

Roadmap For The Implementation Of The Quality Management System In Smes In The Industrial Sector

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ABSTRACT:

This study presented the design of a route to carry out the implementation of a Quality Management System (QMS), under a methodology of continuous improvement, based on the Deming cycle or PHVA (Plan, Do, Check, Act), as a guide for the Kaizen method in which the chapters of ISO 9001:2015 were incorporated, in addition to making use of the 5'S philosophy as a corrective tool; on the other hand, initially a diagnosis was developed that shows the context and degree of compliance with the regulations, following this an analysis of the results obtained was carried out and a contribution was made in the documentation of the processes of each entity and finally a structuring to the route for the implementation of the QMS, contributing to the competitiveness, effectiveness, and efficiency of the organizations and compliance of each of its products.

Keywords: Deming cycle, Kaizen philosophy, ISO 9001:2015, route.

1. INTRODUCTION

The ISO 9001:2015 standard is the guide that stipulates the parameters that must be taken into account for a Quality Management System and is in turn the general strategy on which an organization or company can base itself to carry out the correct design and development of each of the processes (Arciniegas & Gonzalez, 2016). Based on this, both internal and external environments were taken into account, where each of the shortcomings and erroneous methods were identified to evaluate and assess the processes that require improvements in their execution, having within this research the use of ISO 9001:2015 regulations, being this the standard that allows the assessment and implementation of new measures that contribute to the effectiveness of quality in each area of a company or organization and to structure the phases required to establish a Quality Management System.

A quality management system (QMS) is a way of working, by which an entity ensures the satisfaction of the expectations and requirements of customers. Having as a focus to plan, maintain and continuously improve the productivity of the processes, under a guide of efficiency and effectiveness that allows it to achieve competitive results (Johana et al., 2018; Montesinos, 2008; Yañez, 2008). From the above mentioned this was the main variable in which we worked with this research because it is the main problem that was identified within these entities and in turn provided a guideline that allows SMEs in the industrial sector to be able to adjust their environments to give way to an implementation of the QMS.

Therefore, the research was structured and divided into a total of 3 phases, where in the first place an initial approach was made by performing a diagnosis with which, through tools such as the SWOT analysis supported by a CAME analysis, a survey and observation formats such as a checklist, the current situation of the SMEs was identified, which was the basis for this study, having precise characteristics of how they are in their internal and external context; Secondly, an analysis was performed using the Pareto diagram with which the results obtained in the diagnosis were evaluated and analyzed, which allowed identifying the sections that have less similarity to take into account within the implementation of the quality management system and that should be addressed initially; in addition to this, the documentation of the processes of the SMEs was performed, giving a contribution in terms of the documented information of the standard and thus having a start in the adjustment for the SMEs of the industrial sector to comply with the provisions of ISO 9001: 2015.

As for the third and last place, the design of the route for the implementation of the Quality Management System in the companies belonging to the industrial sector of the municipality of Chitagá was established; through the use of the PHVA cycle (Plan, Do, Check and Act) and as a starting point the KAIZEN philosophy to incorporate the requirements of the standard and incorporation of the 5'S method, the execution model was established on which the SMEs of this sector will be based to implement this system and obtain greater efficiency and effectiveness in their processes and in the satisfaction of the needs and expectations of customers.

2. METHODOLOGY

Descriptive research is that description, registration, analysis or potential interpretation that is given to an environment or nature and how the phenomena that make up a being or thing are composed or structured (Tamayo, 2004). Based on the previous concept, this type of research is retaken in this project, which was based in great part and in the same way it was also worked by means of an exploratory one, having the sources with which the purpose of this purpose was reached in the industrial sector of the municipality of Chitagá, Norte de Santander.

In addition, it was based on a mixed approach, both quantitative and qualitative, with the purpose of following a sequence and established order to collect the most relevant information and data within the population under study; making use of numerical measurements and analysis of instruments such as observations and review of bibliographic material that contributed to the development of the research.

2.1. Población y muestra

For this research, the population under study were the SMEs that are within the industrial sector of the municipality of Chitagá, Norte de Santander.

In this study the sample was non-probabilistic, because the collection and selection of the elements or companies does not depend on probability, but on the causes that are related to the characteristics that frame the variables that were worked and that this led to obtain significant results for the population and likewise for the researcher.

Inclusion Criteria

- Companies residing in the municipality of Chitagá.
- Companies within the industrial sector of the municipality.
- Companies that have legal regulations.
- Companies that have constant production.
- Companies that voluntarily want to participate in the research.
- Companies that provided information for the development of the research.

Exclusion Criteria

- Companies that do not reside in the municipality of Chitagá.
- Companies that are not within the industrial sector of the municipality.
- Companies that do not have the required legal documentation in order.
- Companies that do not have constant production.
- Companies that do not want to participate voluntarily.
- Companies that did not provide information for the development of the research.

2.2. Instruments and procedure

This study was approached under instruments such as a survey, a self-diagnosis checklist, a SWOT analysis, a CAME analysis, with which the first stage was fulfilled obtaining the diagnosis that evidenced the internal and external context of each of the SMEs under study; Then, a Pareto diagram, a process flow diagram and a process map were used to carry out a deeper analysis of the similarities in compliance with the requirements of the regulations and the development of the documentation of each of the processes contained in the operational part of each of these organizations.

As for the design of the route, continuous improvement tools such as the Deming or PHVA cycle, the Kaizen method, the 5'S and the ISO 9001:2015 standard were used, which were key to the structuring of this model.

3. RESULTS

3.1. Diagnosis of the context of SMEs

During this stage, visits to the companies were initially carried out, presenting the research proposal for the beginning of the project. Next, the analysis of the data collected from the

companies was carried out through the use of the Minitab 18 program, based on the use of the Excel program. Based on the aforementioned, the following are the instruments applied, such as the diagnostic survey, the checklist and a SWOT analysis supported by a CAME analysis; with which the characteristics of the internal and external environments of the SMEs are identified and with an analysis respectively for each one of them.

Within the SMEs that were linked under the inclusion criteria within this study, we have a diversity of the main micro-enterprises of the industrial sector of the municipality of Chitagá, Norte de Santander, Colombia, as shown in Figure 1.

Consequently, in these SMEs the different stakeholders were identified within their process and operation finding shareholders, public administrations, customers, media, suppliers, society in general, partners, workers and universities; with which it is evident that within the environments of these entities there is a great scope interested in its execution and that it contracts benefits for all these entities. On the other hand, there is evidence of marked affectations within the knowledge of the ISO 9001:2015 standard as shown in Figure 2.

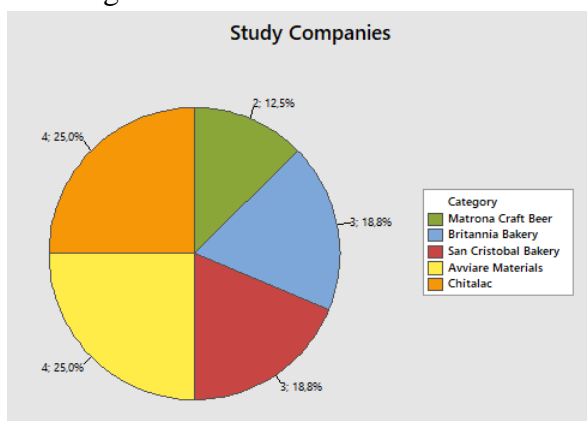


Figure 1. SMEs object of study within the research.

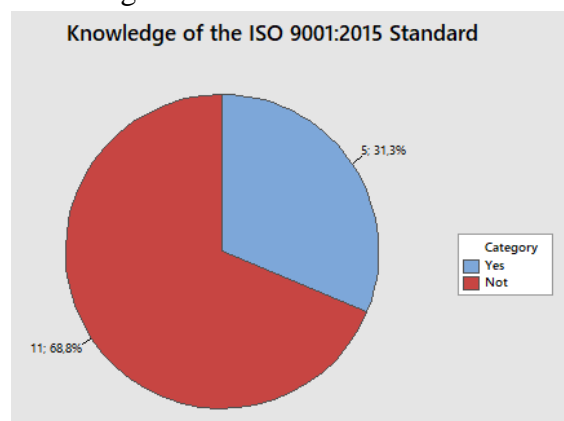


Figure 2. The knowledge that managers and workers have about the ISO 9001:2015 Standard.

This showed that the entities do not have within their perspective how those who have the direction of these should reach a higher focus to give a better result to the final consumers through the use and application of these regulations. On the other hand, there is a lack in the transmission of the benefits offered by these SMEs to the workers, as shown in Figure 3, which does not corroborate whether these requirements are actually met by these entities and denotes the risk run by the members linked in their daily workdays.

On the other hand, it could be identified that within the micro-enterprises under study there is excellent compliance in determining and providing sufficient resources required by reporting to their suppliers to comply with the elaboration of their products, as shown in Figure 4.

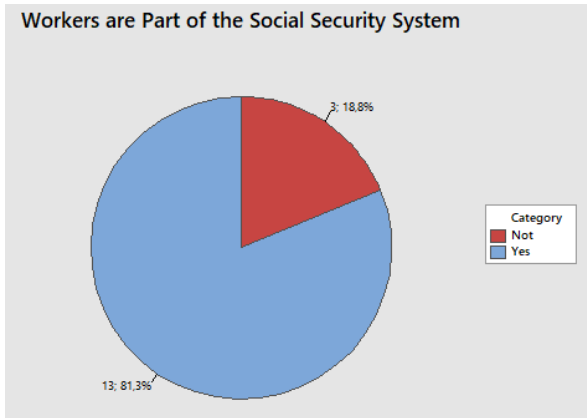


Figure 3. The workers are covered by the social security system provided by the SMEs.

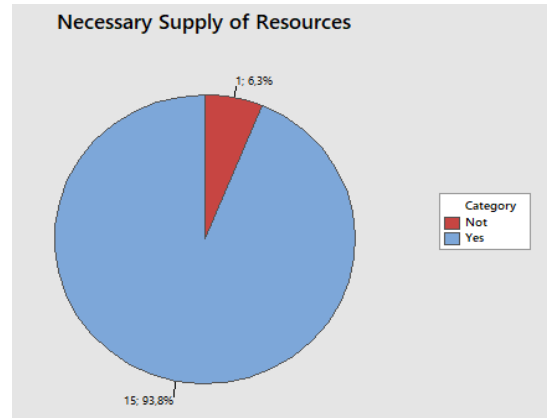


Figure 4. Planning to determine and provide the resources required for the operation from external suppliers.

Therefore, they have a good preparation process for the operational part with which they do not present delays or delays to execute operations and develop each of their products. Similarly, the evaluation and analysis by the SMEs regarding the measurement of sales and the execution of the products they manufacture show a high percentage of measurement as shown in Figure 5, where it is identified that there are forecasts of how sales are developed but there is a percentage of lack, which although it is not very high, has a great impact on them because it generates that production is not controlled under the sales levels and there are overflows of more or less products manufactured.

In the same way, it is presented within the SMEs the part where a follow-up and measurement must be made to each one of the processes and products to have a clarity of how they are being executed and thus to be able to have the necessary for any fluctuation or contingency that may arise, for which it is observed in Figure 6, that a percentage is generated that allows identifying a great impact that is formed by not executing by the entities a control in these processes that are affecting the operative and sales part which consequently generates losses and a higher cost within these.

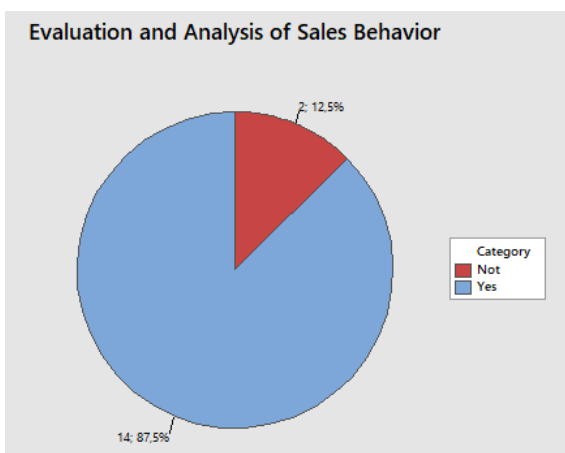


Figure 5. Evaluation and analysis by SMEs to measure sales performance and product execution.

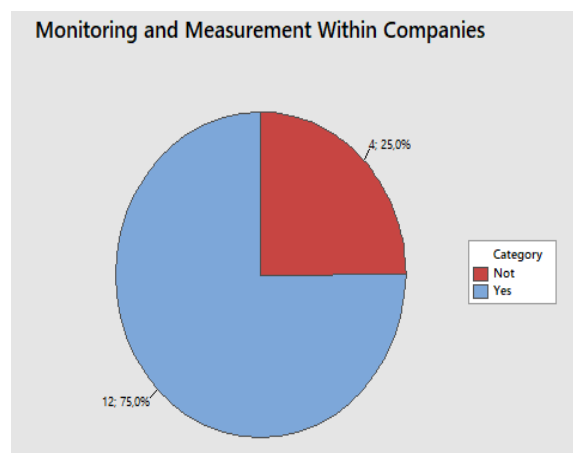


Figure 6. Determination of whether monitoring and measurement of the execution.

processes or operations of the SMEs has been developed.

SMEs have initially established training processes but they are not constantly reinforced, which generates that workers find themselves in situations where they do not have a clear understanding of how to deal with a nonconformity and this is due to the fact that as shown in Figure 7, where it is identified that these companies do not present clear information on whether they have an action plan or if this is not made known to the vast majority of workers, which generates misinformation and thus a bad approach to the contingencies that arise within the operational processes, which causes the production level to have noticeable declines in the supply to customers.

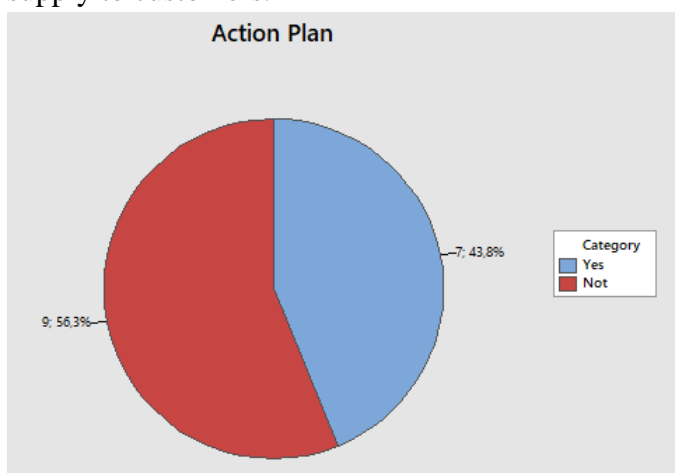


Figure 7. SMEs have an action plan in place to address nonconformities.

In addition to the above, it was identified within this phase of the research that SMEs in the industrial sector have deficiencies, taking into account that the context of these is a very fluctuating environment in which stakeholders are the most important approach; In addition, there are marked affectations in terms of the standard, but it should also be mentioned that from this diagnosis comes to light the problem initially raised, which consists of a lack of quality management system in which a lack of knowledge was denoted, that if we had it, we could readjust the entire operation of the entities and thus strengthen the results.

With respect to this, other aspects that were identified in this study are that there is an 80% lack of structuring a quality policy and its objectives to establish a focus or guide to the development of processes and products; on the other hand, the organizations do not contemplate formats to keep the information documented and from there to create and update it; with respect to the control that must be carried for the output of the process, products and nonconforming services are efficient in a large percentage without detracting that there are shortcomings but that do not affect them to a great extent. Likewise, the management does not encourage thoughts of continuous improvement to improve efficiency and effectiveness, which limits the growth of these microenterprises.

As for the information collected in the application of the Checklist instrument, which is made up of the items of the ISO 9001:2015 standard, a more specific and detailed perception was taken to measure what the SMEs in this sector have to give a deeper contextualization with

respect to the regulations in which the perspective of the managers was taken and what the researcher evidenced; so that in Figure 8, the results are evident at the general level of the microenterprise Britania.

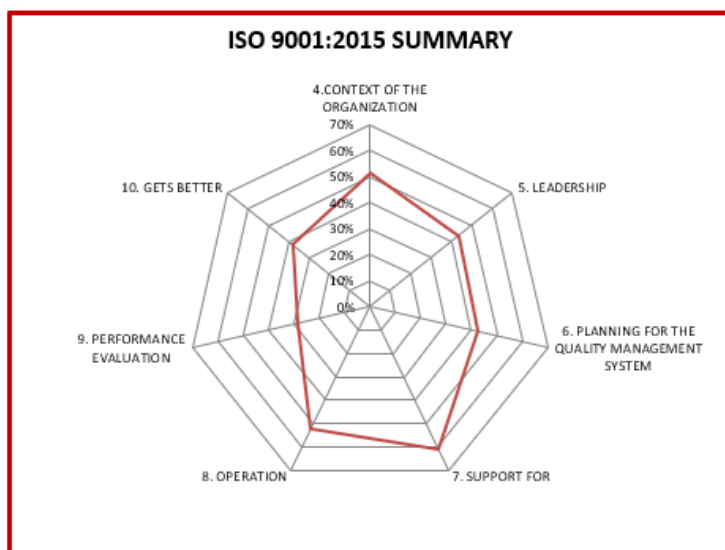


Figure 8. Degree of compliance with regulations by the Britania microenterprise.

In accordance with Figure 8, it can be identified that there is a deficit that affects the evaluation in the performance and implementation of improvement within the company, because the monitoring and measurement of processes, customer satisfaction is in a medium percentage of compliance and also internal audits are not performed and a constant review of its operation is not being executed; but nevertheless there is a strong support from senior management and in the operation of the entity which contributes to comply with the conformity of products and customer satisfaction partially. Figure 9 also shows the general correlation of the ISO standard requirements with those of the San Cristóbal SME.

According to what was observed in Figure 9, it can be identified that there is a deficit that affects the performance evaluation, where internal audits are not performed to evaluate the correct execution of the processes, nor is there a constant review of their operability and productive capacity, as in leadership, there is a total lack of quality policy, which highlights a lack of commitment from the top management within the company, but nevertheless there is a strong support from the top management, in the operation of the entity and in the context of the organization, which contributes to partially comply with the conformity of the products and customer satisfaction. Figure 10 shows the results of compliance with the standard in the company Cerveza Artesanal Matrona.

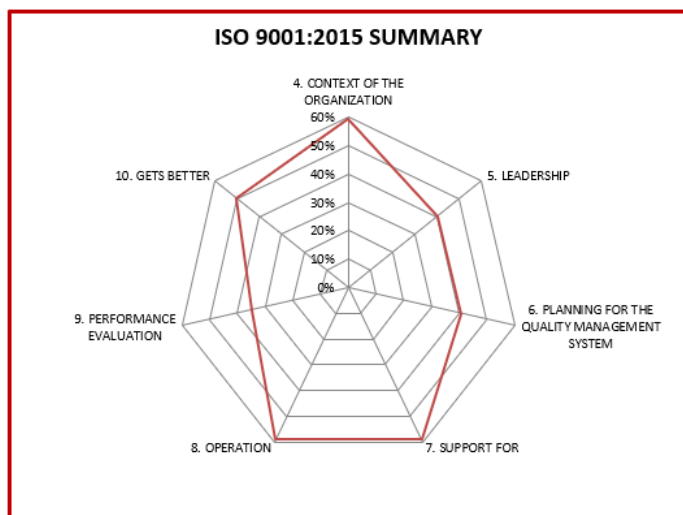


Figure 9. Degree of compliance with regulations by the San Cristóbal microenterprise.

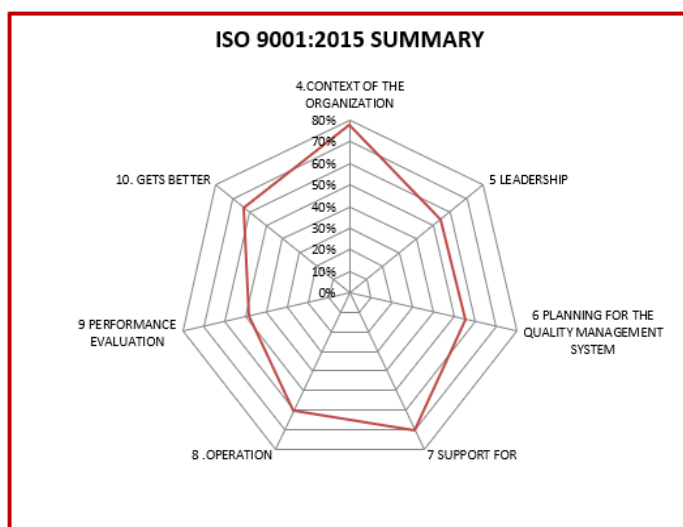


Figure 10. Degree of compliance with regulations by the microenterprise Cerveza Artesanal Matrona.

In accordance with Figure 10, it can be identified that the performance evaluation has a good monitoring and measurement of each of the processes, in addition to having excellent customer satisfaction results, but even with this, internal audits have not been carried out to evaluate that everything is being executed correctly under the parameters established within the company, but nevertheless there is a strong in the context of the organization, which contributes to comply with the conformity of the products, taking into account how it is distributed for its operational capacity. On the other hand, we have the level of compliance of the SME Chitalac in terms of regulations as shown in Figure 11.

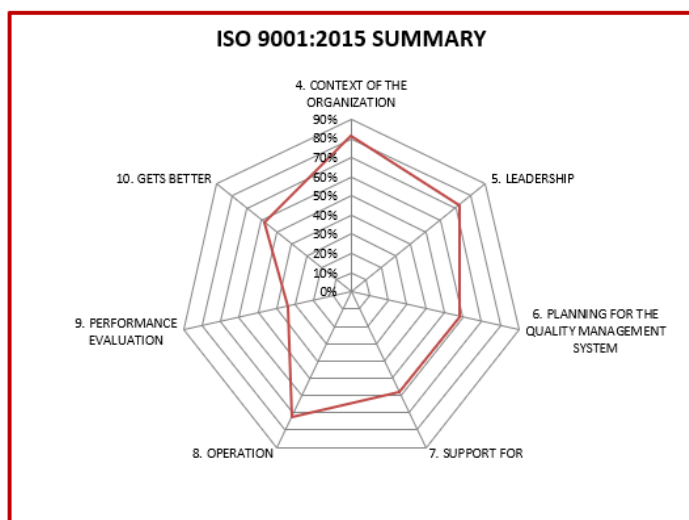


Figure 11. Degree of compliance with regulations by the Chitalac microenterprise.

Based on Figure 11, it is identified that there are some shortcomings within the chapter of the performance evaluation where the monitoring and measurement of each of the processes as well as customer satisfaction are at an average level of compliance but as for the internal audit and the constant review by managers are in very low percentages which gives cavity to defective products and inadequate storage times as affectations in the development of products giving nonconformity of these but on the other hand, there is a strong in the context of the organization which contributes to comply with the conformity of the products taking into account that they have an adequate system that allows them to have a suitable distribution for their operational capacity.

On the other hand, we have the micro-company Avviare Materials where Figure 12 shows the percentages of compliance of this company with the regulations.

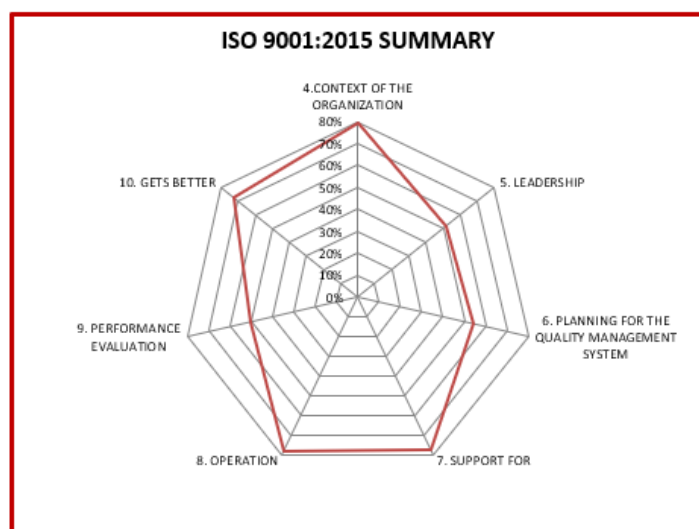


Figure 12. Degree of compliance with regulations by the microenterprise Avviare Materials.

According to the above, it is established that there are deficiencies not so marked but notorious within the performance evaluation due to the lack of measurement and monitoring of each of

the operations that comprise the process of the elaboration of its products, since it focuses only on fulfilling orders, thus having a high level of customer satisfaction, but this is due to the lack of quality objectives and the lack of establishing the mentality of continuous improvement within the company to counteract these deficits.

Based on what was identified in the checklist applied to each of the microenterprises case study, it is established that a key point to work on in order to adjust these entities to the regulations is chapter 9 of the standard that includes the evaluation of performance in which the processes are involved, such as monitoring and measuring both the processes and the quality of the products and services. and measurement of both processes and customer satisfaction, but all of this is based on deficits in leadership and support from the top management of these entities, which is where more care must be taken to achieve the results required to comply with ISO and thus establish the quality management system.

On the other hand, another format used for data collection is the SWOT, which works under this model but is approached under a CAME analysis as shown in Figure 13, which establishes for each of the microenterprises the offensive, defensive, reorientation and survival strategies with which the purpose and projection of each of these entities and their processes can be reinforced.

In accordance with the above, emphasis is placed on the strategies that have been contemplated through the CAME analysis taken from the factors of the SWOT model, where with the offensive strategies the entities have an abundant portfolio of tactics with which they can compete with the other organizations belonging to the sector and in their lines of production; In the same way, the defensive ones have a great variety on the part of the companies that allows them to count on strengths taken advantage of against those latent threats that are present in the external environment and that could generate an affectation in a high degree both directly or indirectly in the production and conformity of the products with which very varied actions are identified in which these micro-companies will cushion if some situation of these were to arise. On the other hand, we have the reorientation strategies which contemplate the guidelines with which the entities seek to make a modification by reevaluating the opportunities with their weaknesses to strengthen the bases of the SMEs, from which it is inferred that the changes within these organizations are necessary to manage an environment of improvement and to be prepared for any situation that may arise; On the other hand, there are those of survival, which address the actions that must be taken into account to stay in the market in the face of the growing increase in direct competition, in accordance with the above, these strategic actions will allow microenterprises to stay afloat in the market and to scale up to become more powerful and increase both productivity and efficiency.

Based on the aforementioned, it is evident that the entities have the necessary tools and approaches required to fully comply with the ISO 9001:2015 standards, which will strengthen their positioning in the market and against the competition, having the opportunity to correct those internal deficiencies, face the latent threats externally, maintain those processes and efficient actions within the internal and external environment of the organizations and explore those opportunities they have in their productive sector, taking advantage of the characteristics that are external to them.

<p style="text-align: center;">DOFA</p>	<p style="text-align: center;">Opportunities</p> <p>O1 Recognition by public entities.</p> <p>O2 Cheaper cost of raw materials compared to the competition.</p> <p>O3 Decrease in tax costs.</p> <p>O4 That the agreements with other municipalities be extended.</p> <p>O5 Decrease in value of the dollar.</p> <p>O6 Achieve greater obtaining of raw material with recycling entities.</p> <p>O7 Open the work for other lines of processes to increase income.</p> <p>O8 Transportation of material for "Vive Entorno" handling different entrances to the main one.</p>	<p style="text-align: center;">Threats</p> <p>A1 Presence of new competition in the sector.</p> <p>A2 Lack of transportation to deliver products.</p> <p>A3 Change of administration in the public entity and this affects the agreement in the garbage collection process.</p> <p>A4 Decrease in sales.</p> <p>A5 Competition with more automated machinery and longer recognition time.</p>
<p style="text-align: center;">Strengths</p> <p>F1 Quality products.</p> <p>F2 Constant production.</p> <p>F3 There is no local competition.</p> <p>F4 There is enough raw material.</p> <p>F5 Legal permissions.</p> <p>F6 Recognition of public and legal entities for the development of execution of processes by the company.</p> <p>F7 Electronic sales.</p>	<p style="text-align: center;">Offensive strategies</p> <p>F1-O1 Maintaining quality products will allow exploring greater recognition by public entities.</p> <p>F3-O4 Maintaining a constant production will allow exploring the extension of more agreements with other municipalities.</p> <p>F3-O6 Not having local competition will make it possible to explore obtaining higher levels of raw materials with recycling entities.</p> <p>F5-O8 Maintaining legal permits will make it easier to explore the transport of materials for Vive Entorno, having different entrances to the main one.</p> <p>F6-O4 Maintaining the recognition by public and legal entities for the development of the execution of the processes by the company will allow exploring a broader route in agreements with other municipalities.</p> <p>F7-O5 Exploring a decline in the value of the dollar may support higher electronic sales.</p>	<p style="text-align: center;">Defensive strategies</p> <p>F1-A1 Maintaining quality products will help to face the presence of new competition in the sector.</p> <p>F4-A5 Maintaining sufficient raw material will make it possible to face the change of administration in the public entity and this will not affect the garbage collection process as well as the company's production.</p> <p>F6-A3 Maintain the recognition of public and legal entities in the development and execution of company processes to deal with a change of administration in the public entity and be able to continue with the agreement.</p> <p>F7-A4 Maintain electronic sales to address and drive the decline in sales.</p>
<p style="text-align: center;">Weaknesses</p> <p>D1 Accidents or contingencies.</p> <p>D2 More construction areas.</p> <p>D3 Increase productivity levels.</p> <p>D4 Larger machinery or obtaining another.</p>	<p style="text-align: center;">Reorientation Strategies</p> <p>D1-O7 Adjusting more construction areas will allow exploring the opening of work through other process lines to increase income.</p> <p>D1-O4 Improve the increase in productivity levels to explore the possibility of expanding agreements with more municipalities.</p> <p>D4-O6 Changing the machinery for a larger one or obtaining others will allow exploring the objective of obtaining greater amounts of raw material with recycling entities.</p>	<p style="text-align: center;">Survival Strategies</p> <p>D1-A1 Adjusting more construction areas will make it possible to face the presence of new competition in the sector.</p> <p>D4-A5 Implementing larger machinery in the operations or obtaining others will help to face the competition with more automated machinery and with a longer recognition time in the market.</p>

Figure 13. SWOT model to support the CAME analysis conducted in SMEs.

3.2. Context analysis and structuring of process documentation

The purpose of this objective was to focus on the data obtained and analyzed in the previous item of the methodology and thus propose an analysis through the use of the Pareto Diagram tool with which it was identified in what the SMEs of the industrial sector of the municipality of Chitagá have similarities or compliance with respect to the ISO 9001 version 2015 regulations and which are in lower proportion of compliance within these entities; Likewise, the description and documentation of each one of the processes of the products of each one of the organizations was developed through a model; in addition, flow charts were presented in a general way of the operational processes of each one of the microenterprises and a mapping of the general process of each one of these of how their different goods or products are developed and thus a contribution was given to these companies to have documented information that facilitates functions of the performance of operations such as training for new personnel in the operational part.

According to the above in Figure 3. It is evident the items that have less proportionality in similarities for compliance with ISO standards and that generate as identified with the Pareto diagram that affect the other chapters of the standard for due compliance for the standard and thus give the transition to the quality management system.

The Pareto diagram is the tool that allows to perform an analysis through which structure in an order the data to determine the causes that have greater deficiency that generate that the others are not executed in an ideal way (De Souza, 2019). In accordance with the aforementioned, it is necessary to use this instrument with which a contribution was developed in the second phase of this research describing the deficiencies in similarities that are most affected of the SMEs in the industrial sector.

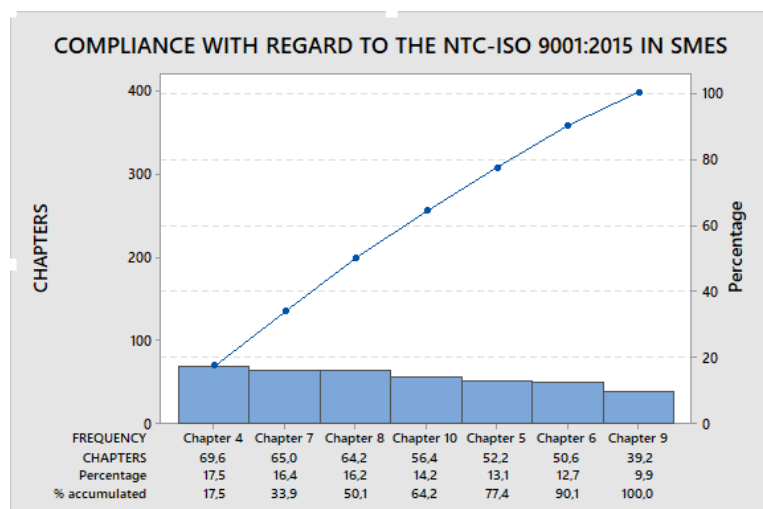


Figure 14. Compliance with NTC-ISO 9001:2015 in SMEs in the industrial sector of the municipality of Chitagá.

According to Figure 14, it is evident as a result that the chapter with the most similarity to the standard is number 4, which contains the context of SMEs with 17.5%. In addition, it is established that, in the results, 77.4 % of the compliance comes from the first five categories, chapters 4, 7, 8, 10 and 5 (Context of the organization, Support, Operation, Improvement and Leadership respectively). It should be noted that in the last two categories, chapters 6 and 9, the degree of compliance with the standard, proportionally the planning for the quality management system (QMS), and the performance evaluation are presented in lower proportion, which allows detecting the most notorious deficiencies in which should be addressed more immediately in a respective implementation of the QMS by these SMEs.

To conclude on the basis of the above, it is identified that the SMEs under study have the necessary tools and approaches required to fully comply with ISO 9001:2015 standards, and also to carry out the planning required for their full operation. Based on this, the direction is given to the design of the route.

A flowchart is the tool used to give a description of a process, system or algorithm in order to be able to plan or improve some of the processes so that they are easier to understand for new workers within the scope of a company (El sitio de once, 2020).

FLOW CHART # 01 PROCESS OF: PEAR TYPE CHITAGA CHEESE								
Starts: at the reception of raw materials End: in temporary cooling Elaborated: Diego Javier Rincon Villamizar, Industrial Engineer Date of elaboration: April 26, 2022				Activity summary		Weather (minutes)		
				○	8	247		
				□	0	0		
				D	0	0		
				⇨	2	0,53		
				▽	1	1200		
Total		11	1447,53					
ACTIVITIES	DESCRIPTION	SIMBOLOGY					WEATHER	
		○	□	D	⇨	▽	TP	TT
RECEIVE AND FILTER	The milk is received, a filtration process is carried out and platform tests are applied taking density, weight, alcohol test, antibiotic discard test in milk	●					15	15
PASTEURIZE	The milk is transferred by means of a hose connected to a motor pump to take it to the pasteurization vat and pasteurization is carried out	●					15	30
INOCULATE	The inoculation of the milk is carried out by adding the rennet	●					40	70
TAKE	Serum removal is performed	●					120	190
COOK	The cooking of the curd is carried out, salt is added	●					35	225
MOLD	The cheese is doubled and molded	●					5	230
PRESS	The pressing of the curd is carried out	●					15	245
PACKAGING	Moved to packing area				●		0,1	245,1
PACK	Cheese packaging is done	●					2	247,1
SHOWCASE	It moves to the showcases				●		0,43	247,53
REFRIGERATE	Placed in temporary refrigeration while customers purchase or ship					●	1200	1447,53

Figure 15. Flowchart model of each one of the SME processes.

According to Figure 16, the model through which the step-by-step information of each one of the processes of the case study SMEs was compiled and which is a contribution of those that were given as a final result is observed.

As shown in Figure 16, there is a model with which a mapping was made at a general level of the flow of the processes of each microenterprise at the operational level with which it is identified that the areas can be readjusted to avoid unnecessary displacements and shorten some optimizing and improving the efficiency within the operational part of these. In addition to the above, it was possible to understand the productive area of the entities, with the support of both managers and workers that make up these microenterprises giving a contribution that will allow progress to comply with ISO 9001:2015 and thus achieve the transition to establish the implementation of a quality management system by the organizations.

As a result according to the above, a more precise description and structuring is presented within a format of it step by step of each of the processes for the elaboration of the different products in the SMEs object of study taking into account the classification of these within the industrial sector, where it is identified that the entities have a great variety of these to offer to their customers, highlighting that in their processes they handle equipment and controlled operations to give the characteristics to each of their products which allows to reduce that nonconformities are presented within the products.

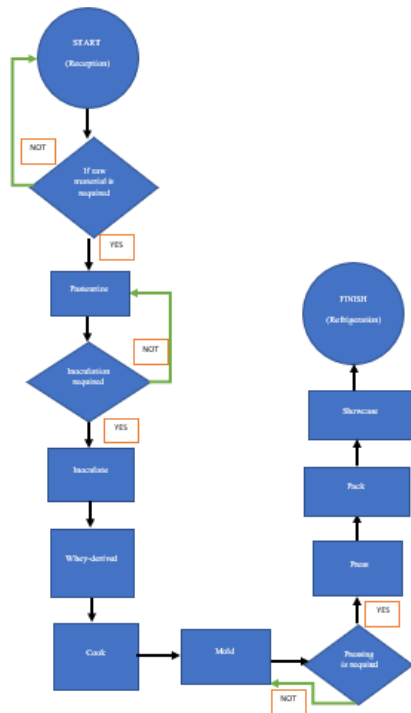


Figure 17. Model of the flowchart mapping of the general processes of SMEs.

Process maps are the tool in which the parts that make up a strategic plan are structured or evidenced (EAE Business School, 2022). This allowed to have the direction and to understand how is the operation within the areas of operation for each of the products with which it was identified if before performing a job a decision should be made and thus improve the training process for new employees with which higher levels of efficiency will be achieved.

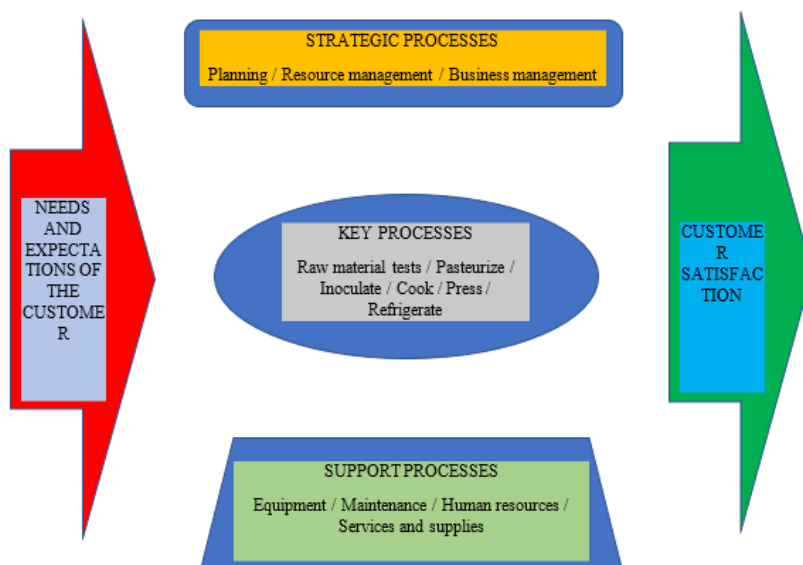


Figure 17. Mapping model of the general processes of SMEs.

According to what is observed in Figure 17, the key processes are presented where the main tools are the equipment that allow to give purpose to each of the products manufactured by

these SMEs; with which it is established that they have a good design to meet the requirements of the needs and expectations required by their stakeholders.

As for the operational part of the companies, there is a good structuring, planning and execution of each of its operational processes that give conformity to the products, evidencing the good management to comply with the requirements established by the organizations for the excellence of these. With which a very good result is generated in the environment within the functional and productive part of these entities, in contrast reducing the presence of nonconformities as well as a proper structuring for the processes through the contribution of documented processes in formats for clear identification and execution by those involved in this space in the organizations.

3.3. Route design

With respect to this phase, an approach to the design of the route was given, taking into account what was obtained in the diagnosis and documentation of operational processes to structure the step by step of this to make a proper implementation of the quality management system within SMEs in the industrial sector, complying with the chapters and parameters stipulated in the Colombian Technical Standard ISO 9001: 2015, which was used as a basis and in turn focused on continuous improvement tools such as the KAIZEN philosophy and the 5'S tool to generate an environment within these SMEs that would contribute not only to adjust the spaces and operations as indicated in the regulations but also to use the constant improvement thinking from top management to the lowest-ranking operator to provide a more complete approach. On the other hand, tools are proposed to address the development of each requirement of the standard, these being optional in a proper implementation of the system.

In addition to the above, according to Brunet and New ((2003), as cited in Suarez-Barraza & Miguel-Dávila, 2011) Kaizen is defined as the strong component for continuous activities, where each of those involved has a very explicit role, to identify and ensure the effects or improvements that contribute to achieving both short and long term objectives of the entities (Suarez-Barraza & Miguel-Dávila, 2011). In other words, this philosophy or method involves each worker and allows them to present their perspectives or points of view together with the top management within the SMEs to give a complete approach in each of the areas to implement actions to increase total productivity or continuous improvement of performance in each operation of the entities.

According to Anvari, Zulkifli and Yusuff ((2011), as cited in Piñero, et al., (2018)) the 5'S methodology is understood as a business concept in which the main objective is to minimize the time and resources required in the manufacturing processes and other activities of an organization and has a specific focus on eliminating all forms in which waste may occur (Piñero et al., 2018). Likewise, the 5'S method can be deduced as a strategy to structure and get rid of unnecessary activities or things that affect the development of an activity within a workplace to increase the use of resources and increase productivity.

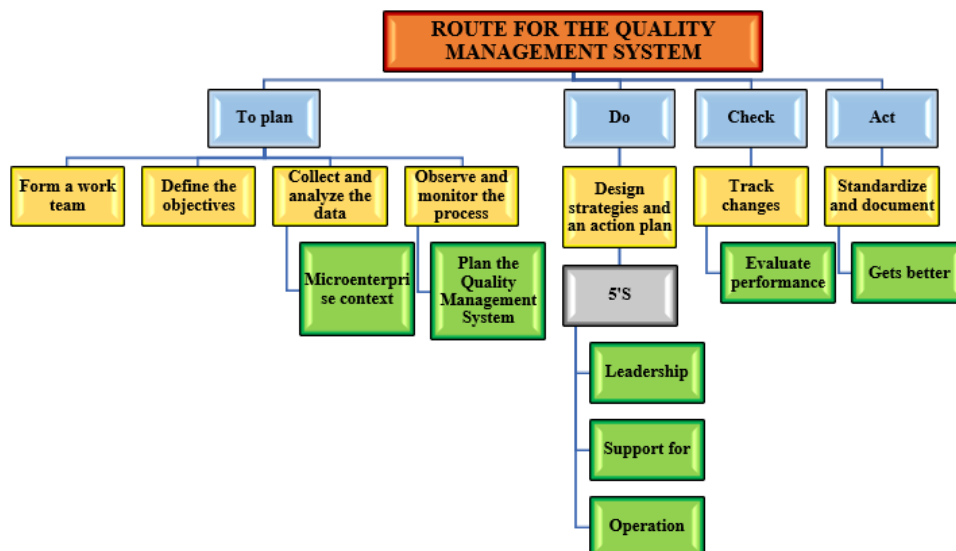


Figure 18. Flowchart of the design of the Quality Management System implementation roadmap

According to Figure 18, and based on the above mentioned, the step by step route for these microenterprises was presented, based on the Deming cycle or PHVA (Plan, Do, Check, Act), which allows to have a control of all processes and within the phases of this tool, the seven steps stipulated by the Kaizen method are incorporated, this being the flag that directs the implementation process; then the items of this are presented, thus having the following steps:

- Form a work team.
- Define objectives.
- Collect and analyze data.
- Observe and monitor the process.
- Action plan.
- Track changes.
- Standardize and document

And as a complement to reduce time and resources within each of the areas, the 5'S methodology is introduced within the execution steps of the Kaizen method, respectively in step five of designing strategies and an action plan in order to restructure each of the areas of each of the SMEs at the time of the execution of the model of the route and implementation of the quality management system. Consequently, the route is structured as follows:

Planning:

- Form a work team.
- Define objectives.
- Collect and analyze data.
- Context of the organization.

- Observing and monitoring the process.
- Planning the quality management system.

To do:

- Action plan.
- Methodology of the 5'Ss.
- Leadership.
- Support.
- Operation.

Verify:

- Follow-up of changes.
- Performance evaluation.

Acting:

- Standardize and document.
- Improve.

According to the above, the design of the route for the implementation of a Quality Management System was developed, where the approach for the steps of the Kaizen method and the ISO 9001:2015 Standard were completely proposed through the tools of industrial engineering to execute a more accurate and adequate process projected to achieve optimal results for SMEs in the industrial sector of the municipality of Chitagá, Norte de Santander, improving their processes, operation, effectiveness, productivity, efficiency and customer satisfaction, contributing to the growth of each of these micro-enterprises.

4. CONCLUSIONS

It is inferred that the companies in the industrial sector of the municipality of Chitagá, are in a context in a very suitable percentage but still do not have a sufficiently adequate proportion to give a transition to the Quality Management System, presenting some deficiencies with respect to the regulations that do not allow the necessary progress in the process of preparation for this system. Taking into account that on the part of the managers of the SMEs there is a very high lack of knowledge of the regulations, this leads to the generation of non-conformities since there is no control or follow-up that allows to evaluate and structure in a better way each activity that is carried out within the entities, which generates that they remain stagnant in the market, only surviving, but not advancing. To conclude we have that within the evaluation of similarity of the items of the ISO 9001:2015 Standard with the SMEs, a great deficiency was found in the part of the planning of the quality management system and the performance evaluation, which allows interpreting and identifying that the top management of the entities does not carry out a study of the processes, which does not allow them to have clarity of the deficiencies of these.

The design of the route that was established frames a very suitable context since both the chapters of the regulations and continuous improvement tools are linked, which leads to create a thought that if it can be measured, it can be improved, attacking the main deficiency within the performance evaluation of the processes and operation of the company.

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