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RESEARCH ARTICLE OPEN ACCESS

QMS development based on the iso 9001:2015 in an oncological Health Care Institute

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ABSTRACT
The purpose of this study focuses on evidencing the importance of the QMS in organizations, in this case within an institution that provides cancer health services, to guarantee the standardization of processes, increase continuous improvement and guarantee an adequate structure for the effective and efficient progress of internal processes. The ISO 9001: 2015 standard was consulted, which helped to identify certain limitations at the level of the design and development of products or services, since the Institutional reason entails a series of state policies that must be complied with. The methodology of this research included quantitative tools to know the internal applicability of this international standard and qualitative tools to analyze the statistical behavior of the processes, this through quality control charts, which helped to find a general acceptance rate of 68 % and regarding quality indicators, 48% must be compared with other institutions, 38% modified and 14% reassessed. Although the ISO 9001:2015 standard is currently being applied in manufacturing companies, this article aims to demonstrate its implementation in a health services industry where not only the institution's certification is recognized, but also the attention and reliability of the patients.

Keywords **-** Continuous improvement, efficiency, PDCA cycle, quality management, standardization

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I. INTRODUCTION

Improving medical quality by ensuring optimal conditions for patients is one of the challenges that the society is facing nowadays, especially in a health service system where the customer expectations are not always being met, according to WHO, one of the essential factors is the level of care in terms of promotion, prevention, treatment, rehabilitation, and palliation [1]. ISO 9001:2015 provides a model for QMS, which helps the alignment of processes with the PDCA cycle, where users and the organization can be favored using effective methods guided through indicators, standardization and risk identification that contribute to achieve continuous improvement in their models.

The first structure of the ISO 9001:2015 was primarily focused on manufacturing industry where the required system documentation was more complicated. The current version of this standard is more versatile and applicable to organizations or industries of any size [2]. This standard is also applicable to healthcare institutions that are committed to provide patients with quality people-oriented services and is increasingly recognized by society.

The development of a quality management system allows an entity to ensure compliance with a set of defined processes to meet the needs of its users through the standardization of the same, and that in turn all members of the organizational system are directed harmoniously to the same need, which is to meet the customer expectations [3]. Among the principles that ISO 9001:2015 entails can be found:

- Engagement of people
- Customer focus
- Leadership
- Process approach
- Improvement
- Evidence - based decision making
- Relationship management

On the other hand, this research identifies the organization as a system oriented to continuous improvement, risk prevention and identification of

opportunities. Currently, the oncological institute studied is facing the need to implement this international standard to guarantee the expectations of users, increase the agreements and achieve the certification. This, through the control and measurement of each of the procedures carried out by the institution, considering the internal order that this aims to achieve [4].

This work includes the development of a quality management system starting with a diagnosis of the institution's status regarding the percentage of application of the standard in the different fields, allowing to evaluate and analyze which ones should be reformulated to provide a higher level of compliance, in addition of complementing its progress through the identification and application of the standard in the most critical process, supported by a non-quality cost structure, which provides a clear perspective regarding the budget that should be considered to achieve its subsequent implementation.

II. METHODOLOGY

2.1 Initial diagnosis that allows the collection of data about the initial state of the institution with respect to the knowledge and application of the ISO 9001: 2015 standard

Analyze the capacity of the institution with respect to the knowledge of the applicability of the ISO 9001: 2015 standard in the various processes that are currently being carried out. This point will involve the quality area in order to learn more about how each of the different clauses are being carried out, on the other hand, direct communication with each of the areas is required to evaluate the performance of each one of the points by means of a diagnostic matrix elaborated based on this international standard [5].

2.2 Statistical control techniques that allow the analysis of the problems obtained in the critical processes carried out by the Institution

It is important to know that tools like control charts, among other statistical analyses, are the most accurate way to measure the criticality in the traceability processes, to identify whether these are being carried out under an adequate statistical control and above all if the tools applied or used in these processes keep a normalized proportion in relation to the expected results of the performance of these activities [6].

2.3 Results obtained from the development of the ISO 9001:2015 quality management system

Among the most relevant documents of the documentary pyramid, it is important to highlight that the quality manual is the one that includes the processes, clauses and regulations that are carried out within the organization and demonstrate the compliance and commitment that the institution has regarding performance of its SGC, and that is why the documents and recommendations acquired from the diagnosis must be contemplated in this, demonstrating the continuous improvement of the organization with respect to its mission processes [7].

2.4 Audit guidelines for continuous improvement in the institution regarding the services provided to users:

The audit consists of collecting and analyzing the data to periodically evaluate the status of the quality management system and report on the correlation rate between the data obtained and the standards stipulated by the standard, which is why it becomes essential. its application to achieve the respective continuous improvements and reviews by senior management.

2.5 Application of the ISO 9001: 2015 standard to verify the effectiveness of the initial diagnosis and the statistical analysis carried out:

It is important to know that what is stipulated in the quality manual and that those documents made from the diagnosis are improvement mechanisms for the institution itself, which is why its application in the most critical clauses allows evaluating whether its applications were correct [8]. In this case guided by the statistical control analysis carried out previously.

2.6 Financial analysis for the feasibility evaluation:

The financial analysis consists of the application of accounting methods to evaluate the profitability and the objective cost of the application of this standard within the institution, this in turn will help the evaluation of the operational capacity

and growth capacity when required to achieve the management adequate economic [9].

RESULTS AND DISCUSSION

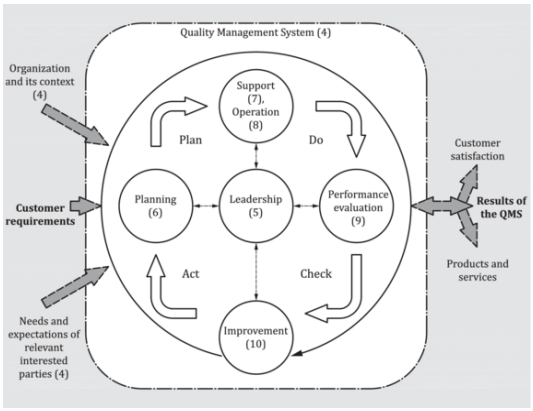
3.1 Diagnosis

The initial diagnosis is a fundamental tool to know the application of the international standard ISO 9001: 2015 within an organization, its theoretical flexibility allows analyzing from several essential points how advanced the execution of the standard is based on the customer focus, the leadership, staff engagement, process-based perspective, improvement, evidence-based decision making, and relationship management [10].

Additionally, compliance with the PDCA cycle must be verified within the executable chapters of ISO 9001: 2015, the fact that the same standard is based on this theory cannot be ignored, and even its normative structure contemplates that this configuration can be applied to any process [11].

Fig. 1 shows the relationship of the ISO 9001: 2015 standard with the PDCA cycle.

FIGURE 1 – The ISO 9001:2015 and the PDCA cycle



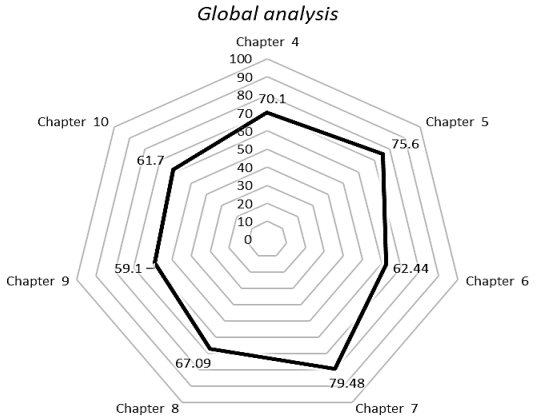
Source: ISO, 2015

Once determined the tool by which the diagnosis was going to be made, the theoretical structuring of the same was carried out, as previously mentioned, there are only 7 chapters of the standard that are executable within a quality management system. Despite containing each of the requirements of the standard, examples of documentation required to demonstrate compliance were added, it should be noted that this is a basis that can be excluded as soon as the applicability can be argued through a similar or complementary executable [12].

It should be clarified that the oncological institution had the implementation of this international standard as a basis, as they must consider the mandatory system of quality assurance, which is a national regulation applicable to the health sector that guarantees the quality of the services provided by each business unit.

Fig. 2 shows the compliance rate regarding each applicable chapter:

FIGURE 2. Global analysis of the ISO 9001:2015 diagnosis



Source: The Authors, 2021

To observe in detail the reason for the rating given, it was necessary to include feedback, this can be found as evidence in Table 1 which is including the changes that must be applied to increase the percentage of compliance and align the QMS with the requirements established by ISO 9001:2015.

TABLE 1 – Feedback from the QMS

Chapter	Feedback
4. Context	• Lack of evidence regarding the identification, monitoring and control of stakeholders and their needs • It is necessary to apply a tool that will allow to review the internal and external factors • It is required to document the QMS scope
5. Leadership	• A procedure to have the QMS reviewed by senior management is required • It is necessary to document the quality policy, establish guidelines and indicators

	that evaluate its execution • A tool to monitor leadership must be created
6. Planning	• Universal training on all targeted risks should be provided • Implementation of quality objectives • Matrix to review the quality objectives must be developed and implemented • The procedure related to change management must be implemented
7. Support	• Standardization of the process and inventory formats, based on infrastructure, monitoring and measurement equipment is required • It is necessary to measure awareness based on the institutional quality policy
8. Operations	• It is necessary to define the design and development of products or services as not applicable based on current regulations • The procedure for identification and contingency plans for non-compliant products or services must be executed
9. Evaluation	• Re-evaluate the current indicators in order to know their consistency with respect to the processes • All indicators should be applied to know the QMS feedback • Standardize the audit procedure including the ISO 9001 factor
10. Improvement	• Execute traceability to improvement processes • Elaboration and application of procedure for non-conformities • Run continuous improvement tools

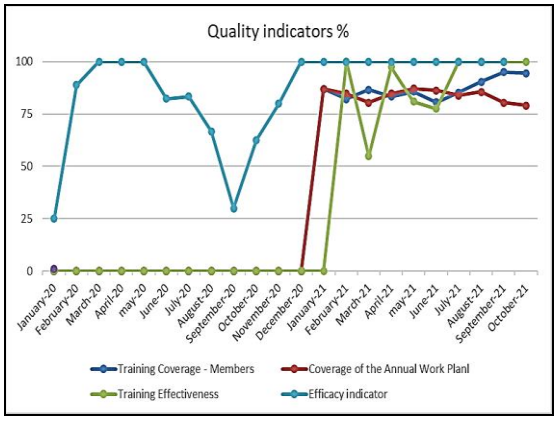
Source: The Authors, 2021

3.2 Statistical control for KPIs

According to the database obtained from the document management system, various analyses were carried out along development graphs, which constitute a contribution to the statistical control for the revision of the measurement in the tools that have currently been implemented within the organization, also allowed the elaboration of continuous improvement plans from a critical point of view.

Initially, the data was screened with the help of a macro developed in Excel, which facilitated the identification of those indicators that had constant information from their first capture, as shown in fig. 3. Additionally, this file was also manually filtered by those that had a monthly measurement of frequency and were directly affecting the QMS, as this guaranteed an adequate information for its correct analysis. Despite constituting a KPI as an organizational source of common affectation and application to all areas of the Institution, as it is known that some can affect more than others, this considering the critical success factors and the quality objectives themselves.

FIGURE 3 – Quality indicators



Source: The Authors, 2021

Tables 2 and 3 show the detailed description of the indicators with the respective recommendations to carry out an adequate analysis of these.

TABLE 2 – KPIs general analysis - Modify KPI

Metric name	Upper limit	Lower Limit	$\bar{x}$	% Upper limit	% Lower limit
OSH training	90	70	141	100	0
Training coverage	95	80	171	77	14
Inventory Reliability	5	10	0,05	100	0
Accounting closing compliance	2	5	-1,81	100	0
Compliance with Improvement Plans	80	60	83,7	50	40
% Requirement compliance	80	70	100	100	0

Compliance Work Plan	95	80	127	77	5
Efficiency of Sessions, Rounds and Measurements	85	65	150	60	10
Request response efficiency	80	70	100	100	0
Delivery management	95	80	98,9	100	0
Institutional Income	100	96	100	40	20
Adverse events – Medication administration pharmaceutical service	5	20	0,01	100	0
Clinical follow-up	95	80	108	68	14
Overall satisfaction rate	96	80	99,5	100	0
Time	15	20	7,07	95	0

Source: The Authors, 2021

TABLE 3 – KPIs general analysis - Change KPI limits

Metric name	Upper limit	Lower Limit	$\bar{x}$	% Upper limit	% Lower limit
Training Coverage - Members	90	70	87,0	33	70
Annual Work Plan Coverage	80	60	83,9	90	10
Training effectiveness	80	60	90,0	78	11
Efficiency in accounting records	10	30	4,42	95	5
Effectiveness indicator	80	70	86,6	81	19

Source: The Authors, 2021

3.3 Quality manual

One of the techniques implemented to update the manual according to the ISO 9001:2015 standard, was the joint evaluation with the Institution where the project was carried out, because in this way each of the identified needs were going to be covered from an external and an internal view, which did not leave aside any information gap nor bias the information to a purely investigative perspective but also practical.

The procedures referenced by chapter in order to check the alignment of the QMS with ISO 9001:2015 standard, are being highlighted below in Table 4.

TABLE 4 – Documentation by chapter of the quality manual

Chapter	Associated documents	PDCA
Chapter 4. Context	• SWOT, IFE and EFE Matrix • Stakeholder identification • Elaboration of documents SOP • Process map • Attention model	Plan
Chapter 5. Leadership	• Leadership and commitment verification • Induction, re-induction, and training • Satisfaction measurement • Active search for adverse events • Event reporting, investigation, and analysis • Organizational context analysis • Quality policy and guidelines • Quality policy evaluation	Plan
Chapter 6. Planning	• Risk management policy • Risk management • Risk control • Quality objectives • Quality objectives matrix • Change management • Change management monitoring	Plan
Chapter 7. Support	• Maintenance of medical equipment, infrastructure, and inventory SOP. • Application, attraction, verification, hiring and retirement of human resources • Process characterisation • Functions, competencies, job profiles and revision. • Quality policy evaluation • QMS communications matrix • Internal communication • Institutional communication	Do
Chapter 8. Operations	• Documented procedures • Communication strategies • Complaints, claims, suggestions, and congratulations procedure • Legal matrix • Technical reception • Supplier management • Selection of pharmaceutical products • Production of central mixing plant	Do

	• Distribution of pharmaceutical products • Handling and filling in clinical records manual • Storage practices	
Chapter 9. Evaluation	• Generation and analysis of indicators • Measurement of satisfaction • Reception, processing and improvement plan for complaints, claims, suggestions, and congratulations. • Internal and external audits • Audit programme • Management review	Check
Chapter 10. Improvement	• Research reporting and event analysis • Improvement management • Continuous quality improvement audit plan	Act

Source: The Authors, 2021

It is important to note that section 8.3 Design and development of products and services, belonging to chapter 8. Operation, of ISO 9001:2015, is not applicable to the institution, therefore this exception was defined in the scope of the QMS, this due to the institutional reason of the oncological entity governed under the Obligatory System of Quality Assurance in Health.

3.4 Audit

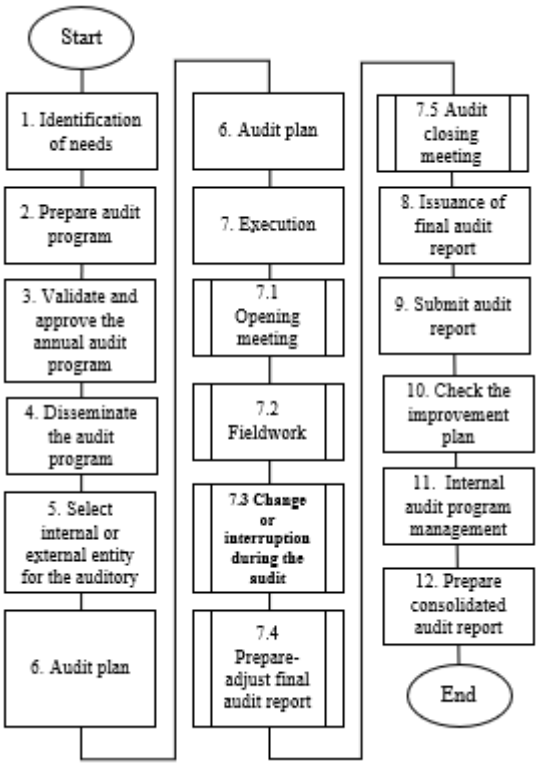
The audit plan is one of the key factors that help the QMS to maintain an environment of continuous improvement through each of its findings, that is why ISO 9001:2015 includes performance evaluation in one of its sections, where not only the management indicators play a very important role, but also the review process itself.

On the other hand, it should be clarified that the success of the organisation not only depends on this process, as the leadership must also be very attentive to the correct execution of tasks, monitoring, and the feedback that the process is constantly providing.

For the development of the audit plan in the Institution, ISO 19011:2018 was considered, since this one dictates the guidelines for the effective progress of this procedure and is very precise in dictating the criteria that must be followed to carry it out in a relevant way. It dictates 7 principles such as integrity, impartial presentation, due professional care, confidentiality, independence, evidence-based approach, and risk-based approach [13].

The above can be seen in fig. 4, providing a better understanding of the procedure carried out complying with each requirement identified.

FIGURE 4 – Audit flow chart



Source: The Authors, 2021

3.5 Implementing improvements to quality KPIs

During the course of the project, short, medium and long term goals were established in order to guarantee the correct execution of the recommendations and indicators established in the second objective, which would later allow a new analysis to be carried out in order to endorse the suitability of the application of these improvements and thus elaborate new development graphs that would allow the effectiveness of the actions established under the identification of deficiencies found in the diagnosis based on the ISO 9001:2015 standard developed in the initial phase to be evaluated.

On the other hand, the KPIs were applied again, considering the limits previously analysed and established as shown in table 5, in order to verify past and present behaviour with an additional month

of application, guaranteeing the correct execution of the improvements identified within the measurement process, the most critical according to the diagnosis initially elaborated.

TABLE 5 –KPIs with limit settings

Metric name	Upper limit	Lower Limit	Points over the new upper limit	Points under the new lower limit	$\bar{x}$
Training Coverage - Members	87	70	4	5	87,4
Annual Work Plan Coverage	84	60	8	2	85,4
Training effectiveness	90	70	6	4	89,6
Efficiency in accounting records	5	25	6	12	4,4
Effectiveness indicator	85	75	15	7	87,2

Source: The Authors, 2021

With the new limits, it can be remarked in the future how the areas are committed to the fulfilment of the goals, in terms of the implementation of the recommendations and thus give increasing support to the continuous improvement required by the ISO 9001:2015.

It should be noted that in the diagnosis initially developed and based on the PDCA cycle within the ISO 9001:2015 standard, chapter 9 was one of the chapters with the lowest average score, which is why the measurement and validation of the management indicators was focused on, in addition to guarantee the application of the gaps found in the quality manual.

3.6 Non-quality cost analysis

In order to elaborate a financial analysis for the assessment of feasibility in the implementation of this development for the institution, the PEF (prevention, evaluation and failure) cost evaluation methodology proposed by Feigenbaum and Juran has been adopted by the American Society for Quality Control and by the British Standard Institute for the required compliance [14].

On the other hand, the methodology identifies the elements of the cost of quality, which are those activities that can be associated with each of the cost categories as they affect the quality of the institution.

After identifying the elements, the costs involved are considered, which is why it was important to know the cost per hour of the different professionals who interact in each of the services, in addition to the costs per service that varies according to the type of pathology, the length of stay, the application of medicines, and the professional in charge. These can be reviewed in tables 6 and 7.

The following formula was used to calculate the costs of each of the established elements.

$$\sum_{i=1}^{n} (Actor's\ hourly\ rate\ x\ hr) + Input\ cost + Service\ cost$$

TABLE 6 – Quality costs

QUALITY COSTS	
PREVENTION COSTS	EVALUATION COSTS
$64.669.362 COP	$25.157.896 COP
50%	20%

Source: The Authors, 2021

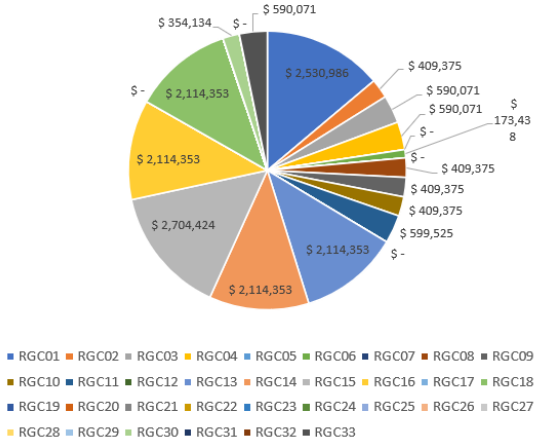
TABLE 7 – Non-quality costs

NON-QUALITY COSTS	
INTERNAL FAILURE COSTS	EXTERNAL FAILURE COSTS
$18.227.632 COP	$20.522.790 COP
14%	16%

Source: The Authors, 2021

On the other hand, fig. 5 shows the behaviour of these costs (COP) with respect to the category and the code of the risks present in the institution, in addition to observe a trend in the costs of prevention since it has a high participation in the risks. evaluated.

FIGURE 5 – Costs with respect to risk category



Source: The Authors, 2021

Conclusion

ISO 9001:2015 is an international standard that can be applicable to any type of organisation. In this research case, despite having an initial diagnosis with a percentage of applicability that did not exceed 70%, it was possible to carry out adequate documentation to obtained certification for the oncological entity, in addition to generating new measurement strategies for proper continuous improvement and promoting an environment of feedback for the optimal iterative operation of the QMS.

A key factor to continue with the management of the QMS is the audit and leadership processes, which must be supported by the application of verification procedures for both the measurement tools and the feedback that is being presented. In addition to ensuring that improvement plans are implemented in accordance with the planning established for each one.

According to the cost structure, it was validated that the sub-processes of document management, user care, audit plan for continuous improvement and enabling system to represent a total of 72% of the planned budget. In addition, it is established that 30% are non-quality costs and 70% are quality costs.

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