Fundamentals of ISO 9001:2015

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Abstract. The choice of an effective quality management system is a non-trivial task which requires a special approach. We consider the main changes in the new edition of the international standard for quality management systems ISO 9001: 2015, its impact on the workflow and benefits.

1. Introduction
A characteristic feature of the modern market is production of quality goods and services in order to ensure the competitiveness of enterprises [3]. The implementation of a quality management system is a strategic decision for a company capable of improving the results of its activities and providing a solid basis for initiatives focused on sustainable development [4]. Although all companies certified for compliance with the ISO requirements should have changed them by September 2018 taking into account ISO 9001: 2015 requirements, not all the companies have done this due to internal problems and other reasons. There are companies that felt the need to implement a QMS. Therefore, the topic remains crucial due to the need for improving management systems in order to confirm compliance and ensure proper quality aimed at internal audit as a tool to find areas for improvement [2]. Improving the quality of products is one of the priority areas for the development of domestic industries [7-]. The most common model is a quality management system (QMS) whose requirements and recommendations are described in international standards ISO 9000 [8].

Consumer requirements for product quality are increasing due to globalization and development of international trade relations. To confirm the quality of products, international quality certificates are required. Until the 1980s, there were various international and national quality standards for goods and services.

2. Results and discussion
International ISO 9000 standards are the most common. Today, the number of certified quality management systems (QMS) exceeds 1.5 million, which tells us about the attractiveness of standards and their positive impact on the performance of companies.

QMS allows you to create a solid foundation for a productive and efficient company. Changes in the QMS caused by the changing edition of ISO 9001 allows you to view the general concept and trend. This consists in a gradual decrease in the degree of rigor in the requirements. The unification of standards is not correct, because each company has its own system and it is not necessary for the QMS to repeat the structure and section numbers.

This tendency is also observed in the transition from an elemental approach to a process approach to the QMS development; the company can set standards at its own discretion in the absence of a
requirement to reproduce the structure of the ISO 9001 standard in the QMS structure; it can use “its” own terms and definitions (Table 1). Documentation of the QMS is necessary in order to indicate the procedure and rules for the implementation of existing processes, as well as record the results achieved [5].

**Table 1. The main stages of ISO 9000 development**

| Year | Stages |
|------|--------|
| 1987 | Development of the first edition of the ISO 9000 standards |
| 1994 | Clarification and updating of standards. The "elemental" principle of QMS GOST R ISO 9000-9004 development |
| 2000 | Radical revision of standards. Process and systematic approach to the QMS development. 2001 implementation of GOST R ISO 9000-9004 |
| 2005 | Updating of ISO 9000 standards. 2008 - updating of GOST R ISO 9001-2008 standards. |
| 2011 | Updating of ISO 9001. Implementation of GOST ISO 9001-2011 - Interstate standard |
| 2015 | Implementation of GOST R ISO 9001-2015. Significant changes in the structure and content of the standard |

It is necessary to understand that such a “free” approach to QMS must be preceded by all previous stages of development, including formalized processes, procedures, personnel training. Only in this case, the company can take advantage of freedom and have an opportunity to build its QMS according to ISO 9001: 2015.

A fundamental change in the QMS models includes the transition from a deterministic approach to company quality management to a probabilistic risk-based approach. In the context of the new version of ISO 9001, risk analysis and management activities become mandatory for organizations [6]. The organization should plan measures to address risks and opportunities, as well as measures that are adequate to possible consequences of non-compliance of products and services [9]. Risks can be reduced [10]. An assessment of risks must be based on the assessment of risk consequences and probability classes. Tables 2, 3, 4 are presented below.

An important feature is the “exit” outside the company through the implementation of section 4 of the standard (ISO 9001: 2015) which tells us that senior management should formulate a mission, a strategy, a policy, goals and objectives taking into account the external and internal environment. An analysis of the internal and external environment should be considered as a process, including identification of factors that affect intents, purposes and sustainability. It takes into account legal, technological, competitive, market, cultural, social and economic factors. When developing a mission, a strategy and goals, company values, culture and knowledge are taken into account (Fig. 1).
Table 2. Identification of a risk consequence class

| Class of consequences | Ranking | Criteria |
|-----------------------|---------|----------|
| 1, 2                  | Can be neglected | Random factors whose influence is leveled over time without special events |
| 3, 4                  | insignificant | affecting but easily eliminated |
| 5, 6                  | observable | Changes that require active intervention and resources but not causing loss of stability |
| 7, 8                  | significant | Significant (more than 30%) drop in turnover and profits, mass layoffs of employees, temporary suspension of business, the need to reprofile activities, partial loss of investments |
| 9, 10                 | crucial | Bankruptcy or closure of an enterprise |

This approach represents the company's QMS as a tool ensuring quality of its activities and managing the competitiveness which allows the company to ensure its stability and outstripping development. The QMS is a tool for solving internal problems and implementing strategic tasks. This development course enables the top management to create and formulate unique development strategies using various models, methods and means. A comprehensive analysis of all factors (counter-partners, competitors, consumers, supervisory organizations, suppliers, economic, social, political, demographic situation) affecting the activities of the company should be a condition for successful solution of strategic problems, etc. "... An effective strategy cannot be developed if managers do not understand what changes are taking place in the competitive environment and how these changes will affect future competitive advantages” [1].
Table 3. Identification of a risk probability class

| Class of probability | Ranking | Criteria               |
|----------------------|---------|------------------------|
| A    Frequent         |         | Very likely to happen  |
| B    Possible         |         | Likely to happen       |
| C    Probable         |         | Might happen           |
| D    Unlikely         |         | Unlikely to happen     |
| E    Impossible       |         | Very unlikely to happen|

Table 4. Risk class identification

| Class of consequences | 1, 2 | 3, 4 | 5, 6 | 7, 8 | 9, 10 |
|-----------------------|------|------|------|------|-------|
| Class of probability  |      |      |      |      |       |
| A    II              | II   | III  | III  | III  |       |
| B    I               | II   | II   | III  | III  |       |
| C    I               | I    | II   | II   | III  |       |
| D    I               | I    | I    | II   | II   |       |
| E    I               | I    | I    | I    | II   |       |

I – Allowable risks not requiring reduction. Such risks must be maintained at an acceptable level.
II – Moderate medium-term risks.
III – Significant risks requiring urgent management measures aimed at reducing them.

Figure 1. The components of the process of understanding the role of the corporate environment in implementing company goals

The company’s strategy and mechanisms of its development occupy a special niche, realizing the connection between expectations and their actual results. The task of aligning the strategy and a
possibility of its implementation is carried out by a management mechanism that combines a set of methods and tools for the development, adoption and implementation of management decisions based on the comparison of the vision and indicators of achievement of established goals.

3. Conclusion.
A creative approach to the QMS using widespread and new methods will allow the company to build its unique QMS, which will become a tool for effective work.

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