



When Recognition Matters



TRANSITION TO
ISO 9001:2015



The International Organization for Standardization (ISO) is a non-governmental organization whose role is to facilitate international coordination and the standardization of industrial standards. These standards contribute to the development, manufacturing and delivery of products and services that are more effective, safer and clearer. ISO performs systematic reviews every 3-5 years to keep these standards up-to-date. It adjusts them to changes in the environment with the aim at improving organization's ability to offer products and services that meet customer's requirements. Currently ISO is revising world's leading Quality Management System (QMS), ISO 9001.

The new version of ISO 9001:2008 will be released in September 2015. The latest draft of the standard, ISO/DIS 9001 (Draft International Standard), was moved to the final stage of the review after it received around 90% approval votes. During the ISO/FDIS 9001 (Final Draft International Standard), the subcommittee goes through the public comments given in the previous stage of the development, and incorporate those relevant to the aim of the final draft.

The Quality Management System standard has gone through some significant changes, and based on ISO/DIS 9001 some of the main ones include:

Structure based on Annex SLA

High-level structure was introduced to ISO 9001:2015. Annex SL defines this structure, which refers to creating the basis of management system standards in terms of an identical clause sequence, common text, and terminology. Annex SL was created by the ISO Technical Management Board and it serves as a way to help businesses reduce duplications in implementation, time and money, and helps them increase efficiency.

Some of the standards that have adopted the high-level structure include ISO 27001, ISO 30301, ISO 22301, and so on. It is expected that in the following years, all management systems will be based on the high-level structure.

Risk-based approach

Risk-based approach is one of the major changes in the new version of ISO 9001. The ISO/DIS 9001 has replaced the 'preventive action' concept with a set of requirements on managing risks. Some risk analysis was implicit in the old version of the standard through preventive action analysis, but the new version makes risk more explicit by incorporating it throughout the quality management system.

The risk-based approach came as a result of the incorporation of Annex SL into ISO/DIS 9001. Risk plays an important part in the new version of the standard, and it has clear clauses to determine risks and take actions. Even though the concept of 'risk' is new in ISO 9001:2015, many organizations already have an approach in place to manage risk. They have to align it with ISO 9001:2015 requirements and show that the requirements are met.

Process Approach

The process approach is more explicit in the current version of ISO 9001, and it is used to develop, implement, and improve the effectiveness of a quality management system. The ISO/DIS 9001 standard provides additional focus on process approach, and clarifies why it is essential to adopt it in each business process of the organization. The aim of the new version of ISO 9001 is to ensure that organizations manage all their processes, and also the interaction between them. Organizations can create the appropriate conditions and provide the necessary resources only if process approach is applied at each business process, making it possible to achieve the QMS goals.

Documentation flexibility

Documentation flexibility is another major change in ISO 9001:2015. While the two previous changes were brought out, documentation requirements do not have the weight that they did in ISO 9001:2008. Terms 'document' and 'record' were replaced with 'documented information'. There are no specific requirements on documented procedures, however processes should be documented to show conformance.

Better focus on stakeholders

The new version of the standard often raises the topic of the interested parties, which in this context denotes both internal and external interested parties of the organization with interests in the process of quality management. ISO/DIS 9001 requires that organizations focus not only on customer requirements, but also on the requirements of other stakeholders or interested parties (i.e. employees or suppliers) that can impact the quality management system.

These are only some of the incorporated changes in ISO/DIS 9001. There are also other relevant changes in the new version of the standard, such as in terminology and requirements. The intent behind these changes is to make the requirements more explicit, change them completely, or to add up to the current ones.



ISO 9001:2015 and all future management system standards will follow the new common structure for management system standards. More and more organizations have to manage several compliance frameworks simultaneously. To simplify the work, to avoid conflicts and to reduce duplication of documents, ISO is harmonizing the management systems to the high-level structure.

The standards' revision will help in today's quick changing market because it will enhance the organization's ability to satisfy its customers. The ISO 9001:2008 focuses more on products, while the 2015 version will also focus on the service industry since it is growing worldwide due to technological innovations. There are also other clauses which were added to the standard to provide a foundation on how to operate in the increasingly complex environments.

PECB (Professional Evaluation and Certification Board) is a certification body for persons on wide range of international standards. It offers 'Transition from ISO 9001:2008 to ISO 9001:2015' training and certification services for professionals wanting to gain a comprehensive knowledge on the difference between ISO 9001:2008 and ISO 9001:2015. The intent of this course is to help organizations in their process of transitioning to the new standard. Individuals taking this course will gain the necessary knowledge to plan and implement the transition to the new version of the standard.

ISO 9001 and Quality Management Trainings offered by PECB:

- Certified Transition Course from ISO 9001:2008 to ISO 9001:2015
- Certified ISO 9001 Lead Implementer
- Certified ISO 9001 Lead Auditor
- Certified ISO 9001 Foundation
- ISO 9001 Introduction

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