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STRUCTURE AND FREQUENCY OF PRODUCT NONCONFORMITIES IN THE CONTEXT OF CUSTOMER SATISFACTION

Abstract: *The main goal of this paper is to evaluate the non-conformity of a product from the end-user point of view (assessment of conformity through second-party audits). A test sample of 510 reports about the estimation of compliance with the end-user requirements included. In doing the research, we identified 246 non-conformities, which we classified into three categories, documentation non-conformities, non-conformities established by verification, and non-conformities determined by validation. Empirically, we found the most significant group of non-conformities and calculated confidence limits for this group by using the beta distribution. We applied this type of distribution because it is a very flexible type, and it covers a wide range of different shapes depending on the values of parameters. The analysis of the obtained quantitative indicators of non-conformity showed that the purpose of the product is of the utmost importance to the end user. In connection with the non-conformity indicators, we analyzed the requirements of point 8.2 "Requirements for products and services" of ISO 9001:2015. In accordance, the manufacturer recommends the aspects on which to focus during the process of designing, developing, manufacturing and defining the requirements of the quality of its product.*

Keywords: *Quality, Nonconformities, Customer Satisfaction, ISO 9001, Beta Distribution*

1. Introduction

Today, the main features of the market are high quality products and services at competitive prices. It is a fact that quality goes abreast of human civilization development, and through history customers have learned to be careful and to use their methods of control and testing. Also, the life cycle of a not ever-changing product is shortening. Any product requires constant changes (of its characteristics) in terms of refinements and adjustments to meet new needs and expectations of higher-level customers (Tang, 2022). The essence is the introduction of innovation (value added) and more modern and better technologies in major processes (Kusuman et al., 2014). As long as the market operates based on supply and demand, the products will be bought and sold based on price, quality, and speed of response to the user and/or selection (customer preferences) (Hallowell, 1996; Kusi-Sarpong, et al., 2018).

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Cruz A.V. (Cruz, 2015) also investigated the extent to which there are relationships between product quality and customer satisfaction and whether product costs and product safety affect this relationship.

Each customer wants to be treated separately (individually) according to their needs. Therefore, the quality management system is primarily based on the principle of "Customer Focus". This principle includes a large number of requirements specified in ISO 9001:2015.

This paper is an analysis of a report on the technical products (special purpose products) that were tested by the end user (Army). It is a conformity assessment for your needs, i.e., assessment of conformity through second-party audits. As a result, the structure and frequency of product non-conformities identified by the user in the process of receiving the product (special purpose product) are determined. Based on this result, it is possible to draw appropriate lessons for organizations and identify which requirements of ISO 9001:2015 stand out as particularly important.

2. Theoretical background

In her work, Pratibha A. Dabholkar (Dabholkar, 2015) addressed the direct and indirect effects of customer influence on service quality, and in their book, Bergman Bo and Klefsjö Bengt (1994) addressed, among other things, the relationship between quality improvements on the one hand, and cost, profitability and success on the other. The organization needs to recognize the customer's requirements promptly to account for the costs arising from the customer's defined quality requirements (Pimentel & Major, 2016). In his work, Brkljač (2017), "The Highest Hierarchical Principle for QMS in Profit Oriented Organizations", defines the relationship between quality assurance and the profit that an organization makes: "The usable characteristics and esthetic value are the essence of the values for the user, in terms of the exchange, determines the corresponding monetary value. If two different products or services can meet the needs and aspirations of people at the same level and at the same time are sold at the same price then they have the same value for the user. The products of better quality (higher usable and esthetic characteristics for the user) create the conditions for the acceptance and higher prices."

Muhammad and Ahmed (2016) says that product quality is a critical determinant of consumer satisfaction. In his work, he proves that Chinese products are perceived as price-effective, but the area of product quality requires the manufacturer's immediate attention because Chinese products are perceived as poor quality.

Also, Herman Tang (2022) says, the quality of service refers to the direct relationship between customer expectations and supplier performance.

Jahanshahi et al. (2011), are based on the result of the study showing that there is a high positive correlation between the appearance of customer service and the quality of the product with the satisfaction of the user and his loyalty.

In their paper, Sari and Ali (2020) analyze the effect of product quality and quality of service on customer satisfaction.

And finally, dr. Ejika Sambo et al. (2021) show that product quality is one of the main determinants of customer satisfaction.

According to ISO 9000:2015, quality assurance means focusing on providing confidence those quality requirements will be met. Testing is the determination according to the requirements for the specific intended use of the product (Du et al., 2016). By the definitions given in ISO 9000:2015, the terms verification and validation are:

- Verification – confirmation, through the provision of objective evidence, that specified

requirements have been fulfilled,
- Validation – confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Likewise, by that standard, conformity implies the fulfilment of the requirement, and nonconformity implies that the requirement is non-fulfilment.

Conformity assessment is any activity that determines whether a product meets the quality requirements (ISO 17000:2020; ISO/IEC 17020:2012; ISO/IEC 17025:2017; EN ISO/IEC 17065:2012). There are three types of conformity assessment which can be distinguished based on who performs the assessment: first-party conformity assessment; second-party conformity assessment and third-party conformity assessment (Dželetovic, 2011).

- First-*party conformity assessment*

In this case, the product organization itself for internal purposes performs the conformity assessment. Usually, the manufacturer issues a declaration of conformity as an output document from the assessment process.

- *Second-party conformity assessment*

In this case, customers of the organization or other persons interested in the product evaluate the conformity for their needs. The results of empirical research, which are presented in this paper, are based on the analysis of conformity assessment reports of the second-party audits (by the Army as a customer).

- *Third-party conformity assessment*

In this case, conformity assessment is performed by a person or organization that is completely independent regarding the product, meaning that neither the manufacturer nor the user, is related to the product. The assessment is carried out by an independent body, and as a result, it usually issues a test report.

3. Experimental section - Structure and Frequency of Nonconformities in Context of Customer Satisfaction

The purpose of this empirical study is to determine the requirements of ISO 9001:2015 which should be emphasized. To achieve the goal of this research, it was necessary to apply empirical methods, especially methods which include content analysis of test results. The content analysis method is applied to the technical product test report analysis (hereinafter referred to as the product) for the needs of the end user (the Army). The subject of the analysis is the reports of the Research and Development Institute, whose main activity is testing (verification and validation) of products according to the requirements of the end users. In this study, the performance of the product is analyzed from the point of view of customer satisfaction. In doing so, the relationship between product performance and customer expectations or between product performance, expectations and customer satisfaction are not considered. The analysis covers 510 compliance assessment reports. A total of 246 nonconformities are identified.

For this research, we classify the product's identified nonconformities into three groups:

- Nonconformities in documentation determined by inspection,
- Nonconformities of products determined by verification, and
- Nonconformities of products determined by validation.

There are 246 discrepancies: 61 (24.8%) relating to documentation discrepancies; 54 (21.95%) are nonconformities determined by verification and 131 (53.25%) nonconformities determined by validation.

From the diagram (Figure 1), it can be seen that the exploitation (user) requests are the most present in the structure of identified non-conformities (53.29%). This indicates

that the user of the product is most interested in the benefits provided by the product. In this regard, the end user prefers to set requirements that are verified during the validation process.

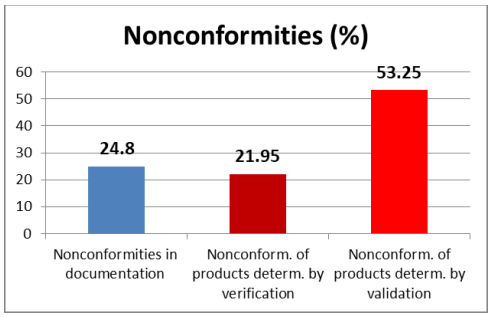

Figure 1. Structure and frequency of identified mismatches by type

Given that the discrepancies identified in the validation process (53.25%) dominate, it is necessary to determine the confidence limits for relative frequency.

3.1. Determining confidence limits for relative frequency: Nonconformities established by validation (53,25%)

To determine the confidence limit for the relative frequency of non-conformities established by validation (53.25%), the beta distribution and the corresponding computer program are used. In their book, Montgomery and Runger (2018) argue that the beta distribution is very flexible because it covers a range of different shapes depending on the values of parameters. It can be used to model a random variable that takes on the values falling within a bounded interval.

Euler (Euler) integral of the first type of form (Brkić & Nikolic, 2007)

$$\beta_{(a,b)} = \int_0^{+1} x^{a-1}\,(1-x)^{b-1}\,dx;\,(a,b>0)$$

Called the beta function. Parameters (a and b) are usually realistic, though they can be complex numbers.

The probability distribution of a continuous random variable X that can take any value between 0 and 1, including these limits, and its probability density function is given by the following expression:

$$f(x) = \frac{1}{\beta(a,b)}\,x^{a-1}(1-x)^{b-1}$$

for $0 \le x \le 1$ and the parameters $a, b > 0$. $\beta(a, b)$ is a beta function.

For $a = b = 1$, the beta distribution becomes the normal interval distribution [0,1].

Mathematical Expectation of X:

$$E(X) = m = \frac{a}{a+b}$$

variance of X:

$$V(X) = \sigma^2 = \frac{ab}{(a+b)\,(a+b+1)}$$

The following figure (Figure 2) shows a graph of this distribution.

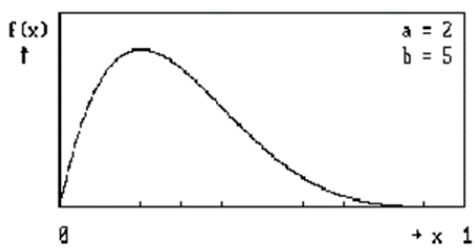

Figure 2. Beta distribution (in the interval [0, 1])

The probability distribution of a continuous random variable X that can take any value between A and B, including these boundaries, and its probability density function is given by the following expression:

$$f(x) = \frac{1}{(B-A)\,B(a,b)}\left(\frac{x-A}{B-A}\right)^{a-1}\left(1-\frac{x-A}{B-A}\right)^{b-1}$$

for $A \le x \le B$ and the parameters $a, b > 0$. A is the beginning parameter and B is the end parameter of this distribution.
By shift we get the following expression:

$$x' = \frac{x-A}{B-A}$$

the interval [A, B] is mapped to the interval [0, 1], so that the random variable x' has a beta distribution in the interval [0, 1].

The following figure (Figure 3) shows a graph of this distribution.

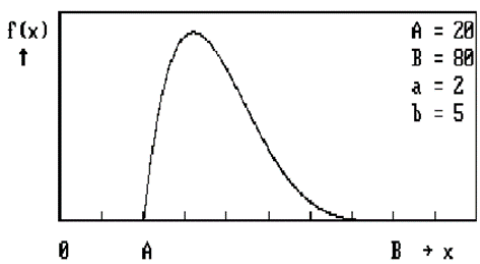

Figure 3. Beta distribution (in interval [A, B])

An appropriate computer program is used to determine the confidence limits for the unknown probability $p = P(A)$.[1]

Numeric values defined by expressions:

$$p_1 = 1 - x_{n-1;m+1}, \alpha_1$$
$$p_2 = x_{m+1;n-m}, \alpha_2$$

Represent confidence limits for the unknown probability of the observed event A, i.e. $p = P(A)$. In the above expressions, p_1 is the lower and p_2 is the upper confidence limit for p, n is the number of trials, and m is the number of successes, i.e. the number of trials in which the observed event A was realized, α_1 and α_2 are the lower and upper risk, respectively, $x_{n-1;m+1},\alpha_1$, and $x_{m+1;n-m},\alpha_2$ are the upper quantizes of the beta distribution, whose values can be found in the corresponding statistical tables, and here they are determined by a single subroutine.

When the confidence limits p_1 and p_2 are determined, then with confidence:

$$P = 1 - (\alpha_1 + \alpha_2)$$

it can be argued that the confidence interval [p_1, p_2] overlaps the unknown probability $p = P(A)$.

In a particular research case, n = 510 (number of conformity assessment results analyzed - number of trials), m = 131 is the number of nonconformities established by validation, and $\alpha_1 = \alpha_2 = 0.05$, confidence limits for unknown probability $p = P(A)$ are: $p_1 = 0.4711$, $p_2 = 0.6020$.

The calculated confidence limits relative to the relative frequency established by empirical research – $f = m / n = 0.5325$ or 53.25% are in the range of 47.11% to 60.20%.

4. Discussion

As pointed out above, the subject of the research is the reports obtained by evaluating conformity assessment on the other side (by the customer). The calculated confidence limits for the discrepancies identified in the validation process range from 47.11% to 60.20%. Relating to that, this level of trust (maximum value of 60%) indicates that the end user wants to make requests that have been verified in the validation process (Ravichandran, 2016). On the other hand, it should be unacceptable for organizations that the customer identifies non-conformities in the last stage of the delivery process, which the manufacturer should do.

All the requirements of ISO 9001:2015 are important and it is important to fulfil them in the context of establishing a quality management system in the organization.

[1] Computer program for determining confidence limits for unknown probability $p = P(A)$ was developed by the Research and Development Institute, author: Dragoljub Brkić, Ph.D.

However, this research indicates the importance of the requirements of clause 8.2 of ISO 9001:2015, which reads "Requirements for products and services". The main points of this request are: "Customer communication" (8.2.1); "Determining the requirements for products and services" (8.2.2); "Review of the requirements for products and services" (8.2.3) and "Changes to requirements for products and services" (8.2.4).

4.1. Customer communication

Stakeholder requirements and their realization are fundamental to an effective quality management system. Stakeholder requirements can be counterbalanced by the price-quality-profit ratio. Customers want the highest quality and faster response time from the supplier (service provider) for the lowest possible cost, and the owners mostly want the highest possible profit and a satisfied user of their product and service. That is why communication with the user of products and/or services is very important.

The organization must identify and implement an effective solution for communicating with users regarding queries. Customer inquiries are the result of the effectiveness of the marketing process. If the marketing function is successful, customers will contact the organization to obtain more information, clarify the price, specification or delivery, request a quote, or the offer itself. Within the sales process, it is necessary to establish a process for handling inquiries. Buyers need to be given the right information. The inquiry process must maximize the ability to sell. Queries need to go through a process that will turn them into sales. Thus, in applied research (surveys, interviews, etc.) in which consumers are questioned about what they are seeking in a product, the expressive (nonmaterial, psychological) attributes of the product are more likely to be mentioned and not the instrumental ones if the respondent is satisfied with the item. However, this research shows that satisfactory instrumental performance is quite important because instrumental requirements must be satisfied before satisfaction from expressive performance can occur.

Therefore, the staff who create inquiries and those who receive inquiries, as well as the personnel who first come into contact with the customer must be competent for the job.

4.2. Determining the requirements for products and services

Every organization needs to know that there is only one thing to do: to help people reach a goal they would not achieve on their own. The purpose of the requirements of the standard (8.2.2 - Determination of requirements for products and services ISO 9000:2015) is that the organization is expected to have established requirements for the quality of the products and services that it must meet before the onset of operational activities on development. This is one of the most significant requirements in the standard. Many of the problems later encountered can be attributed to misunderstood requirements of the user or a lack of attention to the resources needed to meet the user's requirements.

This research shows that the customer identifies a large number of requests in the last stage of delivery, which the manufacturer should have done.

In the dialogue with the user, the organization should also determine the terms of use. That is why an organization needs to have defined declared characteristics so that it can conduct correspondence with customers. The declared characteristics should include both the conditions for using the product and the limitations due to which the product cannot be used. Accepted requirements imply that it has been determined that the organization can satisfy the claims related to the product being offered.

4.3. Review of the requirements for products and services

Reviewing product and service requirements can be completely independent of the order or contract. It may be necessary to repeat the review when a specific order is received or a contract is concluded. A review of product-related requirements is needed to make sure that the outcome of the claim process is credible. The results of the research show that the user identifies the largest number of non-conformities of a product that are related to its exploitation, so the organization should review the request for the product before accepting the obligation to deliver it to the customer (before submitting the offer, before accepting the contract or order, before accepting the changes to the contract or orders). The purpose of reviewing a product request is to ensure that the requirements are complete, unambiguous and can be met by the organization.

4.4. Changes to requirements for products and services

The organization must find, identify and implement effective solutions for communicating with users regarding customer feedback. Information received from users regarding the quality of the product and service delivered includes positive information in the form of thank-you notes or awards or complaints or complaints as expressions of dissatisfaction. The processes for handling compliments and complaints/complaints vary: praise requires gratitude, and complaints and complaints require action (very often changes to requests).

As a rule, through the process of resolving complaints and appeals, there is a need to modify the product and service requirements. Therefore, the organization must establish and implement effective solutions for communicating with customers regarding changes to requirements arising from orders and contracts. The results of these studies confirm this.

5. Conclusion

By evaluating the non-compliance of the product from the point of view of the end user, an assessment of conformity through the other party was carried out. In doing so, three groups of non-conformities were observed: documentation nonconformities, non-conformities established by verification and non-conformities established by validation. The results of the research showed that the largest number of non-conformities was determined in the validation process and amounted to 53.25%. Using the beta distribution, the confidence limit was calculated for it, which ranged from 47.11% to 60.20%. This result confirms that the user of the product is most interested in the benefits provided by the product. In this regard, the end user prefers to set requirements that are verified in the validation process. Based on this quantitative research, we can see the great importance of the requirements of the ISO 9001/2015 standard that directly refer to the user of the product. In doing so, it was noted that special attention should be paid to meeting the requirements of clause 8.2 “Products and services requirements” of ISO 9001/2015. Consistent and quality fulfilment of this requirement is crucial for the effective and efficient functioning of the quality management system. This research recommends manufacturers that during the process of designing, developing, manufacturing, as well as defining requirements, they should focus on the exploitative requirements of product quality.

The relationship between product performance and customer expectations or between product performance, expectations and customer satisfaction could be the subject of future research since they are not considered in this paper.

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