CHALLENGES FACED BY ORGANIZATIONS SEEKING ISO 9001 CERTIFICATION: A CASE OF KENYA MEDICAL RESEARCH INSTITUTE

BY

MUTINDA PATRICK BENIDO
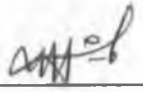
A RESERCH PROJECT REPORT SUBMITTED IN PARTIAL FULFILLMENT FOR THE REQUIREMENTS OF THE DEGREE OF MASTER OF ARTS IN PROJECT PLANNING AND MANAGEMENT

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DECLARATION

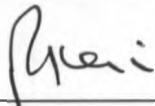This project report is my original work and has not been presented for a degree in any other university.

Signature _____ Date ___19/07/2012___

Mutinda Patrick Benido

L50/64290/2010

This project report has been submitted for examination with my approval as University Supervisor.

Signature _____ Date ___19/7/12___

Dr. Peter Keiyoro

Department of Educational Studies

University of Nairobi

DEDICATION

I dedicate this work to my family, relatives and friends for their support and encouragement.

ACKNOWLEDGEMENT

First and foremost, I thank the Lord almighty for His grace that has been sufficient while undertaking my studies. In undertaking this project, I have benefited enormously from the support of many people. In this regard, I would like to thank my supervisor Dr. Peter Keiyoro who provided invaluable support, the lecturers for their guidance and my colleagues for their moral support and encouragement.

I owe a special note of gratitude to my employer (KEMRI) for partial financial support, creating a conducive environment for learning and according me flexibility in my work schedule that enabled me to pursue academic endeavors.

Finally, I want to acknowledge with special thanks the contribution of my wife Kaari, for her thoughtful critiques and sustained support in making this piece of work a reality. To my children Amara and Leroy as well as the rest of the family, I appreciate your enormous patience in tolerating the inconveniences caused by my academic pursuits.

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LIST OF ACRONYMS

HOD	Head of Department
HRM	Human Resource Management
ISO	International Organization for Standardization
JIT	Just In Time
KEMRI	Kenya Medical Research Institute
MRP	Material Requirement Planning
PDCA	Plan - Do – Check – Act
QM	Quality Management
QMS	Quality management systems
TQM	Total Quality Management

ABSTRACT

Management of quality is a paramount in all organizations. The ISO 9001 standard defines a management system framework which includes the necessary and sufficient elements for the systematic management of quality. A review of literature revealed a major gap in research in the area of quality management system. Information garnered from this study will lead to knowledge transfer and could be used to reduce the severity of challenges encountered during QMS implementation and consequently lead to acquisition of ISO 9001 certification.

The researcher used mixed methods approach to draw from the strengths and minimize the weaknesses of quantitative and qualitative research approaches. A two-stage sampling procedure was used. The sample size comprised 110 employees out of the 550 KEMRI employees which represent a sample size of 20 percent of the total population. A tool kit containing a self administered questionnaire and structured in-depth interview guide was used.

The findings of this study summarize the results from the questionnaires and in-depth interviews. This study ascertained that Kenya Medical institute in its pursuit to acquire ISO 9001 certification encountered key challenges namely lack of commitment by management, inadequate human and financial resources, massive documentation requirements and negative organizational culture.. The study also established other challenges that the organizations was facing in its quest to get ISO certification such as high cost of hiring consultants, complexity of process, lack of understanding of ISO requirements, large size of the organization, inadequate training of staff on QMS, lack of technical knowledge and ineffective internal communication, low quality awareness and low level involvement of top management and employees.

Conclusion drawn from the findings of the study was that it was imperative for top management to commit itself to adoption of Quality Management System within an organization as this would play an integral role in its overall outcome. Any organization seeking to implement ISO 9001 QMS must be aware of the costs involved in both implementation and maintenance aspects of the system but also it is important to quantify the expected benefits. Development of a good organizational culture is a fundamental pre-requisite to the achievement of quality The ISO 9001 standard is highly documentation-driven and requires that all documentation be updated to reflect all its system requirements. The study confirmed that ISO certification process is dependent on the nature of the organization. Size of an organization, interaction of processes and structure of the organization should be factored when planning and executing a QMS.

CHAPTER ONE
INTRODUCTION

1.1 Introduction

This chapter highlights the background to the study, statement of the problem, research objectives, research questions, justification of the study, limitation and delimitation of the study.

1.2 Background to the Study

Quality management systems have become increasingly present in the life of organizations. Their survival is mainly linked to the quality of activities of these organizations. The way in which each organization focuses on quality issues may vary according to their sectors and the environment where it carries its activities and of course the organizations own strategies. There are various ways of focusing on quality and one of the options is to approach the quality management using the ISO 9001 standard practice (Farooqui and Ahmed, 2009).

Researchers widely agree that ISO 9001 is one of the most well – known standards dealing with quality management systems (Gustafison et al, 2001). The process of implementing ISO 9001 can be indeed demanding and many organizations encounter challenges during and after the process of ISO certification. The innate difficulties organizations encounter will affect the implementation of the ISO 9001 processes. Logically, some processes will be strongly affected by these challenges and conceived as being more challenging to establish than others. The degree of perceived difficulty with the implementation of a specific process might show causality with the underlying motivations to apply for ISO certification.

The implementation of a quality management system is a strategic choice of an organization and its design is influenced by the organization's purpose, structure, and size, the products or services presented and its processes. It is optional for an organization to select the individual standards for implementation as well as certification by a third party typically regarded as certification bodies. Certification itself is not a mandatory requirement in implementing ISO 9001. Certification to ISO 9001 simply means that the QMS is formally recognized by an accredited certification body. An accredited certification body is an organization certified by a

national body to perform audits to a standard and to register the audited facility as meeting these requirements for a given standard. Organizations may opt for first, second or third party certification. First party certification involves a firm auditing itself against ISO 9001 standards. Second party certification means that a customer audits its supplier. Third party certification involves a "qualified" national or international standards or certifying agency serving as the auditor. The International Accreditation Forum (IAF) in conjunction with accreditation bodies in each country control the certification process (Gyam, 2007).

After the main certification, assessments of ISO organization are supposed to be instituted periodically say at least once every year. ISO has published more than 15,000 standards but for this study, ISO 9001, Quality Management Systems, (QMS), has been focused for its requirements. ISO 9001 standard has the latest version, 2008. The drivers for ISO 9000 certification vary from one company to another and from one organization to another though the basic themes supporting ISO 9001 are mainly customer satisfaction and continual improvement. According to Youngless (2000), there are two major objectives when implementing a QMS system based on ISO 9001. The first is to achieve quality assurance of the products and services and the second is to enhance customer satisfaction.

In the last two decades, there has been continuous increase in the number of countries which have implemented ISO 9001 as their national quality standard and a continued rise in the number of companies within these countries who have identified ISO 9000 standard as a strategic management tool essential for effective control and best business practice (Farooqui and Ahmed 2009).

Since its advent, ISO 9001 standard has become a research topic within management journals for example study by Tsim et al (2002), Withers and Ebrahimper (2001), and Zandry (2005). Some of the notable themes within their studies pertain to company's motives and benefits of ISO 9000 implementation, as well as various key success factors. ISO 9001 is one of the basic standards in the ISO 9000 family which contain the quality management system requirements. Firms which adopt ISO 9001 can have their quality management system assessed and upon compliance to the requirements of the standard, the firm is granted ISO 9001 certification.

1.3 Statement of the problem

In spite of the various measures that have been put in place to counter challenges faced by organizations implementing QMS which would eventually lead to ISO 9001 certification, the consequential level of success has been insignificant. Empirical evidence shows that the implementation of ISO 9000 meets many different challenges in organizations throughout the world (Fotopoulas and Psomas, 2009). Study by Mersha, (2007) indicate that most of these failures result from lack of top management support and commitment, the resistance of employees towards change, lack of understanding of the ISO requirements, inadequate training and quality knowledge, low quality awareness and culture, the allocation of personal responsibilities and constraints on resources such as manpower time and finance. Another study by Sampio, Saraiva and Rodriguez, (2001) suggest that the major challenges faced in implementing ISO 9000 are the low level involvement of top management and employees, a poor flow of information, resistance to new responsibilities, lack of technical knowledge and difficulty in the communication of new tasks. However there is a much smaller literature base focusing on challenges encountered by organization seeking ISO certification in Kenya.

KEMRI started its journey towards certification in 2006 but the progress has been slow. A key question would be why organizations take longer time to implement quality management system than others and also why implementation of QMS varies from organization to organization. This in turn raises further questions on what the challenges to adoption of the quality management system in Kenya could be. There was need therefore for a study to be carried out focusing on ISO certification process in KEMRI in order to establish distinct challenges affecting the process and determine distinct measures that if put in place would ensure successful QMS implementation and ISO certification as well.

1.4 Purpose of the study

The purpose of this study was to establish the challenges faced by organizations seeking ISO 9001certification, a case study of Kenya Medical Research Institute.

1.5 Research objectives

The general objective of this study was to investigate the challenges that are faced by organizations seeking ISO 9001 certification and in particular Kenya Medical Research Institute (KEMRI)

The specific objectives were to:

i) Establish whether management commitment influences acquisition of ISO 9001 certification in organizations, precisely in KEMRI.

ii) Determine whether organizational culture in KEMRI affected the process of ISO 9001 certification.

iii) Investigate if documentation requirements ISO 9001 standard influences acquisition of ISO 9001 certification in KEMRI.

iv) Establish whether availability of resources affected the acquisition of ISO 9001 certification in KEMRI.

v) Make recommendation on ways of minimizing challenges faced by organizations seeking ISO 9001 certification.

1.6 Research questions

In order to obtain comprehensive information to support the conclusion on the main research objectives, the following research questions were derived.

i) How does management commitment influence acquisition of ISO certification in KEMRI?

ii) Do organizational culture affects acquisition of ISO certification in KEMRI?

iii) Can documentation requirements influence the ISO certification process in KEMRI?

iv) Does availability of resources affect the acquisition of ISO certification in KEMRI?

v) What measures have to be undertaken to minimize the challenges faced during ISO 9001 certification in organizations?

1.7 Significance of the Study

There has been a growing demand in the implementation of quality management system such as ISO 9001:2008, ISO 15189 and ISO 13485 in organizations and in particular research institutions. ISO 9001 is broadly accepted as a research tool for quality management systems.

While there has considerable research in the field of Quality Management Systems (QMS), the study on the challenges encountered by organizations seeking ISO 9001 certification is insignificant. Knowledge of these challenges will provide organizations with an opportunity to take measures to lower their severity, making them easier to overcome and thereby reducing the degree of difficulty perceived in the implementation of ISO 9001.It was therefore important to examine why implementation of Quality Management systems is slow or fails in some organization and what reasons could make them not acquire ISO certification.

1.8 Justification of the Study

As the popularity of the ISO certification has grown, the field of certifications has received a lot more attention in the media. Due to this, an increased awareness of the ISO 9000 standards and its importance in today's trading is acknowledged in this study. With a deepening knowledge base of the subject, an interest to investigate the questions and challenges with the certification process emerged. New organizations are seeking ISO 9001 certification each year with an increase in the number of new certifications being granted. The knowledge gained from this research will enable organizations seeking certification to prioritize and focus their resources on areas that will provide the most benefit. This will help organizations efficiently implement quality management systems and provide guidance to quality managers for customizing their approach to quality system certification.

1.9 Limitations of the Study

Quite a number of quality management systems exist with different components and potentially different implementation successes factors. This study was limited to the quality management system described by ISO 9001 standard.

1.10 Delimitation of the study

The study focused on ISO 9001 standard because it is very understandable and if implemented would enable any organization adopt and operate an efficient quality management system created to certify that the organization provide goods and services that satisfy customers. It is also the most commonly published standards by international organization for standardization, (ISO).

1.11 Assumptions of the Study

During the study the researcher made the following assumptions:-

i)   Motivation and corporate culture of the entire organization was homogenous such that all employees behave the same way and respond similarly to the implementation effort.

ii) The participants were honest and gave correct information.

iii) The target population would be representative of the entire population and questionnaires would be returned on time

1.12 History and Profile of KEMRI

Kenya Medical Research Institute (KEMRI) is a state corporation established through the science and technology amendment Act of 1979 as the national body responsible for carrying out research in Kenya. The Act spells out the mandate and responsibilities of KEMRI as follows:

i)   To carry out research in human health

ii) To cooperate with other research organizations and institutions of higher learning on matters of relevant research and training.

iii) To liaise with other relevant bodies within and outside Kenya carrying out research and related activities.

iv) To disseminate and translate research findings for evidence based policy formulation and implementation.

v)   To cooperate with the institutes responsible for health the National Council for Science and Technology and Medical advisory Research Committee on matters pertaining to search policies and priorities.

vi) To do all such things as appear necessary, desirable or expedient to carry out its functions.

KEMRI has several reasons for implementing ISO 9001 in order to organize the company and improve on research. The objective of getting ISO 9001 certified is to theoretically improve both internal business practices and relations with supplier and both present and future customers.

1.13 Quality management systems in Kenya Medical Research Institute.

The Kenya Government has instituted reforms in the health sector that are part of the wider economic reforms in the health sector that are geared towards rapid economic recovery and improved quality of life in Kenya. The reforms engender organizational transformation of state corporations. This means that the state corporations have to re-examine the way they are structured and make necessary changes in order to improve governance and delivery of service structures. Health is both a basic human right and a perquisite to all forms of human progress. The key challenge for health research in Kenya is to improve the quality of health and human life in Kenya and the region. This is the critical reason for KEMRI embarking on quality management systems.

Research is by its very nature an expensive and demanding undertaking. It requires a highly trained and specialized manpower, high sustainable levels of financial resources, patience and steadfastness to realize the desired goals. KEMRI has twelve research and coordinating Centres with nine in Nairobi, one in Kisumu, one in Busia and one in Kilifi. The institute also works closely with several research collaborators locally, regionally and internationally.

Quality management system in KEMRI was introduced in KEMRI in the year 2006 but it was not until the year 2009 that the search for ISO certification that was enforced. A quality management department became operational headed by a Management Representative. The organization of the QMS department in KEMRI is summarized in the figure 2.3 below.

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┌─────────────────────────────────────┐
│   Management Representative (MR)     │
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                 │
                 ▼
        ┌──────────────────┐
        │  ISO Coordinator │
        └──────────────────┘
          │              │
          ▼              ▼
┌──────────────────┐  ┌──────────────────┐
│  QMS Coordinator │  │  QMS Coordinator │
└──────────────────┘  └──────────────────┘
          │              │
          ▼              ▼
┌──────────────────┐  ┌──────────────────┐
│  ISO Centre      │  │  ISO Centre      │
│  Representatives │  │  Representatives │
└──────────────────┘  └──────────────────┘
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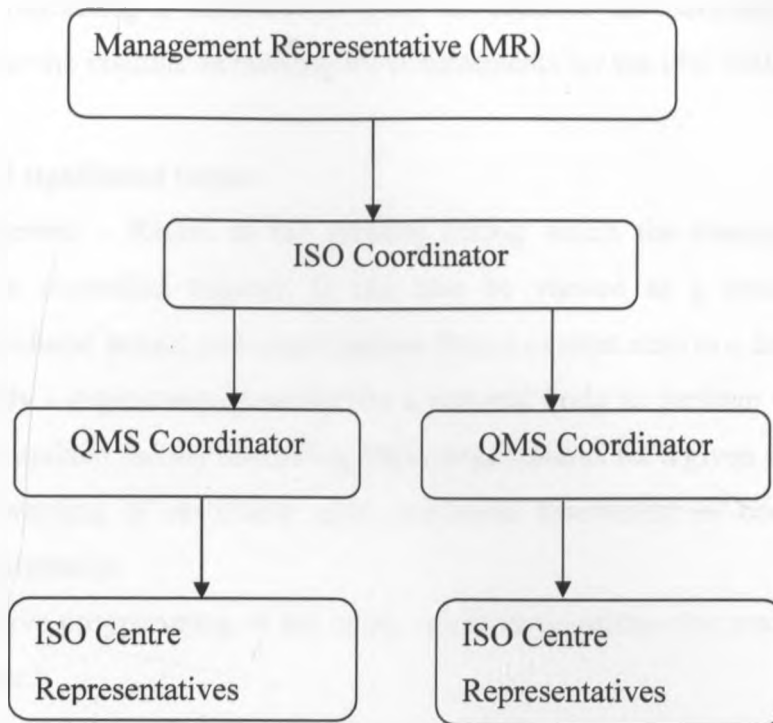
Figure 3: Organogram for the QMS Department in KEMRI

Considerable effort has been put towards implementation of quality management system in KEMRI, for example, the QMS office developed a comprehensive roadmap indicating the timelines of all proposed actives and outlining those responsible for the activities as well. A budget was also drawn with details of the projected cost for each activity during the certification process. The institute went on to engage a consulting firm to give guidance in the certification process. The Consultants conducted a pre-assessment audit to determine the extent of preparedness for the ISO certification. A major campaign was undertaken to sensitize all KEMRI staff on ISO 9001 process and the exercise was successfully completed. Mandatory ISO documents such as quality manual, Quality policy statement, standard operating procedures, and work instructions were developed and harmonized during a document review workshop. A team consisting of centre representatives from the various centers was formed and trained as internal auditors. Their main role was to spearhead ISO certification process in their Centers and assist in conducting of internal audits. Several internal audits have been conducted and the institute is in

the process of contracting a certification body to conduct the necessary audits and upon compliance register the institute as meeting the requirements for the ISO 9001:2008 standard.

1.14 Definition of significant terms

Change Management – Refers to the process during which the changes of a system are implemented in a controlled manner. It can also be viewed as a structured approach to transitioning individuals, teams, and organizations from a current state to a desired future state.

Certification Body - organization certified by a national body to perform audits to a standard and to register the audited facility as meeting these requirements for a given standard

Certification- Awarding of certificate upon successful assessment of compliance to quality management requirements.

Culture – Collective programming of the mind, which distinguishes the members of one human group from another.

International Organization for Standardization (ISO) – A non-governmental organization, established to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services.

Organizational Culture – Is mainly created and maintained into existing frameworks by the founders and the leaders of an organization through their value system.

Quality Management Systems (QMS) - Is defined as a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization.

Total Quality Management (TQM) – Refers to a set of management practices throughout the organization, geared to ensure the organization consistently meets or exceeds customer requirements, places strong focus on process measurement and controls as means of continuous improvement.

1.15 Organization of the study

The study was organized into five chapters. Chapter one gave an introduction to the study while chapter two examined existing literature on the challenges faced by organization seeking ISO certification. Next a description of study methodology was given, precisely, sampling procedure,

data gathering and analyzing techniques (chapter three). Chapter four focused on analysis and interpretation of data while chapter five contained conclusion and recommendations made by the researcher.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

The chapter focuses on the existing literature on quality management systems, the concept of total quality management including its components and the main challenges faced by organization seeking ISO certification.

2.2 Quality Management Systems

The international organization for standardization (ISO) is an international standard setting body composed of representative from national standards bodies and produces world-wide industrial and commercial standards called ISO standards. The word ISO comes from the Greek word "ISOS" which means equal. The reasoning is that this reflects the aim of the organization to equalize or standardize its processes.

As trade has become more globalized, the level of competition and the pursuit of competitive advantages have become more crucial for business survival (Hill, 2010). The increasingly hectic market condition emphasizes the value of being active in the search for the right supplier, which leads to the importance of having a basis of comparison between companies: a standard. This standard creates a basis of evaluation in the choice of a supplier (Wahid and Coner, 2009)

Together with globalization, the integration among businesses is a central factor in the growing importance of standardization. Previously companies have been involved in a larger part of the value chain, but today companies are more integrated with each other and are more familiar with the concept of outsourcing and specialization. The trade of components and the use of semi manufactures between businesses has become more common now than producing everything yourself. In this context relationships between companies are becoming more important which creates a need for standardization between them (Lundmark, 2006)

The need for a reference point has prompted the emergence of different standards that businesses may choose to be certified in. Certification communicates that certain requirements are fulfilled.

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One of the world's largest developer and publisher of standards is the international organization for standardization, ISO (Poksinska, 2006).The most commonly published standards from this body are the ISO 9000 focusing on quality management and the ISO 14000 standard focusing on environmental issues. This study will focus on the ISO 9000 standards which have become one of the most widely used management tools in the world today with almost a million certified organizations worldwide.

The reasons for implementation can be divided into two different categories; external and internal. The external reasons are for example customer requirements, corporate image and marketing purposes while the internal reasons focus on efficiency and improvements of the organization. These factors, both external and internal, may influence the motivation for the implementation affecting the outcome. The public opinion about the effectiveness of the ISO 9001 varies: some say that the certificate is a waste of time and others believe that it a good foundation for quality management. Recent research has shown that a large part of the companies using the standard chose to implement it due to external reasons such as customer requirements (Gyam, 2007). Hill (1991) concluded in her study that the benefits of the standard differ based on whether reasons for certification were external or internal. If businesses only implement ISO 9000 due to external reasons such as customer requirements, the only benefits achieved with the certification will be the possibility to show certificate to others.

Quality gurus like Joseph Juran (1950's) Edward Deming (1950's) and Philip Crosby (1980's) have put forth several approaches to improve company's performance. These approaches are embodied in a set of quality management practices known as total quality management (TQM) Different approaches have been adopted for the introduction of quality management in organizations such as self assessment   and external assessment of institutions, accreditation and certification systems and different models of TQM (Wiklund et al, 2003). Quality management (QM) presents a strategic option and an integrated management philosophy for the organizations which allows them to reach their objectives effectively and efficiently and to achieve sustainable competitive advantage (Gyam, 2007)

The appeal for benefits upon ISO 9001 certification has contributed to the rapid expansion of the newest ISO 9000 standard, ISO 9001:2008 With over one hundred thousand new applicants annually, ISO 9001:2008 has become a truly global standard for quality assurance. As at December 2006, the standard had been adopted by close to nine hundred thousand companies residing in 170 counties. The numbers are summarized in figure 1.

World results	Dec. 2002	Dec. 2003	Dec. 2004	Dec. 2005	Dec. 2006
World total	167 124	497 919	660 132	773 867	897 866
World growth	122 736	330 795	162 213	113 735	123 999
Number of countries/ economies	133	149	154	161	170
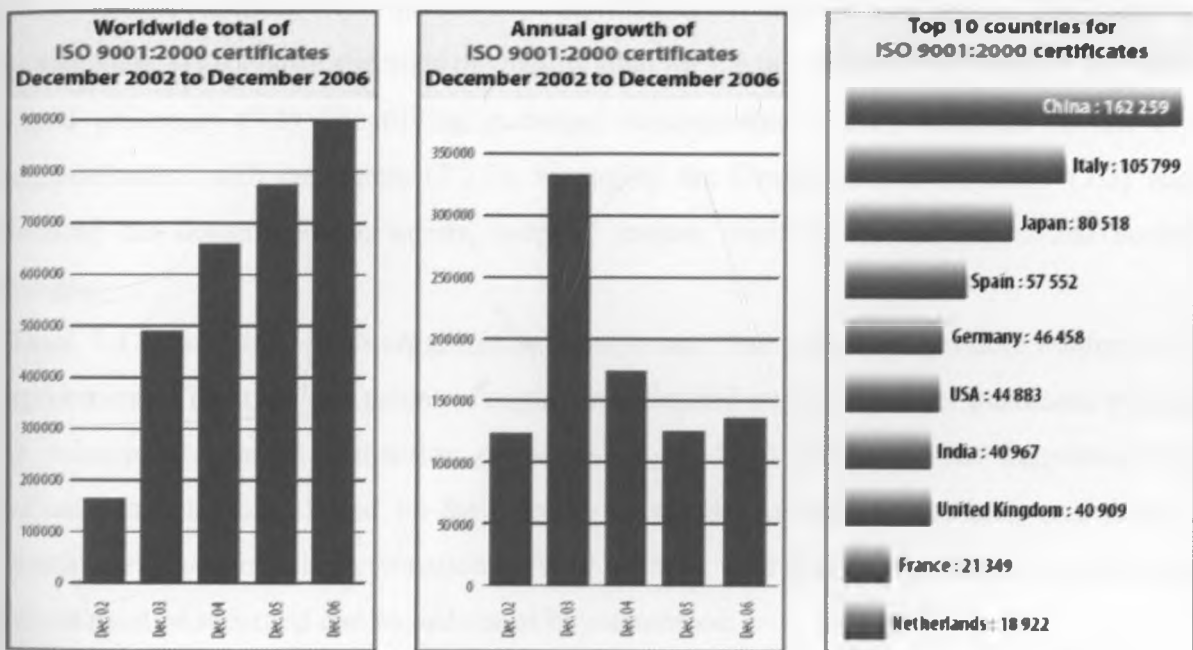
Figure 1: Statistics indicating the impressive growth of ISO 9000 (Source: Withers and Ebrahimpour, 2001).

2.3 Specifications of ISO 9001:2008 Standard

The overall requirements of ISO 9001:2008 are stipulated in eight clauses as below:-

Clause 1 – Scope

Clause 2 – normative references

Clause 3 – Terms and definitions

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Clause 4 – Quality Management System: This clause requires the intent of documentation required on organizations starting from a Quality Policy, Quality manual and records appropriate for the organization.

Clause 5 – Management Responsibility: This clause specifies the requirements from the top management in terms of top management commitment, appointing a management representative, establishing Quality policy, objectives and conducting management reviews.

Clause 6 – Resource Management: This clause specifies the requirements to plan the resources, training of employees and maintenance of records, including the work infrastructure and work environment.

Clause 7.0 – Product Realization: This is the most important umbrella clause, where the sub-clauses can be excluded from the scope of certification, if such clauses are not applicable to the organization. This clause specifies the quality plan for the products and services (7.1), Customer related processes (7.2), identifying customer requirements (7.2.1), Contract review (7.2.2), communication with customers (7.2.3), managing the Design & Development (7.3) such as planning the design, design inputs, outputs, review, verification, validation and control of changes.

Clause 7.4 Purchasing - The organization must ensure that purchased product conforms to the requirements. The type and extent of control will depend on the impact of purchased product on the subsequent product realization processes or the final product. The suppliers must be evaluated and selected based on their ability to supply conforming products and criteria for selection, evaluation and re-evaluation must be defined. The results of evaluations and necessary actions must be recorded and records must be maintained.

Clause 7.5 Product and service provision- This clause specifies the requirements on the production or service set up to plan, schedule, instruct, calibrate, validate and preserve the products to ensure conformity to customer requirements.

Clause 7.6 – this clause requires the calibration of monitoring and measuring equipments, including the software validation.

Clause 8 – Measurement, Analysis and Improvement- The organization must plan and implement measurement, monitoring, analysis and improvement processes needed to monitor the customer satisfaction level, plan and conduct internal audits, control of non-conforming products and manage the corrective and preventive action and estimate their effectiveness.

ISO 9001 is a very understandable standard and the crucial reason for implementing a QMS is to keep organizations of all sizes, from private or public sector to adopt and operate an efficient quality management system created to certify that the organization as well as provide goods and services that satisfy customers (Hill, Self and Roche, 2012). Understanding can defined as the organizations comprehension of the standard influencing both the amount of recourses required for the implementation, the employee commitment as well as top management commitment. A lack of understanding means that the organization might be confronted with unexpected requirements, demanding additional investments both in time and money. Tang and Kam, (1999) and Ashrafi, (2008) indicated that the implementation of quality management system in developing countries has failed due to the lack of understanding of QMS. The failure of some organizations to gain the certificate is caused by lack of understanding, on the part of top management of the ISO standard requirements and of the implementation process.

2.4 The concept of Quality Management.

The term quality has been derived from the Latin word "quails" meaning "what kind of" with a wide variety of meanings and conditions attached to it. Quality is a difficult and illusive term to define; it has a wide variety of meanings and implies different things to different people. It has thus been defined with different perspectives and orientations according to the person, the measure applied and the context within which it is applied. There seems to be no consensus of the definition but they all deal either with the products or the services producing these products/services. From the perspective of the consumers or users, the product or service based definition is more useful. From the perspective of the organization providing goods/services, the process perspective is more useful (Sangeeta and Banure, 2004).

Quality management is a method for ensuring that all the activities necessary to design, develop and implement a product or service are effective and efficient with respect to the system and its performance (Deming, 1986). Quality management, (QM) system, also called total quality management, evolved from many different management practices and improvement process.

Youngless (2000) argued that rather than trying to inspect the quality of products after they have been completed, TQM instills a philosophy of doing the job correctly the first time. Some

experts say that it takes up to 10 years to fully realize the results of implementing quality management. According to Ashrafi (2008), total quality management refers to management methods used to enhance quality and productivity in organizations. TQM is a comprehensive system approach that works horizontally across an organization involving all departments and employees and extending backwards and forward to include both suppliers and clients/customers (Bernard 1999). TQM provides a framework for implementing effective quality and productivity initiative that can increase the profitability and competitiveness of organizations (Deming 1992)

TQM is only one of many acronyms used to label management systems that focus on quality other acronyms that have been used include CQI (Continuous Quality Improvement), SQC (Statistical Quality Control), QFD (Quality function Deployment and TQC (Total Quality control)

2.5 Total Quality Management Components

TQM like any other processes and systems exiting in an organization is composed of various components and in order to reach to its aim, uses different tools. In order to assess the way of implementation of TQM in an organization, indicators are needed. These indicators are primary and basic tools that are used by TQM to improve the quality of organization's product services include:

Top manager's commitment: The commitment of senior managers is necessary and essential means to perform comprehensive quality programs successfully. Senior managers are responsible for determining quality aims and strategies and necessary sources to implement TQM programs (Deming 1982: Garvin, 1987; Leonard and Sasser, 1982; Saraph et al, 1989; Ahire et al 1996)

Focusing on customer: Recent studies indicate that TQM cannot exist without focusing on customers. There should be systems and processes in the organization that continuously endeavor to meet customers' needs, raise their satisfaction and provide new information (Dean and Bowen, 1994: Anderson et al, 1995: Black and porter, 1996: Ahire et al, 1996). It is also

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worth mentioning that more emphasis is on the criterion than other quality criteria (Collier, 1992).

Relationship with suppliers: Deming was the first to defend the idea of decreasing the number of suppliers and creating long term relationship with them (Black and Porter 1992). Research indicate that organizations which select their suppliers according to non-liquidity and non-financial criteria and supervise them, gain remarkable improvement in financial and operational activities (Ittner et al, 1997).

Participation of all staff: As it was mentioned, primary endeavors in Japan for improving quality resulted in the formation of quality offices that relied basically upon active participation of all member of the organization (Lagrosen, 2003). Many researchers emphasize that in order to improve the quality of an organization's products services, its responsibilities should be scattered into all units of the organization (Black and porter, 1996; Deming, 1982: Garvin, 1987).

Staff training: TQM includes concepts and activities in many fields (e.g. management, marketing, psychology and engineering) and it is obvious that staff should get formal and specified trainings about concepts and tools of comprehensive quality in order to act perfectly. In addition to training quality concepts, perfect performance and staff satisfactions are obtained whenever the staff get periodical technical training in addition to formal training. This can improve their skills that are useful and valuable both for themselves and for the employers (Black and porter, 1996; Sila and Ebrahimpour 2005).

Staff empowerment: empowerment is defined as "training and authorizing staff whatever they need to manage their activities". Empowering staff encourages them to take the responsibility of their activities and be more active to find solution for the confronting problems (Glasman, 1995).

Continuous improvement tool: there are specific tools for measurement and controlling deviations in the production process. Their primary forms are the approach of satisfaction processes control (SPC) which was first offered by Shwart and Deming. Afterwards many

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researchers emphasized that SPC is an effective way to improve quality continuously especially for corporations that perform new quality activities in their organization (Glasman, 1995).

Improving designs and process: contains tools and activities that manage and control design and production systems to keep and improve quality in the organization. Improving design and process includes designing and controlling methods of performance, maintenance planning, Zero defect and improving process by analyzing the problem and controlling designing process (Motwani1996). Interaction of the above components is represented in figure 2.1 below

ISO 9001:2000 MODEL

CONTINUAL IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM

MANAGEMENT RESPONSIBILITY

CUSTOMERS

RESOURCE MANAGEMENT

MEASUREMENT, ANALYSIS AND IMPROVEMENT

SATISFACTION

CUSTOMERS

REQUIREMENTS

INPUT

PRODUCT REALIZATION

PRODUCT

OUTPUT

Quality Management System Model
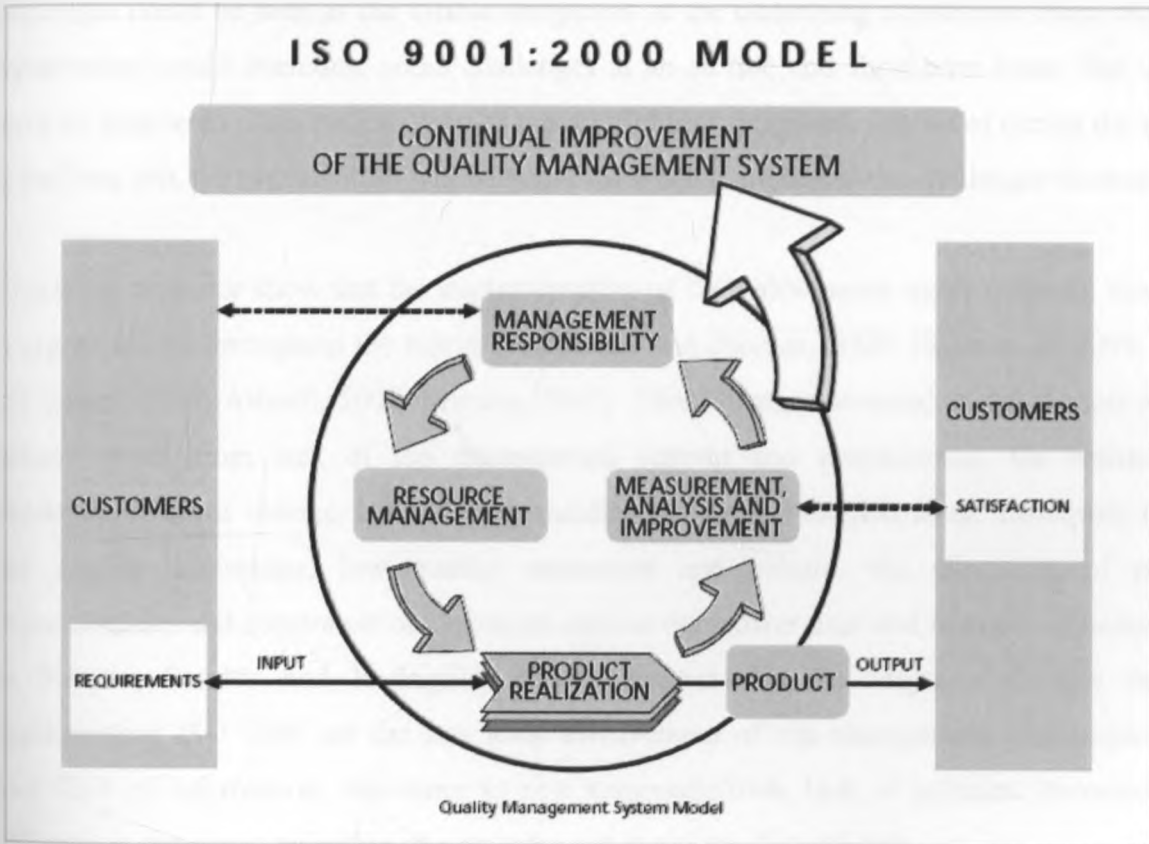
Figure 2: The ISO 9001:2000 Model 9000 (Source: Withers and Ebrahimpour 2001).

2.6 Challenges to ISO certification

Dory and Schier (2002) recognize that the philosophy of quality inherent in ISO standards requires employees and managers within an organization to work together to identify and resolve these challenges. These challenges have become greater as the benefits of further quality

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programme implementation have become more apparent. It is important for all organizations to understand these challenges before and during QMS implementation so that the quality system can be successfully introduced and embedded in the organization. Unfortunately the conditions causing these challenges are not very explicit, nor visible. Organizations might not to be aware of the facts that these conditions are playing within the organization. For instance, resources tend not to be a problem, until an organization run out of them. The conditions should be seen as the root cause of the difficulties being faced during the implementation of ISO 9000. The organization will find it difficult implementing certain processes, rather than others. These challenges could be seen as the visible symptoms of the underlying conditions. Even though an organization could overcome some challenges at an ad hoc and short term basis, this will not serve its long term plans but can seen as merely fighting symptoms instead of curing the disease. In the long run, the organization will be better off when it addresses the challenges themselves.

Empirical evidence show that the implementation of ISO 9000 meets many different challenges in organizations throughout the world (Fotopoulas and Psomas, 2009: Gader et al, 2009: Wahid and Coner, 2009: Ashrafi, 2008: Mersha, 2007) This literature revealed that that most of these failures result from lack of top management support and commitment, the resistance of employees towards change, lack of understanding of the ISO requirements, inadequate training and quality knowledge, low quality awareness and culture, the allocation of personal responsibilities and constraints on resources such as manpower time and finance . Another study by Sampio, Saraiva and Rodriguez, (2001) suggest that the major challenges faced in implementing ISO 9000 are the low level involvement of top management and employees, a poor flow of information, resistance to new responsibilities, lack of technical knowledge and difficulty in the communication of new tasks and functions for each job.

The conditions influencing organizations during the implementation process have been examined in various articles. Chin et al, (2000), Dzus and Syes (1993), Olsen (1994), and McCullough and Laurie (1995) have identified lack of top management support and understanding of ISO requirements as the root cause of failures in surveillance audits. Nwanko, (2000) states that." there are critical issues which must be resolved (e.g. clear strategic intent, leadership

commitment, supportive organizational arrangements) for systematic quality assurance to work in an optimal manner

In this section the researcher will describe and identify the most common challenges faced by organization when they seek certification

2.6.1 Management Commitment

The identification of top management commitment as one of the key condition which determines whether an organization is able to successfully implement ISO 9000, emphasizes the importance of the organization's motivations to opt for ISO certification. Top management may be more likely to take an active part in the implementation process in an internally motivated organization, whereas, if it is imposed on a company for external reasons, management might be less willing to participate or may feel forced to do so. Without this essential element, implementation would generally lead to unsatisfactory results.

Quality gurus like Deming, Juran and Crosby mentioned that top management commitment is one of the most important factors impacting on the success potential of any QMS in any organization. Top management's responsibility for providing commitment, leadership and appropriate support to the technical and human processes are important in the Quality management implementation. Top management is the determinant of successful quality management. It has to provide the necessary leadership to motivate all the employees (Farooqui and Ahmed, 2009: Lundemark and Westlius, 2006).

Senior management role is key to the success of the QMS implementation. Starting from the establishment of the quality policy and project specific quality plan right through the implementation including employee training, monitoring and until the final auditing, the management has a greater responsibility without which the success of the programme is unrealistic. The key input for this process as stated above shows that at the earlier stage of the project, the management focuses all its efforts in incorporating the customer's requirements, which is available in many forms including briefing and contractual requirements. This in turn is compared with the capability of the organization as to whether the organizational resources are

capable to undertake the activities to achieve the client's requirements. The company QMS becomes the key path to achieve the end goal and throughout the project several co-ordination meetings are organized by the management to develop plans and solutions, review progress and facilitate the functioning of the whole QMS programme .The key output of this process is project program and cost programme established in tune with the project quality plan. This together with the other outputs including the service of the management, suggestions and other tangible contributions become input to both the processes quality planning and resource management.

Reasons that can account for the lack of commitment include lack of awareness of the benefits of quality management system and implementation of a quality system because of market pressures. Haeri, (2005) addressed lack of strong and capable leaders as the main problem faced organizations. Leadership is a key issue because it is one of the most important factors of total quality management (Haeri 2005). One of the important roles of management leadership is increasing quality but it can also improve profit, satisfy customers and promote market share throughout the organizations. The role of management leadership in an organization is to develop quality circles and motivating employees to take part in quality improvement. Rad, (2006) cited numerous organizations and firms that had difficulties in performing TQM. According to Rad (2006), lack of strong leadership was one of the main failures in TQM implementation.

2.6.2 Availability of resources

Resources can be defined as the amount of money and time available for the implementation process. They have a direct influence on the understanding of the standard by management and in addition, on top management commitment. More resources allow for better training and more thorough study of the standard, both contributing to a deeper understanding of the standard. If management possesses sufficient resources for the implementation process, this will have a positive effect on its commitment.

Resources management includes identifying, analyzing deploying and monitoring the resources required to undertake the project activities. Right from the early stage of the project, resources are analyzed taking into account the project and cost of the programme. The company capability becomes key information that answers many questions such as resources availability within the

organization and checking the available resources for the necessary skills required to undertake the task. It is commonly understood that inefficient resources analysis leads to poor productivity and quality in the later stages of the project. Project management team or the project manager is the key person responsible for this task. Proper recruitment procedures must be adopted to recruit the right personnel and or hire right equipment and other infrastructure at right time. Resources being capable of undertaking multiple tasks are key to the successful completion of the project, therefore, all necessary measures must be undertaken to develop the resources capable of handling different trades. Quality plan, contractual specifications and other statutory requirements must be considered in the resource management process so that from the results of that standard, it should be able to convince its employees of its importance and raise awareness of its benefits.

2.6.3 Organizational Culture

An organization with a quality culture can be defined as one having "clean values and beliefs that foster total quality behavior". Quality culture is the main component in a successful total quality management plan. Many experts such as Crosby, Deming and Juran indentified the role of quality culture as suitable and important for organizations. There are many elements that defines quality culture namely leadership, training, team working, supplier quality management, process management etc. Prajogo et al. (2005) identified the factors contributing to total quality management as customer focus, Human Resource management (HRM) and Management leadership, Continuous improvement and teamwork. Prajogo also cited that quality culture in organizations leads to successful total quality management. According to Zadry, (2005) management and leadership have a vital role in influencing the quality culture of an organization. The role of this factor is preparing and motivating employees to continuously struggle for continuous improvement and customer satisfaction. This study also mentioned that in organizations whereby employees cannot be successful in implementing process, then the management needs to apply more effort to improve the firm's quality culture

An understanding of culture in an organization can thus offer insight into individual and group behavior and leadership. Furthermore, it can help to explain not just what happens in an organization but why it happens. Companies view culture as something to be influenced to

achieve organizational goals of productivity and profitability. Attempts to change the culture of an organization, may meet with varied levels of success. It has been argued that for an organization to realize the value of implementing quality practices, it must have a culture that is capable of fully supporting the implementation process. Tongwe and Rodriguez, (2008) addresses organizational culture by questioning whether organizational success is tied to its clients' success. The senior leadership's constant role modeling of these principles and the creation of supportive environment to live them is necessary for the organization to reach its true potential.

Mersha, (2007) defined resistance as "employee behavior that seeks to challenge" disrupt or prevent change from taking place. It is a response to feeling threatened that result in anxiety. Resistance to change is closely associated with 'fear of loss' and 'fear of the new' (Youngless, (2000). Resistance to change result in people that are complacent and do not function at their full potential (Mersha, 2007). It can therefore be argued that first line managers need to create and maintain an environment and organizational culture where people are empowered and accountable.

Resistance may perhaps come out due to lack of interest, misunderstanding and different assessment of the need for or desirability of the change on the part of the individual. A study by Tsim et al (2002) and Moser and bailey indicated that the implementation of the ISO 9001 led to employee resistance because it was seen as a lot of extra work, particularly with regard to the preparation of documents outlining all activities at every operational level. Furthermore, a lot of employees resist adopting new changes in the organization because they have been working with the same current system and do not want the challenge of learning new skills.

Staff resentment and resistance can derail the implementation effort if ISO 9001 certification is perceived as non-value added. Understanding that organizations accomplish their work through a network of processes would enable organizations to realize the synergy between ISO 9001 and total quality. The aim is to understand the interfaces and processes that cut across departments. Quality is best achieved by the simultaneous application of product quality standards and quality systems standards

2.6.4 Documentation requirements

Documentation and control can be defined as the written instructions used by an organization to establish its quality management system and the monitoring and measuring of its processes. The ISO 9000 standard requires, as a means to assure quality, that the organization codifies its procedures and increase its monitoring and measuring. Increased monitoring and measuring will increase the administrative burden placed on employees and management. When this becomes excessive, it will temper both employee and management commitment

The documentation of a quality management system in any organization is affected by the complexity in the interaction of its processes and by the competence of its staff. The ideal QMS documentation, according to the new standard is represented in the quality manual, which identifies quality policy and objectives. It also contains QMS procedures that describe the interrelated processes, work instructions and other related documents.

A commonly mentioned disadvantage with the implementation of the ISO 9001 certificate is the immense paperwork and the bureaucracy problem. The control of the fulfillment of the requirements may be perceived as a waste of time and merely a way to accomplish the mandatory requirements agreed on (Poksinska, 2006).

This result is not surprising since the ISO 9001 standards are highly documentation driven and require that all documents be updated to reflect any system change. However, the negative impact of documentation cost is consistent with Ashrafi (2008), Heras et al (2002) and Withers and Ebrahimpour (2001) who reported increased cost as result of ISO certification. For example, lack of available information on development of ISO mandatory documents resulted in high fees charged by international ISO consultants

2.7 Theoretical frameworks

The theory on institutionalism and the various quality systems frameworks will be discussed in this section

2.7.1 Institutionalism

Institutional theories have during recent years become popular as a way to explain the behavior of organizations. An example of institutionalism is when an organization adapts to the norms due to market pressures. These pressures are often external, but they may also come from within the organization or from the top management. One way for a company to adapt to these market pressures has become to certify and standardize their business to get market approval. In other words, institutionalism illustrates the impact of following formal as well as informal rules instead of acting rationally in the decision making process. Furthermore, this theory describes how a corporation affects their surroundings and is influenced by others (Simmons & white, 1999).

The early institutional theory, emerged as a reaction to the classical way of viewing organizations in the economic and political scientific approaches, and emphasizes the importance of change including the surrounding's influences on the occurring transformations of the organizations (Simmons & White, 1999).

2.7.2 Quality system frameworks

The following are examples of management systems or frameworks in common use: ISO 900 Quality Management System standard, The Malcolm Baldridge National Quality award criteria, the capability maturity model, six sigma, and total quality, management (TQM) or the plan-Do-Check –Act cycle.
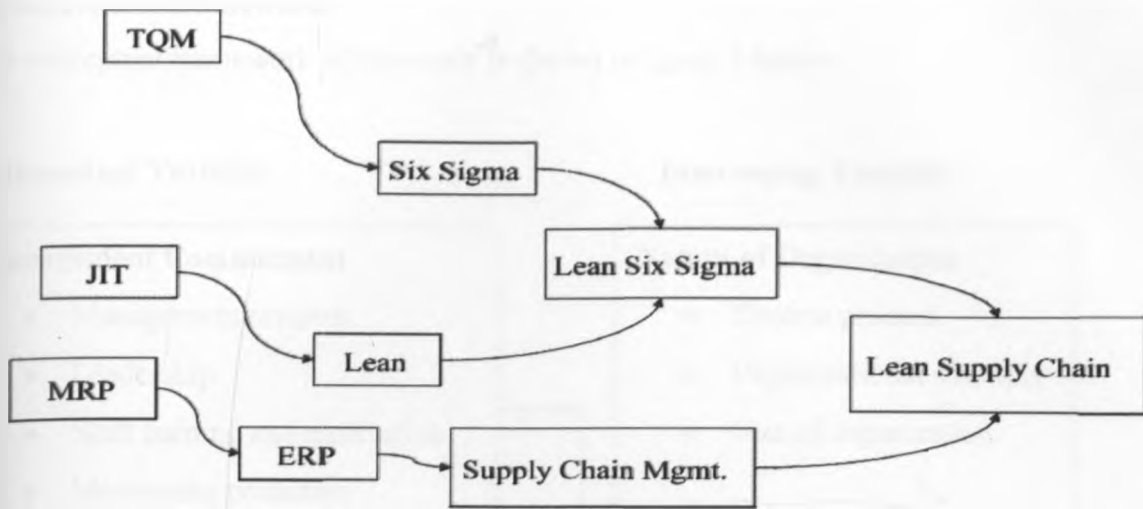
Figure 3: Evolution of Quality Initiatives

According to researchers, the aforementioned quality management frameworks have yielded various degrees of success for organizational that have implemented them. Many researchers have focused on the effects of (TQM) or other quality initiatives. However ISO immerged as the de facto worldwide standard for quality system certification (Brisco et al, 2005). The cost and the benefits of implementing a quality management framework can be substantial. In the 1990s many organizations demanded that their suppliers have a certified quality management system despite the financial and time considerations involved. In 1997, the typical cost of preparing a medium-sized firm for ISO 9001 certification was $250,0000 (Simmons & white, 1999), yet another survey of 1,700 certified firms in the US and Canada identified that firms reported average saving of $179.000 per year from certification (Buttle, 1997) obtaining management system certification can take up to a year of preparation.

Given its widespread use and economic implication for industry, the ISO 9001 management system framework must be best way to maintain their relevancy. Studying the implementation process will lead to new insights, which may help to evolve future versions of ISO 9000. In addition, as companies emerge from the global financial crisis of 2008 issues relating to globalism and global competeveness are important to study (Buttle, 1997).

2.8 conceptual frameworks

The conceptual framework of this study is shown in figure 3 below.

Independent Variable

Intervening Variable

Management Commitment
- Management reviews
- Leadership
- Staff training and motivation
- Monitoring processes

Nature of Organization
- Diverse process
- Organizational structure
- Size of organization

Availability of resource
- Human resource
- Available funds
- Infrastructure

Dependent Variable

ISO 9001 Certification
- Period taken to be ISO certified
- Diverse challenges identified

Organizational Culture
- Level of participation
- Staff attitudes
- Staff responses

Document requirements
- Different documents prepared
- Quantity of documents prepared
- Size of documents
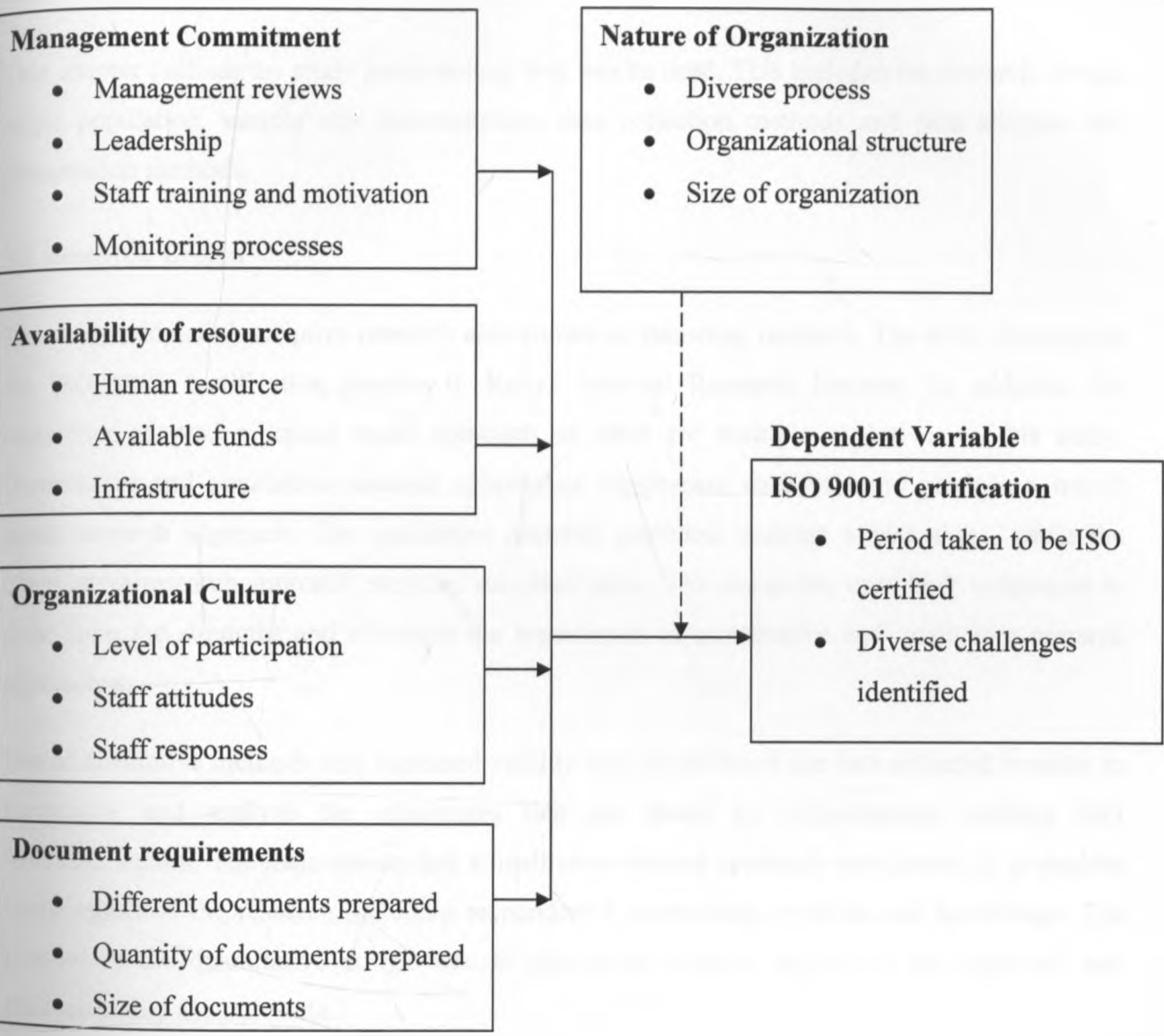
Figure 5: Conceptual Framework

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CHAPTER THREE
RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the study methodology that was be used. This includes the research design, target population, sample size determination, data collection methods and data analysis and presentation methods.

3.2 Research Design

The study adopted descriptive research also known as statistical research. The study focused on the ISO 9001 certification process in Kenya Medical Research Institute. In addition, the researcher adopted a mixed mode approach as there are multiple objectives to this study. Quantitative and qualitative research approaches supplement each other to produce a mixed mode research approach. The qualitative research provided in-depth explanations, while the quantitative research approach provided statistical data. The researcher used both techniques to draw from the strengths and minimize the weaknesses of quantitative and qualitative research approaches.

Use of qualitative methods also increased validity and reliability of the data collected in order to investigate and analyze the challenges that are faced by organizations seeking ISO 9001certification. The main reason that a qualitative method approach was chosen is to explore every aspect of the research including respondent's experiences, opinion and knowledge. The purpose of the quantitative design was to summarize positive aspects of the approach and produce highly accurate data.

3.3 Target Population

The target population of this study comprised Kenya Medical Research Institute employees from all cadres. KEMRI has a total of 550 employees based at various administrative units within Nairobi. These employees include senior managers, middle managers, (HODs, Section heads &

supervisors) and non management staff (clerical staff and support staff) who are currently working in the institute.

3.4 Sampling procedure

The sample utilized included employees of Kenya Medical Research Institute based at various administrative units in Nairobi. The sample size was 110 employees out of the 550 KEMRI employees which represent a sample size of 20 percent of the total population. The study used a two-stage sampling procedure. Stratified sampling technique was used to identify employees in the senior, middle (managers, junior managers, supervisors) and non-management (staff and support staff) levels. Random samples were taken proportionately from each stratum in order to select a sample size of 110 respondents out a population of 550 employees. Simple random sampling assisted to minimize bias when dealing with the population sample.

3.5 Methods of Data Collection

A tool kit comprising of a questionnaire and face-to-face interview guide was used since they were the best tools for this type of study that seeks to establish the causal relationships between the process of seeking ISO certification and challenges associated to it. The questionnaire was prepared based on an extensive review of the literature on implementation of quality management systems. The questionnaire consisted of questions covering the following aspects: profile of the organization, certification requirements, structural changes and training for certification, reasons for ISO 9001 adoption, role of staff in the process and challenges encountered during implementation. Data collection tools were piloted and suggestions made before finalizing the questionnaire. A five-point scale was used to answer most of the questions in the survey.

The study utilized a self-administered questionnaire and face-to-face interview techniques as well as access to secondary data. Questionnaires were distributed to non-management, senior and middle management staff of KEMRI. The questionnaire was structured to allow both open-

ended and close-ended questions. Face-to-face interviews were conducted using a semi-structured questionnaire that was administered by the interviewer.

3.6 Data Analysis

Different data analysis methods were used for different data collected. Quantitative data collected using semi structured questionnaires was analyzed using SPSS statistical software. Prior to analysis, a codebook for the various quantitative variables was prepared. The code book was based on the numbering system of the questionnaires. This was significant in isolating the quantitative data from the qualitative data from each of the structured questionnaires. For qualitative data, which was mainly gathered from the key informants' in-depth interviews and to a lesser extent from the open-ended questions in the questionnaires, the interview notes were first transcribed and trends in the data noted.

3.7 Validity and reliability of the instrument

On the validity of instruments, the researcher carried out a pilot study to appraise soundness of the items and to estimate time required to answer the items. The pilot study covered 20 members in the sample population. The results of the pilot study were discussed with the respondents and adjustments made accordingly. Haeri (2005) considers the reliability of the instruments to be the degree of consistency of the instruments or procedures. The reliability of a standardized test is usually expressed as a correlation coefficient, which measures the strength of association between variables. Such coefficient vary between 0.00 and 1.00 with the former showing there is perfect reliability which is an ideal situation. Reliability was ascertained by splitting the instruments into two: by placing all odd numbered in one sub-set and all even numbered items in another subset and then finding the coefficient of internal consistency.

3.8 Operationalization of variables

Table 1 summarizes the variables drawn from the respective study objectives. The table also highlights the indicators associated with each variable, the mode of measurement and scale used as well as the type of analysis carried out.

Table 1.1: Operationalization of variables

Objective of the study	Type of Variable	Indicators	Measurement	Measurement scale	Type of analysis
To investigate the challenges faced by organizations seeking ISO certification	**Dependent** ISO Certification	Certification by a certification body	Time taken to be certified.	Ratio	Quantitative
	Moderating Nature of organization	Organizational structure. Size of organization.	No. of process No. of admin. units	Ratio	Quantitative
To establish effects of management commitment to ISO process	**Independent** Management commitment	Management reviews. Staff training Leadership	No. of Reviews Training records Vision, targets	Ratio Ordinal	Quantitative qualitative
To determine influence of documentation on ISO process	**Independent** Documentation requirements	Different documents required by the standard.	Availability of manuals, policies quality objectives	Ratio	Quantitative
To establish the effect of availability of resources to ISO process	**Independent** Availability of Resources	Human resource required. Finances required.	Personnel available. Finances available.	Ratio	Quantitative
Establish effect of organizational culture to ISO process	**Independent** Organizational culture	Staff attitudes. Staff participation.	Staff attitude to ISO process. Staff roles in the ISO process	Ordinal	Qualitative

CHAPTER FOUR
DATA ANALYSIS, PRESENTATION INTERPRETATION AND DISCUSSIONS

4.0 Introduction

This chapter presents data analysis and provides the interpretation of analyzed data for this study on the challenges facing organization seeking ISO 9001 certification, a case study of KEMRI.

4.1 An Overview of the collected data

The data was collected from a cross-section of employees of Kenya Medical Research Institute (KEMRI) in Nairobi sampled from a wide range of administrative units. Out of 110 questionnaires distributed to staff, 99 were submitted back to the researcher giving a response rate of 90 percent. The response rate was good and gave a representative sample of the population. Table 4.1 represents the response rate.

Table 4.1 Respondents response rate

Category	Number of cases (n)	Percentage (%)
Questionnaires submitted	99	**90**
Questionnaires not Submitted	11	**10**
Total Questionnaires distributed	**110**	**100**

4.2 Background characteristics of the study population

The population under study had varying demographic and background characteristics including sex, age, length of service and position held in the organization. These factors often influence an individual's perception and response to an issue. In addition, these factors could affect the organizational culture. Table 4.2 summarizes the background characteristics of the respondents.

4.2.1 Demographic Characteristics of Respondents

The proportion of males and females was 51.5 and 48.5 percent respectively. Respondents in the age brackets 30-35 and 36-41 years were 32.3 percent each, those aged above 42 years were 27.2 percent and only 8.1 percent were aged 24 – 29 years as shown in table 4.2

Table 4.2 Demographic Characteristics of Respondents

Variable	Number of Cases (N)	Percentage (%)
Sex		
Female	48	48.5
Male	51	51.5
Total	**99**	**100**
Age bracket of respondents (in years)		
24-29	8	8.1
30-35	32	32.3
36-41	32	32.3
42-47	14	14.1
48 and above	13	13.1
Total	**99**	**100.0**

4.2.2; Respondents' position and length of service in KEMRI

A large proportion of the respondents (73.7 percent) indicated that they had worked in KEMRI for over than 7 years which was a good representation of the population that had been working in the institute since the inception of ISO 9001 certification process in KEMRI 7 years ago. Approximately, 52.5 percent of the respondents were middle level managers, 22 percent were top managers and 25 percent were in non-managerial positions i.e. support and clerical staff. All cadres in the institute were therefore well represented in the study.

Table 4.3; Respondents by position and period of service

Period of service in KEMRI		
Less than 1 yr	2	2.0
1-3 yrs	6	6.1
4-6 yrs	18	18.2
7-9 yrs	32	32.3
Over 10 yrs	41	41.4
Total	**99**	**100**
Position in KEMRI		
Non Managers	25	25.3
Middle Managers	52	52.5
Top Managers	22	22.2
Total	**99**	**100**

4.2.3 Respondents' Distribution by Department

All KEMRI centers and departments within Nairobi were represented in the study. In terms of respondents' distribution by department, table 4.3 shows that 26.3 percent of the respondents served at HQ where majority of the institute staff were based. There was proportional sampling of staff from the centers and departments. In Quality Management system, Legal, Ethical Research Committee departments, only one respondent was sampled from each of the departments.

Table 4.4: Distribution of Respondents by Department

Centre/Department	Number of cases (N)	Percentage (%)
CENTRE FOR BIOTECTNOLOGY RESEARCH AND DEVELOPMENT	4	4.0
CENTRE FOR CLINICAL RESEARCH	6	6.1
CENTRE FOR MICROBIOLOGY RESEARCH	4	4.0
CORPORATE AFFAIRS DEPARTMENT	2	2.0
CENTRE FOR PUBLIC HEALTH RESEARCH	8	8.1
CENTRE FOR RESPIRATORY DISEASE RESEARCH	4	4.0
CENTRE FOR TRADITIONAL MEDICINE RESEARCH	3	3.0
CENTRE FOR VIRAL RESEARCH	5	5.1
ENGINEERING DEPARTMENT	5	5.1
ETHICAL RESEARCH COMMITTEE SECTRETARIAT	1	1.0
EAST AND CENTRAL SACIPAC	4	4.0
GRANTSMANSHIP DEPARTMENT	1	1.0
INFORMATION AND COMMUNICATION TECHNOLOGY DEPARTMENT	4	4.0
KEMRI GRADUATE SCHOOL OF HEALTH SCIENCES	1	1.0
KEMRI HEADQUATERS	26	26.3
LEGAL DEPARTMENT	1	1.0
LIBRARY DEPARTMENT	3	3.0
MARKETING DEPARTMENT	4	4.0
OFFICE OF HEALTH SAFETY AND ENVIROMENT	5	5.1
PROCUREMENT DEAPARTMENT	2	2.0
PRODUCTION DEAPARTMENT	5	5.1
QMS DEAPARTMENT	1	1.0
Total	99	100.0

4.3 Steps in Implementation of Quality Management System

This section sought to establish the respondents' experience and opinion on the ISO 9001 certification process.

4.3.1 Staff Involvement in the ISO 9001 Certification Process

Results showed that all the respondents (100 percent) were aware of the institute's effort to seek ISO 9001 certification as shown in Table 4.4. This implied that the ISO certification process was indeed visible within the organization.

Nearly 95 percent of the respondents indicated that they had been involved in the ISO 9001 certification process in one way or the other with the period of involvement varying from less than one year to over four years. Despite the fact that ISO certification process began seven years ago, an overwhelming majority (87 percent) had only been involved at least for two years. Only 12 percent of the respondents had been involved for three or more years. It was evident from these results that the certification process had been significant embraced in the last two years during which the staff were involved immensely.

In regard to the various ways that KEMRI employees were involved in the ISO certification process, majority of the respondents said they were involved in more than one way. More than half of the respondents (52.5 percent) reported that they had been involved in addressing non-conformities identified during the audit process while 21.2 percent had been involved in coordinating the process. Approximately 19.2 percent gave no response and only 13.1 percent of the respondents had been involved in decision making in view of the process.

Table 4.5: Staff Involvement in the Certification Process.

Variable	Number of Cases (N)	Percentage (%)
Knowledge on ISO Certification process		
Yes	99	100
No	0	0
Total	**100**	**100**
Response if involved in the process		
Yes	94	94.9
No	5	5.1
Total	**99**	**100**
Period of involvement in the process		
Less than 1 year	34	36.0
1-2 years	48	51.0
3-4 years	11	12.0
More than 4 years	1	1.0
Total	**94**	**100.0**
Ways involved in the process		
Decision making	13	13.1
Sensitization	12	12.1
Coordination	21	21.2
Addressing non-conformities	52	52.5
Documentation	7	7.0
Auditing	8	8.0
No response	19	19.2

4.3.2 Staff Perceptions on Certification Process

The study assessed respondents' perceptions and knowledge on when KEMRI begun the ISO 9001 certification process as well whether the management was committed to the process.

Nearly 86 percent of the respondents believed the ISO certification process in KEMRI begun less than two years ago and 14 percent of the respondents believed the process was at least three years old. Staff perceptions on engagement of external consultants in ISO certification process

varied. Approximately 33.3 percent felt that engagement of external consultants was moderate. Approximately 17.2 percent were not aware of the extent of involvement of external consultants. A limited number (7 percent) thought KEMRI had engaged external consultants to a very large extent.

Table 4.6: Staff Perceptions on Certification Process

Variable	Number of Cases (N)	Percentage (percent)
Period KEMRI begun the ISO process		
Less than 1 year	24	24.2
1-2 years	61	61.6
3-4 years	6	6.1
More than 4 years	8	8.1
Total	**99**	**100**
Whether management was committed to the ISO process		
Don't Know	4	4.0
Strongly disagree	7	7.1
Disagree	21	21.2
Agree	48	48.5
Strongly agree	19	19.2
Total	**99**	**100**
Extent of use of Consultants		
Don't Know	17	17.2
Small extent	9	9.1
Average extent	33	33.3
Large extent	33	33.3
Very large extent	7	7.1

4.4 Degree of implementation of Quality Management System

This section highlights the degree of implementation of various activities in regard to the ISO 9001 certification process. Effective implementation of the QMS system is a pre-requisite to certification of an organization.

Table 4.7 Degree of implementation of Quality Management System

Description	Number of cases (N) indicating respective extent of Implementation									
	Don't Know		Very Small Degree		Moderate Degree		Large Degree		Very Large Degree	
	N	percent	N	percent	N	percent	N	percent	N	percent
Adequate awareness creation and sensitization of staff on benefits of ISO 9001 Certification was done	1	1	6	6.1	27	27.3	42	42.4	23	23.2
ISO certification plan of action was communicated to staff effectively	3	3.0	12	12.1	29	29.3	34	34.3	21	21.2
Commitment of top management in ISO certification process evident	5	5.1	18	18.2	29	29.3	36	36.4	11	11.1
A pre-assessment audit was conducted	7	7.1	7	7.1	20	20.2	46	46.5	19	19.2
Quality manual and quality policy were prepared	4	4.0	7	7.1	14	14.1	46	45.6	28	28.3
Standard operating procedures already in place	5	5.1	11	11.1	20	20.2	37	37.4	26	26.3
New standard procedures for key ISO certification processes were prepared	5	5.1	6	6.1	23	23.2	39	39.4	26	26.3
Management review meetings were held at planned interval	8	8.1	13	13.1	17	17.2	43	43.4	18	18.2
Internal audits were conducted as planned	8	8.1	8	8.1	20	20.2	44	44.4	19	19.2
Appointment of ISO certification champions done	6	6.1	12	12.1	22	22.2	33	33.3	26	26.3
External audits were conducted as planned	12	12.1	10	10.1	20	20.2	36	36.4	21	21.2
Funds availed timely to facilitate implementation of QMS	19	19.2	25	25.3	20	20.2	21	21.2	14	14.1
Sequence and interaction of processes in the institute had been determined	12	12.1	16	16.2	28	28.3	30	30.3	13	13.1

Slightly over 65 percent of the respondents affirmed that awareness creation and sensitization of staff on ISO certification benefits was carried out to a large extent. Only 6.1 percent said that sensitization had been done to a small extent. The proportion of respondents who indicated that the ISO 9001 certification process plan of action was communicated effectively was approximately 55 percent while those who felt the communication was moderately done were

29.3 percent. About 36 percent of the respondents agreed that top management commitment of the institute was evident to a large degree with 11 percent saying that the managements' commitment was evident to a very large degree. Majority of the respondents (64.8 percent) were aware that a pre-assessment quality audit had been conducted in KEMRI at least to a large degree whereas 73.9 percent said that the institute had developed the quality manual and policy as required by ISO 9001 standard.

It was apparent from the results that most of the respondents had standard operating procedures in place and new ones were developed for the key processes that were operating without any documented procedures.   About 8.1 percent of the respondents said that they were not aware that management reviews on the certification process were held at planned interval while majority of them (61.6 percent) said that implementation of management reviews was carried out to a large degree.

Responses on whether the management availed funds to facilitate implementation of QMS varied widely with 19.2 percent of the respondents saying that they didn't know whether funds were availed in good time, 25.3 percent said that it was to a small degree, 20.2 percent said that it was to a moderate degree, 21.2 percentage said it was to a large degree and the remaining 14 percent said it was to a very large degree. Approximately 30.3 percent of the respondents confirmed that sequence and interaction of processes within the institute had been established to a large extent.

4.5 Performance Outcome of KEMRI's Quality Management System.

Responses on the performance outcome of the organization's quality management system were determined and are summarized on table 4.6. The outcome of the performance was ranked from 'poor' 'to very good' and responses of those who were not aware of the outcome were also taken into account.

Table 4.8: Performance Outcome of QMS Processes

Description	Number of cases (N) indicating respective performance level of QMS outcome									
	Don't Know		Poor outcome		Average outcome		Good outcome		Very good outcome	
	N	percent	N	percent	N	percent	N	percent	N	percent
Customer focus	5	5.1	10	10.1	42	42.4	33	33.3	9	9.1
Periodic management reviews	5	5.1	13	13.1	37	37.4	41	41.4	3	3.0
Corrective actions	2	2.0	15	15.2	36	36.4	38	38.4	8	8.1
Preventive actions	6	6.1	14	14.1	37	37.4	37	37.4	5	5.1
Continual improvement	3	3.0	10	10.1	36	36.4	40	40.4	10	10.1
Control and monitoring process	2	2.0	10	10.1	36	36.4	42	42.4	9	9.1
Internal audit	2	2.0	9	9.1	37	37.4	35	35.4	16	16.2
Internal communication	4	4.0	11	11.1	32	32.3	33	33.3	19	19.2
Control of documents	3	3.0	10	10.1	34	34.3	42	42.4	10	10.1
Control of records	4	4.0	10	10.1	30	30.3	44	44.4	11	11.1
Development of process procedures	3	3.0	8	8.1	34	34.3	43	43.3	11	11.1
Development of manuals and policies	3	3.0	8	8.1	30	30.3	42	42.4	16	16.2

It was evident from table 4.6 that respondents had divergent views in regard to the outcome of various components of the certification process. Customer focus is a guiding principle in ISO 9001 certification and nearly 85percent of the respondents indicated that the outcome of customer focus was at least average. Approximately 79 percent were in agreement that there was a good outcome in terms of holding management reviews. The ISO 9001 standard requires that an organization puts in place both preventive and corrective mechanisms and at least 79.5 percent of the respondents rated the outcome of these actions as 'average'. The outcome of continual improvement was rated 'very good' by 40.4 percent of the respondents whereas about 10 percent rated it as 'very good'.

It is a requirement by the ISO 9001 that an organization conducts audits as well as controls and monitors its processes. Only 2.0 percent of the respondents were not aware of the outcome of these requirements with over 50 percent confirming that the outcome was somewhat good. The outcome of internal communication, control of records as well as documents was satisfactory with most of the respondents (approximately 80 percent) affirming that the outcome was at least average. The number of respondents who rated the outcome of developing process procedures and development of manuals and policies as good were 43.3 percent and 42.4 percent respectively.

4.6 Challenges Affecting KEMRI's ISO 9001Certification Process

Responses on the extent to which various challenges impacted on KEMRI's certification process were analyzed and recorded in table 4.7.

There were divergent views on how high cost of QMS implementation impacted on the ISO certification process with 45.5 percent of the respondents stating that high cost of implementing QMS affected ISO certification process considerably. About a quarter of the respondents believed the impact was moderate as 19.2 percent of indicated that they were not aware of the effect of the high cost.

More than a third of the respondents confirmed that traditional organizational culture and staff resistance to change posed a significant challenge to the ISO certification process to a large degree with another third rating the extent of the challenge as 'moderate'. Approximately 40 percent of the respondents alleged that top managements' commitment to the ISO certification process affected the process at least to a large extent with 28.3 percent stating that the factor affected the process to a small extent. Slightly over 32 percent indicated that their participation in the process affected the process only to a small degree while 32.3 percent and 23.2 percent said that inadequate training on QMS affected the process moderately and to a large degree respectively. Limited understanding of QMS impacted on the process with 24.2 percent of the respondents saying that it was to a large extent and 18.2 percent of the respondents saying that it was to a very large degree.

Table 4.9: Challenges affecting certification process in KEMRI

Description	Number of cases (N) indicating respective extent of Implementation									
	Don't Know		Very Small Degree		Moderate Degree		Large Degree		Very Large Degree	
	N	percent	N	percent	N	percent	N	percent	N	percent
High cost of implementing the QM S	19	19.2	10	10.1	25	25.3	19	19.2	26	26.3
Traditional organizational culture	7	7.1	18	18.2	30	30.3	23	23.2	21	21.2
Staff resistance to change	2	2.0	26	26.3	33	33.3	27	27.3	11	11.1
Lack of staff participation	2	2.0	32	32.3	28	28.3	27	27.3	10	10.1
Inadequate support from top management	6	6.1	28	28.3	25	25.3	20	20.2	20	20.2
Lack of continuous training on QMS	4	4.0	22	22.2	32	32.3	23	23.2	18	18.2
Lack of understanding of the QMS requirement	4	4.0	23	23.2	30	30.3	24	24.2	18	18.2
Unavailability of relevant documentation	7	7.1	35	35.4	28	28.3	19	19.2	10	10.1
Limited knowledge on benefits of QMS	6	6.1	27	27.3	27	27.3	23	23.2	16	16.2
Inadequate planning for implementation of QMS	8	8.1	32	32.3	24	24.2	19	19.2	16	16.2
High charges by consultants	28	28.3	29	29.3	16	16.2	15	15.2	11	11.1
Large size of the organization	19	19.2	32	32.3	15	15.2	19	19.2	14	14.1
Traditional organizational structure	12	12.1	31	31.3	18	18.2	25	25.3	13	13.1
Complexity of process within KEMRI	14	14.1	21	21.2	24	24.2	24	24.2	16	16.2
Inadequate time to implement the QMS	9	9.1	29	29.3	25	25.3	24	24.2	12	12.1
Lack of qualified personnel to lead the process	10	10.1	31	31.3	29	29.3	20	20.2	9	9.1
Lack of management reviews	11	11.1	29	29.3	30	30.3	23	23.2	6	6.1
Lack of staff involvement	9	9.1	28	28.3	29	29.3	25	25.3	8	8.1
Lack of sensitization /awareness on the process	8	8.1	29	29.3	35	35.4	13	13.1	14	14.1
Unavailability of funds to implement the certification process	16	16.2	28	28.3	26	26.3	16	16.2	13	13.1
Ineffective corrective and preventive measures	9	9.1	32	32.3	23	23.2	18	18.2	17	17.2
Lack of adequate infrastructure	7	7.1	28	28.3	26	26.3	25	25.3	13	13.1
Massive documentation	6	6.1	17	17.2	30	30.3	21	21.2	25	25.3

There were divergent views on how high cost of QMS implementation impacted on the ISO certification process with 45.5 percent of the respondents stating that high cost of implementing QMS affected ISO certification process considerably. About a quarter of the respondents believed the impact was moderate as 19.2 percent of indicated that they were not aware of the effect of the high cost.

More than a third of the respondents confirmed that traditional organizational culture and staff resistance to change posed a significant challenge to the ISO certification process to a large degree with another third rating the extent of the challenge as 'moderate'. Approximately 40 percent of the respondents alleged that top managements' commitment to the ISO certification process affected the process at least to a large extent with 28.3 percent stating that the factor affected the process to a small extent. Slightly over 32 percent indicated that their participation in the process affected the process only to a small degree while 32.3 percent and 23.2 percent said that inadequate training on QMS affected the process moderately and to a large degree respectively. Limited understanding of QMS impacted on the process with 24.2 percent of the respondents saying that it was to a large extent and 18.2 percent of the respondents saying that it was to a very large degree.

Unavailability of relevant documentation, limited knowledge on the benefits ISO certification and inadequate planning for the implementation process were viewed as bottlenecks in ISO certification process. Roughly 35.4 percent, 27.3 percent and 32 percent indicated that unavailability of relevant documentation, limited knowledge on benefits of ISO certification and inadequate planning for the process affected the process only to a small degree respectively. Approximately, 28.3 percent of the respondents said they did not know the extent to which high charges by external consultants affected the process while 29.3 percent were of the opinion that it affected only to a small degree. More than a third of the respondents were of the opinion that large size of the organization and the traditional organizational structure affected the ISO process either to a large or very large degree. Nearly 30 percent rated the two challenges as impacting on the ISO certification process to a small extent. Complexity of the process within the institute and inadequate time to implement QMS were viewed as factors that affected ISO certification process to some degree by more than 60 percent of the respondents. Less than 15 percent indicated they did not know how the two factors affected the process. Further analysis showed

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that 31 percent of the respondents did not view inadequacy of qualified personnel as a key challenge to ISO certification. Those who felt that lack of qualification of personnel leading the ISO certification process affected moderately and to a large extent were 30 percent and 20 percent respectively. An estimated 30.3 percent said lack of management reviews moderately affected the process.

There was need to involve the staff in the process as 25.3 percent of them said lack of staff involvement affected the process to a large degree. Staff sensitization on the process was not adequate as the greatest proportion (35.4 percent) confirmed that lack of sensitization moderately affected the process while 14.1 percent were in agreement that it affected the process to a very large degree. About 16.2 percent and 13.1percent of the respondents indicated that lack of funds affected the process to a large degree and to a very large degree respectively. Majority of the respondents cited that lack of effective corrective and preventive measures affected the process to a large extent while 18.2 percent indicated that ineffective preventive and corrective measures affected the process to a large a large extent. In addition, infrastructure was a major challenge as 25.3 percent of the respondents were of the view that this challenge impacted on the process to a large extent. The process involved developing of massive documents as confirmed by the 25.3 percent of the respondents who indicated that the effect of documentation process to the certification process was to a very large degree.

4.7 Measures to reduce severity of challenges encountered during certification

Respondents were of the opinion that the following key measures should be put in place to reduce the severity of challenges encountered during the certification process.

Top management to avail funds to facilitate effective implementation of Quality Management System (QMS). According to clause 6 of the ISO 9001:2008, top management should determine and provide the resources needed to implement, maintain and continually improve the QMS in addition to enhancing customer satisfaction. These resources include financial and human resource, infrastructure and work environment.

KEMRI management to demonstrate commitment to the process. Strong support by management is a pre-requisite when developing and implementing new programmes. This was in line with clause 5.1 of the ISO 9001 standard which stipulates that the management should provide evidence of its commitment through meeting customer as well as statutory and regulatory requirements, establishing quality policy and objectives, conducting management reviews and ensuring availability of resources.

The organization should rely more on internal auditors than external auditors. High cost of hiring consultants to support in implementation of ISO certification process has negative financial implications.

Ensure there is continuous training of staff on QMS. Sub-clause 6.2.2 narrates that 'an organization shall determine the necessary competence for its personnel and where applicable provide training or take any other actions to achieve the necessary competence'.

Allocate more time to ISO certification process for effective implementation of the process and putting in place control and monitoring mechanisms. There was also need to intensify sensitization on Quality Management System (QMS).

4.9 Comparison of responses from employees of different cadre

The researcher carried out cross tabulation to investigate how responses from employees of different cadre varied as shown in table 4.9. Results showed that the greatest proportion of the top managers felt that commitment of the management affected the process to a very small degree, on the contrary the biggest number of middle managers felt that it was to a large degree. Both cadres were in agreement that unavailability of funds was a major challenge to the ISO 9001 Certification process. Whereas top managers felt that all staff were involved in the certification process, middle managers were of the opinion that they were not well involved. Top managers admitted that lack of staff participation in the process affected the process to a large extent unlike middle managers who indicated that it was only to a very small extent.

Table 4.9   Responses given by staff from different cadre

Description	Cadre	Number of cases (N) indicating respective effect of challenge									
		Don't Know		Very Small Degree		Moderate Degree		Large Degree		Very Large Degree	
		N	percent	N	percent	N	percent	N	percent	N	percent
Lack of management commitment to the certification process	Top managers	1	4.5	9	40.9	8	36.4	2	9.1	2	9.1
	Middle managers	2	3.8	7	13.5	14	26.9	14	26.9	15	28.8
Unavailability of funds to facilitate the process	Top managers	2	9.1	7	31.8	8	36.4	4	18.2	1	4.5
	Middle managers	3	19.2	10	19.2	16	30.8	11	21.2	12	23.1
Lack of staff participation	Top Managers	2	9.1	2	9.1	8	36.4	9	40.9	1	4.5
	Middle managers	1	1.9	17	32.7	16	30.8	13	25.0	5	9.6
Lack of staff involvement	Top managers	2	9.1	5	22.7	9	40.9	7	31.8	2	9.1
	Middle managers	1	1.9	5	9.6	15	28.8	17	32.7	14	26.9

4.10 In-depth Interviews

Discussions with key informants revealed that the process of ISO certification in KEMRI began six years ago but the progress was insignificant in the first three years. Following the change in management in 2009, the new management took up the process with a lot of commitment and ensured the necessary resources and other relevant requirements were determined and provided. The certification process progressed well amidst challenges such as the massive documents requirements, inadequate financial and human resource as well as limited infrastructure to implement QMS. High cost of engaging consultants to assist in the processes, organizational culture, staff resistance to change and lack of training on QMS were also cited as major

challenges. The initial plan of action for QMS implementation was to ensure the institute got certified within a year but this was not possible because of the requirements that had to be met prior to certification and also considering the complexity of the process within the organization. KEMRI has thirteen administrative centers located at various counties within the country and the ISO certification process was being driven centrally from its headquarters in Nairobi thus posing a challenge in coordination of QMS implementation process.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter contains a summary of the main findings, conclusion, recommendations as well as areas that could be explored in future.

5.2 Summary of Main Findings

This study ascertained that Kenya Medical institute in its pursuit to acquire ISO 9001 certification encountered key challenges namely; lack of commitment by management inadequate resources, massive documentation requirements and negative organizational culture. Other challenges identified during the study include high cost of hiring consultants, complexity and interaction of process within the organization and lack of understanding of ISO requirements, large size of the organization, inadequate training on QMS, lack of technical knowledge and inefficient internal communication of new tasks and functions of each job, limited awareness on ISO certification process as well as low level of involvement of top management and employees.

The findings in this research concur with those of other researchers such as that by Mersha, (2007) which indicate that most of these failures in QMS implementation result from lack of top management support and commitment, the resistance of employees towards change, lack of understanding of the ISO requirements, inadequate training and quality knowledge, low quality awareness and culture, the allocation of personal responsibilities and constraints on resources such as manpower time and finance. Findings by Sampio, Saraiva and Rodriguez, (2001) suggest that the major challenges faced in implementing ISO 9001 are the low level involvement of top management and employees, a poor flow of information, resistance to new responsibilities, lack of technical knowledge and difficulty in the communication of new tasks. This study though reveals other challenges unique to KEMRI but may be experiences by other organization such as limited staff participation and involvement, inadequate time to implement QMS process, large size of the organization, complex processes within the organization,

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traditional organizational structure, ineffective corrective and preventive measures and lack of regular management reviews. It is their advisable that organization be aware of these challenges and come up with relevant mitigation measures before embarking on ISO 9001 certification process.

5.2.1 Lack of Commitment by Management

Top managers should focus their attention to determining and providing the resources needed to implement, maintain and continually improve the QMS in addition to enhancing customer satisfaction. This was not the case in KEMRI as 40 percent of the respondents affirmed that lack commitment by top management affected the certification process at least to a large degree. Only 9.1 percent of the respondents rated the outcome of customer focus as 'very good'. Recommendation by 24 percent of the respondents was that management should demonstrate more commitment to the certification process. Top management in KEMRI ought to develop quality circles and motivate employees to take part in quality improvement. Senior management role is key to the success of the QMS implementation, starting from the establishment of quality policy and project specific quality plan right through the implementation including employee training, monitoring up to final audit stage.

5.2.2 Organizational Culture

Negative organizational culture is among the most complex challenges which KEMRI managers must overcome and may be attributed to limited awareness, lack of support and commitment by top management, resistance to change by staff and centralized decision making, all of which are inhibiting elements in terms of the ISO 9001 quality management philosophy. It is natural for people to resist change especially when they do not understand the reasons for it. More than 38 percent of the respondents were in agreement that negative organizational culture and staff resistance impacted negatively on the ISO implementation process to a large extent and the same margin indicated that they were not adequately involved in the process. The results correlate with any employee's natural propensity to resist change. The respondents felt that their participation in the ISO 9001 certification process did not affect the process to a large extent.

5.2.3 Documentation Requirements

Documentation was considered a challenge by employees as an increase in documentation would subsequently increase their workload. It is a requirement of the ISO 9001 standard for an organization to develop a comprehensive quality manual, operating procedures and align all relevant documents. Diverse processes within the institute that range from administration to research called for massive documentation. More than 45 percent of the respondents felt that the massive documentation requirements affected the certification requirements to a large degree. The large size of the organization also contributed to the immense documentation as copies of the mandatory procedures and quality manual had to be reproduced and distributed to all sections within the organization. Majority of the respondents (66 percent) had to develop and document new procedures for the key processes within the institute.

5.2.4 Availability of resources

Inadequate key resources that include manpower, time and finances was cited a major challenge in KEMRI. Resource requirements of ISO 9001 certification manifest itself in the following ways: the costs of training, costs in employee time, registration fee, consultancy fee, and cost of documentation. About 26.3 percent of the respondents were of the view that high cost of implementing QMS affected the process to a very large extent while 23.3 percent of the respondents confirmed that unavailability of funds affected the certification process at least to a large degree. Respondents confirmed that hiring consultants to facilitate the training process increases costs and this puts significant pressure on the finances of the organization.

5.3 Conclusion

Based on the above findings, the researcher came up with the following conclusion:

It is imperative for top management to commit itself to adoption of Quality Management System within an organization as this would play an integral role in its overall outcome. It follows that reluctance by top management to commit itself to the certification process would ultimately

hamper a swift implementation process. Management must also be totally committed to the whole process and for the right reasons.

Adoption of ISO 9001 should be viewed as an investment and as such the typical factors that influence decision to undertake an investment project apply. These factors include cost, scope, performance and duration of certification process. Any organization seeking to implement ISO 9001 QMS must be aware of the costs involved in both implementation and maintenance aspects of the system but also it is important to quantify the expected benefits. Although an organization can benefit significantly from hiring a consultant to guide them in the preparation and execution of ISO 9001 standards, this may exert significant pressure on the finances of the organizations.

Development of a good organizational culture is a fundamental pre-requisite to the achievement of quality. It is natural for people to resist change especially when they do not understand the basis for it hence quality awareness should be intensified.

Documentation of Quality Management System in an organization is affected by the complexity and interaction of its processes as well as staff competence. The ISO 9001 standard is highly documentation-driven and requires that all documentation be updated to reflect all its system requirements.

The study confirmed that ISO certification process is dependent on the nature of the organization. Size of an organization, interaction of processes and structure of the organization should be factored when planning and executing a QMS.

Communication of the results of the current study will enlighten KEMRI staff in regard to the benefits that can be attained from ISO 9001 QMS certification. Information garnered from this study will lead to knowledge transfer and could be used to reduce the severity of these challenges ensuring successful QMS implementation. The research adds knowledge to the field of quality management systems (ISO 9001 in particular) within the context of research institution, having focused on KEMRI and contributes to the limited literature on this subject

5.4 Recommendations

The researcher came up with the following recommendations;

Top management must recognize the value of the principles of ISO 9001 or any QMS that it is considering and be prepared to communicate this effectively, before it commits itself.

An organization should be aware of the costs involved in both implementation and maintenance of QMS. This will help allocate resources for the implementation process and overcome the cost barriers of adopting and maintaining the process. An organization can reduce reliance on external consultants and the associated cost by training an internal member of staff to undertake any future training. This strategy will help to cut the cost of training and improve in-house training programmes and materials.

Appropriate awareness training programmes should be put in place to ensure that employees at each relevant function and level are aware of culture, quality policies, and procedures of the ISO 9000 systems. Intensive training needs to be provided particularly in the areas of problem identification and solving skills.

For an organization to realize the value of implementing quality practices, it must have a culture that is capable of fully supporting the implementation process.

5.5 Future Work

This study was conducted in a research institution, in particular Kenya Medical Research Institute. The findings represent a unique context to which the conclusions may not be generalized. Therefore, there is need to extend similar studies exploring the challenges affecting organization seeking ISO certification in other sectors like educational institutions, development organizations and private business enterprises.

This study was limited to challenges facing organizations seeking ISO 9001 certification, a case study of Kenya medical Research Institute. Other certifications such as ISO 15189 and ISO 1400 are being pursued in the institute and a study may be undertaken to establish the challenges likely to be experienced in pursuit of these certifications.

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APPENDICES

Appendix1: Letter of Transmittal

Patrick Mutinda

P.O Box 14976-0100

Nairobi

Email; benido1@yahoo.com.

Date: 3rd May 2012

Dear Participant,

RE: QUESTIONNAIRE FOR MY ACADEMIC PROJECT

I am a post graduate student at the University of Nairobi pursuing a Master of Arts Degree in Project Planning and Management. . For my final project, I am carrying out a study on the challenges faced by organization seeking ISO 9001 certification. I sincerely believe the findings of this study will of great benefit to KEMRI and other organizations seeking not only this particular certification but others as well. I am inviting you to participate in this research study by completing the attached questionnaire.

If you choose to participate in this research, please answer all questions as honestly as possible. Participation is strictly voluntary and you may refuse to participate at any time. There is no compensation for responding nor is there any known risk. In order to ensure that all information will remain confidential, you may or may not include your name. The data collected will be for academic purposes only.

Thank you for your cooperation.

Yours faithfully,

Patrick Mutinda.

Appendix 2: Questionnaire

Thank you for taking your time to participate in this study that seeks to establish the challenges faced by organizations seeking ISO certification: a case study of KEMRI. This questionnaire is intended to gather research data as part of my academic investigation for my Master of Arts in Project Planning and Management in the University of Nairobi. This Questionnaire is divided into four sections. Section (A) – Information about yourself, Section (B) – Quality management systems steps, Section (C) Degree of Implementing QMS , Section (D) – Challenges affecting ISO certification process. Individual responses will be kept confidential. Kindly answer all the questions in this questionnaire to the best of your knowledge and if you have any queries don't hesitate to call on mobile number 077761274 or send an email to pmutinda@kemri.org. Your participation is highly appreciated. Thank you

SECTION (A) – Information about yourself

A) Personal information (Kindly tick (✓) in the box that best describes your answer)

1) What is your sex   Male ☐   Female ☐

2) What is your age Bracket?

Less than 23 yrs ☐   24 to 29 yrs ☐   30 to 35 yrs ☐

36 to 41   yrs ☐   42 to 47   yrs ☐   48 and above yrs ☐

3) How long have you worked at KEMRI

Less than 1 year ☐   1 to 3 years ☐   4 to 6 years ☐

7 to 9 years ☐   More than 10 years ☐

4) Which of the following best describes your position in KEMRI?

Support staff ☐   Clerical Staff ☐   Section Head (Supervisor) ☐

Manager ☐   Senior Manager ☐

5) In which administrative unit/centre are you stationed? _____

SECTION B: QUALITY SYSTEM IMPLEMENTATION STEPS

The following questions relate to your organizations experience while seeking ISO 9001certification of your of your quality management. Answer the questions below about the steps taken to gain quality systems certification by placing a tick (✓) below the appropriate item.

1. Are you aware of KEMRI's effort to seek ISO 9001 Certification Processes?

   Yes ☐   No ☐

2. If your answer in the question above is Yes, have you been involved in the certification process.

   Yes ☐   No ☐

3. For how long have you been involved in the process?

   Less than 1 Year ☐   1-2 years   ☐
   3-4 years   ☐   More than 4 years ☐

4. In which way(s) have you been involved in the certification process?

   Decision making (Management) ☐   Sensitization/Awareness   ☐
   Documentation   ☐   Auditing   ☐
   Coordination   ☐   Addressing Non-Conformities   ☐
   Others,(Specify)_____
   _____

5. How long ago did KEMRI begin its certification processes?

   Less than 1 Year ☐   1-2 years   ☐
   3-4 years   ☐   More than 4 years ☐

6. Management commitment and buy-in for ISO 9001 certification is evident in KEMRI?

   Don't know ☐   Strongly Disagree ☐   Disagree ☐
   Agree   ☐   Strongly Agree   ☐

7. To what extent did KEMRI use external consultant(s) to assist with quality system implementation?

   Don't know ☐   Small extent ☐   Average extent ☐
   Large Extent ☐   Very large extent ☐

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SECTION C. DEGREE OF IMPLEMENTATION OF QMS

(a) To what degree was the following items implemented as part of KEMRI's certification effort? Please tick (✓) (with the guidance of the key below) in column that best describes your implementation experience.

0 = Don't Know   **1** = Very small degree   **2** = Moderate degree

3 = Large degree   **4** = Very large degree

Item implemented	Degree of Implementation of QMS				
	0	**1**	**2**	**3**	**4**
i). Adequate awareness creation and sensitization of staff on benefits of ISO 9001 certification was conducted					
ii). ISO certification plan of action was communicated to staff effectively.					
iii). Commitment of top management was evident to everyone in KEMRI					
iv). A pre-assessment audit (gap analysis) was conducted					
v). A Quality manual and Quality policy statement were prepared					
vi). Standard Operating Procedures (SOPs) for key processes were in place.					
vii). New Standard Operating Procedures for key processes were prepared					
viii). Management reviews were held at planned interval					
ix). Internal audits were conducted as planned					
x).Appointment of ISO champions (Coordinators)					
xi). External audits were conducted as planned					
xii). Adequate time was given for the implementation of the Quality Management System					
xiii). Funds were available to facilitate implementation of the Quality Management System					
xiv). Sequence and interaction of key processes in the institute was determined e.g. organograms, flow charts etc					

(b) Please indicate below the performance level of your quality management systems outcome by ticking in the appropriate column with the guidance of the key below.

0 = Don't Know   **1** = Poor outcome   **2** = average outcome

3 = Good outcome   **4** = Very good outcome

Description	Performance level				
	0	**1**	**2**	**3**	**4**
i). Customer focus					
ii). Periodic Management reviews					
iii). Corrective actions					
iv). Preventive actions					
v). Continual improvement					
vi).Control and monitoring of processes					
vii). Internal Audits					
viii). Internal communication					
ix). Control of Documents					
x). Control of records					
xi). Development of process procedures					
xii). Development of manuals and policies					

SECTION D: CHALLENGES AFFECTING CERTIFICATION PROCESS

(a) Please indicate by ticking in the appropriate column (with the guidance of the key below) the extent to which KEMRI certification process has been affected by the following:-

0 = Don't Know   **1** = Very small degree   **2** = Moderate degree

3 = Large degree   **4** = Very large degree

Description	Extent of effect				
	0	1	2	3	4
High cost in implementing the Quality Management System					
Organizational Culture					
Staff resisting change					
Lack of staff participation					
Lack of support from top management					
Lack of continuous training on Quality Management Systems(continuous professional development)					
Lack of understanding of the QMS requirements by the staff					
Lack of required QMS documentation such as Quality manual, SOPs, work instruction etc.					
Lack of awareness on the benefits of QMS					
Lack of planning in the implementation of QMS					
High charges by consultants					
Size of the organization					
Organizational structure					
Complexity of the processes within KEMRI					
Lack of qualified personnel to lead the certification process					
Lack of management reviews to the certification process					
Lack of staff involvement					
Lack of sensitization on the certification process					
Unavailability of funds to implement the certification process					
Lack of adequate infrastructure e.g. workspace, storage space etc					
Massive documentation requirements by the standard					

(b) In your view, kindly state measures KEMRI management would have taken to reduce the severity of the challenges encountered during the ISO certification process

_____
_____
_____
_____
_____
_____
_____
_____

Thank you for your time and God Bless

Appendix 3: Interview Guide

1. What is your position in the organization
2. How long have you worked in KEMRI
3. Could please tell me briefly your role in the organization
4. When did the organization initiate the ISO certification process
5. What is the purpose of ISO certification in your organization
6. What kind of processes run in the organization
7. Were KEMRI staff adequately sensitized about the certification process
8. What training /support have you and other employees received in regard to the certification process
9. In you view, what was the reaction of the staff to the initiation of the ISO certification process
10. Did the staff adopt the certification process without difficulty?
11. What has been the extent of support by QMS consultants
12. Has the institute developed all necessary documents for the certification process and were there any challenges in regard to this
13. Has the management been supportive to the process
14. Has the institute been in a position to provide all the required resources and what has been the implication of diverting funds to this process
15. What other challenges has the organization facing in view in view of this process.
16. Do you have any other comments or suggestions?