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Artículos científicos

Sistemas de Gestión en Instituciones de Educación Superior, su Operación y la Correlación con la Calidad en el Servicio

Management Systems in Higher Education Institutions, their Operation and Correlation with Service Quality

Sistemas de Gestão em Instituições de Ensino Superior, seu Funcionamento e Correlação com a Qualidade do Serviço

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Resumen

El objetivo de la presente fue determinar la correlación entre la Operación de un Sistema de Gestión de la Calidad (OSGC) y la Calidad en el servicio en un Sistema de Gestión (CSG). Para la metodología se aplicaron cuestionarios a los trabajadores de una Institución de Educación Superior (IES) en el Estado de Durango, México. Se empleó la técnica de análisis estadístico de regresión lineal simple. En los resultados se confirmó que, existe una correlación lineal positiva entre la variable de OSGC y la variable CSG. Se concluye que el modelo de regresión se puede ajustar para validar estudios que aborden temáticas semejantes a la de la presente investigación y ayude a medir las variables para su mejora continua.

Palabras clave: Análisis estadístico, calidad, educación superior, México.



Abstract

The objective of this was to determine the correlation between the Operation of a Quality Management System (OSGC) and the Quality in the Service in a Management System (CSG). For the methodology, questionnaires were applied to workers of a Higher Education Institution (HEI) in the State of Durango, Mexico. The technique of statistical analysis of simple linear regression was used. The results confirmed that there is a positive linear correlation between the OSGC variable and the CSG variable. It is concluded that the regression model can be adjusted to validate studies that address topics similar to that of the present research and help measure the variables for continuous improvement.

Keywords: Statistical analysis, quality, higher education, Mexico.

Resumo

O objetivo deste foi determinar a correlação entre a Operação de um Sistema de Gestão da Qualidade (OSGC) e a Qualidade do serviço em um Sistema de Gestão (CSG). Para a metodologia, foram aplicados questionários aos trabalhadores de uma Instituição de Ensino Superior (IES) no Estado de Durango, México. Foi utilizada a técnica de análise estatística de regressão linear simples. Os resultados confirmaram que existe uma correlação linear positiva entre a variável OSGC e a variável CSG. Conclui-se que o modelo de regressão pode ser ajustado para validar estudos que abordem temas semelhantes ao da presente investigação e ajude a mensurar as variáveis para seu aperfeiçoamento contínuo.

Palavras-chave: Análise estatística, qualidade, ensino superior, México.

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Introduction

The historical development of products and services in the business, economic, commercial, political and social context of each period will undoubtedly continue to be transmuted together in the context of these factors, intrinsically related to the issue of quality (Amaya et al., 2020; Carro and González, 2012; Vidal, 2014). In this sense, when an organization intends to endure and be competitive, it must establish processes that ensure the satisfaction of its customers by meeting their needs and expectations, offering quality products and/or services (Gremyr et al., 2021; International Organization Standardization [ISO], 2018).

Quality in education is a subject that has been constantly transformed. The Quality Management Systems (QMS) provide the foundation to structure the purposes of education through certified processes that ensure the quality of its results, therefore the importance of analyzing the perception of workers in relation to the activities that support quality improvement in organizations.

Taking into account the standard of fundamentals and vocabulary for quality management systems ISO 9000 (2015a) as a fundamental basis for the definition of client, any person or organization that could receive or receives a product or service intended for that person or organization or required by it. For their part, Garcia et al. (2017), highlight the importance of measuring the satisfaction of customer needs by obtaining accurate information that leads, in turn, to raising the quality of the service.

For Garcia et al. (2017), the client does not depend on the product or service that is provided, but it is the organization that depends on it. The customer is an essential part of the organization; He is not a stranger, he represents more than an indicator of profits or compliance with a service, he is the most important person for an organization. As a human being with feelings, he deserves respectful treatment and the most appropriate care that can be provided.

When a client receives everything he expected and more, exceeding his expectation, he will be satisfied. Thus, customer satisfaction, linked to the expectations that are held, is the result of quality, where such expectations are produced from factors such as needs, context, price, diffusion, implicit technology, prestige, among others. (Amaya et al., 2020). In this sense, organizations must prioritize the analysis of these and other factors to plan and take actions that help meet and exceed the expectations of their customers. In addition, quality management aims to "do things well on a routine basis, as agreed and complying with mandatory requirements, articulating means to detect and satisfy new needs" (Amaya et al., 2020: 637). Quality management must become part of the organization, adopting it as a culture by its members, applying this same approach to all its processes.

According to Hernández et al. (2019: 27), "Service Quality is a concept that derives from the very definition of quality, understood as the satisfaction of customer needs and expectations". Consequently, the parameters must be established to measure the needs and expectations of customers and, based on the results obtained from their evaluation, implement the necessary improvements to raise the quality of the service. (Chountalas et al., 2020).

Importance of the topic

In the present investigation, the correlation between a QMS and its operational part is studied (namely: the planning and control of operations, the establishment of requirements for products and services, including the process for design and development, external control of services, production and provision of the service, its release and control of outputs with non-compliance), providing information on the perception that members of an organization have of a QMS and the status of the elements described above.

With the results obtained, it is intended that the organizations immersed in a quality management system consider the importance of its operations in accordance with the ISO 9001:2015 standard and quality management, since the model presented shows that there is a direct influence between one variable and another. This contributes to complement what exists within the theories of quality that have been presented in history. Likewise, the model presented serves as a basis for having another alternative for the evaluation of a quality management system and its relationship with its operations. It is worth mentioning that, within the analysis, it is possible to have alternatives to replicate the model with different variables in the same context.

General objective

Determine the correlation between the Operation of a Quality Management System (OSGC) based on ISO 9001:2015 and Service Quality in a Management System (CSG).

Specific objective 1

The specific objective is to verify if the analysis of the variables complies with the assumptions of a linear regression model in terms of linearity, independence, normality and homoscedasticity.

Literature Review

Organizations currently carry out various studies to analyze and compare themselves with others within their business, giving greater importance to the quality factor in the service. Well, through this factor, improvements and innovations in services can be constantly implemented, thus increasing customer satisfaction (Hernández et al., 2019). This factor has become a determining factor for organizations that wish to add value to their services through the study of elements that intervene in the continuous improvement of their processes (Fonseca and Domingues, 2018; Gremyr et al., 2021).

On the other hand, Monroy (2019) points out that companies that orient their processes towards customer service must meet the expectations that they have about the quality of the service offered to them. Well, the strong competition in the field of business puts at risk organizations that do not take the pertinent actions to improve the perception that their clients have about the quality of their services.

Derived from this situation, research studies have been dedicated to determine which factors influence and to what degree, in order to redirect the intentions and strategies of the organizations, with the appropriate techniques and tools (Cruz et al., 2017) towards an improvement constant quality of its services.

The constant increase in customer expectations of the products and services offered by organizations forces them to identify issues that may affect or benefit their processes and assess the degree to which the expectations of their interested parties are being met. Having to plan and carry out the necessary structural and operational changes addressing the customer focus and exceeding their expectations, in addition to reducing operational risks, taking advantage of improvement opportunities as a result of non-conformities as well as audits. (Fontalvo y De La Hoz, 2018; Yáñez y Yáñez, 2012).

According to Gómez and Pérez (2017), the Productivity and Quality Improvement process is a permanent and iterative action of the entire organization. It is an attitude that is developed by all the staff and that allows them to maintain their interest in innovation, creativity, doing things better and better and satisfying the needs of customers to a greater extent. If there is an attitude of continuous improvement, the company will always try to find the limit of what it can do with certain resources. This management philosophy seeks to achieve a competitive advantage that builds its bases on the foundations of quality, strategic and operational management by systematically implementing a program of actions based on the improvement cycle (Canales and Soler, 2015).

For its part, the International Organization for Standardization (ISO) issues the ISO 9001 quality standard. In its 2015 version, it is applicable to any type of organization, whether it offers products and/or services, focused on quality from the perspective the culture of its members. It provides a methodological framework for improvement in internal aspects to add value by meeting the needs and meeting the expectations of customers and other relevant interested parties (ISO, 2015b).

To improve the efficiency and effectiveness of an organization, quality management systems, through a set of policies, processes and procedures, identify their objectives and the implementation of measures to achieve them in a systematic and continuous manner. And it can

be certified according to international standards such as ISO 9001. For which, a quality management system must have certain key characteristics, such as the establishment of a clear and defined quality policy, processes and procedures documented and evaluated in a manner consistent, a system of measurement and evaluation of quality under the approach of learning and continuous improvement.

According to ISO 9000 (2015a: 2), "the quality of an organization's products and services is determined by the ability to satisfy customers, and by the intended and unintended impact on relevant interested parties." This includes not only its intended function and performance, but also its perceived value and benefit to the customer. (Betlloch et al., 2019; ISO, 2015a).

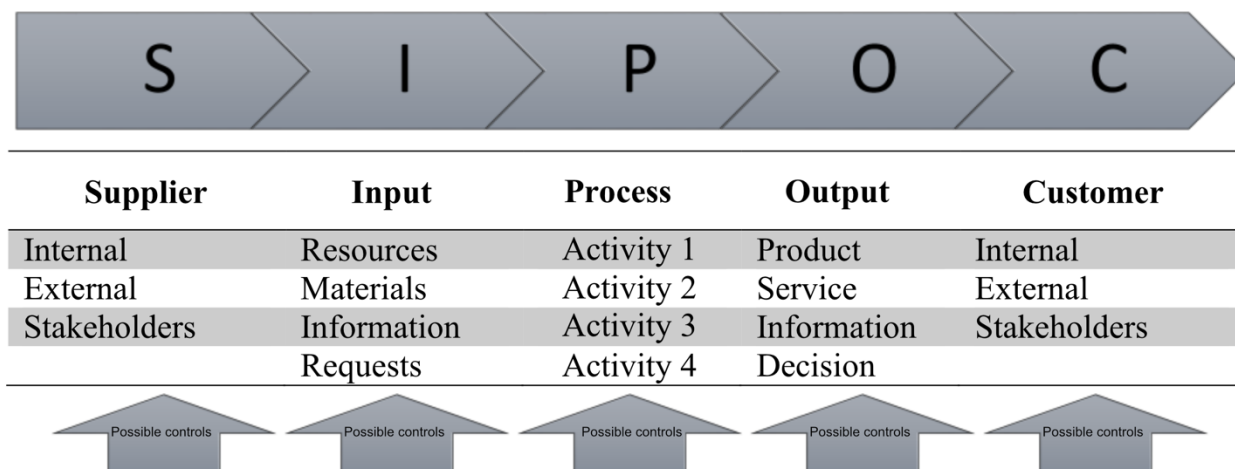
On the other hand, according to the quality standard for management systems ISO 9001 (2015b), the operation of a QMS refers to the operation of the processes determined by an organization to provide products and/or services based on the needs and expectations of its stakeholders. Such processes must be planned and controlled, defining the requirements of their products and/or services, taking into account the design and development stages when warranted, likewise, having control of the processes, products and/or services supplied externally, to ensure the production and provision of services and avoid non-compliant outputs in the release of services products.

The planning and operational control indicated in ISO 9001:2015 (2015b), contemplates the establishment, implementation, control and maintenance of the processes necessary for the satisfaction of the QMS, considering the actions to address risks and opportunities, as well as the quality objectives. and planning to achieve them. Such processes must comply with the previously established requirements for the provision of products and services, making sure that they have the necessary resources to achieve their compliance (Ćwiklicki et al., 2021).

To carry out the realization of the product or the provision of the service, it is important to take into account the essential aspects within a process-oriented approach. According to ISO 9001 (2015b), this approach allows the organization to have control over the interrelationships and interdependencies that are generated between the processes of the Quality Management System (QMS) in order to improve the overall performance of the organization (Stertz et al., 2018).

The approach to SIPOC processes (Supplier, Input, Process, Output, Customer), adopted by the ISO Standard, consists of five elements: Supplier, Input, Process, Output and Customer. Through the establishment and systematic monitoring of the interactions between these elements and the processes, and through the application of the improvement cycle throughout the QMS, it seeks to achieve the strategic objectives established by the organization.

Figure 1. Elements of a process.



Source: Author's own elaboration.

Thus, the appropriate conditions must be provided for the optimal performance of the activities that make up the production and service provision processes (ISO, 2015b), through the implementation of controls, defining the characteristics and results to be achieved. In addition, the availability and operation of the monitoring and measurement tools or instruments must be taken into account, ensuring that activities are carried out that provide certainty of compliance with the controls and compliance criteria (Macas et al., 2018). It should be added that the organization makes sure that the infrastructure and environmental conditions for the operation of the processes (Fernández et al., 2020) of its QMS are ideal (ISO, 2015b), designating the competent people and any necessary level for positions (Sá et al., 2019; Martin et al., 2021; Santos et al., 2021). On the other hand, given the impossibility of verifying the outputs of the processes, prior controls must be established during their development, taking into account methods such as the poka yoke, to avoid human errors, without neglecting those activities that must be implemented to monitor the outputs, once they have been delivered and the corresponding ones before their release.

The continuous and objective review of the elements of the QMS, paying particular attention to its systematic comprehensive improvement, can help prevent the deterioration of the QMS and the loss of the certificate (Cândido et al., 2019; Chiarini, 2019).

The ISO 9001 (2015b) Standard in its chapter 8 establishes the criteria for the operation of a QMS. However, in order to make decisions that improve the products and services that are provided, the measurement criteria that collect the information that helps to decipher the failures in the processes, resources and other elements must be provided, facilitating the evaluation process of the QMS. based on the requirements established by ISO 9001 (2015b). This grants the measurement of the level of maturity of the SGC (Bravi and Murmura, 2021; Ciravegna et al.,

2019; Wolniak, 2019), in addition to the identification of weak elements, as well as unnoticed threats, giving rise to a reorientation of strategies. organizational (Ciravegna et al., 2017; Siltori et al., 2020). For Canales and Soler (2015: 191) "the basis of continuous improvement is self-assessment, knowing the starting situation of the company in order to evolve, detect areas for improvement, to create the improvement project". The previous approach is strengthened by using reliable and valid mechanisms in the evaluation and self-assessment processes, contributing to "evaluate the empirical applicability of theoretical propositions" (Soriano, 2014: 22). The challenge that quality presents to university management in the 21st century, fueled by the changing expectations of society, is reflected in the absence and insufficiency of results. (Rodríguez, 2022).

The general objective of the research is to determine the correlation between the OSGC and the CSG in an HEI in the State of Durango, Mexico, using a linear regression model. The specific objective is to verify if the analysis of the variables complies with the assumptions of a linear regression model in terms of linearity, independence, normality and homoscedasticity.

Methodology

This is a non-experimental, quantitative, correlational and cross-sectional research study. The scope of quantitative research results from the review of the literature and the perspective of the study; it depends on the objectives of the research to combine the elements in the study. The correlational scope, which associates or relates variables, allows making predictions and quantifying relationships between concepts or variables. The non-experimental, transversal or transectional design approach has the purpose of describing variables and analyzing their incidence and interrelationship at a given moment (Hernández et al., 2014).

For the procedure, measuring instruments were applied to the workers of an HEI in the State of Durango, Mexico. For the analysis of results, the statistical technique of simple linear regression was used, where the assumptions of linearity, independence and adjustment were verified, verifying compliance with the third assumption (of normality).

Instrument

The "instrument to measure the operation based on chapter eight of the ISO 9001:2015 standard" (Sotelo et al., 2021) was taken as a basis. Involving 610 users in the OSGC variable, 74,420 responses to the items were obtained in its application. Regarding the CSG variable, a total

of 2,560 user surveys were applied, obtaining 136,760 responses for the items of its dimensions (Carvajal et al., 2011; Sotelo et al., 2021).

For the order or range of values that is assigned to the questions of the instruments, the present investigation used an ordinal type scale, in whose answers the reaction of the respondents is reflected, which are scaled in intensity, from very low, low, medium, high, to very high.

The operationalization of the CSG variable and its dimensions are presented in Table 1.

Table 1. Quality Dimensions in a Management System according to ISO 9001:2015

| Variable | Dimension | No. Ítems | No. of question in the instrument |
|---|-----------------------------|-----------|-----------------------------------|
| Quality in a Management System in accordance with ISO 9001:2015 Standard. | Context of the organization | 20 | 1-20 |
| | Leadership | 30 | 21-50 |
| | Planning | 28 | 51-78 |
| | Support | 50 | 79-128 |
| | Operation | 122 | 129-250 |
| | Performance evaluation | 42 | 251-292 |
| | Improvement | 24 | 293-316 |

Source: Author's own elaboration.

For the OSGC variable, its dimensions are presented in Table 2.

Table 2. Dimensions of the Operation of a QMS of the instrument "to measure the operation based on chapter eight of ISO 9001:2015".

| Variable | Dimension | No. Ítems | No. of question in the instrument |
|--------------------|---|-----------|-----------------------------------|
| Operation of a QMS | Operational planning and control | 12 | 1-12 |
| | Requirements for products and services | 19 | 13-31 |
| | Design and development of products and services | 34 | 32-65 |
| | Control of externally supplied processes, products and services | 21 | 66-86 |
| | Production and service provision | 27 | 87-113 |
| | Release of products and services | 4 | 114-117 |
| | Control of non-conforming outputs | 5 | 118-122 |

Source: Author's own elaboration.

Participants

The scope of the study covers the users of ISO 9001:2015 certified processes within the Quality Management System (QMS) of a Higher Education Institution (HEI) in the state of Durango, Mexico. This includes managers, area managers, coordinators, department heads, teachers and administrative staff. An ordinal scale was used to classify the values and their perception, which varies from very low, low, medium, high, to very high.

Content validation

Regarding the validation of the content, the panel of experts was made up of renowned academics and researchers with professional experience in the sector related to the subject. These experts had adequate and up-to-date knowledge, as well as a willingness to collaborate (López, 2018). The panel of experts was made up of a total of 20 participants, which included academics, researchers, and HEI workers in strategic or related positions. The details can be seen in Table 3.

Table 3. Profile of participant's expert panel.

| No | Area | Genre | Schooling | Position |
|----|---|--------|--------------|--|
| 1 | Rectory | Male | Master | Auditor Researcher |
| 2 | Purchasing Coordination | Male | Master | Auditor Researcher |
| 3 | School of Forestry and Environmental Sciences (FCFA) | Female | Master | Teacher, Auditor and Quality Manager |
| 4 | FCFA | Female | Master | Auditors Teacher |
| 5 | School of Chemical Sciences (FCQ) | Female | Master | Auditor and Quality Manager |
| 6 | Business Center | Male | Master | Business Center Director |
| 7 | Comptroller General's Office | Female | Master | Comptroller General |
| 8 | Institutional Directorate of Graduate Studies and Research | Male | PhD | Institutional Director of Graduate Studies and Research |
| 9 | School of Economics, Accounting and Administration (FECA) and Rector's Office | Male | Postdoctoral | Researcher and Senior Management Representative of the QMS |
| 10 | School of Economics, Accounting and Administration (FECA) | Female | PhD | Research Professor |
| 11 | School of Social Work (FTS) | Female | PhD | Research Professor and Quality Manager |
| 12 | Business Center | Male | Doctorado | Researcher |
| 13 | FECA | Female | Doctorado | Research Professor |
| 14 | Comptroller General's Office | Male | Maestría | Quality Coordinator |
| 15 | Comptroller General's Office | Female | Maestría | Quality Manager |
| 16 | Comptroller General's Office | Female | Maestría | Auditor |
| 17 | Faculty of Exact Sciences (FACE) | Male | PhD | Research Professor |
| 18 | FECA | Male | PhD | Research Professor |
| 19 | Rectory | Female | Master | Auditor |
| 20 | Rectory | Male | Master | Auditor |

Sampling

For the application of the model, the database with which the validation of the ISO 9001:2015 instruments was carried out was used, where the surveys presented in table 4 were applied, considering that, for the present model, It was based on the operation variable and its correlation with the entire quality management system, which includes all the variables mentioned in the following table.

Table 4. Profile of participant's expert panel.

| Chapter ISO 9001:2015 Standard | Items | Surveys applied | Total item responses per instrument |
|--------------------------------|-------|-----------------|-------------------------------------|
| 4. Context of the organization | 20 | 400 | 8,000 |
| 5. Leadership | 30 | 400 | 12,000 |
| 6. Planning | 28 | 140 | 3,920 |
| 7. Support | 50 | 400 | 20,000 |
| 8. Operation | 122 | 610 | 74,420 |
| 9. Performance evaluation | 42 | 210 | 8,820 |
| 10. Improvement | 24 | 400 | 9,600 |
| Total | 316 | 2,560 | 136,760 |

Source: Author's own elaboration.

Reliability

For the analysis of the reliability of the internal consistency, the Cronbach's alpha coefficient, widely used in the study of social sciences, was taken into account (Cronbach, 1951).

Data collection

Regarding the collection of data, the "instrument to measure the operation based on chapter eight of the ISO 9001:2015 standard" was applied in 2019 to members of an HEI with SGC in the State of Durango, Mexico (Santos, 2017).

Analysis of data

The results obtained from the aforementioned methodology were analyzed using the IBM SPSS version 25 statistical analysis tool.

Linear Regression Model

Finally, when performing the regression analysis, the following three aspects were taken into account:

1. Validity and fit of the model
2. Regression equation
3. Analysis of assumptions

Having to meet four assumptions:

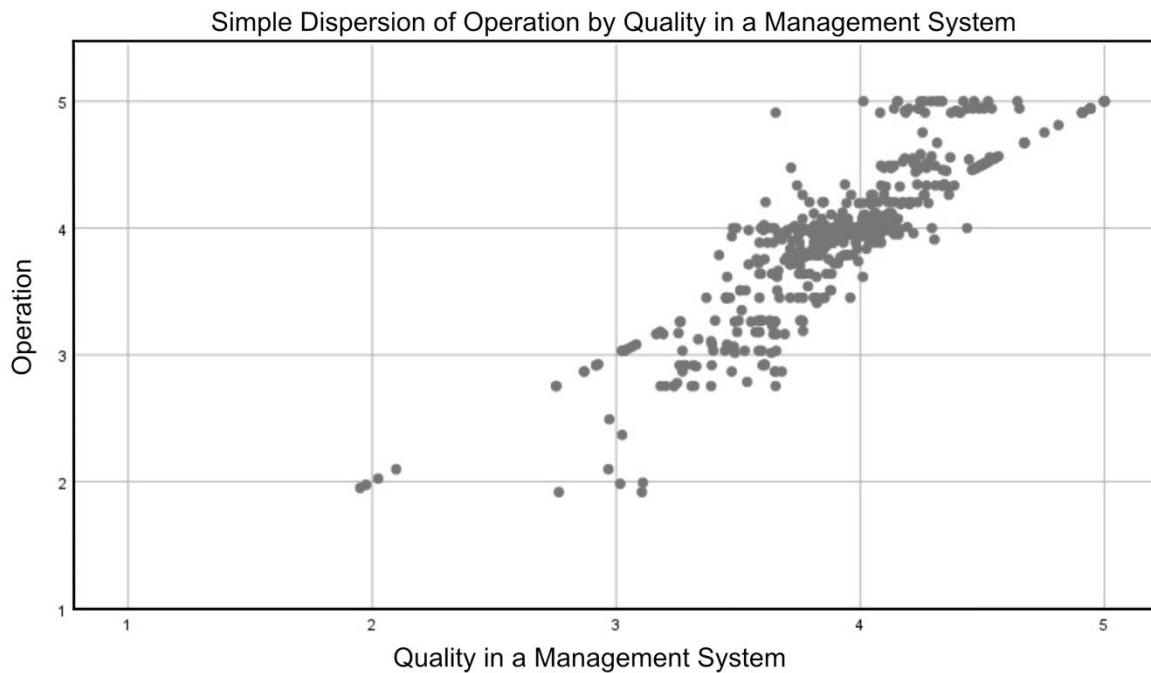
1. Linearity
2. Independence
3. Normality

4. 4. Homoscedasticity

Results

Regarding the regression analysis, it is shown below. First, the behavior of the variables studied in the cloud of points in Figure 2 is presented.

Figure 2. Point cloud of the studied variables



Source: Author's own elaboration.

Figure 2 shows a conglomeration with a linear trend in the cloud of points, showing an interdependent reciprocity of the variables, which indicates that there is positive linearity. As the dependent variable increases, the independent variable also increases. Regarding the model summary, it is shown in Table 5.

Table 5. Model summary

| Summary of the model ^b | | | | | |
|---|-------------------|----------|--------------------|--------------------------------|---------------|
| Model | R | R square | Adjusted R-squared | Standard error of the estimate | Durbin-Watson |
| 1 | .884 ^a | .781 | .781 | .197 | 1.874 |
| a. Predictors: (Constant), Operation of a Quality Management System (QMS), (Constant), Operation of a Quality Management System (QMS), (Constant), (Constant), (Constant), (Constant), (Constant) | | | | | |
| b. Dependent variable: Quality in a Management System (CSG). | | | | | |

Source: Author's own elaboration.

At this stage, the assumptions of linearity and independence, as well as the adjustment, are verified in Table 5. In addition, considering the value of $R=0.884$, it is confirmed that there is a strong linear correlation between the OSGC variable and the CSG variable. .

The value of $R^2=0.781$ indicates a significant adjustment, demonstrating that the analysis process for the regression model can be adjusted to validate studies that address topics similar to that of the present investigation. The proportion of explained variation of 78.1%, product of the correlation 0.884 and its square 0.781.

Considering the Durbin-Watson value of 1.874 (close to two) (in Table 5), the independence hypothesis is accepted, taking into account, in turn, the independence present between the residuals through the Durbin-Watson statistic, which accepts a value of two, as long as there is complete independence in the residuals (it is considered that there is independence within the interval of values between 1.5 and 2.5).

Table 6 shows the hypothesis test, (likewise, the typical error of the estimation is shown) where an F with a value of 2167.338 is shown, which its associated probability according to what is expected of the null hypothesis is less than 0.0001.

Table 6. Anova

| ANOVA ^a | | | | | | |
|--|------------|----------------|-----|----------------|----------|-------------------|
| Model | | Sum of squares | gl | Quadratic mean | F | Sig. |
| 1 | Regression | 84.370 | 1 | 84.370 | 2167.338 | .000 ^b |
| | Residual | 23.668 | 608 | .039 | | |
| | Total | 108.039 | 609 | | | |
| a. Dependent variable: Quality in a Management System (CSG). | | | | | | |
| b. Predictors: (Constant), Operation of a Quality Management System (OQMS) | | | | | | |

Source: Author's own elaboration.

The foregoing is extremely significant, in terms of the data obtained from the individuals under study, which leads to an overvalued R square, with which we also verify that the model is valid. A valid model is considered as long as the p value is close to zero.

Regarding the regression equation, its values are shown in table 7:

Table 7. Coefficients

| Coefficients ^a | | | | | | |
|---------------------------|------------|-------------------------------|------------|---------------------------|--------|------|
| Model | | Non-standardized coefficients | | Standardized coefficients | t | Sig. |
| | | B | Error Std. | Beta | | |
| 1 | (Constant) | 1.370 | .055 | | 24.788 | .000 |
| | Operation | .649 | .014 | .884 | 46.555 | .000 |

a. Dependent variable: Quality in a Management System (CSG).

Source: Author's own elaboration.

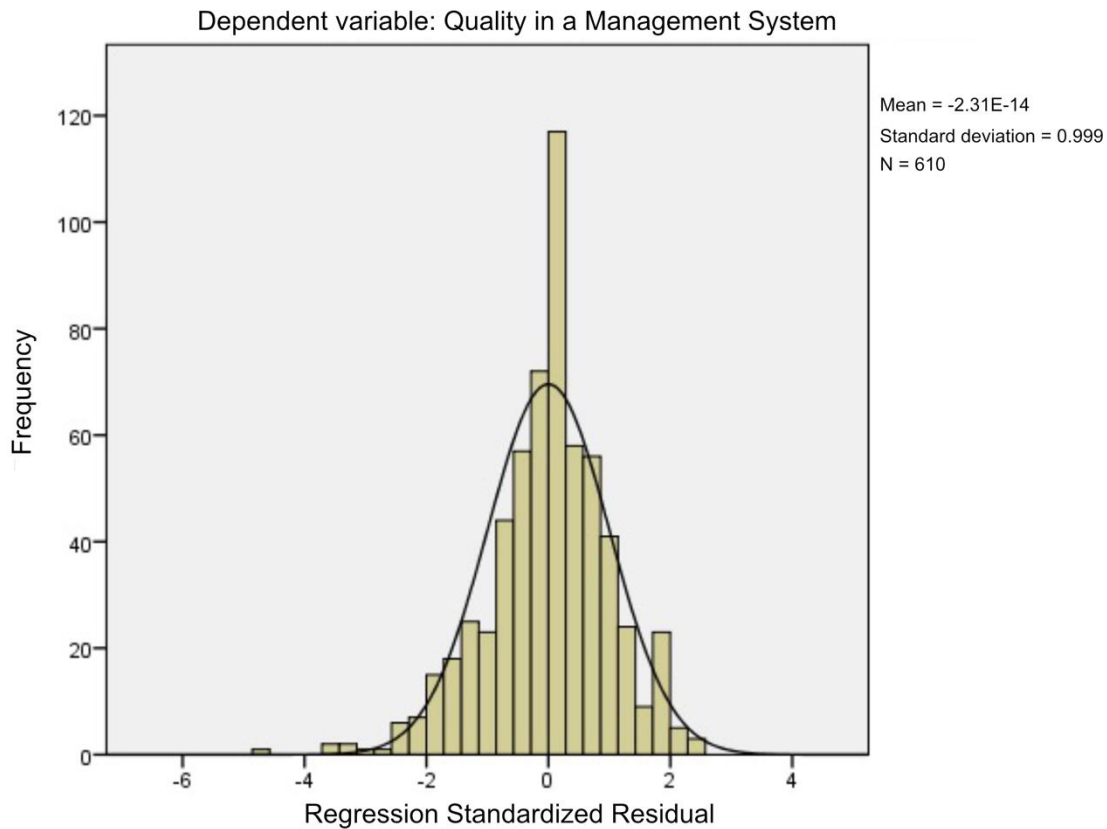
Through the data shown in table 7, the regression equation was obtained, where the parameters $b_0 = 1.370$ and $b_1 = .649$ are verified, the following equation is proposed:

- $y = 1.370 + .649x$

This equation is equivalent to a positive slope in its graphic representation (see figure 4), which indicates that the OSGC is an element that affects the CSG of the institution under study.

Finally, to verify compliance with the third assumption (of normality), the histogram is shown in figure 3 and the P-P graph in figure 4.

Figure 3. Histogram

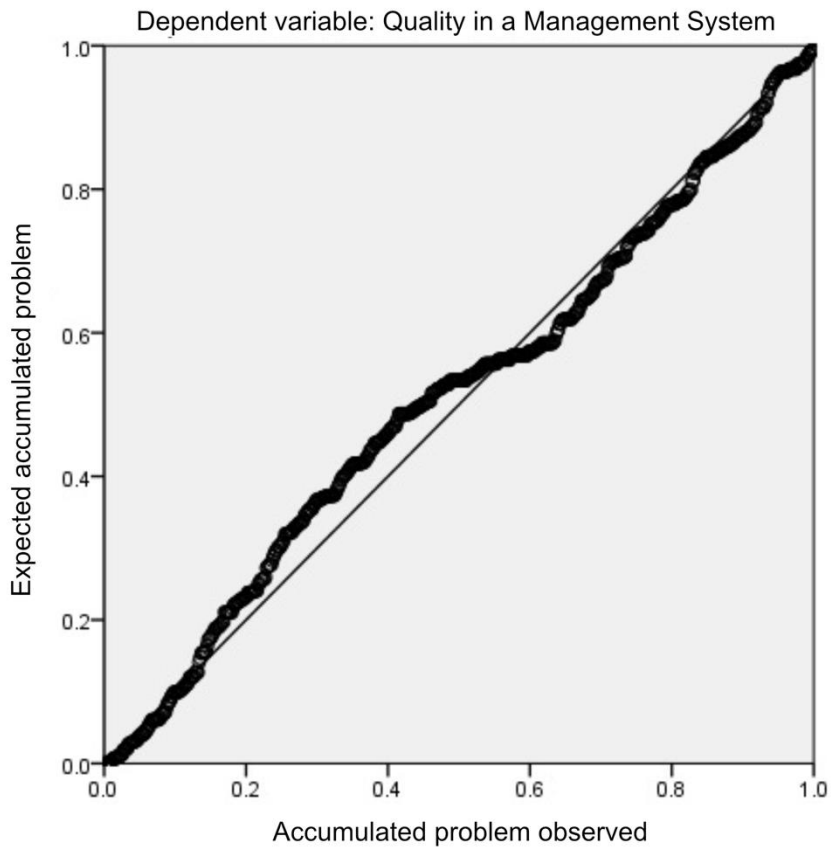


Source: Author's own elaboration.

The normal distribution curve reflected in the behavior of the bars in Figure 3 shows an average of -2.31, in the range of values between -5 and 3, so the CSG variable is acceptable within the model, taking into account a 0.99 deviation from the mean in a population of 610 workers from an HEI.

In the P-P graph (figure 4) the second element is verified to validate the normality of the analysis of the third assumption.

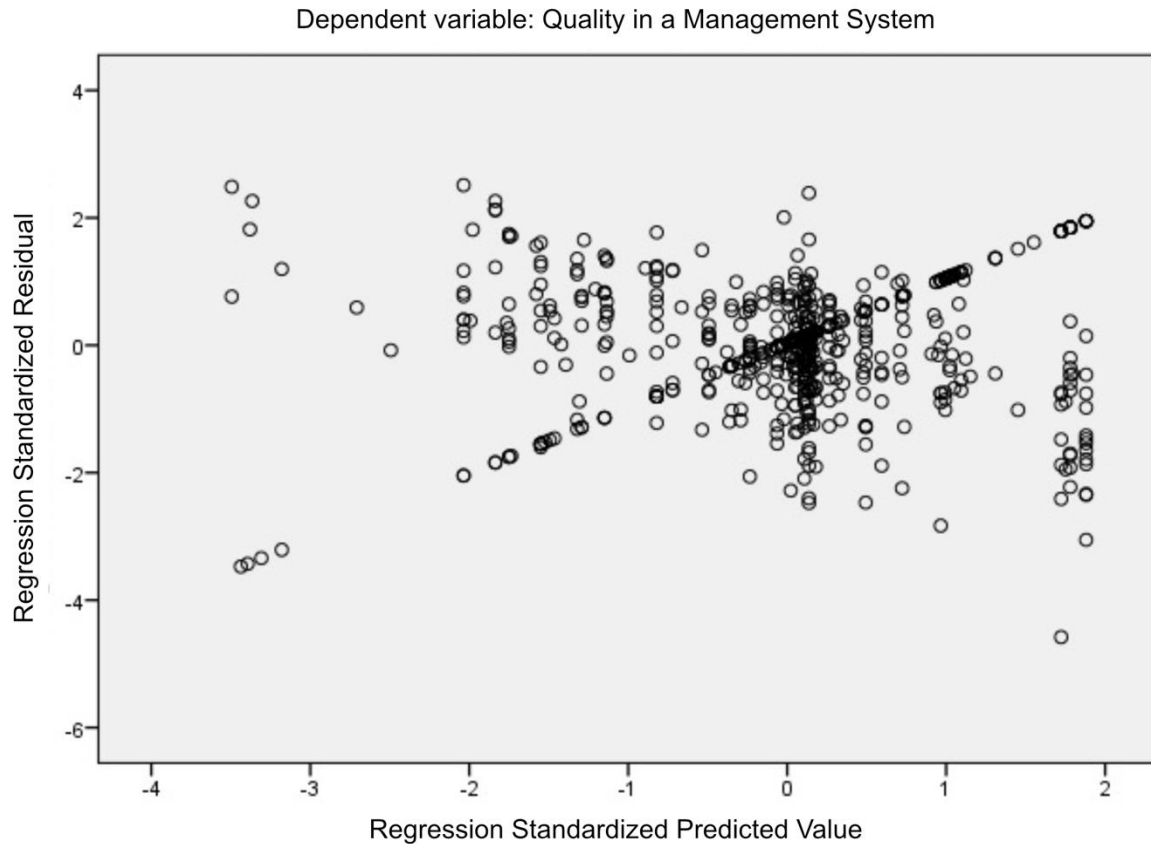
Figure 4. P-P Chart



Source: Author's own elaboration.

The data of the CSG variable (see figure 4) show a behavior closely linked to the slope that resulted from the regression equation, where most of them are projected with a normal distribution, so this assumption is accepted. Figure 5 shows the dispersion diagram, which shows the relationship that links the variables belonging to a population of the same set of individuals.

Figure 5. Scatter plot



Source: Author's own elaboration.

The assumption of homoscedasticity is verified and accepted, since we observe (in figure 5) an optimal distribution of the data, in addition to the absence of agglomerations where most of the data are grouped.

Analysis and discussion

To improve quality processes in organizations, it is important to know them and know how they are related (Cervantes et al., 2018). As Fonseca and Domingues (2017: 924):

The use of improvement approaches, such as radical change, innovation, reorganization, correction and continuous improvement, are relevant approaches for organizations to achieve business excellence. Organizations need to adopt proper business models and ensure they have the right organizational knowledge to successfully manage change and achieve improvements as they need to respond to the challenges of the internal and external environment and foster business excellence to achieve superior results.

Based on the above, del Castillo et al. (2018) emphasize the analysis of the influence of internal and external factors on the performance of a QMS, while Martínez and Arellano (2018) focus on endogenous factors (threats and opportunities) for the organization.

In the present investigation, the relationship between the OSGC and the CSG in an HEI in the State of Durango is objectively described. To do this, an index was calculated for each variable using the survey technique with a Likert scale (1932) ranging from one to five to 610 workers. Then, bivariate statistical techniques were used, specifically Pearson's linear coefficient, to propose a simple linear regression model (Ñaupás, 2018) and verify validity assumptions. In the following paragraphs, an analysis of the results is presented.

For the interpretation of Pearson's linear correlation coefficient, additional information is necessary, beyond the calculation of R and the associated p. A coefficient, such as the one found of 0.884 between the OSGC variable and the CSG variable, may or may not be important, depending on the circumstances. Therefore, we clarify that the significant and strong correlation of 0.884 is not proof of causation (Van Stralen et al., 2008).

The value of R should not be used as an argument to indicate that a cause-effect relationship exists. Taking into account that a low correlation could lead to the conclusion that there is no association when it could be strong, although not linear, the cloud of points was analyzed. When observing a linear trend, it was decided to use the statistical technique of simple linear regression and it was verified that there were no extreme values, since these can alter the value of R when the sample size is small. This is controlled because the modalities of each item associated with each dimension, and these with each variable studied (OSGC and CSG), are found on a Likert scale (Fabila et al., 2012) ranging from one to five.

As demonstrated in the results section, the simple linear regression model meets the assumptions that guarantee the validity of the procedure. It is important to clarify that this model is not intended to make forecasts, since it is built by measuring the variables according to the perception of the study units, that is, the workers surveyed. It serves to describe the relationship between them and obtain objective and precise information that supports decision-making (Jimenez et al., 2020) to improve the operation of the processes in the organization studied (Martínez, 2016). Therefore, the objective of the study was met, since the relationship between the OSGC and the CSG perceived by the workers of an HEI in the State of Durango was objectively described.

Conclusions

Linear regression models allow validating the relationship between variables. In this case, as are the OSGC and the CSG, it is shown that, in accordance with the proposed objective, it can be affirmed that the correlation between the variables analyzed is positive. This means that the operations (processes) carried out in the organization under study have a high degree of influence on its Management System, contributing to its improvement in different aspects.

There is a high correlation between the OSGC variable and the CSG variable. According to the results, it is shown that the better result in the Operation of the processes of a QMS, there is a better Quality in the Service in the Management System. In addition, the proposed linear regression model meets the assumptions shown, the fit of the model is good and valid. Therefore, it is concluded that the measurement of OSGC and CSG in organizations is a key factor for their continuous improvement. It was demonstrated, through the proposed statistical methodology, that there is a significant correlation between the OSGC and the CSG, according to the perception of their workers.

Likewise, the results of this study will contribute to optimal decision-making regarding OSGC in organizations, in order to offer Quality Service in Management Systems constantly and continuously improve their results.

Future lines of research

This analysis allows us to consider carrying out studies to develop models that help analyze the influence that one variable has on another. This opens the possibility of applying the research in any type of organization and with other variables in any of the norms established in the management models. At present, the certifications for organizations contemplate various standards for the comprehensive certification of more than one management system simultaneously. The model proposed in this research exemplifies how to approach the different variables and analyze the influence between them.

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Anexos

Table 8.- Appendix 1. Instrument to measure the operation based on chapter 8 of ISO 9001:2015.

Presentación: Este cuestionario tiene como objetivo principal obtener información que apoye en el desarrollo del Instrumento para medir la operación con base en el capítulo 8 de la norma ISO 9001:2015. Este cuestionario tiene una naturaleza confidencial. Se le solicita cordialmente dar su opinión sobre la veracidad de los siguientes enunciados según su experiencia en esta institución. Le agradecemos su colaboración.

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| 1 | The organization plans, implements and controls the processes necessary to fulfill the provision of products and services. | | | | | |
| 2 | The organization plans, implements and controls the processes necessary to implement actions to address risks and opportunities. | | | | | |
| 3 | The organization determines the requirements for products and services. | | | | | |
| 4 | The organization establishes the criteria for the processes. | | | | | |
| 5 | The organization establishes the criteria for the acceptance of products and services. | | | | | |
| 6 | The organization establishes the criteria for determining the resources necessary to achieve conformity with the requirements of the products and services. | | | | | |
| 7 | The organization establishes the criteria for the implementation of process control in accordance with the criteria. | | | | | |
| 8 | The organization establishes criteria for the determination and storage of documented information to the extent necessary to have confidence that processes have been carried out as planned. | | | | | |
| 9 | The organization establishes criteria for the determination and storage of documented information to the extent necessary to demonstrate the conformity of products and services with its requirements. | | | | | |
| 10 | The output of this planning is appropriate for the organization's operations. | | | | | |
| 11 | The organization monitors planned changes and reviews the consequences of unplanned changes, taking action to mitigate any adverse effects as | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| | necessary. | | | | | |
| 12 | The organization ensures that outsourced processes are controlled. | | | | | |
| 13 | The organization includes in its communication with customers, information related to products and services. | | | | | |
| 14 | The organization includes in its communication with customers, the handling of inquiries, contracts or orders, including changes. | | | | | |
| 15 | The organization includes in its communication with customers, obtaining feedback from customers regarding the products. | | | | | |
| 16 | The organization includes in communication with customers, handling or controlling customer property. | | | | | |
| 17 | The organization includes in the communication with customers, the establishment of specific requirements for contingency actions, when applicable. | | | | | |
| 18 | The organization ensures that requirements are determined for the products and services to be offered to customers. | | | | | |
| 19 | The organization ensures that requirements for products and services are defined. | | | | | |
| 20 | The organization ensures that any applicable legal and regulatory requirements for products and services are defined. | | | | | |
| 21 | The organization makes sure to define the requirements considered necessary for the organization. | | | | | |
| 22 | The organization ensures that it is able to comply with the statements about the products and services it offers. | | | | | |
| 23 | The organization ensures that it has the capability to meet the requirements for the products and services to be offered to customers. | | | | | |
| 24 | The organization conducts a review prior to committing to supply products and services to a customer to include the requirements specified by the customer, including requirements for delivery and post-delivery activities. | | | | | |
| 25 | The organization conducts a review before committing to supply products and services to a customer to include requirements not established by the customer, but necessary for the specified or intended use, where known. | | | | | |
| 26 | The organization conducts a review before committing to supply products and services to a customer to include the requirements specified by the organization. | | | | | |
| 27 | The organization conducts a review before committing to supply products and services to a customer to include the legal and regulatory requirements applicable to the products and services. | | | | | |
| 28 | The organization conducts a review prior to committing to supply products and services to a customer to include differences between the contract or lost requirements and those previously expressed. | | | | | |
| 29 | The organization retains documented information on the results of the review when applicable. | | | | | |
| 30 | The organization retains documented information on any new requirements for products and services when applicable. | | | | | |



| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| 31 | The organization ensures that, when requirements for products and services are changed, the relevant documented information is modified, and that the relevant persons are aware of the modified requirements. | | | | | |
| 32 | The organization establishes, implements and maintains a design and development process that is adequate to ensure the subsequent provision of products and services. | | | | | |
| 33 | In determining the stages and controls for design and development, the organization considers the nature, duration and complexity of the design and development activities.. | | | | | |
| 34 | In determining the stages and controls for design and development, the organization considers the required process steps, including applicable design and development reviews. | | | | | |
| 35 | In determining the stages and controls for design and development, the organization considers the required design and development verification and validation activities. | | | | | |
| 36 | In determining the stages and controls for design and development, the organization considers the responsibilities and authorities involved in the design and development process. | | | | | |
| 37 | In determining the stages and controls for design and development, the organization considers the internal and external resource requirements for the design and development of products and services. | | | | | |
| 38 | In determining the stages and controls for design and development, the organization considers the need to control the interfaces between the people actively involved in the design and development process. | | | | | |
| 39 | In determining the stages and controls for design and development, the organization considers the need for the active participation of customers and users in the design and development process. | | | | | |
| 40 | In determining the stages and controls for design and development, the organization considers the requirements for the subsequent provision of products and services. | | | | | |
| 41 | In determining the stages and controls for design and development, the organization considers the level of control of the design and development process expected by customers and other relevant stakeholders. | | | | | |
| 42 | In determining the stages and controls for design and development, the organization considers the documented information necessary to demonstrate that the design and development requirements have been met. | | | | | |
| 43 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering functional and performance requirements. | | | | | |
| 44 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering information from previous similar design and development activities. | | | | | |
| 45 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| | legal and regulatory requirements. | | | | | |
| 46 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering Standards or codes of practice that the organization has committed to implement. | | | | | |
| 47 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering the potential consequences of failure due to the nature of the products and services. | | | | | |
| 48 | The organization resolves contradictions in design and development inputs. | | | | | |
| 49 | The organization retains documented information on design and development inputs. | | | | | |
| 50 | The organization applies controls to the design and development process to ensure that the results to be achieved are defined. | | | | | |
| 51 | The organization applies controls to the design and development process to ensure that reviews are conducted to assess the ability of the design and development results to meet requirements. | | | | | |
| 52 | The organization applies controls to the design and development process to ensure that verification activities are performed to ensure that design and development outputs meet the requirements of inputs. | | | | | |
| 53 | The organization applies controls to the design and development process to ensure that validation activities are performed to ensure that the resulting products and services satisfy the requirements for their specified application or intended use. | | | | | |
| 54 | The organization applies controls to the design and development process to ensure that any necessary action is taken on issues identified during reviews, or verification and validation activities. | | | | | |
| 55 | The organization applies controls to the design and development process to ensure that documented information on these activities is retained. | | | | | |
| 56 | The organization ensures that design and development outputs meet input requirements. | | | | | |
| 57 | The organization ensures that design and development outputs are suitable for downstream processes for the provision of products and services. | | | | | |
| 58 | The organization ensures that design and development outputs include or reference monitoring and measurement requirements, where appropriate, and acceptance criteria. | | | | | |
| 59 | The organization ensures that design and development outputs specify the characteristics of products and services that are essential for their intended purpose and their safe and correct provision. | | | | | |
| 60 | The organization maintains documented information on design and development outputs. | | | | | |
| 61 | The organization identifies, reviews and controls changes made during the design and development of products and services, or subsequently to the extent necessary to ensure that there is no adverse impact on conformity to | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| | requirements. | | | | | |
| 62 | The organization retains documented information on design and development changes. | | | | | |
| 63 | The organization retains documented information on the results of reviews. | | | | | |
| 64 | The organization retains documented information on the authorization of changes. | | | | | |
| 65 | The organization maintains documented information on actions taken to prevent adverse impacts. | | | | | |
| 66 | The organization ensures that externally supplied processes, products and services conform to requirements. | | | | | |
| 67 | The organization determines the controls to be applied to externally supplied processes, products and services when products and services from external suppliers are intended to be incorporated into the organization's own products and services. | | | | | |
| 68 | The organization determines the controls to be applied to externally supplied processes, products and services when products and services are provided directly to customers by external suppliers on behalf of the organization. | | | | | |
| 69 | The organization determines the controls to be applied to externally supplied processes, products and services when a process, or part of a process, is provided by an external supplier as a result of a decision by the organization. | | | | | |
| 70 | The organization determines and applies criteria for the evaluation, selection, performance monitoring and re-evaluation of external suppliers, based on their ability to provide processes or products and services in accordance with requirements. | | | | | |
| 71 | The organization retains documented information on these activities and any necessary actions arising from the assessments. | | | | | |
| 72 | The organization ensures that externally supplied processes, products and services do not adversely affect the organization's ability to consistently deliver compliant products and services to its customers. | | | | | |
| 73 | The organization ensures that externally supplied processes remain within the control of its quality management system. | | | | | |
| 74 | The organization defines the controls it intends to apply to an external supplier and those it intends to apply to the resulting outputs. | | | | | |
| 75 | The organization considers the potential impact of externally supplied processes, products and services on the organization's ability to regularly meet customer and applicable legal and regulatory requirements. | | | | | |
| 76 | The organization considers the effectiveness of the controls implemented by the external supplier. | | | | | |
| 77 | The organization determines the verification, or other activities necessary to ensure that externally supplied processes, products and services meet requirements. | | | | | |
| 78 | The organization ensures the adequacy of the requirements before | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
|----|---|----------|--------|-------------|----------|----------|
| | communicating them to the external supplier. | | | | | |
| 79 | The organization communicates to external suppliers its requirements for the processes, products and services to be provided. | | | | | |
| 80 | The organization communicates to external suppliers its requirements for approval of products and services. | | | | | |
| 81 | The organization communicates to external suppliers its requirements for approval of methods, process and equipment. | | | | | |
| 82 | The organization communicates to external suppliers its requirements for approval of the release of products and services. | | | | | |
| 83 | The organization communicates to external suppliers its requirements for competence, including any required qualifications of individuals. | | | | | |
| 84 | The organization communicates its requirements to external suppliers. | | | | | |
| 85 | The organization communicates to external suppliers its requirements for external supplier interactions with the organization. | | | | | |
| 86 | The organization communicates to external suppliers its requirements for verification or validation activities that the organization, or its customer, intends to carry out at the external supplier's facilities. | | | | | |
| 87 | The organization implements the production and provision of the service under controlled conditions. | | | | | |
| 88 | The organization implements the production and provision of the service by providing documented information that defines the characteristics of the products to be produced, the services to be rendered, or the activities to be performed, when applicable. | | | | | |
| 89 | The organization implements the production and provision of the service by providing documented information that defines the results to be achieved, when applicable. | | | | | |
| 90 | The organization implements the production and provision of the service ensuring the availability and use of appropriate monitoring and measurement resources, where applicable. | | | | | |
| 91 | The organization implements production and service provision and implements monitoring and measurement activities at appropriate stages to verify that the criteria for control of processes or their outputs, and the acceptance criteria for service products, where applicable, are met. | | | | | |
| 92 | The organization implements the production and provision of the service with the use of the appropriate infrastructure and environment for the operation of the processes, when applicable. | | | | | |
| 93 | The organization implements the production and provision of the service and the appointment of competent persons, including any required qualifications, where applicable. | | | | | |
| 94 | The organization implements production and service provision as well as periodic validation and revalidation of the capability to achieve the planned outcomes of the production and service delivery processes, where the resulting outputs cannot be verified by subsequent monitoring or measurement activities, where applicable. | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| 95 | The organization implements the production and provision of the service and implements actions to prevent human error, where applicable. | | | | | |
| 96 | The organization implements the production and provision of the service and implements release, delivery and post-delivery activities, where applicable. | | | | | |
| 97 | The organization uses appropriate means to identify outputs, where necessary, to ensure conformity of products and services. | | | | | |
| 98 | The organization identifies the status of outputs with respect to monitoring and measurement requirements through production and service delivery. | | | | | |
| 99 | The organization controls the unique identification of outputs where traceability is a requirement. | | | | | |
| 100 | The organization retains the necessary documented information on outputs to enable traceability. | | | | | |
| 101 | The organization takes care of property belonging to customers or external suppliers while it is under the organization's control or being used by the organization. | | | | | |
| 102 | The organization identifies, verifies, protects and safeguards the property of customers or external suppliers supplied for use or incorporation into products and services. | | | | | |
| 103 | The organization informs the customer or external supplier when property of a customer or external supplier is lost, damaged or otherwise deemed unsuitable for use. | | | | | |
| 104 | The organization retains documented information about what happened. | | | | | |
| 105 | The organization preserves outputs during production and service delivery to the extent necessary to ensure conformity to requirements. | | | | | |
| 106 | The organization meets the requirements for post-delivery activities associated with products and services. | | | | | |
| 107 | In determining the scope of required post-delivery activities, the organization considers legal and regulatory requirements. | | | | | |
| 108 | In determining the scope of required post-delivery activities, the organization considers the potential unintended consequences associated with its products and services. | | | | | |
| 109 | In determining the extent of post-delivery activities required, the organization considers the nature, use and expected useful life of its products. | | | | | |
| 110 | In determining the scope of required post-delivery activities, the organization considers customer requirements. | | | | | |
| 111 | In determining the scope of post-delivery activities required, the organization considers customer feedback. | | | | | |
| 112 | The organization reviews and controls changes to production or service delivery to the extent necessary to ensure continued conformity to requirements. | | | | | |
| 11 | The organization maintains documented information describing the results | | | | | |

| No . | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| 3 | of the review of changes, the persons authorizing the change and any necessary actions arising from the review. | | | | | |
| 11 4 | The organization implements planned arrangements, at appropriate stages, to verify that product and service requirements are met. | | | | | |
| 11 5 | The organization releases products and services to the customer until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. | | | | | |
| 11 6 | The organization retains documented information on the release of products and services, including evidence of conformance to acceptance criteria. | | | | | |
| 11 7 | The organization maintains documented information on the release of products and services, including traceability to the persons authorizing the release. | | | | | |
| 11 8 | The organization ensures that outputs that do not conform to its requirements are identified and controlled to prevent their unintended use or delivery. | | | | | |
| 11 9 | The organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services (applying also to nonconforming products and services detected after delivery of products, during or after provision of services). | | | | | |
| 12 0 | The organization addresses nonconforming outputs in one or more of the following ways: a) Correction, b) Separation, containment, return or suspension of product and service provision, c) Informing the customer, or d) Obtaining authorization for acceptance under concession. | | | | | |
| 12 1 | The organization verifies conformity to requirements when non-conforming outputs are corrected. | | | | | |
| 12 2 | The organization maintains documented information that: a) Describes the nonconformity, b) Describes the actions taken, c) Describes all concessions obtained and d) Identifies the authority deciding the action with respect to the nonconformity. | | | | | |
| No . | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
| 1 | The organization plans, implements and controls the processes necessary to fulfill the provision of products and services. | | | | | |
| 2 | The organization plans, implements and controls the processes necessary to implement actions to address risks and opportunities. | | | | | |
| 3 | The organization determines the requirements for products and services. | | | | | |
| 4 | The organization establishes the criteria for the processes. | | | | | |
| 5 | The organization establishes the criteria for the acceptance of products and services. | | | | | |
| 6 | The organization establishes the criteria for determining the resources necessary to achieve conformity with the requirements of the products and | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | services. | | | | | |
| 7 | The organization establishes the criteria for the implementation of process control in accordance with the criteria. | | | | | |
| 8 | The organization establishes criteria for the determination and storage of documented information to the extent necessary to have confidence that processes have been carried out as planned. | | | | | |
| 9 | The organization establishes criteria for the determination and storage of documented information to the extent necessary to demonstrate the conformity of products and services with its requirements. | | | | | |
| 10 | The output of this planning is appropriate for the organization's operations. | | | | | |
| 11 | The organization monitors planned changes and reviews the consequences of unplanned changes, taking action to mitigate any adverse effects as necessary. | | | | | |
| 12 | The organization ensures that outsourced processes are controlled. | | | | | |
| 13 | The organization includes in its communication with customers, information related to products and services. | | | | | |
| 14 | The organization includes in its communication with customers, the handling of inquiries, contracts or orders, including changes. | | | | | |
| 15 | The organization includes in its communication with customers, obtaining feedback from customers regarding the products. | | | | | |
| 16 | The organization includes in communication with customers, handling or controlling customer property. | | | | | |
| 17 | The organization includes in the communication with customers, the establishment of specific requirements for contingency actions, when applicable. | | | | | |
| 18 | The organization ensures that requirements are determined for the products and services to be offered to customers. | | | | | |
| 19 | The organization ensures that requirements for products and services are defined. | | | | | |
| 20 | The organization ensures that any applicable legal and regulatory requirements for products and services are defined. | | | | | |
| 21 | The organization makes sure to define the requirements considered necessary for the organization. | | | | | |
| 22 | The organization ensures that it is able to comply with the statements about the products and services it offers. | | | | | |
| 23 | The organization ensures that it has the capability to meet the requirements for the products and services to be offered to customers. | | | | | |
| 24 | The organization conducts a review prior to committing to supply products and services to a customer to include the requirements specified by the customer, including requirements for delivery and post-delivery activities. | | | | | |
| 25 | The organization conducts a review before committing to supply products and services to a customer to include requirements not established by the customer, but necessary for the specified or intended use, where known. | | | | | |
| 26 | The organization conducts a review before committing to supply products | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | and services to a customer to include the requirements specified by the organization. | | | | | |
| 27 | The organization conducts a review before committing to supply products and services to a customer to include the legal and regulatory requirements applicable to the products and services. | | | | | |
| 28 | The organization conducts a review prior to committing to supply products and services to a customer to include differences between the contract or lost requirements and those previously expressed. | | | | | |
| 29 | The organization retains documented information on the results of the review when applicable. | | | | | |
| 30 | The organization retains documented information on any new requirements for products and services when applicable. | | | | | |
| 31 | The organization ensures that, when requirements for products and services are changed, the relevant documented information is modified, and that the relevant persons are aware of the modified requirements. | | | | | |
| 32 | The organization establishes, implements and maintains a design and development process that is adequate to ensure the subsequent provision of products and services. | | | | | |
| 33 | In determining the stages and controls for design and development, the organization considers the nature, duration and complexity of the design and development activities.. | | | | | |
| 34 | In determining the stages and controls for design and development, the organization considers the required process steps, including applicable design and development reviews. | | | | | |
| 35 | In determining the stages and controls for design and development, the organization considers the required design and development verification and validation activities. | | | | | |
| 36 | In determining the stages and controls for design and development, the organization considers the responsibilities and authorities involved in the design and development process. | | | | | |
| 37 | In determining the stages and controls for design and development, the organization considers the internal and external resource requirements for the design and development of products and services. | | | | | |
| 38 | In determining the stages and controls for design and development, the organization considers the need to control the interfaces between the people actively involved in the design and development process. | | | | | |
| 39 | In determining the stages and controls for design and development, the organization considers the need for the active participation of customers and users in the design and development process. | | | | | |
| 40 | In determining the stages and controls for design and development, the organization considers the requirements for the subsequent provision of products and services. | | | | | |
| 41 | In determining the stages and controls for design and development, the organization considers the level of control of the design and development | | | | | |

| No | Item | | | | | |
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| | | Strongly | Agreed | Indifferent | Disagree | Strongly |
| | process expected by customers and other relevant stakeholders. | | | | | |
| 42 | In determining the stages and controls for design and development, the organization considers the documented information necessary to demonstrate that the design and development requirements have been met. | | | | | |
| 43 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering functional and performance requirements. | | | | | |
| 44 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering information from previous similar design and development activities. | | | | | |
| 45 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering legal and regulatory requirements. | | | | | |
| 46 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering Standards or codes of practice that the organization has committed to implement. | | | | | |
| 47 | The organization determines the essential requirements for the specific types of products and services to be designed and developed, considering the potential consequences of failure due to the nature of the products and services. | | | | | |
| 48 | The organization resolves contradictions in design and development inputs. | | | | | |
| 49 | The organization retains documented information on design and development inputs. | | | | | |
| 50 | The organization applies controls to the design and development process to ensure that the results to be achieved are defined. | | | | | |
| 51 | The organization applies controls to the design and development process to ensure that reviews are conducted to assess the ability of the design and development results to meet requirements. | | | | | |
| 52 | The organization applies controls to the design and development process to ensure that verification activities are performed to ensure that design and development outputs meet the requirements of inputs. | | | | | |
| 53 | The organization applies controls to the design and development process to ensure that validation activities are performed to ensure that the resulting products and services satisfy the requirements for their specified application or intended use. | | | | | |
| 54 | The organization applies controls to the design and development process to ensure that any necessary action is taken on issues identified during reviews, or verification and validation activities. | | | | | |
| 55 | The organization applies controls to the design and development process to ensure that documented information on these activities is retained. | | | | | |
| 56 | The organization ensures that design and development outputs meet input requirements. | | | | | |
| 57 | The organization ensures that design and development outputs are suitable | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | for downstream processes for the provision of products and services. | | | | | |
| 58 | The organization ensures that design and development outputs include or reference monitoring and measurement requirements, where appropriate, and acceptance criteria. | | | | | |
| 59 | The organization ensures that design and development outputs specify the characteristics of products and services that are essential for their intended purpose and their safe and correct provision. | | | | | |
| 60 | The organization maintains documented information on design and development outputs. | | | | | |
| 61 | The organization identifies, reviews and controls changes made during the design and development of products and services, or subsequently to the extent necessary to ensure that there is no adverse impact on conformity to requirements. | | | | | |
| 62 | The organization retains documented information on design and development changes. | | | | | |
| 63 | The organization retains documented information on the results of reviews. | | | | | |
| 64 | The organization retains documented information on the authorization of changes. | | | | | |
| 65 | The organization maintains documented information on actions taken to prevent adverse impacts. | | | | | |
| 66 | The organization ensures that externally supplied processes, products and services conform to requirements. | | | | | |
| 67 | The organization determines the controls to be applied to externally supplied processes, products and services when products and services from external suppliers are intended to be incorporated into the organization's own products and services. | | | | | |
| 68 | The organization determines the controls to be applied to externally supplied processes, products and services when products and services are provided directly to customers by external suppliers on behalf of the organization. | | | | | |
| 69 | The organization determines the controls to be applied to externally supplied processes, products and services when a process, or part of a process, is provided by an external supplier as a result of a decision by the organization. | | | | | |
| 70 | The organization determines and applies criteria for the evaluation, selection, performance monitoring and re-evaluation of external suppliers, based on their ability to provide processes or products and services in accordance with requirements. | | | | | |
| 71 | The organization retains documented information on these activities and any necessary actions arising from the assessments. | | | | | |
| 72 | The organization ensures that externally supplied processes, products and services do not adversely affect the organization's ability to consistently deliver compliant products and services to its customers. | | | | | |
| 73 | The organization ensures that externally supplied processes remain within | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | the control of its quality management system. | | | | | |
| 74 | The organization defines the controls it intends to apply to an external supplier and those it intends to apply to the resulting outputs. | | | | | |
| 75 | The organization considers the potential impact of externally supplied processes, products and services on the organization's ability to regularly meet customer and applicable legal and regulatory requirements. | | | | | |
| 76 | The organization considers the effectiveness of the controls implemented by the external supplier. | | | | | |
| 77 | The organization determines the verification, or other activities necessary to ensure that externally supplied processes, products and services meet requirements. | | | | | |
| 78 | The organization ensures the adequacy of the requirements before communicating them to the external supplier. | | | | | |
| 79 | The organization communicates to external suppliers its requirements for the processes, products and services to be provided. | | | | | |
| 80 | The organization communicates to external suppliers its requirements for approval of products and services. | | | | | |
| 81 | The organization communicates to external suppliers its requirements for approval of methods, process and equipment. | | | | | |
| 82 | The organization communicates to external suppliers its requirements for approval of the release of products and services. | | | | | |
| 83 | The organization communicates to external suppliers its requirements for competence, including any required qualifications of individuals. | | | | | |
| 84 | The organization communicates its requirements to external suppliers. | | | | | |
| 85 | The organization communicates to external suppliers its requirements for external supplier interactions with the organization. | | | | | |
| 86 | The organization communicates to external suppliers its requirements for verification or validation activities that the organization, or its customer, intends to carry out at the external supplier's facilities. | | | | | |
| 87 | The organization implements the production and provision of the service under controlled conditions. | | | | | |
| 88 | The organization implements the production and provision of the service by providing documented information that defines the characteristics of the products to be produced, the services to be rendered, or the activities to be performed, when applicable. | | | | | |
| 89 | The organization implements the production and provision of the service by providing documented information that defines the results to be achieved, when applicable. | | | | | |
| 90 | The organization implements the production and provision of the service ensuring the availability and use of appropriate monitoring and measurement resources, where applicable. | | | | | |
| 91 | The organization implements production and service provision and implements monitoring and measurement activities at appropriate stages to verify that the criteria for control of processes or their outputs, and the | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | acceptance criteria for service products, where applicable, are met. | | | | | |
| 92 | The organization implements the production and provision of the service with the use of the appropriate infrastructure and environment for the operation of the processes, when applicable. | | | | | |
| 93 | The organization implements the production and provision of the service and the appointment of competent persons, including any required qualifications, where applicable. | | | | | |
| 94 | The organization implements production and service provision as well as periodic validation and revalidation of the capability to achieve the planned outcomes of the production and service delivery processes, where the resulting outputs cannot be verified by subsequent monitoring or measurement activities, where applicable. | | | | | |
| 95 | The organization implements the production and provision of the service and implements actions to prevent human error, where applicable. | | | | | |
| 96 | The organization implements the production and provision of the service and implements release, delivery and post-delivery activities, where applicable. | | | | | |
| 97 | The organization uses appropriate means to identify outputs, where necessary, to ensure conformity of products and services. | | | | | |
| 98 | The organization identifies the status of outputs with respect to monitoring and measurement requirements through production and service delivery. | | | | | |
| 99 | The organization controls the unique identification of outputs where traceability is a requirement. | | | | | |
| 100 | The organization retains the necessary documented information on outputs to enable traceability. | | | | | |
| 101 | The organization takes care of property belonging to customers or external suppliers while it is under the organization's control or being used by the organization. | | | | | |
| 102 | The organization identifies, verifies, protects and safeguards the property of customers or external suppliers supplied for use or incorporation into products and services. | | | | | |
| 103 | The organization informs the customer or external supplier when property of a customer or external supplier is lost, damaged or otherwise deemed unsuitable for use. | | | | | |
| 104 | The organization retains documented information about what happened. | | | | | |
| 105 | The organization preserves outputs during production and service delivery to the extent necessary to ensure conformity to requirements. | | | | | |
| 106 | The organization meets the requirements for post-delivery activities associated with products and services. | | | | | |
| 107 | In determining the scope of required post-delivery activities, the organization considers legal and regulatory requirements. | | | | | |
| 108 | In determining the scope of required post-delivery activities, the organization considers the potential unintended consequences associated | | | | | |

| No | Item | Strongly | Agreed | Indifferent | Disagree | Strongly |
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| | with its products and services. | | | | | |
| 109 | In determining the extent of post-delivery activities required, the organization considers the nature, use and expected useful life of its products. | | | | | |
| 110 | In determining the scope of required post-delivery activities, the organization considers customer requirements. | | | | | |
| 111 | In determining the scope of post-delivery activities required, the organization considers customer feedback. | | | | | |
| 112 | The organization reviews and controls changes to production or service delivery to the extent necessary to ensure continued conformity to requirements. | | | | | |
| 113 | The organization maintains documented information describing the results of the review of changes, the persons authorizing the change and any necessary actions arising from the review. | | | | | |
| 114 | The organization implements planned arrangements, at appropriate stages, to verify that product and service requirements are met. | | | | | |
| 115 | The organization releases products and services to the customer until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. | | | | | |
| 116 | The organization retains documented information on the release of products and services, including evidence of conformance to acceptance criteria. | | | | | |
| 117 | The organization maintains documented information on the release of products and services, including traceability to the persons authorizing the release. | | | | | |
| 118 | The organization ensures that outputs that do not conform to its requirements are identified and controlled to prevent their unintended use or delivery. | | | | | |
| 119 | The organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services (applying also to nonconforming products and services detected after delivery of products, during or after provision of services). | | | | | |
| 120 | The organization addresses nonconforming outputs in one or more of the following ways: a) Correction, b) Separation, containment, return or suspension of product and service provision, c) Informing the customer, or d) Obtaining authorization for acceptance under concession. | | | | | |
| 121 | The organization verifies conformity to requirements when non-conforming outputs are corrected. | | | | | |
| 122 | The organization maintains documented information that: a) Describes the nonconformity, b) Describes the actions taken, c) Describes all concessions obtained and d) Identifies the authority deciding the action with respect to the nonconformity. | | | | | |

Source: Author's own elaboration.

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