



## Transitioning quality management system (QMS) from ISO 9001:2008 to ISO 9001:2015 certification

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### Abstract

The ISO 9000 standard is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders, while meeting statutory and regulatory requirements related to the product. The standards are published by ISO, the International Organization for Standardization, and available through National standards bodies, ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which the family of standards is based ISO 9001 deals with the requirements that organization wishing to meet the standard have to fulfill. Third party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over a million organizations worldwide, are independently certified, making ISO 9001 one of the most widely used management tools in the world.

**Keywords:** ISO, QMS, transition

### Introduction

The quality paradigm, or movement, has become a considerable force throughout Europe and in the rest of the world. Although methods to improve and manage quality are numerous, it can be said that the quality paradigm, or movement, is based on two pillars: ISO 9000 and Total Quality Management. At present, more and more people, and not only from the entrepreneurial and academic environments, are familiar with or have heard of ISO 9000. In our opinion, two factors have played an important role in the widespread dissemination of this topic: the extension of the certification itself to include a wide variety of sectors, products, and services (education, social work, financial services etc.); and the intensive promotion of the ISO 9000 certification carried out by some companies as if it were a product or service quality label. One may guess that this popularization process can impact both positively as well as negatively on the future evolution of the norm.

### History of ISO

ISO became a company in 1947 in Geneva, Switzerland. A congregation of twenty-five countries created it. They brought together their concerns after issues in World War II, attempting to purchase parts and components for equipment outside their own borders. They met in the Institute of Civil Engineers in London. During this meeting, the group created a set of international standards. These mirrored the Military Specifications issued by the U.S. government.

ISO 9001 is an International Standard of Quality Management System (QMS). This Standard describes the requirements for organizations to help them promote continual improvements and achieve customer satisfaction. This Standard has been revised several times. The first version which was published in 1987 and known as ISO 9001:1987 was formulated based on the concept of quality assurance. It comprised three classifications i.e. ISO 9001:1987 as a model for organizations with the creation of new products, ISO 9002:1987 for those without the creation of new products, and ISO 9003:1987 as a model for final

inspection and testing purposes. The Standard was later developed into the second version i.e. ISO 9001:1994 and was improved based on the concept of preventive action. The third version, ISO 9001:2000, was formulated based on the concept of quality management to help organizations improve their business process. The fourth version was ISO 9001:2008 which underwent minor changes (merely to improve and make a better version of the standards) from the previous version.

These standards were to be followed by each country's industrial manufacturing industry. A worldwide standard of manufacturing made each country work to the same level. After finding success in this new regime in 1951, ISO created standards for more areas, including the incredibly popular ISO 9001 standard for quality management systems. The organization creates additional standards for multiple industries including food safety, occupational health, risk management, laboratory, environmental, and many more. Since its origins, ISO has published over 22,000 standards. They have grown from that small group of people to having 161 different standards bodies around the globe. Within these bodies are over 700 committees and subcommittees, represented by almost all nations on the globe.

### Objective of the Study

- To Study Transitioning Quality Management System in ISO9001:2008 to ISO 9001:2015.

### Research Methodology

The present paper is basis on descriptive method. The information of the study gathers from secondary sources reports, journals, magazines & websites.

### Major Provisions of the Standards

ISO 9001 Quality Management System Standard is now transforming itself into a new brand with major changes from the earlier 2008 version. This new version was published in 2015 and known as ISO 9001:2015. The changes include more clauses and use a new concept and

approach. If ISO 9001:2008 emphasizes on continual improvement and customer satisfaction, ISO 9001:2015 puts more focus on risk-based thinking. As the concept and approach added in the new version, requires organizations to identify and analyze potential risks that could arise both from inside and outside of the organizations. Thus, Building inside outside strength of organizations can formulate strategies to prevent any impact of the risks and they can be expectantly more resilient and sustainable by accommodating the risks. Other changes in the new version are the consideration of the organizational stakeholders needs, the importance of knowledge management and less emphasis on documentation. The new version of ISO 9001 has 10 clauses and a brief comparison of clauses between both versions is presented in Table 1.

**Table 1:** The comparison of clauses between two latest versions of ISO 9001.

ISO 9001:2008	ISO 9001:2015
Clause 1: Scope	Clause 1: Scope
Clause 2: Normative References	Clause 2: Normative References
Clause 3: Terms and Definitions	Clause 3: Terms and Definitions
Clause 4: Quality Management System	Clause 4: Organizational context.
Clause 5: Management Responsibility	Clause 5: Leadership
Clause 6: Resource Management	Clause 6: Planning
Clause 7: Product Realizations	Clause 7: Support
Clause 8: Measurement, Analysis and Improvements	Clause 8: Operation
	Clause 9: Performance Evaluation
	Clause 10: Improvement

**a. Gap Identification and analysis (Check):**

The main purpose of gap identification was to investigate how the current QMS complies with ISO 9001:2015 requirements.

**a. The gap identification was done through**

1. A Questionnaire
2. Observations and survey

The gap identification followed by its analysis, was aim to present the percentage of conformity and nonconformity of current QMS towards the standards.

**b. Transition designs (Plan)**

Based on previous gap analysis, there would be several opportunities for improvement for transition designs, especially to take into consideration the changes in ISO 9001:2015.

The transition design covered the usage of concept

1. SWOT to analyses the internal and external issues.
2. Stakeholders analysis
3. Risk Analysis

**c. Implementation of the Transition Designs (Do), Evaluation (Check) & Follow-up (Act).**

Process of Implementation based on do, Check & Act. The organizations need to implement the transition designs in order to validate them. After the organizations implement the transition designs, they are then able to evaluate the implementation to ensure the fulfillment of the Standard. Feedback is welcome to revise the previous designs.

**Table 2:** Use of research methods for Qualitative & Quantitative analysis

Sr. No.	Research Step	Research Methods
1	Selection of research objects	Purposive sampling. There were four organizations voluntarily involved in the research, the selection criteria were the needs for upgrading the QMS and having been certified ISO 9001:2008
2	Gap identification between current QMS and ISO 9001:2015 Requirements	Questionnaire, observation & structured interview. Gap identification was done using lists of questions, with two categorical answers i.e. confirm or not, supporting by observation to current QMS and secondary data.
3	Gap analysis	Descriptive statistics. Tabulated data and numerical analysis.
4	Proposed action plan to close the gap	Literature review. Literature search about the new requirements added to ISO 9001:2015 and their practical implications.
5	SWOT analysis, strategies and objectives formulation	Observation & interview. Using the specific concept to identify SWOT, involving the managerial level to validate the SWOT analysis and to formulate relevant strategies and objectives.
6	Stakeholders' analysis	Focus group discussion. Involving the discussion among the stakeholders' parties.
7	Risk identification	Observation & interview. Using the specific concept to identify risk, involving the operational level to registering the risks and determine the risk level.

**ISO 9001:2015 follows the new high level Structure Guidelines**

High level structure is a way to formatting ISO of management systems standards inclusive of all standards. This means that the structure, punctuation, choice of words, and basic terminology will all be consistent and match wherever possible. ISO 9001 is often seen as the fundamental management standard; many of its requirements can also be found in other ISO standards.

**Transition your ISO goal Certification from 2008 to 2015**

The three-Year transition period to move from ISO 9001:2008 to ISO 9001:2015. If your company used to be certified to ISO 9001:2001 and you are considering a transition to ISO 9001:2015, we recommended that you take a good look at your current quality management system. Is it worthwhile to build upon it, or would be better to start with an efficient, business friendly system? The expiration of your certification could be an indicator for a quality management system that is no longer actively used, probably because it didn't add value to your organization.

**1. Difference in the 2015 vs. 2008 version**

Every revision of ISO 9001 also brings along a change in terminology. ISO is trying to make the standard easier to understand while at the same time make it applicable to every business of every industry and every part of the world. The most important changes in definition revolve around products and objects. In ISO 9001:2015, the term object was introduced. It has an extremely broad definition of any sort of conceivable thing in existence. The term products have been changed to "outputs", which can refer to both products and services. In other words, a service-based business may not create a physical, tangible product to sell, but they offer a service. The term "output" can thus apply to both service-based businesses as well as companies that produce actual

products. This change should be particularly beneficial to service providers who, in the 2008 version, had to understand "service" when ISO 9001:2008 said product. Customer property: customer property, in the context of ISO 9001, used to refer to products and services provided by the customer. In ISO 9001:2015, customer property has been expanded to include also processes owned by the customer. Continual improvement: In ISO 9001:2008, continual improvement referred to improving the ability to fulfill requirements. ISO's 2015 revision has broadened the meaning of this term; it now means getting better results by enhancing performance. Risk-based thinking: Risk-based thinking is a new term introduced in the 2015 revision; it replaces preventative action known from previous ISO 9001 versions. Other terms that are no longer used within the ISO 9001:2015 requirements include product Realization, management representative, and equipment.

## **2. ISO 9001:2015 is Process-Based**

The process approach has been part of ISO 9001 since the year 2000 revision. While in the past the concept of process approach may not have been properly addressed and utilized by some companies, the latest revision of ISO 9001 places much greater emphasis on processes. The entire focus of the ISO 9001:2015 requirements is to encourage a comprehensive process approach to quality management.

## **3. ISO 9001:2015 Puts More Focus on Input and Output**

The concept of input and output is closely related to the process approach. In the context of ISO 9001:2015, "input" and "output" refer to the starting point and the results of activities. For example, a raw material, and then transform it into an output, such as a finished product. Of course, this is a very simple example, and the process of turning a raw material into a finished product will incorporate a number of smaller, interrelated processes along the way. The same concept applies to services, where physical and non-physical inputs could enter an activity (process) and in a service. The main thing to remember is that we are focusing on how that process takes the input and uses it to result in an output. This could relate to anything from graphic design to handling complaints.

## **4. Risk-Based Thinking is at the Core of ISO 9001:2015**

As we mentioned above in reviewing ISO 9001:2015 new terminology, risk-based thinking is one of the new aspects of the 2015 revision. While the term is completely new, the concept of risk-based thinking is actually only an expansion of preventive action. It's also interesting to note that the opposite of risk. Opportunity is also part of risk-based thinking.

## **5. The Context of the Organization Is Important in ISO 9001:2015**

Understanding the context of the organization refers to reviewing and understanding the internal and external environment and influences that shape a company. An alternative term for "context of the organization" could be "environment in which the company operates". ISO 9001:2015 groups this environment into internal environment, external environment and interested parties. Interested parties include customers and potential

customers, suppliers, owners, employees, third party organizations like trade unions and activists, as well as government bodies. When analyzing the context of the organization, companies determine interested parties and their requirements and expectations, their importance and their impact on the organization.

## **6. Leadership and Commitment Are Stressed in ISO 9001:2015**

ISO 9001 has always been a quality management system. Since top management has always had a leading role in the ISO 9001 quality management system, the ISO 9001 changes from 2008 to the 2015 version regarding leadership and commitment should be rather minor for those companies that have used ISO 9001 as a real tool for top management. Companies whose top management had delegated ISO 9001 to others will find that ISO 9001:2015 requires significant involvement of executive management. Top managers will put the QMS in line with the overall strategic direction of the business, and top managers will "walk the talk".

## **7. ISO 9001:2015 Can Be Better Integrated with Other ISO Standards**

Finally, ISO 9001:2015 is designed from the top to down to be more compatible with other ISO management standards. This is more than just adhering to the new High-Level Structure. It's about using ISO 9001 as a foundational platform from which other ISO systems can be implemented. Companies with an ISO 9001 QMS in place will find it easier to implement ISO 14001 or other ISO standards that are specific to their industry without duplication of efforts.

## **Conclusion**

Organizations are used to prepare the transition of their quality management system (QMS) from ISO 9001:2008 to ISO 9001:2015 before the previous certification expires. For organization that already implemented the earlier version, there were already high compliance levels of current QMS with the requirements of ISO9001:2015. Formation of effective strategy by analyzing SWOT Stakeholders Needs. Need to register the strategic and operational risk. By performing these three major transition designs, the organization is expected to be able to cover the gap and meet the new requirements in ISO9001:2015.

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