

New approaches to creating quality management systems

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Abstract- The article describes the peculiarities of the new version of the international standard for quality management systems ISO 9001:2015 Quality Management Systems. The requirements were published by the International Organization for Standardization (ISO) in September 2015. It replaces the currently active version of standards for quality management systems ISO 9001:2008 (the Russian analog of GOST ISO 9001-2011). In the new version the approaches to creating quality management systems for businesses and organizations, the structure and content of the standard, are substantially changed, due to which its connection with other standards for management systems is achieved, which improves the compatibility of various management systems' standards and makes it easier for organizations to implement the integrated management systems. The standard ISO 9001:2015 introduces a new concept "Organization environment" (organization context) – conditions in which an organization is functioning, risk-based approach, which requires, that an organization not only understood the conditions, in which it is functioning, but identified the risks, which should be taken into account. In this standard the basic quality management principles have been altered, the concept of "documented information" has been introduced, which changes the approaches to creation and records administration of a quality management system. These and other changes, included into the new standard, give reason to consider it as a standard for business management system. Among the processes of management system the leading role is assigned to business processes, and the standard ISO 9001 can be used as a tool of business administration, when each employee of the organization should know how the organization gains profit, and his part in the organization's success. Such a business-oriented approach is going to meet the requirements of consumers and bring the steady income to the organization.

Keywords: Quality management system; organization context; risk-based approach; products and services; documented information; quality management principles; business management system; business processes.

Introduction

The International Organization for Standardization ISO [1], since 1946 has been developing technical standards in virtually all spheres of business, branches of industry and technologies. The Technical Committee of ISO TK 176 "Quality management and quality assurance" since 1987 has been developing standards in the sphere of quality management, which have been named "ISO standards of 9000 series".

The fundamental difference of standards of these series from technical standards is that they set requirements not to the product quality in the first place, but to quality management systems (QMS). They are universal and can be applied to any organization, independently of number of employees, property category, occupied markets, type of the manufactured products or rendered services. Besides, the ISO standards of 9000 series can be applied to state administrative bodies and their departments, as well as to social organizations [2]. These standards are at the same time the guarantee of product's quality for a consumer, and methodological recommendations for companies, manufacturing products and services, in terms of improving their activities.

The first version of these standards was introduced in October 1987 and included three main models of quality assurance:

– ISO 9001:87 Model for quality assurance at designing and/or elaboration, production, installation and maintenance;

– ISO 9001:87 Model for quality assurance at production, installation and maintenance;

– ISO 9001:87 Model for quality assurance at the finished product control and testing, and the glossary of quality assurance terms ISO 8402:86.

The next version of the international standard ISO of 9000 series was issued in 1994. The version of 1994 was more extensive, it included 24 documents, but most of them were of advisory nature. The main task of the developers of this version was to create a set of requirements, which would allow identifying if a provider organization can make their products meet the consumers' requirements, so it was oriented to satisfying only one of the parties concerned – the client of an organization.

In December 2000 the standards ISO 9001:94 were officially replaced by a new, the third in the row,

and radically renovated version of ISO 9001:2000. The main difference of this version of standards from those which were in action before was in their orientation not to managing the products' quality, but to managing the process of their manufacturing (process approach). Instead of a large number of advisory standards only some of them were left, the most important of which were:

- ISO 9000:2000 Quality management systems. Main provisions and glossary;
- ISO 9001:2000 Quality management systems. Requirements;
- ISO 9004:2000 Quality management systems. Recommendations for the activity improvement.

The standards of this version implied the full compatibility with the standards of other systems, including ISO 14001 and OHSAS 18001. In November 2008 the new official version of ISO standards of 9000 series - ISO 9001:2008 was published, and in 2010 the standard ISO 9004:2010 was published. These standards are in action to date; in Russia their analogs GOST ISO 9001-2011 and GOST R ISO 9004-2010 "Management for achieving the stable success of an organization. Approach based on quality management" [3] are used.

Using the ISO standards of 9000 series in the practical activity of an organization makes it possible to move to a higher level of organizing business, to increase its efficiency by improving the quality of the manufactured products or rendered services. In the modern business world it is the quickest way to make the activity of an organization successful.

Any organization, whatever activity it is engaged in, must have its own management system, which is a complex of organizational structure, authority and responsibility, activity processes, of labour, material and financial resources etc. All these components are united and cooperate within the framework of a quality management system in order to achieve the goals of the organization [4]. So, the management system, based on the requirements and recommendations of the latest version of ISO international standards of 9000 series, is the way of achieving goals, which are stated by a company's administration.

Methodology

This article is a review and is based on comparative analysis of ISO international standards of 9000 series of 2008 and 2015 versions. It describes the distinctive features of 2015 version standards, their goals and approaches, their advantages and disadvantages from the point of view of a Russian consumer.

Research

In September 2015 the International Organization for Standardization ISO published the new version of standard for quality management systems – ISO 9001:2015 Quality management systems. Requirements [5].

The necessity of developing and implementing it, instead of the currently active standard of quality systems ISO 9001:2008 (the Russian analog is GOST ISO 9001-2011) [6], is caused by the intention to improve the connection between standards for management systems, in order to improve the compatibility of various standards for managing systems and to make it easier for organizations to implement the integrated managing systems.

The new version ISO 9001:2015 has been developed in accordance with the appendix to the Directive ISO Annex SL (ISO/IEC Directives Part 1 Consolidated ISO Supplement – Procedure specific to ISO), which provides the necessary compatibility with other standards of management systems.

Organization environment

The implementation of this concept in the new version of standard ISO 9001 has required substantive changes in the structure of the standard: instead of 5 sections in the ISO 9001:2008, the new version consists of 10 sections. The standard includes a new section 4 "Organization environment" (organization context) - conditions in which an organization is functioning. This section requires that an organization identified the demands, which can influence the planning of the quality management system. This means the understanding of an organization and its context and understanding the expectations and demands of the parties concerned. It is necessary for providing the connection with standards of other managing systems. But it doesn't imply that the requirements to a quality system expand beyond its sphere of use. In this version of the international standard there are no requirements that an organization took into account other concerned parties, apart from those which have something to do with its management system. At the same time an organization may determine the additional demands and expectations, which can help to achieve the set goals in the sphere of quality, and decide it at its discretion to apply or not to apply these additional demands.

Products and services

Unlike standard ISO 9001:2008, which uses the term "products", in this version of the international standard a term "products and services" is used. Introducing the term "services" is dictated by the need to emphasize the difference between products and services, as a distinctive feature of services is that the obtained results are normally achieved at the direct interaction with the consumer. Besides, the "outcomes" of many processes include both products and services, and it should be taken into account, as the material products are often accompanied by non-material services and visa versa.

Risk-based approach

Another new feature in standard ISO 9001:2015 is the risk-based approach. The standard requires that an organization not only understood the conditions, in which it is functioning, but identified the risks, which should be taken into account. It's known that one of the key goals of an organization's quality management system is the preventive actions, aimed at

the prevention of defective product output and its getting to the consumers. In the new version of the standard there is no such separate subsection as "preventive actions". The concept of preventive actions is expressed through the risk-based approach at the determining of requirements to quality management system. At the same time this approach contributes to making the requirements less directive and more oriented to the actual practice. In spite of the fact that in the quality management system risks should be identified and studied, there is no direct requirement in the standard about managing risks or about compulsory document procedure of risk management. This remains at the discretion of the quality management systems developers. Such risk-based approach should be applied in the same way to all types of external supplies, regarding the certain external suppliers and externally supplied products and services.

Documented information

To implement the connection with standards of other management systems, the section "Documented information" was included into the new version of the standard and the text of the standard was drawn up with account of this term, having replaced the terms "document procedure" and "quality record", used in standard ISO 9001:2008. But the new standard has no requirement, that the structure of the quality management system's documentation should be a precise reflection of this new international standard. It's not required that the terms, used by an organization, must be replaced with terms, contained in the new international standard. An organization may choose and use terms, which are more fit for its activity, for example, use the terms "record", "documentation", "protocols" etc., instead of "documented information" which is used in the standard.

In the new version of the standard there are no such concepts as "compulsory document procedures" (there were 6 of them), "compulsory quality records" (there were 19 of them), no obligation to develop such a fundamental document of quality system as the "Quality manual". They may be developed at the discretion of those, who creates the organization's quality management system. As any quality system can't function without these documents, it would be more reasonable to leave them in the category of compulsory ones. Though it is explained in the new version of the standard that the alterations in structure, terminology and status don't need to be reflected in the documentation of an organization's quality management system, and the naming and number of sections is for a coordinated, logically constructed presentment of requirements and not for documenting the policy, goals and processes of an organization. This provides the wide opportunities for quality systems' developers, so that each quality management system for a certain organization could be unique. On this ground we can conclude, that there will be no large "stress" at the designing and implementation of the new standard for organizations, having compliance certificates for quality management systems.

Quality management principles

The changes have also affected the basic quality management principles; instead of 8 principles only 7 were left. The principle "System approach" was excluded, the principle "Mutually beneficial relations with suppliers" has acquired the wider meaning and is now called "Managing interactions with the parties concerned", and the principle "Role of the top management" has been transformed into "Leadership". It is formulated in the following way: "The top management of an organization should demonstrate leadership and obligations concerning the quality management system". This means that the top management should accept responsibility for the productivity of quality management system, for its efficient functioning. In this regard the requirement, contained in the standard ISO 9001:2008, to appoint a quality management representative is cancelled, as the principle "Leadership" doesn't allow the top management to shift the responsibility for the maintenance of QMS in working order on the subordinates. It's hardly reasonable for the economy of Russia, as it would be better if managing all the processes of quality management system, its effective functioning and improving would be carried out by an executive official, vested with the necessary authority, in the rank of a deputy chief executive in quality management, how it was stated in the previous version of this standard; the chief executive carries out the periodic analysis in its turn, being thereby responsible for the effective functioning of the quality management system in general.

External suppliers

In the new version of the standard the section, concerning the raw materials and complementary parts procurements, has been substantially changed.

The previous name of this section "Procurements" has been replaced with "Managing the external supplies of products and services". Now the standard requires that an organization determined and used criteria for evaluating and choosing an external supplier, monitoring its activity and evaluating its ability to supply products and services in accordance with the set requirements; at this, the documentation about the evaluation results should be recorded and stored.

An organization should determine the degree of potential influence of externally supplied processes, products and services on the ability to permanently meet the consumers' requirements, legal and normative regulations. Organization should inform the suppliers about the requirements which they should satisfy and provide their validity.

Business management system and business processes

The fundamental distinction of ISO 9001:2008 and ISO 9001:2015 versions of standard is that the first one is considered as a standard of quality management, and ISO 9001:2015 is going to hold oneself out as a standard for business management systems [7]. So, organizations can't consider ISO 9001 as: a means for

controlling documents and records, product discrepancies, internal auditing, preventive and corrective actions. Organizations, which want to be involved into the modern world market, should consider it as business management system.

Among all the processes of quality management system the main role in the new version of the standard is assigned to business processes. The standard ISO 9001:2015 must become a strategic and integral part of the general business plan of an organization. Using ISO 9001:2015 as a tool of managing business means that each employee of an organization should know how the organization gains profit, about the organizational processes flows and their meaning, about the role of each process or employee in the organization's success. Orientation to process approach and using the methods of determining and controlling risks of each process will ensure that the demands of consumers will be understood and satisfied in to the required extent. So, this business-oriented approach, provided in the new version of the international standard ISO 9001:2015 is going to meet the requirements of consumers and bring the steady income to the organization.

Supporting standards

A distinctive feature of the new version of the standard ISO 9001:2015 is the informative annex C, which gives a review of ISO quality management standards of 10000 series, which should be used in conjunction with this standard, as they are connected with corresponding sections of it. There are 15 such standards. The most relevant and essential of them are:

- ISO 10004 Guidelines in monitoring and evaluating the consumers' level of satisfaction [8], which includes recommendations for identifying opportunities to improve processes and features, which are valuable for consumers;
- ISO/TR 10013 Guidelines in documentation of a quality management system [9], which is an instruction of developing and using documentation, necessary for a quality management system;
- ISO/TR 10017 Guidelines in statistical methods [10], which contain the description of statistical methods, based on the concept of variability, which is observed in the behavior and results of processes [11].

The other standards of this series are intended for quality planning, configuration management, information exchange, processes measuring, acquisition of financial and economic benefits, personnel training, their involvement into the quality activities, selecting consultants, managing quality in projects, which improves the efficiency of using the standard ISO 9001:2015, asserted as a standard for business management system.

Conclusion

The comparative analysis of the previous and the new version of ISO 9001 standards allows us to state, that the version of 2015 provides wider opportunities for businesses and organizations, at which

the quality management system is implemented and functioning. ISO 9001:2015 is considered as something more, than a standard of a quality management system (QMS). Its structure and the statement of requirements allow considering it as a business management system standard, as the main attention here is focused on such factors as the leadership of the head of an organization, planning, maintenance and operation, efficiency evaluation and improvement. Among all the processes of an organization the business processes are distinguished, to the efficient functioning of which the efforts of all the organization's staff under the leadership of the chief executive should be fostered. They add external and internal values throughout the whole process of manufacturing product – from receiving the consumer's requirements to the final delivery. Business processes and the risk-based approach at their implementation are the foundation of the successful organization and existing of the business.

Inferences

The comparative analysis of the existing and the new version of ISO 9001 standards allow us arriving to the following conclusions:

- the standard ISO 9001-2015 is more relevant for the present-day development level of world market relations, as it allows creating business managing systems in the organizations, unlike ISO 9001:2008, which is oriented to quality management systems;
- carrying out preventive actions through the risk-based approach at determining requirements to the business management systems increases the degree of reliability and the efficiency of the organization's business processes;
- the new standard allows improving the linkage with other standards of management systems and makes it easier for organizations to implement the integrated management systems;
- the wide opportunities for quality systems' developers, provided by this standard, and the democratic nature of its requirements allow making a conclusion that there will be no large "stress" at implementing the new standard for organizations, having certificates for quality management systems ISO 9001:2008 (GOST ISO 9001-2011);
- at implementing this standard in the Russian organizations it is reasonable to keep the terms, used in the actual practice of quality systems implementation by the standard ISO 9001:2008, and to keep the obligatory nature of certain document procedures, quality records, and particularly, the Quality manual of a QMS.

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