The Relationship between ISO/IEC 17025 Adoption and Operational Performance of Testing and Calibration Laboratories

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Abstract

This paper examines the relationships between the demand for market needs, preparedness of the laboratories, leadership, quality culture and operational performance. It addresses the critical success factors, namely, the internal and external factors, quality cultures (i.e., rational and developmental) and operational performance in addressing the effectiveness of the ISO/IEC 17025 implementation in testing and calibration laboratories. Using a data set of 163 respondents who are in charge of daily operations of the laboratories in 29 countries, reliability and validity analyses were conducted on the study instruments. The results showed that all the Composite Reliabilities values for the selected items have exceeded the minimum value of 0.7. Structural Equation Modeling (SEM) was used to analyse the interrelationships of the variables involved with Partial Least Squares method adopted to compute the path model. The results showed that external factors exerted positive impacts on internal factors, while internal factors had positive impact on leadership and rational culture, respectively, which subsequently influenced the laboratories' operational performance. However, the external factors' influence on leadership and developmental culture were not significant. Leadership not only had a strong influence on the creation of both types of culture, but it also had a great impact on the operational performance of the laboratories. Both rational and developmental cultures had significant impacts on the laboratories' operational performance.

Keywords: SO/IEC 17025; External and Internal Factors; Leadership; Quality Culture, Operational Performance

1 Introduction

Testing and calibration laboratories are facing great demand for quality services from their clients and customers. These laboratories are expected to uphold strict quality control with appropriate documentation, and hiring qualified and professional staff. Every aspect of the services, namely, sampling identification, labeling, testing, analysis and documenting test results, and calibration have to be conducted within strict guidelines. ISO 17025 certification offers testing and calibration laboratories similar type of accreditation that ISO 9001 provides to manufacturing and service organizations. As a global quality standard, ISO 17025 certification helps to attract more business and grow company's client base and profitability. There are several benefits for a company or organisation from adopting ISO 17025 certification; that is,

- Acknowledgment by industry as an ISO 17025 certified service provider.

- A laboratory testing and calibration service provider that has competitive advantage over competitors who are not certified in a globally-accepted quality system.
- Proper documentation on processes and procedures within a quality management system
- A system that focuses on continuous management and technical aspects of the business
- A laboratory testing and calibration service provider that assures improved customer service and high customer satisfaction
- A laboratory testing and calibration service provider that performs the following: internal audit process to rectify non-conformance to standards, corrective actions, and updating the quality system to the new quality standards.

The In general, ISO 17025 comprises of two main parts—Management Requirements and Technical Requirements. The management requirements are similar to ISO 9001. Therefore, a calibration and testing laboratory that is certified with ISO 17025 will also operate in compliance with ISO 9001. The technical requirements in ISO 17025 are concerned about laboratory operations, reporting of tests and calibrations, equipment, testing and staff competency. Similar to other ISO quality standards, ISO 17025 requires extensive documentation and the creation of a detailed quality system and quality manual. If such a documentation does not exist, much time and effort are required to complete it by the management and laboratory personnel. Therefore, before deciding on the ISO 17025 certification process, a company should weigh the benefits against the time and costs involved.

The objectives of this study are as follows;

- To examine the effect of external factors, i.e., demand for market needs and expectation of customers on leadership and internal factors, i.e., preparedness of the laboratories.
- To measure the influence of internal factors on the leadership and the quality culture (i.e., rational and developmental) of the laboratories.
- To examine the effects of leadership and quality culture on the operational performance.

2 Literature Review

There have been many studies on the impact of implementing ISO/IEC 17025 in testing and calibrating laboratories. Halevy (2003) pointed out that few studies have focused on contextual factors in relation to the impact of implementing ISO/IEC 17025 Quality Management System (QMS). Contextual factors consist of the internal and external factors and conditions that affect its products and services (Al Nofal et al., 2005). These factors have influence on the QMS and are relevant to its purpose and strategic direction and its business environment. Internal factors include work system, values, culture, knowledge, and performance. External factors include expectations of interested parties, as well as legal, technological, regulatory, and competitive environment.

It is recognized that high quality work in laboratories is not something that happens spontaneously, but rather requires the development of skills through training and continuous monitoring. There are two types of contextual factors affecting quality culture and operational performance of the laboratories, namely, the internal (e.g., preparedness of the laboratory) and external factors such as demand for market needs. The internal factors may include the lack of preparation, work procedures, work systems and reputation of the laboratory services at national level. Laboratory personnel are encouraged to learn from other laboratory's performance and also expected to communicate with clients about laboratory practices and customer requests. The study on external factors include the demand by regulatory bodies for the laboratories to meet the market needs for the value of change in the laboratory's performance such as corporate management and customers' compliance system

The planning and implementation of an ISO/IEC 17025 quality system start with the commitment by top management or leadership of the laboratories. Management review is a core requirement and considered a vital element of the system as well as ensuring its continuing suitability and effectiveness in many quality management systems. The success of the implementation of a quality management system based on ISO/IEC: 2005 is achievable when there is commitment from top management and through adequate staff involvement.

Quality culture that comprises of developmental and rational cultures, are expected to create significant impacts on the laboratories' operational performance. The developmental culture is related to failures and corrective actions on non-conformance, proficiency testing, preparation of documentation, and calibration of tests and measurement. Meanwhile, rational culture includes training programme, communication with the customers, entertaining customers' request, measuring customer satisfaction, and validating the measurement in testing and calibration.

The inter-relationships between the dimensions are illustrated in Figure 1 below. This framework illustrates the role of internal as well as external factors as independent variables that influence quality culture in laboratories. The quality culture, comprising developmental and rational cultures, are subsequently expected to create significant impacts on the laboratories' operational performance.

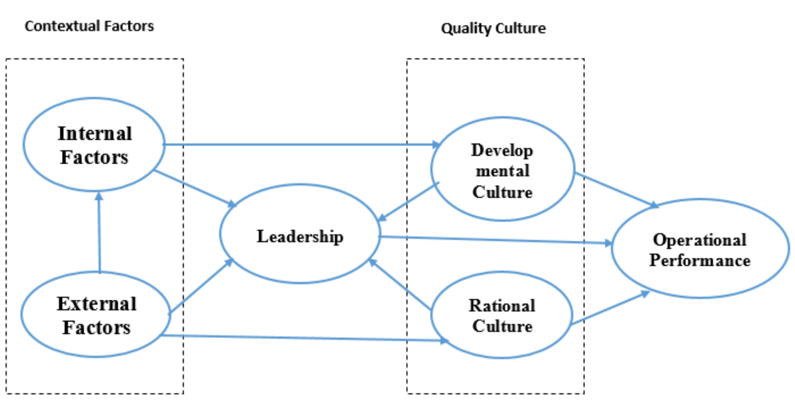

Figure 1: The conceptual framework

2.1 Research Hypotheses

Based on the proposed framework in Figure 1 above, we now formulate a set of research hypotheses as follows:

Hypothesis H_1: There is a significant relationship between demand for market needs (external factors) and preparedness of the laboratories (internal factors).
Hypothesis H_2: There is a significant relationship between preparedness of the laboratories (internal factors) and leadership.
Hypothesis H_3: There is a significant relationship between demand for market needs (external factors) and leadership.
Hypothesis H_4: There is a significant relationship between preparedness (internal factors) of the laboratories and developmental quality culture.

Hypothesis H_5: There is a significant relationship between demand for market needs (external factors) and rational quality culture.
Hypothesis H_6: There is a significant relationship between leadership and developmental quality culture.
Hypothesis H_7: There is a significant relationship between leadership and rational quality culture.
Hypothesis H_8: There is a significant relationship between leadership and operational performance.
Hypothesis H_9: There is a significant relationship between the development culture and the operational performance.
Hypothesis H_{10}: There is a significant relationship between the rational culture and the operational performance.

3 The Methodology

This study adopts quantitative, descriptive as well as causal research designs. A survey questionnaire was designed for the purpose of measuring the variables in the conceptual framework and used to collect information from target respondents. The sample from this study consists of the testing laboratories that have been implementing the ISO/IEC 17025.

The questionnaires were distributed to the target respondents who are in charge of daily operations of the laboratories. They could be the quality management representatives or heads of the laboratories. Currently, a total of 29 countries throughout the world have established testing laboratories. Based on the nature of testing laboratories, the main characteristics of these laboratories are similar in terms of the infra-structure (i.e., equipment's, setups, sizes etc.) and other soft-aspects such as the work systems, the personnel and their minimum requirement of skills and knowledge. With these assumptions, this study has adopted simple random sampling to generate a random sample of testing laboratories. Adequacy of the sample size was determined by using Krejcie and Morgan's (1970) table. The data in this study were obtained through self-administered survey questionnaires and online survey using e-mails.

3.1 Development of Research Instruments

The questionnaires distributed to the respondents consist of five parts. In Part I, respondents were asked to give their information on their demographic profile. Part II of the questionnaires contains seven (7) items that measure internal factors variable. Part III contains the items for external factors variable that consists of four (4) items. Part IV consists of quality culture and leadership variable with fourteen (11) items. Operational performance consisting of eight (8) items constitutes Part V of the questionnaires.

3.2 Internal Factors

The internal factors measures used in this study were adapted from Neilson et al. (2003) and these measures have been amended to suit the laboratory context. The questionnaires were reconstructed to meet the implementation of ISO/IEC 17025 in the laboratories. The 5-point Likert scale used for these items are 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree.

Table 1. Items for Internal Factors

Variable	Items
Internal Factors	1. We are aware of the lack of preparation in our laboratory for the implementation of the QMS. 2. We are aware of the need for improved reputation of the laboratory service at national level. 3. We are facing the lack of work procedures and system. 4. We need to adopt GMP/GLP system for the competitive advantage of our laboratories. 5. We are encouraged to learn from the other laboratory's performance. 6. We are expected to communicate laboratory practices to our clients. 7. We are always reminded to listen to customer request.

3.3 External Factors

The items for external factors in this study were adapted from Neilson et al. (2003) and have been modified to suit the laboratory context. The questionnaires were re-designed to meet the laboratories implementing ISO/IEC 17025. The 5-point Likert scale used for these items are 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree.

Table 2. Items for External Factors

Variable	Items
External Factors	1. There is a need to inculcate corporate management in our laboratories. 2. There is an increasing demand by regulatory bodies for laboratories to implement QMS. 3. There have been requests for laboratories to establish a customer's compliance system. 4. There has been increasing demand for laboratories to meet the market needs.

3.4 Quality Culture

The instruments used to measure the quality culture in this study were adapted from by Halevy (2003) to measure quality services of the laboratories. There are eight (8) items used to measure the quality culture with four (4) items for developmental culture and four (4) items for rational culture using the 5-point Likert scale (1-strongly disagree, …,5-strongly agree) as listed in Table 3.

Table 3. Items for Quality Culture

Variable	Items
Quality Culture	Developmental Culture 1. We do the reporting, investigating and analysis of failures and non-conformance corrective activities. 2. We take part in inter laboratory proficiency testing.

3. We prepare documentation work measurement instruction accordingly.
4. We carry out calibration of test and measurement equipment.

Rational Culture

5. We are always gauging customers' satisfaction level with regard to our laboratory services.
6. We always validate measurement processes and methods.
7. The laboratory staff are regularly trained to ensure quality in job specific skills.
8. The training programmes have improved our QMS knowledge and understanding

3.5 Leadership

The instruments used to measure the leadership in this study were adapted from by Halevy (2003) to measure leadership of the laboratories. There are three (3) items used to measure the leadership using the 5-point Likert scale (1-strongly disagree, …, 5-strongly agree) as listed in Table 4.

Table 4. Items for Leadership

Variable	**Items**
Leadership	1. We are reminded by our superior to keep safety, environment and employees in the laboratories at the high level. 2. The Head of department provides guidance for the lab staff to carry out their tasks effectively and efficiently. 3. The Head of department has been able to identify the right personnel to carry out a particular task.

3.6 Operational Performance

The operational performance measures are made up of eight (8) items. The items measuring operational performance were taken and modified from Halevy (2003). The items were measured using 5-point Likert scale(1-strongly disagree, …, 5-strongly agree). The items on operational performance are listed in Table 5.

Table 5. Operational Performance

Variable	**Items**
Operational Performance	1. We noticed there were fewer errors and fewer failures due to implementation of QMS. 2. There are fewer customer complaints due to proper QMS implementatio in our laboratory. 3. There has been improvement in the laboratory staff skills. 4. We always checked the reliability of findings and test results. 5. We always checked the levels of production and productivity of the laboratory staff.

6. We always make sure that we correctly meet our customers' needs and requirement.
7. We take note of response time to orders, changing requirement and requests from customers.
8. We are experiencing expanding orders for laboratory services.

3.7 Pilot Study

The pilot study was conducted in the testing laboratories implementing ISO/IEC 17025 from 29th April 2014 until 25th May 2014. A total of 30 questionnaires were distributed with the returned rate of 100%. The information on the questionnaires was furnished in such a way that it is fully understood by the target respondents. The questionnaires were then analyzed using *Statistical Package for Social Science* (SPSS). The values of reliability coefficients, i.e., Cronbach's alphas for each variable are shown in Table 6.

Table 6.Reliability coefficient (Cronbach's alphas) for the pilot study

Variables	Number of Items	Cronbach's Alpha
B – Internal Factors	7	0.797
C – External Factors	4	0.814
D – Quality Culture	8	0.906
E– Leadership	3	0.869
F –Operational Performance	8	0.956

Based on the reliability test results, there was no item deleted because the coefficients were in the range between acceptable values of 0.76 and 0.90, respectively. Thus, the same questionnaires were used in conducting the actual survey because of the reliability coefficient values for each variable fall within the acceptable range.

3.8 Data Collection

Data collection for this study involves distribution of questionnaires using online survey to quality management representatives working in testing laboratories throughout Asian countries, Australia, and European countries. Only ISO 17025 certified testing laboratories were selected in this study. A total of 1,176 questionnaires were distributed and the numbers of returned questionnaires are shown in Table 7.

Table 7. Distribution and Collection of Questionnaires

Countries	Total distributed	Total collected	Percentage response rate
Asian	280	41	14.6%
Australia	25	19	76%
Europe	871	103	11.8%
Total	1,176	163	13.8%

A total of 163 questionnaires (of 1,176 questionnaires) were collected and this made up a return rate of 13.8%. Statistical methods, namely, Structural Equation Modeling (SEM) and

Partial Least Squares (PLS) were used to analyse the data. The SEM-PLS analysis consists of two parts, i.e., structural model and measurement model, respectively. Statistical software SmartPLS3 (Hock and Ringle, 2014) was used to assess the measurement and structural models of the SEM-PLS.

4 Model Estimation and Evaluation of Results

4.1 The Measurement Model

The research model of Figure 1 was analyzed using SmartPLS3, a SEM-PLS structural equation modeling software (Hock and Ringle, 2014). The measurement model in PLS is assessed in terms of item loadings and reliability coefficients (composite reliability) as well as the convergent and discriminant validity. Any individual item loading greater than 0.7 is considered adequate (Fornell & Larcker, 1981).A reliability coefficient similar to Cronbach's alpha called 'Composite Reliability (CR)' is used to measure internal consistency of the measurement items. Like Cronbach's alpha, a composite reliability value of .70 or greater is considered acceptable (Fornell & Larcker, 1981). The average variance extracted (AVE) measures the variance captured by the indicators relative to measurement errors, and it should be greater than .50 to justify the suitability of a construct (Barclay et al., 1995). The discriminant validity of the measures is assessed by examining the correlations between the measures of potentially overlapping constructs. Items should load more strongly on their own constructs in the model, and the average variance shared between each construct and its measures should be greater than the variance shared between the construct and the other constructs. The structural model in PLS is evaluated by examining the path coefficients (standardized betas). T-statistics are also calculated using bootstrap methods to assess the significance of these path coefficients. In addition, R^2 is used as an indicator of the overall predictive strength of the model. The PLS path model and the measurement results are summarised in Figure 2.

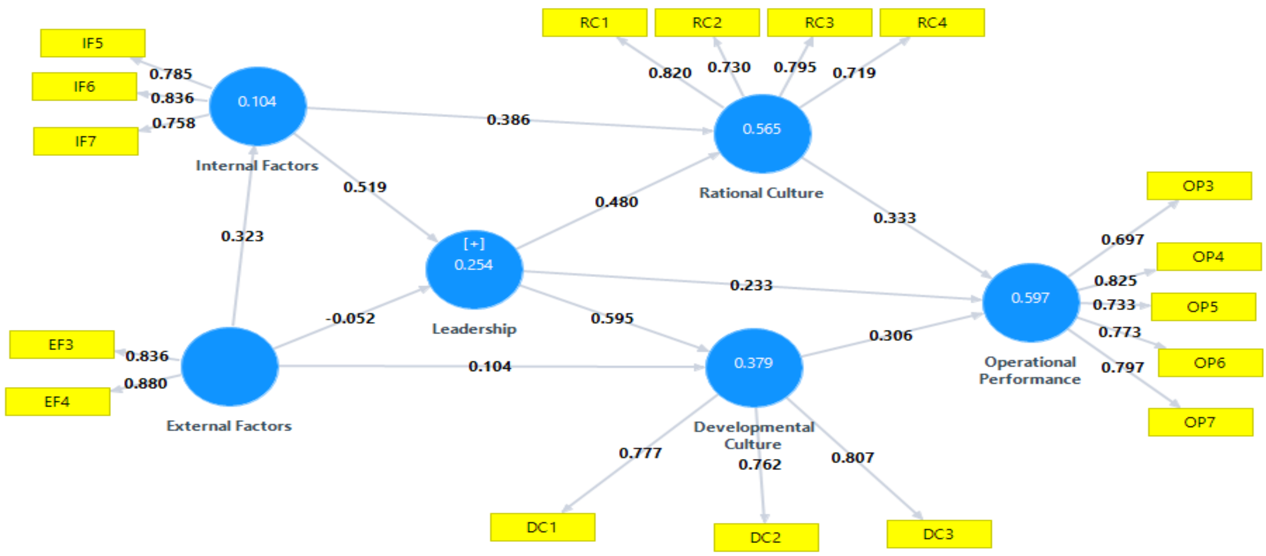

Figure 2: The Computed Path Model

Table 8. Discriminant Validity (Fornell & Lacker 1981)

	1	2	3	4	5	6
Developmental Culture (1)	**0.782**					
External Factors (2)	0.172	**0.858**				
Internal Factors (3)	0.653	0.323	**0.793**			
Leadership (4)	0.607	0.115	0.502	**0.840**		
Operational Performance (5)	0.688	0.243	0.632	0.643	**0.766**	
Rational Culture (6)	0.722	0.214	0.626	0.673	0.711	**0.767**

Note: Diagonal represents the square root of the AVE, while the off-diagonals represent the correlations among the variables.

Table 8 demonstrates satisfactory convergent and discriminant validity of the measures. Average variance extracted (AVE) for all constructs exceeded 0.50. As for the discriminant validity, Table 8 shows that all constructs were more strongly correlated with their own measures than with any of the other constructs. Hence, the results fulfilled the requirement for the discriminant validity.

4.2 Assessment of Structural Model

The next step in SEM-PLS analysis is to develop a structural model by analysing the inner model, i.e., the model that displays the relationships between the constructs. The coefficient of determination,R^2, is used to evaluate the significance of the research model. For this purpose, loadings among the components are tested for the significance of path parameter coefficients using R^2. For a specified SEM-PLS model, the R^2 for each dependent latent variable in the structural model provided by SEM-PLS are firstly calculated, in which case the values of the latent variables are determined by the weight relations (Vinzi et al., 2010).To test the significance, all the data were run using 500 bootstrapped samples throughout the collected sample of 163 cases.

4.2.1 Path Coefficients

The path coefficients are used to evaluate the structural models. The path coefficients or model loadings are evaluated in terms of sign, magnitude and significance and they are interpreted similarly as in regression analysis and equivalent to the standardized beta weights (β) (Henseler at al., 2009). The path coefficients indicate the strength and the direction of the causal links between latent constructs. Therefore, the path coefficients that do not match the algebraic sign from the theoretical expectations do not support the hypotheses.

The path coefficient significant level is determined by examining the path loadings between constructs; and this is determined by using t-statistics. The t-statistics were estimated using the bootstrap resampling procedure. The bootstrapping procedure is a non-parametric approach for estimating the precision of the SEM-PLS estimates (Henseler et al., 2009). Bootstrapping results indicate the stability of the SEM-PLS estimates. In this study, all the data were run using 500 bootstrapped samples, with the same number of cases as original sample, following the method conducted by Navarro et al. (2000).

From Figure 2 it is revealed that all regression weights values are of practical importance (beta values > 0.2) and statistically significant at 0.01 significance level. Also, the direction of the hypothesis is positive and in tandem with the proposed hypothesis as discussed in the literature review.

4.2.2 Coefficient of Determination (R^2)

In terms of the amount of variance in each construct, the coefficient of determination (R^2) of the endogenous latent construct explains the predictive power of the structural model. The R^2 is used to assess the proportion of the variance in the endogenous construct that can be accounted for by the exogenous constructs (Hair et al., 2011) and are interpreted in the same manner as R^2 values obtained from the regression analysis (Casey and Wilson-Evered, 2012; Henseler et al., 2009).

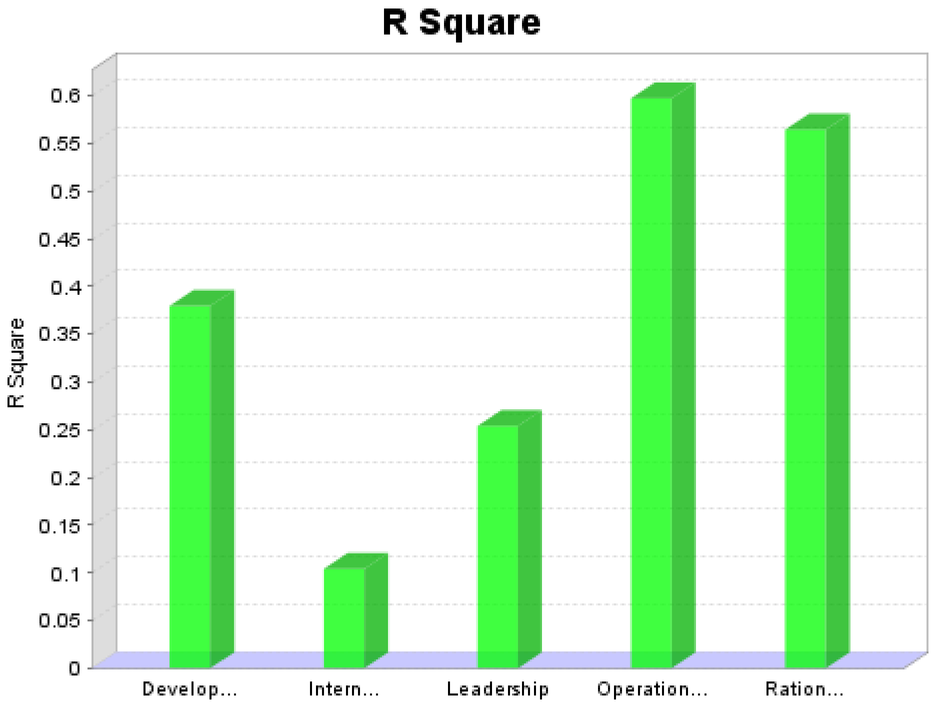

Figure 3: Quality Criteria: R square

In general, the results have shown that the hypothesised model was able to describe the statistically significant amount of variance for each construct. As shown in Figure 3, R^2 value for the endogenous variable, i.e., operational performance is 0.597, while the $R^2$for rational culture, developmental culture, leadership, and internal factors are0.565, 0.379, 0.254 0.014, respectively.

5 Summary and Conclusions

This paper has established some empirical evidence on the significant relationships between leadership and quality culture on operational performance of testing and calibration laboratories. Our findings also indicate the importance of managing internal factors in the laboratories as it was revealed that these factors have significant influences on the leadership and the culture in the laboratories. In our findings, even though the influence of this factor is significant, the external factors failed to exert significant impact on the leadership and the laboratories' culture, and subsequently on the laboratories' operational performance. Such effect seems to indicate that the laboratories' managers have to focus on consolidating the internal systems in order to attract and enhance the customers' confidence with the services offered.

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