

ISO 9001:2015

QUALITY MANAGEMENT SYSTEMS

INTRODUCTION

The standards of management systems undergo periodic review to adapt to the globalized world, market trends and application and / or adaptation of new available technologies.

The ISO 9001 standard is reviewed by the ISO technical committee, called ISO/TC176, in which more than 80 countries are direct participants, with professionals from the most diverse fields of activity, whether consulting professionals, certification body, industry, etc., all linked directly to a standardization body of their country of origin and / or authorized institution. In its portfolio, ISO/TC 176 has more than 20 published standards with the objective of assisting organizations around the world in the implementation of the quality management system.

Since the last revision of ISO 9001 in 2008, ISO/TC176 has planned for revision and publication of ISO 9001:2015, established by the following entries:

- Annex SL, called high-level structure, reference normative for harmonization of management systems standards;
- Seek greater clarity and simplicity of language for a better application of the Standard;
- Worldwide online survey with users getting more than 12,000 responses;
- Review and adequacy of quality management principles;
- Lessons learned from previous draft revisions of the Standard.

Based on all these entries, ISO/TC 176 fostered discussion worldwide about the revision of the ISO 9001 standard and established a complete standard that meets the desires of the market in the search for continuous improvement, in September 2015 ISO officially published the ISO 9001:2015 standard, which aims to remain active for 10 to 15 years being an international reference in the implementation of quality management systems.

DID YOU KNOW?

ISO/TC 176 gathered its members in several countries around the world for periodic meetings, where the revision of the ISO 9001 standard was discussed, in 03/2013 the committee met in Brazil, in the city of Belo Horizonte, where the document called Committee Draft (CD) was prepared.

ANNEX SL – HIGH-LEVEL STRUCTURE

Annex SL is a document prepared by ISO to harmonize the structure of management systems standards. The aim is to align the standards with a common structure and facilitate their respective integrations.

As an example, an ISO 9001 and ISO14001 certified organization will be able to easily integrate its management system with the new requirements and nomenclature structure of Annex SL. The following is the structure of Annex SL for easy comparison of recently published standards:

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

The structure presented above is the same as ISO 9001:2015 and ISO 14001:2015, so the requirements converge between the standards and integration is extremely easy compared to previous versions. Soon all management systems standards will comply with this same structure, optimizing the implementation processes for certified organizations.

DID YOU KNOW?

In 2012 Annex SL had its first application published,
in ISO 22301 – Business Continuity Management
Systems.

PRINCIPLES OF QUALITY MANAGEMENT

The ISO 9001:2015 standard is based on the principles of quality management described in ISO 9000:2015 (Quality management systems – Fundamentals and vocabulary), the reading of the ISO 9000 standard is recommended for a better understanding of the definitions of new nomenclatures, as well as the implementation of the standard will be facilitated.

In the specific case of quality management principles, the descriptions of the ISO 9000 standard include the statement of each principle, the justification of why the principle is important for the organization, as well as examples of benefits associated with the principle of actions to improve the performance of organizations in the application of these.

VERSION: 2008**VERSION: 2015**

In the figure above it is possible to compare the changes of the principles of quality management in relation to the 2008 version of the standard, in this process the main changes were:

- In principle 3 the word involvement gave way to the word engagement, the term intrinsically involves the value of people, the search for empowerment and improvement of skills, in a general way the term also demonstrates the focus on people who act on behalf of the organization.

- Principles 4 and 5 have become only Process approach, the principle makes clearer the interrelationship between processes in order to focus efforts on opportunities for improvement, aligned processes and demonstration to stakeholders of the consistency, effectiveness and efficiency of the QMS.
- Principle 7 has been amended to QMS stakeholder relationship management, aiming at improving the organization's performance through responses to opportunities and constraints with each stakeholder, common understanding of objectives and values, improvement in the ability to add value to stakeholders, and effective supply chain management.

THE STRUCTURE OF ISO 9001:2015

0.1 General	8.1 Operational planning and control
0.2 Principles of quality management	8.2 Requirements for products and services
0.3 Process approach	8.2.1 Communication with the customer
0.3.1 General	8.2.2 Determination of requirements relating to products and services
- 0.3.2 Plan-Do-Check-Act Cycle	8.2.3 Critical analysis of requirements relating to products and services.
0.3.3 Risk mindset	8.2.4 Changes in requirements for products and services
0.4 Relationship with other management systems standards	8.3 Design and development of products and services
1 Scope	8.3.1 General
2 Normative references	8.3.2 Project planning and development
3 Terms and definitions	8.3.3 Design and development inputs
4 Context of the organization	8.3.4 Design and development controls
4.1 Understanding the organization and its context.	8.3.5 Design and development outputs
4.2 Understanding the needs and expectations of stakeholders.	8.3.6 Design and development changes
4.3 Determining the scope of the quality management system.	8.4 Control of processes, products and services provided externally.
4.4 Quality management system and its processes	8.4.1 General
5 Leadership	8.4.2 Control Type and Extent
5.1 Leadership and commitment	8.4.3 Information for external providers
5.1.1 General	8.5 Production and provision of service
5.1.2 Customer focus	8.5.1 Production and service provision control
5.2 Politics	8.5.2 Identification and traceability
5.2.1 Developing the quality policy.	8.5.3 Property belonging to external customers and providers.
5.2.2 Communicating the quality policy.	8.5.4 Preservation
5.3 Roles, responsibilities and organizational authorities	8.5.5 Post-delivery activities
6 Planning	8.5.6 Change control
6.1 Actions to address risks and opportunities.	8.6 Release of products and services
6.2 Quality objectives and planning to 2achieve them.	8.7 Control of non-compliant outputs
6.3 Change planning	9 Operation
7 Support	9.1 Monitoring, measurement, analysis and evaluation
7.1 Resources	9.1.1 General
7.1.1 General	9.1.2 Customer satisfaction
7.1.2 People	9.1.3 Analysis and evaluation
7.1.3 Infrastructure	9.2 Internal Audit
7.1.4 Environment for the operation of processes	9.3 Critical analysis by management
7.1.5 Monitoring and measurement capabilities	9.3.1 General
7.1.6 Organizational knowledge	9.3.2 Inputs of critical analysis by management
7.2 Competence	9.3.3 Outputs of critical analysis by management
7.3 Awareness	10 Improvement
7.4 Communication	10.1 General
7.5 Documented information	10.2 Non-compliance and corrective action
7.5.1 General	10.3 Continuous improvement
7.5.2 Creating and Updating	
7.5.3 Control of documented information	
8 Operation	

CHANGES FROM PREVIOUS VERSIONS

1) REFORMULATION TO MAKE THE STANDARD MORE GENERIC AND EASIER TO UNDERSTAND FOR THE SERVICE AREA:

The nomenclature of the ISO 9001 standard has always been criticized by companies that do not operate in the manufacturing area, the omission of the specific reference of the term "services" in previous versions of the Standard has become unsustainable, so the applicability to the service sector has been reinforced in several requirements of the standard.

The ISO 9001:2015 version uses the term "products and services", where it includes all categories of outputs, as cited in the examples of the Standard itself, these categories can be: materials, machines, tools, services, software, processed materials, etc.

In the requirements framework of the Standard demonstrated above, the term "services" can be highlighted mainly in the following clauses:

8.2 - Requirements for products and services

8.3 – Design and Development of products and services

8.5 – Production and provision of services

These clauses clearly demonstrate that the ISO 9001:2015 standard brings the branch of service provision within the requirements of the standard, thus facilitating the understanding and consequently the implementation of the quality management system in all branches of activity.

For clause 8.3 – Design and Development of products and services it is important to highlight that this can also be applied to the branch of service delivery, organizations must evaluate its applicability in order to implement the necessary

requirements of Design and Development and not simply evaluate the requirement as not applicable, this evaluation must be judicious to the point of a critical analysis of the processes and context of the organization for a coherent definition.

DID YOU KNOW?

The Standard also describes that products and services can be used together, because a product can have a service associated with it, such as a product transport to the end customer, and a service can have some associated product, such as a maintenance company that uses parts that are incorporated into the final service.

2) CONTEXT OF THE ORGANIZATION AND STAKEHOLDERS:

Annex SL – High Level Structure, explained at the beginning of this e-book, introduced two new sections relating to the context of the organization:

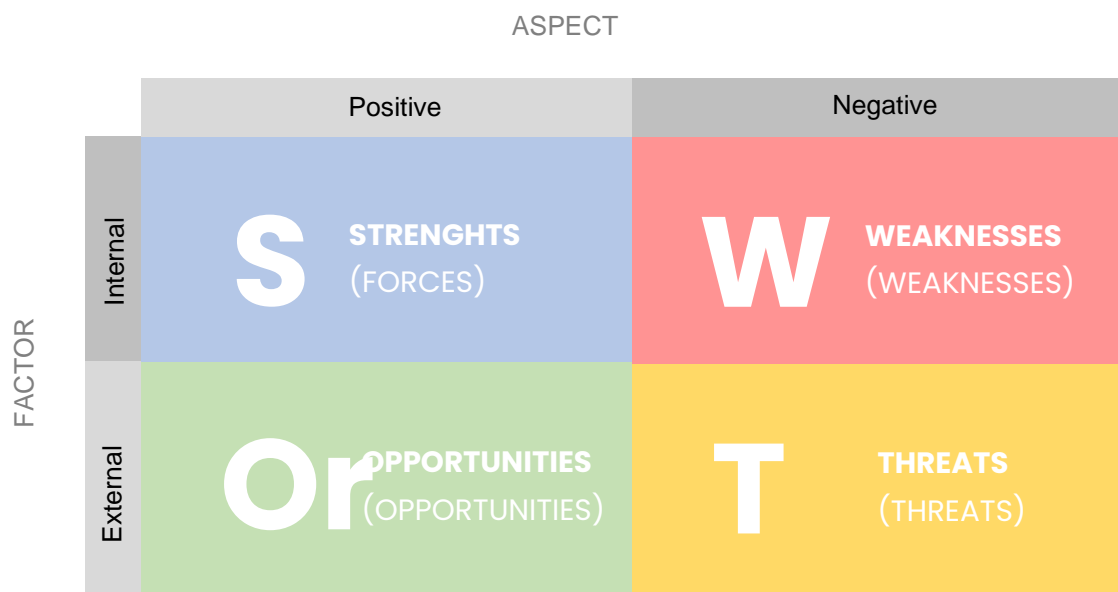
4.1 - Understanding the organization and its context;

4.2 - Understanding the needs and expectations of stakeholders.

Referring to the term "organization and its context", the standard establishes as a requirement the determination of the internal and external issues of the organization to achieve the requirements of the quality management system. In this process, one can align the implementation of the requirement in line with the basis of the company's strategic planning and/or determine a process only with the quality management system according to the requirements of the Standard.

The scope of this process goes according to the objectives of the company and the delimitation of the scope of the quality management system, the standard establishes the minimum requirements of a quality management system, and each organization must evaluate such impact within its purposes and organizational culture.

To determine the internal and external issues of the organization several management tools can already be adapted and used for this purpose, one of them is the SWOT analysis tool. This tool essentially aims to be used for scenario analysis, in the case of item 4.1 of ISO 9001:2015, the tool can be used for this purpose. Below is a model of the tool:



As for the term "needs and expectations of stakeholders" the Standard establishes the determination of these and their respective requirements, but the organization must take into account that item 4.2 does not imply the extension of the requirements beyond the scope of ISO 9001:2015 itself, as well as the Standard itself warns, as such a term may imply in a confusion regarding this process, Thus, it is clear that the determination of stakeholders should be limited to the quality management system, scope of the organization and its context.

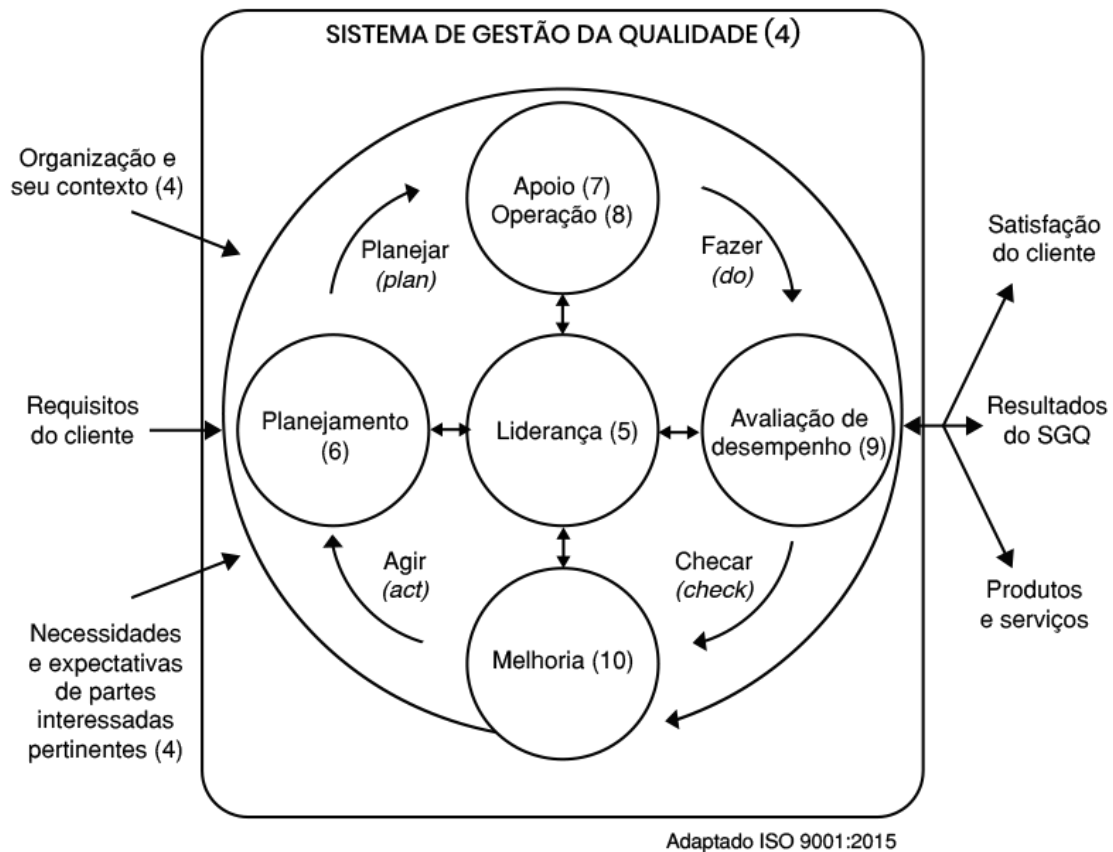
DID YOU KNOW?

The term SWOT is an acronym for Strengths, Weaknesses, Opportunities and Threats. The creation of the tool is credited to Albert Humphrey, who led a research project at Stanford University in the United States of America in the 1960s and 1970s, using large international corporations.

3) PROCESS APPROACH:

The ISO 9001:2008 standard promoted the inclusion of the process approach for developing, implementing and improving the effectiveness of the quality management system. In ISO 9001:2015 this is more explicit in 4.4 with the adoption of specific requirements considered essential to the adoption of this approach.

With the management of the interrelationship between the processes of the quality management system the tendency is that the improvement becomes more evident to the organization when achieving its intended results. In this process, the Standard establishes the use of the PDCA cycle (*Plan, Do, Check, Act*) with a focus on risk management, aiming to identify opportunities and prevent undesirable results. The following figure represents the structure of ISO 9001:2015 in the PDCA cycle:



According to the representation above it is possible to identify the Leadership (item 5) as the center of the quality management system and in comparison to previous versions of the Standard the inputs are not limited to the requirements of the client, but also the needs and expectations of the stakeholders (item 4.2) and the organization and its context (item 4.1).

4) RISK MINDSET:

Initially considered one of the biggest changes of the ISO 9001 standard, the concept of risk mentality has always been present in previous versions, but implicitly, through planning requirements, critical analysis, corrective actions aimed at recurring nonconformities and preventive actions.

Item 6.1 specifies and clarifies this approach and defines planning requirements for this, bringing as the main purpose of the quality management system the functionality of prevention.

According to the preventive purpose, ISO 9001:2015 does not determine a specific requirement such as "preventive action" like previous versions, as this concept is expressed by the risk mentality permeated in the main requirements of the standard.

It is important to point out, as the Standard itself describes, there is no specific requirement for formal methods of risk analysis and management within the organization or even a documented process for this purpose, so organizations can develop their own procedure, whether it is maintained as documented information or not. The scope of the risk management method to be implemented in the organization may vary according to the complexity of the company's activities, the scope of the management system and the context of the organization.

There are several tools for process risk management that can be adapted to meet the ISO 9001:2015 standard, or also as highlighted above, the organization can develop its own methodology, below two examples:

- **FMEA (Failure Mode and Effect Analysis)**, a method originally used for risk assessment in process and design failures, can be adapted to any process for risk management;
- **HAZOP (Hazard and Operability Study)**, a method originally used to identify and evaluate process problems that may cause personal or equipment risk, as well as the previous method, can be adapted for QMS risk management;

As the very nomenclature of the concept establishes, risk management in the organization should be disseminated as a mindset for people acting on behalf of the organization, thus being able to bring significant improvement results.

DID YOU KNOW?

The previous documents prepared by ISO/TC176 cited the ISO 31000 – Risk Management standard as a normative reference, but as the ISO 9001:2015 Standard does not establish a formal method for risk management, this reference was removed so as not to indicate confusion in the understanding of the requirement and inserted only in Bibliography.

5) DOCUMENTED INFORMATION

For adequacy and alignment with Annex SL, cited at the beginning of this e-book, the term "documented information" has been included to replace the old terms "document" and "record". Throughout the standard, the requirements were adapted to this nomenclature, establishing processes that require evidence such as maintaining and retaining documented information.

In the ISO 9001:2008 version the term "registration" was used to refer to documents necessary to provide evidence of compliance with requirements, in the ISO 9001:2015 version the term "retain documented information" is used to denote the old record. In the case of the term "document" from the old version, the current ISO 9001:2015 version refers to this as "maintaining documented information".

This alignment of Annex SL is due to the fact of the advent of new media to denote as a document and/or record, and the always difficult understanding that existed in the market between document and record.

6) ORGANIZATIONAL KNOWLEDGE

The ISO 9001:2015 Standard addresses the topic of organizational knowledge, establishes the need to determine and manage the knowledge held by the organization, to ensure that it can achieve compliance of products and services.

It is already notorious that companies may have losses of their know-how due to turnover of people acting on behalf of the organization and / or deficiency of maintaining and sharing information through effective communication, due to these facts, one of the objectives of this item is to safeguard the organization from losses of the now denominated by ISO 9001:2015, organizational knowledge.

Another objective of this item, as mentioned in the Standard, is to encourage organizations to acquire knowledge, where this can be done in various ways with experiences of projects previously carried out, mentoring, courses, seminars, etc.

The requirement initially may seem generic, but the organization when determining the necessary knowledge, establishing ways to maintain the knowledge already acquired and seeking alternatives to acquire additional knowledge will enter a knowledge cycle, which aims to prepare organizations for adverse situations impacting this process.

QMS CERTIFICATION VISION OF ISO 9001:2015

We at QMS Certification, as active participants in the revision of the previous version, believe that the ISO 9001:2015 Standard has achieved the objectives proposed at the time of its conception and we can conclude that:

- The text of the Standard is clearer and more objective in relation to previous versions and has a more accessible language for a better application in companies seeking certification;
- The Standard can be used as a process management tool and the effectiveness of the quality management system is more noticeable to senior management and all employees acting on behalf of the organization;
- The implementation and maintenance of the quality management system can be directed in conjunction with the strategic planning of the organization, provided that the organization has this objective;
- The easy adherence to implementation and consequently the ISO 9001:2015 certification of small and medium-sized companies, as well as companies that work with service provision activities, due to a better understanding of the requirements of the normative.

HOW QMS CERTIFICATION CAN HELP YOU

PRE-ASSESSMENT AUDIT

Evaluation of your QMS by expert auditors in order to observe gaps in the implementation of ISO 9001:2015.

CERTIFICATION

If your company is not yet certified by QMS Certification, transfer your certification or certify with us and have the best service in the market.



NEIFER FRANÇA

QMS America Director, Author of the Anti-Bribery Blog, Lead Auditor ISO 37001, ISO 9001, ISO 14001, ISO 45001, ISO 27001 and other ISO standards.

+1 (800) 287-8777
contact@qms-certification.com
www.qms-certification.com