

A STUDY ON THE BENEFITS OF IMPLEMENTING ISO/IEC 17025:2017 LAB MANAGEMENT SYSTEM IN CALIBRATION AND TESTING LABS

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Abstract

The standard used for laboratory certification is ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories. Laboratory accreditation in a testing laboratory, the implementation procedures, and the practical benefits received from such an entity. The descriptive research approach was utilised in this study to investigate the Benefits in the implementation of the ISO/IEC 17025:2017 in the Calibration and Testing Laboratories in Chennai. The key variable of the current study is the Benefits in the implementation of the ISO/IEC 17025:2017. The researcher employed a technique known as purposive sampling. This study relies on a 180-respondent survey. The research used SPSS 20 to analyse the data once it was collected. It has been discovered that best practises and believing in the benefits require Top Management to be well aware of the benefits of Implementation of ISO/IEC 17025: 2017 Lab Management System, Task and lab managersto be well aware of the Implementation of ISO/IEC 17025: 2017 Lab Management Calibration and Testing Laboratories infrastructure, and teams to work together and responsibility is associated with Calibration and Testing Laboratories.

Keywords: ISO/IEC 17025:2017, Lab Management System, quality management, Testing laboratory, Calibration laboratory, Effectiveness.

Introduction

The amount of laboratories accredited in accordance with ISO/IEC 17025 globally in the recent years. Accreditation is in high demand due to increased worldwide trade and regulatory requirements. In addition, testing laboratories are increasingly being pressed to produce evidence for the quality and traceability of their discoveries. A study was conducted in the developed country, demonstrated that laboratory certification appears to have a favourable influence on country development, as an increase in the number of accredited laboratories coincides with an

improvement in socioeconomic circumstances. 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 recognised laboratories remains low in some countries.Endorsed to ISO/IEC 17025: 2017, laboratory will be able to establish a strong reputation and demonstrate that it adheres to high standards, placing it ahead of competition.Likewise, having a strong reputation among auditors and regulatory bodies will assist the lab's reputation not just locally, but also nationally and worldwide. ISO 17025:2017 includes stringent rules that require labs to closely monitor outcomes. Obtaining accurate and exact findings aids in lowering the lab's operational expenses. Money will be saved if retesting is decreased. Overall, the standard establishes guidelines to provide control over lab operations, lowering operating expenses. ISO 17025:2017 requires labs to approach their tasks in a methodical manner. As a result, lab protocols are more likely to be followed.The purpose of this article is to present and aside on the attributes of Calibration and Testing laboratories, as well as the reasons, Benefits, and obstacles associated with ISO/IEC 17025 certification, are discussed.

Literature review

Fransiska Sri H K (2022)standards in ISO/IEC 17025:2017 is critical for testing and calibration laboratories to ensure the quality of their measurements. 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.

Julie D. HonsaAndMcintyre(2003) ISO 17025 implementation creates a structure for continual improvement of daily laboratory practises. Direct advantages include faster issue detection and resolution, increased customer happiness, and compliance with quality standards. When the ISO 17025 system was implemented, an internal gap analysis of the current system against the ISO 17025 standard was performed. Results indicated that the ISO 9002 system fulfilled a majority of the management requirements

Irma Permata Sari and RahmatNurcahyo(2018) The success of 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 implementation. The testing laboratory employs the ISO / IEC 17025 standard as a benchmark for the general requirements of testing / calibration competence, including sampling, in order to improve the quality management system. This standard is also used to quality, administrative, and technical tasks.

Khodabocus and Balgobin(2011)The use of standards to improve the quality of management systems is one technique to demonstrate the dependability of test findings. The presence of quality assurance via the application of proper processes and management approaches, ensuring that errors are kept to a minimum. Furthermore, with a quality management system standard in place, the

laboratory has measurement traceability, error prevention, and remedial procedures in the case of a mistake.

Mary Uhl-Bien et al. (2007)Structural effectiveness is important in organisational development because it can manage ambiguity, flexibility, customer-oriented, production, value-oriented, and structured learning, as well as understand the key areas of employment and employee empowerment.

Ines HexselGrochau et al. (2018)accreditation of labs accordance with 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 a number of hurdles on their way to certification across the world.

Objective of the study

To find out the association between Benefits and Challenges in the implementation of ISO/IEC 17025: 2017 Lab Management System based on Calibration and Testing Laboratories

HypothesisoftheStudy

H₁: There is a relationship between Understanding laboratory best practices and believing in the benefits of Lab Management Systembased on Calibration and Testing Laboratories

H₂: There is arelationship between Top Management needs to be well aware of the benefits as well as a clearunderstanding of ISO/IEC 17025: 2017 based onCalibration and Testing Laboratories.

H3:Thereis arelationshipbetweenTaskandlab managersarewellawareoftheimplementationofISO/IEC 17025: 2017 based onCalibration and Testing Laboratories.

H₄:ThereisarelationshipbetweenintroducingLab Management SystemandrisingCalibration and Testing based onCalibration and Testing Laboratories.

H₅:ThereisaRelationshipbetweengroupswhoworkedtogetherandresponsibilitywassharedbyoneano therwhich createdapositive vibe for the implementationonCalibration and Testing Laboratories.

Research Methodology

The descriptive research approach was utilized in this study to investigate the problems in the implementation of ISO/IEC 17025: 2017 in Calibration and Testing Laboratories in Chennai. The major variable of the current study is the benefits and challenges of implementing ISO/IEC 17025: 2017. The survey was done by the researcher using the sampling approach. Purposive sampling was employed by the researcher, and 180 Calibration and Testing Laboratory personnel participated in this

study. This study makes use of a survey with 180 respondents. The study used SPSS 20 to analyse the data once it was collected.

Analysis

Table-1:

Understandinglaboratory

best practices and believing in the benefits by ITS upport teams base on ITC ompany's

| Coefficient | s ^a | | | | | | | | | |
|-------------|----------------------|------------|--------------|--------|------|----------------|-----------|--------|---------|------|
| Model | Iodel Unstandardized | | Standardized | t | Sig. | 95.0% C | onfidence | Correl | ations | |
| | Coefficients | | Coefficients | | | Interval for B | | | | |
| | В | Std. Error | Beta | | | Lower | Upper | Zero- | Partial | Part |
| | | | | | | Bound | Bound | order | | |
| (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. Depender | nt Varial | ble: BLMS | · | • | • | | | • | | |

H₁:There is a relationship between Understanding laboratory best practices and believing in the benefits of Lab Management Systembased onCalibration and Testing Laboratories

The above table 4.22 shows the values of the model. The unstandardized coefficients B value shows .260 and the S.E .036. Standardized Coefficients beta value shows .312. The t value is 7.317. The p value is < 0.05. The lower bound of Confidence Interval in 95% it shows .190 and upper bound of Confidence Interval in 95% it shows .330.

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

Table-2:TopManagementneedsto

bewellawareofthebenefitsaswellasclearunderstandingofISO/IEC 17025: 2017 based onCalibration and Testing Laboratories

| (| Coefficients | s ^a | | | | | | | | | |
|---|--------------|----------------|------------|--------------|--------|------|--------------|------------|---------|---------|------|
| | | Unstandardized | | Standardized | | | 95.0% (| Confidence | | | |
| | | Coefficients | | Coefficients | | | Interval for | r B | Correla | tions | |
| | | | | | | | Lower | Upper | Zero- | | |
| N | Aodel | В | Std. Error | Beta | t | Sig. | Bound | Bound | order | Partial | Part |
| 1 | (Constant) | 33.829 | 1.967 | | 17.199 | .000 | 29.964 | 37.693 | | | |
| | ТМА | .423 | .065 | .278 | 6.470 | .000 | .294 | .551 | .278 | .278 | .278 |
| а | . Dependen | nt Variab | le: CUII | • | | • | • | | | | |

H₂: There is a relationship between Top Management needs to be well aware of the benefits as well as a clearunderstanding of ISO/IEC 17025: 2017 based onCalibration and Testing Laboratories.

The above table 4.22 shows the values of the model. The unstandardized coefficients B value shows .423 and the S.E .065. Standardized Coefficients beta value shows .278. The t value is 6.470. The p value is < 0.05. The lower bound of Confidence Interval in 95% it shows .294 and upper bound of Confidence Interval in 95% it shows .551.

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

Table-3:Taskandlab managersarewellawareoftheimplementationofISO/IEC 17025: 2017 based onCalibration and Testing Laboratories.

| Coefficient | s ^a | | | | | | | | | |
|-------------|----------------|------------|--------------|--------|------|------------------------------|--------|-------|---------|------|
| Model | | | Standardized | t | Sig. | 95.0% ConfidenceCorrelations | | | | |
| | | | Coefficients | | | Interval for B | | | | |
| | В | Std. Error | Beta | | | Lower | Upper | Zero- | Partial | Part |
| | | | | | | Bound | Bound | order | | |
| (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. Depender | nt Varial | ble: LMAI | | • | | • | | | | |

H₃:Thereisa relationship betweenTaskandlab managersarewellawareoftheimplementationofISO/IEC 17025: 2017 based onCalibration and Testing Laboratories.

The above table 4.22 shows the values of the model. The unstandardized coefficients B value shows .261 and the S.E .035. Standardized Coefficients beta value shows .309. The t value is 7.315. The p value is < 0.05. The lower bound of Confidence Interval in 95% it shows .191 and upper bound of Confidence Interval in 95% it shows .328.

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

Table-4:Introducing lab Management System and risingCalibration and Testing basedonCalibration and Testing Laboratories.

| Coefficient | s ^a | | | | | | | | | |
|-------------|----------------|------------|--------------|--------|------|----------------|-----------------|-------|--------------|------|
| Model | Unstandardized | | Standardized | t | Sig. | 95.0% | 5.0% Confidence | | Correlations | |
| | Coefficients | | Coefficients | | | Interval for B | | | | |
| | В | Std. Error | Beta | | | Lower | Upper | Zero- | Partial | Part |
| | | | | | | Bound | Bound | order | | |
| (Constant) | 16.465 | .845 | | 19.481 | .000 | 14.804 | 18.125 | | | |
| ILMS | .219 | .028 | .330 | 7.791 | .000 | .164 | .274 | .330 | .330 | .330 |
| a Depender | nt Varial | ole: RCT | • | | | • | • | | | |

a. Dependent Variable: RCT

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

The above table 4.22 shows the values of the model. The unstandardized coefficients B value shows .219 and the S.E .028. Standardized Coefficients beta value shows .330. The t value is 7.791. The p value is < 0.05. The lower bound of Confidence Interval in 95% it shows .164 and upper bound of Confidence Interval in 95% it shows .274.

The Standardized beta coefficient represents the positive relationship between the variables in a significant p value is < 0.05. Therefore H₄ is accepted.

Table-5:Groupswhoworkedtogetherandresponsibilitywassharedbyoneanotherwhich createdapositive vibe for the implementationonCalibration and Testing Laboratories.

| | Unstand | ardized | Standardized | | | 95.0% | Confidence | ; | | |
|--------------|--------------|------------|--------------|--------|------|----------------|------------|--------------|---------|------|
| | Coefficients | | Coefficients | | | Interval for B | | Correlations | | |
| | | | | | | Lower | Upper | Zero- | | |
| Model | В | Std. Error | Beta | t | Sig. | Bound | Bound | order | Partial | Part |
| l (Constant) | 33.825 | 1.965 | | 17.197 | .000 | 29.962 | 37.691 | | | |
| GWT | .421 | .062 | .274 | 6.469 | .000 | .292 | .550 | .271 | .271 | .271 |

H₅:Thereisa

relationship

betweengroupswhoworkedtogetherandresponsibilitywassharedbyoneanotherwhich createdapositive vibe for the implementationonCalibration and Testing Laboratories.

The above table 4.22 shows the values of the model. The unstandardized coefficients B value shows .421 and the S.E .062. Standardized Coefficients beta value shows .274. The t value is 6.469. The p value is < 0.05. The lower bound of Confidence Interval in 95% it shows .292 and upper bound of Confidence Interval in 95% it 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.

Findings

The research has found that Understanding industry best practices and believing in the benefits of Lab Management Systembased onCalibration and Testing Laboratories having a relationship with the beta value of .312 in a significant p value is < 0.05. Top Management needs to be well aware of the benefits as well as a clearunderstanding of ISO/IEC 17025: 2017 based onCalibration and Testing Laboratories having a relationship with the beta value of .278 in a significant p value is < 0.05. Taskandlab managersarewellawareoftheimplementationofISO/IEC 17025: 2017 based onCalibration and Testing Laboratories having a relationship with the beta value of .309 in a significant p value is < 0.05. IntroducingLab Management System andrisingCalibration and Testing based onCalibration and Testing Laboratories having a relationship with the beta value of .309 in a significant p value is < 0.05. IntroducingLab Management System andrisingCalibration and Testing based onCalibration and Testing Laboratories having a relationship with the beta value of .309 in a significant p value is < 0.05. Finally the study found that

groupswhoworkedtogetherandresponsibilitywassharedbyoneanotherwhich createdapositive vibe for the implementationonCalibration and Testing Laboratories having a relationship with the beta value of .274 in a significant p value is < 0.05. The Standardized beta coefficient represents the relationship between the independent variable and dependent variable. If the beta coefficient is a positive value, the independent variable plays a positive role in dependent variable. A higher absolute value of the beta coefficient indicates a more significant influence (Chunlei Chai et al., 2015). Hence the analysis highlights the positive relationship among the variables.

Conclusion

The descriptive research approach was utilised in this study to investigate the Benefits of Implementing ISO/IEC 17025: 2017 Lab Management System in Calibration and Testing Laboratories in Chennai.It has been discovered that best practises and believing in the benefits require Top Management to be well aware of the benefits of Implementation of ISO/IEC 17025: 2017 Lab Management System, Task and lab managersto be well aware of the Implementation of ISO/IEC 17025: 2017 Lab Management System, Calibration and Testing Lab management tools, and development Calibration and Testing Laboratories infrastructure, and teams to work together and responsibility is associated with Calibration and Testing Laboratories. Some of respondents stated that ISO/IEC 17025: 2017 implementation will need the attention, competence, impartiality and consistent operation of laboratories. It is the commitment of the testing and calibration laboratories to maintain their metrological traceability and to provide clients with dependable findings. As a result, compliance with the standard and completion of all associated paperwork are critical in obtaining accreditation status from the national accrediting body. Particular emphasis is placed on resource requirements and how to meet these requirements in labs. This research is aimed to assist laboratories in implementing ISO/IEC 17025:2017, maintaining documentation relevant to this standard, and improving the quality of their testing or calibration services.

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