

The Advantages of Adopting the ISO/IEC 17025: 2017 Lab Management System in Calibration and Testing Laboratories

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(Received 21 July 2024; Revised 26 August 2024, Accepted 2 October 2024; Available online 15 November 2024)

Abstract - International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards for testing and calibration laboratories are known as ISO/IEC17025:2017, which is the standard for laboratory certification. The testing laboratory's accreditation, the methods of execution, and the tangible advantages of working with such an organization. This study examined the advantages of ISO/IEC17025:2017 implementation in Chengalpat region's calibration and testing laboratories using a descriptive research design. The advantages of putting ISO/IEC 17025:2017 into practice are the main variable in the current study. The investigator utilized a method called purposive sampling. This research is based on a survey with 180 responses. After the data was gathered, analysis was done using SPSS 20. It has been found that to implement best practices and believe in the benefits, Top Management must fully understand the advantages of enacting the ISO/IEC 17025: 2017 Lab Management System, task and lab managers must fully understand the Lab Management System ISO/IEC 17025: 2017 implementation, the management tools for the Calibration and Testing Labs, the infrastructure that is being developed for the Labs, teams must collaborate, and accountability is linked to the Labs.

Keywords: Quality Management, Testing Laboratory, Lab Management System, Calibration Laboratory, Effectiveness, ISO/IEC 17025:2017

I. INTRODUCTION

The number of laboratories certified according to ISO/IEC 17025 globally in recent years. Accreditation is in high demand due to increased worldwide trade and regulatory requirements. In addition, testing facilities are under increasing pressure to provide proof of the caliber and verifiability of their findings (Pešević et al., 2019). A study conducted in a developed country demonstrated that laboratory certification appears to have a favorable influence on country development, as improved socioeconomic conditions are correlated with a rise in the number of recognized laboratories. Additionally, accredited laboratories

in Calibration and Testing may meet a need that commercial laboratories in the country are unable to provide. Nonetheless, the proportion of Calibration and Testing laboratories among total recognized laboratories remains low in some countries. Endorsed to ISO/IEC 17025: 2017, the laboratory will be able to establish a strong reputation and demonstrate that it adheres to high standards, placing it ahead of the competition. Likewise, having a strong reputation among regulators and auditors will support the lab's credibility locally, nationally, and globally. ISO 17025:2017 includes stringent rules that require labs to closely monitor outcomes (Kumar & Shivakumar, 2024). Retaining precise and accurate results helps reduce the lab's running costs. If there is less retesting, money will be saved (John & Baskar, 2023). In general, the standard provides instructions to give lab operations management, reducing operating costs. ISO 17025:2017 requires labs to approach their tasks methodically. As a result, lab protocols are more likely to be followed (Culpa et al., 2021). The purpose of this article is to at hand and aside from the attributes of Calibration and Testing laboratories, as well as the reasons, reimbursement, and obstacles associated with ISO/IEC 17025 certification, are discussed (Krismastuti & Habibie, 2022; Malhotra, 2010).

II. LITERATURE REVIEW

Guarantee the accuracy of their measurements, testing and calibration laboratories must adhere to the requirements in ISO/IEC 17025:2017. The current edition of ISO/IEC 17025:2017 differs in structure from the previous version, ISO/IEC 17025:2005. As a result, changes to quality documentation and laboratory operational procedures are urgently needed.

Honsa & McIntyre, (2003) ISO 17025 implementation creates a structure for continual enhancement of routine laboratory procedures. Direct advantages include faster issue

detection and resolution, increased customer happiness, and compliance with quality standards. An internal gap analysis of the existing system against the ISO 17025 standard was carried out before the implementation of the ISO 17025 system. Results showed that most of the management requirements were met by the ISO 9002 system.

Sari & Nurcahyo, (2018). The success of the ISO / IEC 17025 application is critical for testing laboratories. The Focus Group Discussion (FGD) approach, which is comprised of numerous qualified assessors, is useful in evaluating any provisions linked to the success of ISO execution. The test laboratory shall use the ISO 17025 standard as a benchmark for broad requirements of testing and calibration competencies, e.g. sample collection, to enhance its quality management system. In addition, quality, administrative, and technological duties are performed using this standard.

Khodabocus & Balgobin, (2011) one method of demonstrating the reliability of test results is to use standards to improve the quality of management systems. The presence of superiority assertion by applying appropriate procedures in addition to administration approaches to ensure that errors are avoided at all costs. Furthermore, using a standard for a quality management system in place, a measurement traceability system, error avoidance, and remedial procedures in the case of a mistake.

Uhl-Bien et al., (2007) Structural effectiveness is important in organizational development due to its capacity to handle production, value-oriented, ambiguity, flexibility, and structured learning, as well as understanding the key areas of employment and employee empowerment.

Grochau et al., (2018) accreditation of labs by ISO/IEC 17025 helps countries achieve national regulatory requirements and participate in international commerce. Furthermore, the implementation of quality principles and practises can assist these laboratories. Testing and calibration laboratories confront several hurdles on their way to certification across the world.

Analysis

TABLE I UNDERSTANDING LABORATORY BEST PRACTICES AND BELIEVING IN THE BENEFITS OF LAB MANAGEMENT SYSTEM BASED ON CALIBRATION AND TESTING LABORATORIES

Coefficients											
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	13.694	1.069		12.815	.000	11.594	15.793			
	ULBP	.260	.036	.312	7.317	.000	.190	.330	.312	.312	.312

a. Dependent Variable: BLMS

There is a relationship between Understanding laboratory best practices and believing in the benefits of a Lab

Objective of the Study

To determine how the adoption of the Lab Management System, ISO/IEC 17025: 2017 for Testing and Calibration Laboratories pertains to the advantages and problems.

Hypothesis of the Study

H₁: There is a relationship between Understanding laboratory best practices and believing in the benefits of Lab Management System based on calibration and Testing Laboratories.

H₂: There is a relationship between the advantages that must be fully understood by top management as well as a clear understanding of ISO/IEC 17025: 2017 based on Labs for Calibration and Testing.

H₃: There is a relationship between the applications of ISO/IEC 17025: 2017 based on Labs for Calibration and Testing is widely known to task and lab managers.

H₄: There is a relationship between introducing a Lab Management system and raising calibration and Testing based on calibration and Testing Laboratories.

H₅: There is a Relationship between groups who worked together and responsibility was shared by one another which created a positive vibe for the implementation of calibration and Testing Laboratories.

III. RESEARCH METHODOLOGY

This study used a descriptive research design to examine the issues surrounding the calibration and testing facilities in the Chengalpat region that have adopted ISO/IEC 17025: 2017. The advantages and difficulties of applying ISO/IEC 17025: 2017 are the main study variable. The researcher used the sampling approach to conduct the survey. The researcher used purposeful sampling, and 180 employees of the Calibration and Testing Laboratory took part in the investigation. This study makes use of a survey with 180 respondents. After collecting the data, the study analyzed it using SPSS 20 (Kothari, 2004; Etikan et al., 2016).

Management System based on Calibration and Testing Laboratories.

The values of the model are displayed in the Table I above. The unstandardized coefficient B value shows .260 and The beta value of the Standardized Coefficients S.E..036 indicates. 312. The t value is 7.317. The p-value is < 0.05. The lower bound of Confidence Interval in 95% shows.190

and it displays the top bound of the confidence interval in 95%.330.

The Standardized beta coefficient represents the positive relationship between the variables in a significant p-value is < 0.05. H₁ is therefore supported.

TABLE II TOP MANAGEMENT HAS TO BE THOROUGHLY CONSCIOUS OF THE RESOLUTION AND HAVE A GOOD GRASP OF ISO/IEC 17025: 2017 BASED ON LABS FOR CALIBRATION AND TESTING

Coefficients											
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	33.829	1.967		17.199	.000	29.964	37.693			
	TMA	.423	.065	.278	6.470	.000	.294	.551	.278	.278	.278

a. Dependent Variable: CUII

H₂: There is a relationship between the advantages that must be fully understood by top management as well as a clear understanding of ISO/IEC 17025: 2017 based on Labs for Calibration and Testing.

equal to 6.470. P is less than 0.05. The Confidence Interval's lowest bound of 95% shows.294 and the upper bound of the Confidence Interval of 95% shows.551.

The values of the model are displayed in the Table II above. The unstandardized coefficient B value shows.423 and the S.E.065. Standardized Coefficients beta value shows.278. t is

The Standardized beta coefficient represents the positive relationship between the variables in a significant p-value is < 0.05. H₂ is therefore supported.

TABLE III TASK AND LAB MANAGERS ARE WELL AWARE OF THE IMPLEMENTATION OF ISO/IEC 17025: 2017 BASED ON CALIBRATION AND TESTING LABORATORIES

Coefficients											
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	13.691	1.065		12.812	.000	11.590	15.790			
	Task	.261	.035	.309	7.315	.000	.191	.328	.310	.310	.310

a. Dependent Variable: LMAI

H₃: There is a relationship between the applications of ISO/IEC 17025: 2017 based on Labs for Calibration and Testing is widely known to task and lab managers.

equal to 7.315. P is less than 0.05. The Confidence Interval's lowest bound is 95% which shows 191 and the upper bound of the Confidence Interval is 95% which shows.328.

The above Table III shows the values of the model. The unstandardized coefficient B value shows.261 and the S.E.035. Standardized Coefficients beta value shows.309. t is

The Standardized beta coefficient represents the positive relationship between the variables in a significant p-value is < 0.05. H₃ is therefore supported.

TABLE IV INTRODUCING LAB MANAGEMENT SYSTEM ANDRISING CALIBRATION AND TESTING BASED ON CALIBRATION AND TESTING LABORATORIES

Coefficients											
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	16.465	.845		19.481	.000	14.804	18.125			
	ILMS	.219	.028	.330	7.791	.000	.164	.274	.330	.330	.330

a. Dependent Variable: RCT

H₄: There is a relationship between introducing a Lab Management System and increasing Calibration and Testing based on calibration and Testing Laboratories.

The above Table IV shows the values of the model. The unstandardized coefficient B value shows.219 and the S.E.028. Standardized Coefficients beta value shows.330. t is

equal to 7.791. P is less than 0.05. The Confidence Interval's lowest bound of 95% shows.164 and the upper bound of the Confidence Interval of 95% it shows.274. The Standardized beta coefficient represents the positive relationship between the variables in a significant p-value is < 0.05. H₄ is therefore supported.

TABLE V GROUPS WHO WORKED TOGETHER AND RESPONSIBILITY WAS SHARED BY ONE ANOTHER WHICH CREATED A POSITIVE VIBE FOR THE IMPLEMENTATION OF CALIBRATION AND TESTING LABORATORIES

Coefficients											
Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			
	B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	
1	(Constant)	16.465	.845		19.481	.000	14.804	18.125			
	ILMS	.219	.028	.330	7.791	.000	.164	.274	.330	.330	.330

a. Dependent Variable: RCT

H₅: There is a relationship between organizations that collaborated and shared accountability led to a conducive atmosphere for the establishment of calibration and testing laboratories.

The above Table V shows the values of the model. The unstandardized coefficient B value shows.421 and the S.E.062. Standardized Coefficients beta value shows.274. t is equal to 6.469. P is less than 0.05. The Confidence Interval's lowest bound is 95% which shows.292 and the upper bound of the Confidence Interval is 95% which shows 550. The Standardized beta coefficient represents the positive relationship between the variables in a significant p-value is < 0.05. Therefore, H₅ is accepted.

IV. FINDINGS

The research has found that Understanding industry best practices and belief in the benefits of Lab Management Systems based on calibration and Testing Laboratories have a relationship with a beta value of.312 in a significant p-value is < 0.05. The advantages must be fully understood by top management as well as a clear understanding of ISO/IEC 17025: 2017 based on Testing and Calibration Laboratories having a relationship with the beta value of.278 in a significant p value is < 0.05. Task and lab managers are well aware of the implementation of ISO/IEC 17025: 2017 based on calibration and Testing Laboratories having a relationship with the beta value of.309 in a significant p-value is < 0.05. Introducing Lab Management System and rising Calibration and Testing based on Calibration and Testing Laboratories having a relationship with the beta value of.330 in a significant p-value is < 0.05. Finally, the study found that groups who worked together and responsibility was shared by one another which created a positive vibe for the implementation and Testing Laboratories having a relationship with a beta value of.274 in a significant p-value is < 0.05. The relationship between an individual variable and a dependent variable is represented by the Standardized Beta

coefficient. An independent variable shows a constructive part in dependent variables if the beta coefficient is positive. A stronger influence can be seen by increasing the beta coefficient's Absolute Value (Chai et al., 2015). Hence the analysis highlights the positive relationship among the variables.

V. CONCLUSION

Using a descriptive research design, this study investigated the gain of applying the ISO/IEC 17025: 2017 System for Lab Management in Chengalpat region's Facilities for testing and calibration. This study used a descriptive research technique to explore the gains of applying an ISO/IEC 17025: 2017 Laboratory management system for calibration and testing in the Chengalpat region. It has originated to apex administration has got to wholly comprehend the gain of putting into practice the ISO/IEC 17025: 2017 System for Lab Management in enjoin to hold to best exercise and consider its benefits, use of the ISO/IEC 17025: 2017 Lab Management System, as well as the calibration and testing of lab management instruments, should be thoroughly understood by task and lab managers, and Infrastructure for the growth of Calibration and Testing Laboratories, teamwork, and accountability are linked to these facilities. Some of the respondents stated that ISO/IEC 17025: 2017 implementation will need the attention, capability, neutrality, and constant function of laboratories. The testing and calibration labs are dedicated to keeping their metrological traceability and giving clients consistent results. As a result, compliance with the standard and completion of all associated paperwork is critical in obtaining accreditation status from the national accrediting body. Particular emphasis is placed on resource needs along with how to meet these needs in labs. The success of the application of ISO/IEC 17025:2017 in laboratories is contingent upon the dedication of senior management and staff engagement, as laboratory certification is a demanding procedure. The purpose of this research is to help laboratories better their testing and calibration services, manage documentation related to

ISO/IEC 17025:2017, and apply this standard. It will be very useful for them to make the assessment effective and efficient in lab management.

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