

The Impact Of The International Standards Organization Quality Management System On The In Vitro Diagnostics Industry In South Africa

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Abstract

Quality is an important subject in the modern business world and Total Quality Management (TQM) and the ISO-based Quality Management System (QMS) have been the most common approaches to quality management by organizations. This paper assesses customer service, operational performance, quality, competitive advantage and benefits obtained through ISO certification of IVD products. Five hypotheses were tested through a survey conducted among a random probability sample of 337 employees of IVD companies in South Africa, using the online platform, Survey Monkey. The findings revealed that top management's commitment has a strong positive effect on the adoption of ISO certification in the IVD industry and ISO certification has a positive and strong effect on product quality performance, customer service satisfaction focus as well as organisational performance. Based on the research findings, it is recommended that top management of IVD companies should be committed to the adoption of ISO certification and use it as a strategic tool to influence product quality performance, customer service satisfaction focus and organisational performance in the IVD industry.

Keywords: quality; quality management systems, ISO; health sciences; invitro devices

Introduction

Quality management is a challenging topic with an abundance of different views on what to do and how to do it (Knowles, 2011), and in order for companies to make sense of it all, impartial guidance is required, since Knowles (2011) warns that quality standards are for guidance purposes and not a manual on how to do things. Quality is an important subject in the modern business world (Dahlgaard, et al., 2007). Total Quality Management (TQM) and the ISO based Quality Management System (QMS) have been two of the most common approaches utilised by companies since the 1980s (Chen, et al., 2016). According to Chen, et al., (2016) empirical evidence indicates that both TQM and QMS are difficult to implement and sometimes they conflict with each other.

One of the most popular standards is the ISO 9001 Quality Management Standard, which is the focus of this research since ISO 9001 is used in over 175 countries and the number of certifications is increasing (Hallberg, et al., 2018). More than 25 years of research have been conducted on the various ISO (International Organization for Standardization) standards and their impact on

organisations (Carnerud, 2018).

The purpose of ISO is strategic in nature and this is confirmed in clause 4.1 of the ISO 9001:2015 quality management system requirements, which states that the organisation shall determine external and internal matters that are relevant to its purpose and its strategic direction, and that affect its ability to achieve the intended results of its quality management system (ISO, 2015). The South African Department of Health stated that companies must provide the SAHPRA with evidence of their Quality Management System certification. This means that all IVD companies must have ISO certification.

In 2019, only 45% of IVD companies operated with ISO certification (Maseko, 2019). Implementing ISO and obtaining certification without any prior experience is not easy and it is very costly. Much resources are required and the timeline for implementation is very short; thus many organisations decide not to implement ISO certification due to various reasons (Santos, et al., 2016).

More than 25 years of research have been conducted on quality management with the main themes being implementation, performance, cost,

motivation and customer service (Carnerud, 2018). To date, no research has been performed on the IVD industry and quality and/or certification. Irrespective of the specific theme or topic being researched regarding ISO 9001 certification, the findings are generally conflicting, unclear and usually subjective. The main themes in academic articles associated with ISO 9001 certification are a motivation for ISO implementation, management involvement, customer satisfaction, financial impact and operational performance.

Little information is available on why some South African IVD companies are ISO-certified and others are not. It is also unclear what contribution ISO certification makes to the South African IVD medical device industry and customers' perceptions regarding ISO-certified and non-certified companies. Moreover, the impact of compulsory ISO certification on the IVD industry in South Africa is also not documented. With the mandatory implementation of a Quality Management System within each IVD company, the research will critically evaluate ISO certification in the IVD Industry in South Africa.

In light of the above, the problem which warrants research is the value, benefits and sustainability of the change in the quality criteria with regard to ISO certification of products in the IVD industry in South Africa. More specifically, the research will evaluate and assess various topics that include customer service, operational performance, quality of IVD products, competitive advantage and benefits obtained regarding ISO certification.

Literature Review

With the introduction of mandatory ISO certification within the IVD industry in South Africa, and added to this a specific Quality Management System for medical devices (ISO 13485:2016), the value, benefits and sustainability of the change in the quality criteria with regards to ISO certification in the IVD industry in South Africa need to be assessed. Amir et al. (2020) argue that top-level management's awareness of ISO's value and willingness to invest in the standard's implementation have an impact on the standard's ability to improve operations. Several researchers (Fonseca and Domingues, 2018; Yusliza 2019; Burki et al. 2019; Almeida et al. 2018) found that a lack of commitment from upper management hinders the implementation of new procedures. Top-level management's support for ISO can be in the form of the company's ability to develop quality policy and publicise it to ensure that quality objectives are propagated throughout

the organization (Latan, 2018).

The implementation of ISO can have far-reaching effects, and if top management is fully committed to quality programs, it will foster a culture of constant product improvement throughout the entire firm. Dellana et al., (2019) discovered that organizations that want ISO 9000 certification to better serve their clients' needs report different perceived benefits from those that pursue certification to better serve their own needs. According to Latan (2018), top management commitment is critically important for registration of ISO certification in order for the company to communicate to its customers a clear commitment to quality. The extant literature indicates that top management commitment facilitates the adoption of ISO certification (Latan, 2018; Spencer et al., 2013). Therefore, drawing from the aforementioned discussion and the empirical evidence, it is hypothesised that:

H1: Top management commitment has a significant positive effect on the adoption of ISO certification in the IVD industry in South Africa.

ISO Certification and Product Quality Performance

Adoption of ISO certificate plays a significant role in product enhancement, according to (Chen, et al., 2021). The benefits of implementing ISO certifications have been well documented in the empirical literature. Among others, these benefits include faster deliveries, better processes, higher quality products, better documentation, and less testing (Boiral et al., 2018; Sartor et al, 2019; Balzarova & Castka, 2018; Wiengarten et al, 2017; Mirtsch, 2020; Boiral and Amara, 2009).

According to del Castillo-Peces et al., (2018), the goal of implementing ISO standards is to increase the effectiveness, efficiency, and reliability of products and processes. This means that the adoption of ISO is strongly associated with enhanced product quality performance (Castillo-Peces, et al., 2018). Stamatis (2018) note that companies that are actively working to enhance their customer service, marketing, internal efficiency, and quality are more likely to implement ISO. According to research conducted by Purwanto et al. (2020), product quality performance is the single most important element influenced by the adoption and maintenance of quality standards such as those stipulated by ISO. The correlation between adoption of ISO standards and product quality enhancements have been supported empirically by studies done by (Prajogo,

2011; Fonseca, 2016; Orcos and Palomas, 2019). These findings can be buttressed by prior research findings ISO certification process and product quality enhancement found by Mhatre, et al, (2017). Based on the foregoing discussion and empirical findings, in the current study it is postulated that:

H2: Adoption of ISO certification has a significant positive effect on the product quality performance in the IVD industry in South Africa.

ISO Certification and Customer Service Satisfaction

An important element of ISO 9001 is the emphasis on customer service (ISO, 2015). According to the research of Brito et al. (2020), ISO certification can dramatically increase customer satisfaction. Furthermore, Hadidi et al. (2017), assert that adopting ISO 9001 standards enhances not just a company's quality management systems, but also its planning, public image, products and services, decision making, competitiveness and customer service satisfaction focus (Martin, 2017; Siltori et al., 2020).

Numerous previous findings seem to indicate that there is a positive relationship between ISO implementation and customer satisfaction (Betlloch-Mas et al, 2019; Usman et al., 2019; Martin, 2017; Guo, 2020; Andry et al., 2018; Tomic & Brkic, 2018). Deducing from previous empirical evidence in the literature, it is expected in this study that the adoption of ISO certification is motivated by the company's customer service satisfaction orientation. Thus, by adhering to the norms of ISO certification, a company can be expected to achieve a customer satisfaction focus goal by improving customer interactions and a reduction in customer complaints. Based on the above positions on the relationship between the adoption of ISO and customer service satisfaction focus, the following hypothesis is posited:

H3: The adoption of ISO certification has a significant positive effect on the customer service satisfaction focus in the IVD industry in South Africa.

Product Quality Performance and Customer Service Satisfaction

An examination of the empirical literature seems to indicate that product quality performance has a positive impact on customer service satisfaction (Beckers et al. 2017; Rubera and Kirca 2017). It, therefore, goes to say that a company can use product quality performance as a tool to achieve its customer service satisfaction focus. This assertion

has also been supported by Febryanto and Bernarto, (2018) who found that customer satisfaction is directly correlated with product quality. In fact, the proposition of a positive effect of product quality on customer satisfaction was noted by several researchers such as (Kristiawan et al, 2021; Bernarto 2018; Suchánek, Richter, and Králová 2016; Zhong and Moon, 2020). Drawing from this discussion and a plethora of empirical evidence on the relationship between product quality and customer satisfaction, it is postulated that:

H4: Product quality performance has a significant positive effect on the customer service satisfaction focus in the IVD industry in South Africa.

Product Quality Performance and Organizational Performance

Product quality plays a critical role in achieving a firm's competitive advantage and affects different elements of organisational performance (Ibrahim & Daniel, 2019) since product quality performance is the primary product characteristic. Performance quality refers to the levels at which the product's primary characteristics operate. According to Agus (2015), buyers will pay more for better performance as long as the higher price does not exceed the higher perceived value. The empirical literature further suggests that the role of product quality in enhancing organizational performance is better understood when product quality mediates the relationship between several organizational and managerial practices and organisational performance (Khan & Naeem, 2018). However, as noted by Sim et al., (2010) and Yuen et al., (2018) in the extant literature, product quality performance also directly affects organisational performance. Based on the aforementioned discussion and the empirical evidence, it may be postulated that:

H5: Product quality performance has a significant positive effect on organisational performance in the IVD industry in South Africa.

Customer Service Satisfaction Focus and Organisational Performance

The term "customer satisfaction focus " refers to "a pleasure resulting in the purchase of the service, including the satisfaction level below or above," as defined by (Villagomez, 2018). The concept of organizational performance is often discussed in academic research, but there is no agreed-upon definition of organizational performance because

of the variety of meanings it can take on. Bonoface (2019) found that in today's competitive environment, traditional financial accounting measures like return on investment (ROI) can send misleading signals regarding continuous improvement and innovation, suggesting that measuring organizational performance based on financial bottom-line metrics will be misleading (Kaplan & Norton, 1992). Thus, the balanced scorecard of Kaplan and Norton is more in line with employing customer satisfaction and economic success as measurement indicators for organizational performance.

A fundamental tenet of business is that a satisfied consumer will stick with the company and is likely to be loyal customer who repeatedly buy in the future. Thus, the more customers are satisfied, the more likely the repeat buy in the future and hence, the more profit the company realize and thus improved organisational performance (Tripathi, 2017; Farooq et al., 2018). Thus, deducing from the foregoing argument, it can therefore be posited that:

H6: Customer service satisfaction focus has a significant positive effect on organisational performance in the IVD industry in South Africa.

ISO Certification and Organisational Performance

Alsyouf et al. (2021) assert that ISO certification is linked to an increase in sales revenues, a drop in the value of items sold, an increase in sales revenues, and an increase in the asset turnover ratios of certified firms. According to a study by Muturi et al. (2015), ISO-certified manufacturing companies outperform non-certified companies in terms of product quality, customer satisfaction, operational, market, and financial performance. Furthermore, the empirical literature notes that, enterprises benefit from ISO certification through increased quality consciousness among employees (BSI, 2020), enhanced product and service quality (Drosos, et al., 2017), and enhanced productivity and efficiency (Magana, 2020; Noryani, 2020; Castka & Balzarova., 2018). Moreover, it is also noted in the extant literature that, adopting ISO certification gives a company a competitive advantage over rivals (Wilson & Campbell, 2018; Casado Salguero et al, 2019; Skordoulis et al, 2020).

Scholars such as Hussain, Eskildsen and Edgeman (2020) have presented evidence that ISO has a direct effect on organizational performance. In their study, the two found out that the implementation of the ISO 9001 standard led to

increased customer satisfaction, staff happiness, social impact, and corporate success. Fatima et al. (2018) observed that ISO certification enhanced financial performance for large and medium-sized businesses but had little effect on small businesses. The comprehensive analysis undertaken by Nurcahyo and Habiburrahman (2021) illuminated the positive effects of the ISO standard on organisational performance. Companies in Norway and elsewhere have demonstrated that firms with ISO accreditation perform better in terms of the reduction of defective products and customer complaints, profitability, and productivity (Valmohammadi et al., 2015; Marde 2015). Based on the above-mentioned discussion and empirical evidence in the extant literature, the current study therefore, hypothesise that:

H7: Adoption of ISO certification has a significant positive effect on organisational performance in the IVD industry in South Africa. The postulated relationships were tested using the research methodology described below.

Research Methodology

A survey was conducted among a sample of employees of IVD companies in South Africa using the online platform, SurveyMonkey. The contact details of the in vitro diagnostics (IVD) companies in South Africa were obtained from SALDA and permission was granted by SALDA to approach them to participate in the research. The 2725 employees of the 54 South African IVD companies that are members of the South African Laboratory Diagnostic Association (SALDA) were the target population for the research (Dudovskiy, 2018). A random probability sampling technique was used to target 337 participants, in line with Scholtes et al.'s (2011) assertion that the goal of any sampling method is to extract a sample from the population to generalize the results back to the population.

Data Collection and Analysis

A questionnaire was employed consisting of two sections, the first (Section A) asked respondents to provide background information, and the second (Section B) focused on the top management commitment, adoption of ISO certification, the performance of the research participants' products in terms of product quality, customer service satisfaction focus, and organizational performance. To measure "Top management commitment" a seven-item scale was adopted from Tzempelikos (2015), and to measure "adoption of ISO

certification,” a four-item scale was adapted from Mohammed, et al., (2016). To measure “product quality performance” a four-item instrument was adopted from Tracey, et al., (2004). “Customer service satisfaction focus” was measured on a seven-item scale which was adapted from Psomas (2013). Furthermore, “Organisational performance” was measured using a four-item scale adapted from Shams-ur Rahman (2000).

All of the research items were measured on a 5-point Likert scale, with 1 standing for strongly disagree and 5 for strongly agree, to reflect the degree of agreement. To analyse the data, SPSS (Version 23) and Smart PLS statistical packages were used. Confirmatory Factor Analysis (CFA) was conducted to check for Model Fit, Reliability and Validity of the scales used in the research questionnaire. To test the validity of the scales, the shared variance was compared to the average variance extracted (AVE). Path Modeling (PM) was conducted to check for model fit, and to test

the hypotheses postulated in this study.

Research Findings

A total of 262 questionnaires were completed, which implies that the response rate was over 77 %, which is quite high and acceptable for a survey.

Reliability of the measurement instrument

The Cronbach's Alpha test was employed to assess the reliability of the measurement instrument and according to Babin and Zikmund (2010), the minimum acceptable level of the Cronbach's Alpha test for the measurement is 0.70. The results in Table 1 reflect that all the constructs have a Cronbach Alpha greater than 0.70, which exceeds the minimum recommended value, thus implying that all the measurement instruments are reliable.

Table 1: Reliability Statistics

Constructs	Number of items	Cronbach's Alpha
Adoption of ISO certification (AISOC)	4	0.775
Customer service satisfaction focus (CSSF)	7	0.933
Organisational performance (OP)	4	0.950
Product quality performance (PQ)	4	0.971
Top management commitment (TCM)	7	0.833

Source: Developed by the Researcher

Validity of the measurement instrument

To examine the validity of the measurement instrument and detect the severity of multi-collinearity, discriminant validity was assessed by computing the bivariate correlation matrix using

Pearson's correlation. The results of the correlation matrix which are presented in Table 2 reveal that all the construct bivariate correlation coefficients are less than 0.75, which is less than the 0.85 acceptable threshold (Sarstedt, et al., 2021). Therefore, there is sufficient evidence that the measurement instruments are valid.

Table 2: Correlation matrix

	TMC	AISOC	PQ	CSSF	OP
TMC	1.000				
AISOC	0.423	1.000			
PQ	0.556	0.557	1.000		
CSSF	0.626	0.457	0.572	1.000	
OP	0.484	0.388	0.349	0.704	1.000

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Structural equation modelling

Data analysis was performed using structural equation modelling (SEM), which is described as “a multivariate, statistical technique largely employed for studying relationships between latent variables (or constructs) and observed variables

that constitute a model” (Schumacker & Lomax, 2016). Confirmatory Factor Analysis (CFA) and path analysis were performed using Smart PLS simultaneously (Burton, et al., 2003).

The Smart PLS software was used in order to statistically analyse the measurement and structural models. SEM included two

interconnected models: the measurement model and the structural model (Hair, et al., 2020). The measurement model, also known as confirmatory factor analysis (CFA), defines the model's constructs (latent variables) and assigns observed variables to each, whereas the structural model, also known as regression or path analysis, defines the model's hypothetical relationship between the latent variables (Gefen, et al., 2000). It is worth noting that a latent variable is a representation of a theoretical construct that cannot be directly observed and can have an exogenous (i.e., independent variable) or endogenous (i.e., dependent variable) form in the model (Hair, et al., 2008).

A two-step approach is recommended using SEM (Jalilvand, et al., 2017), within the first step a

Table 3: Reliability Results using Confirmatory Factor Analysis

Construct	Cronbach's Alpha	Composite Reliability	Average Variance Extracted (AVE)
AISOC	0.755	0.839	0.566
CSSF	0.926	0.941	0.694
OP	0.948	0.963	0.866
PQ	0.966	0.975	0.908
TMC	0.973	0.977	0.859

Note: AISOC= Adoption of ISO certification; CSSF= Customer service satisfaction focus; OP= Organisational performance; PQ= Product quality performance; TMC= Top management commitment

Discriminant and convergent validity were also examined using the AVE as suggested by Crego et al., (2015). According to Voorhees et al. (2016), a low correlation between variables in a conceptual model, signifies discriminant validity whilst strong loading of items on their familiar construct is an indication of convergent validity. The estimates of the factor loadings greater than 0.5 are presented in Table 4, demonstrating convergent validity.

Table 4 indicates the inter-correlation values for all the variables and are less than 0.89 hence marginally confirming the existence of discriminant validity. Based on the results all the measurements meet the recommended threshold (Kline, 2016); Hair, et al., (2014).

Average Variance Extracted (AVE) is expected to

measurement model is assessed by observing uni-dimensionality, reliability, validity (convergent and discriminant) of the model. In the second step, the structural model is evaluated by verifying the causal relationships based on path significance between theoretically proposed latent constructs.

Reliability and Validity

It evident from Table 3 that all Cronbach alpha values and Composite Reliability calculated using the Smart PLS meet the acceptable threshold, which implies that all the measurement instruments used in the study are deemed reliable (Zikmund, et al., 2010); (Hair, et al., 2008).

be greater than 0.5, which is the acceptable threshold (Hair, et al., 2014). Therefore, the AVE results in Table 4 reveal that they are acceptable. In the current study, the lowest AVE is 0.566 while the highest AVE is 0.908.

According to Hox, et al. (2015), discriminant validity can be assessed by comparing the AVE value to the Highest Shared Variance (HSV). An AVE that is greater than HSV indicates an existence of discriminant validity (Hair, et al., 2016). Table 4 below which reflects the discriminant validity by comparing Average Variance Extracted (AVE) and Highest Shared Variance (HSV), confirms the existence of discriminant validity.

Table 4: Construct AVE compared to HSV

	Average Variance Extracted (AVE)	Highest Shared Variance (HSV)	Decision
AISOC	0.566	0.320	Discriminant Validity confirmed
CSSF	0.694	0.481	Discriminant Validity confirmed
OP	0.866	0.749	Discriminant Validity confirmed
PQ	0.908	0.824	Discriminant Validity confirmed
TMC	0.859	0.737	Discriminant Validity confirmed

Note: AISOC= Adoption of ISO certification; CSSF= Customer service satisfaction focus; OP= Organisational performance; PQ= Product quality performance; TMC= Top management commitment

5.9 Summary of Measurement Model Assessment

Table 5 shows the descriptive statistics and item-

to-total correlation values that were generated using the SPSS statistical software and the Reliability and Validity indicators that were

generated by the Smart PLS software.

Table 5: Inter-correlation values

	TMC	AISOC	PQ	CSSF	OP
TMC	1.000				
AISOC	0.447	1.000			
PQ	0.443	0.466	1.000		
CSSF	0.601	0.399	0.581	1.000	
OP	0.565	0.492	0.351	0.638	1.000

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

The results in Table 6 indicate that all the item-to-total correlation values reached the cut-off threshold of 0.5 and therefore are acceptable. Thus, all the factor loadings for the measurement instruments were retained, thus indicating that the measurement instruments converged well on what they should measure and that they could explain at least 50% of what they were supposed to measure,

hence, confirming convergent validity. The Cronbach Alpha values for all the variables confirms the existence of reliability since they are greater than 0.5. Furthermore, the Composite Reliability Values for all variables were above 0.6, hence confirming that all the measurement instruments used to measure the research variables are reliable.

Table 6: Scale accuracy analysis

Research constructs	Mean	SD	Item-to- total Correlation value	Cronbach's Alpha value α	Composite Reliability values (CR)	Average Variance Extracted (AVE)	Factor Loadings	
AISOC	AISOC1	4.328	0.895	0.582	0.755	0.839	0.566	0.683
	AISOC2	4.103	1.133	0.682				0.763
	AISOC3	4.122	1.185	0.712				0.816
	AISOC4	3.698	1.366	0.625				0.741
CSSF	CSSF1	4.351	0.751	0.767	0.926	0.941	0.694	0.834
	CSSF2	4.321	0.803	0.821				0.878
	CSSF3	4.225	0.851	0.819				0.880
	CSSF4	4.225	0.877	0.756				0.827
	CSSF5	4.130	0.924	0.766				0.832
	CSSF6	4.252	0.855	0.774				0.837
	CSSF7	4.405	0.898	0.653				0.733
OP	OP1	3.649	1.185	0.897	0.948	0.963	0.866	0.940
	OP2	3.584	1.185	0.899				0.941
	OP3	3.931	1.024	0.835				0.910
	OP4	3.916	1.052	0.871				0.930
PQ	PQ1	4.424	0.746	0.896	0.966	0.975	0.908	0.942
	PQ2	4.439	0.727	0.938				0.966
	PQ3	4.447	0.728	0.919				0.955
	PQ4	4.401	0.733	0.908				0.948

Research constructs	Mean	SD	Item-to- total Correlation value	Cronbach's Alpha value α	Composite Reliability values (CR)	Average Variance Extracted (AVE)	Factor Loadings	
TMC	TMC1	4.256	1.059	0.862	0.973	0.977	0.859	0.901
	TMC2	4.107	1.151	0.917				0.940
	TMC3	4.076	1.137	0.907				0.933
	TMC4	4.031	1.149	0.889				0.917
	TMC5	4.088	1.151	0.911				0.934
	TMC6	4.164	1.105	0.909				0.934
	TMC7	4.122	1.116	0.900				0.928

Note: SD= Standard Deviation CR= Composite Reliability AVE= Average Variance Extracted

Structural Model Assessment

After the reliability and validity were established, the next step was to assess the presumed causal linear relationships between the exogenous and endogenous latent variables. The following statistics were used to evaluate the structural model of the study using Smart PLS: coefficient of determination (R^2), standardized root mean square residual (SRMR), Chi-square (x^2/df), Normed Fit Index (NFI), and the root mean square error correlation (RMS-Theta).

R-square (R^2), also known as the coefficient of determination, measures the model's predictive accuracy (Hair, et al., 2016). In simple terms, R^2 statistics explain the variance in the endogenous variable (dependent variable) explained by the exogenous variables (independent variable). R^2 values range from 0 to 1, with higher values indicating higher levels of predictive accuracy (Hair, et al., 2016). However, Hair et al., (2014) suggested that scholarly research should use R^2 values ranging from 0.75, 0.50 and 0.25. Chin (1998) suggests R^2 values for endogenous latent variables of 0.67, 0.33 and 0.19 to be “substantial”, “moderate” and “weak” respectively. The R^2 value for, AISOC, CSSF, OP and PQ (endogenous variables) in Table 7 below indicates that the research model’s exogenous variables explain 0.325 (32,5%), 0.381(38.1%), 0.246 (24.6%) of the variance in the endogenous variable. The study's model is thus considered to have moderate fit according to Chin's (1998) criterion.

Table 7: R Square Statistic

	R Square	R Square Adjusted
AISOC	0.325	0.323
CSSF	0.381	0.377

OP	0.499	0.493
PQ	0.246	0.243

The model fit was further assessed using the SRMR, Chi-square (x^2/df), Normed Fit Index (NFI) and RMS Theta. The SRMR, Chi-square (x^2/df), NFI and RMS Theta met the acceptable threshold and the results in Table 8 can be regarded as acceptable. For instance, A SRMR values less than 0.1 indicate a good fit (Byrne, 2006), NFI values above 0.8 indicate a good fit (Naqvi, et al., 2018), while 0.9 is regarded as satisfactory (Prabumenangh, et al., 2020), and RMS-theta values should be close to zero, whereas 0.16 should be deemed marginally acceptable indicate good model fit.

Table 8: SEM Model Fit Indexes

	Saturated Model	Estimated Model
SRMR	0.082	0.094
Chi-Square	1434.503	1508.143
NFI	0.822	0.813
RMS_theta	0.161	

By and large, the SRMR, Chi-square, NFI and RMS Theta provided in Table 8 indicate an acceptable fit of the data to the proposed conceptual model. On the basis of the acceptable fit, after the hypothesized measurement and structural model had been assessed and finalized, the next step was to examine causal relationships among latent variables through path analysis (Henseler, et al., 2016). According to Lefcheck, (2016), SEM demonstrates that particular latent variables directly or indirectly influence other latent variables in the model, which results in estimation results that interpret how these latent variables are related.

A positive or negative relationship between two or

more constructs is described as a directional hypothesis (Hair, et al., 2020). Non-directional hypotheses, on the other hand, posit a difference or a relationship but do not specify the direction of the difference or relationship (Hair, et al., 2020). For the current study, estimation results resulting from hypothesis testing are indicated in Table 9. Bootstrapping resampling method was used to test the statistical significance of the relationships. Table 9 reflects the proposed hypotheses, path

coefficients, t-statistics and whether a hypothesis is rejected or supported. Path coefficients are evaluated in terms of the sign (positive or negative), magnitude and significance (p-value and t- test). Literature asserts that $t=1.96$, $p<0.05$ are indicators of relationship significance and that higher path coefficients indicate strong relationships among latent variables (Kim & Park, 2017).

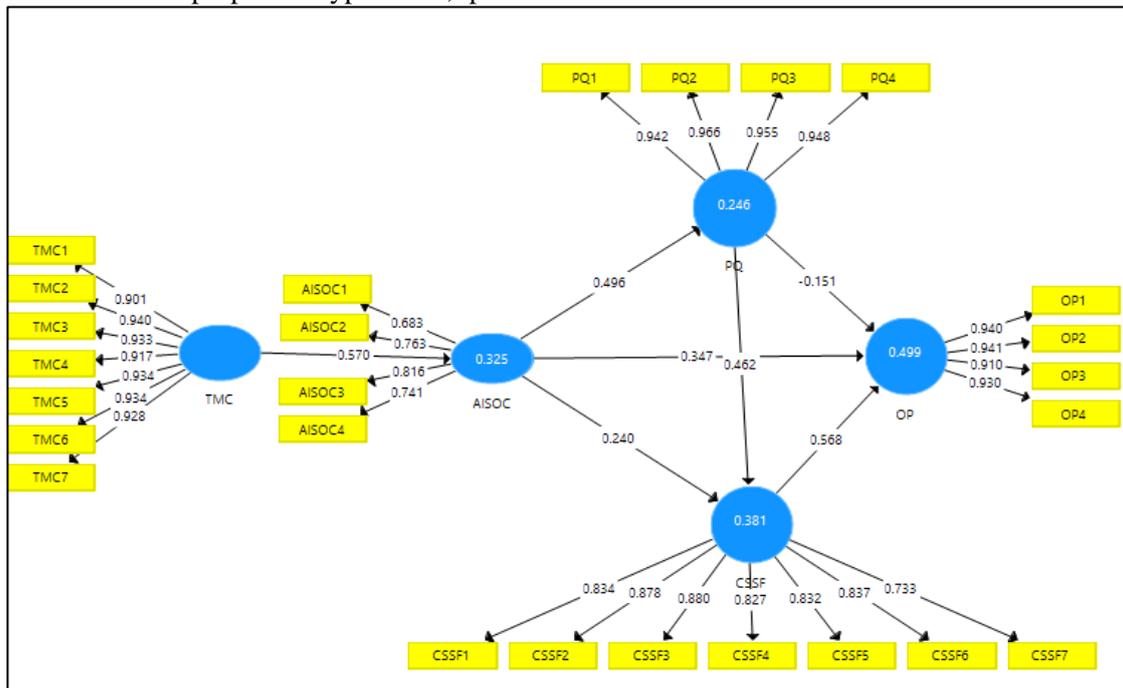


Figure 2: Structural Model

Note: AISOC= Adoption of ISO certification; CSSF= Customer service satisfaction focus; OP= Organisational performance; PQ= Product quality performance; TMC= Top management commitment

Seven hypotheses were tested, and the path coefficients are provided in Figure 2 and the hypotheses were either accepted or rejected according to the sign of the path coefficient. The significant levels were assessed using p-values and t-statistics. Respectively using the p-values, the hypotheses are viewed as significant at a 95% or higher level of significance ($\geq 95\%$), that is to say, that the p-value is ≤ 0.05 (Di Leo & Sardanelli, 2020).

The t-statistics are expected to be greater than 1.96 for the proposed relationship to be deemed acceptable (Kartika, et al., 2017). In Table 9, the proposed hypotheses and path coefficients are provided first and followed by t-statistics and p-values which indicate the significance level of the

proposed relationship. Finally, the last column indicates the decision on whether to accept or reject the proposed hypotheses given the research findings.

The path coefficients demonstrate whether the relationship between two constructs is negative or positive, and the strength of the relationships between the dependent and the independent variables (Johnston, et al., 2018). Upon assessing the effect of the relationship (positive or negative), the probability value also referred to as the p-value, it was demonstrated that six of the seven hypotheses were supported, and five hypotheses postulated were significant at $p<0.05$. Table 9 reflects the results of the seven hypotheses tested.

Table 9: Path Analysis Results

Hypothesized relationship	Hypothesis	Path Coefficient (β)	T-Statistics (t)	P- Value	Outcome
TMC -> AISOC	H ₁	0.570	10.777	0.000	Significant and supported

Hypothesized relationship	Hypothesis	Path Coefficient (β)	T-Statistics (t)	P- Value	Outcome
AISOC -> PQ	H ₂	0.496	7.095	0.000	Significant and supported
AISOC- > CSSF	H ₃	0.240	4.119	0.000	Significant and supported
PQ -> CSSF	H ₄	0.462	5.935	0.000	Significant and supported
PQ -> OP	H ₅	-0.151	2.368	0.000	Significant but NOT supported
CSSF -> OP	H ₆	0.568	9.142	0.000	Significant and supported
AISOC -> OP	H ₇	0.347	6.101	0.000	Significant and supported

Note: AISOC= Adoption of ISO certification; CSSF= Customer service satisfaction focus; OP=

Organisational performance; PQ= Product quality performance; TMC= Top management commitment

Discussion of the Findings

Top Management’s Commitment and Adoption of ISO Certification

The findings revealed that top management commitment has a positive association with the adoption of ISO certification ($\beta=0.570$; $t=10.77$; $p=0.000$). This finding is supported by the empirical literature. For instance, Amir et al. (2020) argue that top-level management's awareness of ISO's value and willingness to invest in the standard's implementation have an impact on the standard's ability to improve operations. Furthermore, some research findings by Fonseca and Domingues, (2018) and Yusliza (2019), also reveal that a lack of commitment from upper management hinders the implementation of new procedures. Thus, the implementation of ISO can have far-reaching effects, and if top management is fully committed to quality programs, it will foster a culture of constant product improvement throughout the entire firm (Latan, 2018).

Buttressing the same notion, according to Spencer et al. (2013), top management commitment is critically important for registration of ISO certification in order for the company to communicate to its customers a clear commitment to quality. Besides, it is argued in the empirical literature that top managers in organisations are committed to ISO 9000 certification in order to better serve their clients' needs through quality standards adherence and assurance (Latan, 2018; Spencer et al., 2013; Burki et al. 2019; Almeida et al. 2018; Dellana et al., 2019).

Adoption of ISO Certification and Product Quality Performance

After assessing the association between the adoption of ISO certification and product quality performance, a path coefficient of $\beta=0.496$ ($t=7.095$, $p= 0.000$) was realized, which implied that adoption of ISO certification positively influences product quality performance in a

significant way. The benefits of implementing ISO certifications and its positive effects on product quality are well documented in the extant literature – and thus, validating the current research finding. For example, a study by Chen, et al., (2021), indicated that the adoption of ISO certificates plays a significant role in product enhancement. Echoing the same sentiments, Castillo-Peces et al., (2018), note that the goal of implementing ISO standards is to increase the effectiveness, efficiency, and reliability of products and processes. This means that the adoption of ISO is associated with enhanced product quality performance (Castillo-Peces, et al., 2018). Moreover, Stamatis (2018) noted that companies that are actively working to enhance their customer service, marketing, internal efficiency, and quality are more likely to adopt and implement ISO certification standards.

According to research conducted by Purwanto et al., (2020), product quality performance is the single most important element influenced by the adoption and maintenance of quality standards such as those stipulated by ISO. By and large, the correlation between adoption of ISO standards and product quality enhancements have been validated by numerous previous studies (Prajogo, 2011; Mhatre, et al, 2017; Fonseca, 2016; Orcos & Palomas, 2019).

Adoption of ISO Certification and Customer Service Satisfaction Focus

In this study, adoption of ISO certification was found to be positively correlated with customer service satisfaction focus in a significant way ($\beta=0.240$; $t=4.195$, $p= 0.000$). The implication of this research finding is that customers are more satisfied with the services offered when ISO certification is adopted by companies. It is important to note that one of the ISO certification elements (ISO 9001) focuses on and emphasises customer service (ISO, 2015). Besides, empirical studies such as one by Brito et al., (2020), noted that ISO certification drastically increases

customer satisfaction. Furthermore, Hadidi et al., (2017), assert that adopting ISO 9001 standards enhances not just a company's quality management systems, but also its planning, public image, products and services, decision-making, competitiveness and customer service satisfaction focus (Martin, 2017; Siltori et al., 2020). Perhaps too, as echoed in numerous previous findings – the adoption and implementation of ISO certification are motivated by the company's customer service satisfaction orientation (Betlloch-Mas et al, 2019; Usman et al., 2019; Martin, 2017; Guo, 2020; Andry et al., 2018; Tomic & Brkic, 2018). Thus, by adhering to the norms of ISO certification, a company can be expected to achieve a customer satisfaction focus goal by improving customer interactions and a reduction in customer complaints.

Product Quality Performance and Customer Service Satisfaction Focus

The results emanating from the current study indicate that product quality performance and customer service satisfaction are positively associated ($\beta=0.462$). This relationship is highly significant at $t= 5.935$, $p=0.000$. A cross-examination of the empirical literature seems to validate the current study finding that product quality performance has a positive impact on customer service satisfaction (Beckers et al. 2017; Rubera and Kirca 2017). It, therefore, goes to say that; a company can use product quality performance as a tool to achieve its customer service satisfaction focus. In fact, this assertion of a positive and significant relationship between product performance and customer satisfaction focus has also been supported by numerous scholars in the empirical literature such as Febryanto and Bernarto, (2018); Kristiawan et al, (2021); Ramdhani, Daryanto, and Rifin, (2015); Iskandar, Nurmalina, and Riani, (2015); Anwar and Balcioglu, (2016); Suchánek, Richter, and Králová, (2016); and Zhong and Moon, (2020).

Product Quality Performance and Organisational Performance

The results showed that there is a significant negative relationship between product quality performance and organisational performance ($\beta=0.151$; $t= 2.368$, $p=0.018$). This finding is surprising, given that even prior empirical evidence has found a positive association between product quality performance and organisational performance (Ibrahim & Daniel, 2019; Agus,

2015; Khan & Naeem, 2018; Sim et al., 2010; Yuen et al., 2018; Khan & Naeem, 2018). Given that the extant literature found that product quality performance directly affects organisational performance (Sim et al., 2010; Yuen et al., 2018), the findings are contrary to the general perspective informed by the empirical literature.

Customer Service Satisfaction Focus and Organisational Performance

The results showed that the relationship between customer service satisfaction focus and organisational performance is positive in a significant way ($t= 9.142$, $p=0.000$). A fundamental tenet of business is that a satisfied consumer will stick with the company and is likely to be loyal customer who repeatedly buy in the future (Villagomez, 2018; Bonoface, 2019). Thus, the more customers are satisfied, the more likely they repeat buy in the future and hence, the more profit the company realizes and thus improved organisational performance (Tripathi, 2017; Farooq et al., 2018).

Adoption of ISO Certification and Organisational Performance

It was ascertained from this study that there is a positive relationship between the adoption of ISO certification and organisational performance as posited in the study hypothesis. The path coefficient was $\beta=0.347$ and this association was found to be significant ($t= 6.101$, $p=0.160$). This research finding is supported in the extant academic literature since Alsyuf et al. (2021) assert that ISO certification is linked to an increase in sales revenues, an increase in sales revenues, and an increase in the asset turnover ratios of certified firms. According to a study by Muturi et al. (2015), ISO-certified manufacturing companies outperform non-certified companies in terms of product quality, customer satisfaction, operational, market, and financial performance. Furthermore, the empirical literature notes that, enterprises benefit from ISO certification through increased quality consciousness among employees (BSI, 2020), enhanced product and service quality (Drosos, et al., 2017), and enhanced productivity and efficiency (Magana, 2020; Noryani, 2020; Castka & Balzarova., 2018). Moreover, it is also noted in the extant literature that, adopting ISO certification gives a company a competitive advantage over rivals (Wilson & Campbell, 2018; Casado Salguero et al, 2019; Skordoulis et al, 2020).

Scholars such as Hussain, Eskildsen and Edgeman (2020) have presented evidence that ISO has a direct effect on organizational performance after they found out that the implementation of the ISO 9001 standard led to increased customer satisfaction, staff happiness, social impact, and corporate success. Fatima et al. (2018) and Nurcahyo and Habiburrahman (2021) noted that ISO certification enhanced financial performance for large and medium-sized businesses but had little effect on small businesses.

Conclusion and Recommendations

The primary purpose of this research was to examine the role ISO certification plays within the IVD industry with regard to management involvement, the benefits of ISO certification, the value of ISO certification to product quality and services and the customer service impact.

These research findings contend that top management's commitment has a strong positive effect on the adoption of ISO certification in the IVD industry. Furthermore, this study validates that the adoption of ISO certification has a positive and strong effect on product quality performance, customer service satisfaction focus as well as organisational performance. Interestingly to note too, is the fact that product quality performance has a strong positive effect on customer service satisfaction focus, while it has a negative but significant effect on organisational performance. The negative effect of product quality performance on organisational performance is surprising since empirical evidence seems also to support a positive relationship as postulated in this study hypothesis. However, despite the fact that product quality performance has a negative significant effect on organisational performance, it is important to note that product quality performance has stronger positive indirect effects on organisational performance via customer service satisfaction focus respectively. Finally, this research concludes that customer service satisfaction focus has a strong positive effect on organisational performance.

Based on the research findings, it is recommended that top management of companies in the IVD industry should be committed and involved with the adoption of ISO certification. In other words, top management commitment can be used as a strategic tool to influence the adoption of ISO certification, product quality performance, customer service satisfaction focus and organisational performance in the IVD industry. Furthermore, since top management's commitment

has significant effects on the three mediators (adoption of ISO certification, product quality performance and customer service satisfaction focus), the management in the IVD industry can successfully use these mediators to amplify the effects of top management commitment on organisational performance, especially via the adoption of ISO certification and customer service satisfaction focus.

From the current study, it is also recommended that more policy interventions should be focused on encouraging companies in the IVD industry to adopt the ISO certification since this has a strong and significant effect on product quality performance, customer service satisfaction focus and organisational performance. This will comply with the ISO requirements, rules and regulations as instructed by the Government of South Africa.

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