TOTAL QUALITY MANAGEMENT IN ISO 15189 ACCREDITED MEDICAL LABORATORIES IN KENYA

BY
JACCODUL ANTONY OMBEWA
D61/77170/2015

A RESEARCH PROJECT REPORT SUBMITTED IN PARTIAL FULFILLMENT OF REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF BUSINESS ADMNISTRATION, SCHOOL OF BUSINESS UNIVERSITY OF NAIROBI

DECEMBER, 2018

DECLARATION

I wish to affirm that this research project report is my original work and has not been submitted in any other University around the world for any award.

Signature …… Date: ……..

ANTONY JACCODUL D61/77170/2015

As the University supervisor this project research has submitted for examination with my approval .

Signature ……Date: ……

ZIPPORAH KIRUTHU

DEDICATION

This project paper is dedicated to my dear parents Mr. and Mrs. Jaccodul whose contribution in my education is immense and I remain forever greatful. My dear wife Purity Atayi and our two sons Aiden and Athan for your support and encouragement throughout this journey. My siblings who gave a pat on the back for each milestone covered and pushed me to the end.

AKNOWLEDGEMENT

I am really thankful for God The Almighty for giving me the tenacity, courage and health to successfully completing this eventful journey.

I wish to sincerely thank my supervisor Zipporah Kiruthu for her endless and kind guidance throughout this process. My moderator Onserio Nyamwange for timely input in reshaping the project together with other lecturers whose input enriched the paper. The Department of Management Science and School of Business for great support and logistics coordination.

My fellow classmates for the continuous positive criticism and input throughout the process of this journey.

The respondents from the ISO 15189 accredited medical laboratories in Kenya for taking time to respond to my data collection tools in a timely manner.

I remain solely responsible for any errors or omissions in this project research report.

ABSTRACT

Total Quality Management uses the competitive and know-how of all personnel as well as arithmetical problem resolving and projecting approaches of numerical method and mechanism. (Summers, 2000). Medical laboratories are accredited to ISO/IEC 15189: 2012, to ensure impartiality and competence. In Kenya, medical laboratory services spread across private, individual specialists, donor funded, faith-based and public health facilities. There are a total of 32 Accredited Medical laboratories in Kenya as per the published data on the websites of accreditation bodies at the time of the study. The objective of the study was to determine TQM practices adopted by ISO 15189 accredited medical laboratories in Kenya and factors influencing these laboratories in adopting the same. The factors that affect these principles of TQM were determined. These factors were measured against TQM practices adopted by ISO 15189 accredited laboratories. A descriptive cross-sectional survey design considered the entire populations of 32 accredited medical laboratories in Kenya with 100 questionnaires sent out. 23 accredited laboratories returned a total of 70 questionnaires which were used for data analysis and deduction of findings. Factor analysis was used to cross tabulate the factors and how they influence the TQM adoptions within the accredited Medical Laboratories in Kenya. The 8 factors identified to have played a great role in ISO accreditation included teamwork, environment, organizational structure, training, communication, QMS documentation and leadership in that order. TQM practices adopted by ISO accredited medical laboratories in Kenya included systems-based approach, factual decision making, process approaches, management commitment, employee involvement and training, continuous improvement, and factual-based decisions. These practices, according to respondents, had a positive effect on the quality and competitiveness of the medical laboratories. The findings pointed out that TQM practices should be fully adopted to ensure attainment of competitive advantage; client satisfaction and positive public perception in the decision making of the said laboratories. Based on the findings the laboratories are recommended to adopt teamwork, continuous training, effective communication strategies and transformative leadership to ensure satisfactory services are offered to clients. Limitation involved biasness that could have arisen by respondents favoring their laboratories to be offering effective and quality services.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABREVIATIONS AND ACRONYMS

CAP- College of American Pathologists

IAF- International Accreditation Forum

ILAC- International Laboratory Accreditation Cooperation

ISO- International Organization for Standardization

KENAS- Kenya Accreditation Service

SANAS- South Africa Accreditation System

SLMTA- Strengthening Laboratory Management towards Accreditation

SLPTA- Stepwise Laboratory Quality Improvement Process towards Accreditation

TQM- Total Quality Management

QMS- Quality Management System

PDCA- Plan Do Check Act

WHO- World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

The development of ISO which denotes the International Organization for Standardization, was started in 1946 in Switzerland in 1946 to promote principles which were mutual in manufacturing, trade and communication. More than 145 national standards bodies have come together to promote harmony in and break barriers to trade by standardizing operations through standard bodies of signatory countries (ISO, 2003). The procedural principles help promote world trade through multilateralism, this has been achieved through ISO 9001 quality management sequence which is the most well-known set of standards taking a key effect on global trade. . ISO 9000 pedigree speaks of numerous features of quality management that holds some of the very dominant and widely acknowledged standards giving direction and implements for businesses and corporations who want to certify that their output conform to the expectation of customers in quality asked and demanded for by the clients. Standards in ISO 9000 class comprise of ISO 9001:2015 which sets out prerequisite for a system for quality management; ISO 9000:2015 contain elementary ideas and language; ISO 19011:2011 sets out regulation on internal and external audits of any quality management systems (ISO, 2003).

In Kenya the sole standards body, The Kenya Bureau of Standards was established by an act of parliament, The Standards Act, Cap 496 of the Kenyan decrees operationalized in August 2002. The Certification framework (KEBS) is one of the principal Certification organizations in the East and Central African Region

Certification is a process by which an influential body provides formal acknowledgment that an institution is capable to carry out a particular responsibility. Usually this involves independent evaluation by accreditation bodies against recognized standards. Medical laboratories are however subjected to accreditation and not certification since accreditation delves deeper into technical competence requirements which certification looks at processes and procedures. Medical laboratories are accredited to ISO/IEC 15189: 2012, to ensure impartiality and competence (ISO 15189:2012). Bodies mandated to carry out accreditation are affiliates of International Accreditation Forum (IAF) which is a global organ of conventionality valuation bodies already peer reviewed and found to meet mutual recognition requirements. The accreditation bodies carrying the scope of laboratories must also be members of International Laboratory Accreditation Cooperation (ILAC) especially in matters testing, medical, calibration and inspection of laboratories. This International Standard is founded upon ISO/IEC 17025 and ISO 9001 which was transitioned to ISO 15189 stipulates necessities for competency and quality that are specific to medical laboratories. It is admitted that a nation might have its own explicit guidelines or necessities relevant to some or all its professional employees and their accomplishments and duties in this field ISO, 1994).The reason of this information is to better understand the difference between certification and accreditation and not to confuse the two as is usually the case.

Total Quality Management resides prominence on endless development and system enhancement as an avenue of accomplishing client satisfaction to guarantee firm's long-term achievement. TQM uses the competitive and know-how of all personnel as well as arithmetical problem resolving and projecting approaches of numerical method mechanism. (Summers, 2000). Total quality management is a

constant determination to run into the approved necessities of the client at lower cost through full commitment of all workforces. It is virtually involvement of everybody in creating all feature and characteristics that make a product or a service fit for its purpose and satisfying customer needs implied or stated with management providing enabling leadership to achieve these processes and procedures. Total quality management is the new paradigm based around whole systems approach and customer value. Key determinants of organization success are seeing employees as the most valuable assets, satisfying customers, providing quality with competitiveness and raising productivity by continuous improvements. In total quality management all resources are deployed in a coordinated and integrated systems covering technical, administrative and social aspects of an organization. Requirements for TQM may be well-defined distinctly for a specific business that may be inconformity to recognized codes such as international standardization ISO 9000 series of which greatest quality management systems are built.

Globally, international differences exist in the guidelines on good quality laboratory services. The quality of service provision and the challenges laboratory practitioners face are different in developed versus developing countries (Saliki, 2000). In the developed world, the challenge is the selection of appropriate testing techniques. Quality assurance schemes in the developed countries are incorporated in the laboratory operations policies; there are established standards and enforced regulations. In developing countries, the challenge is the lack of diagnostic tests. Developing countries are resource poor so the challenges are resource based, like human resource and financial resource based. Resultantly, there are considerable differences between countries in the implementation of quality laboratory services, in particular between highly developed countries and less developed countries

(Kamau, 2013; Kovacs, 2004). Laboratory medicine plays a cornerstone role in provision of essential care to patients through proper diagnosis of ailments. Such amenities comprise provisions for examination appeals, patient preparation, patient documentation, gathering of tests, carriage, storage, dispensation and inspection of clinical mockups, organized with successive clarification, recording and recommendation including the concerns of care and integrities in medical laboratory work. When permitted by national, regional or local guidelines and codes, it is anticipated that medical laboratory services contain the analysis of patients in discussion of cases, and that those services aggressively contribute in the inhibition of disease in accumulation to diagnosis and patient administration. Each laboratory must similarly deliver appropriate educational and scientific prospects for professional workforce engaged with it.

1.1.1 Accreditation

Conformity assessment is acknowledged through consistent audits or valuations either yearly or semi-annually contingent on the basis of the quality management system. This is so, to certify the conservation of standards and dependability of results made by the laboratory. (Anwar, 2012) In Accreditation, third party provides inscribed reassurance that the product or service conforms to precise competencies. Accreditation authorities are ISO 17011 qualified to carry out their accomplishments by peer evaluators through International Accreditation Forum and International Laboratories Accreditation Corporation (Zima, 2017). Internationally, excellence in laboratory service is benchmarked by Accreditation bodies. The other countries have established their own standards for example Canada uses guidelines from Canadian Council on Health Services Accreditation (Hui and Adeli, 2009).

Total Quality Management (TQM) is an example of a system used to implement end to end quality service. TQM has been adopted by laboratories in China, USA, and other first world countries (Neel et al., 1998). In several less developed countries in Asia, like Bhutan, Bangladesh, Korea, Maldives, Nepal, and Sri Lanka there is no formal accreditation (WHO, 2003), while in India and Africa accreditation is on a voluntary basis largely in private laboratories (WHO, 2003).

Laboratories accredited to ISO 15189:2012 mostly take two routes to accreditation either the direct implementation of the technical and management necessities of the ISO 15189:2012 standard by identifying the gaps in the management system which can be quite rigorous and may involve consultancy services to guide the process and ready the laboratory for accreditation in a precise stage and period .The other route was advanced by WHO to guide laboratories in Africa and Asia to accreditation through a method known as SLMTA(Strengthening Laboratory Management Towards Accreditation). Furthermost African and Asian Public laboratories that have been accredited have followed the WHO –SLMTA process and have positively been endorsed after 18 months of laborious SLMTA practice.

Whenever acceptable by national, regional or local guidelines and requirements, it is needed that medical laboratory services include the inspection of patients in consultation circumstances, and that those services keenly contribute in the stoppage of diseases in accumulation to diagnosis and patient supervision. Individual laboratory must also offer appropriate informative and scientific chances for professional workforce operating with institution (WHO, 2003).

Accreditation bodies operating in Kenya include Kenya Accreditation Service

(KENAS), South Africa National Accreditation System (SANAS) and College of American Pathologists (CAP) which most of the ISO 15189 Accredited laboratories in Kenya have used to enable proof of capability and value. ISO 15189 Medical Laboratories specify the need for quality and capability stipulating quality management system requirements particularly to medical laboratories which was established based on the details of ISO17025:1999 and the first version was published in 2003 (Byori, 2004).

1.1.2 Total Quality Management

Total quality management practices are approaches implemented to improve service quality and delivery. These covers: Customers focus which denotes the goods and services be provided based on customer requirements and needs as prescribed by the customers themselves. This is generally by seeking the greatest value which is the maximum amount of quality they obtain from service or product per shilling they plan to spend on it. The management commitment looks at leadership approaches and origination of business visions and objectives on the anticipated end-state of the business. Subsequently, visions and objectives can be structured into an operating plan through program and policy. This is an instrument for constant development and it is an instrument for a continuing effort to increase products, services or processes. These purposes can seek incremental progress over time or advance growth one off. Amid the most widely used instruments for constant growth is a four-step quality model--the plan- do-check-act (PDCA) series (Deming 1991). Persistent Development can be instigated from end to end on quality policy, quality objective, and audit results, analysis of information, remedial and protective arrangements and organization assessment. This requisite covers both the responsive

and practical action of development. The responsive accomplishment are those activities engaged to address non-conformities of products, procedures and mechanism such as the rectification considered on non-conformity or a fault and the complement on corrective action to eliminate the cause of the nonconformity (ISO, 9001).

Employee Involvement and Training involves employee empowerment through training, measurement and recognition, suggestion scheme and excellence teams. Preparation offers the staffs with the essential implements to achieve and apply the new approach in training. The Process Approach allows the business to achieve client desires and provide constant development. It means that procedures are accomplished and organized. It also shows that we not only appreciate what the core courses are, but we also reflect on how they suitable together. The foundation for factual approach to resolution in the performance centered management structure. An operative QMS is one that is routine determined and effects oriented. A QMS that conform to the desires of the ISO 9001 standard is recognized to be outcomes driven. In other means, the mechanism must be able to appraise and observe the scheduled effects and to take prerequisite engagements to certify its attainment. Shareholders commitment covers the complete series of characters and organizations who have applied, predisposed or compacted by corporations or any particular commercial institution and those with capabilities themselves to inspire, impress business. (Zairi & Youssef, 1995).

1.1.3 Kenyan Medical Laboratories

In Kenya, medical laboratory services spread across a broad range of providers including private or individual specialists, Non-Governmental Organizations (NGOs), Public Centered Organizations (CBOs), faith-based and public health facilities. The government adopts a collaborative inter-ministerial approach to the co-ordination and improvement of health services. As a result, the Kenyan health sector comprises of NGOs, missions, private and public health facilities. In Kenya, health care amenities are distributed over by a system of registered health amenities, with the community health scheme denoting for 51% of the total number of facilities (MOH, 1999). Medical laboratories are grouped into various categories (MOH/ KMLTTB, 2002) based on administrative structure devolving from the national and county levels. This excludes other criteria such as assays performed, work load and work capacity, staffing norm, and types of patients served. The general quality standards include employment of qualified technical laboratory staff, application of safety procedures, recording and maintenance of laboratory generated data, disposal of waste products, preparation of the patient and incorporation of internal and external quality assurance schemes (Shahangian and Snyder, 2009).

Classification by the KMLTTB (2002), medical laboratories fall into categories based on capacity and the level of affiliated hospital housing the laboratory. The categorization is in levels 1: dispensary, level 2: health center, level 3: former sub-district, level 4: former district, level 5: former provincial and level 6: national or referral. The Board classification tends to focus the government operations. While accreditation of medical laboratories is common worldwide,

most African facilities still lag behind in term of ensuring their facilities are accredited and safe for patients who are the major customers. As per the published data on the websites of the three accreditation bodies operation in Kenya, there are a total of 32 Accredited Medical laboratories in Kenya. Majority of these laboratories are accredited by Kenya Accreditation Service (KENAS) 24, South Africa Accreditation System (SANAS) 7, and College of American Pathologists 1. The World Health Organization SLIPTA and SLMTA is the most favored route by these facilities to achieve accreditation process and more published literature exists on these processes. (Gachuki et al, 2015), enumerates the SLMTA process in his facility as tool well used to achieve accreditation. SLMTA program uses a checklist highlighting 12 quality system essentials. Laboratories are assigned stars based on their score with Zero star (0-54%) being lowest while five stars (>95%) being the highest signaling readiness for accreditation. The same program was adopted by most facilities to achieve accreditation especially in public and faith-based institutions. The impact of accreditation these laboratories has led to adherence to quality standards, improved operational efficiency, reduced laboratory errors and improved customer service (Trevor ,2010). Though the voice of the customer is the most important, it has been ignored in the process of driving quality in these facilities due to weaknesses in Total quality management practices.

1.2 Research Problem

Medical Laboratories have been at the fore front of integrating managerial quality principles into their operations, the history of which is seen by instituting quality systems through World Health Organization SLMTA as part of ISO 15189:2012

accreditation process. *(*Rutledge, 2010) emphasized that while laboratories have achieved accreditation to ISO 15189, total quality management still remains a gap in these facilities. The laboratories dwell so much on processes and procedures of institutions forgetting other tenets of quality management. The elements emphasized in TQM comprise client satisfaction, total worker assurance, group effort and value chain, tactical and methodical attitude, incorporated structures, resolutions founded on evidences, continuous enhancement, actual communication, learning and progression thinking. Internationally, quality laboratory service is bench-marked by accreditation authorities. Accreditation of medical laboratories in numerous developed nations like Japan, USA, and Canada is controlled by provincial health experts. In Canada, five out of ten provinces have provincial accreditation organizations. The other provinces have established their individual criteria using the Canadian Council on Health Services Certification (Hui and Adeli, 2009). Total Quality Management (TQM) is an example of a system used to implement quality service. TQM has been adopted by laboratories in China, USA, and other first world countries (Neel *et al.*, 1998). In several less developed countries in Asia, like Bhutan, Bangladesh, Korea, Maldives, Nepal, and Sri Lanka there is formal accreditation (WHO, 2003), while in India and Africa accreditation is on a voluntary basis largely practiced by private laboratories (WHO, 2003).

There are few researches done on ISO standardization with scanty information specifically delving on challenges facing ISO 15189 accredited medical laboratories on Kenya in implementing TQM. Atieno (2007) studied the perception of employees of ISO 9001:2000. Thiongo (2007) did a research study on the execution of quality and environmental management systems as an integral

management system in Kenya's companies. Gatimu (2008) did a study on the benefits that are strategic in nature and difficulties faced by firms in the manufacturing sector in embracing ISO 9000 quality management systems in Kenya. Kimani (2008) studied the role of ISO 9001 accreditation in increasing competitive advantage for Kenyan firms. Tanui (2008) did a survey of quality management practices in pharmaceutical companies in Kenya. Gatimu (2008) did a study on the tactical advantages and problems confronted by manufacturing companies in the implementation of ISO 9000 quality management systems in Kenya. Kimani (2008) considered a research study on the contribution of ISO 9001 accreditation in raising competitive advantage for Kenyan firms. Tanui (2008) did a survey of quality management practices in pharmaceutical companies in Kenya but there is limited information on TQM Practices of ISO 15189 Accredited medical laboratories in Kenya or studies on medical laboratories in Kenya. It is on this basis that the researcher sought to determine the kinds of TQM practices adopted by ISO Accredited Medical Laboratories in Kenya and the factors that determine adoption of TQM by these ISO Accredited Medical Laboratories in Kenya

1.3 Objectives of the Research Project.

The broader purpose of the project research was to establish the Total Quality Management Practices in ISO 15189 Accredited Medical Laboratories in Kenya.

1.4 Specific Objectives

i. Determination of the TQM practices that have been adopted by Kenyan medical laboratories that accredited to ISO 15189.

ii. Determination of the factors that influence Kenyan Medical Laboratories that

are accredited to ISO 15189 in adopting TQM Practices.

iii. Found out whether TQM as a best practice has enabled ISO 15189 Accredited Medical Laboratories achieve operation excellence.

1.5 Value of the Study

The project research outcomes will be applied in the medical industry in Kenya and beyond. TQM practices of ISO 15189 accredited medical laboratories would inform discussions on better ways of improving patient safety and care. The research study is destined consequently to offer in-depth evidence that TQM practices of ISO 15189 accredited medical laboratories improves the operational excellence.

The outcome of this research study will contribute to research with obtainable material and assist as an orientation point during research study time on TQM by ISO 15189 accredited medical laboratories in Kenya there being very limited studies conducted in this area. It is projected to enhance to the frame of understanding through constructing on the ISO Standard and the principles of TQM as well as the theories supporting the study. Scholars will be anticipated to appreciate from this research study when conducting interrelated research studies and for further studies. The research-study is anticipated to benefit and add in-depth material to the legislators in régime and other accreditation and certification organs.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This section focused and delved deep on the past project studies conducted related to the paper and other literature on accreditation concepts and TQM by first looking at the theoretical anchorage that supports the study. Other studies of related subject was reviewed empirically targeting TQM and ISO 15189 accredited medical laboratories in Kenya and beyond.

2.2 Theoretical Framework

The anchorage of the project dwelt on Standardization theory, medical laboratory science theory and Crosby's theory. The Standardization theory (Henry 1926) states that standardization is an orientation dimension processes done through the unbroken chain of measurement system vital to accomplish superior comparability of laboratory test standards amid diverse clinical testing. Crosby (1996) postulates that quality is attained by averting faults and comply with guidelines which must be decided on and all workforces must be acquainted with how to attain them. Medical Laboratory Science theory spans Hippocratic era (300BC) among other pioneers.

2.1.1 Standardization theory

Henry (1926) designates that standardization is an orientation measurement and formation of reference systems essential as a dependable transmission of logical exactness of a system of continuous referral accomplishing the reference procedures in a great - homogenous operational settings. Both the guideline and synchronization procedures target to advance the comparable of test outcomes concerning laboratories. Both the regularization and coordination procedures target

to progress the comparability of experiment outcomes among laboratories. While standardized outcomes faces more thoroughly of the true assessment, synchronized results may be predisposed in terms of genuineness.

Governmental institutions, metrological centers, standards system of governance, medical laboratory, biomedical technology players, etc. have functioned carefully as a unit to quickly and efficiently advance the standardization of examinations used in medical laboratories. Worldwide authorities such as the ISO, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), International Union for Pure and Applied Chemistry (IUPAC), International Council for Standardization in Hematology (ICSH), and the Clinical and Laboratory Standards Institute (CLSI). The new series of ISO 9000, 9001, 9002, 9003 and 9004), was releases by 1994, namely ISO 9000:1994 (Mead (2011).

2.1.2 Medical Laboratory Science Theory

(Athanasius Kircher 1602-1680) Medical laboratory science has been the anchor of medicine since the time immemorial and the began from the earlier onset of tasting urine by mouth to microscopy to current genomics as the technology continues to advance .The Greeks of ancient times saw the value in testing body fluids to predict and diagnose diseases, making it the true authority of medicine. The theory of medical laboratory science started with at around 300BC where Hippocrates broadcasted the use of mind and senses as diagnostic tools a principle that contributed hugely on his part as the father of Medicine. The core of Hippocratic doctrine of humoral pathology attributed all maladies to disorders of body fluids. To advance this, a testing protocol was advocated for that included tasting patients urine, listening to the lungs and looking

the colour of the skin and general appearance of patients. Appearance of foam on the upper layer of urine samples was attributed to kidney disease and other chronic diseases and these gave other pioneers better ways of diagnosing ailments especially when pus and blood was also observed in urine.

When microscopy was invented through telescope work of Galileo which opened doors on vast astronomy and the ability to observe artefacts through his telescope. Jesuit Priest, Anthanasius Kircher (1602-1680) of Fulda Germany did not take long to discover a microscope and used it to investigate disease and their causes through their early experiments that showed maggots and other microbes developed in decaying matter.
The early reports from Kircher included 'worms' that were seen in patients' blood who suffered from plague. But what he thought to be worms were actually pus cells and red blood cells because Bacillus pestis could not be observed with a 32 power microscope. Later came Robert Hooke(1635-1703) who used the microscope to document the existence of ' little boxes' or cells which later influenced the foundation of histopathology with biggest contribution coming from Marcello Malpighi(1628-1694) as a leading microscopist through his many discoveries.

Modern biomedical Sciences has advanced through deliberate scientific research and caucuses in the last century. Technology has enabled refinement of methods and theory from earlier years to what we have today as superior as tele-diagnosis.
Today's diagnosis has relied on precision, standardization of quality practices like implementation of ISO 15189 among other best practices. Medical practice has evolved to target the genetic makeup of the disease with efforts being put in place to erase certain traits that cause disease though issues of ethics continue to be discussed. The synergy

between the old theories and new theories of medical laboratory practice will lead us to better diagnosis and understanding of human medicine.

.

2.2.3 Crosby's theory

Philip Crosby postulates the theory of Zero defects, simply put do it right the first time which would surpass the coat one pays to fix a damaged product or service. Quality is actually free when these principles are followed .Defects prevention sits at core of efficiency and effectiveness of a product or a service and these necessities staff must know to drive down management cost and financial cost which are tracked along the way to bring value to the stakeholders and customers. The theory of zero defects is rooted deep onto the organization culture and promoted to come up with defect free merchandises and all of these are corrected according to management criterion promoting quality is free philosophy and conformance to precisely thought out conformance requirements.

The critical goal of his approach is to make available defect-free merchandises and services to the clients (Crosby, 1996).

Quality correspondence like Deming, Juan and Crosby revealed that upper most management understanding and ownership is one of the most significant features influencing the achievement of quality culture in business. The link flanked by upper management ownership of the process in business and excellent products must be clear. Team members must be motivated by upper management, in order to empower more asset in the foundations for which they are accountable, thus developing the effect of these features on the merchandise's superior quality. The quality management system has been applied positively in any business by the upper

administration it is the team's commitment to adopt and uphold the TQM in execution processes and constant assessment is approved as part of the process. Quality must begin with the top administration and streams downward to lower echelons of administration or sometimes deliberation starts from the bottom to the uppermost. Influencers must do extra than just discourse then push for transformation practically and systematically to bring governance to life at all levels. The TQM champion must arrange with major resource pronouncements and new guidelines not just every day's leadership (Liang Tan, 1997).

2.3 ISO Accreditation Concept and Factors Influencing Accreditation

Medical laboratories are accredited to ISO 15189 which has a rich history having been influenced by other earlier ISO standards one of them being ISO 9000 which offers meanings and perceptions of a quality management system explaining how to use other standards. The first step in accreditation involves building an enthusiastic team with education and knowledge on quality management system, selection of methods and scope of accreditation follows, describing processes in the laboratory, developing and improving metrology system, definition, structuring and preparation of all relevant documentation such as quality manual, standard operating procedures, policies and other accreditation criteria documents (Zima, 2017). In Kenyan scenario ,there are a few accreditation bodies who draw their membership from umbrella organizations for accreditation bodies such as ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) and they include Kenya Accreditation service (KENAS) which is a national accreditation body established under state corporation Act ,Cap 446, Legal Notice No.55 of May 2009; South African National Accreditation Systems (SANAS) and College of American Pathologists (CAP).

ISO 15189 accreditation by laboratories contains a development acknowledged as the SLIPTA and SLMTA courses presented by World Health Organization in 2009. SLIPTA offers a point of reference basis that measures laboratory agreement with ISO 15189 on a five-star measure using a wide-ranging audit instrument. SLMTA on the other hand offers training, mentoring and evaluation to support laboratories application of quality management system to achieve instantaneous quantifiable development of laboratories resource in the imperfect surroundings. To assess the growth, SLIPTA audit must implement framework used before and after SLMTA practice. The progression has been useful among Kenyan laboratories both in private and public sector enabling achievement of ISO 15189 accreditation within eighteen months (Wakaria et al, 2017). The SLIPTA /SLMTA process is mostly used by the medical laboratories in public and faith-based institutions to achieve accreditation and mostly is donor supported, however laboratories in private sector are mostly inclined to implement the ISO 15189 standard directly by a help of consultancy service.

Structure of organizations involves basic administrative setup such as culture and leadership styles. Some experiential research carried out from the opinion and approach of Organizational Ecology shows an improvement of TQM. This reveals that innovation in business management influence key managerial characteristics such as strategy, structure and culture, these being precise facets which offer the main risks to existence. There can also be some hostility in accepting these innovations, even if their anticipated values are helpful for the business (Hannan and Freeman, 1984, Singh et al., 1986). Carman (1993), put forth that many business establishments will show some opposition to adopting basic changes even if development in organizational

performance is estimated from them either due to their restraint to taking risks, their outlooks that the policies followed promptly will bear fruit a little late or their anxiety of fronting the disorder brought about by such a transformation.

Environment according to Shin, Kalinowski, and El-Enein (1998) uphold that one feature to success of TQM is its congruence with its strategic main concern in an enterprise which are in accordance with a competitive environment and the firm's goals. An enterprise using TQM should not overlook that it practices one part of the setting with precise structures to attain precise objectives (Zhang, Linderman, and Schroeder, 2012). Assuming the suitable use of quality for the benefit of this method is substantial; difference in businesses using TQM is gotten about by environmental interfaces. Firms are open systems; accordingly, they are using an assortment of devices to construct links concerning business environment and performance. In fact, the administrative soundings make use of numerous ways in diverse circumstances. The affiliation between business and environment is an issue with great scopes, so it can be quantified that the variances in the outcomes achieved from the companies on qualitative use hang greatly on their environment.

The workforce is an important aspect and component of the corporate setting, being an important component that influence organizational output, productivity, performance (Ooi, Teh, & Chong, 2009). Increasing the measurement to improve efficiency and the ability to perform optimally for a business enterprise is a requirement that must be attained and sustained methodically through Total quality Management and harnessed human capability.(Hataani & Mahrani, 2013). The objective of TQM is to enhance competitiveness by continuously developing a product or a service by encompassing

all features of quality in it by involving all people, equipment and environment (Jumenez & Martinez-Costa, 2009). With military execution in mind in terms of quality circles of organization, these must be well coordinated to bring out the desired competitiveness and performance. (Azizan , 2010). High performance organizations implement TQM principles embedding the same tightly in their culture, valuing productivity and measurement of human capital. (Ooi, Teh, & Chong, 2009). The human resource quality, professional development initiatives and alignment of the same with quality needs form contemporary needs of businesses.

The philosophy of leadership works to link people and processes in the long term, with corporate culture of quality as a key business strategy. (MacKelprang et al., 2012). The philosophy of TQM and its cultivation must be based on a whole system approach of bringing everybody on board in an institution. This approach works better to enhance strategy development, coordination, implementation, execution and measurement. Each and every employee committed to continuous improvement with the review of all business plans, process, and strategies converging around TQM. (Stokols et al., 2013). The surmountable challenge involves development of a strong adaptable culture where stepwise continuous quality improvement is understood by everybody and embraced simultaneously to make quality the center of engagement in institutional functional areas. Regular feedbacks by management and leadership through principled deep diving on key highlights makes employees more agile and motivated to continually adopt TMQ principles. Leadership with a bird's eye view of quality requirements would easily invest in quality intelligence and arrest obstacles to quality before they actually happen. Feedback from both internal and external customers must be relied upon by the leadership when setting quality objectives, performance goals, monitoring

models and methods and these ads to overall management and operational costs and ensures all sectors are covered. TQM puts the leadership as the starting point to ensure ownership of the whole process in the long run. The leadership must active, resourceful, involved to ensure the employees run with the project in the most understood way and as efficiently as possible. With this precedence set, errors are eventually reduced leading reduction in cost of doing business by getting it right the first time and always. Transparent systems are created through TQM ownership where each employee is involved and knows what to do, when to do it and how to do it as per set performance standards. Laboratories benchmark on these principles as they move towards accreditation goals once the upper management inculcates the TQM culture. With this managerial requirements such as planning, coordination, innovation, goal setting for better achievement of quality goals. The high ranking managers in medical laboratory such as chief technologists or laboratory directors may possess even technical and managerial skills to ensure competence this being a highly technical field. (Nyongesa et al., 2015).

On job training ensure better results since employees are apply to acquire practical skills crucial for success of accreditation. Staff who are trained on job have better cognitive, emotional intelligence and are system oriented. When a laboratory is accredited staff are gratified since their involvement in the whole process of accreditation journey helps them appreciate the small but important steps taken from inception to make success out of it. Training and continuous refreshment of the same helps staff better understand accreditation and is actually the first step in the journey of accreditation. Laboratories that are accredited are believable in the results they produce since error proofing is part of the process and clinicians and customers appreciate the work of laboratory medicine

through accreditation. However continuous surveillance assessments must be carried out to ensure labs continuously improve to guarantee improved patient care. The post analytical cycles of laboratory processes enable risk management and ring fencing to delete errors from these processes. The pre and analytical phases must also be continuously monitored to achieve improved performance. (Stokols et al., 2013).

Fitness for purpose work processes and documentation must be carefully selected to facilitate onward implementation and sustenance of all QMS documentation while using unambiguous, simple, concise language, to ensure clarity in understanding and followership of the document. Careful gap analysis for documentation must be done to ensure only the documents to that improve efficiency and effectiveness of the work methods and techniques. Technology is a key enable in management of the documents needed ensuring synchronized mapping of documentation desired. The size of documents needed depend on the size, capacity and complexity of the organization since good planning at this stage will ensure better uses of resources and effort later (Deming, 1991).

Teamwork and Team spirit forms the foundational building block of any organization performing Total Quality Management. The responsibility of implementation of quality initiatives is usually left with management representatives for quality or a group of people steering the quality process in the organization. They are supposed to build, inspire, motivate and at times push the whole organization towards quality success. An organization is like a spider web with never ending complex processes and procedures and the only way an excellent output can be realized is through a team working together towards a common goal. People work better through involvement of others and it's

important for supervisors to gel with other team members. Working together must involve structural design that fits into the quality strategies of the organizations for achievement of quality goals. When people work through and with others, ideas are perfected and refined, information flows seamlessly, knowledge is shared and matured which eventually produces economic value through getting right first time principle. Team spirit is an integral part of a total quality institution enhancing trust to be built, communication enhanced and intradependence and interdependence rather than a one man's show. (MacKelprang et al., 2012).

Communication within organization enhances better management of activities to avoid overlap between activities with greater contribution to overall quality objectives of an organization. Hele (2003) reiterates that employees at all levels in an organization must be involved to ensure the organization benefits from their abilities. Additionally, Ashire *et al.* (1996) encouraged use of quality circles to enable people identify matters arising from day to day activities involving quality which would enable them give suggestions, solve work related problems, evaluating quality improvement initiatives and availability of profit sharing schemes. This actually improves communication within and without the organization through a synchronized process of feed backs which plays a great role in ISO 9001:2000 standards implementation {Hele (2002), Fuentes *et al.* (2000) and Tang and Kam (1999)

2.4 Total Quality Management Practices

Total quality management practices ensure that, customer satisfaction, as the key driver of quality in organizations, as most of the principles of TQM are addressed on ISO 15189. As competition rises globally organizations especially accredited laboratories must monitor how their products or services are used or viewed by the customer from the moment they come into contact with them until the time they are disposed of some of the clauses of the ISO15189 Standard has emphasized on the management requirement sections of the standard covering organization and management responsibility, resolution of complaints, continual improvement and management review but principles of TQM been deeply highlighted in this ISO standard but certain requirements are given more emphasis as opposed to customer-centric focus and employees involvement are weakly implemented (Zeh et al ,2010)

Customers focus denotes the goods and services generally by seeking the greatest value which is the maximum amount of quality they obtain from service or product per shilling they plan to spend on it. Noted authorities on the subject refer quality as the entire combined product or service features of marketing, engineering, manufacturing and maintenance from end to end in which a product or service in consumption will accomplish the anticipation of the client. There are five major characteristics found in relating service quality that comprises of consistency which is the capacity to achieve the guaranteed service reliably and precisely, Receptiveness is the readiness to help clients and deliver rapid services, Tangibility is the physical facilities, equipment, and the appearance of employees. Assurance is the awareness and courteousness of staffs

and their capacity to transfer trust and on the other hand Empathy is the gentleness, individual responsiveness provided to clients (Gentile et al., 2007). Quality is gradually supposed to be judged not by the creator but by the receiver (KEBS, 2007). Based on those research studies, a true value of acceptable quality is client satisfaction, which takes into consideration both the objective and subjective clarifications of the desires and anticipations of the client and shareholders (KEBS, 2007; Price, 2005; Rhaman, 2001).

Management commitment involves articulation of administrative visions, objectives, or more basically, the anticipated end state of the enterprise. Subsequently, visions and aims can be structured into a functioning strategy over procedure and plan. In relative to quality administration execution, procedure is a control for assimilating quality management ideologies into strategic processes, while plan is a way to converse and converge the aim so as to create the strategy effectively within the business. In relations of the fundamentals of quality management procedures and plan concealment matters of workforce, finance capitals and processes (Irianto, 2005).

Therefore, TQM has the whole business functioning together to warrant and thoroughly improve quality. The goal of TQM is to satisfy clients by creating products with zero faults by accommodating the voice of the client in all divisions of the value chain process. The essential segment of Total Quality Management is the workforce; you picture the influence of people delivering on a process and each individual becomes accountable for transitory on strategic unit that are of good quality and this comprises job widening and quality at source or station. Quality series become central part of executing

TQM, with workforce consultation frequently to solve challenges encountered throughout the whole practice of value chain. Deming (1986), upholds that the administration of the business must be aggressively involved in the quality undertaking and determinations considering that it's the only technique to confirm the organizational competitiveness in the global market is arrived at (Liang, 1997).

Continual Improvement can be familiarized over the use of quality process, quality objective, and audit outcomes, analysis of statistical information, counteractive and deterrent actions and administration evaluation. This obligation shelters both the responsive and proactive action of development. The responsive action are those activities taken to address non-conformities of product, procedures and system such as the adjustment taken on noncompliance or a fault and the follow-up remedies are to eradicate the root-causes of the noncompliance. Continual improvement pushes the business to frequently find ways to diminish costs, advance organizational performance and client satisfaction (ISO, 2008). In system management, the essentials for CI is in the management of discrepancies. Variation is the reduction of the output of a procedure, sometimes called noise. Improvement of any procedure is to decrease disparity so that the procedure can constantly meet expectancy level of either the internal clients or external clients. Learning on deviation leads to treating it, as this will aid to recognize the basis of the difficulty and to find the action best possible to resolve it.

Deming Cycle matrix of: Plan; Do; Check and Act idea is founded on refining products and services by eradicating uncertainty and inconsistency in the enterprise and

industrialized business practices. In Deming's opinion, variation is the main culprit of reduced quality. In mechanical assemblages, for instance, variations from qualifications for part scopes lead to unpredictable performance and untimely wear and letdowns. Likewise, discrepancies in service upset clients and damage a firm's appearance or image. To realize reduced difference, he supports a never-ending cycle of product strategy, production, trial, and sales, trailed by market analyses, then reform or redesign the product (Deming, 1991).

The other principle of TQM involves employee empowerment and involvement through training, measurement and recognition, suggestion scheme and excellence teams. Above all the customer focus of TQM is viewed as the most important encompassing supplier partnerships, service connection with internal clients, non- concession on quality and client focused standards. The continuous improvement standard safeguards constant review. The human resource factors that affect service provision have been widely researched (Armstrong, 1999; Timmons and Spinelli, 2003; Rao, 2004). Many personal factors are subjective and semantic differences exist among the dimensions, for example terms like leadership, confidence and creativity have many connotations. Commitment and determination were considered to be important success factors by several researchers.

Training offers the personnel with the required outfits to do and implement the new strategic training. Mature business establishments realized high volumes of career development in many fields extending from common awareness to practical courses.

Training varies rendering to the level of the member of staff. Training should improve the indulgence of the firm's and developments. Employees have a duty to set the gears required to inspect these procedures, propose alterations to them, and conceive the outcomes of these changes. Patel and Randell (1994) quoted Chase (1991) whose opinions on training and development has an imperative influence to the QM transformation process and it provides initial cognizance of the fundamentals of QM. Training function as a means of communication delivery, it increases abilities of teams to take part in the development process. Also, it aids the workforce in the business to reorganize their approaches towards quality (Madu, 1997). Ashire *et al.* (1996) revealed that the firm must see costs of training programs as investments in human capital.

ISO 9001 adopts a process-oriented approach and observes over 20 practices in its opportunity, one of which is the whole Quality Management System (QMS). The process style is the fundamental principle of ISO's outlook of a QMS. Thus, a QMS can be understood as a sole large progression that aims at many contributions to produce many productivities. ISO 9001 endorses the process approach in managing a business and necessitates the QMS to deliberate the firm as a sequence of interlinked processes. The efficiency of the complete system is focused on the usefulness of each development and the interactivity of these procedures within the system. By beginning quality aims and auditing how efficiently the procedures accomplish those aims, firms can establish whether the practices add value. Using the Process Approach while scheming and mounting a quality management system enables process enhancement. A QMS

using the process approach shown by principles can meet their clients' (internal or external) requests and continual improvement in the Process Approach allows the business to meet client requirements and deliver continual progress (ISO, 9000).

System approach is administrative plan which combines the plan-do-check-act cycle and risk- based aspect to ensure that procedures are accomplished, organized and controlled. It also denotes that we not only comprehend what the essential developments are, but reflect on how they fit together. A systems approach embraces that a business should be preserved like a coordination, where the interdependency, or connection, flanked by the progressions building up the system that is recognizable by the firm. A key conception of systems-based philosophy is that by enlightening distinct procedures and attaining confined objectives you do not essentially mend the system. Since the interdependence and disparity, the ideal performance of a system as a fully if not the equal to the summation of all the limited goals. In fact, if all the elements procedures of a system are acting at their extreme level, the system entirely will not be executing at its finest. ISO 9001:2000 standard has diminutive meaning about handling and refining procedures jointly as a system

The foundation for factual methodology to making a decisive choice is the performance based administrative system. An operational QMS is one that is performance focused and outcomes oriented. A QMS that fulfils the necessities of the ISO 9001 standard is well-known to be outcomes oriented. Meaning that the system must be capable to assess and observe the strategic outcomes and to take obligatory engagements to confirm its accomplishment. Under ISO 9001 Clause 8 Dimension, Investigation and

Development, the firm must strategize and implement the observing, extent, examination and enhancement procedures to ensure that QMS is efficiently applied and persistently being enhanced. In other words, QMS emphasizes on 3 key parts; guarantee that the product meets clients identified desires. To certify self-control in effecting QMS and to guarantee continual improvement of the efficiency of QMS. This solicit for the use of information and study for policymaking and for introducing engagements to best accomplish strategic results and developments (ISO 9001).

Shareholder's engagement incorporates the full variety of persons and firms who are affected, swayed or impacted by big business or any specific commercial activities and those with prospective ideals to impact or affect firms. The new form of ISO 9001 gotten a lot of modifications with innovative requirements. In the midst of them, the outline of the conception of interested parties is principally motivating. So far in the development of this standard over the years and over the diverse phases of improvement, the client has been nearly the lone emphasis, citing suppliers, workforce and watchdogs as transferors of main necessities but not exactly connecting any other body that might have taken an influence on the definite outcomes attained and even proprietors of the business. While the client possesses being the stellar of the new kind of ISO 9001 as habitual, they are not by themselves alone, currently the standard carries about the need of seeing other investors that could influence ultimate outcomes and client's satisfaction as an imperative fragment of the quality management system. These shareholders are christened concerned parties.

2.4 Empirical Studies

Beatle (2003) surveyed Singapore companies on perceived benefits of ISO 9000 certification. The outcome of the study reiterated that accreditation enabled better performance in terms of processes and financial performance and showed that companies that were not listed in the stock exchange experienced but were ISO certified produced better products or services, better communication among workforce than listed uncertified firms. Chow-Chua, Goh and Wan (2000), carried out research whether ISO certification improved business performance and found out that there was no link that they later improved. But other research carried out have always tied quality to business improvement. Eras, Dick and Casadesus (2000) carried out a research study concluded that the superior performance of certified firms was due to firms with superior performance having a greater urge to go for ISO certification.

Nyongesa, (2015) studied perceptions of medical students towards healthcare devolution and found a relationship. Mayura and Panadda (2005), assessed standards of quality in medical laboratories in Thailand. Kubono (2007) researched on implementation and accreditation to ISO 15189 of medical laboratories for specified health checkups. Rinsho Byori and Arumugam (2008), investigated Total Quality Management practices and quality management performance and found relationship. Akacho (2013) examined factors influencing provision of health care services delivery in Kenya. Kaynak (2003) explored whether there was relationship between firm's performance and total quality management and a strong correlation was found.

2.5 Conceptual Framework

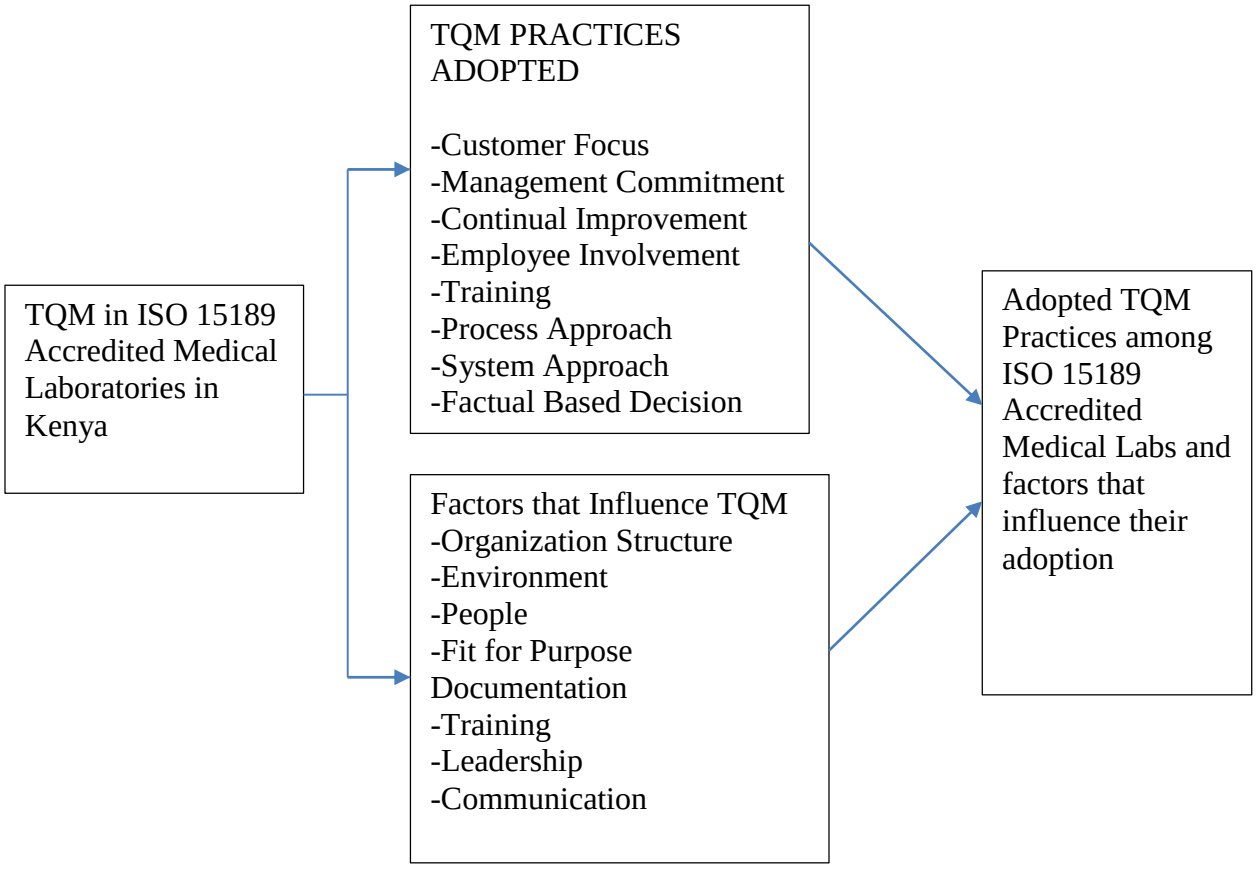


Figure 2.1: Conceptual Framework Source: Researcher, (2018)

The conceptual framework shows the TQM Practices of ISO 15189 accredited medical laboratories in Kenya and TQM Factors.

Principal Component Factor Analysis used to determine which of these factors and TQM practices are adopted by these medical laboratories.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This section discussed the methodology that was used to conduct the research. It generally explores the design of the research, the population targeted, collection and analysis of data.

3.2 Research Design

This study implemented a descriptive cross-sectional survey design. A descriptive research was embraced so as to detect, define the condition as it reasonably happens (Ngechu, 2004). This comprises the gathering of data that would deliver an explanation or an account of individuals or group. Cooper & Schindler (2006), denote that in a cross-sectional design, either the whole population is selected then individual data is collected to help answer research objectives (Ngechu, 2004).

A survey endeavor to gather facts from members of a population and pronounces phenomena by asking persons about their insight, assertiveness, and behavior or values (Mugenda & Mugenda, 2003). Cross sectional research design is selected since it calls for simplification to allow within a certain limit. The data attained was regulated to permit easy contrast. The enhanced systematic description that is accurate, valid and reliable aided in establishing the TQM Practices adopted by ISO Accredited Medical Laboratories in Kenya and factors that influenced the same.

3.3 Population of Study

Mugenda (2003), a population is a set of all units of analysis in one's problem area. Kothari (2011) refers population to all items in any field of inquiry which is also known as the universe. Basing on these concepts, the research considered the entire populations which consisted of **32** accredited laboratories. The 100 questionnaires were distributed to Laboratory Technologist, Pathologists, Laboratory Directors, Quality Monitors, Medical Laboratory Officers, Laboratory Managers, Quality Managers, Quality Assurance Managers and Section Heads. 23 accredited laboratories returned a total of 70 questionnaires which were used for data analysis and deduction of findings. The population size made the study a census.

3.4 Data Collection Method

The primary data was collected by use of questionnaires that are semi-structured which contained closed ended questions tallying with the objectives of the study. This made the sorting of data simple, accurate, easy to understand and scrutinize. Likert scale of 5 points was used to better grade responses expected. The questionnaires were individually delivered by the project investigator to the various accredited health facilities.

3.5 Data Analysis

The data collected was cross reviewed for inclusiveness and accuracy then coding, organization and consolidation followed. Descriptive statistics was used to find measures of central tendency (mean, mode and median) and measures of dispersion

(variance and standard deviation). Section A: addressed demographic characteristics, Section B: determined the kinds of practices adopted by ISO Accredited Medical Laboratories in Kenya. Section C determined the factors ISO Accredited Medical Laboratories follow in adopting TQM Practices. The Statistical Packages for Social Sciences (SPSS) software version 23 was used for data analysis to aid in analyzing and summarizing the data for better understanding. Factorial analysis was used to cross tabulate the factors and how they influence the TQM adoptions within the accredited Medical Laboratories in Kenya. According to (Lawley and Maxwel 1962), a technique of analyzing factors help scale down large number of variables into thinner number of factors. Maximum variance that is common was extracted and put in a score that is common.

CHAPTER FOUR: DATA ANALYSIS, RESULTS AND DISCUSSION

4.1 Introduction

This chapter highlights the research findings of the data collected and analyzed, interpretation and respective discussion of the results in line with the overall research objectives. This section documents the general demographic characteristics of the assessed medical laboratories, the factors that influence adoption of TQM practices, and the extent to which adoption of TQM determines attainment of competitive advantage by the medical laboratories in Kenya. The respondents included doctors, quality managers, technologists, section heads, quality analysts, and other medical practitioners working in or affiliated with laboratory operations.

4.2 Response Rate

A total of 100 questionnaires were developed and distributed to 32 accredited questionnaires across Kenya. Out of the 100 questionnaires developed and distributed, 70 questionnaires were duly filled and returned, representing a 70% response rate. This response rate was considered substantive enough to proceed with the study as affirmed by Bailey (2008) that a response rate of 70% and above is high enough to conduct an effective study with minimal biasness.

4.3 Descriptive Statistics

4.3.1 Period respondents have worked with the facilities

The respondents were asked to state the length of time they have worked with the healthcare institutions surveyed. Table 4.1 shows that majority of the respondents (28.6%) had worked with the facilities for more than five years. However, the duration in service of the respondents is equally distributed as shown in the table on the next page.

Table 4.1 Period Working with the Facility

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0-1 year	14	20.0	20.0	20.0
	2-4 years	19	27.1	27.1	47.1
	5-10 years	20	28.6	28.6	75.7
	Over 11 Years	17	24.3	24.3	100.0
	Total	70	100.0	100.0	

4.4.2 Distribution of Respondents by Department

Table 4.2 Distribution of Respondents by Department

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Deputy Bio Safety Officer	1	1.4	1.4	1.4
	Biosafety Officer	1	1.4	1.4	2.9
	Deputy Lab Manager	1	1.4	1.4	4.3
	Director	2	2.9	2.9	7.1
	Lab Tech	24	34.3	34.3	41.4
	Laboratory Manager	4	5.7	5.7	47.1
	Laboratory Technologist (HOD Microbiology)	1	1.4	1.4	48.6
	Medical Laboratory Officer	3	4.3	4.3	52.9

Medical Technologist (HOD, Hematology)	1	1.4	1.4	54.3
Molecular Analyst	1	1.4	1.4	55.7
Pathologist	1	1.4	1.4	57.1
QMS Monitor	1	1.4	1.4	58.6
Quality Assurance	12	17.1	17.1	75.7
Quality Manager	1	1.4	1.4	77.1
Section Head	12	17.1	17.1	94.3
Serology/Parasitology Section Head	1	1.4	1.4	95.7
Technical	1	1.4	1.4	97.1
Technical Manager	1	1.4	1.4	98.6
Technologist (HOD Histology)	1	1.4	1.4	100.0
Total	70	100.0	100.0	

Respondents were requested to state the departments in which they work. From the table 4.2 above, there was a wide variety of departments or job functions from which the responses were derived. However, this is not completely representative as nurses, doctors, and other medical practitioners play an integral role in enhancing TQM in healthcare facilities.

4.4 Factors Influencing ISO Accreditation

Medical laboratories are accredited to ISO 15189 after adoption of quality management systems and building an enthusiastic team of medical practitioners with an understanding of quality management systems, processes, and systems (Zima, 2017). The researcher sought to find out the rate of ISO accreditation and compliance among Medical laboratories in Kenya. Out of the respondents surveyed, 2.9% indicated less than 50% compliance to TQM practices, 28.6% indicated that they were 60-80% compliant while 68.6% indicated

that they were more than 90% compliant with TQM practices. This information implies that majority of the surveyed institutions had ISO compliance to TQM practices. The table below summarizes the data obtained from the study:

Table 4.3 Rate of ISO Compliance to TQM Practices

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Below 50%	2	2.9	2.9	2.9
	60-80%	20	28.6	28.6	31.4
	90% and above	48	68.6	68.6	100.0
	Total	70	100.0	100.0	

Factor analysis was used to determine inherent factors that influence ISO accreditation. Principal component analysis and varimax rotation were used to extract 8 factors out of the 25 variables that the researcher investigated through the questionnaire. To test for sampling adequacy and significance of the correlation prior to continuation of the analysis, the following summary out was attained;

Table 4.4 KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.678
Bartlett's Test of Sphericity	Approx. Chi-Square	813.876
	Df	300
	Sig.	.000

Appendix 2 and 3 provide a summary output of the factor loadings with an indication that about 70.74% of the variance in ISO accreditation among laboratories is attributable to the

8 extracted factors. The remaining 17 factors account for 29.26% of variance. From the analysis, teamwork, organizational structure and environment are the top-ranking factors influencing ISO accreditation. Surprisingly, leadership and QMS documentation have little.

4.4.1 Organizational Structure

Hannan and Freeman (1984) and Singh et al., (1986) concur that organizational structure influences the success of leadership or management practices and the eventual attainment of a firm's goals. Resistance to change, especially to TQM practices, could impede the accreditation of institutions to ISO standards. When asked whether the organizational structure adopted by the laboratories supports adoption of TQM practices, 62.9% strongly agreed, 34.3% agreed while only 2.9% had a neutral perspective about the influence of organizational structure on TQM practices. The results indicate that indeed, structure has a huge role in promoting ISO accreditation and adoption of TQM practices by medical laboratories.

Table 4.4: The Organization Structure envisaged TQM Practices

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	2	2.9	2.9	2.9
	Agree	24	34.3	34.3	37.1
	Strongly agree	44	62.9	62.9	100.0
	Total	70	100.0	100.0	

The respondents also indicated that organizational structure helps enhance customer confidence. Respondents strongly agreed (75.7%) and 24.3% agreed that organizational structure that supports adoption of TQM ensures customer confidence in the medical laboratories. This view could be based on the notion that ISO compliant institutions offer quality services that enhance customer satisfaction and thus confidence in the institutions. Table 4.5 summarizes this.

4.4.2 Structure and Customer Confidence

Table 4.5 The Current Structure help in Building Customer Confidence

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	17	24.3	24.3	24.3
	Strongly agree	53	75.7	75.7	100.0
	Total	70	100.0	100.0	

4.5.3 Environment

The environment in which an organization operates plays an integral in the trajectory that the said firm takes in terms of success or failure. Firms operate as open systems implying that they attain resources from the environment and offer products or services to stakeholders in the external environment. Zhang, Linderman, and Schroeder (2012) posit that the qualitative aspect of the environment, though at times overlooked, it plays an integral role in facilitating attainment of set objectives. Respondents were asked to indicate to what extent they agree that TQM practices depend on the business environment. The majority strongly agreed (58.6%), 8.6% agreed while 4.3% of the respondents disagreed that TQM practices depend on the business environment.

Table 4.6 Result of TQM practice depends on environment

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	3	4.3	4.3	4.3
	Neutral	6	8.6	8.6	12.9
	Agree	20	28.6	28.6	41.4
	Strongly agree	41	58.6	58.6	100.0
	Total	70	100.0	100.0	

4.5.4 People

The coordination and execution of quality product or service delivery is hinged on the people factor (Azinan, 2010). People enhance attainment of competitive advantage by adopting TQM and a culture of performance and continuous quality improvement to satisfactorily serve customers. When asked about the role of people factor in ISO accreditation and TQM practices, 65.7% strongly agreed while 32.9% agreed that people factor supports TQM.

Table 4.7 People Factor Support TQM Practice Form part of Open System to Accomplish TQM practices

People factor support TQM practice

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	1	1.4	1.4	1.4
	Agree	23	32.9	32.9	34.3
	Strongly agree	46	65.7	65.7	100.0
	Total	70	100.0	100.0	

When asked about people as part of the open system to accomplish TQM practices, 64.3% and 31.4% of the respondents strongly agreed and agreed respectively. This shows that the people factor is an important aspect in enhancing ISO accreditation and adoption of TQM practices.

People form part of open system to accomplish TQM practices

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	3	4.3	4.3	4.3
	Agree	22	31.4	31.4	35.7
	Strongly agree	45	64.3	64.3	100.0
	Total	70	100.0	100.0	

4.5.5 Training

Continuous training of staff is pivotal in equipping them with skills and competencies linked to laboratory accreditation to facilitate attainment of quality performance (Stokols, et al., 2013). Table 4.8 below shows that institutions with over 90% compliance with ISO accreditation strongly agree that they conduct on-job training on a timely basis. The mean values of the responses based on a 5-point Likert Scale are above 4.3, thus indicating that all institutions surveyed strongly agree that training is an important aspect for accreditation to take place and that their employees are equipped with latest training to improve the quality of services offered.

Table 4.8 Training and Rate of ISO Accreditation

Variable	Perception of ISO Accreditation	Mean Response	Frequency	Percentage
On-job training conducted on a timely basis	Below 50%	5.00	2	2.9%
	60-80%	4.35	20	28.6%
	90% and above	4.65	48	68.6%
	Total	**4.57**	**70**	**100.0%**
Training is crucial for accreditation to take place	Below 50%	5.00	2	2.9%
	60-80%	4.85	20	28.6%
	90% and above	4.67	48	68.6%
	Total	**4.73**	**70**	**100.0%**

Employees are well equipped with latest training	Below 50%	5.00	2	2.9%
	60-80%	4.45	20	28.6%
	90% and above	4.44	48	68.6%
	Total	**4.46**	**70**	**100.0%**

4.4.6 Teamwork

The respondents indicated that they strongly agree that teamwork is an imperative building block for ISO 15189 accreditation. Besides, they indicated that quality of service is enhanced when people work together for a common goal. These results can be shown by the mean value of more than 4 (portraying agree and strongly agree).

Table 4.9 Teamwork and ISO Accreditation

Variable	Perception of ISO Accreditation	Mean Response	Frequency	Percentage
Teamwork forms building block for QMS	Below 50%	5.00	2	2.9%
	60-80%	4.90	20	28.6%
	90% and above	4.42	48	68.6%
	Total	**4.57**	**70**	**100.0%**
Quality lies with people working for a common goal	Below 50%	5.00	2	2.9%
	60-80%	4.55	20	28.6%
	90% and above	4.56	48	68.6%
	Total	**4.57**	**70**	**100.0%**

4.4.7 QMS Documentation

Quality management systems are a solid determinant for ISO 15189 accreditation as shown by the mean score of more than 4.5 thus portraying that respondents held that QMS documentation was an imperative feature in ensuring implementation of ISO 15189 accreditation.

Table 4.10 QMS Documentation ISO Accreditation

	N	Mean
Size and type of work are all feature in QMS Documentation	70	4.5429
A well-documented QMS procures yield result	70	4.7857
Our QMS documentation procedure is fit for purpose	70	4.8000
Valid N (list wise)	70	

4.5.8 Leadership

Effective leadership influences teams in organizations to be innovative, offer quality services and result to attainment of competitive advantage. A cross-tabulation of the

relationship between ISO accreditation and leadership showed that irrespective of the rate of compliance to ISO accreditation, leadership was important in linking people with quality as well as achieving TQM. Table 4.11 below summarizes this concept.

Table 4.11 Leadership and ISO Accreditation

	N	Mean
Linking people and quality in our firm is through leadership	2	4.0000
	20	4.4500
	48	4.5625
	70	4.5143
In order to achieve TQM, organizational leadership must commit to quality in its processes	2	5.0000
	20	4.8000
	48	4.5625
	70	4.6429

4.4.9 Communication

The mean values of more than 4 (agree and strongly agree) indicate that respondents thought that communication was an integral component of promoting ISO certification in medical laboratories. Indeed, teams that work together ought to have effective communication to be able to offer quality services to clients.

4.12 Communication and ISO Accreditation

Variable	Perception of ISO Accreditation	Mean Response	Frequency	Percentage
Communication is key in QMS Implementation	Below 50%	4.00	2	2.9%
	60-80%	4.45	20	28.6%
	90% and above	4.56	48	68.6%
	Total	**4.51**	**70**	**100.0%**
Quality lies with people working for a common goal	Below 50%	5.00	2	2.9%
	60-80%	4.80	20	28.6%
	90% and above	4.56	48	68.6%
	Total	**4.57**	**70**	**100.0%**
We improve communication inside and outside our organization for proper ISO Implementation	Below 50%	5.00	2	2.9%
	60-80%	4.47	20	28.6%
	90% and above	4.44	48	68.6%
	Total	**4.46**	**70**	**100.0%**

4.5 TQM Practices

Principal component factor analysis was conducted to determine the factors that influence adoption of TQM practices by accredited medical laboratories. The sampled variables were tested for sampling adequacy and significance and both met the requirements to permit analysis.

Table 4.6.1 shows the output;

Table 4.13 KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.722
Bartlett's Test of Sphericity	Approx. Chi-Square	785.638
	Df	231
	Sig.	.000

Principal component analysis with varimax rotation was used to and 6 factors were extracted from the variables analyzed regarding TQM practices adopted by accredited medical laboratories. The 6 extracted factors accounted for 67.83% of the variance in adoption of TQM practices while the rest of the factors accounted for 32.17%. The system-based decisions ranked the highest as it explained over 30% of the variance in the adoption of TQM practices. This finding is in line with the fact that fact-do-check-act procedures needed to be adopted to ensure that risks are minimized and quality services are offered (ISO 9001:2000).

4.5.1 System-Based Decisions

Respondents indicated that their operations were based on system-based procedures and decisions. The research showed that 62.9% of the respondents strongly agreed that their institutions' processes were largely guided by system procedures to make decisions. Besides, 32.9% of the respondents agreed while only 4.3% were undecided. These facts imply that system-based decisions form an integral part of TQM practices among accredited medical laboratories.

Our processes are largely guided by system procedures to make decisions

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	3	4.3	4.3	4.3
	Agree	23	32.9	32.9	37.1
	Strongly agree	44	62.9	62.9	100.0
	Total	70	100.0	100.0	

4.5.2 Process Approach

In line with the ISO 9001, interlinked processes that result to provision of quality services through adoption of QMS were evident through the respondents surveyed in this study. The respondents strongly agreed (60%) that process approach is the basis of QMS. In addition, 35.7% agreed to this question making process approach to rank highly as a TQM practice among accredited institutions.

Process Approach is the basis of QMS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	3	4.3	4.3	4.3
	Agree	25	35.7	35.7	40.0
	Strongly agree	42	60.0	60.0	100.0
	Total	70	100.0	100.0	

4.5.3 Management Commitment

Top management teams ought to provide leadership and direction by setting visions and goals of an enterprise to ensure it accomplishes its predetermined goals. Management

commitment, according to the respondents, is at the core of TQM practices as 72.9% strongly agreed that management is committed to ISO accreditation and implementation of TQM practices. The table below summarizes the responses:

Management is in full support of accreditation and implementation of ISO 15189

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neutral	3	4.3	4.3	4.3
	Agree	16	22.9	22.9	27.1
	Strongly agree	51	72.9	72.9	100.0
	Total	70	100.0	100.0	

4.5.4 Employee Involvement and Training

When asked about whether employees understand the application of ISO standard and whether they are committed to practices that enhance implementation of ISO procedures, 58.6% strongly agreed while 34.3% agreed implying that majority of the respondents are trained about ISO accreditation and are committed to provision of quality services in line with TQM practices.

Our employees are always committed in the pursuit of ISO implementation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	2	2.9	2.9	2.9
	Neutral	3	4.3	4.3	7.1
	Agree	24	34.3	34.3	41.4
	Strongly agree	41	58.6	58.6	100.0
	Total	70	100.0	100.0	

4.5.5 Continuous Improvement

Continuous improvement was a factor that the researcher noted as vital regarding based on the respondent's views. Out of the surveyed respondents, 38.6% and 47.1% agreed and strongly agreed that the institution conducts benchmarking to identify ways of continually improving its processes and systems. The table below corroborates these assertions:

The facility does benchmarking periodically to see how been the system can improve in its processes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	1	1.4	1.4	1.4
	Neutral	9	12.9	12.9	14.3
	Agree	27	38.6	38.6	52.9
	Strongly agree	33	47.1	47.1	100.0
	Total	70	100.0	100.0	

4.5.6 Factual Based Decisions

When asked about QMS and factual based decisions, respondents strongly agreed that factual decision making was necessary to reach quality strategic outcomes in an organization. The results showed that 30% agreed while 70% strongly agreed that firms ought to factually implement decisions or procedures to facilitate efficient application of QMS in medical laboratories.

Firms must factually implement procedures to ensure QMS is efficiently applied

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	21	30.0	30.0	30.0
	Strongly agree	49	70.0	70.0	100.0
	Total	70	100.0	100.0	

4.6 Discussion of Research Findings

The author noted that accreditation of medical laboratories is influenced by an average of 8 factors including teamwork, environment, organizational structure, training communication, communication, QMS documentation and leadership. Appendix 3 provides a detailed interpretation of the variables under each of these factors and the extent to which they influence ISO accreditation.

The TQM practices adopted by accredited medical laboratories in Kenya fall into 6 main factors; systems-based decision making, process approaches, management commitment, employee involvement and training, continuous improvement, and factual-based decisions.

An integration of these composite factors enhances quality of service, client satisfaction, and overall attainment of positive outcomes by medical laboratories in Kenya.

Table 4.14: The accreditation has improved service quality and delivery

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	14	20.0	20.0	20.0
	Strongly agree	56	80.0	80.0	100.0
	Total	70	100.0	100.0	

There is a positive relationship between adoption of TQM practices and attainment of competitive advantage by accredited medical laboratories. When asked whether accreditation improves quality of service delivery, respondents strongly agreed (80%) and agreed (20%) thus implying that indeed TQM have a positive effect with respect to improving a firm's competitive edge as shown in Table 4.7.1 above.

CHAPTER FIVE: SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This section provides a summary of the research findings, conclusions, and makes recommendations in line with the study's objectives. The chapter is divided into five sections; summary of findings, conclusions, recommendations, limitations, and suggestions for further research.

5.2 Summary of Findings

This research sought to determine the TQM practices adopted by ISO 15189 accredited medical laboratories in Kenya. The author also investigated the TQM practices adopted and whether they influence attainment of competitive advantage by the medical laboratories. The study found out that 8 factors influence ISO accreditation by medical laboratories in Kenya, 6 factors are the main TQM practices embraced by laboratories in Kenya. The overall response rate from the respondents was 70% and this was considered optimal enough to reach objective findings.

The factors that influence ISO accreditation and TQM practices were identified through principal component factor analysis coupled with varimax rotation method. The variables that had an explained variance of less than 0.5 was excluded to focus on only more relevant and "stronger" components that led to the reduction of the factors for easier analysis. The 8 factors identified to have played a great role in ISO accreditation included teamwork, environment, organizational structure, training, communication, QMS documentation and leadership. These factors a statistically significant relationship with ISO accreditation and

had a high KMO index, indicating that they met the sampling adequacy test.

The factors identified to be core TQM practices adopted by ISO accredited medical laboratories in Kenya included systems-based decision making, process approaches, management commitment, employee involvement and training, continuous improvement, and factual-based decisions. These practices, according to respondents, had a positive effect on the quality and competitiveness of the medical laboratories.

5.3 Conclusions

From the preceding sections of this paper, it can be inferred that ISO 15189 accredited medical laboratories in Kenya have embraced a myriad of TQM practices. The greatest determinants of ISO accreditation include team work, the environment, communication, organizational structure, leadership, and training. These factors are significant as they ensure that there is a holistic approach in which processes and systems are coordinated in an organization. An institution that has employees channeling their efforts towards a common goal have smooth interactions among themselves and their client base. Well defined roles (through organizational structure) and effective interactions with the environment (open systems) acts as a catalyst for understanding client needs and training employees to continually respond to such needs efficiently.

To enhance QMS, employees ought to be trained implying that medical laboratories should conduct timely on-job training and utilize skills. Skilled employees would offer satisfactory and quality experiences compared to unskilled ones who could even deter clients from using a facility's services.

5.4 Recommendations

Based on the research findings and conclusions, the researcher reached at the following recommendations;

1.To facilitate quality services delivery in medical laboratories in Kenya, the said institutions ought to adopt teamwork, training, effective communication strategies, and transformational leadership. Teamwork will ensure that efforts are channeled to client satisfaction; training and effective communication would ensure employee commitment to ISO accreditation implementation, and finally ensure that they offer satisfactory services to clients.

2. Continuous benchmarking, especially between private and public medical laboratories (whether within the country or cross-national) should be adopted to compare extent of QMS and efficacy with which services are offered to clients and undertake corrective mechanisms to improve quality of services offered.

3. Medical laboratories should ensure that TQM practices are fully adopted to ensure attainment of competitive advantage; client satisfaction and positive public perception of the institutional capabilities of the said laboratories.

5.5 Limitations of the Study

The study intended to collect data from all the 32 accredited institutions but only 23 medical laboratories duly completed and returned the questionnaires. The questions could have also been answered with bias as they related to the quality of the services offered and the respondents might have aligned their responses to portray their laboratories as effective and offering quality services. The data collection process was time consuming as some

respondents took long to return the questionnaires.

Other cadres of staff such as nurses and doctors were not able to fill and send questionnaires due to limited knowledge on the subject matter. Other cadres of staff such as nurses and doctors were not able to fill and send questionnaires due to limited knowledge on the subject matter. The study relied on data collected from "insiders" implying that there could be a possibility of biasness to reflect their institutions as compliant with ISO certification and practicing TQM.

5.6 Suggestions for Further Research

Further studies should widen the scope of research to make comparisons of accredited medical laboratories in Kenya and those from other countries. A comparative study of this nature could enable policy makers to implement TQM strategies that would immensely improve the quality of healthcare services offered to the public. Further studies could consider incorporating moderating and intervening variables such as size and age of medical laboratories or private/public so as to ascertain the differences in the extent to which TQM practices are adopted by ISO 15189 medical laboratories. Further studies should be done from a customers' point of view as the current study relied on information from insiders in medical laboratories only.

REFERENCES

Akacho, E.N (2013). Factors Influencing provision of Health Care Services delivery in Kenya: A Case of Uasin Gishu Referral Hospital. *An Unpublished MBA Project*, School of Business, University of Nairobi.

Albarq, A. (2013). Applying a SERVQUAL Model to Measure the Impact of Service Quality on Customer Loyalty among Local Saudi Banks in Riyadh. *American Journal of Industrialand Business Management, 3*(8), 700-707. http://dx.doi.org/10.4236/ajibm.2013.38079.

Atieno M. (2007) *The perception of employees on ISO 9000:2000 certification in Kenyan Companies.* An unpublished business project, School of Business, University of Nairobi.

Anwar, S. etal (2012). Medical Laboratory Accreditation a benchmark of Performance, *Bangladesh Journal of Medical Microbiology* 06(01):22-28.

Arumugam, V et al, (2008). "TQM practices and quality management performance – An investigation of their relationship using data from ISO 9001:2000 firms in Malaysia." *TQM Journal 26* (8): 778-794.

Bailey. K., (2008). *Methods of Social Research*. 4th ed. NY: Simon and Schuster.

Berry, T.H. (1991). *Managing the Total Quality Transformation*. McGraw-Hill, New York, NY.

Chow-Chua, C., Goh, M. & Wan, T.B. (2002). Does ISO 9000 certification improve business performance? *International Journal of Quality & Reliability Management*, 20(8), :936-953.

Chow-chua, Mark Goh, Tan Wan, (2000). Does ISO 9000 certification improve business Performance? *International Journal of Quality & Reliability Management.*

Deming, W. E. (1989, revised 1991). *Foundation for management of quality in the Western World.* Paper presented to the Institute of Management And. Sciences, Osaka, Japan, July 1989.

Frost, R. (2011). *ISO Survey – Certifications up by 6%.'* Available: http://www.iso.org– retrieved on 23rd November 2014.

Gachuki, T. et al (2014). *Attaining ISO 15189 accreditation through SLAMTA*: A

journey by Kenya National HIV Reference laboratory, *African Journal of Laboratory Medicine.*

Hui L. and Adeli K. (2009) Laboratory Quality Regulations and Accreditation Standards in Canada. *Journal of Clinical Biochemistry* 42 :4-5 March, 2009 p. 249-255.

Irianto. D. (2005). *Quality Management Implementation: A Multiple Case Study in Indonesian Manufacturing Firms*, University of Twente, The Netherlands.

ISO 9004 Standard, (1994), "*Quality management and quality system elements", International Organization for Standardization*, Geneva, Switzerland.

Jasni, A. L., & Hazman, S. A. (2003). ISO 9000 implementation and perceived organizational outcome: The case of a service organization. *Asian Academy of Management Journal*, 8(2), 91-107.

Kawai T. & Byori R. (2004). Accreditation of Clinical Laboratories Based on ISO Standards, *The Japanese journal of Clinical Pathology*.

Kaynak, H. (2003). "The relationship between total quality management practices and their effects on firm performance. ." *Journal of Operations management* 21(4): 405-435.

Kenya Bureau of Standards (KEBS) (2007) Management Systems Handbook, Nairobi, Kenya. *Kenya National Bureau of Statistics* (2007) Kenya Facts and Figures, Ministry of Planning and National Development.

Kenya National Bureau of Statistics (2012). *The final report of the IEBC as ratified in the National Assembly Constituencies and County Assembly Wards Order*. Ministry of Planning and National Development.

Kimani, M (2008). The role of ISO certification in developing competitive advantage for organizations, *Unpublished MBA Research Project.* University of Nairobi.

Kovacs, G. (2004). Laboratory Medicine in Central and Eastern Europe: Can We Catch Up? *Jugoslov Med Biochem* **23:** 3 pp 229-304.

Kubono K. (2007). "Outline of the revision of ISO 15189 and accreditation of medical laboratory for specified health checkup." *Rinsho Byori*.(55): 1029-

1036.

Liang-Tan P., (1997), "An evaluation of TQM and the techniques for successful implementation", Training for Quality, Vol.5, No.4, Pp.150-159.

Lawley, D. N., & Maxwell, A. E. (1962). Factor analysis as a statistical method. *The Statistician*, *12*(3), 209-229.

Lewinsohn R. (1998). *Medical theories, science, and the practice of medicine*. Mayura Kusum &Panadda.S. (2005). "Quality Standards in Health Laboratories. 46(10):1261-70

Implementation in Thailand: A Novel Approach, ." *WHO Regional Office for South- East Asia*, New Delhi MSH (2012).

Ministry of Health (MOH) (2001). *Health Management Information Systems. Report for the period 1996-1999*, Kenya pp. 20-21.

Ministry of Health/The Kenya Medical Laboratory Technicians and Technologists Board (MOH/KMLTTB) (2005). *Pre-Registration General Procedures Inspection and Evaluation Check List for Bachelor of Science Medical Laboratory Sciences Training Institutions* KMLTTB/ELC/BSc. MLS Vol.1 pp 5-9.

Mugenda, O.M. and Mugenda, A.G. (1999). *Research Methods: Quantitative and Qualitative Approaches.* Acts Press, Nairobi.

Mugenda, O.M & Mugenda A.G (2003). "*Research Methods: Quantitative and Qualitative Approaches*." ACTS Press, Nairobi, Kenya.

Nyongesa, H *et al*. (2015). Perceptions of medical students towards healthcare devolution: an online cross-sectional study. *The Pan African medical Journal*, 20:355.

Oluoch K.J., (2010), Benefits and Challenges of implementing ISO 9001:2008 certification at Kenya Medical Training College: *Unpublished MBA Project: University of Nairobi.*

Kimani, M (2008). The role of ISO certification in developing competitive advantage for organizations, *Unpublished MBA Research Project* University of Nairobi.

Patel A. and Randell G., (1994), "Total Quality Management-The solution to more training in Britain. A survey of small-to-medium sized manufacturing firms

in the North England." *Training for Quality*, Vol.2, No.1, and Pp.23-28.

Panteghini M, Forest JC. *Standardization in laboratory medicine: new challenges.* Clin Chim Acta. 2005; 355:1–12 ISO 17511:2003. Metrological traceability of values assigned to calibrators and control materials. ISO; Geneva, Switzerland: In vitro diagnostic medical devices - Measurement of quantities in biological samples.

Summers, D.C.S., (2000). *Quality concepts*. New Jersey: Prentice-Hall Inc. Page 14.

Zeh C.E et al (2010). Field Experience in implementing ISO 15189 in Kisumu, Kenya, *American Journal of Clinical Pathology*.

The international Organization for standardization ISO 15189:2007(E) *Medical Laboratories Particular requirements for Competence Switzerland ISO 2007-2007*

Wakaria, N.E et al (2017). Implementing SLMTA in the Kenya National Blood Transfusion Service Lessons Learned, *African Journal of Laboratory Medicine*.

World Health Organization (WHO) (2003). The World Health Report: Quality Assurance in Health Laboratory Services. *A Status Report Project* No. ICPBCTOO

World Health Organization (WHO) (2003). *The World Health*.

Yusof, S.M. and Aspinwall, E. (2000). TQM Implementation Issues: Review and Case Study. *International Journal of Operations and Management*. Vol. 20 No. 6 pp 634-655.

Zairi, M. (2002). Beyond TQM implementation: The new paradigm of TQM sustainability. *Total Quality Management, 13*, 1161-1172.

Zima, T (2017). *Accreditation of Medical Laboratories-System, Process, Benefits for Labs*, Journal of Medical Biochemistry 36:231-237.

APPENDICES

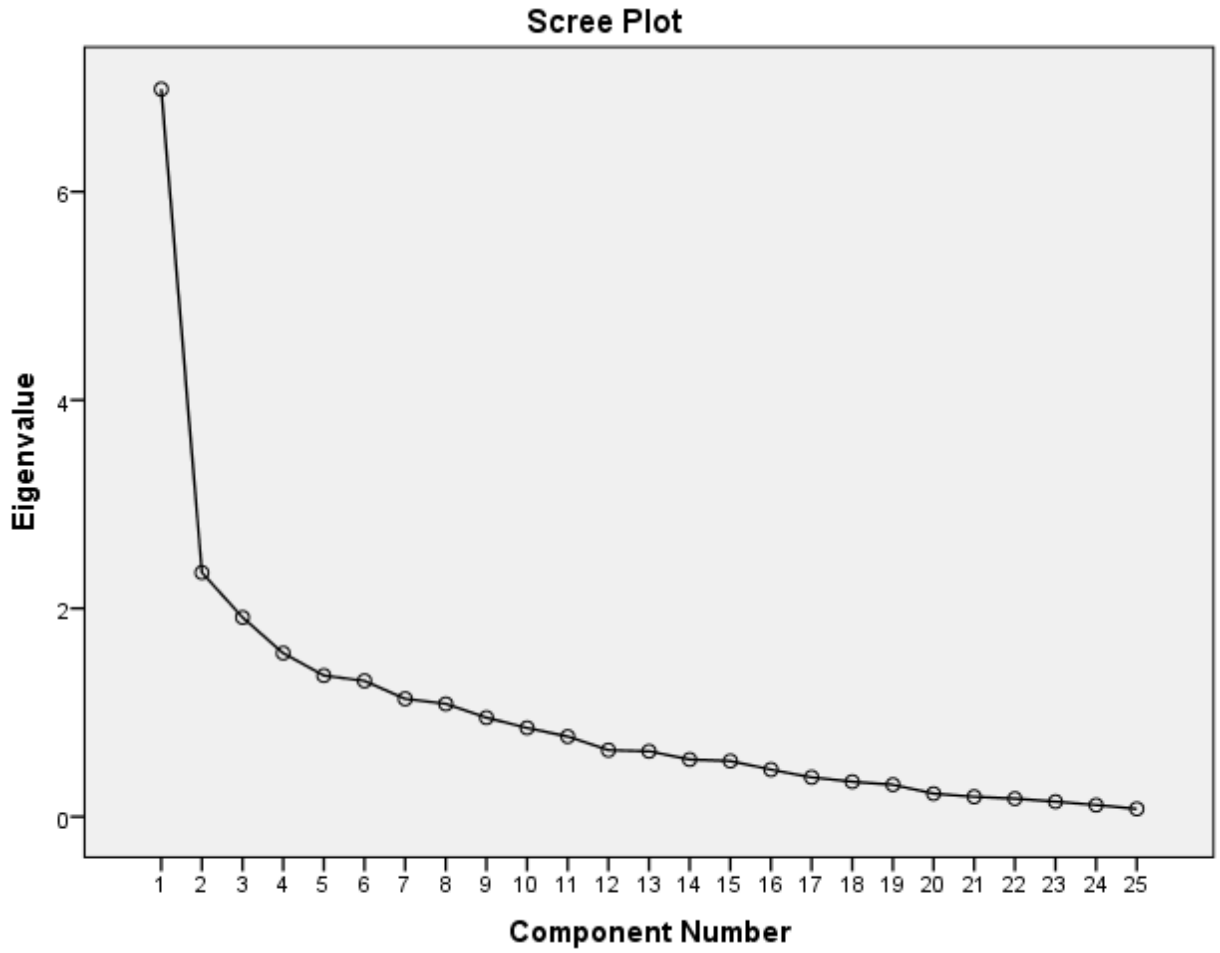
Appendix 1: Total Variance Explained

Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	6.984	27.938	27.938	6.984	27.938	27.938	2.706	10.824	10.824
2	2.343	9.373	37.311	2.343	9.373	37.311	2.579	10.314	21.138
3	1.914	7.655	44.966	1.914	7.655	44.966	2.365	9.460	30.598
4	1.570	6.282	51.247	1.570	6.282	51.247	2.343	9.372	39.969
5	1.355	5.420	56.667	1.355	5.420	56.667	2.306	9.223	49.193
6	1.304	5.215	61.883	1.304	5.215	61.883	2.281	9.124	58.317
7	1.132	4.526	66.409	1.132	4.526	66.409	1.788	7.154	65.470
8	1.083	4.334	70.742	1.083	4.334	70.742	1.318	5.272	70.742
9	.951	3.804	74.546						
10	.852	3.409	77.955						
11	.769	3.078	81.032						
12	.639	2.556	83.588						
13	.629	2.515	86.103						
14	.549	2.196	88.299						
15	.535	2.139	90.438						
16	.452	1.809	92.247						
17	.378	1.513	93.760						
18	.336	1.342	95.102						
19	.307	1.227	96.329						
20	.221	.886	97.215						
21	.191	.765	97.980						
22	.173	.691	98.671						
23	.144	.577	99.249						
24	.112	.448	99.697						
25	.076	.303	100.000						

Extraction Method: Principal Component Analysis.

Scree Plot for Factors Influencing Accreditation



- Scree plot (Figure above) is a plot of total variance associated with each factor and shows a distinct break between steep slope of large factors and gradually trailing off of rest of factors
- From scree plot, it appears that an 8-factor model is sufficient

Appendix 2: Rotated Component Matrix

ISO Accreditation: Rotated Component Matrix[a]

	Component							
	1	2	3	4	5	6	7	8
How long have you been working with the Facility?					-.244	.219	.247	.710
When was the Facility Accredited?	-.230	.332		.615		.249		
The current structure supports TQM Practices at the facility	.208	.675	-.117	.236	.113		.244	
The current structure help in building customer confidence	.293	.490	.307	.516	.128			
The organization structure envisaged TQM Practices	.325	.529	.211	.181		.101	.140	.233
The current environment is conducive for TQM Practices	.232	.466	.352	-.109	.412	.190		.395
The interaction within the environment is influence TQM practice	.146	.306	.750	.280	.120	.115		.145
Result of TQM practice depends of environment			.940	.110			.167	
People factor support TQM practice	.440		.458	.435			.212	
People form part of open system to accomplish TQM practices	.399		.167	.723				.144
Size and type of work are all feature in QMS Documentation			.124	.709			.337	-.183
A well-documented QMS procures yield result				.286		.110	.822	.210
Our QMS documentation procedure is fit for purpose	.191	.376	.189				.758	
We conduct on - job training on timely basis					.885	.119		
Training is crucial and is an element for accreditation to take place		.207			.829	-.152		-.121

Our employees are well equipped with the latest training so as to improve on our mandate of service delivery	.196	-.208	.120		.637	.429	.111	
Teamwork form building block of QMS and is magpie to process improvement	.732	.257				.175		-.148
Quality lies with people working together for a common goal	.700		.174					.123
Our employees are well engaged to attain continual improvement				.117	.361	.673		.223
Our system include feedback from customers and this help us in setting quality standards	.269		.108	.338		.606	.223	-.213
Linking people and quality in our firm is through leadership	.270	.372	.463	.120		.379	.274	-.175
In order to achieve TQM, organizational leadership must commit to quality in its processes	.683	.197		.242		.278		
Communication is key in QMS Implementation	.482	.205				.324	.133	-.494
People within organization communicate to know and understand relevance of QMS in the processes execution		.739	.188			.342	.145	-.102
We improve communication inside and outside our organization for proper ISO Implementation	.130	.306				.756		.140

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 11 iterations.

Appendix 3: Factors influencing ISO Accreditation

Factors	Variables	Summary
1	Teamwork form building block of QMS and is magpie to process improvement	
	Quality lies with people working together for a common goal	**Teamwork**
	In order to achieve TQM, organizational leadership must commit to quality in its processes	
2	The current structure supports TQM Practices at the facility	
	The organization structure envisaged TQM Practices	**Organization Structure**
	People within organization communicate to know and understand relevance of QMS in the process's execution	
3	The interaction within the environment influence TQM practice	
	Result of TQM practice depends of environment	**Environment**
4	When was the Facility Accredited?	
	People form part of open system to accomplish TQM practices	**Undefined**
	Size and type of work are all feature in QMS Documentation	
5	We conduct on - job training on timely basis	
	Training is crucial and is an element for accreditation to take place	**Training**
	Our employees are well equipped with the latest training so as to improve on our mandate of service delivery	
6	Our employees are well engaged to attain continual improvement	
	Our system include feedback from customers and this help us in setting quality standards	**Communication**
	We improve communication inside and outside	

	our organization for proper ISO Implementation	
7	A well-documented QMS procures yield result	
	Our QMS documentation procedure is fit for purpose	**QMS Documentation**
8	How long have you been working with the Facility?	
	Linking people and quality in our firm is through leadership	
	In order to achieve TQM, organizational leadership must commit to quality in its processes	**Leadership**
	Communication is key in QMS Implementation	
	People within organization communicate to know and understand relevance of QMS in the processes execution	
	We improve communication inside and outside our organization for proper ISO Implementation	

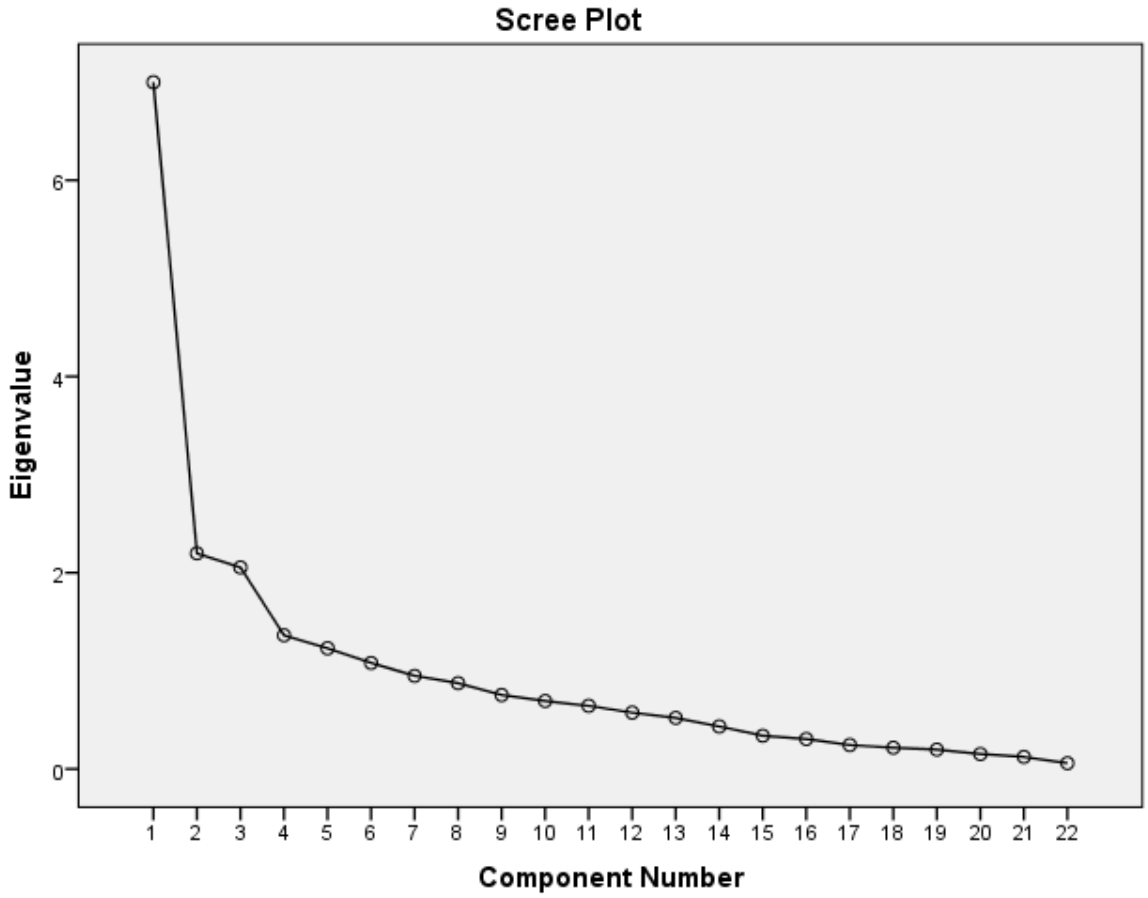
Appendix 4: Factors for TQM Practices

Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	6.999	31.813	31.813	6.999	31.813	31.813	2.931	13.322	13.322
2	2.197	9.987	41.800	2.197	9.987	41.800	2.882	13.100	26.422
3	2.054	9.336	51.136	2.054	9.336	51.136	2.707	12.304	38.727
4	1.362	6.192	57.329	1.362	6.192	57.329	2.359	10.725	49.451
5	1.230	5.589	62.918	1.230	5.589	62.918	2.322	10.556	60.007
6	1.081	4.914	67.831	1.081	4.914	67.831	1.721	7.824	67.831
7	.949	4.315	72.147						
8	.874	3.974	76.121						
9	.754	3.428	79.549						
10	.692	3.147	82.696						
11	.643	2.924	85.620						
12	.574	2.609	88.229						
13	.521	2.367	90.596						
14	.433	1.968	92.564						
15	.339	1.539	94.103						
16	.305	1.388	95.491						
17	.244	1.109	96.600						
18	.216	.984	97.584						
19	.197	.897	98.481						
20	.152	.693	99.174						
21	.122	.557	99.730						
22	.059	.270	100.000						

Extraction Method: Principal Component Analysis.

Scree Plot for TQM Practices



- Scree plot (Figure above) is a plot of total variance associated with each factor and shows a distinct break between steep slope of large factors and gradually trailing off of rest of factors
- From scree plot, it appears that a 6-factor model should be sufficient.

TQM Practices: Rotated Component Matrix[a]

	Component					
	1	2	3	4	5	6
The accreditation has improved service quality and delivery		.558	.406	.155		
Management is in full support of accreditation and implementation of ISO	.105	.152	.700	.185	.140	
There is need to implemented ISO standard in all levels of management.	.242	.659	.155	.243	.106	
There is timely and periodical management review of ISO implementation.	.366		.665	.325	.112	
Identified areas of noncompliance are often addressed in the firm for further progress.		.318	.623			
Corrective actions are done periodically to comply with the requirement.		-.119	.645		.225	.506
The facility does benchmarking periodically to see how been the system can improve in its processes.	.125		.147	.165	.826	

Our staff understand the application of ISO standard in their daily activities.			.330	.854		.172
Our employees are always committed in the pursuit of ISO implementation		.132		.905	.110	
Staff suggestions are take taken into perspective in the course of implementing ISO.	.250	.286		.597	.322	
Process approach is the basis of QMS.	.363	.389	.213		.565	
Our processes and procedure conform with the QMS System		.718	.221		.392	.189
Our processes add value to the overall aim of QMS.	.227	.741		.128	.289	.229
Our processes are largely guided by system procedures to make decisions.	.529		.526	-.206		
Our system based decision is largely recognized by entire firm for progression	.759	.120	.284		.251	
Our system is executed at its finest when supported by system standard and procedures.	.512	.490	.323			

Performance based administrative system form foundation to decisive decision making backed by QMS.		.186		.249	.709	.347
Our system capable of assessing and observing the strategic outcome.	.480	.131	.141		.411	.266
Firms must factually implement procedures to ensure QMS is efficiently applied	.121	.150	.111	.170	.100	.780
Stakeholders' decision is an important fragment of quality management system.	.319	.512	-.234			.549
The ISO Standard implementation covers the need and requirement of stakeholders.	.580	.224			.336	.439
Our processes takes into account the stakeholder perspective all the time	.807	.163		.156		.140

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.
a. Rotation converged in 13 iterations.

Appendix 5: TQM Practices Adopted by Accredited Institutions

Factors	Variables	Summary
1	Our processes are largely guided by system procedures to make decisions	
	Our system based decision is largely recognized by entire firm for progression	**Systems-based Decision**
	Our system is executed at its finest when supported by system standard and procedures	
	The ISO Standard implementation covers the need and requirement of stakeholders	
	Our processes takes into account the stakeholder perspective all the time	
2	Accreditation has improved service quality and delivery	
	There is need to implemented ISO standard in all levels of management	**Process Approach**
	Our processes conform with QMS	
	Our processes add value to the aim of QMS	
	Stakeholders decision is an important fragment of quality management system	
3	Management is in full support of accreditation and implementation of ISO	
	There is timely and periodical management review of ISO implementation	
	Identified areas of noncompliance are often addressed in the firm for further progress	**Management Commitment**
	Corrective actions are done periodically to comply with the requirement	
	Our processes are largely guided by system procedures to make decisions	
4	Our staff understand the application of ISO standard in their daily activities	
	Our employees are always committed in the pursuit of ISO implementation	**Employee Involvement & Training**
	Staff suggestions are taken into perspective in the course of implementing ISO	
5	The facility does benchmarking to see how been the system can improve in its processes	
	Process approach is the basis of QMS	**Continuous Improvement**
	Performance based administrative system form foundation to decision making backed by QMS	
6	Corrective actions are done periodically to comply with the requirement	

	Firms must factually implement procedures to ensure QMS is efficiently applied	**Factual-Based Decision**
	Stakeholders decision is part of QMS	

Dear Sir/Madam

Appendix 6: Questionnaire

We wish to ask you to participate and offer us information for this research project which would take at most 10 minutes to fill. You are not needed to provide your name as the data provided will be used for expanding academic course.

Section A. Demographic Information

1. Laboratory Name----------
2. Name of the Accreditation Body----------
3. What is your position at the Laboratory----------?
4. How long have you been working with the Facility?
   i. 0-1 years [ ] iv) Over 11 Years [ ]
   ii. 2-4 years [ ]
   iii. 5-10 years [ ]
5. When was the Facility Accredited?
   i. 0-1 Year ago [ ] iv) Over 11Years [ ]
   ii. 2-4 Years ago [ ]
   iii. 5-10 Years ago [ ]
6. When is the rate of ISO Compliance to TQM Practices?
   i. Below 50% [ ]
   ii. 60-80% [ ]
   iii. 90% and above [ ]

Section B: Factor influencing the TQM Practices

7. To what extent do you agree with the following statements?

Use the key 1-5 for this sections as outlined below.

5. Strongly agree 4. Agree 3. Neutral 2. Disagree 1. Strongly disagree

Statements	**5**	**4**	**3**	**2**	**1**
Organization structure					
The current structure supports TQM Practices at the facility					
The current structure help in building customer confidence					
The organization structure envisaged TQM Practices					
Environment					
The current environment is conducive for TQM Practices					
The interaction within the environment is influence TQM practice					
Result of TQM practice depends of environment					
People					
People factor support TQM practice					
People form part of open system to accomplish TQM practices					
Fit for Purpose QMS Documentation					
Size and type of work are all feature in QMS Documentation					

A well-documented QMS procures yield result						
Our QMS documentation procedure is fit for purpose						
Training						
We conduct on - job training on timely basis						
Training is crucial and is an element for accreditation to take place						
Our employees are well equipped with the latest training so as to improve on our mandate of service delivery						
Teamwork						
Teamwork form building block of QMS and is magpie to process						
Quality lies with people working together for a common goal						
Our employees are well engaged to attain continual improvement						
Leadership						
Our system include feedback from customers and this help us in setting quality standards						
Linking people and quality in our firm is through leadership						
In order to achieve TQM, organizational leadership must commit to quality in its processes						
Communication						
Communication is key in QMS Implementation						
People within organization communicate to know and understand relevance of QMS in the processes execution						
We improve communication inside and outside our organization for proper ISO Implementation						

Section C: TQM Practices

8. To what extent do you agree with the following statements?

Use the key 1-5 for this sections as outlined below.

5. Strongly agree 4. Agree 3. Neutral 2. Disagree 1. Strongly disagree

Statements		**5**	**4**	**3**	**2**	**1**
Customer Focus						
The accreditation has enabled the facility to fulfil customer needs						
Customer needs monitoring has informed the organization's milestone						
The accreditation has improved service quality and delivery						
Management Commitment						
Management is in full support of accreditation and implementation of						
There is need to implemented ISO standard in all levels of management						
There is timely and periodical management review of ISO						
Continual Improvement						
Identified areas of noncompliance are often addressed in the firm for further progress						
Corrective actions are done periodically to comply with the requirement						

The facility does benchmarking periodically to see how been the system can improve in its processes					
Employee Involvement					
Our staff understand the application of ISO standard in their daily activities					
Our employees are always committed in the pursuit of ISO implementation					
Staff suggestions are take taken into perspective in the course of implementing ISO					

Process Approach					
Process approach is the basis of QMS					
Our processes and procedure conform with the QMS System					
Our processes add value to the overall aim of QMS					
System Approach					
Our processes are largely guided by system procedures to make decisions					
Our system based decision is largely recognized by entire firm for progression					
Our system is executed at its finest when supported by system standard and procedure					
Factual Based Decision					
Performance based administrative system form foundation to decisive decision making backed by QMS					
Our system capable of assessing and observing the strategic outcome					
Firms must factually implement procedures to ensure QMS is efficiently applied					
Stakeholders Decision					
Stakeholders decision is an important fragment of quality management system					
The ISO Standard implementation covers the need and requirement of stakeholder					
Our processes takes into account the stakeholder perspective all the time					

THANK YOU FOR YOUR RESPONSE

The general purpose of the study was to establish the Total Quality Management Practices in ISO 15189 Accredited Medical Laboratories in Kenya.

ORIGINALITY REPORT

10%	7%	4%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Berger, Darlene. "Ancient times through the 19th century.(A Brief History of Medical Diagnosis and the Birth of the Cl", Medical Laboratory Observer, July 1999 Issue Publication	1%
2	chss.uonbi.ac.ke Internet Source	1%
3	orsea.net Internet Source	<1%
4	Submitted to University of Nairobi Student Paper	<1%
5	Submitted to Asia Pacific University College of Technology and Innovation (UCTI) Student Paper	<1%
6	Submitted to Mount Kenya University Student Paper	<1%
7	Submitted to International University -	

48	Library Hi Tech News, Volume 30, Issue 8 (2013-10-19) Publication	<1%
49	survey.cirprotec.com Internet Source	<1%
50	repo.pusikom.com Internet Source	<1%
51	docobook.com Internet Source	<1%
52	ir.knust.edu.gh Internet Source	<1%
53	thesportjournal.org Internet Source	<1%
54	bura.brunel.ac.uk Internet Source	<1%
55	www.readbag.com Internet Source	<1%
56	gbata.org Internet Source	<1%
57	ebeec.teikav.edu.gr Internet Source	<1%
58	Yelamanchili, Rama Krishna. "RELATIONSHIP BETWEEN LEADER BEHAVIOR AND SUBORDINATE INTENTION TO REMAIN:	<1%

	MEDIATING ROLE OF CRITICAL THINKING AND EMPOWERMENT.(Report)(Statistical data)", Academy of Strategic Management Journal Publication	
59	isdkandy.org Internet Source	<1%
60	annuairetsubasa3.free.fr Internet Source	<1%
61	pezzottaitejournals.net Internet Source	<1%
62	ec.europa.eu Internet Source	<1%
63	eps.udg.es Internet Source	<1%
64	repository.um.edu.my Internet Source	<1%
65	Simani, Wamalwa Lucy. "TQM PERSPECTIVES UNDER THE COMPETITIVE STRATEGIES AND THE ORGANIZATION PERFORMANCE IN KENYAN MANUFACTURING SECTOR.(Total quality management)(Report)", Academy of Strategic Management Journal Publication	<1%

	VNUHCM Student Paper	<1%
8	27.251.28.59:8080 Internet Source	<1%
9	www.ijsrp.org Internet Source	<1%
10	Submitted to Universiti Utara Malaysia Student Paper	<1%
11	Submitted to Kenyatta University Student Paper	<1%
12	Submitted to University of Northumbria at Newcastle Student Paper	<1%
13	Submitted to De Montfort University Student Paper	<1%
14	www.aacb.asn.au Internet Source	<1%
15	Submitted to Asia e University Student Paper	<1%
16	Chan, Albert PC, and C M Tam. "Enhancing Project Performance through the Introduction of Safety Programs", Architectural Science Review, 2001. Publication	<1%

17	Submitted to South Bank University Student Paper	<1%
18	Submitted to University of Huddersfield Student Paper	<1%
19	www.aph.gov.au Internet Source	<1%
20	Submitted to Greenville College Student Paper	<1%
21	siteresources.worldbank.org Internet Source	<1%
22	www.math.kent.edu Internet Source	<1%
23	ebiz.bm.nsysu.edu.tw Internet Source	<1%
24	Submitted to St. Patrick's College Student Paper	<1%
25	ethesys.library.ttu.edu.tw Internet Source	<1%
26	Submitted to Napier University Student Paper	<1%
27	Submitted to Quest International University Perak Student Paper	<1%

28	www.gdufs.biz Internet Source	<1%
29	Submitted to Higher Education Commission Pakistan Student Paper	<1%
30	ir.amu.ac.in Internet Source	<1%
31	www.kingspanpanels.nl Internet Source	<1%
32	espace.curtin.edu.au Internet Source	<1%
33	ro.ecu.edu.au Internet Source	<1%
34	www.scribd.com Internet Source	<1%
35	pdfs.semanticscholar.org Internet Source	<1%
36	soar-dev.wichita.edu Internet Source	<1%
37	cchdo.ucsd.edu Internet Source	<1%
38	erepository.uonbi.ac.ke Internet Source	<1%

39	www.soberit.hut.fi Internet Source	<1%
40	Submitted to Glyndwr University Student Paper	<1%
41	citeseerx.ist.psu.edu Internet Source	<1%
42	Submitted to University of Ulster Student Paper	<1%
43	Submitted to Florida Memorial College Student Paper	<1%
44	Submitted to Argosy University Student Paper	<1%
45	Submitted to Arts, Sciences & Technology University In Lebanon Student Paper	<1%
46	Sewe, Risper, Jane Mwangi, David Turgeon, Mary Garcia, Elizabeth T. Luman, and Mamo Umuro. "Attaining ISO 15189 accreditation through SLMTA: A journey by Kenya's National HIV Reference Laboratory", African Journal of Laboratory Medicine, 2014. Publication	<1%
47	etd.aau.edu.et Internet Source	<1%