Transport, Mobility & Society. 2025; 4:151
doi: 10.56294/tms2025151

REVIEW

Design and Implementation of an ISO 9001:2015 Quality Management System in Various Organizational Sectors

Diseño y Aplicación de un Sistema de Gestión de Calidad ISO 9001:2015 en Diversos Sectores Organizacionales

Franklin Jesús Piñerez Díaz[1] ✉, Eduvigis Sorrentino[1] ✉, Oscar Antonio Caldera Molleja[1]

[1]Universidad Nacional Experimental "Francisco De Miranda", decanato del área de postgrado dirección de Postgrado del área de tecnología, maestría en gerencia de la calidad y producto. Venezuela.

Cite as: Piñerez Díaz FJ, Sorrentino E, Caldera Molleja OA. Design and Implementation of an ISO 9001:2015 Quality Management System in Various Organizational Sectors. Transport, Mobility & Society. 2025; 4:151. https://doi.org/10.56294/tms2025151

Submitted: 15-06-2024 **Revised:** 10-09-2024 **Accepted:** 28-12-2024 **Published:** 01-01-2025

Editor: Prof. Emanuel Maldonado

Corresponding Author: Franklin Jesús Piñerez Díaz ✉

ABSTRACT

Introduction: the research focused on the design and implementation of a Quality Management System (QMS) under the ISO 9001:2015 standard, considering its relevance in a highly competitive organizational environment. It started from the recognition of quality as a strategic axis and set as its main objective the analysis and adaptation of a management model appropriate to the characteristics of a specific organization.
Development: a literature review was conducted of relevant studies that applied this standard in sectors such as transportation, legal services, aircraft maintenance, food distribution, and roadside assistance. Cases such as those of López, Solano , and Vargas demonstrated how the standard made it possible to standardize processes, increase efficiency, and improve customer satisfaction. Tools such as process maps, checklists, and risk analysis were also applied to develop proposals for continuous improvement.
Conclusions: it was concluded that the ISO 9001:2015 standard is an effective tool for strengthening organizational processes and ensuring the quality of products and services. The key to success lay in management commitment, ongoing training, and the use of appropriate methodologies. In addition, it was evident that the standard offers greater flexibility compared to other quality models such as EFQM and Deming, making it particularly applicable to different types of organizations.

Keywords: ISO 9001:2015; Quality Management; Continuous Improvement; Organizational processes; International Standards.

RESUMEN

Introducción: la investigación se orientó al diseño e implementación de un Sistema de Gestión de la Calidad (SGC) bajo la norma ISO 9001:2015, considerando su relevancia en un entorno organizacional altamente competitivo. Se partió del reconocimiento de la calidad como eje estratégico y se planteó como objetivo principal el análisis y adaptación de un modelo de gestión adecuado a las características de una organización específica.
Desarrollo: se realizó una revisión bibliográfica de estudios relevantes que aplicaron dicha norma en sectores como transporte, servicios jurídicos, mantenimiento aeronáutico, distribución de alimentos y asistencia vial. Casos como los de López, Solano y Vargas demostraron cómo la norma permitió estandarizar procesos, aumentar la eficiencia y mejorar la satisfacción del cliente. Asimismo, se aplicaron herramientas como mapas de procesos, listas de verificación y análisis de riesgos para desarrollar propuestas de mejora continua.
Conclusiones: se concluyó que la norma ISO 9001:2015 constituye una herramienta eficaz para fortalecer los procesos organizacionales y asegurar la calidad de productos y servicios. La clave del éxito radicó en el

compromiso gerencial, la capacitación constante y el uso de metodologías apropiadas. Además, se evidenció que la norma ofrece mayor flexibilidad frente a otros modelos de calidad como EFQM y Deming, lo que la hace especialmente aplicable a diferentes tipos de organizaciones.

Palabras clave: ISO 9001:2015; Gestión de Calidad; Mejora Continua; Procesos Organizacionales; Estándares Internacionales.

INTRODUCTION

In today's organizational context, quality is no longer an added value but an essential requirement for the sustainability and competitiveness of any institution, company, or service. The rapid pace of the market, the globalization of production processes, and increasing customer demands have led organizations to implement systems that guarantee continuous improvement, process standardization, and compliance with international standards. In this regard, the ISO 9001:2015 standard has established itself as a fundamental tool for effective quality management by setting clear guidelines that allow strategic objectives to be aligned with customer expectations.

This research is based on the design and implementation of a Quality Management System (QMS) based on the ISO 9001:2015 standard, focused on strengthening the key processes of a specific organization. To this end, an exhaustive review of national and international background information was conducted, which provided valuable information on methodologies applied, results achieved, and critical elements in the development of quality management systems. Works such as those by López[1], Solano[2], and others studies demonstrate the relevance of this standard in sectors as diverse as transportation, law, aircraft maintenance, food distribution, and roadside assistance services. These studies, using different approaches and methodologies, demonstrate that ISO 9001:2015 not only improves service or product quality, but also operational efficiency, customer satisfaction, and organizational competitiveness.

In this context, the overall objective is to analyze and apply a quality management model adapted to the needs and particularities of the organization under study. The research is based on a qualitative approach, under a feasible project modality, and contemplates the use of diagnostic tools such as flowcharts, process maps, and checklists, in order to propose improvements aimed at standardizing and controlling processes.

This work is relevant in that it responds to the need to establish mechanisms that ensure quality as a cross-cutting organizational principle and provides a documentary and methodological basis for future research on the implementation of quality management systems in various organizational contexts.

DEVELOPMENT

Research Background

At this stage of the research, it was necessary to review the relevant work in order to use it as a reference and to guide the present research appropriately. Two international and three national contributions were considered to be of great importance in relation to the objectives associated with the topic under development, They also provided details on how these problems were previously addressed, what solutions were implemented, and thus explained all the ideas and concepts necessary to fully understand the subject under study.[3,4,5,6]

In summary, the background information cited below is of great importance, as it provides a clear and precise outline of how to do things and improve them for the benefit of both the researcher and the readers, and will serve as a future reference for future research on quality management systems.[7,8]

López[1] in his master's thesis entitled: Design of a quality management system based on the ISO 9001:2015 standard in the transport management of Transterre SAC - Surco 2020, to qualify for the title of the Graduate School, Master's Degree in Operations and Logistics Management, from the César Vallejo University, Lima North Campus, whose main objective was the design, application, activation, and operation of a quality management system under ISO 9001: 2015 standards, providing consistent delivery of quality products and services, complying with applicable requirements. It also focuses on business and thus directs quality as a relevant factor for companies to endure successfully, ensuring effective development of the quality management system.

The research was qualitative, non-experimental, cross-sectional, and descriptive, with a feasible project research methodology and field design. The study population consisted of 20 employees, and the company's main office is located in the Santiago de Surco district. The company is dedicated to the outsourcing of heavy cargo and freight transportation services under a multimodal system.

For all the reasons stated above, this is an important bibliographic reference for the development of this research project, as it allows the variable studied to be determined and supported on the basis of the quality management system based on the ISO 9001:2015 standard. The contribution to the information provided important theoretical foundations for the implementation of the quality management system, providing a solid

basis for the collection of information necessary for compliance with the international standard ISO 9001:2015.

Solano[2] In her master's thesis entitled: Creation of a Quality Management System based on the ISO 9001:2015 standard for a law firm in the Dominican Republic. Case study: Dr. Kennia Solano & Asociados SRL. To obtain a Master's degree in Comprehensive Auditing and Management Control at the APEC Postgraduate Dean's Office – Dominican Republic, the objective was to design value processes based on a Quality Management System to achieve the effectiveness and efficiency of that law firm in controlling the performance of the organization, which will allow the company to exercise greater control over the processes to increase their effectiveness.

In this research project, the creation of a quality management system based on the ISO 9001:2015 standard was proposed, based on a survey and analysis of the policies and procedures carried out by the law firm Dra. Kennia Solano & Asociados. This creation allowed for the theoretical application of work programs, process maps, flowcharts, among others. As a result of this research, deficiencies in staff training, failure to perform duties due to lack of supervision, and decreases in company revenue due to weaknesses in customer service were identified.

The type of research is a micro-enterprise in the legal sector, adopting a qualitative, non-experimental, descriptive, feasible project and field design model, with a population of 12 employees who collaborate directly with its main economic activities, including legal services for the preparation of contracts, legalizations, real estate title management, evictions, and collection management. The scope of the Quality Management System applies to the processes considered key to ensuring that the firm consistently performs its functions correctly with respect to the various responsibilities involved in these practices.

This research is related to the present work, as it proposed the creation of a quality management system based on the ISO 9001:2015 standard, based on a survey and analysis of policies and procedures, allowing the theoretical application of work programs, process maps, flowcharts, among others. As a result of this research, deficiencies in staff training, failure to perform duties due to lack of supervision, and decreases in company revenue due to weaknesses in customer service were identified.

It was concluded that, when gathering information, it was found that the value process: property title management, evictions, and collections, including practices that lead to better organization of functions, so that operations are carried out with greater agility and obtain better results. This research contributed to the understanding of the problem and the methodological framework, providing an overview of the limitations and scope of the research, the type of methodology used, and the expected approach or scope of its development. In addition, the results of the field research are highlighted, expressed through frequency tables, graphs, and a brief and concise analysis of the same.

A study developed a master's thesis on quality systems at the Andrés Bello Catholic University, whose overall objective was focused on the Quality Management System Based on ISO 9001:2015 Applicable to the Aeronautical Maintenance Process in Venezuelan Airlines.[9,10,11] This objective contributed to establishing the guidelines and requirements subject to the standard that will improve the processes and sub-processes carried out in the performance of aeronautical maintenance tasks and that encompass all the quality requirements demanded by the new ISO 9001:2015 standard, adapting both the requirements of the regulation as those stipulated in international standards, in order to provide the necessary attributes to airline quality management systems in the performance of aeronautical maintenance tasks.[12,13]

To this end, a qualitative and descriptive field investigation will be carried out, and different quality management systems will be reviewed using a data collection instrument, in this case a survey, which will contribute to the sampling for the analysis of possible shortcomings in the current processes. The interviews will be conducted with managers, department heads, and individuals involved in the process in order to understand the entire picture and design and propose a quality management system that is applicable to various organizations and provides benefits that help them improve their operations and serve as support when they decide to pursue international certification.[14,15,16]

Aeronautical maintenance process in Venezuelan airlines. They have demonstrated the importance of continuously improving their operational and administrative processes in order to measure service quality based on variables such as costs and fares, in-flight services, boarding/unloading of aircraft/baggage, flight crew, aircraft, registration, and reservations, with the aim of creating niches that distinguish them from other airlines, generating a competitive advantage over them.[17,18]

The contribution made by this work was extremely important, as it provided guidance on the identification of quality policy and objectives, organizational structure, and functions based on the collection of information using flowcharts and process maps, with the corresponding identification of key, support, and strategic processes carried out by the company Cardon Rent. Car C.A.[19,20,21,22,23]

Wrote a master's thesis to obtain a master's degree in quality systems from the Andrés Bello Catholic University, entitled: Design of a quality management system for the logistics processes of pasteurized cheese distribution companies. The objective was to analyze, market, and profit from this highly competitive sector, where the cost-benefit ratio plays a decisive role in economic survival. Among its core operations are inventory maintenance and product distribution to customers.[24,25,26,27,28]

The research project was developed using techniques and procedures employed to formulate and solve problems, with research as an assertive strategy to achieve continuous improvement and customer satisfaction. This gave rise to the need to design a Quality Management System for the logistics processes of pasteurized cheese distribution companies in the capital region of Venezuela.[29,30,31]

This study is part of a feasible project research, using a non-experimental, descriptive, and documentary research design, as it was based on the review and analysis of documents to extract key data that fed into the proposed design. In this sense, a quality diagnosis was carried out on the distributors with a population of 18 distributors,which carry out the logistics processes for pasteurized cheese. Three were selected as a sample at the researcher's discretion, and the quality management system that best suits the sector's needs was identified by applying a series of qualitative and quantitative tools for the collection and analysis of information, processes, control points, and the cost/benefit ratio in the application of the design.[32,33,34]

As a result of the research, the knowledge gained provides a more in-depth understanding of the variable studied in the current thesis, since it is necessary, after obtaining the results, to formulate alternatives or strategies that promote compliance with and implementation of the quality management system. This work served as a basis for selecting the tools to be used to analyze the current processes in order to improve them and increase productivity.

Machado[3] developed a master's thesis on quality systems at Andrés Bello Catholic University, whose overall objective was to formulate a quality management system for service companies that offer roadside assistance based on the ISO 9001 2015 standard. This objective contributed to establishing the guidelines and requirements subject to the standard that will improve the processes identified for the development of quality products. This research consists of formulating a Quality Management System in service companies that offer roadside assistance based on the ISO 9001:2015 standard. This proposal is based on the fact that a Quality Management System guarantees, or at least to a high degree, that the characteristics of the service meet customer requirements and satisfy their needs and expectations, ensuring the percentage of sales necessary for the sustainability of the company.

To achieve the general objective and specific objectives, the study is part of a non-experimental research project, supported by documentary and field research at a descriptive level. The population consists of companies providing roadside assistance services in the city of Caracas, and the sample is targeted or intentional, non-probabilistic. The data collection techniques used for the research will be direct observation, document reviews, and interviews. The results of this research represent a positive impact for the sector, since in this economic and decisive environment, becoming competitive is part of personal and organizational strategies to face the different scenarios of economic and business turbulence in the country.

To develop the thesis, the current situation was first analyzed, evaluating the different parameters of the standard through a checklist, which yielded reliable results, with a non-compliance rate of 75,77 % based on the evaluation of 214 items. The processes and sub-processes were also identified, for which the information corresponding to the process map was collected as a proposal, which includes the identification of: the key, support, and strategic processes carried out by the service companies that offer roadside assistance. It should be noted that strategies were proposed to improve quality by measuring customer satisfaction, as well as the continuous improvement to which it is subject.[35,36,37,38]

Subsequently, the document structure was conceptualized based on a hierarchical pyramid model, identifying the different documents distributed across levels, such as: First level: mission, vision, policies, and quality objectives. Second level: quality management manual. Third level: manuals by department and associated procedures. Fourth level: Work instructions. Fifth level: Forms and records, to then document the operational processes of the service company that offers roadside assistance,

and then establish an implementation plan. This work served as support in the research process by providing a checklist model that would be applied to analyze the current situation of the company Cardon Rent. Car C.A.

Theoretical basis

The theoretical foundations associated with the main areas to be developed favor the design of an ISO 9001:2015 quality management system that allows for the control and improvement of the most sensitive aspects of the organization related to quality. The main theoretical areas that support this research are summarized below:

Quality Management

Authors such as Castillo et al.[14] define quality management as "the general management function that determines and implements quality policy, including strategic planning, resource allocation, and quality-related actions". Thus, it can be said that the structure of management systems must be such that it is feasible to carry out coordinated and permanent control over all activities performed. It must be structured and adapted to the type and characteristics of each organization, taking into particular consideration the elements that are

appropriate for its structuring and following the stages of the quality management system. The evolution of quality is shown below (table 1).

Table 1. Evolution of Quality Management

Stage	Concept	Objective
Artisanal stage	Do the things well regardless of the cost or effort required.	Satisfying the customer. Satisfy the craftsman for a job well done. Create a unique product.
Industrial revolution	Doing many things is important, regardless of their quality (production is identified with quality).	Satisfaction a large demand of goods. Make a profit.
World War II	Ensuring the effectiveness of armaments regardless of cost, with the largest and fastest production (effectiveness equals quality).	Guarantee the availability of effective weapons in the right quantity at the right time.
Post-war (Japan)	Do things right the first time.	Minimize costs through quality. Satisfy the customer. Be competitive.
Post-war rest of the world	Produce as much as possible.	Satisfy the high demand for goods caused by the war.
Quality	Production inspection techniques to prevent the of goods from	Satisfying the technical requirements of the product.
Quality assurance	Organizational systems and procedures to prevent defective goods from being produced.	Satisfy the customer. Prevent errors. Reduce costs. Be competitive.
Total quality	Management of business administration focused on permanent customer of the expectations of the customer.	Satisfying both external and internal customers. Be highly competitive. Continuous improvement.

Quality Management System

According to Simat[4], "A quality management system is a way of working through which an organization ensures that its customers' needs are met. To this end, it plans, maintains, and continuously improves the performance of its processes under a framework of efficiency and effectiveness that allows it to achieve competitive advantages".

In general, a quality management system can be defined as the aspect of an organization's overall management that determines and implements its quality policy, with the aim of guiding the organization's activities to achieve and maintain the level of product or service quality required by its customers. In simple terms: "say what you do, do what you say, record what you did, check the results, and act on any differences found."

The purpose of a quality management system is to direct and control an organization with regard to quality. It is therefore integrated into the operations of the company or organization and serves to ensure its proper functioning and control at all times. It also provides tools for implementing actions to prevent defects or problems (preventive action procedures) and to correct them. It also includes human and material resources and the responsibilities of the former, all properly organized to meet its functional objectives.

Therefore, a quality management system encourages organizations to analyze customer requirements, define the processes that contribute to the achievement of products acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continuous improvement in order to increase the likelihood of increasing customer and other stakeholder satisfaction.

Continuous Improvement Processes

According to Fleitman[5], "improvement is a necessity for any person or company that wants to be competitive, based on the premise that things can always be done better. Continuous improvement is a culture, a way of being for people and companies where improvement is the name of the game." In summary, for a company to become competitive, it is not enough to implement isolated or accidental improvements; rather, they must

be made constantly and strategically. This is the secret to continuity and process improvement. The same author states that continuous improvement processes and the pursuit of quality and excellence are not ends in themselves, but rather means that enable companies to become more successful every day.

Continuous improvement must be established as a policy, and strategies must be put in place to implement it. The Deming cycle of continuous improvement is shown below.

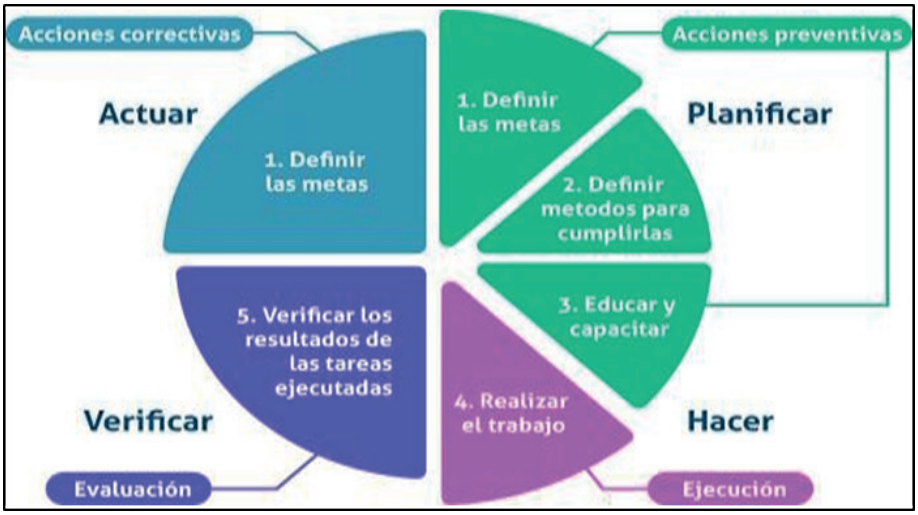

Figure 1. Deming Cycle Model

Plan

This involves establishing the objectives and processes necessary to achieve results in accordance with customer requirements and organizational policies, which are:

- Identify services.
- Identify customers.
- Identify customer requirements (5.1).
- Translate customer requirements into specifications (6.3).
- Identify key steps in the process (flow chart) (7.1).
- Identify and select measurement parameters (9.1).
- Determine process capability (9.1).
- Identify benchmarks (5.1 of ISO 9004).

Do

- Implement the processes.
- Identify opportunities for improvement (10).
- Develop the pilot plan.
- Implement improvements.

Verify

- Monitor and measure processes and products against policies, objectives, and product requirements, and report on results.
- Evaluate effectiveness (9.1.2).

Take

- Take actions to continuously improve process development.
- Institutionalize improvement or return to the do step (9.3).
- Applies to corrective and preventive actions and improvement plans as a result of audit reports. In addition, the methodology for problem analysis and solution is applied to those sub-processes that need continuous improvement so that they can then be incorporated into the sub-processes and become part of everyday operations again.

Quality Management Models

The models are designed to assess the degree of development of both small and large companies whose objectives are to implement quality management in such a way that the model becomes a permanent reference

point and an effective tool for improving the processes of any company seeking to improve the products or services it offers. In this regard, we find the most relevant models for analysis and implementation to solve the problems that arise in companies, which are mentioned below: the Deming model, the EFQM model, the Malcolm Baldrige model, and ISO 9001 certification. Each of these is summarized below:

Deming Model

This model was created by Shewhart and perfected by Deming, developed on October 14, 1900, in Sioux City, Iowa. Dr. Deming, who was despised in the United States, is possibly best known for his achievements in Japan, where he devoted himself to teaching engineers and senior executives his concepts and methodology in quality management since 1950. "These teachings would radically change the Japanese economy." In this sense, the author explains that the Deming model is based on a process-oriented approach to business management, achieving great gains in product or service quality and reliability.

EFQM Model

This model was created in 1992 by the European Foundation for Quality Management (EFQM), and its main function is to "strengthen the position of European companies in global markets.",[6] with the aim of accelerating the acceptance of quality as a competitive advantage and the development of activities linked to continuous improvement, created especially to recognize Eastern European countries. The model consists of the evaluation of the following nine (9) criteria: leadership, policy and strategy, employee orientation, resources and relationships, processes, products and services, customer satisfaction, employee satisfaction, social responsibility, and results orientation. What characterizes this model is the separation between criteria related to results and those related to promoting agents, so that business results are evaluated in parallel with the evaluation of how the company acts today to be successful tomorrow.

Malcolm Baldrige Model

This model appeared in the United States in 1987, promoting three important characteristics: rewarding quality in order to increase competitiveness, understanding the requirements for excellence in quality, and sharing information and benefits derived from effective quality strategies employed by companies. In the same vein, the award given for compliance with this model "is not given for a specific product or service, but is given to companies that have world-class management to manage their employees and processes".[7] This model is based on seven (7) criteria to be evaluated in order to qualify for an annual award, including: leadership, strategic planning, customer focus, measurement, analysis and management improvement, people orientation, operations orientation, and results.

International Standard Model ISO 9001 Certification

This same international standard, ISO 9001, states that it promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system to increase customer satisfaction through the fulfillment of customer requirements. In addition, this standard incorporates the plan-do-check-act (PDCA) cycle and risk- and opportunity-based thinking, focusing on all the elements of quality management that a company must have in order to have an effective system that allows it to manage and improve the quality of its products or services. The potential benefits for a company implementing a quality management system based on this international standard are:

- The ability to consistently provide products and services that meet customer and applicable legal and regulatory requirements.
- Facilitating opportunities to increase customer satisfaction.
- Address risks and opportunities associated with its context and objectives.
- The ability to demonstrate conformity with specified quality management system requirements.

Continuous compliance with requirements and constant consideration of needs and expectations represent a challenge for companies in an increasingly dynamic and complex environment. To achieve these objectives, companies may find it necessary to adopt various forms of improvement in addition to correction and continuous improvement, such as abrupt change, innovation, and reorganization.

Comparison of Applicable Management Models, Deming, EFQM, Malcom Baldrige, and ISO 9001 Certification

These models are of great importance for companies to take into account when orienting themselves and clarifying their horizon, where to focus, and having a model adapted to the needs of the company. In these competitive times, the idea and interest in satisfying customer needs and ensuring that these needs are met over time arises, delivering high performance in processes through continuous improvement, taking into account the competition from other companies that serve as benchmarks in the comparison of these management

models, such as the Deming model, the EFQM model, the Malcolm Baldrige model, and the international quality standard ISO 9001:2015. As a result of this comparison, the ISO 9001 certification model will be recommended for Cardon Rent. Car C.A. promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system with the purpose of increasing customer satisfaction through compliance with customer requirements. Table 2 below shows a comparison of the origin and structure of the different management models to be compared in this study and applicable to the company to achieve the objectives set.

Table 2. Comparison of the Development of Management Models

	Deming Prize	**EFQM Award**	**Baldrige Award**	**ISO 9001 Certification**
Year of Creation	1951	1992	1987	1987
Basic Structure	Long-Term Award Term	Annual Competition	Annual Competition	Certification
Applicability Main Geographic	Japan	Europe	United States	Worldwide
Winners	Few	Very few	Few	Many

In relation to the table above, it is possible to see the difference in maturity due to years of use, with the Deming Award being the oldest, established in 1951. The models compared have a similar basic structure of annual competitions, with the Deming Award having a long-term structure and the ISO 9001 management model having certifications. The difference according to the study is that the international ISO 9001 certification places it in the model with the greatest applicability worldwide. The number of winners of each certification differs according to the management model. In the case of the Deming and Baldri , there are only a few winners, while there are very few winners of the EFQM award, but there are many winners of ISO 9001 certifications.

In conclusion, the international standard ISO 9001 was chosen from the four different models because it is a model that is more focused and applied to processes, risks, and opportunities, making it the most suitable for the company under study, as it revolves around customer satisfaction. given that today's world is very changeable and demanding. The ISO 9001 standard focuses on all the elements of quality management that a company must have in order to have an effective system that allows it to manage and improve the quality of its services with the aim of exceeding expectations. In short, all these models are global in scope, as their concepts are universal.

Basic Principles of Management Systems Based on ISO 9000

According to ISO 9001:2015, to successfully run and operate an organization, it must be managed and controlled in a systematic and transparent manner. The management of organization includes quality management among other management disciplines. Seven quality management principles have been identified that can be used by top management to lead the organization toward improved performance.

ISO 9001:2015 establishes that a quality management principle is a rule or fundamental belief for directing and operating an organization, focused on continuous improvement of long-term performance and centering on customers. Therefore, they are based on seven principles, which are:

1. Customer focus: organizations depend on their customers and therefore should understand their current and future needs, meet their requirements, and strive to exceed their expectations. To do this, the following activities must be carried out:
2. Leadership: leaders establish the unity of purpose and direction of the organization. They should create and maintain an internal environment in which people can become fully involved in achieving the organization's objectives.
3. People commitment: personnel at all levels are the essence of an organization, and their total commitment enables their abilities to be used for the benefit of the organization.
4. Process approach: this involves the systematic definition and management of processes and their interactions in order to achieve the intended results in accordance with the organization's quality policy and strategic direction. The management of processes and the system as a whole can be achieved using the pdca cycle.
5. Improvement: identifying, understanding, and managing interrelated processes as a system contributes to the effectiveness and efficiency of an organization in achieving its objectives.
6. Evidence-based decision making: continuous improvement of the organization's overall performance should be a permanent objective.
7. Relationship management: effective decisions are based on the analysis of data and information.

These seven principles of quality management form the basis of quality management system standards.

Advantages of the Management System

"List some of the advantages obtained from the definition, development, and implementation of a quality management system, including the following:

From an external point of view

- It enhances the company's image with current and potential customers by continuously improving their level of satisfaction. This increases trust in customer and supplier relationships, generating new revenue streams.
- It ensures quality in commercial relationships.
- It facilitates the export of products and services by ensuring that recipient companies comply with quality requirements, enabling penetration into new markets or the expansion of existing ones abroad.

From an internal perspective

- Improves the quality of products and services through more efficient processes for different functions within the organization.
- It introduces a vision of quality into organizations, promoting continuous improvement of internal and external operating structures and demanding certain levels of quality in management systems, products, and services.
- Costs decrease (non-quality costs) and revenues increase (possibility of reaching new customers, larger orders from existing customers, etc.).

International Organization for Standardization (ISO)

ISO (International Organization for Standardization) is a worldwide federation of national standardization bodies (ISO member bodies). This organization was created in 1947 and works to achieve a common way of establishing quality systems, ensuring that consumer needs and expectations are met. The work of preparing international standards is usually carried out through ISO technical committees.

ISO 9000 standards is the term used to indicate a family of standards relating to quality management systems. ISO 9000 standards have been developed to assist organizations of all types and sizes in the implementation and operation of effective quality management systems. ISO 9000 standards are based on the British national quality system standards, namely the BS 5750 series developed by the British Standards Institute in 1979.

Evolution of ISO 9001 Standards

Table 3. Evolution of ISO 9001 Standards

	Year
Requirements	ISO 9001:2015 This revision was launched to adapt the standard to the current reality of organizations. This is a very important and delicate change because ISO 9001 accounts for 80 % of all global certifications.
	Year 2008
	ISO 9001:2008 No major changes to highlight
	Year
	ISO 9001:2000 Incorporated changes in the effectiveness of the quality management system and improved organizational performance. Some experts said that this version moved from the concept of "conformance" to "performance."
	Year
	Year 1986/87
	ISO 9001:1987 Model for quality assurance in development, design, service, production, and installation. ISO 9002:1987 Model for quality assurance in production, service, and installation. ISO 9003:1987 Model for quality assurance in inspection and testing. These standards contained certain requirements that ensured quality wherever they were applied.

The ISO 9001 standard was created in 1987, and since then it has undergone revisions that have led to various updates to the standard. The latest revision corresponds to the 2015 version, which was completed with the publication of the standard on September 23 of that year. It was the precursor to all those that came after it in 1987, 1994, 2000, and 2008. Below is a summary of the standards from their inception to the present day (table 3).

Structure of the ISO 9001:2015 standard

On September 23, 2015, the new 2015 version was published. The revision of the standard arose from the need to adapt to the current times in which organizations find themselves. It presents changes in its structure.

The structure of the chapters is intended to provide a coherent presentation of the requirements, rather than a model for documenting an organization's policies, objectives, and processes. For ISO 9001:2015, on page 26, the structure of the ISO 9001:2015 standard is as follows:

1. Scope and field of application: the need to comply with the legal and regulatory requirements associated with the product is reinforced. Likewise, the term "product" is differentiated from "service."
2. Normative references: mentions the standards for consultation, but emphasizes the implementation of ISO 9001 with ISO 9000, which deals with fundamentals and vocabulary.
3. Terms and definitions: Serves as a reference and is continuously updated, with obsolete terms removed.
4. Context of the organization: this point discusses the need to understand the organization and its context, as well as the needs and expectations of interested parties, and to determine the scope of the quality management system. This point has the following structure:

Understanding the organization and its context

Understanding the needs and expectations of interested parties. 4.3 Determining the scope of the quality management system.

Quality management system and its processes.

5. Leadership: this chapter highlights the role of leadership alongside management. It reiterates the assignment of responsibilities and roles within the organization. It also emphasizes the participation of senior management in the management system. This point has the following structure:
    - Leadership and commitment.
    - Policy.
    - Roles, responsibilities, and authorities in the organization.

6. Planning: this chapter highlights the preventive nature of the standard, emphasizing the approach to risks and opportunities that arise in the organization. It also includes the planning of objectives and how to achieve them. The clause has the following structure:
    - Actions to address risks and opportunities.
    - Quality objectives and planning to achieve them.
    - Planning for changes.

7. Support: this chapter outlines the aspects necessary to support the management system and thus meet the organization's objectives and goals.
    - Resources.
    - Competence.
    - Awareness.
    - Communication.
    - Documented information.

8. Operation: chapter for the planning and control of all processes, both internal and external, which has the following structure:
    - Operational planning and control.
    - Requirements for products and services.
    - Design and development of products and services.
    - Control of externally provided processes, products, and services.
    - Production and service provision.
    - Product and service release.
    - Control of non-conforming outputs.

9. Performance evaluation: the monitoring of the effectiveness and performance of the management

system through measurements, analyses, evaluations, as well as audits and reviews by management, which has the following structure:

- Monitoring, measurement, analysis, and evaluation.
- Internal audit.
- Management review.

10. Improvement: this chapter emphasizes the importance of evaluating and implementing improvement actions in all components of the management system, as shown in the following structure:

- General.
- Non-compliance and corrective action.
- Continuous improvement.

In summary, this structure of the ISO 9001:2015 standard is fundamental to the operation of any company and can initially be associated with production processes. That is why companies have adopted measures to implement all their processes and be at the forefront of innovation, standing out among the first to comply with each of its clauses and gaining the trust of all their customers by obtaining this extraordinary certification, thus generating advantages in being recognized worldwide and establishing the necessary requirements that every organization must meet for subsequent certification and increased customer satisfaction.

CONCLUSIONS

Based on the analysis carried out, it is concluded that the implementation of a Quality Management System (QMS) based on the ISO 9001:2015 standard is an indispensable strategic tool for organizations that want to remain competitive, sustainable, and focused on continuous improvement. By focusing on processes, customer satisfaction, and risk management, the standard allows daily operations to be aligned with strategic objectives, which strengthens organizational performance and ensures compliance with international standards.

The national and international background information reviewed shows that different productive and service sectors have made significant progress by adopting this standard. Research show that the structure and approach of ISO 9001:2015 is suitable for organizations of various types, such as transportation, legal assistance, aircraft maintenance, food distribution, and roadside assistance. In all cases, the ISO standard was key to optimizing processes, documenting critical procedures, establishing more effective quality controls, and raising customer satisfaction levels.

It also confirms that the successful implementation of a QMS depends not only on technical knowledge of the standard, but also on the commitment of senior management, staff training, and the use of appropriate methodological tools such as process maps, checklists, internal audits, and performance measurement systems. These elements, integrated under a preventive and corrective approach, make it possible to identify opportunities for improvement, manage risks, and reduce non-conformities.

From a theoretical perspective, models such as Deming, EFQM, and Malcom Baldrige served as a comparative framework to highlight the advantages of ISO 9001 in terms of applicability, structure, global scope, and results orientation. The review of these approaches reaffirms that, although all promote excellence, it is ISO 9001:2015 that offers greater flexibility and adaptability for implementation in diverse organizational environments, making it a solid choice for companies seeking certification and growth.

In summary, the research confirms the importance of designing and implementing robust, sustainable quality management systems that are aligned with international standards. It also provides valuable methodological and conceptual foundations for future research seeking to strengthen the culture of quality in organizations of all types.

BIBLIOGRAPHIC REFERENCES

1. Avilez J. El estudio del trabajo en los sistemas de procedimiento de oficinas. 2007. http://www.gestiopolis.com/recursos/documentos/fulldocs/rrhh/woficina.htm

2. Solano F. Creación de un sistema de gestión de calidad en base a la norma ISO 9001:2015, para una firma de abogados en la República Dominicana. Caso de estudio: Dra. Kennia Solano & Asociados SRL. Santo Domingo: Universidad APEC; 2022.

3. Machado M. Formulación de un sistema de gestión de la calidad en empresas de servicios que ofrecen asistencia vial basado en la norma ISO 9001:2015. Caracas: Universidad Católica Andrés Bello; 2019.

4. Simat. Definición de sistema de gestión de la calidad. 2010. http://www.sma.df.gob.mx/simat/pncalidad.htm

5. Fleitman J. Negocios exitosos. México: McGraw-Hill; 2009.

6. Membrado J. Innovación y mejora continua según el modelo EFQM de excelencia. España: Díaz de Santos; 2007.

7. Rao Tummala VM, Tang CL. Strategic quality management Malcom Baldrige and European Quality Awards and ISO 9000 certification: core concepts and comparative analysis. Int J Qual Reliab Manag. 1996;13(3):8-38.

8. Albornoz JH. Diccionario de filosofía. Caracas: Vadell Hermanos; 2011.

9. Antonorsi M. Guía práctica de la empresa competitiva. Caracas: Centro de Artes Integradas, Universidad Metropolitana; 1999.

10. American Psychological Association. Guía resumida de uso del Manual de Normas APA. 7ª ed. 2020. https://normasapa.pro

11. Barrios. Manual de trabajos de grado de especialización y maestría y tesis doctorales. 3ª ed. Caracas: FEDUPEL; 2003.

12. Chávez N. Introducción a la investigación educativa. Maracaibo: Universidad del Zulia; 1994.

13. Chávez N. Introducción a la investigación educativa. Maracaibo: C.A. Columna Editora La; 2001.

14. Castillo y García. Manual del lenguaje de la calidad total. San Luis Potosí: Universidad Autónoma de San Luis Potosí; 1994. http://books.google.co.ve/books?id=g1xU8GNOFt4C

15. Camisón C, Cruz S, González T. Gestión de la calidad: conceptos, enfoques, modelos y sistemas. Madrid: Prentice Hall; 2006.

16. Díaz de Santos. El plan de negocios. España: Ediciones Díaz de Santos; 1994.

17. Dürsteler J. Los mapas conceptuales. Revista Infovis. 2004;(141). http://www.infovis.net/printMag.php?num=141&lang=1

18. Fernández R, Baptista P. Metodología de la investigación cuantitativa. 3ª ed. Caracas: FEDUPEL; 2012.

19. Fondo Norma. COVENIN-ISO 9001:2000. Caracas: Fondo para la Normalización y Certificación de la Calidad (FONDONORMA); 2001.

20. Gutzeit B. Charlas ISO 9000:2000. Caracas: Fondo Nacional para la Normalización y Certificación de la Calidad (FONDONORMA); 2000.

21. Hurtado J. El proyecto de investigación: un enfoque holístico. 3ª ed. Caracas: Sypal; 2000.

22. Hernández R, Fernández C, Baptista P. Metodología de investigación. 6ª ed. México: McGraw-Hill Interamericana; 2014.

23. Hernández F. Metodología de la investigación. México: McGraw-Hill; 2006.

24. Hernández Sampieri R. Metodología de la investigación. Madrid: McGraw-Hill; 2006.

25. Universidad Autónoma de Tamaulipas. ISO 9001:2015 - Principios básicos de los sistemas de gestión. http://www.sub-adm.uat.edu.mx/iso.html

26. Kaizen. Implicación de los principios de la gestión de la calidad. 2006. http://www.wikilearning.com/principio_5_enfoque_de_sistemas_para_la_gestion-wkccp-11150-6.htm

27. López D. Diseño de un sistema de gestión de calidad basado en la norma ISO 9001:2015 en la gestión de transporte de Transterre SAC. Lima: Universidad César Vallejo; 2020.

28. Méndez C. Metodología, diseño y desarrollo del proceso de investigación. Colombia: McGraw-Hill Interamericana S.A.; 2011.

29. Oñate J. Gerencia de procesos. 2007. http://www.gerenciadigital.com/artículos/proceso.htm#uno

30. Palella S, Martins P. Metodología de la investigación cuantitativa. 3ª ed. Caracas: [editor no especificado]; 2006.

31. Pérez JA. Gestión por procesos. 4ª ed. Madrid: EISIC; 2010.

32. Rodríguez E. Metodología de la investigación. México: Universidad Autónoma de Tabasco; 2006.

33. Strauss AL, Corbin J. Bases de la investigación cualitativa: técnicas y procedimientos para desarrollar la teoría fundamentada. 2ª ed. Medellín: Editorial Universidad de Antioquia; 2002.

34. Sabino C. El proceso de la investigación. Nueva ed. Caracas: PANAPO; 2002.

35. Silva J. Metodología de la investigación: elementos básicos. Caracas: Colegial Bolivariana; 2013.

36. Sierra R. Técnicas de investigación social. Madrid: Paraninfo; 2004.

37. Serna H. Gerencia estratégica: planeación y gestión – teoría y metodología. 9ª ed. Colombia: Editores 3R; 2006.

38. Tamayo M. El proceso de la investigación científica. 4ª ed. México: Limusa; 2003.

FINANCING

None.

CONFLICT OF INTEREST

Authors declare that there is no conflict of interest.

AUTHORSHIP CONTRIBUTION

Conceptualization: Franklin Jesús Piñerez Díaz, Eduvigis Sorrentino, Oscar Antonio Caldera Molleja.
Data curation: Franklin Jesús Piñerez Díaz, Eduvigis Sorrentino, Oscar Antonio Caldera Molleja.
Formal analysis: Franklin Jesús Piñerez Díaz, Eduvigis Sorrentino, Oscar Antonio Caldera Molleja.
Drafting - original draft: Franklin Jesús Piñerez Díaz, Eduvigis Sorrentino, Oscar Antonio Caldera Molleja.
Writing - proofreading and editing: Franklin Jesús Piñerez Díaz, Eduvigis Sorrentino, Oscar Antonio Caldera Molleja.