported by proper resources. While assessing the quality the economic aspect is related to the costs borne for quality, effects of a lack of quality and the achieved effects (Řeháček, 2017). This lack of the quality could be filled with risk-based thinking.

The risk management process (Šefčík, 2009) is a general term of some spontaneous and systematic actions to control risk. Christensen et al. (2003) state that risk is an element of danger, which individually or in combination with other elements, has the ability to be a source of consequence. Zhou et al. (2012) validated risk management process by a stochastic simulation model. According to the international OHSAS 18001: 1999 (Tichý, 2006) this consequence in the form of damages can be expressed in monetary or other units. Three elements relate to risk: time frame, the likelihood of events, and the level of seriousness of the consequence (Procházková, 2012).

According to ISO 31010: 2011, risk assessment may take place at the organizational level, the departmental level, within projects, and during individual activities. Aven (2011) highlights the need to focus on the selection of appropriate methods for identification and risk assessment. For the risk assessment of the human factor, HRA - Human Reliability Analysis, is used, which assesses the human-machine interface and tries to predict the behavior of the operator and its interaction in the production process (Bedford, 2003). The main trends and emerging themes of management practices and also in the risk management in the current business world and their synergy effects were identified, reviewed and classified eg. in articles Blahova et.al (2017). Risk management it is only one parameter, that we can also include into EFQM Excelence Model (Chodůr et al, 2011).

1. Statement of a problem

In February 2016, there was an update of the CSN EN ISO 9001: 2016, Quality Management Systems – Requirements in the Czech Republic. Every organization implementing the quality management system based on this international standard should deal with the new elements, risk-based thinking and context of the organization, in the process approach, and should have the goal of achieving improved results and preventing negative effects (ISO 9001: 2015). Each organization can itself select the form of integration of the risk-based thinking (ISO 9001: 2015). Particularly, in an economic downturn in a country an organisation needs to understand their organization and its strategic direction in order to be prepared for this situation. It means to determine and address its associated risks (Medic et al., 2016).

The last update, ISO 9001: 2008, included risk-based thinking in carrying out preventive actions (ISO 9001: 2015). Organizations certificated in ISO 9001: 2008 had

to solve internal and external nonconformities and other procedural and systematic problems. The solution of nonconforming outputs was ensured after their creation. However, the new requirement from ISO 9001: 2015 – Action to address risks and opportunities – must be included in process planning to prevent or decrease negative events and to estimate opportunities. Tuček (2016) mentions in his research that the process of Strategic management and planning of resources belongs to the second most significant managing process. This requirement should "establish a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects" (page 9, ISO 9001: 2015).

The deadline for the implementation of the new version of the norm is September 2018. Also, a time period of approximately 1 year was introduced for the members of the International Organization for Standardization for the transition to the new requirements. Most of the organisations do not clearly understand how to fulfil the vague requirements of this new ISO norm. Based on the vagueness in business area a following research question is dealt with in this article: What kind of integration of two new terms – Risk-based thinking and context of the organisation – do production organisations select?

2. Methods

This article is focused on 5 middle and big sized production organisations from the different industrial area in the Czech Republic, which have already started the implementation of risk management according to the new requirements of ISO 9001: 2015. Two of these organization got a certificate during the update ISO 9001: 2015, also their management system has proven the ability to fulfil the new requirements of this norm. The other three organizations are currently implementing the new requirements to their processes and quality management system.

Tab. 1: List of interviewed production organizations

Sign of organization	Size of organization	Implementation of norm ISO 9001: 2015	Interviewed person
A	Big company	Implemented	Senior quality manager
B	Big company	Implemented	Quality manager
C	Big company	Implementing	CEO
D	Middle company	Implementing	Industrial engineer
E	Middle company	Implementing	Quality manager

Source: (the authors)

The author used the qualitative method in the form a structured interview. Interviews are a qualitative technique for collecting data from individuals; data are often descriptive and going deep (Pickard, 2013). The interviews in the framework of research were managed and structured. The interview questions are described in chapter Research results in a form best practice.

The structured interview was selected to find out more details and direct information about risk management and the context of the organization. The author describes the best practices in the integration of risk-based thinking into a quality management system and

in understanding the context, both based on the experiences of the selected organizations.

3. Research results in a form best practice

The introduction of the results presents progressive steps for the integration of the context and the risk-based thinking in their organization. The certification companies in the Czech Republic see the difference between the new 9001: 2015 and the old norm 9001: 2008 Quality management systems – Requirements in two terms – the context of the organization and the risk-based thinking (Bureau Veritas Czech Republic, 2015). Sitnikov et al. (2017) describe that new version of the norm ISO 9001: 2015 represents a major opportunity to forge an integrated system of performance management, through the creation of significant ties between quality management and continuous improvement, on the one hand, and corporate risk management on the other hand.

In this research all five of the selected organizations implemented the requirements in similar, which is described in this part of article.

3.1 Context of the organization

In connection with strategic planning an organization needs to define its context. Context of the organization consists of external and internal issues, understanding the needs and expectations of interested parties and determining the scope of the quality management system (ISO 9001: 2015). All managers of an organization shall know this new term. Islam et al. (2017) illustrate the effect of organizational context (e.g., structure and climate) on knowledge conversion in the service industry. It is essential to understand the effect of organizational contexts on knowledge conversion using socialization as a mediator and IT as a moderator (Islam et al., 2017). In this research we can claim that understanding the context of the organization and making the strategic and operational decision in organization can be done according to the requirements of ISO 9001:2015 and process owners.

The managed interviews found out the following:

- Q1: Which job positions define the organization context
- Q2: How do organizations proceed in defining the organization context?

The results from the managed interviews point to the fact that in two production companies (large B and middle D organizations) the quality manager himself defined the context of the organization (external and internal issues) and submitted it to the company's director, who edited it and presented it to comment at the management's meeting. One middle organization (middle E organization) set the context of the organization by cooperation of all top management members at the management meeting using the SWOT analysis (the Strengths, Weaknesses, Opportunities, and Threats Matrix). The remaining two organizations (big organizations A, C) created the context based on brainstorming of the team formed by the members of quality management, strategy and industrial engineering departments. The final form of organization context for all companies was put into effect as a controlled document. All employees of the organizations were acquainted with it.

3.1.1 External and internal issues of the organization

The norm ISO 9001: 2015 highlights that the organization shall determine external and internal issues, which are relevant to its purpose and its strategic direction (ISO 9001: 2015). Managers need to know the external and internal issues of their organization to make correct decisions. Each of the interviewed organizations introduced a different register of external and internal issues. This difference is understandable due to the diverse strategies of the organizations.

The author would like to explain this statement on the Tab. 2. If the personal managers can understand the internal and external issues of the organization, then they should plan and decide with the information – Skilled and hardworking people, our work is handicraft – in the personal process. It means that in the production process the human resources cannot be substituted by automation. The main source of the production process are the employees and the organization has to work on a correct benefit´s system to keep their employees inside the organization and other actions which can ensure new skilled employees. To understand this internal issue, the long-terms objectives should be defined. For example, this organization should work on building cooperation with a vocational school or should establish its own school for the incoming production employees. This decision is depending on the personal manager.

Tab. 2: Example of the internal issue in the organization

Issue	**Kind**
Skilled and hardworking people, our work is handicraft	Internal

Source: (the authors)

3.1.2 External and internal interested parties

Due to another requirement on the context of the organization managers have to understand the needs and expectations of interested parties (stakeholders). Organizations shall detect all interested parties and their requirements, which might be relevant to their quality management system (ISO 9001: 2015). All the interviewed companies have a similar list of stakeholders. The expectations of the stakeholders are very similar. In Tab. 3 we can see the example of the internal interested party - employees and its needs and expectations.

Tab. 3: Internal interested party – its needs and expectations

Interested party	**Needs and expectations**
Employees	Reasonable salary and motivation bonuses for work Acceptable working conditions for occupational safety and health Professional growth - up skilling

Source: (the authors)

Defined needs and expectations must be monitored and reviewed in order to respect all relevant parties. Competitive employees have to cope with this information to be able to perform planning, management, decision-making and controlling. The organization has to ensure exact communication channels to both, external as well

as internal parties. It is important to ask questions such as: who, how, when and with whom - will communicate within the organization.

3.1.3 Scope of the quality management system

Within the context of the organization, the scope of the quality management system must be defined. When defining this scope, the organization shall consider following issues: internal and external relations, requirements of relevant interested parties and the products and services of the organization (based on the ISO standardization 9001: 2015). The managed interview revealed that all the interviewed companies have a defined scope of the quality management system. This is understandable because it is a requirement of the procedural approach.

3.2 Risk-based thinking

Firstly, the managers of the processes shall define a context of their organization and then they shall fulfil other requirements related to the actions to address risks and opportunities. Top management shall demonstrate a commitment with respect to the risk-based thinking. Another commitment to the customer is to determine and solve the risks and opportunities that can affect conformity of products and services. (ISO 9001: 2015)

Chiarini (2016) detects a lack of risk-based assessment in research of European manufacturing small- and medium-sized enterprises, which could be caused by not enough experience in dealing with risk-based thinking according the norm ISO 9001: 2015. The norm ISO 31 000 Risk management – Principles and guidelines defines the risk management process. This norm defines to establish the context of the organization and progressive steps of risk assessment and risk treatment. The top management shall also monitor and review the risks. (ISO 31000: 2010). ISO 9001: 2015 standard does not require an implementation of the risk management process. It is up to the organization, if they implement the risk management process to their quality management system or not.

Questions from managed interviews to determine the integration of risk-based thinking into quality management system of organizations were as follows:

- Q3: What job positions define process risks?
- Q4: How do you define the risks in your processes?
- Q5: Based on which criteria is the level of risk determined?
- Q6: What scale of risk level do you use in risk evaluation?
- Q7: What other information (apart from Evaluation of risk, Description of problem, Action to risk, Responsibility and Date) do you find out when defining risk?

Tables 4 and 5 show individual approaches in integration of risk-based thinking into their processes within the interviewed production organisations. Tab. 4 describes who defines risks in business processes and how organizations define the risks in their processes. Process risks are mostly defined by the process owner alone, the process owner and their colleagues or by internal interested parties (top management, managers

and employees). Also the quality manager with the process owner, customers or external consultants are involved into risk definition. The form of risk definition - brainstorming - was used in all five cases. Organization mostly applied the knowledge of experts and in one case SWOT analysis and fishbone diagram were used for risk definition.

Tab.4: Defining risks

Q3: What job positions define process risks?					
What job positions/ Organization	A	B	C	D	E
Process owner (manager) alone	√	√	√		
Process owner with their colleagues (subordinates)	√		√		
Quality manager with process owners		√			
Top management	√				
Customers			√		
External consultants			√		
Internal interested parties (top management, managers, employees)				√	√
Q4: How do you define the risks in your processes?					
How/ Organization	A	B	C	D	E
Knowledge of experts	√		√	√	√
Brainstorming	√	√	√	√	√
SWOT analyze					√
Fishbone diagram			√		

Source: (the authors)

Tab. 5 shows which criteria are chosen by organizations for risk evaluation. All organizations established the level of risk based on the consequence for customer and organization. Likelihood of events are mostly determined through a gross estimation. One organization is interested into the cause and the consequence of risk by risk identification.

Tab.5: Level of risks and other information

Q5: Based on which criteria is the level of risk determined?					
Which criteria of level of risks/ Organization	A	B	C	D	E
Likelihood of events	√		√	√	√
Consequence (for customer)	√	√	√	√	√
Consequence (for organization)	√	√	√	√	√
Time frame		√			
Q6: Which scale of level of risk in risk evaluation you are using?					
What kind of scale/ Organization	A	B	C	D	E
3 scale of risk evaluation (low, medium and high risk)	√	√	√	√	√
Q7: What other information (without Evaluation of risk, Description of problem, Action to risk, Responsibility and Date) do you find out about the defined risk?					
What other information/ Organization	A	B	C	D	E
Cause of risk (what happens if..)					√
Consequence of risk (outcome of an event in detail)					√
Nothing	√	√	√	√	

Source: (the authors)

Based on the structured interviews, the author of this article has set the procedure, how to implement the risk-based thinking into the processes of the organization. The scope of the organization determines all processes. Each manager of its process has to plan actions to address risks and opportunities, has to integrate and implement these actions and evaluate the effectivity of these actions. All risks and opportunities can be defined in a list of risk and opportunities as a form of documented information.

In Fig. 1 a personal manager with the responsible team defined risks of the personal process. Process risks was defined by process owner, managers of top management, other employees, external consultants and customers in the realized interviews. This definition and assessment of processes risks based on the experience of managers and other internal or external interested parties could appear very simple. These interested employees should be experts in this area. Pačaiova et al. (2017) find out according to the performed research that qualitative approach in multi-criteria decision making brings a high level of uncertainty in risk assessments.

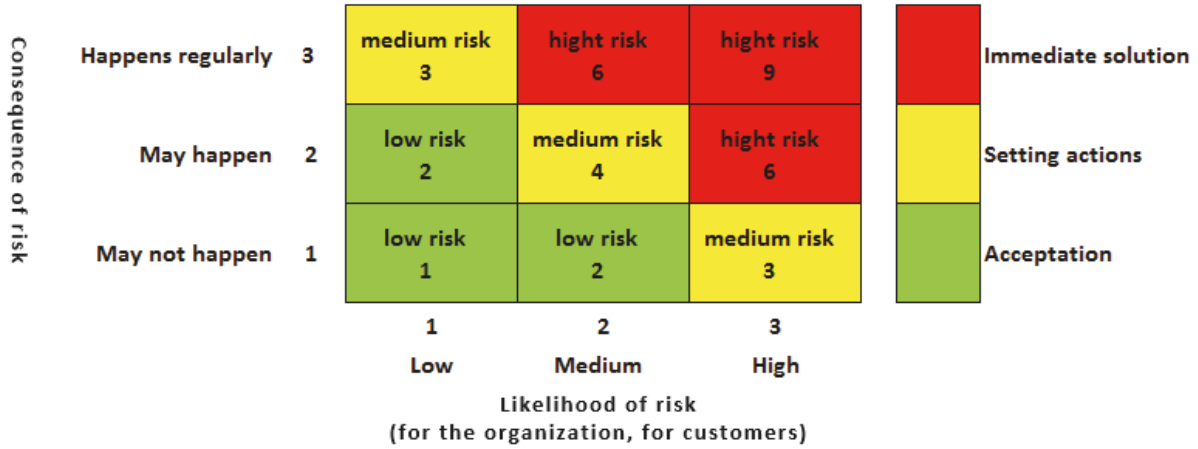
Fig. 1: Risks and opportunities of personal process

Risks / Opportunities	Evaluation of the risk/opportunities			Description of the problem	Risk treatment - Action	Responsibility	Date
	Consequence	Likelihood	Level of risk				
Risk: Shortage of qualified staff	3	2	6	1. The age composition of current employees - average age 38 years 2. A high proportion of manual work - specialized activities 3. Demographic structure in the location of this organization	1. Setting cooperation with universities, colleges, secondary and vocational schools.	Name of employee, Department	January 2017
					2. Extending the benefit program for employees	Name of employee, Department	December 2016
					3. Awakening interest among employees of small businesses in the area	Name of employee, Department	December 2012
Risk: The unsubstitutability of the key managers	2	1	2	Not each managers has its successor	To create a substitutability plan	Name of employee, Department	May 2017

Source: (the authors)

Defined risks in this process are shortage of staff and the unsubstitutability of the key managers. The personal manager should explain the problem of this risk or opportunity. In relationship to risk management process the personal manager identified the risks and now he should do the analysis and evaluation these risks or opportunities. This phase is dependent on the method which the organization will decide to use. The organization can use the method from the norm EN 31010 Risk management – Risk assessment techniques (EN 31010). The research showed that most organizations used the Winterling Crisis Matrix, which can be seen in Fig.2. This solution of risk matrix was used when using FMEA (Failure Mode and Effects Analysis) method to view critical drawback (Čížek, 2017). Fonseca et al. (2016) describe that risk matrix could be used for operational risk assessment.

Fig. 2 Risk evaluation



Source: (the authors)

After risk assessment the manager has to set an action, define responsibility and plan a date of the action. The manager of process has to monitor the tasks and their fulfilment. The organization has to determine the frequency of monitoring and review of the risks and opportunities. The research showed that most organizations reviewed risks and opportunities within management review of the quality management system at the end of the year. Risks and opportunities should be updated at the beginning of each year together with the goals of the quality management system of the organization.

4. Conclusion

Context of the organization should be determined using the facts about the organization. Top management and managers of processes have to manage and make decisions through information derived from the context of the organization. Aspects of the organization are main determinants of ensuring the success of the organization. They may take the form of opportunities as well as threats. Needs and expectations of all interested parties must be monitored and reviewed for the purpose of increasing the prosperity and reputation of the organization. Expectations and needs of internal stakeholders are the basis for organizational culture. External stakeholders with their needs and expectations are fundamental to the correct settings of the social responsibility of the organization. The interviewed organizations defined the context of the organization with either one employee or a team of executives and employees in the form of brainstorming or SWOT analysis. We cannot confirm whether the difference in these approaches influences the final effect due to the short period of the defined context. This document should be based on the organization´ strategies and should be an interactive means for making the strategic and operational decisions in organizations.

The process approach is not a new term for the organization. From the point of view of the process approach, each process should include the necessary elements. The new element resulting from the requirements of the ISO norm is to manage risks and opportunities. The research has shown that organizations use a simple solution – the table or the list of process risks defined by one job position or a team to fulfil the requirement of ISO norm 9001: 2015 - Actions to address risks and opportunities.

This register of risks involves the evaluation of risks, the description of problems, the actions to address risks, the responsibility and the dates. The level of risk is established based on the consequences for customers and the organization and the likelihood of events. The interviewed organizations use three levels of risk evaluation – low, medium and high risks. Managers of business processes have to assess and deal with the main risks and opportunities of these processes. Until the update ISO 9001: 2015, improving the process depended on the abilities of each manager or top management. If the manager or top management has no interest in continual improvement, then this should be recognized and the internal or external auditor should highlight the absence of these requirements. The new requirement – an action to address risks and opportunities – is to define problem areas in the processes and possible potential opportunities for improvement. Managers of the processes are responsible for these activities. The level of evaluation of risks and opportunities depends on the choice of appropriate methods. The treatment of the major risks should be provided in the form of action to eliminate or minimize the risk. Top management shall review the context of the organization and the list of risks and opportunities at the end of each year.

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