

Relationship between ISO 9001 Certification and the Number of Non-Conformities Identified during System Audits in Selected Public Universities in Kenya

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ABSTRACT

The quest for International Standard Organization (ISO) 9001 certification as an international quality tool has been embraced for process improvement and positive perception by customers. With ISO 9001 certification, an institution is anticipated to offer exemplary goods or services that meet client prerequisites, needs and expectations thus enhance organizational performance. As evident in previous studies, despite ISO 9001 certification, cases on wastages, missing student marks and time wastage were indicators of non-conformance. There was no clear evidence of past studies on the relationship between ISO 9001 certification and organizational performance with special interest on number of non-conformities identified during systems audit being a component of organizational performance. The purpose of the study was therefore to establish the relationship between ISO 9001 certification and the number of non-conformities identified during system audits in selected public Universities in Kenya. Explanatory research design was used in the study. The research targeted a population of 433 respondents from which a sample size of 205 respondents was selected using purposive and simple random sampling designs. A questionnaire was used to collect data. To answer the objectives of the study, simple linear regression analysis was performed. From the model, ($R^2 = .600$) shows that ISO 9001 certification account for 60% variation in number of non-conformities identified during system audits. There was a positive significant relationship between ISO 9001 certification and number of non-conformities identified during system audits ($\beta=0.611$ and $p < 0.05$). Therefore, a unit increase in ISO 9001 certification led to reduced number of non-conformities identified during system audits. The ISO 9001 certification had a significant influence on the number of non-conformities identified during system audits. For every adoption of the ISO 9001 certification in public universities the number of non-conformities identified during system audits reduced. The study concludes that ISO 9001 certification had a significant positive influence on the number of non-conformities

identified during system audits. Thus, for every adoption of the ISO 9001 certification in public universities the number of non-conformities identified reduced. The study recommends that there is need for management of public universities through the department of quality management to address the non-conformities raised during system audits, need for university management to raise awareness on the importance of standardization and conformity assessment and to entrench the culture of quality in the Kenyan society by promoting practical usage of standards and development of quality related curricula in public universities.

Keywords-- ISO 9001, Certification, Non-Conformities, System, Audits, University

I. INTRODUCTION

The way to increase efficiency and prosperity is through enhancing quality [1]. It is believed that the process of considering quality is of great value to the organization and should be considered a key component of performance. As indicated by [2], the confirmation gives an organizations more prominent view in national and global markets, as certification makes and entity broadly acknowledged in numerous nations. It is acknowledged that ISO 9001 has positively turned around global quality aspect.

While using a quality system to prevent defects as well as measuring quality as the price of conformance and adopting zero defects. It requires integrating the standard with practices already in place. When a new practice such as ISO 9001 is introduced, the organization must find a fit between the ISO 9001 rules and its old ways of operating [3]. In QMS, Non-Conformities (NC) are usually classified based on their frequency and, in some cases, on their impact

on the final product. Non-conformities are classified into major or minor depending on their impact on the product or service. Major non-compliance is regularly observed as a breakdown of a necessity of the quality management system[4]. A minor non-conformance occurs where the impact of the deviance may not cause major impact to the product or service.

Quality in product lifecycle is a new focus in quality management, which holds the promise of seamlessly integrating all quality data produced throughout the life of a product [5]. Quality Management (QM) encompasses a set of mutually reinforcing principles, each of which is supported by a set of practices and techniques. It can be defined as a holistic management philosophy that fosters on all functions of an organization through continuous improvement and organizational change [6].

Sousa and Voss [7] state that Quality Management has become an all-pervasive management philosophy, finding its way into most sectors of today's business society, while [8] divides QM into four dimensions, i.e. (i) Quality planning, (ii) Quality control, (iii) Quality assurance and (iv) Quality improvement. In this context Six Sigma was considered as a new QM method [9] "for strategic process improvement and new product and service development that relies on statistical methods to make dramatic reductions in customer defined defect rates" [10].

Similarly, Total Quality Management (TQM) is a widely recognized quality management philosophy. It has become the key slogan for organizations that strive for competitive advantage in markets [11] favoring excellence in a sustainable development approach [12]. TQM provides a set of practices emphasizing among others, continuous improvement, meeting customers' requirements, reducing rework, long-range thinking, increased employee involvement and teamwork, process redesign, competitive benchmarking, team-based problem-solving, constant measurement of results, and closer relationships with suppliers [13].

Sun and Li,[14] focused on reduction of surface quality-related problems of large plastic products through product design, raw material selection, forming method and structural design. Similarly, [15] chased the "zero defects" goal through the control of critical parameters related to the performances of casting process. They obtained a defectiveness reduction by limiting manual operations to help the repetition of processes through automation and introducing on-line measurements along the production process. Both authors faced non-conformities based on the analysis of design measures and geometrical product conformity.

Similarly, Savino [15] defined a set of pointers to front quality non-conformities and to measure production improvements. Certification to ISO 9001 management of quality set-up models is intended to enable firms to assure

that they take care of customers' issues as well as stakeholders while attaining statutory and regulatory requirements recognized with products or services. ISO 9000 manages the essentials of value management frameworks, including the 8 principles of management. ISO 9001 provides for conditions that organizations wishing to meet the standard must satisfy [16].

Accredited certification entities provide independent audits and confirmation that the institutions have met the provided requirements to enable them get certified to ISO 9001. ISO 9001 international standard is reviewed periodically based on the market need and emerging issues that may necessitate reviews. The current version is ISO 9001:2015 international standard that gives an opportunity for 10 clauses which provides a comprehensive cover of all areas of focus[17].

As commented by Schroeder [18], "...ISO 9001 Certification majorly affects overall global quality practices. Numerous establishments are requesting ISO certification from their providers as a condition for partnering together". This circumstance has made more of service/product organizations strive to achieve ISO 9001 certification. Progressive performance is relied upon to build information and database on ISO 9001 certified organizations. Aguilar-Escobar & Garrido-Vega, [19], study findings showed that ISO 9001 affirmation has prompted an expansion in the quantity of clients in the Hospital, prompted arrangement of work guidelines and enhanced performance in organizations through anticipation of deformities and enhanced authoritative reputation.

The impact of ISO of ISO 9001 accreditation may be positive or negative depending on specific contextual issues and factors, the use of the standard can improve organizational efficiency and mitigate the risks of improper use[20]. In itself ISO certification should not be considered as a goal, but a process with its own drawbacks, benefits and surprises. Upon certification, a number of public universities have reported growth according to Schroeder [18] "...ISO 9001 Certification majorly affects overall global quality practices. Most institutions are seeking ISO certification from their providers as a condition for engaging each other". Certification has further allowed public universities to demonstrate their commitment to best practice, efficiency, and sustainability.

II. STATEMENT OF THE PROBLEM

The success of organizations such as institutions of higher learning largely depend on an organization's human resources [21]&[22]. Chacha[23] on Higher education in Kenya found out that the student enrolment was higher at public universities while resources were strained. The situation affected service and product delivery.

Thujo[24] argued that the institutions Internal infrastructure and the Quality Management System of public universities in Kenya are expected to influence quality performance of universities. ISO 9001 certification being a quality management tool for implementing and monitoring organizational[25].

Most certified organizations continue to offer services which to a large extent do not meet customer requirements[26] and public universities are no exceptions. Despite ISO 9001 certification, there are reported cases of poor service delivery, re-works and defects, wastages, ineffectiveness, failure to achieve targets, slow service delivery, missing marks for students and poor time management which among the indicators of wanting performance which continue to affect various public universities[27]. While there exists a number of evidences of positive effects of ISO 9001 outside Kenya[28]&[29] on organizational performance, such evidence is scanty in Kenya. Universities embrace different mechanisms to capture and address customer complaints.

The complaints raised have negative connotation to service and product delivery at the universities. Solving complaints require management attention, resource provision and proper and appropriate actions. If not addressed, complaints result to non-conformities. Failure to comply on a number of areas serve as a clear indication of how service delivery deviates from the set objectives and procedures [30]. Therefore, this study sought to establish the relationship between ISO 9001 certification and number of non-conformities identified during system audit at selected public universities in Kenya.

III. LITERATURE REVIEW

A quality audit is conducted to verify conformance of products according to quality manuals and product design specifications, and to control six factors affecting quality such as man, machines, material, methods, environments and measurements [31]. A quality audit aims at monitoring actions and processes, and at analyzing the states and conditions to solve quality problems [5]. A complete definition of quality that somewhat reaches a consensus in products and services domain can be given by international standards [32], it defines quality as the measure by which intrinsic features meet requirements. The concept of quality may have different definitions and applications, depending on the specific work area [33].

In particular, Murthy and Ravi Kumar [34] proposed three definitions of quality, i.e. (i) quality of performance, (ii) quality of conformance, (iii) quality of service (repairs during post-sale period) where quality of conformance is determined by quality of manufacturing e.g. technologies and quality control schemes used by the manufacturer. The concept of quality along product

lifecycle gained attention by the application of Quality Function Deployment (QFD) which is a product development method dedicated to translating client requirements into activities to develop products and services by the use of appropriate matrixes [35].

Forza and Filippini[36] analyzed the impact of Total Quality Management (TQM) on quality conformance and customer satisfaction identifying four critical aspects for its implementation in companies. The concept of quality conformance is strictly related to non-conformity (NC) of Quality Management Systems (QMSs) where a NC is a mistake that is found in some phases of a production process and/or on the finished product, or something that did not go as planned [37].

Savino [15] developed a QMS methodology defining a set of finalised pointers to measure production improvements and to deal with quality management non-conformities. An extension of such work based on fuzzy logic by[38]. According to practical findings [39], without an effective corrective and preventive action program, problems will occur again, continuous improvement will be difficult and any of the other quality management system elements might not work properly.

QMS is essentially based on the requirements of ISO 9001 standard where its audits are used to evaluate the level of compliance to the requirements of relevant standards [40] and[41] analysed the difficulties during implementation of QMS according to these international requirements and among the challenges was deformities of products and services. A study by Wu[42] developed an information analysis system to isolate the causes of non-conformity and quickly identify the causes of problems thereby reducing the time taken to solve quality-related problems.

Boer and Blaga[32] presented the strategy for the joint use of quality tools and human resources management to achieve positive results. There were reported cases of failure to meet the set threshold and thus resulted in non-compliance. An organizational audit is possible during this period, because it enables some non-conformities with the ISO requirements to be avoided. Quality management policies in majority of companies evolve continuously over a number of years by focusing on quality issues that are critical at any given instant of time [43], since quality is widely recognized broadly as one of the key factors to success in global market for all kind of business [44]. Quality management practices and programs such as total quality management (TQM), six sigma, statistical process control and external certification programs such as the ISO 9000 series have been extensively researched in almost any industry sector [45].

Quality and production control are key functions to enhance competitiveness in industrial firms. The link between Quality and firms' performances[46]and [47]who

explored the relationship between quality management practices and competitive performance in manufacturing companies. Colledani and Tolio[46] affirm that Quality control allows to meet high product quality standards, reducing scraps and reworks. Usually, manufacturing systems start in an 'in-control' state, producing conforming items of acceptable quality and, after a random span, they shift to the 'out-of-control' state and start producing non-conforming items [48].

Ahire and Dreyfus [49]state that "Product quality is the result of manufacturing resources – people, processes, materials, and equipment – oriented to varying degrees for achieving customer satisfaction and low deficiencies" and the consensus of results from other empirical studies is that quality management practices effectively improve product quality and overall performance [50]. In light to these studies, it seems fundamental to drive firm efforts and resources towards a prioritization of interventions aimed to front quality problems and to reduce wastes, with related production losses and costs.

According to Love [51]costs of Non-Conformities (NC) are typically broken down into two areas: (i) cost of internal failures (scrap, rework and other excesses before the product is shipped) and, (ii) cost of external failures (warranty services, costs of product failures during its use). While in conformity costs we may also include those ones relative to fault prevention, within NC costs are encompassed all the direct and indirect costs of faults [52].

An interesting finding of Khana[53] relates the new cost of the product to the probability that a defectiveness may be found by the inspector or by the buyer. On the same line, the works of [55]and Khana[54]inspired us in modeling the approach. In their works, Wahab [55]appraise the learning effects related to poor quality and related holding costs of defective items. The examination recommended further training and top management responsibility.

Martin [56] on impact of quality management systems (ISO 9001) Certification on hierarchical execution in Tanzania found that the idea of items and its sum (volume) has been improved in those institutions which have been affirmed with Quality Management System (ISO 9001). The paper points out some quality issues such rejects of a couple of items which don't meet client prerequisites, it was likewise apparent that best management ought to be conferred and dynamic in actualizing the necessity stipulated in the ISO 9000 certification requirements. Management of the organization look for speedy benefits from ISO 9001 compliance confirmation, ISO 9001 affirmation positively affects performance[57].

Tetik and Karahan [58]found out that certification had a positive impact on performance but there were defects in product production. The literature reviewed indicated mixed findings on the performance of ISO 9001

certified organizations and some cases of defects from the firms and low performance of some organizations despite their compliance.

IV. THE ORETICAL FRAMEWORK

The theory of constraints (TOC) Goldratt [59]is a management paradigm that observes any management system as being confined in achieving a more noteworthy measure of its targets by couple of requirements. The theory considers that there is at least one constraint and applies the focusing approach process to identify the constraint and rework on the structures of the institution around the provisions [60].

A constraint is anything that shields the structure from achieving a set measure of its goal. There are various ways that requirements can show up, however a middle rule inside ToC is that there are not enough resources[61]. Imperatives can be internal or outside to the structure. At times, the internal systems can cause constraints whereas on some instances external factors may lead to constraints[62]. Resources will and have never been sufficient and a struggle between resources needed and production is a challenge to most organizations.

V. RESEARCH METHODOLOGY

This study adopted explanatory and descriptive research designs as it seeks to explain the phenomena under study by testing hypotheses by measuring relationships between variables. According to Saunders[63], studies that establish causal relationships between variables use explanatory design. The design was deemed appropriate for the study allowed the study to be carried out in the natural settings and allow the researcher to employ probability samples. The explanatory research design was suitable because the study was mainly be concerned with quantifying a relationship or comparing groups purposely to identify a cause-effect relationship. The study solicited quantitative data which is analyzed descriptively and inferentially.

This study targeted process owners who are the custodians of the system, Management Representatives who are in charge of implementation and working of the system and Internal Quality Auditors who monitors and report the performance of the system in selected six public universities in Kenya and selected 433 respondents. The study focused on the universities that have been in existence for the last 10 years this six public universities, however the study is to be conducted at the universities that were certified by Kenya Bureau of Standards. The research targeted a sample size of 205 respondents who were appropriate for providing a focal point for the study.

The sample should be illustrative and allow the scientist to make precise appraisals of the contemplations and conduct of the bigger populace. The sample size of the study was calculated using the formula recommended [64]:

$$S = \frac{X^2NP(1-P)}{d^2(N-1) + X^2P(1-P)}$$

S = required sample size

X² = the table value of chi-square for one degree of freedom at the desired confidence level

N = the population size

P = the population proportion (assumed to be .50 since this would provide the maximum sample size)

d = the degree of accuracy expressed as a proportion (.05)

At least 10% of the respondents was incorporated to take care of attrition factors that may negatively influence the response rate and thus the study added 20 more to have an overall sample size of 205. A sample size for this study was therefore be 205 respondents

The study utilized multiple sampling techniques. Purposive sampling was used to select deans, internal quality auditors, and management representatives. The study utilized purposive sampling to settle on the most fitting sample to use in the assessment, which used for process owners and management representatives. This was followed by stratified sampling technique to divide the universities into strata with each forming a stratum. Stratified random sampling was appropriate as it enables the researcher to represent not only the overall population but also key sub-groups of the population. Simple random sampling was used to select the 205 employees to participate in the study. Simple random sampling technique was used to select employees that ensured an equal chance of inclusion in the sample.

The final questionnaire had 58 items which were used to measure the various constructs of both independent and dependent variable and service delivery. Each of the respondents as stated in the sample size was issued with a questionnaire to fill. Questionnaires also save time and information can be collected from a very large sample. The questionnaire was designed based on a 5-point likert-type scale which is an ordered scale from which respondents choose one option that best aligns with their view.

The researcher sought expert opinion on content validity. The experts were able to review the items and comment on whether the items cover a representative sample of the behaviour domain. To test the validity of the instruments that were used in the study, the questionnaire was availed to three supervisors together with a panel of experienced researchers of University of Kabianga to review the instruments. The comments from the experts were incorporated into the final instrument.

The reliability of the instruments was determined by undertaking a pilot study in University of Kabianga

which did not take part in the study. Experts input and concerns on the consequence of the research was looked for with the view of setting up the reliability of information and the outcome. The reliability of the research study was enhanced by improving the analysis of the study.

The Cronbach's alpha (α) test of reliability was used to perform a scale test. A Cronbach's alpha of greater than 0.7 indicated reliability of the study [65]. The instruments were tested using pilot study until an acceptable threshold was achieved. The highest Cronbach's alpha was observed for quality service delivery coefficient of 0.951 and the lowest coefficient was Non-conformities had a coefficient of .839 as shown in Table below, while enrolment had a coefficient of 0.893 and training (0.892). The study findings depicted that on overall the Cronbach's Alpha coefficient was 0.979. Since the coefficient was above 0.7 all the constructs when combined were reliable.

The researcher obtained a research permit from the National Commission for Science and Technology and Innovation (NACOSTI) through an introduction letter from the Board of Graduate studies, University of Kabianga. The researcher sought aid of respective research assistants in respective universities to distribute the questionnaires. Questionnaires gave the respondents freedom in providing information without interference. A correlation analysis was conducted to establish the relationship between the independent and dependent variables; this helped to test the hypotheses of the study and show the degree of relationship between the independent and dependent variables. Research hypothesis one to three was tested using the simple regression analysis.

VI. RESULTS

A linear regression model was used to explore the relationship between ISO 9001 certification and number of non-conformities identified during system audits. The R² represented the measure of variability in number of non-conformities identified during system audits that ISO 9001 certification accounted for. From the model, (R² = .600) shows that ISO 9001 certification account for 60% variation in number of non-conformities identified during system audits. The ISO 9001 certification predictor used in the model captured the variation in the number of non-conformities identified during system audits. The change statistics were used to test whether the change in adjusted R² is significant using the F-ratio as shown in Table 1. The model caused adjusted R² to change from zero to .598 and this change gave rise to an F-ratio of 280.567, which is significant at a probability of .05. Based on the regression model, the coefficient of determination (R squared) of .600 showed that 60% of the variation in number of non-conformities identified during system audits can be explained by ISO 9001 certification. There was a significant

change in the explanatory power (F change of 280.567 and p value of 0.000).

Table1:

Model Summary on ISO 9001 certification and number of non-conformities identified during system audits

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.775 ^a	.600	.598	.30455

a. Predictors: (Constant), ISO Certification

The analysis of variance was used to test whether the model could significantly fit in predicting the outcome than using the mean as shown in (Table 2). The regression model with ISO 9001 certification as a predictor was significant (F=280.567, p value =0.001) shows that there is a significant relationship between ISO 9001 certification and number of non-conformities identified during system audits. Thus, reject the null hypothesis that there is no significant relationship between ISO 9001 certification and number of non-conformities identified during system audits.

Table 2:

Analysis of Variance on ISO 9001 certification and number of non-conformities identified during system audits

Model	Sum of Squares	df	Mean Square	F	Sig.
Regression	26.022	1	26.022	280.567	.000 ^b
Residual	17.344	187	.093		
Total	43.366	188			

a. Dependent Variable: Non-conformities

b. Predictors: (Constant), ISO Certification

In addition, the β coefficients for ISO 9001 certification as independent variable were generated from the model, in order to test the hypotheses under study. The t-test was used as a measure to identify whether the ISO 9001 certification as predictor is making a significant contribution to the model. Table 3 shows the estimates of β -value and gives contribution of the predictor to the model. The β -value for ISO 9001 certification had a positive coefficient, depicting positive relationship with number of non-conformities identified during system audits as summarized in the model as:

$$Y = 1.377 + 0.611X + \epsilon$$

..... Equation 1

Where: Y = Non-conformities, X = ISO 9001 certification, ϵ = error term

Table 3:

ISO 9001 certification and number of non-conformities identified during system audits Coefficients

Model	Unstandardized Coefficients	Standardized Coefficients	t	Sig.

	B	Std. Error	Beta		
1 (Constant)	1.377	.145		9.469	.000
ISO Certification	.611	.036	.775	16.750	.000

a. Dependent Variable: Non-conformities

From the findings the t-test associated with β -values was significant and ISO 9001 certification as the predictor was making a significant contribution to the model. The coefficients result in table 3 showed that the predicted parameter in relation to the independent factor was significant; $\beta_2 = 0.611$ ($P < 0.05$). The study hypothesized that there is no significant influence of ISO 9001 certification on number of non-conformities identified during system audits.

The study findings showed that there was a positive significant relationship between ISO 9001 certification and number of non-conformities identified during system audits ($\beta = 0.611$ and $p < 0.05$). Therefore, a unit increase in ISO 9001 certification led to solving of a greater number of non-conformities identified during system audits. The null hypothesis (H_{01}) was rejected. Therefore, we can conclude that ISO 9001 certification had a significant influence on the number of non-conformities identified during system audits. This implies that for each adoption of the ISO 9001 certification in public universities lead to reduced non-conformities identified.

From the study findings the number of non-conformities has significantly reduced since certification, number of non-conformities classified as major have significantly reduced since certification, the non-conformities are closely monitored and addressed in public universities in Kenya. This agrees with [66] findings on their study showed that performance assumes an essential part in deciding to adopt ISO 9001 certification. The management pay close attention to both major and minor non-conformities, process owners fully understand causes of non-conformities, mechanisms of preventing non-conformities are understood by process owners and process owners have been sensitized on ISO 9001 standard expected and required of them and there was increased performance at the university as a result of implementation of documented procedures.

The number of non-conformities has changed since ISO 9001 certification/re-certification and resources required to address raised non-conformities were not always availed as requested. The findings indicated that ISO 9001 certification had a significant influence on the number of non-conformities identified during system audits. Certified organizations were also seen to achieve greater operational results (including productivity) than non-certified organizations.

For every adoption of the ISO 9001 certification in public universities the number of non-conformities identified during system audits reduced. This concurs with Redmond *et al.* (2008) who affirms that performance processes should be aligned, where applicable, to the quality system requirements; at the same time produce records of evidence that system requirements have been met. Measuring, monitoring and reporting the extent of compliance with those performance procedures, analyzing changes to the requirements and conformance that all changes are reflected in the specific requirements when necessary should be monitored and evaluated.

VII. CONCLUSION

From the study findings the number of non-conformities has significantly reduced since certification, number of non-conformities classified as major have significantly reduced since certification, the non-conformities are closely monitored and addressed in public universities in Kenya. The management pay close attention to both major and minor non-conformities, process owners fully understand causes of non-conformities, mechanisms of preventing non-conformities are understood by process owners and process owners have been sensitized on ISO 9001 standard expected and required of them and there was increased performance at the university as a result of implementation of documented procedures.

The number of non-conformities has changed since ISO 9001 certification/re-certification and resources required to address raised non-conformities were not always availed as requested. The ISO 9001 certification had a significant influence on the number of non-conformities identified during system audits. For every adoption of the ISO 9001 certification in public universities the number of non-conformities identified during system audits solved increased. The study concludes that ISO 9001 certification had a significant positive influence on the number of non-conformities identified during system audits. Thus, for every adoption of the ISO 9001 certification in public universities the number of non-conformities identified during system audits reduced.

RECOMMENDATION FOR THE STUDY

The number of non-conformities has changed since ISO 9001 certification and re-certification. Therefore, there is need for management of public universities through the department of quality management to address the raised non-conformities requested during the yearly ISO compliance targets.

There is need for university management to raise awareness on the importance of standardization and conformity assessment and to entrench the culture of

quality in the Kenyan society by promoting practical usage of standards and development of quality related curricula in public universities.

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