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# OVERVIEW OF ISO/DIS 9001:2015 CHANGES

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***Abstract.*** *The next revision of ISO 9001, the international standard specifying requirements for quality management systems is under development and currently at the Draft International Stage (DIS) with a scheduled publication date of September 15, 2015. While a new structure of the standard demonstrates the significant visual change, the standard also uses different words to explain requirements that have already existed in the current revision ISO 9001:2008. Some of the changes are based on the fact that the text related to certain concepts is part of the standard structure and definitions that have been established for every management system standard to follow. This paper highlights the major changes that are expected in ISO 9001:2015.*

***Key Words:*** *ISO/DIS 9001:201, ISO 9001:2008, Quality Management System*

## 1. INTRODUCTION

Draft International Stage (DIS) of ISO 9001:2015 the international standard for quality management systems (QMS) has been released. The scheduled date for publication of the final revision is September 15, 2015. The new structure of the standard exhibits the significant visual change and the standard has incorporated different terminology to explain the requirements that have always been stipulated in ISO 9001 standard. All ISO standards have been reviewed every five years to determine its competency and if a new revision is required to keep it up-to-date. ISO/DIS 9001:2015 provides the answer to the latest trends on the market and also is compatible with the other management systems such (i.e. ISO 14001). SO/TC 176, the committee that is responsible for ISO 9001 QMS standard, is currently reviewing the standard and preparing its final release. Industry related standards such as aerospace standard AS9100 or telecommunications standard TL9000 will probably be revised to reflect the changes in this "base standard". The new revision of ISO 9001 will follow a new, higher level “standardized” structure to make it easier to use in combination with the other management system standards. Organizations will be granted a three-year transition period after the final revision is released to transition their QMS to the new revision of the standard.

Since ISO 9001 standard incorporates the best business practices from different industries, it slowly influences the transition process from QMS to business management system. If ISO 9001 is effectively implemented it could be profound cost savings tool. Businesses and organizations grow through innovation and competition, neither of which can thrive without standards – the shared vision, understanding and vocabulary for meeting the needs of key stakeholders. Certification to ISO 9001 standard is often an expected condition of doing business and it is a common criterion for qualifying suppliers.

All ISO standards are periodically updated to maintain relevance. Regarding ISO 9001:2015 in particular, the revision will respond to the increasing diversity of users, ensuring that needs of all user groups and industry sectors are met and to allow easier integration with other management system standards. The revision will use a common structure defined for management system standards such as environmental, health and safety, energy, and emergency preparedness. During development of ISO standards the interests of all interested parties are taken into account, including companies, suppliers, users, consumers, consultants, testing facilities, governments, engineering professional societies, research organizations and many other parties.

This paper summarizes the major changes that can be expected when the final revision of ISO 9001 is finally released.

## 2. ISO/DIS 9001:2015 CHANGES

### 2.1. ISO/DIS 9001:2015 New Structure

The new ISO 9001 standard will be aligned with high-level organizational structure and this trend will be applied to all new ISO management system

standards. The following table shows some of the key differences between ISO/DIS 9001:2015 and the existing ISO 9001:2008:

Table 1. ISO 9001:2015 and ISO 9001:2008 Structure Comparison

| Structure Comparison | |
|---|---|
| **ISO/DIS 9001:2015** | **ISO 9001:2008** |
| 1. Scope | 1.Scope |
| 2. Normative References | 2. Normative References |
| 3. Terms and definitions | 3. Terms and definitions |
| 4. Context of the organization | 4. Quality Management System |
| 5. Leadership | 5. Management responsibility |
| 6. Planning | 6. Resource management |
| 7. Support | 7. Product realization |
| 8. Operation | 8. Measurement, analysis, and improvement |
| 9. Performance evaluation | |
| 10. Improvement | |

The clauses of ISO 9001:2015 have been renumbered but technically it is just the stuff that has been moved around the standard. It is the general recommendation that if the organizations want to renumber their procedures according to the new system they can go ahead and do it, but if they do not want, they can just keep them as they are.

The use of new common structure for management system standards is because their smoother integration with other management standards. The entire arrangement of the standard that includes standardized core text, structure and definitions increases from eight clauses to ten.

**2.2. Defining the Context of the Organization**

Context of the organization is one of the new concepts and differences between the ISO 9001:2008 and ISO 9001:2015. The context of the organization as described in the ISO 9001:2015 requires top management to define influences of numerous elements on the organization and its QMS like organizational culture, quality objectives and goals, flow and interaction of the processes, organizational structure, markets, potential customers, etc. The output of this context evaluation will be determination of the scope of organization's QMS. When the organization defines its context, it will outline its boundaries, where does QMS apply and where does not apply. This will be the hard part but also this is going to be the core of establishing QMS along with the identification of all interesting parties, who is going to be interested in the results of the company. The customers will be number one on the list of course, than the employees of the company, the owners, investors and many other parties as well.

**2.3. Removal of Quality Manual**

Certain requirements for quality manual from ISO 9001:2008 are included in different clauses of ISO/DIS 9001:2015. The new revision of the standard does not require the documented information of quality manual. Even though the new standard is not going to require quality manual, quality manual is going to be profoundly beneficial and the recommendation is to keep a quality manual which is not against the rules - it is just not prescribed anymore in the standard. There is no necessity to eliminate quality manual if it serves its purpose and works well. There are still requirements that need to be kept as documented information, such as the scope of the QMS, quality policy and others. While these requirements can be documented separately as documented information, it is acceptable to document them together in a quality manual if a company finds this helpful. A manual is not required to be documented for some other management standards as well. In an effort to ensure synchronization between different management system standards the requirement to have documented quality manual will no longer exist after the release of new revision of ISO 9001.

**2.4. Diminishing Requirements for Documented Procedures and Records / Introduction of Documented Information**

The requirements related to control of documents and control of records in ISO 9001:2008 are included in different clauses of ISO 9001:2015 as documented information. Since there are substantial changes related to control of documented information, the difference between a document and a record has become more difficult. Both of them are considered "documented information" but when standards refers to documents it uses the term "maintain" while when it refers to records, it uses the term "retain". Organizations that have a QMS that is in compliance with ISO 9001:2008 requirements should be compliant to ISO 9001:2015 requirements as well.

With the current standard ISO 9001:2008 there are six required documented procedures. The wording of the new draft standard does not include these requirements, but does not mean they are not needed. The new draft revision of ISO 9001:2015 uses the phrase "documented information" to indicate when a company needs to document and retain such information. Even though there is no requirement for documented procedures, there is a requirement to retain documented information as evidence.

This increased flexibility regarding the use of documentation provides more freedom to the companies regarding creating QMS that fits their needs.

### 2.5. Elimination of Management Representative

ISO/DIS 9001:2015 has shifted the role of Management Representative to the top management of the organization and the organization does not require an individual to be particularly assigned as a Management Representative. All requirements related to management representative from ISO 9001:2008 are included in the new revision of the standard with some minor improvements. The ISO/DIS 9001:2015 just does not define the term Management Representative considering that not only one person but everybody in the company and especially top management is ultimately responsible for QMS.

### 2.6. Incorporated Risk-Based Thinking / Approach

In new revision of ISO 9001 standard there is a greater emphasis on risk-based thinking as a basis for the management system

The organizations have to apply risk-based thinking, an approach that includes mechanisms for managing risks. There are many elements of risk-based thinking in the draft international standard of ISO/DIS 9001:2015 that may affect organizations as they work toward compliance to the revised standard. ISO/DIS 9001:2015 defines risk as the "*effect of uncertainty on an expected result*." An important element of the ISO/DIS 9001:2015 is the process approach, which requires an organization to "determine the processes needed for the quality management system (QMS)" and its application of those processes throughout the organization. This includes identifying:

- inputs, outputs and resources,
- sequence and interaction,
- effective operation,
- responsibilities and opportunities for improvement and
- risks and the opportunities and actions needed to address them.

ISO/DIS 9001:2015 requires that top management must "demonstrate leadership and commitment with respect to customer focus by ensuring that the risks and opportunities that can affect products, services and the ability to enhance customer satisfaction are determined and addressed" and also to "determine the risks and opportunities" that must be addressed to ensure that QMS can:

- achieve its intended results,
- prevent or reduce undesired effects and
- achieve continual improvement.

Actions taken to address risks and opportunities must be proportionate to the potential effects on conformity of goods and services and customer satisfaction. Furthermore, the organization should implement changes in a "planned and systematic manner," identifying risks and opportunities, and reviewing the potential consequences of changes. Options for addressing risk can include avoidance, eliminating the source, sharing the risk and deciding whether to take the risk.

According ISO/DIS 9001:2015, when applicable, an organization must determine and meet requirements for post-delivery activities associated with the nature and intended lifetime of the goods and services, accounting for:

- risks associated with the goods and services,
- use and lifetime,
- customer feedback and
- statutory and regulatory requirements.

ISO/DIS 9001:2015 also requires that an organization must consider the effectiveness of the actions taken to address risks and opportunities. This includes:

- determining what needs to be monitored and measured so the organization can demonstrate conformity of goods and services to requirements,
- evaluating the performance of processes,
- ensuring conformity and effectiveness of the QMS and
- evaluating customer satisfaction.

The new revision of the standard similarly requires that an organization has to "plan, establish, implement and maintain an audit program," and establish the "frequency, methods, responsibilities, planning requirements and reporting." The audit program must consider the quality objectives, importance of the processes concerned, related risks and results of previous audits.

Section A4 of Annex A describes a risk-based management approach consisting of:

- requiring the organization to understand its context consisting of internal and external issues,
- understanding that one of the key purposes of a management system is to act as a preventive tool,
- determining its risks and opportunities and
- addressing the risks and opportunities identified.

### 2.7. Applicability

In ISO 9001:2008, organizations could exclude certain requirements if they do not affect an organization's ability to provide products or services that conform to requirements. In the ISO/DIS 9001:2015, an organization can determine that a requirement from the standard does not apply if it does not affect the organization's ability related to product or service conformance to requirements. This determination has to be maintained as documented information.

### 2.8. Exclusion of Preventive Actions

The main idea behind ISO/DIS 9001:2015 is that QMS acts as a preventive tool itself resulting that the formal requirements associated with preventive

action do not exist in the current draft revision of the standard. This has been replaced with risk-based approach. Formalized preventive action process will be excluded in the official revision of ISO 9001:2015 and preventive actions have to be addressed in different ways in order to assure compliance with the new revision of the standard. Preventive actions will be established on “risk-based thinking”. The new revision of the standard integrates risk analysis and identifies opportunities for improvement as preventive tool in all aspects of QMS. Continuous improvement and preventive actions are not going to disappear or become less important or replaced by some new mandate but rather they are going to progress into a more effective and practical application of QMS.

## 3. CONCLUSION

The interest in the new ISO 9001:2015 revision is significant given that the draft has important changes comparing to the existing revision. There are some additional requirements in the new revision and those requirements are pretty important. New structure of the standard, context of the organization, removal of quality manual as mandatory requirement, introducing documented information instead of documents and records, elimination management representative, adopting risk-based thinking in all aspects of QMS, determining applicability and exclusion of preventive actions are considered the major changes in the new revision of the standard. Even though to a very large degree companies could keep what they already have as a part of documented QMS, they should start the transition process as soon as possible in order to save significant time later on since there will be given three year period to incorporate this standard. The new revision of ISO 9001 is less prescriptive and leaves to the organizations choice how they are going to run business and meet the requirements.

## REFERENCES


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