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ORIGINAL

Implementation of a Process-Based Quality Management System

Implantación de un Sistema de Gestión de Calidad Basado en Procesos

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ABSTRACT

Introduction: the research addressed the design and implementation of a Quality Management System (QMS) in accordance with ISO 9001:2015, considering its importance in the contemporary organizational context. Quality was recognized as a fundamental strategic axis for improving competitiveness, operational efficiency, and customer satisfaction in a globalized environment.
Development: the study focused on the principles, structures, and tools required by the standard, such as process maps, flowcharts, the PEPSC model, and the distinction between process and procedure. The types of processes—strategic, operational, and support—and their relationship to the value chain were identified. The basic elements of a process, process management, and the regulatory requirements distributed throughout the chapters of ISO 9001:2015 were also addressed. The process-based approach allowed activities to be organized in a logical, measurable, and results-oriented manner, strengthening quality control.
Conclusions: it was concluded that the ISO 9001:2015 standard is an effective tool for structuring organizational processes, improving institutional performance, and establishing a cycle of continuous improvement. Leadership, planning, adequate support, and staff participation were key factors in the sustainability of the implemented system. The standardization of procedures and process management provided a solid foundation for auditing, evaluating, and optimizing operations, consolidating a culture of comprehensive quality.

Keywords: ISO 9001:2015; Process Management; Quality; Organizational System; Continuous Improvement.

RESUMEN

Introducción: la investigación abordó el diseño e implementación de un Sistema de Gestión de la Calidad (SGC) conforme a la norma ISO 9001:2015, considerando su importancia en el contexto organizacional contemporáneo. Se reconoció la calidad como un eje estratégico fundamental para mejorar la competitividad, la eficiencia operativa y la satisfacción del cliente en un entorno globalizado.
Desarrollo: el estudio se centró en los principios, estructuras y herramientas requeridas por la norma, tales como mapas de procesos, diagramas de flujo, el modelo PEPSC y la distinción entre proceso y procedimiento. Se identificaron los tipos de procesos —estratégicos, operativos y de apoyo— y su relación con la cadena de valor. También se abordaron los elementos básicos de un proceso, la gestión por procesos y los requisitos normativos distribuidos en los capítulos de la ISO 9001:2015. El enfoque basado en procesos permitió organizar las actividades de manera lógica, medible y orientada a resultados, fortaleciendo el control de calidad.
Conclusiones: se concluyó que la norma ISO 9001:2015 constituye una herramienta eficaz para estructurar procesos organizacionales, mejorar el desempeño institucional y establecer un ciclo de mejora continua. El liderazgo, la planificación, el soporte adecuado y la participación del personal fueron factores clave en la sostenibilidad del sistema implantado. La estandarización de procedimientos y la gestión por procesos ofrecieron una base sólida para auditar, evaluar y optimizar las operaciones, consolidando una cultura de calidad integral.

Palabras clave: ISO 9001:2015; Gestión por Procesos; Calidad; Sistema Organizacional; Mejora Continua.

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INTRODUCTION

Quality in organizational management has become strategically important in today's business environment, which is characterized by dynamic markets, more demanding consumers, and intense competitive pressure. Given this scenario, organizations seek to ensure the efficiency of their processes, customer satisfaction, and continuous improvement through the implementation of standardized and structured systems. One of the most recognized and widely applied regulatory frameworks internationally is the ISO 9001:2015 standard, which establishes the requirements for a Quality Management System (QMS) focused on processes, leadership, and commitment to quality.[1]

The process-based approach proposed by ISO 9001:2015 allows for the identification, planning, implementation, control, and improvement of all activities necessary to achieve the desired results. This perspective facilitates a systemic understanding of the interactions between processes and how their proper management impacts the overall performance of the organization. From this perspective, the standard promotes an organizational structure capable of responding to customer needs and applicable legal and regulatory requirements.[2]

In this context, this research focuses on the study and implementation of a quality management model based on the ISO 9001:2015 standard, addressing everything from fundamental principles to practical tools such as process maps, flowcharts, the PEPSC model, and the differentiation between processes and procedures. It also explores the different types of processes—strategic, operational, and support—and their link to the organizational value chain.[3]

The purpose of this work is to provide a theoretical and methodological framework for understanding and effectively applying the key elements of a QMS in organizations seeking to optimize their operations. It begins with the identification of key processes, the assignment of responsibilities and resources, performance measurement, and the implementation of preventive and corrective actions to ensure product or service conformity. In addition, it considers the importance of leadership, adequate documentation, and staff participation as fundamental pillars of a successful quality management system.[4]

This research aims to contribute to the generation of knowledge applicable in business practice and to provide a solid foundation for organizations interested in adopting a structured approach aligned with international quality standards.

DEVELOPMENT

Quality Management System Approach

The Quality Management System approach involves all company structures in the pursuit of quality. According to Sierra[1], it should be noted that an approach to developing and implementing a quality management system comprises different stages, such as:[5]

1. Determine the needs and expectations of customers and other interested parties. The organization monitors information about customer satisfaction and dissatisfaction. The methods for obtaining and using this information must be defined.

2. Establish quality policy and objectives. The standard requires an express commitment from the company's management; this is a general activity that applies to all tasks and departments. Quality policies are formally expressed by senior management and provide a framework for establishing and reviewing quality objectives, which must be consistent with the quality policy and commitment to continuous improvement, and their achievement must be measured and have a positive impact on product quality. According to ISO 9001, senior management must ensure that the quality policy:
    - Is appropriate to the purpose of the organization.
    - Is communicated and understood within the organization.
    - Is reviewed regularly for continued suitability.

3. Determine the processes and responsibilities necessary to achieve the quality objectives. When defining and documenting the responsibility, authority, and interrelationship of personnel who direct, execute, and verify work that affects quality, particularly personnel who need authority and freedom. It is necessary to create a matrix of functions for the different administrative and technical positions involved in the operation of the company.

4. Determine and provide the resources necessary to achieve quality objectives. Senior management is responsible for identifying and providing the resources necessary to ensure the quality of products or services. These resources include audits of systems, processes, products, and suppliers, with personnel trained to use the resulting information as a mechanism for feedback and planning to implement the system.

5. Establish methods to measure process efficiency. In order to provide feedback on the efficiency and progress of the quality assurance system implementation process, it is necessary to design and implement the means to evaluate the procedures that will determine whether or not the planned expectations have been met.

6. Determine means to prevent non-conformities and eliminate causes. When the service does not meet the requirements, it is referred to as a non-conforming service, and the organization must define, develop, issue, implement, and maintain procedures for the control of materials and products that do not meet the requirements.

The Process-Based Quality Management System Model

As a first step in considering how to approach the process-based model in a quality management system, it is worth reflecting on how the ISO 9001:2015 standard establishes the structures for implementing it. The standard itself, in its introduction, establishes the promotion of the adoption of a process-based model in a quality management system to increase customer satisfaction through the fulfillment of their requirements. According to this standard, when this model is adopted, the importance of the following is emphasized:[6]

- Understanding and complying with requirements.
- Considering processes in terms that add value.
- Obtaining results of process performance and effectiveness.
- Continuously improving processes based on objective measurements.

The emphasis of the process-based model on these aspects serves as a starting point for justifying the structure of the standard itself and for translating this approach into the requirements in a particular way. In fact, the significance of the process-based model in the standard is so evident that the contents themselves are structured using this model, which in turn allows the interrelated requirements of the standard to be conceived and understood.[7]

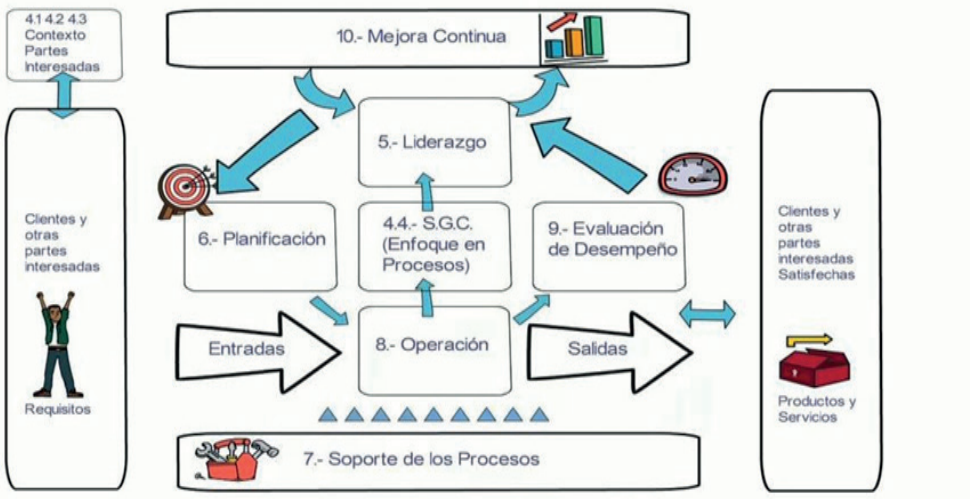
Within the context of the ISO 9001:2015 standard, the process-based model includes the processes necessary for the realization of the product and the other processes necessary for the effective implementation of the quality management system. The requirements for these processes are specified in the following chapters of the ISO 9001:2015 standard (table 1).

Table 1. ISO 9001:2015 Standard - Requirements

Item	Description	Chapters
	Context of the Organization	Chapter 4
2	Leadership	Chapter 5
3	Planning	Chapter 6
4	Support	Chapter 7
5	Operation	Chapter 8
6	Performance Evaluation	Chapter 9
7	Improvement	Chapter 10

Source: ISO 9001:2015

As an example of the above, figure 1 graphically shows the links between the processes introduced in the chapters of the reference standard:



Source: (DIS/ISO 9001:2015)

Figure 1. Model of a Process-Based Quality Management System

The ISO 9001:2015 standard on quality management systems and their processes is a fundamental part of establishing, documenting, implementing, and maintaining a quality management system, since an organization is made up of processes at all hierarchical levels, laying the foundations for the implementation of a quality management system.

Process Management

According to a study, "the ultimate purpose of process management is to ensure that all processes within an organization are carried out in a coordinated manner, improving effectiveness and satisfaction for all stakeholders".[9]

According to ISO 9000:2015, "process management is based on modeling systems as a set of interrelated processes through cause-effect links," and the process-based approach consists of "the systematic identification and management of the processes developed in the organization and, in particular, their interaction" (p. 08). Both concepts are closely related and should therefore be worked on together.

The ISO 9001:2015 standard promotes the adoption of a process-based approach when developing and improving the effectiveness of a quality management system with the aim of increasing customer satisfaction by meeting their requirements. This standard specifies in section 4.4.1 that "The organization shall determine the processes necessary for the quality management system and their application throughout the organization". Section 4.4.1 b) requires "determining the sequence and interaction of these processes" (p. 06). Both concepts are closely related and must therefore be worked on together.[10]

Based on the above, it can be concluded that process management is the way to manage the company as a whole, taking its processes as a basis and understanding them as a sequence of activities and tasks that generate value from an input to achieve a result that meets the requirements of the customer, whether internal or external. To deepen our understanding of the concept of process management, it is necessary to address certain basic concepts, which will be explained below:

Types of Processes

According to Camisón et al.[2], "processes can be divided into three types: strategic, key or operational, and support. This division is based on the impact they have on the final result. These processes are described below:

- Strategic Processes: these are the processes that guide the business by defining and controlling its policies, strategies, goals, and objectives. According to Camisón et al.[2], "these types of processes impact the entire organization because they provide limits and guidelines for all processes within the organization."
- Key or Operational Processes: these types of processes add value to the customer because they respond to the business's raison d'être, a study point out that "these are the processes that have a direct impact on the customer because they are generally the processes responsible for transforming inputs into goods or services according to customer requirements."[11]
- Support Processes: as their name suggests, these are processes that support core (operational or key) processes by providing the necessary resources and supporting their development.

Depending on the type of organization, the classification of processes may change. For example, a process that may be classified as a support process in one organization may be classified as operational or strategic in another organization, whether in the same industry or not.[12]

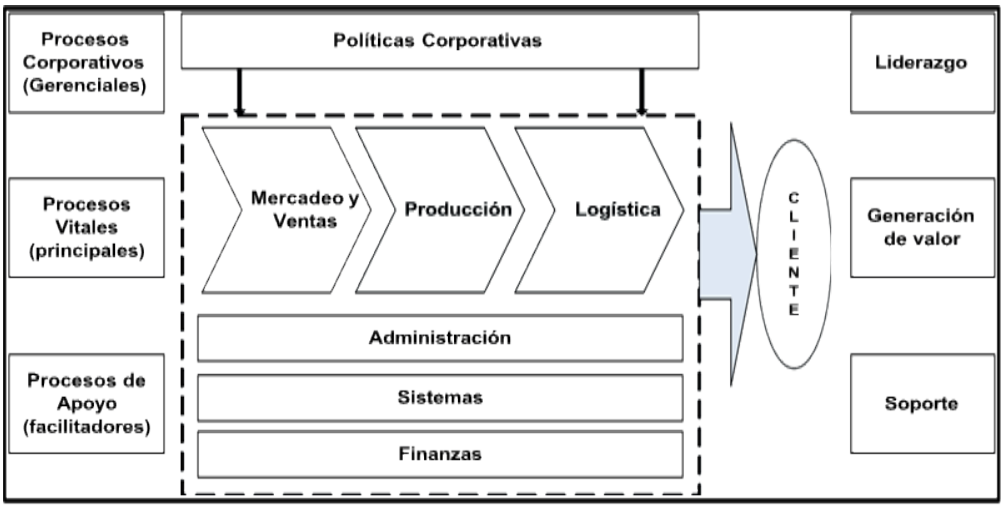


Figure 2. Process Map

According to a study, "the value chain (process map) is where the mission-critical (main) processes and their horizontal integration generate value in each interaction; strategic (or managerial) processes and their global direction, and support (or facilitating) processes as vertical drivers for the performance of mission or main processes, so that these ultimately produce a margin or value" (figure 2).

Suggestions for Creating a Process Map

These suggestions are provided by a study to facilitate the development of process maps. They are as follows:

- Involve people who know (focus on) "how it is."
- Clarify the boundaries of the process and define stages.
- Use verbs.
- Do not include who in the description of stages.
- Combine, eliminate duplicates, clarify stages, organize stages in the appropriate flow, and add arrows.
- Respect the boundaries.
- Do not start with a solution to the problem.
- Validate and refine before analyzing.

Elements of a Process

- Suppliers: organization or person that provides a product.
- Inputs: (requirements and resources needed to develop the product, from personnel to time, including software and hardware).
- Process: set of mutually related or interacting activities that transform input elements into results.
- Outputs: (results of the process).
- Customers: organization or person that receives a product.
- Control: (known control system (measures and indicators. Internal/external customer satisfaction level process).

Next, referring to a study, the definition of each group of processes in the value chain is detailed below:

- Management processes: these refer to the direction of the organization to project it into the future, maintain and improve its competitiveness, and monitor the company's relationships with customers and the environment in general.
- Processes specific to the core business lines (mission-critical or main): these are those whose product or result is received directly by the organization's external customer. They respond directly to the customer, so customer satisfaction depends on their effectiveness.
- Support processes: these are processes that support the execution of the core business processes, i.e., their product or result is received by another process or another area of the organization, or in other words, by an internal customer.

Process vs. Procedure

The ISO 9001:2015 standard is supported by a series of procedures and documented information required by the standard itself. This is why the procedures now called documented information according to ISO 9001:2015 are used to establish how an activity or set of activities should be carried out, emphasizing how the work should be done or how the different tasks should be performed.[13]

Table 2. Process vs. Procedure

Process	Procedure
Processes transform inputs into outputs through the use of resources.	Procedures define the sequence of steps to perform a task.
The processes behave behave; they are dynamic.	Procedures exist; they are static.
Processes are driven by the achievement of a result.	Procedures are driven by the completion of the task.
Processes are operated and managed.	Procedures are implemented.
The processes are focus on the satisfaction of customers and other stakeholders.	The procedures are on compliance with standards.
Processes contain activities that can be performed by people from different departments. With one common bjectives.	Procedures include activities that can be performed by people from different departments with different objectives.

Source: Pérez et al.[3]

Unlike a procedure, a process is responsible for transforming inputs into outputs, adding value to them. In order to carry out this transformation, a series of activities or tasks must be performed in a set order. Table 2 below presents the definitions of process and procedure according to ISO 9001:2015.

PEPSC diagram

The purpose of a PEPSC diagram according to a study is to "show an overview of the process. It identifies the main components of the process: suppliers, inputs, transformation activities, products or services, and customers." Each of these is mentioned below:[14]

- Suppliers: these are all suppliers, government entities, individuals, among others, who provide any input, material, or information intended to be transformed.
- Input: this includes the inputs, printed or electronic documents that will be processed and to which value will be added at the end of the process.
- Process: a series of linked activities or sub-processes that must be carried out to transform an input into an output with added value.
- Output: all products or services resulting from the transformation or modification of the process input.
- Customer: companies, public bodies, individuals, among others, who receive the outputs of the processes and are the most important components of the process.

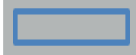
The PEPSC is used to standardize, within the work team, knowledge about the services and products of the unit or department, the inputs it uses, and its processes. The steps to follow to create a PEPSC diagram are:

1. Express the fundamental objectives of the department or unit in a concrete and specific manner.
2. List the customers of the department or unit.
3. List the services or products that the department or unit delivers, indicating the attributes that customers value about them.
4. Define the processes that lead to the provision of the service or delivery of the product.
5. List the necessary inputs, with the attributes that the department or unit values.
6. Identify the suppliers that provide the inputs for the process.
7. Identify the human, technological, and material resources necessary to carry out the process.

Flowchart

According to a study, "It is a diagram that graphically expresses the different operations that make up a procedure or part of it, establishing their chronological sequence. These flowcharts have the advantage of indicating the sequence of the process in question, the units involved, and those responsible for its execution. In short, it is the symbolic or pictorial representation of a procedure." (See Table 3), this will allow you to visualize how the system works, what the system will achieve, and how the system will be implemented. They can be used to provide the end user with a physical idea of how the data will ultimately turn out and how they affect the structure of the entire system.[15]

Table 3. Flowchart symbols

Symbol	Name	Description
	Start and end of process	Used to start and end a flowchart
	Process activity	The tasks in the process are described
	Process decision	Used in cases where decisions are made in the process
	Process reference document process	Documents to be used in the development of the process
	Process page connector	Used when connecting different tasks in the process
	Connector between process pages	Used when connecting the task flow on different pages in the process

Source: Cardon Rent. Car C.A.

It should be noted that, when creating process diagrams, the company should not produce excessive documentation, so it is advisable to adjust the level of detail that the process diagrams to be developed will have. This will ensure that only the necessary documentation is generated and that the process can be controlled and executed correctly.

Implementation of a Quality Management System

According to a study, "The application of ISO 9000 quality standards is a way for organizations to reduce costs and improve their production processes or services, bearing in mind that quality is a key factor for competitiveness in any market. The person responsible for standardization must be knowledgeable about this task, thus ensuring the incorporation of a procedure that is adapted to the reality of the process, useful, and easy to understand." With regard to the author's comments, as companies become increasingly interdependent across international borders, there will be growing pressure to ensure the quality of processes. In such an environment, there is a considerable set of international standards and a single international organization that makes the effort to promote them.[16]

In view of this globalization and the knowledge that a functioning quality management system creates the basis for "knowledge-based" decision-making, an optimal understanding between "stakeholders" and, above all, achieving increased business success through the reduction of failure costs (hidden costs) and friction losses, companies seeking to improve their organizational performance should begin implementing a quality management system based on customer focus, leadership, staff involvement, a process-based approach, systems-based management, continuous improvement, fact-based decision-making, and mutually beneficial relationships with suppliers.[17]

To begin implementing a quality management system, it is necessary to analyze work processes. A useful tool for this function is the process structure or process map. Once the process structure has been defined, the system is documented by developing or improving procedures and instructions, taking into account the documentation structure of the quality system (figure 3).

Figure 3. Structure of the ISO 9000:2000 Quality System Documentation

As represented by the documentation pyramid, the implementation of the quality management system begins at the third level, with the collection of plans, instructions, and records that provide technical details on how to do the work and record the results. These represent the fundamental basis of the documentation. Subsequently, the specific information on the procedures for each area of management is determined: Who? What? How?, When?, Where?, and Why? carry out the activities (2nd level), in order to generate the procedure manuals for each area.

The documented procedures of the quality management system must form the basic documentation used for the overall planning and management of activities that have an impact on quality. They must also cover all applicable elements of the quality management system standard. These procedures must describe the responsibilities, authorities, and interrelationships of the personnel who manage, perform, and verify the work that affects quality, how the different activities should be performed, the documentation to be used, and the controls to be applied. Some of the main objectives pursued in the development of procedure manuals are:

- Help establish better operations and activity programs.
- Provide a documentary basis for audits.

Basic Terms

Quality: according to a study a structured systematic approach that seeks the continuous improvement of work processes through the identification, quantification, reduction, and prevention of waste to achieve quality and excellence in products or services.[18]

External Customers: according to a study defined as someone who purchases or uses the company's services but is not part of the organization.

Operating Agreement: according to a study it is an agreement for works or services entered into by PDVSA or its operating subsidiaries with third parties to carry out certain operations without affecting the essence of the reserved activities.

System Approach to Management: according to Kaizen[4], it is identifying, understanding, and managing interrelated processes as a system that contributes to the effectiveness and efficiency of an organization in achieving its objectives.

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.

Process: according to Pérez[3], it is an orderly sequence of repetitive activities whose product has intrinsic value for its user or customer.

Quality Improvement: according to a study it is a structured process to reduce defects in products, services, and processes, used to improve results that are not considered deficient but nevertheless offer an opportunity for improvement.[19,20]

Process Map: according to a study it is based on systems theory, starting from the concept that a system is a set of interrelated principles, according to a logical arrangement, to achieve a specific objective.

Quality Plan: a document that establishes the operating practices, procedures, resources, and sequence of relevant quality activities for a particular product, service, contract, or project.

Variable Operationalization System

At this point, it basically consists of the research variable, where the aim is to rethink the variables and elements involved in the problem to be investigated and move from abstract knowledge to concrete and measurable knowledge through indicators. This structures the variable as a cross-cutting axis throughout the research process. Thus, if the researcher identifies, characterizes, and contextualizes the variables from the outset, they can be analyzed and measured with precision, validity, and reliability, so that meaningful conclusions can be drawn.[21,22] The following table details the variable and its definitions, dimensions, and indicators that will be used in the research (table 4).

Table 4. Operationalization system for the variable

Variable	Definition Conceptual	Definition Operational	Dimensions	Indicators	Number Indicators	Items of the Quality Management System
Quality Management System	ISO 9000:2015: it is a set of policies, processes, and procedures used by an organization to ensure that its products or services meet quality standards and satisfy the needs and expectations of its customers.	Quality management systems influence the company Cardon Rent. Car C.A., towards the monitoring and control of the services it offers, ensuring that these are improved every day through time and experience. In addition, they are interrelated to meet the quality requirements that an organization needs to satisfy the requirements agreed with its customers through continuous improvement in an orderly and systematic manner.	Leadership	Management commitment	5,1	1, 2, 3
				Quality policy	5,2	4, 5
				Organizational roles, responsibilities, and authorities	5.	6, 7, 8, 9
			Planning for the quality management system	Actions to address risks and opportunities.	6,1	10, 11
				Quality objectives and planning objectives to achieve them.	6.	12, 13
				Planning for changes	6,3	14, 15
			Support	Resources	7,1	16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30
				Competence	7,2	31,
				Awareness	7	36,
				Communication	7,4	38
				Documented information	7,5	40, 41, 42, 43, 44
			Operation	Planning and control Operational	8,1	45, 46, 47, 48, 49

				Requirement for the products and services	8,2	50, 51, 52, 53, 54, 55, 56, 57
				Control of externally obtained products and services 8,2	8,4	58, 59, 60, 61, 62, 63, 64
Quality Management System	ISO 9000:2015: It is a set of policies, processes, and procedures used by an organization to ensure that its products or services meet quality standards and satisfy the needs and expectations of its customers.	Management systems Quality influences the company Cardon Rent. Car C.A., in monitoring and controlling the services it offers, ensuring that these improve every day through time and experience. In addition, they are interrelated to meet the quality requirements that an organization requires to satisfy requirements agreed with its customers through continuous improvement, in an orderly and Systematic.	Operation	Production and/or provision of service	8,5	65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80
				Release of products or services	8,6	81, 82, 83, 84, 85, 86, 87, 88
				Control of the process of process outputs, products, and non-compliant services	8,7	89, 90, 91, 92, 93
			Performance evaluation improvement	Monitoring, measurement, analysis, and evaluation	9,1	94, 95, 96, 97, 98, 99, 100, 101, 102
				Internal audit	9,2	103, 104, 105, 106, 107, 108
				Management review	9	109, 110, 112,
				General	10,1	114
				Not compliance and actions corrective	10,2	115, 116, 117
				Continuous improvement	10,3	11

Source: ISO 9001:2015

CONCLUSIONS

This research established that the implementation of a Quality Management System (QMS) based on the ISO 9001:2015 standard is an effective and structured approach to ensuring continuous improvement, customer satisfaction, and compliance with legal, regulatory, and contractual requirements. Throughout the study, it was found that this standard provides a robust methodological framework that facilitates process management, adequate documentation, and systematic control of organizational operations.

One of the key findings was the usefulness of the process-based model as the core of the QMS. This approach allows for the identification, classification, and optimization of strategic, operational, and support processes, promoting a systemic and interrelated view of organizational activities. Tools such as process maps, PEPSC diagrams, and flowcharts proved essential for visualizing and structuring procedures, facilitating standardization, assignment of responsibilities, and performance monitoring.

Likewise, it became clear that the distinction between process and procedure is key to understanding how value and efficiency are added within an organization. While processes are geared toward transforming inputs into outputs with value for the customer, procedures ensure repeatability and regulatory compliance. Both elements, when properly managed, strengthen a culture of quality and evidence-based decision-making.

The theoretical review, accompanied by methodological proposals and the operationalization of variables, demonstrated that committed leadership, customer focus, strategic planning, adequate support, and continuous improvement are pillars that ensure the sustainability of the implemented system. The application of these principles not only improves internal results but also increases organizational credibility with external stakeholders.

It is concluded that the design and implementation of a QMS in accordance with ISO 9001:2015 is a strategic decision that enables organizations to efficiently manage their processes, reduce errors, document their performance, and achieve high levels of customer satisfaction. In addition, it provides a solid basis for internal audits, management reviews, and improvement actions, thus contributing to long-term organizational success.

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None.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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