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## **Some Aspects Related to the “Context of the Organization” Clause for a Quality Management System and the Correlation with “Risk Based Thinking” Stated in SR EN ISO 9001:2015**

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### **Abstract**

“Context of the organization” is a new clause in SR EN ISO 9001:2015, which requires that an organization must consider both the internal and external issues that can impact its strategic objectives and the planning of the Quality Management System (QMS). In this paper are approached some external and internal relevant aspects, which in a strategic vision may influence the performance and the capability of a QMS. Because of their influence and their direct and/or potential effects, these aspects may influence the organization’s performance and capability.

The actual structure of the SR EN ISO 9001:2015 with documented information and “risk-based thinking” approach helps to reduce the uncertainties, to properly identify the risks, treating them and to determine new improvement opportunities.

### **Keywords**

context of the organization, risk, quality management system

### **1. Introduction**

In the current conditions of economic globalization and diversification of competitive markets it is important for organizations to be coordinated and controlled in a transparent and systematic way. These conditions can ensure a successful management and functioning if at the organizational level is designed, implemented, maintained and improved a Quality Management System (QMS) as a component of the organizational system.

Both the organizations already certified and those that are planning to implement and certifying their QMS accordingly to SR EN ISO 9001, will have to take into consideration the new requirements specified in SR EN ISO 9001:2015 version and change, adapt or implement them [1].

Given that there is now a new challenge – quality- that became a driver of competitive advantage it is appropriate to be considered the environment where the processes/activities take place.

Because they are influenced by a wide diversity of disturbing factors, the organizational processes can be affected in different ways that can lead to losses in a competitive market as a consequence of not meeting the needs and expectations of interested parties.

Under these circumstances, the standards SR EN ISO 9000:2015 and SR EN ISO 9001:2015 define the “context of the organization” concept that represents “*combination of internal and external factors and conditions that can have an effect on an organization’s approach to its products, services and investments and interested parties*”. An organization’s context is its business environment. It includes all of the internal and external aspects that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction [2].

One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to risk, respectively “risk based thinking”.

## 2. The “Context of the Organization” Clause and the Correlation with “Risk Based Thinking”

### 2.1. Some aspects related to the “context of the organization” clause

“Context of the organization” is a new clause in SR EN ISO 9001:2015, which requires that an organization must consider both the internal and external issues that can impact its strategic objectives and the planning of the Quality Management System (QMS). This new requirement modifies the application in practice, because it leads to the opportunity of identifying the risks and opportunities related to the management system of the organization, with business implications.

Considering the above mentioned aspects for identifying the “context of the organization” it is necessary to consider:

a) The way the activities are conducted – which from the “context of the organization” point of view must consider:

- External context (EC), represents the amount of the external factors that interact with the organization, related to: social and political situation, national and international microeconomics, technological environment, needs and expectations of the interested parties, legal, regulatory and competitive environment.

- Internal context (IC), represents the amount of the internal factors that may influence the quality level of products and services, related to organization’s availability to ensure: the infrastructure, organizational culture, human resources level, informational resources, business organization, decision making process and organizational performances.

b) Relationship with interested parties, it refers at *“person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity”* [2].

Through this concept the organization must identify the needs and expectations of its customers and interested parties (suppliers, employees, partners, shareholders, investors, bankers, regulatory bodies, competitors, pressure groups).

Due to the diversity and involvement of these factors it is appropriate a rigorous and careful identification and prioritization and a systemic approach.

c) Continuous monitoring and upgrade of the “context of the organization” can be considered as entry element for management reviews through which is proposed the revision and addressing of short-term strategy of the organization.

### 2.2. Correlation between “context of the organization” and “risk-based thinking” requirements

For strategic planning SR EN ISO 9001:2015 introduced the “risk-based thinking” term which is considered the process approach where the preventive action is a part of the strategic planning [3].

Having as main organizational objectives continuous providing of quality products and services, respectively customer satisfaction, appears the uncertainty of achieving objectives, therefore “risk”.

The introduction of “risk based thinking” clause gives additional credibility to SR EN ISO 9001:2015 within the organization by adding some systematic evaluation of potential and actual issues with the aim of making processes more robust and capable [4].

Risk is generally conceptualized in terms of loss, but “risk-based thinking” can also help to identify opportunities that can be considered to be the positive side of risk [5].

According to SR EN ISO 9000:2015 risk is defined as “effect of uncertainty” and the organization must determine the risks that can affect its ability to achieve objectives [2]. Risk-based thinking replaces what the SR EN ISO 9001:2008 version used to call preventive action.

This new requirement brings benefits to the organization by providing permanently quality products and services and enhancing customer satisfaction. Through this concept it is implemented an improvement and preventive organizational culture.

Based on those mentioned the “risk-based thinking” approach is considered appropriate and it helps to:

- identify risks and opportunities;
- risks and opportunities analysis and prioritization;
- develop actions plan to address risks and opportunities;

- implement the resulted action plan;
- verify effectiveness of actions;
- learn through experience and continuous improvement.

In relation to the context of the organization concept, the main factors which can influence the management systems performances and the approach of the identified risks are shown in figure 1.

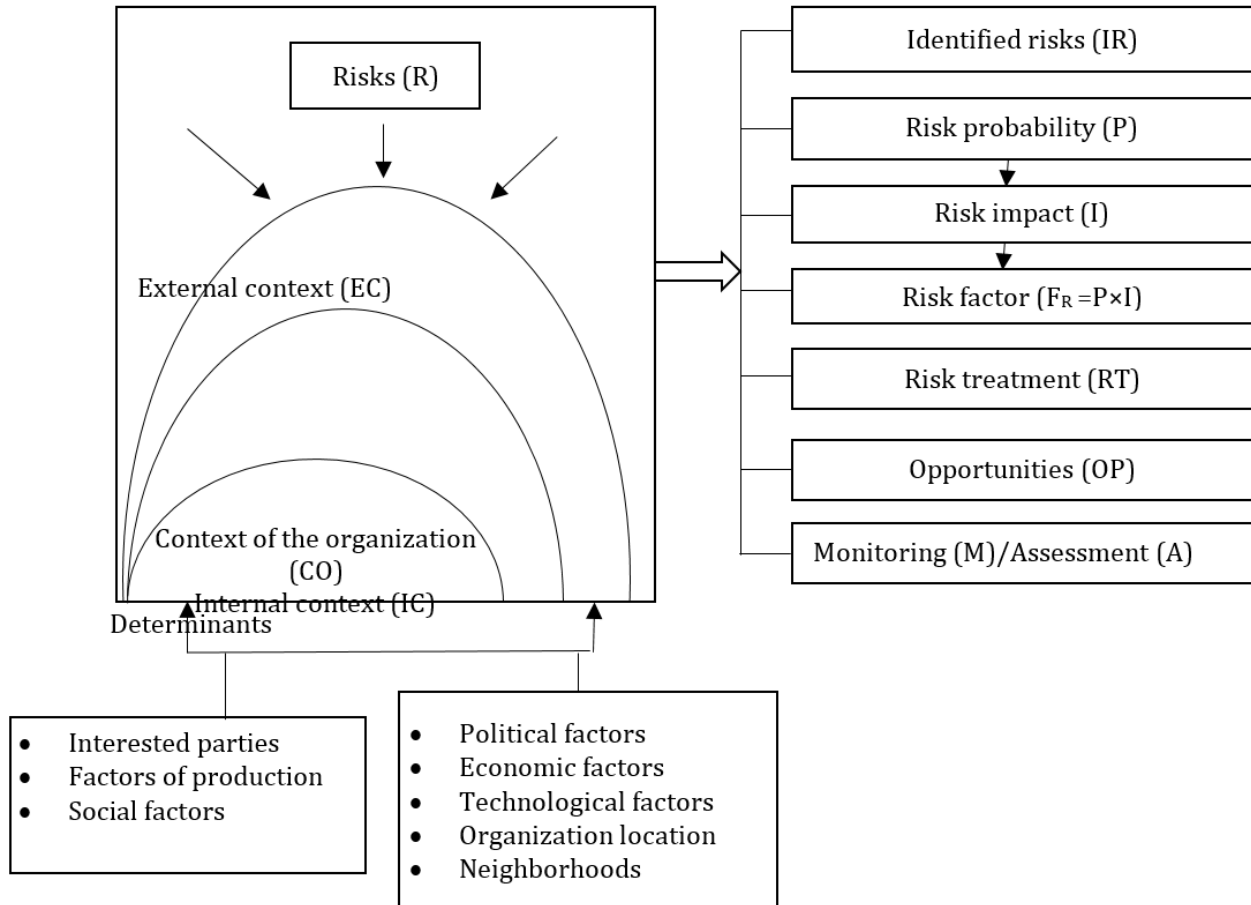


Fig. 1. Context of the organization and risks approach

For example, in the external context frame, the determinants factors, respectively political factors, are:

- stability and economic policy coherence;
- national/international legislation;
- influence on the market/interested groups;

Thereby, in the first category one can identify the following risks:

- changes of government policy guidelines;
- changes in investment programs;
- budget adjustments;
- changes in structure and leadership at government level.

In these situations, risk treatment consists in:

- organization political adaptation;
- setting up new objectives. Opportunities will refer to the coincidence of views and the activities of the organization will be established to the new orientation of investments.

For internal context, the determinants factors, respectively factors of production can be considered:

- aspects regarding research and development;
- creative and innovation potential;
- supply activity;

- design activity;
- developing technologies;
- technology / equipment;
- developing technological flows;
- testing activities;
- maintenance activities;
- logistics activities;
- intellectual property.

These factors of production can cause risks that must be identified by competent knowledge of activities and, depending on known vulnerabilities, the risks can be treated, factor of risk can be calculated and specific opportunities are proposed.

Also, it is appropriate the continuous monitoring and the aspects assessments to keep them under control and not to reduce the company's performance.

### 3. Conclusions

In the frame of the "context of the organization" clause, this paper highlights aspects regarding key factors, identified risks, risk factors and proposes improvement measures for the identified aspects.

The new approach of the "risk based thinking" concept has a significant importance due to its utility as a prevention tool at planning and implementing a QMS.

One of the most important aspects of risk assessment is the communication of probabilities and impacts for different situations, which involves the establishment of a database that will lead to fair and objective evaluations.

The mentioned aspects have an important value especially for the certification audit of QMS according to SR EN ISO 9001:2015.

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