



# NEW STANDARD ISO 9001:2015 AND ITS EFFECT ON ORGANISATIONS

Srđan Medić\*, Biljana Karlović and Zrinko Cindrić

Karlovac University of Applied Sciences  
Karlovac, Croatia

DOI: 10.7906/indecs.14.2.8  
Regular article

*Received:* 2 January 2016.  
*Accepted:* 6 March 2016.

## ABSTRACT

ISO 9001 is the international standard which specifies requirements for quality management systems (QMS). Organisations implement requirements of the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements. It is the most popular standard of the ISO 9000 series and the only standard in the series to which organisations can certify.

The new version of ISO 9001 was released in September 2015 and changes made in ISO 9001:2015 are more significant than those produced during the 2008 revision. On first view are clearly seen changes in structure of ISO 9001:2015, where the number of sections expanded from 8 to 10 but this paper explain the main changes in understanding quality which include context of organisation, risk based thinking, knowledge as resource and leadership.

## KEY WORDS

quality management system, context of organisation, risk based thinking, leadership, ISO 9001:2015

## CLASSIFICATION

JEL: L15

\*Corresponding author, *η*: [smedic@vuka.hr](mailto:smedic@vuka.hr); +385 41 843 525 / 120;  
Karlovac University of Applied Sciences, I. Meštrovića 10, HR – 47 000 Karlovac, Croatia

## INTRODUCTION

ISO 9001 was first published in 1987 by the International Organisation for Standardization (ISO), an international agency composed of the national standards bodies of more than 160 countries. The current version of ISO 9001:2015 was released in September 2015 [1].

Changes introduced in the 2015 revision are intended to ensure that ISO 9001 continues to adapt to the changing environments in which organisations operate. Some of the key updates in ISO 9001:2015 include the ‘context’ of the organisation, restructuring some of the information, an emphasis on risk-based thinking to enhance the application of the process approach, improved applicability for services, and increased leadership requirements, Table 1.

Changes in structure of ISO 9001:2015, expanding the number of sections from 8 to 10 with additions for performance management and evaluation which is said to help with future closer alignments among different standards through a new so called “Annex SL’ model” which provides a framework for drafting standards which can be applied concurrently (integrated management systems or multiple management systems) such as such as ISO 9001, ISO 14001, ISO 27001, or ISO 22301 [2].

**Table 1.** Comparison of sections in two versions of ISO 9001.

Section	Current Standard Sections	Proposed Standard Sections
Section 1:	Scope	Scope
Section 2:	Normative Reference	Normative References
Section 3:	Terms and Definitions	Terms and Definitions
Section 4:	General Requirements	Context of the Organisation
Section 5:	Management Responsibility	Leadership
Section 6:	Resource Management	Planning
Section 7:	Product Realization	Support
Section 8:	Measurement, Analysis and Improvement	Operation
Section 9:	–	Performance Evaluation
Section 10:	–	Improvement

## CONTEXT OF THE ORGANISATION

The “context” of the organisation (sometimes called its business or organisational environment) refers to the combination of internal and external factors that can be effect on organisation’s approach to its products, services and investments. As a result, implementation of an organisation’s QMS will be influenced by its context.

An organisation’s context can include, for example [6]:

- the specific objectives of the organisation,
- the needs and expectations of its customers and any other relevant ‘interested parties’ like state, regulatory agencies,
- the products and services,
- the complexity of both the processes that the organisation uses and the way in which they interact,
- size and organisational structure of the organisation.

This is not a completely new concept for Quality Management Systems, because Introduction of ISO 9001: 2008 (in section 0.1 General) can be found that the design and implementation of an organisation's Quality management system is influenced by [7]:

- i) its organisational environment, changes in that environment, and the risks associated with that environment,
- ii) its varying needs,
- iii) its particular objectives,
- iv) the products it provides,
- v) the processes it employs,
- vi) its size and organisational structure.

An organisation has to identify those external and internal factors (both positive and negative) which are relevant to its 'context' and that can affect its ability to achieve the intended outcome(s) of its management system.

The organisation must also continue to monitor and review those issues to establish whether any changes to them will affect its QMS, or its purpose.

Although many organisations will already be monitoring internal and external issues, this is a new requirement with which all clients will now need to comply.

There is no specific requirement that these internal and external issues, or their monitoring and review, have to be documented by an organisation, so auditors cannot simply ask for a list of issues or records of reviews.

However, in many cases this information could be available from several different sources. It may form part of an organisation's documented business plan or business strategy, for example, or be referenced on the organisation's website, in its annual reports, or can be one section in the Management Review.

However, there may be occasions where no such documentation is available. In such circumstances auditors cannot raise a finding unless they have clear evidence that an organisation has not identified particular internal or external issues that are relevant to its 'context'.

It may be that during an audit other QMS compliance problems are identified which are actually caused by the organisation's failure to identify such internal/external issues; in such a case the finding could be raised against clause 4.1 even though the actual problem was found, for example, in relation to the customer requirements for products and services.

It could be that auditors will be unable to reach a decision as to whether an organisation has identified those external and internal issues that are relevant to its 'context' until the end of the audit when they have reviewed all the other elements of the organisation's QMS. Only then, will they be able to identify whether there are any internal or external issues that the organisation has not identified.

Given the nature of the requirements relating to the 'context' of an organisation and the absence of any direct requirement for internal and external issues to be documented, there is likely to be occasions when a change in audit approach is required. Auditors approved for the organisations appropriate Technical Area will have knowledge of the general internal and external issues usually relevant to organisations operating in that business sector, but not necessarily any issues which are specific to the organisation.

Because of this reason, auditors may need to allow time before that audit to investigate their understanding of an organisation's own context; this may be through the organisation's website, or those of other which interact with the organisation. This is, in part, because the auditors must be in a position to challenge an organisation if they believe the organisation's has not satisfactorily considered all relevant internal and external issues.

Auditors are also now more likely to need to interview senior management in relation to the organisation's context. Since the organisation has to consider its 'strategic direction' when identifying internal and external issues, it is likely that discussion of these elements of an organisation's context will have to involve senior management.

Depending on an organisation's management structure, its Quality Manager (who is not obligatory in new version ISO 9001:2015), for example, may not have sufficient knowledge of the issues relevant to the organisation's context and be unable to provide the information necessary for the auditors to verify compliance with the requirements of this clause.

## **RISK BASED THINKING**

ISO 9001:2015 incorporates term "Risk-based Thinking" in its requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. This additional requirement in new version of standard is logical requirement in a way of achieve preventive management system.

In ISO 9000:2015, "Quality management systems – Fundamentals and vocabulary," risk is defined as the "effect of uncertainty." Notes in the definition further describe risk as a "deviation from the expected," either positive or negative. The term "uncertainty" is clarified as a lack of information or knowledge about an event that can be expressed in terms of consequences the likelihood of occurrence. Finally, ISO 9000:2015 states that risk is related to potential events, and that it's typically expressed as a result of the likelihood and consequence of such an event [3].

Let us consider risk as it is defined in ISO 14001:2015, "Environmental management systems," and in ISO 31000, "Risk management – Principles and guidelines." The definition of risk in ISO 14001:2015 is identical to ISO 9000:2015, even though it includes only four of the six notes from ISO 9000 [4]. However, the definition of risk in ISO 31000 is a little more specific than ISO 9001 and ISO 14001, and is defined as an "effect of uncertainty on objectives."

This is a good time to emphasize a few notions about risk. Risk in ISO 9001:2015 and ISO 14001:2015 is general, that is, it is a concept that can be applied anywhere in an organisation, including planning (Clause 6.0), i.e., the setting of objectives as it is defined in ISO 31000. Risk can be described as a potential event that can be expressed in terms of consequence, impact, or severity of the impact and its related likelihood of occurrence.

Risk appears in the normative parts of ISO 9001 eight times, and risk-based thinking appears once. Risk and risk-based thinking appear many times more when we study the informative portions of the standard, e.g., the introductory sections and the appendix.

Planning actions to address risks and opportunities can include: avoiding risk, eliminating the risk source, changing the likelihood or consequences (likelihood and impact), sharing the risk, retaining risk by informed decision and even taking risk in order to pursue an opportunity.

When planning actions to address risks, it is again imperative quality professionals must consider the context of their organisation. For example, the process of planning actions to mitigate a potential fault with a nuclear reactor at a power plant will be much more thorough and meticulous than planning actions to mitigate the risk of the wrong sandwiches being ordered for the staff vending machines.

Similar to this, the risk of an economic downturn in a country an organisation has little trade or links with is minor in comparison to a recession in the country it solely trades and operates. It is essential to understand your organisation and its strategic direction as this will enable you to determine and address its associated risks.

In easy way, to check the effectiveness of actions to address risk requires the organisation to ask, 'Does it work?'. There are various methods that organisation can check the effectiveness of actions to address risk, including:

- audits and internal reviews,
- KPI analysis, and
- project evaluations.

An important aspect of checking the effectiveness of actions to address risk is having the right data available to make informed decisions. By improving risk data aggregation capabilities, organisations can strengthen the capability and the status of the risk function to make judgments. This leads to gains in efficiency, reduced probability of losses, enhanced strategic decision-making and ultimately increased profitability.

Instant access to risk assessments, audit reports, customer complaints, non-conformance and document notification confirmations give management the ability to understand the organisation management system, carry out trend analysis and demonstrate control of 'culture of compliance'.

## **KNOWLEDGE LIKE A RESOURCE**

In its 2015 revision, ISO 9001 is once again adapting to its times. Knowledge has become key element and crucial resource to successful projects and business development. The new standard considers knowledge like any other resource to be managed [3]:

- identify the knowledge necessary to carry out the activity in compliance with the QMS and to achieve the defined objectives,
- knowledge must be maintained, protected and made available where necessary, and
- anticipate changes in knowledge needs and manage the risk of failing to acquire knowledge in due time.

This is very important new requirement which help organisations in maintaining organisation knowledge and help all employers to perform every day operation on better way.

## **LEADERSHIP**

ISO 9001:2015 places more emphasis on leadership and management commitment. It requires greater involvement by top managers and business leaders in controlling the quality management system [1].

On this way, ISO 9001:2015 is intended to encourage integration and harmonization with business processes and business strategies. The top management now has to take more responsibility for the effectiveness of the quality management system. In last version of ISO 9001:2008 this responsibility was addressed to Quality Manager.

Because ISO 9001:2015 pays more attention to risk management, interested parties and the context of the organisation, the quality management system also fits in better with the needs of the top management.

The quality management system is now more than ever a means for being strategically successful by addressing the needs of interested parties and by managing opportunities and threats. The 'management representative' of ISO 9001:2008 was a member of the management committee who had the responsibility and authority for steering the quality management system along the right lines. ISO 9001:2015 does not mention this aspect any more. The idea behind the change is that quality is a matter for everyone and for all levels within the organisation which is originally Japanese idea from their famous Total Quality Management.

The purpose of the standard is to take account of technological and societal changes. Information is no longer created, organised, managed, maintained, disseminated and accessed as it was 20 years ago when paper was the primary medium.

This change also allows for greater flexibility in companies' organisation. It is now possible to comply with the standard without jeopardizing managerial agility, as long as the fundamental principles are respected.

## **CONCLUSION**

ISO 9001 standard has played great and perhaps the most important role in the perception of quality and understanding of the quality assurance and quality management in the last thirty years. Despite all attacks and objectively mistakes of these standards, it should be underline the great contribution of ISO 9000 to the World order of quality.

The new issue of ISO 9001:2015 was released in September 2015 and changes introduced in the 2015 revision are intended to ensure that ISO 9001 continues to adapt to the changing environments in which organisations operate and especially include the 'context' of the organisation, restructuring some of the information, risk-based thinking to enhance the application of the process approach, improved applicability for services, and increased leadership requirements [1].

ISO 9001:2015 expanding the number of sections from 8 to 10 and definitely better define the specific requirements which ISO 9001:2008 left incomplete.

Some requirements like Management review conduction in planed intervals or conduction of internal audits in planed intervals are still not strictly defined. It is left to organisation to define the period of conduction of management review or internal audit and my opinion is that those requirements certainly should be considered in the next revision [5].

## **REFERENCES**

- [1] Cindrić, Z.: *Requirements for the Implementation of Quality Management System According to the Draft of the New standard ISO 9001:2015*. Thesis. In Croatian. Karlovac University of Applied Sciences, Karlovac, 2015,
- [2] Karlović, B.: *Implementation of Requirements of ISO 9001:2008 in a Production Organisation*. Thesis. In Croatian. Karlovac University of Applied Sciences, Karlovac, 2015,
- [3] EN ISO 9001:2015,
- [4] EN ISO 14001:2015,
- [5] Medić, S.; Runje, B.; Groš, J. and Markučić, D.: *Procedures for the implementation of ISO/TS 29001:2010 in the Croatian manufacturing companies*. Technical Journal 7(3), 306-310, 2013,
- [6] Atcheson, A.: *ISO 9001:2015 Revision Explained: 'Context of the Organisation'*. <http://quality.eqms.co.uk/ISO-9001-2015-Revision-Explained-Context-of-the-organisation>, accessed 9<sup>th</sup> January 2016,
- [7] EN ISO 9001:2008.