

CONTRIBUTION OF NEW STANDARD ISO 9001:2015 TO THE QUALITY

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DOI: 10.7906/indecs.22.5.6
Brief report

Received: 24 June 2024.
Accepted: 14 October 2024.

ABSTRACT

ISO 9001:2015 is an international standard which defines the minimum requirements for the quality management system. It is part of an overall family of Standards known as ISO 9000ff. ISO 9001 standard is applicable to any type of business and companies of all sizes and can help organisations to provide consistent products and services leading to customer satisfaction, regulatory compliance and continual improvement. It is the most popular, best-selling and best-known standard in the world and the only standard in the ISO 9000 family to which organizations can certify. Since the first edition in 1987, there have been several revisions of ISO 9001 standard, and the last revision was made in 2015. The valid version of ISO 9001 standard was released in September 2015 and changes made in requirements of ISO 9001:2015 are much more significant than those made in the 2008 revision. The main changes are in structure of ISO 9001:2015, where the number of chapters increased from 8 to 10 and in completely new requirements which include context of organization, risk management, knowledge as resource and leadership. There were great expectations from these changes, and the paper explain whether these changes achieved the expected results on quality.

KEY WORDS

quality, ISO 9001:2015, quality management system, risk

CLASSIFICATION

JEL: L15

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INTRODUCTION

Global market changes, new production technologies, new requirements of global manufacturing companies and suppliers, increasing customer requirements and other interested parties, limitations of target markets, condition such management of business systems, in which management must find efficient and quick solutions. Only quality management systems that continuously improve operations lead to a better position on the global market and increase of customer satisfaction.

The goal of every organization is very clear: to live and succeed. This means producing what the market wants, with a certain level of quality, an acceptable price and delivery times, continuously increasing the satisfaction of customers and other interested parties. Quality, according to many in the world, is considered the most significant phenomenon of our time with a permanent trend of increasing importance. The question is how to achieve this and is it ISO 9001 standard the solution?

The history of the ISO 9001 quality management system begins in the 1950s when the US and UK governments introduced standards for military procurement. Large organizations supplying services and products to government agencies often had to adhere to certain quality assurance requirements for each contract awarded, which caused the defence industry to adopt mutual respect for NATO AQAP, MIL-Q and Def Stan standards.

The first edition of the ISO 9001 standard was published in 1984. by the International Organization for Standardization (ISO), an independent nongovernment body that develops standards to ensure the quality and safety of products and systems. This was followed by revisions from 1994, 2000 and 2008. The valid version of ISO 9001 standard was released in September 2015 and changes in requirements made in ISO 9001:2015 are much more significant than those made in the 2008 revision [1]. The main changes in ISO 9001:2015 include the completely new requirement ‘context’ of the organization, risk management, there is no longer a requirement for preventive actions, the concept of interested parties is introduced, and increased leadership requirements.

KEY CHANGES IN REQUIREMENTS OF ISO 9001:2015 COMPARED TO ISO 9001:2008

Valid revision of the ISO 9001 standard, published in September 2015. brings more significant changes compared to the previous revision from 2008, namely: organizational context, risk-based thinking, knowledge as a resource and leadership.

The number of chapters in valid revision from 2015. has been increased from 8 to 10 chapters [1], and this chapters are harmonized with “Annex SL”, which sets a template for chapters of all other standards which can be integrated into the one integrated management system like ISO 9001, ISO 14001, ISO 45001, ...

Table 1. Comparison of standard ISO 9001:2008 and ISO 9001:2015 chapters.

Chapter Number	ISO 9001:2008	ISO 9001:2015
1	Scope	Scope
2	Normative Reference	Normative References
3	Terms and Definitions	Terms and Definitions
4	General Requirements	Context of the Organization
5	Management Responsibility	Leadership
6	Resources	Planning
7	Production	Support
8	Measurement, Analysis and Improvement	Operation
9	-	Performance Evaluation
10	-	Improvement

The “context” of the organization (it can also be mentioned as business environment) refers to the combination of internal and external issues that can be effect on organization’s approach to its production and services. As a result, implementation of an organization’s QMS will be influenced by its context. This is a completely new requirement and did not exist in ISO 9001:2008 and it is very problematic for the auditors to check conformity of this requirement during the audit [2].

The organization must identify those external and internal issues (positive and negative) that are relevant to its “context” and that can affect the ability to achieve the desired outcome of the quality management system. In the ISO 9001:2015 standard, there is no obligatory requirement that these internal and external issues have to be documented by the organization, which makes it difficult for auditors to check the implementation of this requirement during the audit; organizations should consider these, but they do not have to document it and analyse the effectiveness of the organization’s response to this issues.

However, in many cases this information can be check during audit from several sources. It can be part of the organization’s business plan or business strategy, for example, or it can be stated on the organization’s website, in its annual reports, or it can be one part of the Management’s assessment. However, there is a possibility that such documented information is not available because the standard does not require for it as such, so auditors in that situation need to interview senior management in relation to the organization’s context. Since the organization has to consider its ‘strategic direction’ when identifying internal and external issues, it is likely that discussion of these elements of an organization’s context will have to involve senior management.

Depending on the organizational chart of the organization, its Quality Manager (which is not an obligatory requirement in the new version of ISO 9001:2015), for example, may not have sufficient knowledge of the context of the organization and may not be able to provide the information necessary for auditors to check compliance with the requirements of this point of the standard. From the past experience of the author of this paper as auditor, in the majority of cases, organizations have kept the quality manual, which is no longer a mandatory document regarding to ISO 9001:2015 standard, harmonized it with the points of the new standard ISO 9001:2015 and described their “context” of the organization and interested parties under point 4.

In particular, this problem applies to production organizations because their Quality Manager or even the top management sometimes do not have to know the issues of the production process itself, so it is accordingly much more difficult to determine the context of the organization resulting from the product that is delivered to customers. Accordingly, how can organizations prove that they consider external and internal issues when they do not have to conduct analysis or documented information about this consideration. Therefore, the authors of this paper consider that, for the stated reason, this requirement should be better defined in some new version of ISO 9001 standard.

Another new requirement in ISO 9001:2015 standard is incorporation of “Risk management” concept in requirements for the implementation, maintenance and continual improvement of the quality management system.

In ISO 9000:2015, “Quality management systems - Fundamentals and vocabulary”, risk is defined as the “effect of uncertainty”. The note in the definition also describe risk as a “deviation from the expected”, whether positive or negative. The term “uncertainty” is explained as the lack of information about a possible event that can be expressed in terms of consequences and the probability that the event will occur. Likewise, ISO 9000:2015 states that risk is associated with a potential event and is usually expressed as a weighting of the probability and consequences of such an event [2].

Considering the description of the requirements of the standard related to risks and opportunities and the absence of any direct requirements for documenting risks, except for the assessment of actions related to risks and opportunities as an input requirement of the management assessment, as well as the obligation to use some of the recognized methods for risk assessment such as is, for example, the Failure Mode and Effect Analysis (FMEA) method, it would be desirable for some new revisions of the standard to consider a more detailed definition of risk requirements, especially since organizations have a varied approach to implementation regarding this requirement. From the experience of the authors of this paper, organizations mostly assess risks using a recognized method for risk assessment and keep documented information about this assessment in a way that they make an FMEA analysis for all steps in the flow diagram of the process and for defined risks in the same document they also define action plans for identified risks.

The IATF 16949:2016 standard (Automotive QMS Standard issued by International Automotive Task Force) defines the risk requirements much better than ISO 9001:2015. Therefore, it is recommended that IATF 16949:2016, which is a requirement for production organizations in the automotive industry, be considered as a guideline for expanding and clarifying the application of ISO 9001:2015 in a wide range of organizations, especially in the area of risk assessment.

CONCLUSION

Standards of the ISO 9000ff series have played a very important role in the perception of quality and quality management in the last forty years. Although originally European, the ISO 9001 standard is now accepted worldwide and ISO 9001 is becoming a worldwide movement. This generally accepted standard should satisfy the needs and requirements of companies of various activities, which is not always easy due to the specific nature of the activity.

ISO 9001:2015 increased the number of chapters from 8 to 10 and definitely much more better define the specific requirements of standard which ISO 9001:2008 left unclear [1], but it would be desirable that in some new revisions of the standard, a more detailed definition of risk requirements should be considered, especially because organizations have a varied approach to this requirement in implementation due to the absence of any direct requirements for documenting risks, as well as the obligation to use one of the recognized methods. for risk assessment.

Likewise, it would be desirable to define a time period for the conduction of internal audits and Management review, which was missed in the ISO 9001:2015 edition [3].

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