Abstract

Successful maintenance of laboratory accreditation is a dynamic process underpinned by the establishment of an effective quality management system (QMS). Similarly accredited laboratories are expected to establish a QMS based on the requirements of ISO/IEC 17025 standard and to continually improve its effectiveness. However due to lack of flexibility during the design stage including lack of future predictions and quality trends, laboratories at times are faced with immense challenges when establishing and maintaining such a QMS.

The underlying assumption of this study supported by literature, is that the QMS based on ISO 9001 standard will continue to set the tone and continually influence trends and patterns for ISO/IEC 17025 QMS. From literature point of view, there are sufficient reports on the evolution of ISO 9001 QMS and its future trends, however no literature reports is currently available on the patterns and trajectory perspective with regard to the future of ISO/IEC 17025 standard.
This study therefore seek to provide a trace on the synthesis with regard to the current and future trends for ISO/IEC 17025 QMS using ISO 9001 trends as a basis. The main aspects that will be discussed in this study are the following: Findings from the report conducted by Thema (2014) during the investigation of the attitude of senior laboratory management towards the QMS, followed by a discussion of the findings from literature with regard to the effect of ISO 9001 QMS towards business performance, and finally a discussion from literature on the diffusion and future trends for ISO 9001 QMS.

The results and conclusions from literature revealed that ISO 9001 certification continue to increase worldwide and countries adopting ISO standards happen to experience a “saturation effect” after a certain period of fast growth. These conclusions are also predicted to be true for ISO/IEC 17025 future trends. Furthermore it is predicted that future emphasis by accreditation bodies towards laboratory accreditation will be on issues such as credibility, continuous improvement and effectiveness. Proficiency testing or Inter-laboratory comparison results will also be used as one of the key elements to confirm technical competence of laboratories.

1. Introduction

As the global economy and industries continue to evolve, similarly the standards that influence them continue to change patterns with time. According to Franceschini, Galetto and Cecconi (2006:539), this argument is predicted to remain true for ISO 9000 series of standards. Karapetrovic and Willborn, 1998 (cited by Psomas, Pantouvakis and Kafetzopoulos, 2012:150) stated that competition in the global economy and the current markets demands that the service companies establish a well-designed QMS and implement an effective quality management systems according to internationally accepted standards. Therefore the need to implement an effective QMS based on the ISO/IEC 17025 standards will remain a requirement that will not be avoided in the future due to the high global demand of quality products and services. ISO 9001 standard defined the word “effectiveness” as the extent to which the anticipated objectives are achieved (ISO 9001:2000, 2000).
The above mentioned definition is supported by ISO/IEC 17025 (2005:4) standard whereby top management is expected to be committed to the development and the implementation of the management system and to continually improve its effectiveness. Laohavichien, Fredendall and Catrell (2011:1051) echoed the same view and maintained that commitment and support from management play a crucial role to ensure that the QMS is effective.

The purpose of this study can therefore be summarised in two parts: firstly to present the findings from the recent study conducted by Thema (2014) during the investigation of the impact of the attitude of senior laboratory management toward the QMS based on ISO/IEC 17025 and secondly to predict future patterns of ISO/IEC 17025 standard. In order to predict future patterns for ISO/IEC 17025 standard, findings drawn from literature with regard to the effect of ISO 9001 QMS toward business performance are considered as a basis together with the diffusion and future trends of ISO 9001.

2. Literature Review

2.1. The impact of the attitude of senior laboratory management toward the quality management system.

According to Sadikoglu and Temur, 2012 (cited by Thema, 2014:4) there are limited studies on the relationship between ISO 17025 accreditation and laboratory performance. Furthermore Sadikoglu and Temur (2012:228) argued that top management commitment to quality is crucial to give adequate resources and to motivate employees for their participation. Very few reports could therefore be identified in literature reporting on the impact of the attitude of senior management towards the QMS. Moreover no report could be found specifically reporting on the QMS based on ISO/IEC 17025 standard. Amongst those few reports that were identified during literature review, the focus was based on specific sectors such as chemical industries, hospitals or government departments. An exploratory study by Dondashe-Ntise (2011:33) for example, focused on hospitals and the recommendation was that top management at the hospital should come up with strategies in order to enhance positive attitude amongst nursing managers.
Maluleke (2008:69) focused on one of the South African government departments and echoed the same view as Dondashe-Ntise (2011:33), stating that issues of people’s attitudes should be addressed in various ways, including through the provision of training and the implementation of change management programmes. Davis and Fisher (2002:410) who focused on quality based organisation, supported the position taken by Maluleke (2008:58) and Dondashe-Ntise (2011:33) emphasising the need for middle management to always get involved for the success of quality programs.

2.2. Leadership and senior management commitment

Various authors have defined in their own ways the concept on management commitment and the role of senior management in pursuit of an effective QMS. For example Lee, To and Yu (2009:657), analysed the implementation of ISO 9001 QMS in service organisation and argued that management in organisations should realise that ISO 9001 QMS is capable of generating a competitive advantage if senior management is fully committed to the implementation of QMS from a strategic point of view. Sharif (2005:23) on the other hand argued that senior management should create clear quality values and encourage all employees to work and be fully involved in achieving the organisational objectives. According to Dale, Wiele and Iwaarden (2007:15), the American Society for Quality conducted a survey during 1992 to understand the opinions of senior management from both large and small organisations. The finding from the survey revealed that:

- At least 6 out of 10 senior managers reported to have a great deal of personal leadership impact on customer focus and customer satisfaction, strategic quality planning, quality and operational results and financial results.
- Most senior managers believed that management play a great role than their board members in determining quality policies within their organisations
- At least 45% of senior managers reported that their board members discussed quality frequently, whilst 43% of senior managers reported that their board members report on customer satisfaction frequently.

Dale et al. (2007:48) made further conclusions that senior management should be responsible for the development of the mission, vision, values and ethics and
should act as role models of culture and custodians for excellence. The crucial role that is played by senior management and their responsibility in pursuit of quality improvements is also echoed by quality gurus such as Deming, Juran, Feigenbum and Crosby. In view of the aforementioned reports it is clear that top management play an important role to ensure that the QMS remain effective.

2.3. The effect of ISO 9001 QMS toward business performance

A number of reports have also been presented in literature focusing on the impact of ISO 9001 towards business performance. For example, the report by Psomas, Pantouvakis and Kafetzopoulos (2013:149) measured the effectiveness of ISO 9001 and determined the impact on the performance dimensions of service companies related to product/service quality, operational and financial performance. On the other hand the report by Tzelepis, Tsekouras, Skuras and Dimara (2006:1146) explored the effect of ISO 9001 on productive efficiency of firms from three sectors (food and beverages, machine and electrical sector), whilst the report from Sampaio, Saraiva and Rodrigues (2011:5) covered the development of the statistical models characterising the ISO 9001 certification evolution on a country basis as well as worldwide.

2.4. Diffusion and future trends for ISO 9001 standard

Considering the report from the study conducted by Franceschini et al. (2006:523), the study presented a cross-sectional analysis of the worldwide evolution of ISO 9000 and suggested new production model for the diffusion of ISO 9000 certification. Another report form Sampaio, Saraiva and Rodrigues (2011:5) covered the development of the statistical model characterising the ISO 9001 certification evolution a country basis as well as worldwide.

The results from these predictions have been used as a basis during this study to outline a prediction model for ISO/IEC 17025 standard. The rationale and motivation to use these results was encouraged by the fact that ISO/IEC 17025 share similarities with ISO 9001 standard although the two are not interchangeable. Khodabocus and Balgobin (2011:32) also confirm that the
quality system elements of ISO 9001 are also covered in ISO/IEC 17025. ISO 9001 can therefore be applied to an entire organisation and used as a management tool whilst ISO/IEC 17025 is used as a general requirement for the competence of test and/or calibration laboratories including sampling. In other words, ISO 9001 cannot provide an assurance that test or calibration data are accurate and reliable from a technical perspective.

3. Results

3.1. Results from the primary data during the investigation of the impact of the attitude of senior laboratory management toward the QMS

The study conducted by Thema (2014) was based on the following research objectives: (1) To investigate the impact of the attitude of senior laboratory management towards the QMS. (2) To determine critical success factors influencing the implementation of the QMS (3) To establish whether senior laboratory managers are familiar with their own quality management system (4) To make recommendations for improving the current practices and approaches during the implementation of a QMS and the accreditation process. For the purpose of this study, only the results from the first research objective including a summary of results from the demographic information.

3.1.1. Characteristics of the Targeted Sample and Respond rate

Considering the report presented by Thema (2014), the sample was comprised of both testing and calibration laboratories. Using a probability sampling technique, a sample of 120 laboratories was chosen. A total of 79 completed questionnaires were returned leading to a respond rate of 65.83%.
3.1.2. Demographic information

During the study conducted by Thema (2014), a questionnaire was send to both calibration and testing laboratories around Gauteng. Respondents were asked to provide demographic information related to gender, age, race, level of education, level of experience since working with the QMS, the number of employees employed in each laboratory and whether their laboratories operate independently or as part of a bigger organisation. The rationale behind the design of demographic questions was to assess if they have any influence to the research findings. The results revealed that none of the factors considered during the demographic analysis had any significant influence on the attitude of senior laboratory management except one element whereby laboratories had to indicate if they operate as part of a bigger organisation or operate independently. In this case the nature of operation had a significant influence on the attitude of senior laboratory management toward the QMS. Results as shown in figure 1 revealed that out of 79 participants who responded, 53.2% of them were operating independently whilst 46.8% were operating as part of the bigger organisations. The analysis from the cross tabulation which was drawn from the Statistical Package for Social Sciences (SPSS) output, indicated that laboratories who operated as part of a bigger organisation had a positive attitude toward the QMS than those who operates independently. These findings are in line with the report from Viswanathan and Sulphey (2012:80) who revealed that business performance is found to be efficient in medium and large organisations. According to Viswanathan and Sulphey (2012:80) business performance depend on a number of factors such as economic of scale and competitive advantage. The fact that most of the larger organisations are ISO 9001 certified help them to streamline their QMS and their practices and compels top management to improve processes in all stages of the value chain, which is seen as a competitive advantage.
Table 1: Frequency table on whether the laboratory operates independently or as part of a bigger organisation

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percentage</th>
<th>Valid Percentage</th>
<th>Cumulative %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operates independently</td>
<td>42</td>
<td>53.2</td>
<td>53.2</td>
<td>53.2</td>
</tr>
<tr>
<td>Part of bigger organisation</td>
<td>37</td>
<td>46.8</td>
<td>46.8</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>79</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: Frequency bar chart on whether the laboratory operates independently or as part of a bigger organisation

3.1.3. The Research Instrument

3.1.3.1. Reliability

The research instrument used during the study conducted by Thema (2014) consisted of 16 items, with a level of measurement at a nominal and ordinal level.
Chronbach’s alpha equalled to 0.834, which indicated a high reliability ($\alpha = 0.834$, N = 16)

3.1.4. Factor analysis

A factor analysis was also conducted as a data reduction technique during the study conducted by Thema (2014). The primary purpose to conduct factor analysis was to identify if there were factors that would explain the correlations within a set of observed variables and the latent variable. Firstly the sample was proven to be adequate to perform a factor analysis with the Kaiser-Meyer-Olkin measure scoring 0.710 > 0.5, revealing that the sample was producing reliable results as correlation were relatively compact. Secondly the output from Bartlett’s test of sphericity was found to be significant ($p < 0.001$) as shown in table 4.8. Which is an indication of data not multi-collinear and not an identity matrix and as a result factor analysis was appropriate.

Figure 2: KMO and Bartlett’s Test

| Kaiser-Meyer-Olkin Measure of Sampling Adequacy. | 0.710 |
| Bartlett's Test of Sphericity | Approx. Chi-Square | 585.591 |
| df | 153 |
| Sig. | 0.000 |

3.1.4.1. Results from the factor analysis

A six factor solution was reached by the factor analysis results suggesting that a model with six factors was adequate to represent data. Those factors accounted for approximately 69.28% of the variation indicating a 69.28% relationship between the measured variables and the latent factor. A closer examination into the contents of each question under each factor led to the following six common group factors (1) Improvement opportunities which can be achieved through the implementation of an effective QMS (2) Evidence of commitment from senior Laboratory managers toward the QMS (3) Factors that indicate the benefits senior laboratory management can achieve through the implementation of an effective
QMS within their laboratory (4) Responsibilities of senior Lab managers and their contribution toward the establishment of QMS (5) Integration of the QMS with the organisational strategy (6) Level of knowledge of senior managers towards the QMS. Table 1 below indicates a summary of the correlation coefficient (r) for items B8 to B15 related to the first research objective as defined in the questionnaire, whilst table 2 provide a summary of the response from the cross tabulation analysis for item B8 to B15.

3.1.5. Correlation Analysis

Table 1: A summary of correlation coefficient for item B8 to item B15

<table>
<thead>
<tr>
<th>Variables</th>
<th>B8</th>
<th>B9</th>
<th>B10</th>
<th>B11</th>
<th>B12</th>
<th>B13</th>
<th>B14</th>
<th>B15</th>
</tr>
</thead>
<tbody>
<tr>
<td>B8</td>
<td>1.000</td>
<td>.663**</td>
<td>.637**</td>
<td>.419**</td>
<td>.332**</td>
<td>.480**</td>
<td>.435**</td>
<td>.509**</td>
</tr>
<tr>
<td>B9</td>
<td>.663**</td>
<td>1.000</td>
<td>.469**</td>
<td>.416**</td>
<td>.327**</td>
<td>.378**</td>
<td>.306**</td>
<td>.461**</td>
</tr>
<tr>
<td>B10</td>
<td>.637**</td>
<td>.469**</td>
<td>1.000</td>
<td>.482**</td>
<td>.411**</td>
<td>.345**</td>
<td>.316**</td>
<td>.402**</td>
</tr>
<tr>
<td>B11</td>
<td>.419**</td>
<td>.416**</td>
<td>.482**</td>
<td>1.000</td>
<td>.558**</td>
<td>.554**</td>
<td>.472**</td>
<td>.508**</td>
</tr>
<tr>
<td>B12</td>
<td>.332**</td>
<td>.327**</td>
<td>.411**</td>
<td>.558**</td>
<td>1.000</td>
<td>.548**</td>
<td>.569**</td>
<td>.477**</td>
</tr>
<tr>
<td>B13</td>
<td>.480**</td>
<td>.378**</td>
<td>.345**</td>
<td>.554**</td>
<td>.548**</td>
<td>1.000</td>
<td>.841**</td>
<td>.760**</td>
</tr>
<tr>
<td>B14</td>
<td>.435**</td>
<td>.306**</td>
<td>.316**</td>
<td>.472**</td>
<td>.569**</td>
<td>.841**</td>
<td>1.000</td>
<td>.788**</td>
</tr>
<tr>
<td>B15</td>
<td>.509**</td>
<td>.461**</td>
<td>.402**</td>
<td>.508**</td>
<td>.477**</td>
<td>.760**</td>
<td>.788**</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Correlations are significant at p < 0.01, N = 79

- Indication of a significant correlation
- Indication of an insignificant correlation
Table 2: summary of the response from the cross tabulation analysis

<table>
<thead>
<tr>
<th>Item No</th>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>B8</td>
<td>ISO/IEC 17025 QMS has improved our long term laboratory survival prospects</td>
<td>45.6</td>
<td>32.9</td>
<td>21.5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B9</td>
<td>Our laboratory have adopted ISO/IEC 17025 QMS as a possible means for improvement to our test and calibration results</td>
<td>45.6</td>
<td>34.2</td>
<td>17.7</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>B10</td>
<td>Our laboratory produce results that meet our clients requirements</td>
<td>49.4</td>
<td>31.6</td>
<td>17.7</td>
<td>1.3</td>
<td>0</td>
</tr>
<tr>
<td>B11</td>
<td>Identifying and improving technical skills within our laboratory</td>
<td>39.7</td>
<td>34.6</td>
<td>16.7</td>
<td>9.0</td>
<td>0</td>
</tr>
<tr>
<td>B12</td>
<td>Decreasing the number of complaints</td>
<td>21.5</td>
<td>40.5</td>
<td>27.5</td>
<td>10.1</td>
<td>0</td>
</tr>
<tr>
<td>B13</td>
<td>Improving management review and internal audits processes</td>
<td>32.9</td>
<td>41.8</td>
<td>12.7</td>
<td>11.4</td>
<td>1.3</td>
</tr>
<tr>
<td>B14</td>
<td>Improvement in document control and control of records</td>
<td>36.7</td>
<td>38.0</td>
<td>12.7</td>
<td>12.7</td>
<td>0</td>
</tr>
<tr>
<td>B15</td>
<td>Improvement in corrective and preventive actions</td>
<td>25.3</td>
<td>38.0</td>
<td>25.3</td>
<td>11.4</td>
<td>0</td>
</tr>
</tbody>
</table>

The results as indicated in table 2 revealed that the respondents either strongly agree or agree to item B8 up to B15, an indication of a positive attitude from the respondents towards the QMS.

3.2. Results on the effect of ISO 9001 towards business performance

According to Psomas, Pantouvakis and Kafetzopoulos (2013:149), the product/service quality and operational performance of the service companies are directly and significantly influenced by ISO 9001 effectiveness. However, financial performance is directly influenced only by the operational performance. This conclusion is supported by Sampaio, Saraiva and Monteiro (2012:891) who argued that it is not unanimous that certified companies would be less profitable if they had not implemented their QMS. Psomas et al. (2013:149) stated that by
defining ISO 9001 effectiveness in terms of its objectives, organisation and managers may be in a position of what to improve to increase the standard’s effectiveness and subsequently improve service performance in terms of quality and operative results and directly in terms of financial results.

3.3. Results on the diffusion and future trends of ISO 9001

Sampaio, Saraiva and Rodrique (2011:5) conducted an analysis on the ISO 9001 certification worldwide between 1993 to 2010. The analysis revealed that there is an upward increase of ISO 9001 certification worldwide as time progresses. However Franceschini, Galetto and Cecconi (2006:523) observed in their study that there would be a saturation effect after a certain period of fast growth.


At the International Laboratory Accreditation Cooperation (ILAC) General Assembly held in October 2013, the laboratory committee recommended to ILAC to request that ISO/CASCO establish a new work item to revise ISO/IEC 17025:2005. According to the United Kingdom Accreditation Service (2014), the ILAC Executive committee has now commenced work on the preparation of a New Work Item Proposal (NWIP) to revise ISO/IEC 17025:2005 for submission to ISO/CASCO with a projected publication date of 2017. Based on the results from this study a prediction model for ISO/IEC 17025 is therefore predicted as follows:

- A steady upward increase in laboratory accreditation worldwide is predicted due to high demands of reliable, traceable and competent results.
- Individual countries will continue to experience a saturation effect after a certain period of fast growth during laboratory accreditation after they have adopted ISO/IEC 17025.
- Future emphasis by accreditation bodies will be on issues such as credibility, continuous improvement and effectiveness
- Competence of laboratory accreditation will be emphasised through the use of proficiency testing (PT) or inter-Laboratory comparisons (ILC).
4. Conclusion

Findings from the study conducted by Thema (2014) were presented during this study. The results revealed that senior laboratory management from SANAS accredited laboratories in general demonstrated a positive attitude towards the QMS based on ISO/IEC 17025 standard.

All the reports sampled during literature review in this study are also in agreement that senior management play a crucial to ensure that the QMS remain effective. Between laboratories that operate independently and those that operate as part of the bigger organisation, results revealed that senior management from those laboratories that operate as part of the bigger organisation appear to demonstrate a positive attitude towards the QMS more than those that operate independently. With regard to future trends and patterns for ISO/IEC 17025 standard the following are predicted: A worldwide steady increase in laboratory accreditation and saturation effect after a certain period of fast growth is predicted, emphasis on technical competence for laboratories is expected to be confirmed through the use of PT/ILC. Accreditation bodies are expected to emphases issues such as credibility, continuous improvement and effectiveness when implementing their accreditation process.
References


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