

Critical Success Factors of ISO/IEC 17025 Implementation within Arabic Countries: A Case Study of Libyan Research Centres and Laboratories (LRCL).

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Structured ABSTRACT

Aim– This paper aims to review the existing literature relevant to the subject of ISO/IEC 17025 within Arabic countries and Libyan Research Centres Laboratories (LRCL), especially to the Critical Success Factors (CSFs) that effect the implementation of ISO/IEC 17025 standards. Therefore, a review of the literature revealed a major gap in studies in this area of quality standards for testing and calibration laboratories.

Methodology– The aspects listed were based on a review of the literature. This paper summaries the key findings result within LRCL using SWOT and Template analysis to analyse the data collected from existing literature and LRCL data.

Findings –The findings revealed that despite some organisations have faced challenges undertaking ISO/IEC 17025 implementations, many others have enjoyed the benefits that the systems have brought to the organisations. Outcomes of the research are important for Arabic and Libyan organisations implementing ISO/IEC 17025 systems and for consulting companies assisting with ISO/IEC 17025 implementation. The distribution of the current study results will lead to knowledge transfer and help organisations, among Arabic and developing countries including Libya, in the process of achieving standardisation.

Originality, Value – The novelty of this research paper stems from the realisation of critical factors determining a successful implementation of ISO/IEC 17025 within research centers and Laboratories in Arabic countries and LRCL. The originality and value of this research paper is to fill the gap in knowledge in this area, which is explicit to the Arabic countries and Libya in particular. In addition, it contributes to the literature and professional practice by offering new insights into the CSFs for the implementation of ISO/IEC 17025 in Arabic countries and LRCL.

Keywords: ISO/IEC 17025, Critical, Success, Factors (CSFs), Arabic Countries, Libya, Motives, Obstacles, LRCL.

1. Introduction

The introduction of Quality Management Systems (QMS) and the accreditation of laboratories according to ISO/IEC 17025 standard are not easy tasks, mainly for those laboratories located at teaching and research initiations (Al-mijrab and Elgharib, 2016). In order to become efficient and competitive in today's business environment, the majority of organisations are being encouraged not only to change their old operation habits, but also to develop better ways to ensure that customers are satisfied with the quality of products and services (Magd, 2010). ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. It is specifying the basic requirements for the competence verification of laboratories carrying out testing and calibration activities, focused in meeting customer expectations and keeping organised laboratory records and documents (ISO/IEC 17025, 2017). These requirements relate to most, if not to all, the laboratory activities concerning testing and calibration services provided by the laboratory, from the control of documents and records to the technical procedures' standardisation. Up to this date, ISO/IEC 17025

standard was last revised and confirmed by ISO in 2017 and is currently under a new revision process (Gheraout et al., 2018). Laboratories accreditation has been a subject of considerable interest to many institutions in the Arabic world, including Libya, because product quality guarantee has become one of the prime factors to be considered in the present time of highly competitive industrial activity. The reliability of the test results, as well as the technical competence of laboratories gives its accreditation, according to international quality standard, such as ISO/IEC 17025 a necessity of major importance (Al-mijrab and Elgharib, 2016). Therefore, the laboratory's technical competence becomes critical to the manufacturer, supplier, exporter and consumer, which enforce many testing and calibration laboratories to practice the quality systems (Neves et al., 2017). The focus of this research arose as a result of the authors personal experience, gained from working in a Libyan research Centre and Higher Education.

There are many difficulties facing LRCL and higher education institutions in today's competitive market. These include technical, financial, political and organisational factors. LRCL should focus on quality improvement methods and values, as they are the crucial standards with which to measure success. It is vital to invest current resources through the use of good improvement programmers particularly in laboratories accreditation, where the effectiveness of people and equipment can provide high productivity and low expenditure. Many ISO research studies have determined several Critical Success Factors (CSFs) in ISO/IEC 17025 implementations (Rebelo et al., 2015; Shihub, 2009; Grochau and Caten, 2013; Elsmuai and Collin, 2013; Karthiyayini and Rajendran, 2017). These studies, however, discussed the success factors from different prospective and in different contexts.

1.1 Research Aim

The overall aim of this research was to review the existing literature relevant to the subject of ISO/IEC 17025 within Arabic countries and LRCL, especially to the CSFs that effect the implementation of ISO/IEC 17025 standards.

1.2 Research objectives

The purpose of this research is to demonstrate the work done by the researchers in this paper to:

- Outline some of the factors that are perceived to be critical in the successful of ISO/IEC 17025 within Arabic countries and Libya in particular.
- Identify the CSFs of success or failure; in order to build an understanding and a clearer picture of the factors that are considered to be vital for a successful ISO/IEC 17025 implementation.
- Make recommendations to ease the implementation of ISO/IEC17025 in LRCL.

1.3 Research question

In order to obtain comprehensive information to support the conclusion to the main research question, relevant to professional practice the authors have also designed the specific supporting research questions, which were derived from the literature review. The questions for this research are as follows:

1. What are the Critical Success Factors (CSFs) affecting the implementation of ISO/IEC 17025 standards in LRCL?
2. Why the CSFs to implementing the standards are importance?

1.4 Significance of the Study

It has been said that “*Research can be considered as a journey of discovery and whether anything is discovered or not-the essential feature is that it should make an original contribution to knowledge*” (Yin, 2003). The research will review the most importance CSFs of ISO/IEC17025 implementation. This will help Arabic Laboratories and LRCL have a comprehensive understanding on what factors that they have to focus on in order to achieve the successful laboratory quality system that will meet customers need and goal of organisation. Arabic laboratory and LRCL can use this result as guide to develop and implement a laboratory management system that is in compliance with ISO/IEC17025. In addition, it seeks to fill the gaps in the current literature debate on the prospects of ISO 17025 factors that affect the development of CSFs.

2. Relevant Literature Review

In recent years, the ISO/IEC 17025 and Quality Management System (QMS) has been widely accepted and adopted as a national / international standard for testing and calibration laboratories. The progressive increase in applications from manufacturing firms, for approval to standards such as ISO/IEC 17025, suggests that quality certification has been, and continues to be, viewed as important to competitive position (Elgharib and Almijrab, 2017; Elsmuai, 2015). Therefore, quality guarantee has become one of the prime factors to be considered in the present time of highly competitive industrial activity.

The developing countries, particularly the Arab countries, needs to adopt and improve the pathways of developed countries if they want to achieve a competitive advantage and form an effective international economic power (Wahed and El-Baz, 2018). The main reason of accreditation ISO/IEC 17025 according to Catini et al., (2015) is to prevent many deviations from occurring and to give the laboratory's customers confidence in the quality of the services provided by the laboratory. So, laboratories that have an official statement such as an accreditation certificate will receive more confidence from economic agents in the services supplied. In addition, many researchers, such as (Barradas and Sampaio., 2011; Grochau et al., 2010), suggested that the purpose of laboratory accreditation bodies is to assess the capability of laboratories and their ability to produce dependable data. Another benefit encompass documentation, standards, quality awareness, market share, customer satisfaction and competitive advantage. The nature and strength of drives behind the decision to seek ISO/IEC 17025 plays a key role in the success of the implementation process, and simultaneously in the emergence of organisational problems arising from certification (Ashrafi, 2008).

In particular, consideration of the purpose or reasons for implementing ISO/IEC 17025 standards can predict the benefits that an organisation could gain once certified (Almijrab et al., 2016). ISO/IEC 17025 allows firms, on the one hand, to obtain a high degree of professionalism, and strengthening customers' confidence on test / calibration results, and on the other, reduce costs by preventing mistakes and time wasting and allowing improvements in the corporation's process. However, in spite of its advantages, the problems can be also found in its implementation (Algharibi and Abdulla, 2017; Khodabocus and Balgobin, 2011). Hence, for successful implementation, laboratories must find out what activities or factors will affect the results that laboratories expect based on their culture and their goal.

Various attempts have been made by different researchers to identify the critical quality factors that were absolutely essential for the success of the implementation of laboratories' accreditation and quality issues. CSFs are widely used in any business. Rockart (1982) stated " *CSFs as the limited number of areas in which results, if they are satisfactory, will ensure successful competitiveness performance for organisation*". The advantage of identifying CSFs is to help the organisation focus attention on major concerns, easy to monitor and can be used in accordance with strategic planning methodologies.

The authors of this paper will present the most common CSFs in the Arab countries that approved by laboratories during their journey in implementing ISO/IEC 17025 initiatives. However, the common factored captured from literature were gathered, summarised and then tabulated as shown in table (1.1), which includes the author, year of study, country of study, and the specific factors that were faced during the implementation of the initiatives in that country. This table gives an overview of the CSFs effecting the implementation of the ISO/IEC 17025 standards which can be used by the researcher and other researchers, and could be considered as guidelines by those companies which intend to implement the programme as well as during the implementation process. Authors such as Tene et al., (2018); Elsmuai and McCollin, (2013); Abusa and Gibson (2013); Kamleh et al., (2012); Shihub, et al, (2009); Ashrafi (2008); Mersha (2007), report that the CSFs of ISO/IEC 17025 implementation include aspects such as top management support, cooperation and education of employees, although with different emphases in each case.

Clearly, there is a large amount of information in this literature, but for brevity in this research, the researchers have highlighted and identified eleven CSFs in the below table 1.1 which is the most important factors for the success of ISO 17025 implementation within Arabic countries includes, *top management commitment, employees commitment, understanding ISO 17025, training and support, financial support, organisation culture, external consultant, teamwork, government support, continuous improvement and availability of resources in Arabic countries.*

The literature indicates the **support of top management** as the most important factors in achieving successful and effective complete implementation of laboratories. As a result, it is very importance to the

success of the whole laboratory's accreditation project is getting true commitment provided by management due to the management supply the laboratories by necessary resources such as money, training and time as well as any type of support. The second was *employees commitment*, successful ISO 17025 implementation requires a committed and well-trained workforce that participates fully in improvement activities. The third key factor was *understanding ISO/IEC 17025*, it is important for all organisations to understand ISO/IEC 17025 requirements before and during implementation, so that the quality system can be successfully introduced and embedded into the organisation. The fourth key factors were *training and support*, it reflects managerial and employee training in quality principles and, to a lesser extent, managers involvement in training and development of strategies and plans. The fifth key factors supported by the authors from different Arab countries was *financial support*, it is one of the most important factors for successful implementation of the programme and the government must support quality development of the laboratories financially. The sixth *organisation culture*, were it is the value, traditions, beliefs and behaviors of any company or organisation. It has been suggested that culture is the umbrella which covers all the elements of social activities, and it can have a series impact on behavior, communications, relationships and other social parameters. The seventh *external consultant*, should be considered as a key element of the government laboratories strategy in the Implementation process and accreditation.

Table1.1: Critical Success Factors (CSFs) Identified from the literature

(CSFs)	Country	Experience	Team Work	Continuous Improvement	Government support	Implementation Framework	External Consultant	Effective Communication System	Improved Documentation System	Organisation Culture	Management Planning and Process	Financial Support	Availability of Resources in Arabic	Employees commitment	Training and support (employees)	Top Management Commitment	Understanding ISO/IEC17025 standards
		Authors Name & Year															
	Egypt			✓	✓							✓		✓		✓	✓
	Libya	✓	✓	✓			✓			✓			✓	✓	✓	✓	✓

(Elsmuai and McCollin, 2013);	Tunis	✓	✓		✓		✓		✓						✓		
(Aldowaisan and Youssf, 2006)	Kuwait		✓	✓	✓	✓						✓					
(Baidoun, 2003);	Palestinian		✓		✓			✓								✓	
(Magd et al, 2003);	Saudi Arabia	✓	✓	✓	✓					✓						✓	
(Al-Zamany et al., 2002);	Yemen		✓	✓		✓									✓		
(Ashrafi, 2008)	Oman	✓	✓		✓										✓		✓

The eighth *factor teamwork*, is another important factor in the human resource category, with the use of teams, the laboratories will receive quicker and better solutions to problems. Teams also provide more permanent improvements in processes and operations. The ninth *government support*, it can play an essential role with regard to strong support in ISO/IEC 17025 implementation process by leading moral support, legitimizing quality programs and by licensing of instruction.

Tenth factor was *continuous improvement* could increase productivity and capacity, reduce costs, increase profits and customer satisfaction. The eleventh and the final factor *availability of resources in Arabic countries*, the quality standard institute and accreditation bodies in Arabic counties should the necessary translation of the quality international standards in Arabic languages.

3. Research Methodology, Data and Analysis

The purpose of research methods is to identify and develop a research methodology most suitable to support the research study. This study included two phases. In the first phase, the pilot study, email interviews were conducted, followed up by telephone interviews to provide a greater degree of flexibility. In order to obtain a general perspective regarding the motives for seeking ISO/IEC 17025 certification, the interviews were focused on quality professionals most likely to be aware of all aspects of the certification process. In the second phase of the study, semi-structured interviews were carried out to gain more in-depth information. Interview guides were developed from the pilot study and the research strategy was designed to increase validity and reliability in the interview questions. As a research strategy, a case study approach was adopted in order to gain a depth of understanding of the information necessary to identify and investigate the reasons which engendered the LRCL implementation of ISO/IEC 17025 standards. Also, following a constructivist viewpoint, it was appropriate to apply an interpretive paradigm, which is integral to qualitative research (Denzin and Lincoln, 2005). This paradigm is compatible with the exploratory nature of this study. The data

collected from the case study was recorded as qualitative transcripts of the semi-structured interviews held with case study participants. The data collected from the case studies was analysed using Template and SWOT Analysis. King (2012) defines template analysis as a particular approach to analysing qualitative data: “The data involved are usually interview transcripts but may be any kind of textual data including diary entries, text from diary entries, text from electronic “interviews” (email) or open-ended question responses on a written questionnaire” (King, 2012).

King's also stated that the purpose of template analysis is to provide the reader with an overview of the key themes and subthemes emerging from the interviews. The themes and codes are defined by King as relevant features of the participant's accounts and the process of identifying the themes. The key themes are identified from the original research questions and developed into sub-themes and then coded once the interviews have been transcribed. An initial template for analysis of the data was subsequently created using the codes presented in table 2.1. This enabled adjustments to be made to the themes and sub-themes as the analysis evolved before developing the “final” template, although King further states that because there are other ways of interpreting qualitative data sets there is no stage where you can say with absolute certainty that the template is finished.

A **SWOT** analysis is used for businesses to determine their current internal and external positions within their industry. SWOT stands for strengths, weaknesses, opportunities, and threats. SWOT stands for strengths, weaknesses, opportunities and threats. **SWOT** analysis, which was developed in the 1960s, is a strategic assessment tool for gathering and organising the information needed to evaluate positive (strengths, opportunities) and negative (weaknesses, threats) elements of a strategy, project, business model, company, or laboratories (Teece, 2017). The internal factors are strengths and weaknesses while the external factors include opportunities and threats. The analysis of strengths, weaknesses, opportunities and threats (SWOT) was adopted as the research method to collect opinions on the ISO/IEC17025 standard.

4. Results

In this section the authors of this paper will present the findings of the present study that covers the most common critical factors that approved by laboratories during their journey in implementing ISO/IEC17025 initiatives. These factors should be understood and considered as a main CSFs before and during the ISO/IEC17025 implementation process. The following template in Table (2.1) was produced using the transcriptions from the interviews carried out in LRCL.

Table 2.1: SWOT and Template Analysis classification factors for CSFs of ISO/IEC 17025 in Libya and Arabic countries

Aspect	Laboratories (Internal) factors	Laboratories (External) factors
Positive	Strengths (factors)	Opportunities (factors)
	<ul style="list-style-type: none"> Improving quality of Laboratories. 	<ul style="list-style-type: none"> Public recognition.
	<ul style="list-style-type: none"> Improving performance. 	<ul style="list-style-type: none"> Advantage in market competition.
	<ul style="list-style-type: none"> Increasing lab productivity. 	<ul style="list-style-type: none"> Development of suitable accreditation standards for local use.
	<ul style="list-style-type: none"> Success of the Laboratories 	<ul style="list-style-type: none"> Improve reputation of the laboratories.
	<ul style="list-style-type: none"> National and international recognition 	<ul style="list-style-type: none"> Results accepted nationality & abroad.
	<ul style="list-style-type: none"> Improving data collection. 	<ul style="list-style-type: none"> Laboratory development.
	<ul style="list-style-type: none"> Increased Lab Productivity. 	<ul style="list-style-type: none"> Export products and results abroad & Establish place in local market.
	<ul style="list-style-type: none"> Quality as a paramount goal. 	<ul style="list-style-type: none"> Using one standard system.
<ul style="list-style-type: none"> Build trust between you and your customer. 	<ul style="list-style-type: none"> Allowed data accompanying exported goods to be more readily accepted on overseas markets. 	

	Weaknesses (sub-factors)	Threats (sub-factors)
Negative	<ul style="list-style-type: none"> Lack of employee awareness of the concept of QMS. 	<ul style="list-style-type: none"> Resource & funding cuts.
	<ul style="list-style-type: none"> Lack of available information in Arab language. 	<ul style="list-style-type: none"> Lack of incentives for participation.
	<ul style="list-style-type: none"> Lack of management support and commitment. 	<ul style="list-style-type: none"> High costs for sustaining the programmes.
	<ul style="list-style-type: none"> Employee absenteeism. 	<ul style="list-style-type: none"> Process of ISO 17025 too complicated.
	<ul style="list-style-type: none"> Wrong person in the wrong position. 	<ul style="list-style-type: none"> The difficulty of having arguments or discussions with the managers.
	<ul style="list-style-type: none"> No desire to change. 	<ul style="list-style-type: none"> Bureaucratic administration.
	<ul style="list-style-type: none"> lack of technical knowledge. 	<ul style="list-style-type: none"> Inadequate training.
	<ul style="list-style-type: none"> calibration difficulties. 	<ul style="list-style-type: none"> Difficulties in accepting new approach/direction.
	<ul style="list-style-type: none"> cultural barriers. 	<ul style="list-style-type: none"> Economic Crisis.
	<ul style="list-style-type: none"> Expertise. 	<ul style="list-style-type: none"> Absence of Libyan experts. No accredited local agencies.
<ul style="list-style-type: none"> Cost. 	<ul style="list-style-type: none"> Training Programmes are costly. Calibrations are costly. 	

Based on the outcome of the SWOT & Template analysis results in Table 2.1, it is possible to answer developed research questions of the study. The reliability of the test results, as well as the technical competence of laboratories gives its accreditation, according to international quality standard, such as ISO/IEC 17025 is very importance. In Libya (a rather small country), testing laboratory needs to develop a quality assurance system, according to these international standards, in order to prove their technical reliability and competence. Accreditation is still a new issue for the laboratories in Libya, a developing country these laboratories need to establish a new strategy towards accreditation focuses on the difficulties and barriers to implementation. Among them are a variety of industries which included Laboratories, industries, industrial research centres, and petrochemical industries and so on. Although there has been a substantial interest in the improvement of business management; quality management has been significantly less predominant in Libya.

5. Conclusions

We have surveyed the literature of success and failure factors of implementing ISO/IEC17025 standards. CSFs are crucial for successful implementation of ISO/IEC17025 practice and polices. Laboratories benefit from a comprehensive understanding of the factors that are critical to the implementation of ISO/IEC17025 standards. The main contribution of this study is to provide an extensive literature review of CSFs of ISO/IEC17025 implementation. The research reflects empirical results of a number of ISO/IEC17025 -Accredited laboratories in Libya, in order to identify CSFs implementation, based on research questions as mention in section.1.

The following conclusions are based upon the entire case study research and the full SWOT & Template analysis. The key findings from the full template analysis indicates that it:

- The ISO /IEC 17025 international standards have been widely accepted by many organisations across all Arabic Laboratories and LRCL.
- The ISO/IEC17025 certification has delivered important internal and external benefits to the certified Libyan Laboratories regardless of their size, field of operation and ownership.
- The research findings found that the ISO/IEC17025 standards is most often implemented to satisfy the demands of external customers and potential customers.
- The study has identified problems, issues and attitudes that the decision makers within the laboratory's environment might face towards this implementation.

Additionally, more attention should be paid towards generating improved management commitments in the implementation process, and taking the full responsibility to encourage and motivate all the involved teams

to take part in the task. Generally, training and ongoing education is essential and should be provided to all the involved teams/employees at all levels. Ensuring a high level of understanding of the whole process to all involved teams may lead to a complete implementation of all the Laboratories and testing and calibration results, but also complete status of laboratory equipment, staff training and ambient conditions, thereby moving the LRCL towards world class Laboratories.

6. Recommendations for Practitioners

From the results presented in the SWOT and template analysis above, one can glean a number of recommendations that could be put in place, both to aid organisational performance and to increase the number of ISO/IEC 17025:2017 certificates issued in Arabic countries and in particular Libya. The practical implications of this study are as follows:

- **The governmental institutions** can play essential role to encourage all the LRCL to move towards achieving successful and effective complete ISO/IEC17025 implementation goals and quality techniques and philosophies. The full acceptance of these techniques and philosophies by the management body crucial to empower the related teams and individuals to overcome the barriers in the implementation processes throughout their laboratories, especially within the Libyan environment.
- **Training centres** for human resource development should be created, which emphasis on lifelong learning and on-going training programmes for the LRCL.
- **Leadership and culture** to change towards continuous improvement throughout the entire Arabic countries Laboratories and LRCL.
- **A strategic and operational plan** to achieve laboratory objective of performance excellence.
- **Financial resource** commitment for delivery of the strategic and operational plan so that training, education and learning, along with implementing the latest technology and techniques that are needed to improve the Arabic Laboratory and LRCL.
- **Teamwork approach** should be used throughout the laboratory. This will allow the cultural change to develop so that all stakeholders have ownership of the changes begin implemented. However, the teamwork approach will need openness, communication and a suitable environment for criticizing and suggesting ideas for updating and Improving the current status within the LRCL.
- **The consultancy and advisory** institutions should be considered as a key element of the government's Laboratories strategy by playing a vital role in assigning the LRCL to improve their quality, productivity and work towards achieving ISO/IEC17025 CSFs implementation.
- The government and Libyan National Center for Standardization & Metrology (LNCSM) must provide more information, translation all the standardization in Arabic language, conferences, training and awareness and seminars. This should then increase the number of certified companies so that Libya's rank in the Arab list of companies holding ISO certification becomes more in line with other Arab countries.
- To increase the number of local agencies and Libyan experts in the ISO /IEC17025:2017 field, the LNCSM should train more people, thus reducing the problem of the lack of expertise and supporting those LRCL by opening more local accreditation agencies. The high costs of accreditation and those pertaining to the auditing process could be reduced as some of these agencies charge substantial fees.
- To help CSERS laboratories establish a programme for a laboratory management system that is suitable for their size and workload, and that will meet their clients' needs. The researchers of this paper recommended ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories, that will help the CSERS laboratory develop and implement a laboratory management system. CSERS will continue improvement by adopting ISO/IEC 17025 in their laboratories and will gain international recognition for its commitment to quality, competency and reliable results. Tested products would be almost eligible for international recognition; this would also eliminate the need for dual testing in different countries.

7. Limitations of the research

The design and subject matter of this research was subject to the constraints imposed by availability of information and statistical data. Libya, like most developing countries, lacks the skills and qualifications, the know-how, and the sophisticated facilities needed to compile more comprehensive data that serve all the purposes of social and economic development. One of the limitations of this research was the use of some literature of ISO/IEC17025 version 2017 because the shortage of literature on the topic of CSFs affecting implementation of ISO/IEC17025 standards in previous research and work studies, especially research or studies that were carried out organisations across the Arabic, African and the Middle East countries which have a similar working environment to LRCL. In addition, the qualitative research is a common approach to survey in social studies such as interviews. However, the importance of critical factors needs to use quantitative tools such as questionnaires. Therefore, determining factor's importance through quantitative research methods may include the importance of ISO/IEC17025 CSFs issue in future researches.

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