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## Context of Organization and Quality Management

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# Context of Organization and Quality Management

V Makolov<sup>1</sup>

<sup>1</sup>Ulianov Chuvash State University, Cheboksary, Russia

E-mail: vmakolov@yandex.ru

**Abstract.** The new version of the standard ISO 9001:2015 strengthened and defined concretely the requirements for determining and accounting for external and internal environmental factors affecting the organizational quality management system. Important aspects of this issue are: the priority of environmental factors for monitoring and the choice of methods for their analysis, key categories of stakeholders and the main objectives for determining their requirements and expectations. The subject of this study concerns the expert evaluation of these aspects as to the context of an organization.

The purpose of the study is to assess on the basis of an expert survey the key aspects of the context of an organization relevant to the quality management system in the context of the practical implementation of ISO 9001:2015 requirements.

In this paper, we present the results of an empirical study conducted in the format of an Internet survey of quality experts, to identify the perception of the elements of the context of an organization that are relevant to the quality management system.

Results. The study allowed us to identify the most important external and internal factors for the context of an organization.

## 1. Introduction

A high quality level is not achievable without effective management [2,3,13,15,16,18]. The most important direction of a modern company's business is the provision and development of the quality management system (QMS) which allows developing effective ways to increasing customer satisfaction with the quality of products and services that ensure the growth of the efficiency and competitiveness of a company in a modern dynamic business environment. In modern conditions, it is the context of an organization that plays a key role in ensuring the viability and effectiveness of the quality management system; any organization is an open system that interacts with the external environment.

The role of the environment, or context, is one of the most important from the point of view of the organization existence and development. Understanding the environment, or context, is the key to the right business strategy, not to mention the right quality strategy [1,4,5,10,11,14].

The term "context of the organization" is defined and fairly clearly structured in strategic management (the terms "habitat", "business environment", "organizational context", and "ecosystem of an organization" are also used). In accordance with ISO 9000-2015, the context of an organization is a combination of internal and external factors that can influence the organization's approach to setting and achieving its goals [6].

The main requirement of ISO 9001-2015 [7] for understanding the context is that an organization must identify external and internal factors related to its intentions and strategic direction and affect its ability to achieve the planned results of its system quality management. The organization should also



monitor and analyze information on these external and internal factors. ISO/TS 9002:2016 "Quality management systems -- Guidelines for the application of ISO 9001:2015" [8] presents examples of internal and external factors related to the context of an organization. Internal factors include: general results of the organization's activities, resources, personnel, factors of activity (processes, production and supply, the results of the functioning of the quality management system, consumer evaluation), management factors (managerial decision-making procedures). The external environment includes economic, social, political and technological factors, competition, and also factors affecting the working environment (legal and legislative requirements) [17,19,20].

Analysis of internal factors makes it possible to assess the organization's ability to manage its resources and thereby ensure the effective functioning of the quality management system. Evaluation of external factors is aimed at identifying opportunities for realizing the internal potential of an organization in a competitive economy and identifying threats and risks for the organization.

## 2. Methodology

In order to assess the attitude of quality experts to the requirements of ISO 9001:2015 related to the context of an organization in the quality management system, we conducted an online survey using the Google Docs service. The process of the conducted research consisted of the following stages:

1) Setting a goal of the study and formulating the hypothesis. The specific goal of the survey was to test the hypothesis about the strategic role of the context of an organization in quality management systems. The objectives of the study were to identify the most important external and internal factors of the environment (context).

2) Creation of a questionnaire and its placement on the Internet using the Google Docs service. The questionnaire included 16 questions related to clarifying the respondents' attitude to various aspects of the context of an organization in quality management systems;

3) Choosing the target group of respondents and asking them to participate in the survey. The following respondents were asked to complete the questionnaire: heads of organizations / deputy quality head, quality service manager, quality specialist in the organization, quality expert / quality auditor (an employee of the organization (any organization unit)), a teacher of an educational organization (specialist in quality management). 40 respondents took part in the survey, and one questionnaire was received from each of them.

4) Receiving and accumulating responses from respondents. According to their professional position, the respondents were as follows: the head of an organization / deputy quality head - 22 people (55%), the quality service head - 8 people (20%), a specialist on quality in the organization - 5 people (12.5%), quality expert / quality auditor - 3 people (7.5%), the teacher of the educational organization - 2 people (5%).

5) Analysis of research results;

6) Feedback from respondents.

## 3. Results

The new version of the international standard ISO 9001:2015 strengthened the requirements for the analysis of external and internal factors of an organization, in this regard, the respondents were asked whether they agree that the inclusion of the section "Context of the organization" in ISO 9001:2015 is an important step towards the harmonization of a quality management system with an organization strategic management system. 87.5% of respondents answered "Yes, definitely", and 12.5% answered "In part".

Indeed, the international standard ISO 9001:2015 and the corresponding national standard note that the application of a quality management system is a strategic solution oriented to the sustainable development of the organization. This aspect is also confirmed when answering the following question: "Does the implementation of the "Context of the organization" section requirements from the quality management system increase the management mechanism at the strategic level?" The majority of respondents (65.0%) answered "Yes", 35.0% of the respondents chose the answer "In part, the quality

management system was at this level even earlier (before the adoption of the new version of ISO 9001:2015). The developers of the standard only emphasized additionally to the level of the quality management system".

It should be noted that ISO 9001: 2008 also noted that the creation of a quality management system requires a strategic decision of the organization and emphasized the impact of the external environment, changes or risks on the development and implementation of a quality management system. However, these provisions were specified in the introduction to the document, and they were not sufficiently specific and clearly deployed in the requirements of the standard. Therefore, in our opinion, the development of ISO 9001:2015 in this respect was the specification of requirements to the context of an organization and making them cross-cutting (factors of the environment → identification and assessment of risks and opportunities → implementation of actions → evaluation of the effectiveness of actions taken → audit and management review → improvement). The implementation of this chain of actions is initially based on an analysis of external and internal factors related to the intentions and strategic direction of an organization.

An important issue is the analysis of specific factors in the context of an organization. It is clear that one or the other set of these factors depends on the industry sector organization, priorities and peculiarities of its development, the degree of competitiveness, etc. However, within the framework of the survey, we were interested in the priority of those factors for analysis, which are specified in ISO 9001:2015. The results of the analysis of respondents answers on the most important external and internal factors of the context of an organization for analysis within the quality management system are presented in Table 1.

**Table 1.** The most important external and internal factors of the context of an organization for analysis within the quality management system,% of respondents (respondents chose no more than 3 factors).

Context of an organization factors	%
1. External factors	
1. 1. Economic forces	87.5
1. 2. Competitive factors	77.5
1. 3. Technological factors	45.0
1. 4. Legislative factors	45.0
1. 5. Social factors	35.0
1. 6. Market factors	12.5
1. 7. Cultural factors	0
2. Internal factors	
2. 1. Factors related to the performance of the organization	100.0
2. 2. Organizational management factors, such as rules and procedures for decision making or organizational structure	87.5
2. 3. Factors related to the organizational knowledge	67.5
2. 4. Factors related to organizational culture	22.5
2. 5. Factors related to the values of an organization	0

Table 1 shows that the experts interviewed firstly prefer to analyze economic and competitive factors. The cultural factor is considered as a non-priority for the analysis. Among the internal factors, all respondents noted factors related to the results of the work of the organization. Also, the organization management factor is of priority. The respondents attributed organizational values and culture to the number of insignificant factors for the analysis.

Respondents were also asked to indicate the priority objectives for the analysis of external and internal factors. All respondents noted the identification of risk and opportunity factors as the purpose of this analysis. The goal is to find information to improve the quality of products and services (77.5%)

and form the basis for the development of policies and objectives in the field of quality (45.0 %). Also, respondents noted an assessment of the level of competitiveness of the organization (32.5%) and an analysis of the quality management system by management (22.5%).

In the new version of ISO 9001:2015, special attention is paid to the identification of stakeholder groups relevant to the organization quality management system and monitoring of their requirements. In this connection, a question was asked about the key stakeholders of the organization, except for consumers. All respondents noted, first of all, the staff of the organization (100%). Then there follow the company (55.0%), external suppliers (45.0%), regulatory and supervisory bodies (32.5%), and competitors (22.5%).

The respondents consider the most effective methods for analyzing the requirements of key stakeholders: systematic surveys (100%), collection of analytical information from open sources (55.0%), participation in activities of public structures, professional associations (45.0%), and involvement of specialized firms for the collection and analysis of information (22.5%).

A question was also asked about the main purposes of monitoring and analyzing the requirements of stakeholders related to the organization quality management system. The answers were distributed in the following order:

- 1) Identification of factors (sources) of risks and opportunities for the organization (87.5%);
- 2) Use of information from stakeholders to improve the effectiveness of the quality management system (77.5%);
- 3) Securing the long-term success of the organization on the basis of achieving a balance of interests of the stakeholders (55.0%);
- 4) The desire to expand the circle of direct partners in the main activity of the organization (45.0%);
- 5) Expansion of direct consumer groups as to products and services of the organization (22.5%).

In accordance with the recommendations of practicing auditor group from IAF (International Accreditation Forum) and ISO on ISO 9001, information on the context of an organization can be obtained from the following sources [9]: business plan; development plans (organizational strategies); reports on the analysis of competitors; economic reports; results of SWOT analysis; minutes of meetings, proceedings, etc.; plans and programs of action; reports of external consultants, etc. An auditor should conduct interviews with top managers to collect evidence of managerial understanding of the environment and content, risks and opportunities, and their use in process planning.

#### 4. Conclusions

Thus, the conducted research showed that quality experts, first of all, prefer to analyze, within the framework of the context of an organization, the economic and competitive factors, organization management and the results of activities of the organization. The basic methods of analysis of external factors are SWOT-analysis, PEST and PESTEL, scenario method, and of internal factors are SWOT, SMART and management analysis. And in our opinion, the more complex the environment and context, and the higher the level of competition in the industry, the more carefully and qualitatively the context of an organization will be explored.

The key groups of stakeholders related to the quality management system (except for consumers) are staff, society and external suppliers. Effective methods for analyzing stakeholder requirements are surveys, data collection and analysis of open sources, participation in the activities of public organizations and professional associations.

The main objectives of monitoring and analysis of the requirements of stakeholders within the quality management system are: identification of sources of risks and opportunities, application of information from stakeholders to improve the effectiveness of the quality management system, long-term success of the organization based on balancing the interests of different stakeholder groups.

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