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The impact of laboratory quality assurance standards on laboratory operational performance

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Abstract

It has become a trend for companies to implement and be certified to various quality management systems so as to improve consistency, reliability, and quality of product delivery to customers. The most common quality management systems adopted are the ISO 9000 series of standards for manufacturing and services related organisations, with ISO 17025 and Good Laboratory Practices (GLP) standards adopted specifically by laboratories as quality assurance initiatives. There are various reports on the impact of the ISO 9000 series on organisational performance but no studies or reports have been done on the performance of laboratory standards. Therefore this article reports on a study conducted to investigate the impact of ISO 17025 and GLP on the operational performance of both commercial and non-commercial laboratories. A qualitative research study was conducted to examine the impact standards on the aspects of health and safety, supplier selection and performance, human resources, customer satisfaction and profitability of the laboratory. The data collected suggest that there is no difference in laboratory operational performance with or without the standards. In other words it appears that the basic fundamental requirements inherent with laboratories are sufficient to perform both operationally and optimally. This leads to the view that standards are implemented as a customer requirement and not as an operational requirement.

Key phrases: laboratory, laboratory quality, laboratory standards, laboratory performance, ISO 17025, GLP, laboratory quality assurance

Introduction

Organisations around the globe invest a lot of resources in the implementation and certification or accreditation of quality assurance systems, mostly the International Organization for Standardization (ISO) standards. The objective of the ISO is to develop standards that have economic and technical impact on countries around the world (Boyer & Verma, 2010:43). Many organisations have implemented and some are still implementing standards such as ISO 9001 for quality management and ISO 14001 for environmental management to enhance operational performance. Srivastav (2009:438) conducted research on the implementation of ISO 9001 and reported its advantages as promoting a culture of teamwork and continuous improvement while Prajogo (2010:78) reports that there has been a major increase in the number of organisations implementing ISO 9001 in a number of countries and that certification has had a positive impact on the operational performance of organisations and improved quality performance. Laboratories are no exception to the trend of the implementation of appropriate laboratory standards with the hope of gaining competitive advantage in the marketplace.

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The standards studied on which this article is based are ISO 17025 and GLP (also referred to as OECD GLP). The customers who receive services from the laboratories request the implementation and accreditation to laboratory standards as a means of quality assurance (Srivastav, 2009:438). Accreditation means that the laboratory has been assessed by an external body which has declared it to be competent enough to carry out the work that it does (Robinson, 2005:1). Robinson (2005:1) eludes that test or calibration reports issued by non-accredited laboratories may lack credibility and they do not carry much legal weight if the results are presented to resolve any disputes that may arise.

As South Africa is part of the global economy, there is demand to issue or produce laboratory results that are comparable to those issued by laboratories from other countries (Apps, 2006:1). Most organisations that offer laboratory services are subjected to stringent supplier selection criteria before being listed as preferred suppliers, or considered for supplier contracts. Demanding accreditation from potential suppliers is very evident in this industry (Apps, 2006:1).

Although laboratories are implementing quality assurance systems to satisfy their customer requirements, it is not clear what the benefits and impact of these systems are on laboratory operations (Fisicaro, Durbiano & Giuffredi, 2006:336). Hence the focus of this study on which this article is based was centred on investigating the impact of laboratory quality assurance standards, ISO 17025 and GLP on operational performance.

Laboratories

Crosland (2005:234) defines laboratories as “places dedicated to the practical rather than the theoretical investigation of the natural world”. The Concise Oxford Dictionary (1995:757) defines a laboratory as a room or building fitted out for scientific experiments, research, teaching or the manufacture of drugs and chemicals. In the context of this article, a laboratory is considered as a centre offering chemical analytical services for the examination of the quality of products. Further, commercial laboratories are those that have external customers demanding analytical services and non-commercial laboratories are those that offer services to internal customers only. Baiulescu, Pompilia and Zugrăvescu (1991:141) report that the main purpose of any laboratory involved in analytical analysis is to obtain results as reliable as possible, in the shortest possible time. This means that irrespective of the type of laboratory, high quality and reliable analytical results are essential. There is a need to effectively manage resources such as personnel, test equipment and apparatus, chemicals and reagents, the laboratory environment and any other contributor to the production of results and data. When selecting a laboratory to provide services of testing or calibration, the potential customer needs to be sure that the supplier can issue valid results. There are many factors such as competence of laboratory personnel, the reliability of equipment, documented and validated test methods, proper sampling procedures and traceability of measurement to national and international standards that contribute to a laboratory’s technical competence (Robertson, 2010:1).

In order to ensure that laboratories produce accurate and reliable results, quality assurance and control programmes are essential and need to be implemented (Klinkner, 2008:487), for example Suksai, Suksripanich & Pobkeeree (2010:23) report that hospital mortality rates can be lowered if testing laboratories produce the correct results the first time to assist doctors with their diagnosis. Quality can be maintained by the employment of appropriate quality standards such as ISO 17025 and other

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good laboratory practices such as the general laboratory requirements (GLP).

ISO 17025

The ISO Guide 17025 was developed by merging other quality standards such as ISO 9001 and ISO guide 25 and was adopted by many countries as a national standard for establishing quality systems in laboratories and for the recognition of laboratory competence by the national accreditation bodies (Kumar & Varadan, 2001:195). This standard was first published in 1999 and revised in 2005 and is known as the "General requirements for the competence of testing and calibration laboratories". These guidelines facilitate the operationalisation of a quality system ensuring that the laboratory is technically competent and able to generate valid results (Kumar & Varadan, 2001:195). It is applicable to all organisations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification. Laboratory customers, regulatory authorities and accreditation bodies may also use it to either confirm or recognise the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.

Implementation of the standard increases the confidence in the personnel performing work and makes test results even better. It facilitates better control of laboratory operations and its quality assurance, and it further create potential for more business owing to enhanced customer satisfaction and confidence, which lead to accreditation and international recognition, improved national and global reputation and image and ensures there is a culture of continual improvement of laboratory quality and effectiveness (http://www.standards.org/standards/listing/iso_17025).

The standard is made up of five major elements; scope, normative references, terms and definitions, management requirements and technical requirements (Walker, 2002:1). The scope refers to the collection of methods which include those it performs routinely and those where either commercial or legal issues make accreditation to 17025 advantageous. Normative references refer to documents that give the most recent information about every area of the process and equipment standards. Terms and definitions define for example the labeling of all equipment, instruments, workstations, employee instructions, protocols, procedures and safety measures. Management requirements focus on the organisation, quality system, document control, review of requests, tenders and contracts, subcontracting of tests and calibrations, purchasing of relative services and supplies, service to clients, compliant management, control of nonconforming testing and/or calibration work, corrective and preventative action, the control of records, internal audits and management reviews. Technical requirements refer, for example, to safe working conditions, functional equipment, proper calibration of devices, handling of tests and substances, result reporting, training, audits, and so forth. (http://www.ttelaboratories.com/tte-university/iso-17025). A formal certification of compliance often portrays prestige and excellence and that a laboratory has demonstrated an ability to produce accurate tests and/or calibration data and has displayed excellence in technical and management competence. It is seen as a seal of approval, and therefore increases public confidence. It facilitates trade and economic growth, gives laboratories a marketing advantage, international recognition and can be used as a benchmark for performance (Robertson, 2010:4).

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GLP

In the past, there have been unfortunate instances of a small but disturbing history of falsifying or "massaging" of data from studies. Companies invest a lot in developing expensive products and some would do anything to ensure that their products reach the marketplace (Prichard, 1995:221). In the United States of America major events took place in 1975 when Senator Edward Kennedy and members of Food and Drug Administration (FDA) made allegations against research laboratories (Searle and Hazelton, to be specific) in the USA related to preclinical research studies. Both sides were investigated, and this revealed serious problems with the conduct of safety studies submitted to the agencies. Violations included poor recordkeeping and data storage, inadequate personnel training, poor test facility management, and even fraud (Robinson, 2003:38). As a result, in 1976 the United States Food and Drug Administration (FDA) developed a set of principles for such studies which had to be adhered to before a regulatory authority could accept data from the studies (Prichard, 1995:221). The Organisation for Economic Cooperation and Development (OECD) established and published an international standard in 1982 to enable study data to be accepted between countries (Prichard, 1995:221). By January 1986, scientists at Searle had developed a document called, Good Laboratory Practice. The document was developed to be used as a guide to evaluate research activities, and submitted it to both the FDA and the Pharmaceutical Research and Manufactures Association of America (PhRMA). In August of the same year, the FDA released a draft GLP document based on the Searle paper and published GLP regulations in the federal registry (Robinson, 2003:38). Further changes to the GLP rules were proposed in 1984, and in September 1987, FDA published its "Final Rule" – Compliance Program Bioresearch Monitoring: Good Laboratory Practices, which was expanded to incorporate the requirement for a quality assurance department, the requirement for protocol preparation (study plan), the characterisation of test and control materials, the requirement to retain specimens and samples (Robinson, 2003:39).

Since then, the requirement for laboratories to apply and comply with GLP principles has extended from pharmaceutical companies to many other types of research and testing establishments throughout the world. In Europe, adherence to the principles of GLP is governed by European Union (EU) law. An inspection programme confirms that "toxicological studies for the regulatory assessment of industrial chemicals, medicines, veterinary medicines, food and animal feed additives, cosmetics, and pesticides must be conducted in accordance with GLP" (Robinson, 2003:39).

The OECD member governments and their chemical industry have a major responsibility to ensure that chemicals are produced in a safe manner and used as safely as possible (Sigman, 1999:5).

The Organisation for Economic Cooperation and Development (OECD) is an intergovernmental organisation from thirty industrialised countries. Its purpose is to monitor economic trends in those countries. It is a centre for discussion where governments express their view points, share experiences and search for a universal position (Leballo, 2006:3).

The OECD clarifies the economic and social problems facing its member countries quantitatively. There is also an exchange of information on how the problems are approached in different countries and it also promotes learning between member countries. Member countries also analyse the effectiveness of economic and social policies; make countries aware of the impact of their actions on the others; and

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search for common solutions or strategies to address the challenges that they are facing (Leballo, 2006:3). Leballo (2006:4) further announces that South Africa participates in the Working Group on GLP via the national accreditation body, and is invited to participate in the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT).

South Africa is the first non-member country to join OECD Mutual Acceptance of Data as a full member. This means that South Africa will accept data from OECD countries generated under Mutual Acceptance of Data (MAD) conditions and OECD countries will accept data from South Africa generated under MAD conditions. A team of experts from three OECD country governments has evaluated the South African GLP authority/national accreditation body on site. The OECD council has invited South Africa to become a full member of the system with the same rights and obligations as OECD countries. The decision was based on the positive outcome of the evaluation (Leballo, 2006:4).

The principles of Good Laboratory Practice (GLP) have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemical products (Leballo, 2006:1). It defined as a managerial concept that covers the organisational process and the conditions under which laboratory studies are planned, performed, monitored and reported. These principles need to be followed by laboratories conducting studies that have to be submitted to national authorities for the purposes of assessment of chemicals. Other uses relate to the protection of humans and the environment (Sigman, 1999:7).

Most of the principles are contained in ISO 17025 standard. But there is a different focus for OECD GLP compliance due to the type of work that they are engaged in and also the results originating from the investigations (Leballo, 2006:2).

There are benefits of being certified to OECD GLP. The OECD GLP system saves huge amounts of money for governments and chemical producers around the world. The system permits the results of different safety tests done on chemical products to be shared across Organisation for Economic Cooperation and Development (OECD) countries (Leballo, 2006:1). Compliance with the principles of GLP allows the validity of the test results to be accepted between organisations and countries. This minimises the need to repeat the testing in different countries. This leads not only to monetary savings, but also saves the lives of countless laboratory animals (Prichard, 1995:222).

The OECD GLP principles have requirements that laboratories need to be compliant with, in order to satisfy GLP. Those includes test facility management‘s requirements, study director’s responsibilities, principal investigator’s responsibilities, study personnel’s responsibilities, quality assurance programme, facilities, apparatus, materials and reagents, test systems, test and reference items, standard operating procedures, performance of the study, reporting of the study results, storage and retention of records and materials (Leballo, 2006:1).

Performance measurement criteria within operations

Operations management is the management of activities within an organisation that produces goods or services required by customers. It is critical for personnel managing operations to be able to measure the performance of their activities in order to improve efficiency and effectiveness (Radnor & Barnes, 2007:384). “Efficiency is based around the notion of output divided by input, which focuses

measures around the productivity of a process and the utilization of resources. Effectiveness is based around the notion of the appropriateness of the outputs of the process" (Radnor & Barnes, 2007:385). According to Radnor and Barnes (2007:385) there are factors like customer satisfaction that are used within operations as criteria to measure performance. Ritzman & Krajewski (2003:25) advise that it is wise to use multiple factors in an attempt to measure and improve performance in operations. It is based on this that five factors have been identified and used to measure operational performance for the purpose of the study. These are customer satisfaction, profitability, suppliers, human resources and health and safety.

Customer satisfaction

Radnor and Barnes (2007: 389) identify customer satisfaction as one of the important factors that needs to be measured. Uyar (2009:74) and Bourne et al (2005:381) agree that customer satisfaction measurement gives an indication of the performance of operations. Price (2005:452) supports the measure of customer satisfaction by using questionnaires as a good means of measuring laboratory operations. Questions like sample turnaround times can be included in questionnaires sent out to customers. Johnston and Clark (2005:105) explain that if operations meet customer expectations, or even exceed them, then the end result is satisfied customers. When customers are satisfied or delighted, there is a chance that they will recommend the product or service to other potential customers (Johnston & Clark, 2005:105).

Bakar, Hakim, Chong and Lin (2010:76) describe customer satisfaction as a "psychological attitude which indicates a customer's positive or negative feeling about the value he or she receives as a result of using a particular organisation's products or services". Most organisations have made customer satisfaction the heart of their slogans in working towards achieving 100% customer satisfaction. Customer satisfaction is adopted as a strategic objective for most organisations. It is not only acknowledged in the private sector, but also in the public sector (Bakar et al, 2010:76).

Profitability

It has become standard practice globally to assess the performance of a business by using financial measures as profitability. The financial status of an organisation is what is looked at when reporting whether a business is successful or not. Eventually, the success of an organisation depends on whether or not it makes money. Organisations are now realising that assessing the performance of an organisation using only financial measures does not provide enough information to help guide the organisation (Sidney, 2004:1). Uyar (2009:73) agrees that though financial measures report the performance of an organisation in monetary terms, looking at financial performance only, does not cover a lot of critical performance activities happening behind the scenes. The financial reports do not do justice to the activities behind the numbers presented. For laboratories to gain their competitive advantage, they need to change their strategy from low cost operation to that of focusing on quality, better sample turnaround times, and flexibility when customer needs change and implemented operations management ideas and guidelines to be able to view laboratory performance in a complete manner (Ndlovu, 2005:3). However, the impact is still considered as a performance measure due to the commercial nature of some laboratories.

Suppliers

The operations function is not independent; it is linked to other functions like purchasing in an organisation. The performance of suppliers can have a positive or negative

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impact on the performance of operations, therefore supplier selection and performance is identified as one of the factors affecting the performance of operations (Radnor & Barnes, 2007:390). Bourne et al (2005:375) raise the importance of supplier characteristics and performance in relation to the performance of operations. A selection of good suppliers and the management of selected suppliers can have a positive impact on operations performance (Ambrose, Marshall and Lynch, 2010:1269). Chin, Yeung and Pun (2006:743) advice that operations managers need to manage the performance of their suppliers and always strive to correct any deficiencies as and when they arise. Chin et al (2006:744) point out that suppliers have the ability to influence customer satisfaction; therefore it is imperative that supplier selection and performance be measured as part of measuring operations performance. The main responsibility of the purchasing function is to source the right suppliers who will supply products that meet the needs and requirements of the organisation. An organisation normally has a number of suppliers for different materials and services, and therefore it is the organisation's responsibility and function to develop and maintain close working relationships with its suppliers (Rowbotham et al, 2007:308).

Human Resources – Personnel Performance Measurement

Regarding the human resources factor as one of the critical factors that can be used as a criterion for measuring operations performance, attention needs to be paid to training and improving competency levels of personnel. Teamwork, communication and employee involvement need to be encouraged (Radnor & Barnes, 2007:392). The motivation level of employees also needs to be monitored (Radnor & Barnes, 2007: 385).

Bourne et al (2005: 381) add that employee satisfaction needs to be measured and employees need to be trained so that they are fully capable of doing their jobs. When human resources issues like competency are addressed, it will lead to high-performance personnel, and therefore, high-performance operations. Price (2005:451) advises that it is also important to monitor the workload in the laboratory. Price (2005:452) has identified that when it comes to laboratory operations, quality control and quality assurance schemes need to be used to measure performance. These include participating in proficiency testing schemes and taking preventive and corrective measures when a need arises to take performance to the next level (Price, 2005:452). According to ISO 17025 standard, the competency of the laboratory is normally defined in the scope of certification. The laboratory scope specifies information on tests performed by the laboratory, methods used and material tested. In order to be certified to ISO 17025, a laboratory has to satisfy requirements on the competence of laboratory personnel. There should be a documented procedure on the validation and traceability of measurement results. The competence level of personnel who are directly involved in testing must be known. The records of their training must be maintained (Bednarova & Waddington, 2010:539).

Health and Safety

Groover (2007:668) identifies health and safety as factors that need to be used as criteria to measure performance in operations. Compliance to health and safety requirements has become a primary requirement enforced by governments around the world. Tayler (2003:2) is of the opinion that if health, safety and environmental issues are not addressed, there could be a negative impact on operations in the laboratory. The quality of the results issued by the laboratory and the safety and well-being of employees might

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be compromised if issues like housekeeping and health and safety policies are non-existent or not adhered to (Tayler, 2003:2). A healthy work environment and safety are not just desirable objectives, but they are primary requirements in the industry. In other words healthy working environment and safety are a major issue in industries and for governments around the globe (Groover, 2007:668).

Research methodology

A qualitative approach was used for this study due to the limited availability of literature on laboratory quality assurance standards and laboratory performance based on the suggestions of Leedy and Ormonde (2010:95) towards a qualitative study when the available literature is limited and when the study is exploratory. Strauss and Corbin (1998:10) define qualitative research as "any type of research that produces findings not arrived at by statistical procedures or other means of quantification".

The population of possible respondents consisted of laboratory managers and senior laboratory personnel from the 200 laboratories listed on the website of the national accreditation body and the national laboratory association in South Africa. These laboratories were grouped as commercial and non-commercial laboratories. Each group had three subgroups indicating that they were: (1) ISO 17025 certified, (2) ISO and GLP certified and (3) no certification. Potential respondents were approached by the researcher, giving them the scope to participate in the research. If they agreed, a date was set and agreed upon between the respondent and the researcher. If the potential respondent declined to participate, the next potential respondent on the list was approached. The process continued until there were at least two participants per subgroup. Finally 19 laboratories participated with the composition shown in the table below.

Table 1: Sample of participating laboratories

Number of commercial laboratories		Number of non-commercial laboratories	
ISO 17025 and /or GLP Certified	No Standards	ISO 17025 and /or GLP	No standards
6	3	6	4

Appropriate data was collected by means of semi-structured interviews with laboratory managers. The interview focus area guideline was developed based on the literature review. The purpose of developing the interview focus area guideline was to enable the researcher to collect uniform data that could be compared consistently. The interview guideline covered the factors that were identified as factors to be used as criteria for measuring performance in operations. Those factors are health and safety; supplier selection and performance; human resources; customer satisfaction; and profitability.

The purpose of section A was to collect data on the background and responsibilities of the respondents. The nature of the laboratory and the quality standards implemented were clarified. Section B of the interview guideline focused on operations within the laboratories and the management of human resources; sampling; training and competency issues; and also on health and safety issues. The section also focused on

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the effort made by laboratories to comply with the environmental, health and safety requirements by identifying laboratories that were certified for health and safety; and also the environmental system. This section of the interview guideline; assisted the researcher in understanding operations in different laboratories.

Section C of the interview guideline assisted the researcher in identifying the different methods used by laboratories to measure competency, supplier selection and customer satisfaction. The impact of laboratory quality assurance standards on factors like marketing advantage, laboratory recognition, acceptance of exported goods in overseas markets, retention and growth of customer base and the impact on profit margins were explored. The section also used the factors that have been identified as performance measurement criteria to determine whether laboratory quality assurance standards have an impact on the operational performance of laboratories.

Prior to the actual data collection, appointments were scheduled when there was voluntary telephonic acceptance with the researcher to participate, followed by the formal acceptance in writing before the actual start of the data collection. The respondents were made aware of the recording of the interview from which transcriptions were processed. Evidence that was presented during the interview such as policies, procedures, and so forth was noted to maintain the validity of the data collected. Other observations such as housekeeping, safety awareness, laboratory layouts and many others were also noted. The duration of each interview was between 60-90 minutes. A copy of the transcription was e-mailed to each respondent to ensure the accuracy of contents of the interview before the commencement of the analyses. This also improves the validity of the data.
The data was analysed by means of the content analysis methodology. Content analysis is a detailed and systematic examination of the contents of a particular body of material for the purpose of identifying patterns, themes, or biases. Content analyses are typically performed on forms of human communication (Leedy and Ormond, 2010:144).

The coding process of the data collected was conducted after reading the documents several times to get a general understanding. Creswell (2003:192) defines coding as a "process of organising the material into chunks before bringing meaning to these chunks". The data was grouped into five factors which were determined as the criteria for measuring operational performance in laboratories. The interpretation of the data and formulation of factors used to measure performance criteria are based on the understanding that the researcher got from the collected data. The interpretation is also based on the literature review conducted.

Results

All respondents had appropriate academic analytical qualifications and had more than three of laboratory management experience.

The results of the content analyses are presented in the categories of certified laboratories (laboratories with quality assurance systems) against those that do not have quality assurance systems. All the results have been combined into one table which shows that there is no difference in the operational performance of the laboratories irrespective of if it is commercial or non-commercial or if there was a quality assurance system or not.

Table 2: Qualitative results certified and non-certified laboratories.

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Operational performance measure	Commercial and non-commercial laboratories certified to ISO 17025, or to GLP or both.	Commercial and Non-commercial laboratories without a certified QA systems
Customer satisfaction	Positive culture and procedures for managing customer issues Customer satisfaction measurement conducted Communication of customer issues to all staff	Positive culture and procedures for managing customer issues Customer satisfaction measurement conducted Communication of customer issues to all staff
Supplier selection	Clearly documented procedures for supplier selection and supplier performance management	Clearly documented procedures for supplier selection and supplier performance management
Human resources	Documented procedures to address human resource issues Clear procedures to train and ensure that employees (analysts) are competent Procedures to measure the effectiveness of training programmes Various methods to check analyst's technical competence	Documented procedures to address human resource issues Clear procedures to train and ensure that employees (analysts) are competent Procedures to measure the effectiveness of training programmes Various methods to check analyst's technical competence
Profitability (inconclusive)	Mixed responses on what the effect of quality assurance system is on profitability	Mixed responses on what the effect of quality assurance system is on profitability
Health and safety	Positive culture and approach to implementation and maintenance of health and safety procedures. Induction programmes in place Personal protective equipment available Shared housekeeping responsibilities and high demand on keeping clean laboratory area clean, neat and tidy.	Positive culture and approach to implementation and maintenance of health and safety procedures. Induction programmes in place Personal protective equipment available Shared housekeeping responsibilities and high demand on keeping clean laboratory area clean, neat and tidy

It appears that health and safety is equally important for all laboratories irrespective of the nature of the laboratory or whether it has got a quality assurance system or not. This is probably due to the fact that health and safety can be deemed as an obvious requirement based on the South African government's stand on health and safety issues at the workplace as per the Occupational Health and Safety Act No.85 of 1993 (the OHS Act). This shows that health and safety obligation is not dependent on the implementation of a quality assurance standard. Tayler (2003:5) reports that both the OHS Act and ISO 17025 have a requirement that internal audits be conducted and that can be used to identify any non-conformances to the health and safety rules. Tayler (2003:5) further mentions that some laboratories

develop checklists as an internal control, and they check their systems against this checklist. To avoid running parallel systems, laboratories can develop an integrated checklist that would review safety issues as stipulated in the OHS Act.

In terms of the supplier selection, there appears to be no difference whether the laboratory has a quality assurance standard or not. This may be due to the general practice in laboratories to seek high quality goods and services from reputable suppliers. It once again seems obvious that laboratories engage themselves with suppliers of high quality goods and services.

Similar to the discussion on suppliers, we can have the same discussion on human resources. It appears that having a quality standard or not, does not impact on the employment and development of laboratory employees.

In terms of customer satisfaction, the methods of determining customer satisfaction comprises customer surveys and monthly or quarterly meetings. These methodologies seemed not to rely on whether there was a quality assurance standard or not. It appeared as part of the laboratory function.

In terms of profitability, there were mixed contributions from the various laboratory managers or senior laboratory personnel. Some managers indicated that certification made it attractive to gain more customers and therefore improve profitability. Wu and Liu (2010:44) are of the opinion that ISO certification improves profitability and the productivity of facilities. Some managers did not support the notion of growing profitability with certification of a quality assurance standard but, felt that profitability depended on good relationship with their customers.

Conclusion

Like many other studies, this study has its limitations. The literature on laboratory operations and performance and the availability of up to date information on this topic posed some limitation. In addition, some potential respondents did not want to participate in the research. But when that happened, other suitable respondents were approached to participate until the set sample size was achieved. There was no funding for the study to reach laboratories all over the country therefore the respondents were limited to Gauteng and the North West provinces.

Future research on this topic should be done with a bigger sample. Further, the profitability performance of the laboratories should be considered as a future financial research project. It appears that the laboratories can be managed with a set of general laboratory principles; hence, the justification of the quality assurance standards on external performance needs to be investigated. The study focused on testing laboratories and not on other types of laboratories like calibration laboratories or research laboratories.

The results obtained show that there is no notable difference in the performance of laboratories that are with or without quality assurance standards such as ISO 17025 and/or GLP or whether they are commercial or non-commercial. This means that there is some “natural good practices” that are always inherent and characterise a laboratory. Further the view of obtaining certification appears to be of cosmetic value.

This study also sets the foundation for future research. Further studies should focus on the investigation into the value of laboratory accreditation.

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