

An Investigation into the Barriers Affecting the Adoption of ISO/IEC 17025 Certification in Arabic Countries: A Case Study of Libyan Research Centres and Laboratories (LRCL)

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ABSTRACT

The purpose of this paper is to investigate and analyse the difficulties that affect the adoption of ISO/IEC 17025 in Libyan Research Centres and Laboratories (LRCL). A review of the literature revealed a major gap in studies in this area of quality standards for testing and calibration laboratories. The aspects listed were based on a review of the literature. A case study approach was favoured to collect the necessary data. This paper summarises the results from face to face semi-structured interviews conducted within LRCL, using template analysis to analyse the data from the case study. The findings have possible implications for the Libyan government, the LRCL, Libyan experts and quality managers. The distribution of the current study results by the LRCL will lead to knowledge transfer and help organisations, among Arabic and developing countries, in the process of achieving standardisation. It is hoped by the authors that their findings can help those organisations deal with domestic customers and serve the local market, in addition to helping the LRCL find a place in the international market by seeking ISO/IEC 17025 certification. The paper highlights the strong potential of ISO 17025 in affecting organisational performance improvements. The study also offers a beneficial source of information for organisations in Libya, which are still lagging far behind when it comes to ISO implementation. The originality and value of this research paper is to fill the gap in knowledge in this area, which is explicit to Libya, and contributes to the literature and professional practice by offering new insights into the motivations for the implementation of ISO/IEC 17025 in LRCL.

Keywords: Libya; Developing Countries; Laboratory Accreditation; ISO/IEC 17025; Reasons; Motives; Barriers; LRCL.

1. Introduction

There has been a rapid increase in international competition in the last two decades. This competition has forced the developed countries to adopt the philosophies in Quality Management such as Quality Control, Quality Assurance, Total Quality Management and Quality Management System. The developing countries, particularly the Arab countries, need to adopt and improve the pathways of the developed countries if they want to achieve a competitive advantage and form an effective international economic power (Elsmuai and McCollin, 2013).

Ferguson (1996) pointed out that numerous quality standards have been developed and adopted over the years, with the ISO family of standards representing an international consensus on good management practices that have the aim of ensuring that an organisation can deliver products or services that meet the customers' quality requirements. The ISO standards can be applied to any type of organisation (private or public including government services) independent of the size of the organisation or the kind of products manufactured or services provided (Shihub, 2009). ISO/IEC 17025 specifies the basic requirements for the competence verification of laboratories carrying out testing and calibration activities, focused in meeting customer expectations and keeping organized laboratory records and documents. 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 standardization. Up to this date, ISO/IEC 17025 standard was last revised and confirmed by ISO in 2010 and is currently under a new revision process (Neves, et al., (2017) and ISO/IEC 17025 (2005).

Accreditation of laboratories has been a subject of considerable interest because product quality guarantee has become one of the prime factors to be considered in the present time of highly competitive industrial activity. 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 (Elhuni,2016).The study was conducted by the researchers from Centre for Solar Energy Research and Studies (CSERS). The Libyan Research Centres and Laboratories (LRCL) was the case study of this research. LRCL, part of the Libyan Authority for Research, Science and Technology, is responsible for research, and maintaining a reasonable level of scientific progress in accordance with a national scientific research policy. This research was also supported by CSERS and LRCL.

The focus of this research arose as a result of the authors personal experience, gained from working in a Libyan research centre. As highlighted previously, there are many difficulties facing LRCL 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 programmes particularly in Laboratories Accreditation, where the effectiveness of people and equipment can provide high productivity and low expenditure.

Research into the implementation and accreditation of ISO/IEC 17025 standard is limited. Only a few articles in the literature deal with this topic. Therefore, this study will, hopefully, contribute to filling this gap. Most of the articles related to the implementation and accreditation of ISO/IEC 17025 have confirmed the usefulness of the system application while recognizing the existence of many obstacles.

The purpose of this paper is to demonstrate an understanding gained in the area of the difficulties affecting and challenges arising during implementation of ISO **ISO/IEC17025:2005** – General Requirements for the Competence of Testing and Calibration Laboratories is the standard used for laboratory accreditation. There are four key proceeding sections to this paper. The first part sets out the key literature and identifies the gaps in knowledge that lead into an explanation of the research background, including an explanation of the significance of this research, the aim and objectives of the research and the main research questions. The second part focuses on the research strategy, data collection methods and data analysis techniques, which includes the background to the research philosophy, research approach and selection of data collection methods. The third part describes the findings and results of the study, revealing which and why barriers to **ISO/IEC17025:2005** adoption and implementation might occur in Libya and how this relates to existing literature. In the final section, conclusions are drawn and recommendations are made as to how this research may be used by professional practitioners or by Libyan authorities whilst also considering the limitations of the research.

2. Relevant Literature

The process of implementing ISO/IEC 17025:2005 certification can be notoriously problematic and many laboratories encounter difficulties during and after the process of certification. While there has been considerable interest in the improvement of business management in Libya, the study of quality management has been significantly less prominent, a situation that is also found in other Arabic countries (Shihub, et al, 2009). It is therefore valuable to examine the reasons why many laboratories fail to be familiar with, and understand the advantages of ISO/IEC 17025:2005.

Elhuni (2016) stated that to effectively implement the ISO/IEC 17025, there are a number of measures and factors that should be taken into consideration such as senior management support, training, documentation, laboratory test methods, audits' review and equipment validation method.

Elsmuai and McCollin, (2013) recognise that the philosophy of quality, inherent in ISO standards, requires employees and managers across all departments in the organisation to work together to identify and resolve quality problems. However, empirical evidence often shows that the implementation of ISO/IEC 17025 meets many different barriers in laboratories throughout the world (Neves, et al., 2017;Khodabocus and Balgobin ,2011;Barradas and Sampaio, 2011;Hokoma, et al., 2008;Grochau, et al.,2010;Shihub, et al., 2009; Khan and Ahmad, 2009).Specifically and emblematic of many of these studies, Shihub, et al.,(2009)identified three main categories of difficulties of implementing ISO/IEC 17025in the Arab countries .Factors related to government issues such as lack of governmental support program's to the quality issues, selection and assessment of managers in public organisations.

Neves, et al., (2017) suggest that the major difficulties faced in implementing ISO/IEC 17025 are the low level of involvement of top management and employees, a poor flow of information (for the functioning of the quality system), resistance to new responsibilities, a lack of appropriate technical knowledge, and difficulty in the communication of new tasks and functions for each job.

Although the literature on QMS in general and ISO/IEC 17025 in particular is clearly significant, there is a smaller literature-base focused on barriers and problems with ISO/IEC 17025 and even more so when examining Arabic countries. For brevity here, in Table 1 the authors identify four key papers that provide an Arabic country context and which highlight well the key reasons stated in the literature why laboratories may have difficulties with the implementation of ISO/IEC 17025 certification.

Table 1: Common obstacles of implementing ISO/IEC 17025 certification in Arabic Countries

Author	Country	Difficulties of implementing ISO/IEC 17025 certification
Elsmuai and McCollin, (2013)	Tunisia	<p>Lack of governmental programmes which are needed to support quality activities, lack sufficient knowledge of new techniques, lack of information, education and training, lack of awareness, understanding and importance, lack of trust between the employees and their manager, lack of effective communication methods that transfer their voice into goals through the organisations, Technical Barriers to Trade, inadequate training, lack of management commitment and employees, lack of government support, financial capacity, tariff and trade barriers, lack of qualified personnel, improper technological infrastructure and lack of well-established facilities the managers.</p>
Shihub, et al, (2009).	Libya	<p>Lack of culture change as a major problem, lack of knowledge and skills of top management, limited resources to implement change, wrong people in the wrong positions and promotions based on nationality (particularly in the case of Libyan citizens) rather than on qualifications, and difficulties associated with empowerment at lower employee levels were added, lack of time, lack of information, education and training. lack of governmental support program's to the quality issues, selection and assessment of managers in public organizations, lack of information such as lack of statistical data, effective information and liaising program between the organizations and their ministries to facilitate improvement activities. Lack of technical knowledge, short of skilled personnel to implement these activities, lack of effective communication systems. Difficulty in calibration, unavailability of a locally accredited calibration and accreditation body.</p>
Abdel-Fatah, (2010)	Egypt	<ul style="list-style-type: none"> • High expenses for establishing, implementing and maintaining the system. • There were no new customers or/and new contracts as expected. • The whole system has a tendency to increase bureaucracy • Time-consuming efforts. • Difficult calibration of the electrical breakdown voltage measuring device as well as the difficulty in the availability of an organisation to calibrate it. • Lack of technical knowledge, short of skilled personnel to implement these activities. • Lack of governmental support program's to the quality issues, selection and assessment of managers in public organizations.

<p>Ashrafi Rafi (2008)</p>	<p>Arab region</p>	<p>Language barriers and lack of awareness; Lack financial and other resources as compared to more developed countries; a shortage of people trained in QMS seems to be a significant barrier to improving quality in most of the Arab countries; awareness and promoting quality in the Arab counties business culture seems to be a lack of available information in the Arab language ;wrong people in wrong positions; employees resistance to change; limited resources to implement change and bureaucratic culture in the organisation and rigid hierarchical and authoritative structure in the organisation.high cost of certification,technical barriers to trade,time-consuming and costly,Difficulty in calibration,unavailability of a locally accredited calibration.</p>
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Clearly, there is a large amount of information in this literature, but to summarise, the key factors for ISO 17025 failure include, a **lack** of top management support and commitment, the resistance of employees towards change,**Difficulty** in calibration,**unavailability** of a locally accredited calibration and accreditation body,and high cost of certification, a **lack** of understanding of the ISO 17025 requirements, inadequate training and quality knowledge, a low level of quality awareness and culture, the allocation of personal responsibilities and constraints on resources such as manpower, time and finance.

A key question to ask following this evidence is why is the adoption of ISO 17025 so low in Libya? This in turn raises a further question of what the barriers to adoption are and whether they might be specific to Libya. Therefore, the study is exploratory in nature and seeks to collect data related to the difficulties that affect the implementation of ISO 17025 in LRCL.

3. Research Methods

The study included two phases, in the first phase email interviews were conducted, followed up by telephone interviews to provide a greater degree of flexibility. In order to obtain a general perspective on difficulties regarding implementation of ISO17025, 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 a pilot study and the research strategy was designed to increase validity and reliability of 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 barriers regarding the LRCL implementation of ISO 17025. Also, following a constructivist viewpoint, it was appropriate to apply an interpretive paradigm, which is integral to qualitative research (Denzin and Lincoln, 2005), and which is also consistent with this as an exploratory study. The nature of the data collected from the case studies were qualitative transcripts of the semi-structured interviews held with case study participants.

The data collected from the case studies was analysed using Template Analysis. King (2009) 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, 2009.

The purpose of template analysis is basically to provide the reader with an overview of the key themes emerging from mass of information garnered from the interviews. The themes and codes are defined by King (2009) as relevant features of the participant’s accounts and the process of identifying the themes. The essential purpose of Template Analysis is to provide an overview of the key themes and sub-themes emerging from qualitative data, where those themes and sub-themes are features of the data that are relevant to the research questions. It is essentially a qualitative data reduction and categorization exercise. In this case, the research questions focus on the need to understand the barriers to adoption of ISO17025 across a range of different circumstances.An initial template for analysis of the data was subsequently created using the codes presented in table 2. This enabled adjustments to be made to the

themes and sub-themes as the analysis evolved before developing the “final” template, although King (2009) 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.

In this study, this Final Template is the one where no further propositions were emerging from the case studies and could be assumed to be an exhaustive listing of all propositions that explain why barriers to ISO17025 adoption in Libya occur.

4. Results

Table 2 presents the ‘final template’ reached for the study, the following template was produced using the transcriptions from the interviews carried out with the 10 respondents in the case study (LRCL), and comprises different first-order propositions grouped into 6 second-order sub-themes. The column on the right identifies each of the initial propositions directly identified from the interview transcripts, and the left hand column identifies the higher order sub-theme within which these propositions can be grouped, under the overall subject of reasons for seeking ISO/IEC 17025.

Table 2: Template Analysis results of barriers to ISO/IEC 17025 adoption.

Themes	Sub-Themes Initial High Code	Sub-Themes Initial Low Code
1. Barriers to ISO/IEC 17025 adoption.	1.1 Awareness /Training	1.1.1. Lack of employee awareness of the concept of QMS. 1.1.2. Inadequate training. 1.1.3. Training programmes take time. 1.1.4. Lack of directed guidance for the employees to understand the ISO 17025 requirements. 1.1.5. Lack of free advice. 1.1.6. Lack of available information in Arab language 1.1.7. Lack of governmental programmes which are needed to support quality activities. 1.1.8. lack of technical knowledge.
	1.2. Cultural Barriers	1.2.1. Lack of management support and commitment. 1.2.2. Difficulties in accepting new approach/direction. 1.2.3. Employee absenteeism. 1.2.4. Lack of Accountability. 1.2.5. Lack of trust in the Libyan Training. 1.2.6. Wrong person in the wrong position. 1.2.7. The difficulty of having arguments or discussions with the managers. 1.2.8. Bureaucratic administration. 1.2.9. Setting targets and then being held accountable by higher level management. 1.2.10. Large workforce. 1.2.11. Economic Crisis. 1.2.12. Financial support difficulties.
	1.3. Internal Resistance	1.3.1. No desire to change. 1.3.2. Increase in workload by increase in documentation. 1.3.3. Unwillingness to change from the existing system. 1.3.4. Process of ISO 17025 too complicated. 1.3.5. Bureaucracy.

	1.4 Expertise	<p>1.4.1.Absence of Libyan experts. 1.4.2.shortage of skilled personal. 1.4.3.No accredited local agencies. 1.4.4.calibration difficulties.</p>
	1.5 Cost	<p>1.5.1.Cost of contracting foreign consultants. 1.5.2.Training Programmes are costly. Calibrations are costly. 1.5.3.Lack of documentation and Materials. 1.5.4.Consultation process. 1.5.5.unavailability of a locally accredited calibration and accreditation body. 1.5.6. High cost of certification.</p>
	1.6. Quality Manual	<p>1.6.1.The presence of foreign languages documents + Manual in English. 1.6.2.Lack of people to translate. 1.6.3.Lack of English quality language courses and Arabic translator. 1.6.4.Lack of available information in the Arab language.</p>

From the answers given by all respondents it was clear that the most significant problem was a lack of employees awareness and difficulty in understanding the purpose of ISO 17025, because of this, employees have been very resistant to the introduction of ISO 17025 standards, which is seen as a lot of extra and possibly unnecessary work partly due to the dogma associated with working with the current system for a long time and them not wanting the challenge of learning new skills. This sits comfortably with propositions by Khodabocus and Balgobin,(2011) and Barradas and Sampaio,(2011) but as Crosby (1996) proposed, it is more likely that poor management creates such quality problems and, as discussed by Elsmuai and McCollin, (2013),Shihub, et al, (2009), Abdel-Fatah, (2010), and Al-Zamanyet al. (2002), problems with training and skills may be more related to a lack of awareness of skills requirements than the actual training itself, which came through in the template analysis as shown where there was a clear lack of information, education and training programmes available on quality issues.

The second significant problem area is related to cultural barriers, where barriers occur due to, resistance to change, wrong people in the wrong position, inappropriate managerial traditions, relationships with supervisor, relationship of individuals, people involvement in attending meetings, the celebration of social events, ease of adjustment to new requirements, senior managers taking time to talk informally to employees, more co-operation than competition between different departments. These findings were similar and consistent with other Arabic researchers such as (Elhuni, (2016); Elsmuai and McCollin, (2013); Abdel-Fatah, (2010); Shihub, et al, (2009); Ashrafi Rafi (2008) and Al-Zamanyet al. (2002).

Internal resistance is identified by the respondents as another problem area. Where there was no desire to change, the Process of ISO 17025 too complicated, Unwillingness to change from the existing system and bureaucracy. These problems and difficulties were consistent and supportive of previous studies, for example, Safadel et al., (2013);Gader et al., (2009);Shihub, et al, (2009); Al-Zamanyet al. (2002), and Al-Khalifa and Aspinwall (2000). Similarly, a lack of relevant expertise including an absence of Libyan professionals and experts in this field, which in turn led to the contracting of external organisations to carry out training created further barriers to adoption and implementation. Further,unavailability of a locally accredited calibration and accreditation body that issue ISO 17025 certifications means dealing with foreign institutions which causes delays in obtaining the certificate as well as the absence of accredited institutions that assess the trainers and coaches that adopt the training programmes on ISO 17025 and the cost of contracting foreign consultants. This again is consistent with studies carried out by(Neves, et al., (2017); Kumar and Antony (2008); Al-Zamanyet al. (2002) and Yahya and Goh (2001)where they indicated that a lack of 'local' experts in QM is a barrier to ISO 17025 implementation.

The final barriers to ISO 17025 to emerge as sub-themes from the, respondents answers were related to Cost and issues related to the Quality manual itself. In terms of the former, respondents identified that training programmes, quality calibrations and consultation processes were the most costly items that created reduced adoption rates and although these are unlikely to be specific to Libya, there was also felt

to be a lack of accessible Libyan documentation and all materials were in foreign languages, principally with the Manual being in English. Combined with the fact that there was a lack of Quality-qualified people to translate, a lack of English Quality-based language courses with Arabic translators and a lack of available information in the Arab language, this has serious implications for the success or failure of the ISO 17025 implementation, and could again drive up costs.

Some organisations have found it necessary to translate the manual into Libyan, but this normally results in ambiguities, effectively making the quality system more costly and less efficient. These findings are similar to another study by Elsmuai and McCollin, (2013) and Shihub, et al, (2009) where they indicated that the relatively high cost of the certification is a barrier facing most organisations. It is generated by training, time, and consultancy fees to facilitate the registration process. Abdel-Fatah, (2010) identified that the lack of financial capacity to meet implementation costs and maintaining QMS costs in Egyptians organisations is one of the barriers affecting the adoptions of ISO 17025 standards. The findings indicate the urgent need to ensure that proper training and awareness education programmes on ISO 17025 standards are available and provide solutions to overcome these barriers during the implementation process.

5. Conclusions and Recommendations

The adoptions of laboratories accreditation requires a great deal in management and technical issues such as human resources, top management commitment, organisational effort, expertise and expenses. From the results presented in the Template Analysis above, the researchers recommends that the following points be addressed if LRCL are to successfully implement and sustain ISO17025 in Libya:

1. Resolve the lack of quality awareness when implementing the ISO 17025 certifications including top management; managers and employees. Refresher courses could be conducted to ensure employees and managers are familiar with what is required of them. Also, to resolve the problem of unawareness of new employees towards the standard, in-house adaptations of external training sessions can be conducted for them.
2. Increase management support in the implementation process, the government and LRCL management should support their employees by motivating them and providing more information in Arabic about ISO requirements including the quality manual.
3. Resolve the lack of information regarding ISO 17025 standards introduction where most of documentation is written in English, and little has been translated in Arabic. Hence within a quality management system there is a need to ensure that all documentation of the quality management system should be written in Arabic to help the employees understand the system.
4. To increase the number of local agencies and Libyan experts in the ISO 17025 field the Libyan National Centre for Standardization and Metrology (LNCSM) should train more people thus reducing the problem of the lack of expertise and support those organisations by opening more local accreditation agencies to reduce the cost of accreditation and solve the problem of the high cost associated with the auditing process, as some of these agencies charge substantial fees.
5. The LNCSM and LRCL must provide more information, 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.
6. A copy of the recommendations will be sent to a group of the top leaders in the LRCL to be considered as guidelines' to help support and promote ISO 17025 standard.
7. 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 recommend ISO/IEC 17025:2005 – *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.
8. The LRCL and CSERS need to undergo a cultural change to establish accreditation according to ISO/IEC 17025 and this change would rely heavily on a strong lead being given by those in charge.

6. Limitations of the Study

No major constraints were found while conducting the study. However, the research was limited to LRCL only. Furthermore as far as conducting the interviews was concerned, there was a limit imposed upon the maximum duration of the individual interviews, as they were taken during normal working hours and thus the respondents could not afford to spend more time with the researchers.

7. Suggestion for Future Research

The findings of this study have raised a question that requires further exploration. This question is what type of framework can be used to overcome the barriers affecting the adoption of ISO/IEC 17025 certification in LRCL?

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Authors' Backgrounds

Dr. Maged Elmabruk Elgharib holds a PhD in Mechanical and Manufacturing Engineering from the University of Birmingham and a Master's Degree in Manufacturing System Engineering from Coventry University. Currently, is member of various committees concerned with laboratories and workshops.

Dr. Anwar Salih Ali Al-mijrab holds a Doctorate of Business Administration from Newcastle Business School at Northumbria University, UK. Dr. Anwar is currently Head of Quality Management Department at the Center for Solar Energy Research and Studies (CSERS) in Libya and is also a member of the Libyan Group for Quality and Excellence and a financial representative of CSERS in STAGE_STE European project.

From: ANWAR SALEH [mailto:anwar75uk@yahoo.co.uk]
Sent: Monday, April 3, 2017 6:23 AM
To: samkmho@gmail.com
Subject: Re: 21-ICIT: Apr 14-16 in Zhuhai ~ Southern China (URGENT)

Dear Prof. Ho,

With reference to your kind invitation for attending and participating in the 21th International Conference on ISO & TQM to be held in China on the 14-16/04/2017. We regret to inform you that we: Dr. M M Elgharib and Dr. A S AL-Mijrab are unable to attend the Conference on the specified date due to current situation in Libya and the subsequent difficulties concerning travel arrangements which caused the closure of China embassy in Tripoli. In addition, to apply for China's visa we have to travel to Tunisia and it takes time to get the visa on our passport.

The security situation in Libya remains unpredictable and unstable. Clashes are ongoing throughout the country and attacks by armed groups can occur nationwide.

The conference very important to us as well as we are very interested in the subject, hoping to honour invitations in future events. If it is possible if you would send us a copy of Proceedings + Softcopy to the below address.

Again, I sincerely apologise for my delay reply and all inconveniences caused. I appreciate your understanding and corporation in this matter.

Your Sincerely,

Dr. Anwar Al-mijrab and Dr. Maged Elgharib