The Application of the New Version of the Quality Management System, its Impact on Enterprise Development

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Abstract

International Standards for Quality Management System are reviewed within five to ten years and pass to the new version of the year when they are officially published. The most applied and the required standard worldwide is the standard for Quality Management System ISO 9001: 2008 and from September 15, 2015 is the version 9001: 2015. This standard has many changes compared to past versions and includes some important processes such as: documentation, complete meaning of a model to implement this standard, the involvement of all staff, operational processes analyzed also on the basis of risk and continuity of processes for the maintenance and quality development that enables to its customers a quality product or service. In this study we will see how available they are and how it will affect this standard in relation to the previous version.

Introduction

Customer satisfaction is the mission and purpose of every organization (Drucker, P, 2005). Every enterprise is obliged to document and implement a quality management system ensuring that the system as it follows the development of products or services are required by certain of one or more international standards. Medium and large enterprises focus on the maintenance and their development (Raimi, N.2008). What it is in fact the quality management? We can see this officially from iso.org ISO9001, Quality Management System/Quality Management System (iso.org), related to "quality management", it means that an organization that implements it guarantees that complements, reinforces the seven principles (iso.org) and Quality Management system, such as: Customer focus, Leadership, Engagement of people, Process approach, Improvement, Evidence-based Decision Making., Relationship management (iso.org).

Table 1: changing from the old version to the new version

ISO 9000:2005/ISO 9001:2008	Proposed ISO 9001:2015
1. Customer Focus	1. Customer Focus
2. Leadership	2. Leadership
3. Involvement of People	3. Engagement of People
4. Process Approach	4. Process Approach
5. System Approach to Management	5. Improvement
6. Continual Improvement	6. Evidence-based Decision Making
7. Factual Approach to Decision Making	7. Relationship Management
8. Mutually Beneficial Supplier Relationships	

SOURCE: Fonceta, L. Researchgate-International Journal for Quality Research, March 2016.

Quality Management

Human perception is incorrect. Although people have the ability to understand the characteristics of the subjects in detail definition is often impossible to carry out only through our senses (Arsovski M, Shehabi E. 2013).
In many respects updating and improvements in the standard is always necessary, so as mentioned above international standards for Quality Management System reviewed within five to ten years and spend the new year's version when he published officially.

"Management system" refers to what the organization does to manage the process or its activities, so that the products or services it produces meet the objectives that the organization has set itself, ISO 9001: 2015 (the most recent version of standard) is composed of a number of different sections, each focusing on the requirements involved in various aspects of the quality management system (iso.org).

- Clause 1.2 and 3 – Background and purpose of the standard
- Clause 4 – The context of the organization
- Clause 5 – Leadership
- Clause 6 – Planning
- Clause 7 – Support
- Clause 8 – Operations
- Clause 9 – Performance
- Clause 10 – Improvement (iso.org)

Quality standard for ISO 9001: 2015 is built from ten clause and built and more easily understood by the organization in a mode of operation based on the PDCA cycle model:
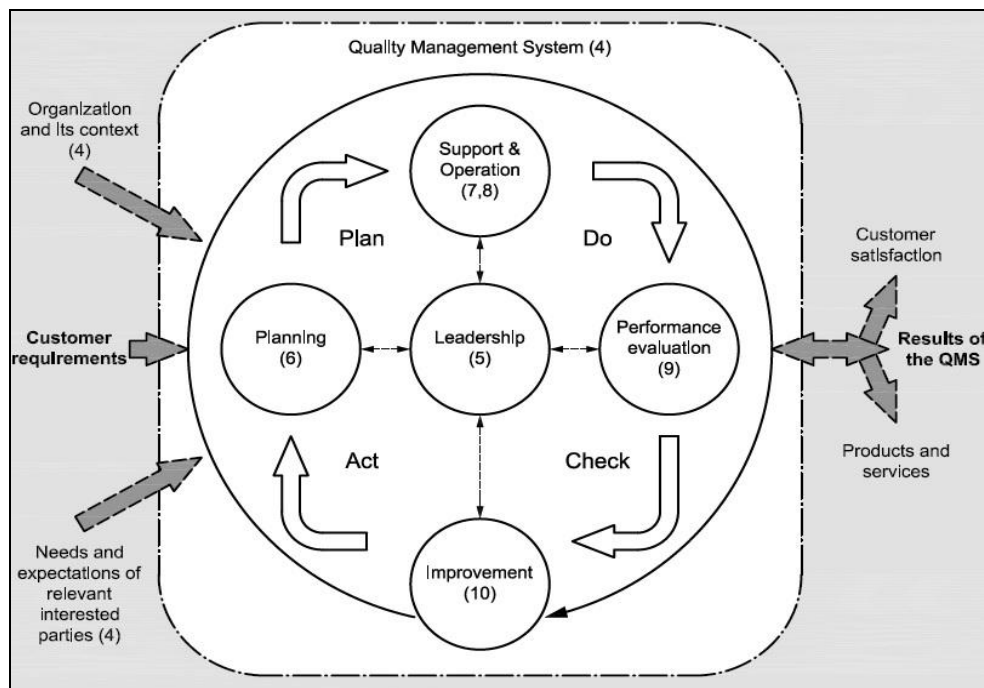

SOURCE: ISO.ORG/ Representation of the structure of this International Standard in the PDCA cycle.

Risk-based thinking

Preventive actions are also used in other versions. An organization needs to plan and implement measures to address the risks and opportunities. Addressing both risks and opportunities create a basis for enhancing the effectiveness of the quality management system, achieving the best and prevent negative effects (iso.org).

Table: Process Approach
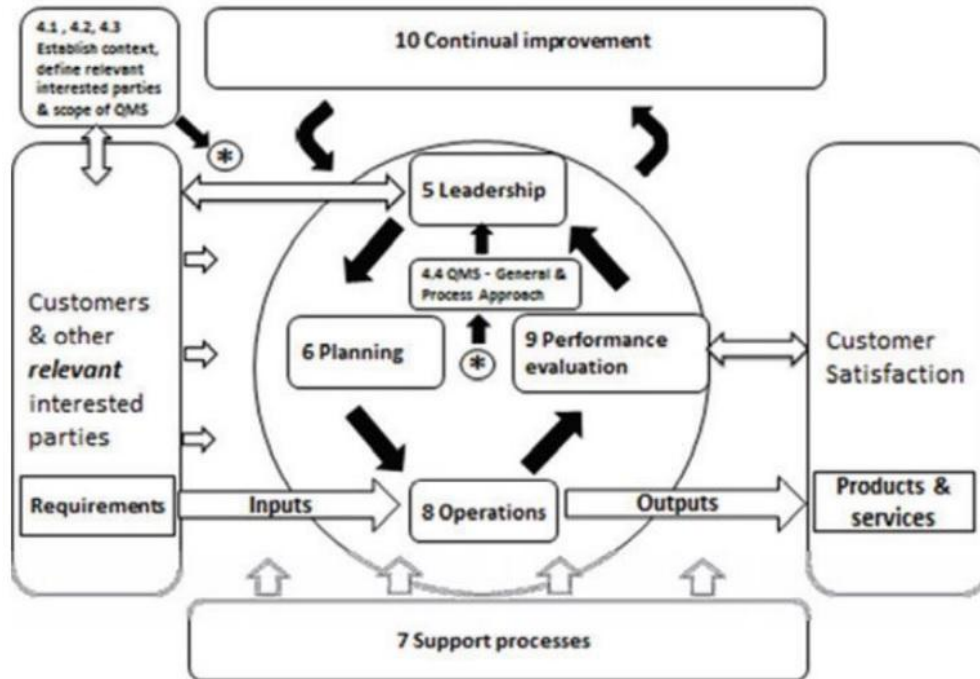
SOURCE: Fonceta, L. Researchgate-International Journal for Quality Research, March 2016.

As a standard applied will share the differences between ISO 9001: 2008 as its requirements are recognized and ISO 9001: 2015 as shown in the table below.

ISO 9001:2008	Draft ISO 9001: 2015 Number of points
4. Quality management systems	N/A
(general to all organizations, exclusions do not apply) (The total for all organizations, the exceptions do not apply) To ensure that the documented system of quality management implemented and auditable data set providing data for continuous improvement and to verify compliance. The system is based on process Clause 4.1 contains important information to ensure that outsourced processes are quality controlled effect so adekuate.Kjo clause also provides that compliance with relevant documentation requirements and are backed by good document and record control.	4.4 Quality management system and its processes None (a Quality Manual is no longer specifically required, however the content previously found in a quality manual is noë specified under Klauzola 4.3 Determining the Scope of the Quality Management System, 7.5.1 General, and 4.4 Quality Management System and it's processes) 7.5 Documented Information, 7.5.1 General, 7.5.3 Control of Documented Information, 8.5.6 Control of changes 7.5 Documented Information, 7.5.1 General, 7.5.3 Control of Documented Information, 8.5.6 Control of changes
5.Management responsibility	N/A
(generic to all organizations, exclusions do not apply) (The total for all organizations, the exceptions do not apply) Commit to managing the implementation and continuous improvement of quality management, through policy, planning and management analysis. This provision clarifies the areas of quality	5.1 Leadership and commitment 5.2 Policy 6.2 Quality objectives and planning to achieve them 6.2 Quality objectives and planning to achieve them, 6.3 Planning of changes 5.3 Organizational roles, responsibilities and

management system where necessary direct involvement by senior management (see terms and definitions - 8 seconds of this manual).	authorities None (this position has been eliminated) 7.4 Communication 9.3 Management revieë
6.Resource management	N/A
(generic to all organizations, exclusions do not apply) (The total for all organizations, the exceptions do not apply) To determine and provide adequate resources to ensure compliance of the product through human resources, infrastructure and work environment.	7.1 Resources, 7.1.1 General 7.1.2 People, 7.2 Competence, 7.3 Awareness 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes
7.Product realization	N/A
(exclusions may apply) (Exceptions may apply) To provide planning, product development and distribution of meeting customer requirements. This is the engine of a standard that covers all aspects of operational planning, design, development agreements, all aspects of direct control of production and service delivery. An organization may request exemption (s) of some parts of this clause To have provided for exemptions not adversely affect the ability to meet customer and regulatory requirements.	8.1 Operational planning and control 8.2 Requirements for products and services 8.2.2 Determination of requirements related to products and services, 8.5.5 Post-delivery activities 8.2.3 Review of requirements related to products and services 8.2.1 Customer communication 8.3 Design and development of products and services 8.4 Control of externally provided products and services, 8.4.1 General, 8.4.2 Type and extent of control 8.4.3 Information for external providers 8.4.2 Type and extent of control 8.5 Production and service provision, 8.5.1 Control of production and service provision 8.5 Production and service provision, 8.5.1 Control of production and service provision 8.5.2 Identification and traceability 8.5.3 Property belonging to customers or external providers 8.5.4 Preservation 7.1.5 Monitoring and measuring resources
8.Measurement, analysis and improvement	N/A
(generic to all organizations, exclusions do not apply) (The total for all organizations, the exceptions do not apply) Planning and implementation of measures and systems to ensure that product requirements, customer satisfaction , quality management systems are effective and continuous improvement have been identified and managed . This provision mainly covers: • Collection and use of performance information • Provisions relating to internal audit , corrective actions and preventive measures	9.1.1 General 9.1 Monitoring, measurement, analysis and evaluation 9.1.2 Customer satisfaction 9.2 Internal audit 9.1 Monitoring, measurement, analysis and evaluation 8.6 Release of products and services 8.7 Control of nonconforming outputs, 10.1 General, 10.2 Nonconformity and Corrective Action 9.1.3 Analysis and evaluation 10.1 General, 10.3 Continual Improvement 10.2 Nonconformity and Corrective Action None (although in spirit this requirement is found in Klauzola 6.2.1 and 6.2.2)

Source: International Organiation Standard ISO, (www.iso.org) 23.09.2015.

According to data from 100 enterprises certified by the certification body EAS International Standard ISO 9001: 2008 and in relation to the changes as mentioned above, are the following commit some key issues:

Clause 4 (QMS ISO9001: 2015) - The context of the organization
The ability to identify all matters of internal and external that are important and can affect, the organization's strategic direction and SMC

Clause 4.1 (QMS ISO9001: 2015) - Understanding the organization and its context - (New Requirements).
for: internal and external important issues for an organization; monitoring process of internan and external issues; the impact of any change on issues

Clause 4.2 (QMSISO9001: 2015) - Understanding the needs and expectations of stakeholders - (New Requirements).
It provides that has been identified, monitored and reviewed all things to stakeholders that are relevant to their QMS and requirements enabling: Information about the stakeholders that affect or may affect our SMC; Information about their needs and expectations; Monitoring and review process for stakeholders and their needs.

Clause 4.3 (QMS ISO9001: 2015) - Determination in the field of quality management in a systematic way REQUIREMENT
The new standard now requires that you consider "the context of the organization" (paragraph 4.1) and "stakeholders" (paragraph 4.2). You will need to identify the limits and applicability of SMC . This can include all organization or specific functions, information on: The boundary information on the applicability and scope of QMS; products and / or services included in the quality management system.

Clause 4.4 (QMS ISO9001: 2015) - Quality management system and changes in its processes
The last requirement is to establish, implement, maintain and continually improve the QMS. The list of processes, process sequences and interactions, methods to manage processes, resources to support processes, responsibilities and authorities of the process, the risks and opportunities of each process and ensure quality processes and improves system quality management system.

Clause 5 (QMS ISO9001: 2015) - Leadership
It's a new clause, but covers some requirements that were in ISO 9001: 2008 top managers are now required to have more involvement in SMC and ensure that requirements are integrated into the organization's processes and policies and objectives are consistent with the strategic direction of the organization. Finally clause sets the requirements for senior executives of relevant SMC assign responsibilities and authorities, but should remain responsible for the effectiveness of SMC.

Clause 5.1 (QMS ISO9001: 2015) - Leadership and commitment - NEW REQUIREMENT
The inclusion with more people in the strategic direction and accountability and promoting risk -based thinking, customer focus and improvement.

Clause 5.2 (QMS ISO9001: 2015) - policy *(OTHER CHANGES).*
This clause introduces only minor changes by 5.3 point in ISO 9001: 2008 for example Top management should establish, implement and maintain a quality policy and to ensure that communicated both within the organization, but also for the relevant stakeholders by case.

Clause 5.3 (QMS ISO9001: 2015) - organizational roles, responsibilities and Authorities
(OTHER CHANGES)
Requirements in this clause are more extensive than those provided in the version of 2008. They now apply to all "relevant role" not only to "those involved in the management system." Top management should ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organization. However, there is a fundamental difference in approach when considering the guidance provided by clause.

Clause 6 (QMS ISO9001: 2015) - PLANNING
Planning has always been a well-known element of ISO 9001, but now has an increased focus on ensuring that it is considered "part of the organization" and "stakeholders". Now there is a requirement to identify risks and opportunities, the impact these can have on the conformity of products and services and how you plan to handle them.

Clause 6.1(QMS ISO9001: 2015) - Actions to address risks and opportunities
(ENHANCED REQUIREMENT). This clause requires to identify the risks and opportunities that must be managed.

Clause 6.2 (QMS ISO9001: 2015) - Quality objectives and planning to achieve them *(OTHER CHANGES)*
This provision preserves some of the requirements contained in section 5.4 of the 2008 version, but is more

specific. The quality objectives must be consistent with the policy of quality, important for conformity of products and services, and increase customer satisfaction. Once set, the objectives are to be monitored, communicate and update accordingly.

Clause 6.3 (QMSISO9001: 2015) - Planning change requests (<u>ENHANCED</u>)
There is little difference in paragraph 5.4.2 of ISO 9001: 2008 QMS in that integrity must be maintained when the changes planned.

Clause 7 (QMS ISO9001: 2015) - SUPPORT
Clause 7 provides that you have the right resources, people and infrastructure necessary to meet the goals of the organization. A key requirement is to ensure that knowledge and nphurit are held to ensure the conformity of products or services.

Clause 7.1 (QMS ISO9001: 2015) – Human Recources - (<u>REQUEST</u>)
This clause is based on Articles 6.1, 6.2, 6.3 and 7.6 by 2008 and divided into 6 sub-clauses. You now need to consider providers and internal and external clients and to meet legal and regulatory requirements in force. Monitoring and measuring devices has changed the resources; it can be visual inspection, basically the same application as the 2008 standard. It includes considering the requirements of internal and external resources for the creation, implementation and improvement of management system.

Clause 7.2 (QMS ISO9001: 2015) – Competence - *(OTHER CHANGES)*
No significant changes within this section; it is a combination of Articles 6.2.1 and 6.2.2 2008.

Clause 7.3 (QMS ISO9001: 2015) - awareness *(OTHER CHANGES)*
This clause covers the awareness of quality policy, objectives and implications of not complying with the requirements. However, there is a fundamental difference in approach when considering the guidance provided within Klauzola. Please provide information on how you have raised awareness of the policy and QMS requirements.

Clause 7.4(QMS ISO9001:2015)- Communication, (*REQUEST*)
Similar to the requirements in the 2008 version, but this has now been expanded to include both internal communication and external relevant to the quality management system.

Clause 7.5 (QMS ISO9001: 2015) - Documented information (iso.org) – OTHER CHANGES
Clause 7 replaces 'documented procedures' and 'data' 2008 version of "information document". Additional requirements now include activities to control the "distribution" of the necessary information documented, particularly with regard to the first license and authority to change . However, there is a fundamental difference in approach when considering the guidance provided in the content disposition of 7.5.3.

Clause 8 (QMS ISO9001: 2015) - OPERATIONS
This clause deals with the implementation of plans and processes meet the requirements for the provision of products and services and is the clause that covers most of SMC specific requirements. There is also a new clause covering the post - delivery activities such as maintenance or work programs carried out under warranty.

Clause 8.1 (QMS ISO9001: 2015) - Operational planning and control - *(REQUEST)*
This clause is comparable with the requirements of paragraph 7.1 of the 2008 version , but is more specifically defined. For example, the processes required to meet the requirements should be planned, implemented and controlled, as the actions identified in 6.1. Inquiries regarding change control and processes are also given insert.

Clause 8.2 (QMS ISO9001: 2015) - Requirements for products and services - *(OTHER CHANGES)*
Although these requirements are increased from the previous version, 8.2.1 Point remains largely unchanged. However, now it requires communication regarding contingency operations where required and also handling of client assets. Cover requirements in Clause 8.2.2 Communication communication with potential customers' which is beneficial to bring new offerings or solutions in the market place. It has the ability to meet specified requirements and to prove the claims about the products and services it offers.

Clause 8.3 (QMS ISO9001: 2015) - Design and development of products and, that service *(OTHER CHANGES)*
This clause requires the organization to establish, implement and maintain a design and development process that is appropriate to ensure the provision of products and services later. Clause 8.3.3 is clearer in terms of c) standards or codes of practice that the organization has committed to implement; d) internal resources and external needs for the design and development of products and services; e) the possible consequences of failure due to the nature of products and services please provide information on how to achieve this . Finally Point 8.3.5

is largely unchanged in relation to point 7.3.3 of the 2008 version, but with additional requirements to include or reference monitoring and measurement requirements and acceptance criteria, as applicable.

Clause 8.4 (QMS ISO9001: 2015) - Control processes provided from abroad, products and services - (_OTHER CHANGES_). This clause is very similar to section 7.4.1, 7.4.2 and 7.4.3 of 2008 covering control processes provided by outside products and services . You need to ensure that staff are competent and have the necessary qualifications, their interactions with SMC and check the performance of the external provider.
An additional requirement of the 2008 version is the need to establish specific criteria for performance monitoring and communicate with external providers.

Clause 8.5 (QMS ISO9001:2015) - Production and service provision - (_OTHER CHANGES_)
Clause 8.5.1 can be aligned with a combination of points 7.5.1 and 7.5.2 of 2008, and focuses on activities that will be performed and results achieved. No significant changes in "identifying and tracing" (clause 8.5.2), although it should be noted that the results of the process are the results of any activity that are ready for delivery to the client organization or the next stage of the process. point 8.5.3 demand has increased and now covers property belonging to customers and external providers. This should be identified, verified, protected and preserved, and if damaged, inappropriate or loss must be reported to the customer or provider outside. Please provide information on how you comply with this change. A part of the original 7.5.5 Cause in 2008 is now included in the notes.

Clause 9.1 (QMS ISO9001: 2015) - Monitoring, measurement, analysis and evaluation (_OTHER CHANGES_) Requirements under this paragraph are already defined more specifically than those in the 2008 version . For example, you will need to determine when monitoring and measurement will be carried out and when the results will be analyzed and evaluated. However, there is no fundamental difference in approach when considering the guidance provided within the content points and Quality Management Principles.

Clause 9.2 (QMS ISO9001: 2015) - Internal Audit - (_OTHER CHANGES_)
Additional requirements are now specified in relation to the definition of "audit criteria" and to ensure that the results of the audits are reported to "proper management", but there is no fundamental change in approach when considering the guidance provided in the content clause. Please provide information on how your organization addresses audit requirements and details of any changes that have had to be made to existing provisions, if required.

Clause 9.3 (QMS ISO9001: 2015) - Menagement Review _(OTHER CHANGES)_
Management review process contained in Clause 5.6 of the 2008 version remains, however, there are additional requirements, including consideration of changes in foreign affairs and the interior that are important to SMC; however there is no fundamental difference in approach when considering the guidance provided in the content clause.

Clause 10 (QMS ISO9001: 2015) - IMPROVEMENT
This clause begins with a new section that organizations must define and identify opportunities for improvement such as improved processes to increase customer satisfaction . There is also a need to actively seek opportunities to improve processes, products and services, as well as SMC especially with future customer requirements in mind.

Clause 10.1 (QMS ISO9001: 2015) - General - _(OTHER SOURCES)_
This clause covers the general need for improvement, either to meet existing and future requirements of customers, correction or reduction of side effects to improve performance or efficiency of the system.

Clause 10.2 (QMS ISO9001: 2015) - Nonconformity and corrective actions – (_OTHER SOURCES_)
Now there are additional requirements specified in connection with the management of non-conformities require the organization to make changes at SMC, if necessary. However there is no fundamental change in the approach of the guidelines provided within the content of the clause.

Clause 10.3 (QMS ISO9001: 2015) - Continuous Improvement - _(OTHER SOURCES)_
Finally, there are additional requirements related specifically to constantly improve the "suitability" and "appropriateness" of SMC 's not just "efficiency". Notes within clause to provide additional guidance.

Drawing data from enterprises certified with the Quality Management System QMS/QMS version 2008 all large enterprises will spend although no changes from the previous version. But small and medium enterprises will need to include their leaders work commitments except they will engage in the process of comprehensive QMS in their department. Studies by officials from ISO International Standard ISO ORGANIATION (iso.org) "ISO has published standards of business management system." Many studies have been conducted on the impact of these standards in the industry and the general feedback by summarizing company like below:

External benefits (iso.org):

• Increase business, competitive advantage and market share
• Improve customer confidence and satisfaction
• Improvement of conformity to customer and regulatory quality requirements .

Internal Benefits (iso.org):

• Improved operational efficiency and productivity
• Improved process consistency and stability
• Continuous Improvement
• The focus and effectiveness of training programs to improve
• Improved employee motivation and participation
• Leadership for improving the performance of suppliers
• Increase the profitability of business

The extent of these benefits vary significantly from one organization to another, but those organizations that planned and implemented ISO 9001 using external professional assistance have won far superior results, both in terms of speed of implementation and effectiveness of the results. The repayment of investments was offset somewhere between 1-2 years, often sooner." (iso.org)

Conclusion

The new standard ISO 9001: 2015, unlike ISO 9001: 2008 is based on seven principles of quality management. These principles have been chosen because they can be used to enhance the performance of enterprises and achieve sustainable success. They form the conceptual basis for the quality management portfolio and are used to guide the development of this new standard. The main principles of quality management in version ISO 9001: 2015, include the whole enterprise and provide a better efficiency. Maintenance and implementation of the Quality Management System ISO 9001: 2015 gives each enterprise a new image in continuous growth and development of quality. For organizations that embrace standards management system, will likely little effect. Changes pressure on organizations to take a superficial approach and are probably just "interested in the certificate". The new provisions are intended to align with business standards. The new provisions are intended to help prevent the devaluation of the management system standards through the adoption of surface low-level auditing and certification meaningless. The new requirements of ISO 9001: 2015 will help to increase the powers of the auditor, if certification is to be seen to be beneficial for business.

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