

THE MAIN CHANGES IN THE NEW VERSION OF THE ISO 9001 STANDARD IN COMPARISON WITH THE CURRENT VERSION OF 2008 FOR ENTERPRISE MANAGEMENT

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Abstract

Article is devoted to the detailed analysis of the ISO standard of 9001 of 2015 versions, and its comparison with the older 2008 version. A main goal of the research is to find distinctions in requirements and in basic concepts which are mentioned in the standard, and also in their practical application. The main research method is the contents analysis of the 2015 version standard and its comparison with the text of the 2008 version. Great attention is paid to reduction of risks and process approach application. Thus, all innovations are aimed to make the standard more universal and easy for application. As the standard of the ISO 9001 series is the most widespread, therefore, the release of the new version is one of the main events of 2015. This article is of great interest to managers, whose companies are going to pass certification on obtaining the certificate of the ISO 9001 series.

Introduction

Nearly thirty years passed from the moment of emergence of the initial edition of the international ISO 9000 standard establishing requirements to quality management systems (QMS) for organizations. In 2015 the fifth edition of this standard will be published. The ISO 9000 standard for the thirty-year period of existence deserved the international recognition on all continents of the world, because it can be used in any organization, irrespective of its field of activity and the size. The ISO 9001 standard is unique because it is the only standard according to which certification can be carried out. Also, the standard is very popular because it guarantees quality of production for a consumer, and serves as methodical instruction on improvement of the activity for a producer.

Today in the world the number of the enterprises certified according to the ISO 9000 standards exceeds 500 thousand. Leaders are China, Japan, countries of Western Europe, the USA. In recent years active work on introduction of quality management system at the enterprises is conducted by countries of Eastern Europe and the Commonwealth Of Independent States. The number of the certified enterprises in Russia is about 50 thousand.

The main changes in the new version of the ISO 9001 standard in comparison with the current version of 2008

ISO 9001 was changed to make it more universal and easier for application in a services sector. The concept "product" is replaced with "goods and services", that is the final result for a client.

Eight sections of ISO 9001:2008 are replaced with 10 sections (see Table 1). It doesn't mean that the revised standard adds new categories, it generally changes an order and classification of its contents by division and extension of the existing sections.

Table 1. Difference sections of ISO 9001: 2008 and ISO 9001: 2015

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative Reference	2. Normative Reference
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management Systems	4. Context of the organisation
5. Management Responsibility	5. Leadership
	6. Planning
6. Resource Management	7. Support
7. Product Realisation	8. Operation
8. Measurement, Analysis and Improvement	9. Performance Evaluation
	10. Improvement

The follow two new sections which are connected with a context of the organization were included in the new version:

- understanding of the organization and its organizational environment;
- understanding of requirements and expectations of interested parties.

The purpose of these two sections is demanding from the organization to define problems and requirements, which can have influence on planning of QMS, and also can be used as input data for QMS development.

In new version standard: terms, sections and principles were changed. The most significant change in terminology concerns the application of the term "production". In former versions of the standard this term united material goods and non-material service. In the new version it was decided to apply the terms "product" (goods) and "service" instead of the term "production". Usually the product (goods) is considered something tangible and countable. And work, product delivery of a product, training, communication services, etc. are considered as services.

I was decided to unite two former terms "documentation" and "records" in one general term "documentary information".

Another important innovation is introduction of the concept "organizational environment" in ISO 9001:2015. By organizational environment it is understood the surrounding business environment including set of internal and external factors. In particular, the organizational environment is used for the and an risks analysis and assessment, for strategic planning. The most significant component of the organizational environment is interested party; i.e. physical or legal entity which interests are connected with the organization. The understanding of the organizational environment allows to specify all requirements to quality management system and also to define exactly application field for the quality management system. If there are some exceptions of requirements of the standard, then they should be reasonably proved.

The term "corrective action" and corresponding section were deleted. From the previous editions of the standard it wasn't clear, why and how organization should define and implement the preventive actions. But it doesn't mean that now the organization shouldn't carry out preventive actions. Such actions will be realized within risk management.

The risk management has also become the requirement of the ISO 9001:2015 standard now. Now the organization is obliged to identify and operate its risks connected with the quality and consumers satisfaction. The risk is defined as a probability of approach of danger multiplied by consequences from this danger. In other words, it is how probable that the event will occur, in total with weight of consequences. Risk level has to define measures of management in system. In fact, ISO 9001 says how to operate risks to provide its functioning and development.

Changes also concerned the principles QMS. Instead of 8 principles there are principles 7 now. The principle "System approach" was excluded. The principle "Mutually beneficial relations with suppliers" was expanded to the principle "Management of relationship with interested parties" (see Table 2).

Table 2. Differences in principles QMS ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
1.Customer focus	1.Customer focus
2. The role of leadership	2.Leadership
3. Engagement of people	3. Engagement of people
4. Process approach	4. Process approach
5. System approach to management	5. Improvement
6. Continual improvement	
7. Evidence-based decision making	6. Evidence-based decision making
8. Mutually beneficial	7. Relationship management

relationships with suppliers	
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The new fifth section is devoted to "Leadership". The concept "Representative of a Quality Management" which allowed the top management to delegate works on quality to the employees has disappeared. Now all top management has to be committed to quality management system. Leadership of the management consists of making decisions, based on fact and indicators, providing implementation and functioning of QMS strategy creation them and implementation, including policy and purposes of quality, and also bringing them to the personnel.

Satisfaction of the consumer was reformulated once again to emphasize the importance of understanding of the client needs including consumer's responses, the client's views of the organization and also perception of its goods and services.

Requirements to nonconformity were expanded. The version 2015 of the standard underlines that when there is a discrepancy; the organization has to react to nonconformity. The 2015 standard demands "to make changes in QMS, if necessary".

The key change in the new version of the ISO 9001:2015 standard is a replacement of preventive actions by risk management. Instead of ISO 9001:2008 which is considered as the standard of quality management, ISO 9001:2015 positioned as the standard for systems of business management is established. The organization can use the new standard as the business management tool to increase the value, improvement the work of organization and decrease its risks.

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