SOKOINE UNIVERSITY OF AGRICULTURE

Framework and Guidelines towards Attaining ISO 9001:2015 Certification & IEC 17025:2017 Accreditation of Laboratories by June 2021

September 2018

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ACRONYMS & ABBREVIATION

CAR	Corrective Action Report
CB	Certification Body
CQAB	Coordinator of Quality Assurance Bureau
CSP	Corporate Strategic Plan
DVC	Deputy Vice Chancellor
EAQF	East African Quality Assurance Framework
HEDP	Higher Education Development Programme
HLI	Higher Learning Institution
HLS	High Level Structure
HoD	Head of Department
ICT	Information Communication Technology
IEC	International Electrotechnical Commission
QMS	Integrated Management System
ISO	International Organization for Standardization
IUCEA	Inter University Council for East Africa
LMS	Laboratory Management System
MIS	Management Information System?
MSS	Management System Standard
NC	Nonconformance
OFI	Opportunities for Improvement
QA	Quality Assurance
QAB	Quality Assurance Bureau
QAP	Quality Assurance Policy
QAPB	Quality Assurance and Promotion Bureau
QMS	Quality Management System
SNAL	Sokoine National Agricultural Library
SOP	Standard Operating Procedures
SUA	Sokoine University of Agriculture
TCU	Tanzania Commission for Universities
VC	Vice Chancellor

DEFINITION OF TERMS AND CONCEPTS

Academic Staff means personnel of the University whose primary assignment is instruction/teaching, research, or public service.

Assistants to Academicians means employees/staff directly involved in providing technical supportive roles to fulfillment of academic activities.

Administrative Staff means a member of the staff of the University who holds position related to administration and health cadres and such other members of the staff of the University who are not engaged in teaching or research as the Council may from time to time determines.

Assurance means the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of service delivery or production.

Benchmarking means formal and structured process of evaluating institution's performance and standards against those of its peers to monitor relative performance and to develop improvement strategies

Certification refers to the issuing of written assurance (the certificate) by an independent external conformity assessment body that it has audited a management system and verified that it conforms to the requirements specified in the relevant standard (in this case, ISO 9001:2015)

Guidelines mean statements that provide direction with respect to specific principles.

Head of Department means a person heading an academic, administrative or service department.

Implementation involves carrying out systematic quality activities and uses quality audits to determine which processes should be used to achieve the university requirements and to assure they are performed efficiently and effectively.

Implementing Champion's means a team of trained technical staff set up at the level of a Department, College, Directorate, School, Institute, Centre or Bureau for the purpose of implementing issues of quality as defined in this framework.

Implementing Units means all Departments (academic and administrative), Colleges, Directorates, Schools, Institutes, Centers or Units, who collectively implement activities related to QMS within the University.

Interested Parties means stakeholders/groups that have an interest in the Quality Management of the SUA. They may include government, employers, students, academic and administrative staff, institutional managers, prospective students, parents of students etc.

Qualifications Framework means an instrument for the development and classification of qualifications according to a set of criteria for levels of learning and skills and competences achieved.

Quality means degree to which a set of inherent characteristics fulfills requirement.

Quality Assurance means a systematic and continuous process for ensuring that conditions are in place to achieve standards set by the institution or the means by which an institution can guarantee that the standards and quality of its mandates are being maintained. It is part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality Management includes establishing quality policies, quality objectives and processes to achieve these quality objectives through quality planning, quality assurance, quality control and quality improvement.

Quality Management System (QMS) means a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Quality Promotion means activities implemented for the aim of achieving quality.

Registration means that the auditing body records the certification in its client register.

Technical Committees means a body or team of experts dedicated to specified components of the Universities' mandates at levels of Department, School, Institute, Directorate or Centre such as the committees dealing with Undergraduate Studies, Postgraduate Studies, Research and Publications, Student Affairs and Social Welfare.

Technical Staff means laboratory and workshop technicians; laboratory technologists; field officers; library technicians and ICT technicians.

Top Management means a person or group of senior-level executives of an organization, or those positions that hold the most responsibility.

FOREWORD

Higher education institutions are currently intensively competing among themselves at national, regional and global levels. Hence SUA as an institution seeking to claim her position in the national, regional and global higher learning institutions, must pay due attention to quality as the natural way to go. The increased competition also dictates that quality be embedded in all aspects of the teaching, learning, research, outreach, administration, services and living environment.

In quest to achieve the above, the 4th Sokoine University of Agriculture Corporate Strategic Plan (SUA CSP, 2016-2021) sets forth the vision to be *'a leading University in the provision of quality knowledge in agriculture and allied sciences'* with a mission to *'promote development through training, research, and delivery of services'*. To realize these and advance the larger goal of an even stronger and more vital University, the key step forward is to ensure that SUA strives to reach high heights by locating itself within the international platforms such as the International Standards Organization (ISO). It is imperative therefore, that SUA formulates and uses ISO framework and guidelines towards attaining ISO 9001:2015 certification and at least two laboratories be accredited by June 2021.

Thus, having a quality management system (QMS) is critically important as Universities are now competing for high quality students as inputs and offer quality education to yield quality graduates. Hence, SUA must claim her rightful position in the global, national and local academic arena by embracing quality as the guiding principle in all activities conducted in the course of implementing the SUA mandate. With determination and resolve, implementation of the Quality Assurance Policy (QAP) using tools as ISO 9001:2015 framework and guidelines shall provide for systems that ensure quality teaching, learning, research and outreach activities as well as services at levels that are comparable and competitive at the national, regional and international levels.

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Sokoine University of Agriculture, Morogoro
September 2018

EXECUTIVE SUMMARY

Background information

There has been an increase in number of higher learning institutions in Tanzania, which are intensely competing among themselves at national, regional and global levels. Sokoine University of Agriculture (SUA) as an institution would like to also claim her position among the National, Regional and global higher learning institutions. To achieve this, special attention need to be paid to quality management as the right approach to towards becoming a global model institution. The increased competition also requires that quality be rooted in all aspects of the training, research and outreach services. This requires continuous quality improvement towards achieving and sustaining SUA's performance in all spheres.

Situational analysis

SUA Charter and Rules of 2007 give mandate to SUA to undertake training to meet the high level of human resource requirements of Tanzanian society, undertake research, provide public services as well as engaging in production. The mission of SUA is to "Promote development in agriculture, natural resources and allied sciences through training, research, and delivery of services" with a vision "To be a leading University in the provision of quality knowledge and skills in agriculture and allied sciences". To achieve the above, it is important therefore, that SUA defines the path to follow in order to arrive at the desired destination.

Therefore, during its 107th meeting held on 18th December 2009 SUA Council approved the establishment of the Quality Assurance and Promotion Bureau (QAPB) under the office of the Vice Chancellor (VC) to oversee all quality matters across the University. Furthermore, during its 120th meeting held on 30th June 2011 SUA Council approved the Quality Assurance and Promotion Policy (QAPP) to guide operations of the QAPB. This policy was also reviewed and approved by SUA Council on 29th June 2017 along with the development of Quality Assurance Good Practices Handbook (QAGPHB) and restructuring of the Bureau to assume a new name, 'Quality Assurance Bureau' (QAB) with an advisory board chaired by an external member.

The approval of these documents and restructuring of the bureau to have an advisory board (i.e. Quality Assurance Board), marked an important milestone for SUA to pay due attention to quality based on recognizing standards for both academic and non-academic aspects. Thereafter SUA management approved the internal quality assurance framework and guidelines, quality assurance policy implementation plan, and now the ISO/IEC implementation framework and guidelines as per SUA corporate strategic plan (2016-2021).

Rationale for SUA to become ISO certified

The education and training world is losing much of its special status, and is being considered more and more like an "ordinary" economic sector. This also implies that schools, universities, and training providers are increasingly expected to perform at high level, behave professionally, and provide quality services throughout. Two important trends may be observed in this regard:

- External demands (from governments, students, employers, etc.) on the education system are increasing; this puts pressure on the deployment of resources and the efficiency of the organization.
- The continuing education and training sector is becoming a more mature and "established" economic sector, alongside many other service sectors.

Such trends suggest that the education and training paradigms are changing from supply-driven teaching to demand-led learning. Although many educators do not feel comfortable with such developments, they would seem to be inevitable. Indeed, similar customer-driven trends can also be witnessed in other areas, such as public services. Having this in mind, implementation of ISO 9001 seems like a logical step in gaining a competitive advantage.

The objective of this framework and associated guidelines is to provide guidance to SUA management and members on how to develop and implement a quality management system (QMS) so that SUA become ISO 9001:2015 certified at least two of its laboratories become IEC 17025:2017 accredited by 2020. The quest for SUA to become ISO certified and IEC accredited is based on strategy 1.2.3 of its Corporate Strategic Plan (CSP 2016-2021 pp. 38) which has itemized four main actions/activities namely i-ii) to develop framework and

guidelines towards attaining ISO 9001:2008 (now ISO 9001:2015), iii) train SUA staff on ISO 9001:2008 (now 2015) and iv) at least 2 SUA laboratories become ISO 9001:2008 certified (but more correctly become IEC 17025:2017 accredited) by June 2020.

It is from this basis that Quality Assurance and Promotion Bureau (QAPB) by then (now simply Quality Assurance Bureau) was mandated to seek expert consultation (2017/2018 work plan and budget) to formulate and develop framework and guidelines towards attaining ISO 9001:2015 and IEC 17025:2017 by June 2020. Therefore, this document presents an ISO 9001:2015 and IEC 17025:2017 framework and guidelines to guide and/or assist SUA achieve its CSP targets. It validates and extends the dispersed experience by providing a useful unifying conceptual model of the impacts and success factors of ISO 9001 and ISO/IEC 17025 in higher learning institutions.

Moreover, the establishment and implementation of an ISO 9001:2015 standard will bring the following benefits to the education institution such as SUA:

- A shift in emphasis from a focus on the quality of the instructors/staff toward the performance of the institution as a whole;
- The introduction of new or additional quality control mechanisms; and
- The creation, for the first time, of quality assurance systems and performance-related mechanisms in a government owned institution of higher learning.

However, these advantages in the process are possible only if top management is able to engage people for the cause. Every person who affects quality should have the required competence, and be given training in the principles and dimensions of quality. They must understand why it is necessary to measure trends in processes, and to declare non-conforming services and not hide them.

ISO 9001 and ISO/IEC 17025 Implementation guidelines

In the process of attaining ISO 9001:2015 Certification and IEC 17025:2017 Accreditation, SUA should abide into the following:

a. Form an ISO Project Team Leader (PTL) who will be responsible for implementing ISO 9001:2015 requirements
b. Determine the scope of ISO 9001:2015 implementation under the first phase, and finalize the same through discussion with the SUA, QAB.
c. Approve the consultant to guide the PTL & QAB to define the scope for ISO 9001:2015 requirements and implement within an agreed time frame.
d. Work closely with the Consultant to perform Gap Analysis (GA) of the existing systems including available documentation of the University against the requirements of ISO 9001:2015 and produce a gap analysis report.
e. The PTL, QAB & the Consultant should plan ways to address the gaps in order to develop the mandatory documentation for ISO 9001:2015 certification and guide the ISO project team on implementing the developed documents.
f. The Consultant will be required to develop customized training course material in soft copy (as well as hard copy) for conduct of all necessary trainings for SUA staff. The trainings will include but not limited to:
    - The Top/Senior management briefing (ISO Awareness)
    - An awareness program for all employees
    - The team of ISO 9001 implementation champions who will be responsible for Planning, documentation and implementation
    - The ISO 9001 Internal Auditors who will attend a 5 days detailed course on ISO 19011:2018 focusing on Management Systems auditor competence requirements.
g. Furthermore, the consultant should:
    - Advise the ISO steering committee on change management and the success factors to support effective implementation of ISO 9001:2015 at SUA.
    - Conduct Internal Auditors training (mentioned in “e” above) and guide the Internal Auditor team in conducting required numbers of internal audits.
    - Conduct an evaluation of implemented ISO 9001:2015 quality management system through internal audits including implementation of Corrective Actions (CAs).

- To conduct a Management Review for close review of final SUA documented system prior to Final & External certification audit. The consultant to assist in coordination of required management reviews prior to certification.
- Guide the ISO project team to take the necessary corrective actions on identified non-conformities and final review of documents as advised by the Top Management Review meeting.
- Guide the ISO Project team in selecting the registrar and making an application for certification process.

h. The Consultant and the QAB should plan and co-ordinate payment of required fees and providing necessary support during final certification of the University and ensure that SUA is audited and certified by a select certification body.

i. The consultant, together with QAB should take necessary actions to implement Corrective Actions to nonconformities raised by the External Auditor. Submit report to Top Management of with a copy to QAB and other experts for review of Corrective Actions (CAR) Report forms before submission to the Certification Body for review.

j. Submit CAR to the CB for review and final recommendation

k. Ensure ISO 9001:2015 Certificate is issue to SUA.

l. **SUA maintains ISO 9001 Certification because** QMS certification is not a one-time event, as the CB registrar will perform a surveillance site audit once every year in order to verify continued ISO 9001 compliance and even improvement of the Management System. QMS Certification can be both easy and rewarding if done right.

ISO 9001:2015 principles, processes and procedures

The ISO 9001:2015 standardization, which has replaced the ISO 9001:2008 is awarded after a successful audit by a certification body. The new standard provides many benefits to the organization that includes better process integration, improved evidence for decision making, engagement of staff and students, improvement of customer satisfaction and improvement in the credibility and image of the organization. The key components of the new standard

include its scope, quality policy, quality objectives, six main processes, 32 sub processes and 81 procedures.

Unlike the ISO 9001:2008 standard, which had eight principles, ISO 9001:2015 standard is constructed around seven principles:

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making and
7. Relationship management

Each of these principles is detailed in this framework and guideline document.

CHAPTER ONE

1.0 BACKGROUND INFORMATION

1.1 Brief history of 'quality' movement

The quality movement has its roots back in medieval Europe, in the late thirteenth century, where craftsmen organized themselves into guilds. Until the early nineteenth century, manufacturing in the industrialized world continued to follow this guild model. In the mid-1750s, the factory system, which emphasized product inspection, was introduced in Great Britain and developed into the Industrial Revolution in the early 1800s. The Industrial Revolution led to a system in which large groups of people that performed similar work were brought together under the supervision of an individual, who was appointed to control the quality of work being undertaken. This is referred to as 'quality control' perspective.

During the mid-1920s, Walter Stewart, a statistician with Bell Laboratories, A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. Process approach to quality, broadened the focus on quality to include not only the finished product but also the processes needed to achieve that quality. He recognized that the processes provided useful data that could be analyzed using statistical techniques to ascertain whether a process was providing the optimum outcome or required refinement to deliver the expected level of quality. To this day, that activity still plays a key role in any quality management system (QMS).

Another statistician, William Edwards Deming, was an advocate of Shewhart's methods and became a leader of the quality movement in both Japan and the United States of America. Deming triggered a revolution in manufacturing, which led to a significant improvement in product quality. His influence in Japan, through his quality management (QM) initiatives,

was a key driving force behind the country's economic rise in the period after World War II. In the 1970s, many major public and private sector organizations published their own QM standards, which introduced the idea that confidence in a product could be gained through the use of an approved QMS and quality manuals.

Growing international trade stimulated the development of internationally recognized QM standards. It was feared that a variety of national standards would emerge and become a barrier to international trade. It was therefore recognized that there was a need for an international standardization system, which led to the establishment of the International Organization for Standardization (ISO). Today, this is an independent, non-governmental organization, and its members are standards organizations within more than 170 member countries, including Tanzania through the Tanzania Bureau of Standards (TBS). ISO is responsible for the development and maintenance of the ISO 9000 series of quality assurance standards, which are the cornerstone of subject matter being considered here – the ISO 9001:2015 framework and guidelines.

1.2 The ISO 9000 family of standards

In 1987, an ISO committee chaired by Canada developed an international quality standard based on the then British Standard BS 5750, which was the first of the ISO 9000 series. Since 1987, this series has grown and now includes associated guidelines applicable to particular industries. The ISO 9000 family comprises two kinds of QM standards: *requirements and guidelines*. The series consists of the following three standards, which represent international consensus on good QM practices:

i. **ISO 9000:2015, QMS – Fundamentals and Vocabulary (ISO, 2015b).** This standard describes the fundamentals of QMSs and specifies the terminology used in ISO 9000.

ii. **ISO 9001:2015, QMS – Requirements (ISO, 2015c).** These requirements can be applied to all types of organizations, both in the public and private sectors, regardless of size or industry group. Therefore, they are generic in nature and can be adopted by, and adapted to, almost any organization because standards of quality are internationally recognized and respected throughout the world. ISO 9001:2015 is the

only standard in the ISO family against which organizations can be certified (or registered), through a third-party audit process.

iii. **ISO 9004:2009, Management for the Sustained Success of an Organization-Quality Management Approach (ISO, 2009a).** This standard focuses on achieving sustainable success in today's complex, demanding and ever-changing environment by meeting the needs and expectations of customers and other stakeholders. An interesting facet of this standard is that it promotes self-assessment as an important tool, which enables ongoing review of the level of maturity attained by QMSs. However, it should be noted that the self-assessment tool is not a substitute for a third-party audit process, which is fundamental to ISO 9001.

Note, however, these (above) may be purchased online, as PDF documents, from the ISO store (http://www.iso.org/iso/store.htm). As the standards are updated at regular intervals, it should be ensured that the latest edition is obtained. Therefore, this framework and guidelines should be used in conjunction with the above-mentioned ISO 9001:2015 standard, to ensure the requirements are fully understood and addressed and that maximum benefits (outlined at the end of this chapter) are gained.

1.3 Importance of the ISO 9000 family of standards

The ISO 9000 family of standards, in particular ISO 9001, is important because of its international orientation. It has the support of national standards bodies from more than 160 countries, Tanzania inclusive, and is therefore the logical choice for an organization such as Sokoine University of Agriculture (SUA). The adoption of a QM approach to the delivery of products and services may require the implementation of a change management strategy. The ISO 9001 standard provides an appropriate framework to implement the required change management processes. The framework helps to identify the most-appropriate policies, procedures, records, technologies, resources and structures needed to achieve and enhance the quality of processes, procedures, products and services. The development and successful implementation of a QMS will instill a quality attitude at all levels of an organization, which, in turn, will help to ensure the delivery of products and services of an international standard.

The application of ISO 9001:2015 in higher education institutions will lead to:

i. Improved quality of services at the university
ii. Establishment of strategic plans towards quality management and continual improvement
iii. Raising the need to improve process & systems performance
iv. Increased ability to meet current and future customer requirements and expectations
v. Toll for meeting the requirements of a government via its institutions
vi. Promotion of the dynamics of continuous improvement
vii. Facilitation of data gathering for management
viii. Clear definition of responsibilities with regards to quality and related aspects
ix. Standardization of work procedures (SOPs) and
x. Improvement of the documentation of processes

1.4 Drivers for adopting a quality management approach in higher learning institutions

The key driver for adopting quality management approach in higher learning institutions is based on the fact that quality education is the main driver for the lifelong learning of people and the development of the organizations and society. Accordingly, also UNESCO's global vision for education towards 2030 is endeavoring to 'ensure inclusive and equitable quality education and promote lifelong learning opportunities for all'. From the quality point of view, the existing situation is however very fragmented. A great variety of educational organizations provide formal and non-formal education for lifelong learning to people having very different needs and expectations, and the education providers and experts are not very aware of the **general professional quality concepts and practices**.

The good news here is that the international standardization committee ISO/PC 288 has started the work of harmonizing quality management in the educational organizations with the other organizations of the society by using the common professional approach. This new standardization will challenge all educational organizations, because it requires the adoption of the general basic quality concepts and quality management structures and practices. This will enable educational organizations to demonstrate their ability to provide consistently education to the requirements and strive for enhancing satisfaction of the involved parties.

Furthermore, the need for quality education services has increased in recent days due to increased competition in the global and regional contexts as well as stiff competition in the graduates' job market. In Tanzania, this is also aggravated by the increase in number of students from public and private secondary level education hence pushing for increased number entrants (students) into institutions of higher education. Therefore, ensuring quality of educational services and hence quality graduates (product of higher learning institutions) within these nexus is an obvious challenge now and years to come.

Moreover, the increased demand for university level education, coupled by the increase in population generally, and qualified students from secondary schools have led into the establishment of many public and privately owned institutions of higher learning, which creates competition in all dimensions, with quality education being at the forefront. Therefore, to remain relevant and competitive, institutions of higher learning must take all necessary measures to maintain quality in all academic programs and service delivery to students and the general public. The focus to quality of services is inevitable as trends in higher education at national level; regional level and global level indicate an increasing attention to quality.

1.5 Benefits of implementing Quality Management System

The benefits of implementing a QMS and achieving certification of compliance with ISO 9001:2015 are significant. Below is some key benefits enjoyed by organizations with mature QMSs (not listed in order of priority) worldwide:

i. Customer needs identified, met and monitored within a consistent management framework;
ii. Improved management control and reporting;
iii. Continuous improvement and enhanced quality culture embedded in the organization;
iv. Clear processes in place to address poor-quality/non-conforming products;
v. Marketing tool for promoting the organization internally and externally, so that it stands out from potential competitors;
vi. External audit by a third party, which is a powerful tool to establish and imbed the credibility and accountability of an organization;

vii. Well-defined procedures and processes – employees know what to do and how to do it, and do not waste time duplicating efforts;
viii. Enhanced teamwork, and internal and external communication;
ix. Greater clarity of job specifications, descriptions and duties;
x. Improved work health and safety practices;
xi. Greater quality assurance of products and services;
xii. Enhanced response to customer feedback/complaints to rectify non-conformances;
xiii. The organization functions in a well-organized manner as a result of the systematic approach to the delivery of its products and services and associated activities;
xiv. As the QMS matures, more time is spent on improving products and services, as opposed to rectifying and reacting to the demands of dissatisfied customers;
xv. Significant decreases in time and money spent on recurring problems, as many are resolved permanently;
xvi. The organization builds the inner resources and skills necessary to identify and resolve problems more expediently;
xvii. Significantly improved documentation processes and procedures that, in turn, enhance the capture of corporate knowledge;
xviii. Improved document control, which enhances the ability of the QMS to produce high-quality responses to the legal community on matters pertaining to requests such as those associated with accident/incident investigations and weather-related insurance claims;
xix. Competencies are identified, gained and maintained through appropriate training;
xx. Job satisfaction of employees can be significantly improved;
xxi. The QMS is a powerful change management tool;
xxii. The QMS is a powerful tool to ensure important issues are highlighted at the appropriate
xxiii. Organizational level;
xxiv. Although no longer a requirement of ISO 9001:2015, those QMSs already maintaining a quality manual have identified it as a useful induction tool for new staff and as a road map for how the QMS operates;
xxv. Risk-based thinking – identifying opportunities and threats;

xxvi. Control and monitoring of externally provided processes, products and services;

xxvii. Enhanced understanding of the context of the organization – internal and external issues that affect it.

Based on the above list of benefits, it is obvious that the adoption of a QM approach and certification of compliance with ISO 9001 can deliver a vast range of benefits to SUA. However, it should be remembered that the achievement of ISO 9001 certification of compliance is not an end in itself – it is a milestone in the QM journey, so should be guided.

CHAPTER TWO
2.0 SITUATIONAL ANALYSIS

2.1 Overview

Higher education institutions are currently intensively competing among themselves at national, regional and global levels. Hence SUA as an institution seeking to claim her position in the national, regional and global higher learning institutions, must pay due attention to quality as the natural way to go. The increased competition also dictates that quality be embedded in all aspects of the teaching, learning, research, outreach, administration, services and living environment.

The 4th SUA Corporate Strategic Plan (SUA CSP 2016-2021: pp4-15) provides a detailed internal and external analyses which cover mandates and functions of the University; review of the implementation of the 3rd CSP (in terms of achievements recorded and main challenges faced); environmental scanning (both internal and external) with a summary of SWOC-AR (Strengths, Weaknesses, Opportunities, Challenges/Threats, Aspirations and Results) analysis. The implementation of the current SUA CSP (2016-2021) is guided by the SUA vision and mission statements and core values provided below.

2.2 SUA vision, mission and core values

2.2.1 The vision

SUA aspires '*to be a leading University in the provision of quality knowledge and skills in agriculture and allied sciences'*

2.2.2 The mission

'To promote development in agriculture, natural resources and allied sectors through training, research and delivery of services'

2.2.3 Core values

In achieving its vision and fulfilling its mission, SUA adhere to the following core values:

i. Pursuit of excellence in service delivery;

ii. Entrepreneurial and innovative spirit;
iii. Competitive orientation;
iv. Integrity, transparency and accountability
v. Results/achievement oriented;
vi. Diligence on duty;
vii. Adaptive and responsive;
viii. Freedom of thought and expression;
ix. Gender sensitive; and
x. Continuous learning.

2.3 Overall goal and strategic corporate objectives of SUA

The overall goal of the Corporate Strategic Plan (CSP) is to enable SUA become a reputable world-class university that is responsive to national, regional and global development needs. In order to achieve its vision and fulfill its mission, SUA CSP (2016-2021) addresses and implements seven strategic objectives as follows:

i. Increasing student enrolments and improving quality of graduates
ii. Increasing the volume of research and quality of publications
iii. Enhancing outreach, publicity, linkages and partnerships
iv. Enhancing University financial capacity and sustainability
v. Improving teaching and learning environment
vi. Improving management and institutional governance and
vii. Mainstreaming gender issues in all SUA activities and reducing the impact of HIV/AIDS and other crosscutting issues.

Achievement of these objectives will ensure that SUA is able to contribute to the advancement of knowledge and technology and take responsibility to preserve and transmit the same in line with internationally accepted standards of academic excellence. Quality assurance will provide a platform on which to gauge the extent to which the programs are aligned to the Mission and objectives of the institution.

2.4 Rationale for SUA to become ISO/EIC certified/accredited

In addition to global demands for quality management systems in higher learning institutions, the East Africa Countries (EAC), through the Inter-University Council for East Africa (IUCEA), in collaboration with the German Academic exchange services (DAAD) and the Germany Rectors' Conference (HRK) within the framework of their joint Higher Education Management Support programmed referred to as 'Dialogues on Innovative Higher Education Strategies (DIES)' started to work on quality assurance system (QAS) for universities that was initiated in 2006.

The project aimed at harmonizing regional quality assurance system by establishing a common East African Quality Assurance Framework (EAQAF), among others. This also implies that universities within EAC are increasingly expected to perform at high level, behave professionally, and provide quality services throughout. This compels higher learning institutions to go for developing higher level quality management system in accordance to the requirements of the International Organization for Standardization (ISO).

The objective of this ISO framework and associated guidelines is to provide guidance to SUA management and members on how to develop and implement a QMS so that SUA become ISO 9001:2015 certified and at least two of its laboratories become IEC 17025:2017 accredited by 2021. The quest for SUA to become ISO certified and IEC accredited is based on strategy 1.2.3 of its Corporate Strategic Plan (CSP 2016-2021 pp. 38) which has itemized four main actions/activities namely i-ii) to develop framework and guidelines towards attaining ISO 9001:2008 (now ISO 9001:2015), iii) train SUA staff on ISO 9001:2008 (now 2015) and iv) at least 2 SUA laboratories become ISO 9001:2008 certified (but more correctly become IEC 17025:2017 accredited) by June 2020.

It is from this basis that Quality Assurance and Promotion Bureau (QAPB) by then (now simply Quality Assurance Bureau) was mandated to seek expert consultation (2017/2018 work plan and budget) to formulate and develop framework and guidelines towards attaining ISO 9001:2015 and IEC 17025:2017 by June 2020. Therefore, this document presents an ISO 9001:2015 and IEC 17025:2017 framework and guidelines to guide and/or assist SUA

achieve its CSP targets. It validates and extends the dispersed experience by providing a useful unifying conceptual model of the impacts and success factors of ISO 9001 and ISO/IEC 17025 in higher learning institutions.

Moreover, the establishment and implementation of an ISO 9001:2015 standard will bring the following benefits to the education institution such as SUA:

- A shift in emphasis from a focus on the quality of the instructors/staff toward the performance of the institution as a whole.
- The introduction of new or additional quality control mechanisms;
- The creation, for the first time, of quality assurance systems and performance-related mechanisms in a government owned institution of higher learning.

However, these advantages in the process are possible only if top management is able to engage people for the cause. Every person who affects quality should have the required competence, and be given training in the principles and dimensions of quality. They must understand why it is necessary to measure trends in processes, and to declare non-conforming services and not hide them.

CHAPTER THREE

3.0 PRINCIPLES AND APPROACHES OF QUALITY MANAGEMENT SYSTEM

3.1 Overview

The principles of QM underpin the ISO 9000 standards and need to be embedded in a QMS to provide a sound foundation for achieving the goals and objectives of organizational (SUA) programmes and operations. These principles have been derived from the collective experience and knowledge of international experts who participate in the ISO Technical Committee (ISO/TC 176) responsible for developing and maintaining the ISO 9000 standards. The following are key principles underlying ISO 9001:2015 which will be used to develop and implement ISO 9001:2015 for SUA by 2020.

3.2 Principles of quality management

A quality management principle is a fundamental rule for leading, operating and developing an organization, with the objective of continually improving performance over the long term through a focused approach to all stakeholders, particularly customers. There are seven principles of QM that provide a sound foundation for achieving goals and objectives of an organization. Standard ISO 9001:2015 is based on the seven principles of:

i. Customer focus
ii. Leadership
iii. Engagement of people
iv. Process approach
v. Improvement
vi. Evidence-based decision-making
vii. Relationship management

According to ISO 9001:2015, each organization will need to apply the principles in terms of their own particular activities. Fortunately, ISO has produced an extremely informative and contemporary document (ISO 2015), which provides, for each principle, a description, an

explanation of the rationale as to why it is important, and examples of the key benefits and actions that can be taken to improve performance when applying the principles.

The following are quality principles of quality management system:

Principle 1 – Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations. To achieve this, SUA is currently developing a 'Client Service Charter' and management has already engaged all principals, dean and heads of academic, administrative and service units to work on the provided guidelines.

Principle 2 – Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives. The new Vice Chancellor, as chief executive officer is responsible to make this effective.

Principle 3 – Engagement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit. The Quality Assurance Bureau, in consultation with the office of the Deputy Vice Chancellor-Academic, College Principals and Heads of Departments (academic, administrative and service departments) has constituted the Quality Assurance Board and various quality assurance committees across the university.

Principle 4 – Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 – Improvement

Improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 6 – Evidence-based decision making

Effective decisions are based on the analysis of data and information. SUA take decisions based on evidence-based research through task forces or independent consultants.

Principle 7 – Relationship management

An organization and its external providers (suppliers, contractors, service providers) are implemented and a mutually beneficial relationship enhances the ability of both to create value.

3.3 Approaches used in implementing QMS in an Organization

This International Standard can be used by internal and external parties. It employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

3.3.1 The PDCA cycle

The PDCA cycle (**Figure 1**) enables an organization to ensure that its processes are adequately resources and managed, and that opportunities for improvement are determined and acted upon while risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

For successful QMS, the implementers need to thoroughly know the organization and its context, the customer (student) requirements, needs and aspirations of relevant interested parties (stakeholders), customer satisfaction and products and services as key results of the QMS. Planning, leadership, support operations and performance evaluation are key cross-

cutting activities that need to be taken into consideration in the PDCA cycle. In summary, planning entails establishing the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organizations' profiles, and identify and address risks and opportunities. Doing entails the actual implementation of what was planned. Checking entails monitoring and (where applicable) measure processes and the resulting products and services against policies, objectives, and requirements and planned activities and reports the results. Acting entails taking actions to improve performance, as necessary.

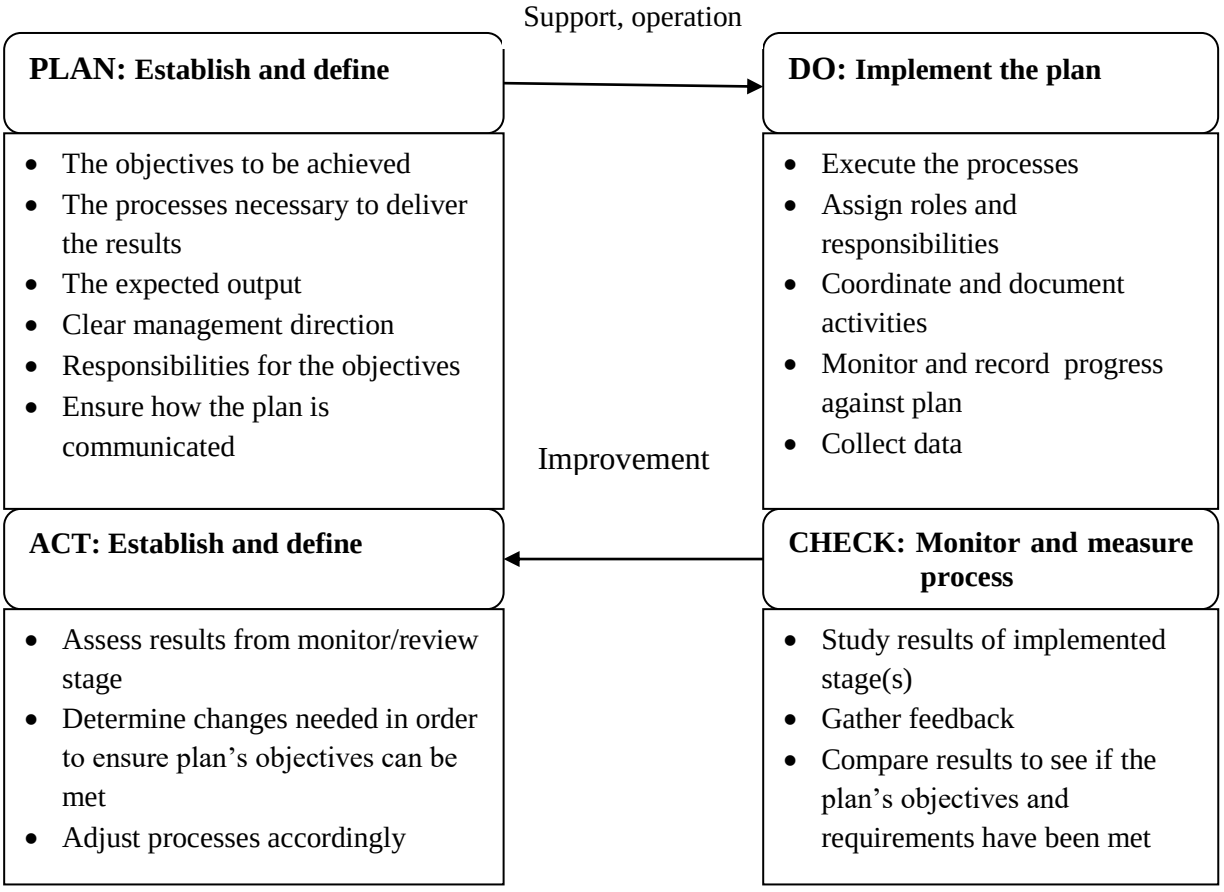

Figure 1: The PDCA cycle.

3.3.2 Risk-based thinking

Risk[1]-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in the previous editions, for example carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformity that do occur and taking action to prevent recurrence that is appropriate for the effects of the nonconformity. To conform to the requirements of the ISO 9001:2015, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers (e.g. students), develop new products (e.g. degree programmes) and services (e.g. TV and radio outreach facilities), reduce waste or improve productivity. Action to address opportunities can also include consideration of associated risks. In a nutshell, to establish a QMS the organization needs to demonstrate its ability to consistently provide products and services that meets customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

[1] Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities (ISO 9001, 2015).

CHAPTER FOUR

4.0 STEPS FOR IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

4.1 Quality Management System Framework

The principles of Quality Management System (QMS), presented in the next section, underpin the ISO 9000 family of standards and need to be embedded in a QMS to provide a sound foundation for achieving the goals and objectives of an organization. These principles have been derived from the collective experience and knowledge of international experts who participate in the ISO Technical Committee (ISO/TC 176) responsible for developing and maintaining the ISO 9000 standards and certification in a given context.

However, the success of QMS largely depends on the effectiveness of the management framework (**Figure 2**) providing the foundations and arrangements that will embed it throughout the organization at all levels. This framework assists in QMS effectively through the application of the Process Approach at varying levels and within specific contexts of the organization. The framework ensures that information about QMS derived from various processes across and/or along different levels is adequately reported and used as a basis for decision-making and accountability.

Therefore, the QMS Framework is an integral part of sound management practices and must be fully integrated into the organization's Corporate Strategic Plan, policies and procedures in use. This implies that the ISO framework should not be seen, or practiced, as a separate program, rather as an adds-on tool to the existing frameworks within an organization. Specifically, the ISO framework and guidelines presented herein are meant to fulfill SUA's target to be ISO certified by 2020 and at least two of its laboratories become ISO/IEC accredited within the same time.

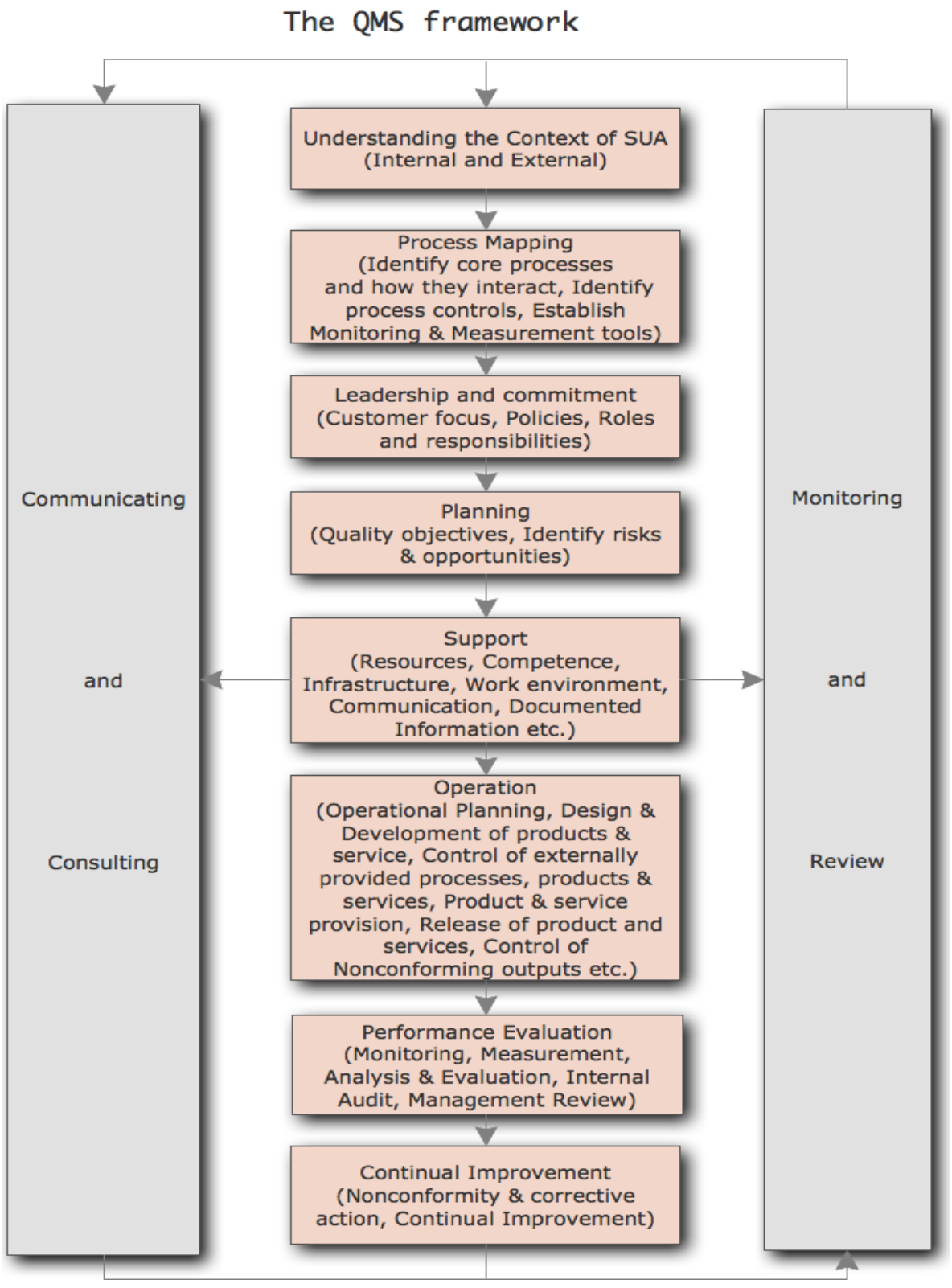

Figure 2: Quality Management System Framework

4.2 Steps for implementing a quality management system

Step 1: Obtain formal endorsement of top management

Clause 5.1 of ISO 9001:2015 emphasizes the need for demonstrated commitment from top management. In fact, it is a critical first step in the development and implementation of a QMS. The demonstration of commitment should involve formal endorsement, communicated to all staff. Top management must ensure that the finances to support the QMS will be available. The proposed development and implementation of the QMS should be formally documented and include the proposed implementation strategy, a broad timeline and an estimated budget. It is strongly suggested that the early development and implementation stages of the QMS be within a project framework.

It is not possible within the context of this Guide to indicate the exact cost of implementing a QMS. The scope of the QMS and the costs of training, consultancies and certification bodies will differ significantly across the organization. However, this Guide points to some important questions concerning the financial commitment required. Although the answers to these questions will enable the development of a reasonably accurate budget, it would also be advisable to set up a contingency fund to cover indirect costs that may not have been identified initially. For example, it may be decided to upgrade QMS instrumentation to enhance the quality of the observation network.

A word of caution regarding this step: unless the formal endorsement and commitment of top management can be obtained, and the appropriate level of resources secured, attempting to implement a QMS could be a waste of time and resources. The failure of this process will have a significant and adverse impact on staff.

Step 2: Select a professional quality manager

The appointment of a professional quality manager is a key factor to the success of a QMS. It is strongly recommended that a full-time staff member be appointed at a senior level, and it is beneficial for the implementation process if the officer has knowledge of the business. The

position will inevitably be the driving force behind the QMS and the primary focus for issues pertaining to the QMS. It requires an individual with a specific set of skills, knowledge and character traits that will earn him/her the trust of top management and direct access to it. For details please refer the guidelines for auditing management systems in ISO 19011:2018.

A generic job description and selection criteria for this key role is provided in **Appendix 1**, which may be used as a starting point for establishing such a role. It is essential that the individual appointed has a strong desire for, and interest in, undertaking the challenges associated with developing and implementing a QMS. A forced or political appointment will potentially, if not inevitably, undermine the QMS and result in its failure.

Step 3: Select the Consultant and training provider

It is strongly recommended that several potential training providers be interviewed, to ascertain their knowledge and relevant experience, and how well they would align with the culture of the organization. The interview process provides an opportunity to assess their commitment to working with the organization. The level of interest they have shown prior to the interview in obtaining information about the activities of the organization and the products and services it provides should be ascertained.

The credentials of any potential training providers should be carefully assessed by checking their qualifications and course content. It is important that they are accredited trainers and can provide an introductory course that will "demystify" ISO 9001 for all staff involved in the QMS. A basic set of questions for establishing the credentials and the suitability of potential QM consultants/training providers is provided in **Appendix 2.**

Step 4: Provide introductory quality management training

An introductory training session for all staff involved in the QMS should be organized, starting with the core QMS team including the top management (e.g. Chief Executive Officer/Director). A basic introductory ISO 9001/ISO/IEC 17025 training course helps to ensure the successful implementation of a QMS by providing sound understanding of the principles and practices pertaining to ISO 9001. Ideally, this course should be provided by a

registered training organization with expertise in this area. Although not ideal, if a staff member has to conduct the training session, he/she must have a sound and demonstrated background in the subject matter combined with, wherever possible, formal training skills.

Step 5: Conduct a gap analysis

A gap analysis is a technique for determining the steps to be taken to move from the current state to a desired future state. In the case of QMSs, a gap analysis is undertaken to clearly identify which clauses of ISO 9001 are currently not being fully addressed (or not addressed at all) and to develop remedial actions. The gap analysis should be conducted by members of the QM team/section who have formal auditing qualifications. Gap analyses can be conducted with small groups of staff. For example, a gap analysis can be conducted with the senior management group and a separate gap analysis with middle management and/or operational staff. It is not unusual to receive different responses to questions depending on the position and level of staff within the organization.

The two gap analysis tools (part A and part B) listed below provide a structured framework to assess the current status of a QMS in terms of fulfilling the ISO 9001 clauses:

a. **Part A, Gap analysis**, is aligned with the clauses of ISO 9001. The gap analysis template in Appendix 19 provides comments and notes to assist users.
b. **Part B, Gap analysis findings**, lists the findings and remedial actions that are required to close the identified gaps between ISO 9001 and the current management system of an organization (**see Appendix 3**).

An important consideration in using the gap analysis tools is that, for most staff, this will be an introduction to an audit-like process and the practical aspects of a QMS. It is therefore important that it is a positive experience from all perspectives. Any gap analysis or audit should be focused on the processes and the overall system, not the individuals following the practices and procedures provided.

Step 6: Conduct quality management review meetings

There are no specified time periods applicable to conducting quality management review meetings (QMRMs). However, they are essential during the initial development and implementation stages of the QMS and should be conducted on an as-required basis. Some organizations may also find it beneficial to conduct a QMRM prior to an external surveillance or certification audit, in order to identify gaps that can be filled prior to the external audit(s) being conducted. Clause 9.3 of ISO 9001:2015 provides detailed specifications (inputs) for management reviews (QMRMs).

Appendix 4 provides a generic template that may be adapted for QMRM agenda and minutes. As per clause 5.1 of ISO 9001:2015, it is important that a member of top management chairs QMRMs. The meetings provide useful insight into the basic processes and enable management to respond accordingly. It is imperative that the management fully understand and appreciate the requirements under clause 9.3 and sub-clauses 9.3.2 and 9.3.3 of ISO 9001:2015. The secretarial duties should nominally be undertaken by the quality manager/section. Attendees at QMRMs should include senior officers and other staff within the scope of the QMS, as appropriate, and the internal auditor(s) should also attend. As mentioned previously, a definition of top management" is provided in the preliminaries of this framework as defined in ISO 9000:2015.

Step 7: Commence work on rectifying identified gaps

The outcomes of step 5 (gap analysis) and actions resulting from step 6 (QMRMs) will provide a priority for rectifying identified gaps. It is important to monitor progress and to document the actions and results that will need to be considered at the next QMRM.

Step 8: Identify processes and develop procedures

Developing and writing processes and procedures that are currently being followed is a critical component of a QMS. It is imperative that they are developed in close consultation with the staff that follows them as part of their duties. There may be merit in providing specific QMS staff with training in how to write procedures. It is important to find a balance

between over-documenting and not providing sufficient information, while ensuring that processes and procedures are clearly articulated and unambiguous.

Finding the right balance usually comes through experience, including learning from others who have been through the same or a similar process, such as the University of Nairobi and the Kirinyaga University, both found in the United Republic of Kenya which are already been ISO 9001:2015 certified. A process matrix (**Appendix 5**) is a key outcome of this step. At the commencement of implementation, it is important to develop specific, measurable, attainable, relevant, and timely and, where possible, automated key performance indicators (KPIs) that reflect the actual activities of the QMS.

Step 9: Measure customer satisfaction

It is essential that appropriate client satisfaction measuring tools are established from the outset, so as to provide a baseline from which to assess improvement in service delivery. Standard ISO 9001 notes that there are several ways in which the level of client satisfaction can be measured. Industry focus groups can be used as viable measuring tools where the organization communicates face to face with representatives of a particular industrial sector that it serves. Focus groups are also useful because they provide an opportunity to ask questions, clarify customer feedback and expectations, and develop strategies with the customer to rectify any problems. They can also help to establish a core reference group that will gain better knowledge and understanding of the environment in which the organization operates – this will add useful input for addressing clauses 4.1 and 4.2 of the ISO 9001:2015.

It is important that the actions arising from these meetings and the levels of customer satisfaction thereby identified are fully documented and agreed by all the parties concerned. The (agreed) documented outcomes will enable the identification of trends in customer satisfaction over a specific period of time. Customer survey tools can enable the QMS to reach a larger audience. However, it is notoriously difficult to get customers to respond to surveys. It takes a great deal of tenacity and patience to obtain a sufficient number of responses that will provide credible and meaningful feedback on customer satisfaction.

When preparing a customer satisfaction survey, the following key points should be considered:

a. The reason for conducting the survey, its target group and the most appropriate time to conduct it should be clearly established;
b. The contents of the survey should be well organized;
c. A budget for the survey should be prepared;
d. The questionnaire should be well designed and the questions clearly formulated;
e. The method that will be used for the survey (email, web, hard copy, telephone, focus group, etc.) should be clearly defined;
f. The method for analyzing the results should be clearly established;
g. The questionnaire should be pre-tested before finalization;
h. Dates for dispatching and returning the questionnaire should be set;
i. The survey should be conducted on a scheduled basis to provide continuity of feedback and trends in the data;
j. Those conducting the survey should display tenacity and patience when collecting the questionnaires;
k. The data analysis process should be clearly defined and implemented;
l. Due care should be taken in interpreting and evaluating findings;
m. Special attention should be paid to developing the actions needed to address the issues
n. Raised (root cause analysis);
o. A survey report should be disseminated to key stakeholders and, most importantly, the QMS staff.

NB: A customer feedback mechanism on the QMS web page can also be a useful too.

Step 10: Identify and train staff to undertake the role of internal auditor

It is critical that due care be taken in selecting staff to perform the role of internal auditor. Individuals who show potential as auditors should be given formal training by a registered training organization. It is imperative that the required level of competence of all internal auditors is maintained via refresher training or, more importantly, active participation in the

audit programmed. Apart from having the appropriate training, selected staff should also possess the necessary personal qualities and attributes that enable them to act in accordance with the principles of auditing.

Standard ISO 19011:2018 lists six principles of auditing:

a. **Integrity: the foundation of professionalism**

   Auditors should perform their work with honesty, diligence and responsibility, observe the law and make the disclosures required by law and the profession.

b. **Fair presentation: the obligation to report truthfully and accurately**

   Audit findings, conclusions and reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the individual being audited should be reported.

c. **Due professional care: the application of diligence and judgment in auditing**

   Auditors should exercise care in accordance with the importance of the task they perform and the trust placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

d. **Confidentiality: integrity and security of information**

   Auditors should be prudent in the use and protection of the information acquired in the course of their duties. Auditors should not disclose information without appropriate authority unless there is a legal or professional obligation to do so.

e. **Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions**

   Auditors should be independent of the activity being audited and should be free from bias and conflict of interest, wherever practical. Auditors should maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions are based only on evidence.

f. **Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process**

   Audit evidence should be verifiable. It will be based on samples of the information available, as an audit is conducted during a finite period of time and with finite

resources. The appropriate use of samplings is closely related to the confidence that can be placed in the audit conclusions (Adapted from ISO (2011), pp. 4 and 5). It is suggested that organizations obtain a copy of ISO 19011:2011, which provides excellent guidelines on auditing. A copy may be purchased from the ISO online store (https://www.iso.org/store.html).

Step 11: Conduct internal audits

Conducting an audit and developing a robust internal audit schedule is a critical component of a QMS. It is strongly recommended that an organization's internal auditors widely publish an audit schedule, as it will provide a useful planning tool for key stakeholders. The internal audit process should cover all facets of preparing for and conducting audits based on a sound audit programmed: audit scope, audit criteria, references, definitions, audit schedule, audit performance, follow-up audits, corrective action, audit documentation, audit failure and management review. A generic internal audit procedure is illustrated in **Figure 3** below.

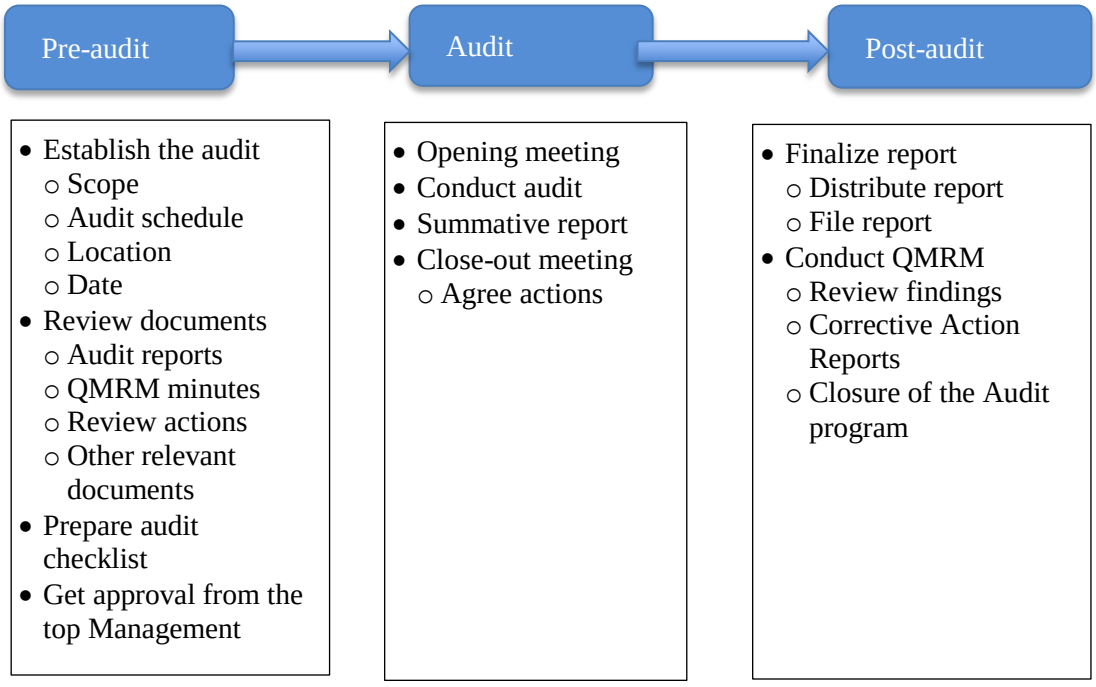

Figure 3: Internal audit process

However, it is also important to note that auditors must be objective and impartial and shall not audit their own work. This situation can be relatively easily achieved within a QMS internal audit environment. The quality manager should ensure that internal audits are conducted by staff that do not work in the area being audited. It should be noted that the exchange of internal auditors among different organizations can be a useful process. The exchange of auditors, where possible, can also be used to enhance the value of the audit and the individual auditor's competencies.

Step 12: Select a certification body to conduct the certification audit

In the case of the certification body (third party or external auditor), the need for objectivity and impartiality is even more important. There are many organizations globally offering consulting services to assist in the development and implementation of a QMS. It is important to note there are some organizations that, in addition to their consulting services, may also offer their services as the third-party certification body. This is totally inappropriate and removes the impartiality and objectivity from the process, and will create a potential conflict of interest. Any organization contemplating engaging a conformity assessment body should give it considerable thought, as the credibility of the QMS and its certification of compliance with ISO 9001 is underpinned by the independence of the third-party external audit process. Refer ISO 19011:2011, subparagraph (e) for more details.

Hence, when selecting a certification organization, the QMS should consider the following:

a. Whether it complies with standard ISO/IEC 17021:2011, Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems(ISO/IEC, 2011), and whether it can demonstrate a positive track record;
b. Whether its profile and standard mark are credible from both national and international perspectives;
c. Whether it currently provides certification for organizations providing similar products and services;
d. Whether it can commit to providing strict and thorough audits and whether an auditor is available with a sound understanding and appreciation of the activities, products and services of the organization;

e. Whether it has a definitive fee structure for the three-year certification period including any costs associated with travel;
f. Whether it can obtain testimonials from current and former clients as to the quality of its services.

To ascertain further credentials pertaining to potential certification bodies, it is highly recommended to consult the website of the relevant national accreditation organization. This will provide a list of national certification bodies, and access can be obtained through the International Accreditation Forum website (http://www.iaf.nu/). Additional information on selecting a certification body may be accessed through the following ISO web page: http://www.iso.org/iso/home/standards/certification.htm

Step 13: Prepare for and perform an external audit

Preparing for an ISO 9001 third-party certification audit can be a daunting experience for all concerned. However, the following are some guidelines for this process:

a. The organization should embrace the audit process as a positive experience, which will help to improve its processes, systems and overall quality of its products and services.
b. The organization should liaise with the certification body to establish dates for the audit that suit all concerned. Most importantly, the organization should not consider undergoing the certification audit unless there is a strong indication – based on the success of internal audits – that it will be successful. It may be useful to undergo a pre-audit provided by the certification body if funding allows.
c. All staff should be provided with adequate lead-time to prepare for the audit. The proposed 5-month period for preparation for external audit (see Table 4) is a nominal period. The actual development and implementation of the QMS throughout the proposed 18-month minimum period should ensure a significant amount of the pre-external audit preparation has been done – if not, the implementation has not been undertaken correctly.

d. If there is a lack of confidence in the ability of the QMS to successfully undergo an external third-party audit, then it should be delayed until such time it is ready. To do otherwise would be setting up the QMS for failure, which is unacceptable.
e. The certification auditors should be briefed on any potential safety issues concerning the location they will visit.
f. All documentation that may be needed during the audit should be easily accessible (including reports of previous internal audits and QMRMs) and available at the point of use.
g. A culture should be developed within the QMS that encourages staff not to attempt to hide or cover up any known problem areas.
h. It should be noted that an audit finding of minor non-conformances is not a negative. In fact, it shows that the audit process is working by providing a mechanism for identifying potential risks to the QMS.

Step 14: ISO certificate award

It is imperative that the achievement of certification of compliance to ISO 9001:2015 is appropriately recognized by top management and celebrated by all staff. In fact, it is a reward and recognition of the high standard of products and services they provide.

4.3 Key points to remember and/or consider

Based on the above main steps, the following are six key points to remember and/or consider:

i. Developing and implementing a QMS without the formal endorsement and commitment of top management should not be attempted.
ii. Conducting a gap analysis is a critical step as it identifies the current status of the existing management system relative to the standard – it provides a foundation for planning the development and implementation of the QMS.
iii. Ensuring that a significant body of evidence has been gathered, demonstrating the successful implementation of the QMS, prior to an external certification of compliance audit (for example, levels of customer satisfaction), is important.
iv. It is important that a member of top management, preferably the VC, chairs QMRM.

v. An organization that assists in the development and implementation of the QMS cannot also provide its services as the third-party certification body. This will create a potential conflict of interest.

vi. If there is a lack of confidence in the ability of the QMS to successfully undergo an external third-party audit, then the audit should be delayed until such time it is ready. To do otherwise would be setting up the QMS for failure.

4.4 Information flow during the design and implementation of QMS

Figure 4 shows a summary of information flow during the process of implementing QMS.

Figure 4: Information Flow Model

Figure (4) above shows a pyramid shape representing the operational flow of information in day-to-day processes in an organization.

CHAPTER FIVE

5.0 WORK PLAN AND TIMELINE IN DEVELOPING AND IMPLEMENTING QMS

5.1 Overview

In terms of timing, experience suggests that, with due regard to the factors provided in chapter four, 18–24 months is a realistic and achievable time frame for a small QMS or for specific sections of a large QMS. Small sections or units (approximately 20 staff) in a QMS could implement and achieve certification of compliance with ISO 9001 within a minimum of 18 months. That time period should also provide the opportunity to accumulate a body of evidence that clearly demonstrates, at audit, the successful implementation of the QMS.

It may also be advisable to adopt an incremental approach where a QMS is developed and implemented for different sections or programmed areas. Success in these individual or smaller areas has the real potential to raise the confidence and level of staff buy-in, as well as making the task more manageable for the QM team overseeing the QMS implementation process. Therefore, SUA is advised to closely work with QMS consultant to identify and implement QMS for which ISO 9001:2015 will be achieved.

5.2 Primary steps and broad timelines

Table 1a-c shows primary steps and broad timeline for first, second and third 6 months respectively of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015.

Table 1a: Primary steps and broad timeline for the first 6 months.

Step	**QMS development and implementation activity**	**Month**					
		1	2	3	4	5	6
1	Gain formal commitment and endorsement of top leadership/management						
2	Select a professional quality manager						
3	Select a recognized training provider and/or where possible utilize the QMS mentor						

Step	QMS development and implementation activity	Month					
		1	2	3	4	5	6
4	Provide introductory QMS training						
5	Conduct a gap analysis						
6	Conduct an initial QMRM [This establishes the importance of the role of the QMRMs. It is appreciated that all aspects of the QMRM agenda will not be addressed at this early stage]						
7	Commence work on rectifying identified gaps						
8	Identify processes and develop procedures						
9	Establish levels of customer satisfaction and tools to acquire and measure this information						
10	Identify and train appropriate staff to undertake the role of internal auditor						

Table 1b: Primary steps and broad timeline for the second 6 months.

Step	QMS development and implementation activity	Month					
		7	8	9	10	11	12
11	Conduct a first internal audit						
12	Conduct a QMRM						
13	Select a third-party organization to perform the ISO 9001:2015 certification of compliance						
14	Conduct a second internal audit						
15	Conduct a QMRM						
16	Conduct a third internal audit						

Table 1c: Primary steps and broad timeline for the third 6 months (a total of 18 months).

Step	QMS development and implementation activity	Month					
		13	14	15	16	17	18
17	Conduct QMRM						
18	Prepare for the external audit						
19	Conduct a third-party certification audit (stages 1 & 2)						
20	Celebrate certification of compliance						

CHAPTER SIX

6.0 QMS IMPLEMENTATION CHAMPIONS AND INTERNAL AUDITORS

As part of SUA's continuous improvement to processes and to help drive quality management throughout the business, it is important to develop a team of experts across multiple functions who will receive comprehensive training for QMS implementation process. This will not only increase the knowledge of the individuals, facilitates shared learning, makes the quality function more visible but also focuses on the quality requirements as detailed in SUA's Quality Management System (QMS). The focus of this initiative is to continually drive improvement through the organization so the customer at the end of the process receives a higher quality product or service.

6.1 Selection of QMS Champions

The QMS Champions is a team of successful staff who have demonstrated competence in the area of QMS and Laboratory Management System (LMS). They are selected from among staff and are required to attend a detailed 5-day course. The course usually focus on:

a) The structure of the standards (i.e. ISO 9001 & ISO/IEC 17025).
b) The requirements of the Standards
c) Emphasis on customer satisfaction
d) Emphasis on top management commitment and responsibility.
e) Understanding the process model used as the basis for the operation of the Management Systems at all levels
f) Understanding the QMS system as applied to SUA and its Context.
g) Ensuring stakeholders involvement in the QMS system.
h) The team is established and the team Leader is appointed by the Top Management as its coordinator to plan and oversee implementation. Implementation team members should include representatives of all SUA functions - Marketing, Design, Development, Planning, Production, Quality control, etc.
i) The Implementation Team Leader is the SUA's expert on ISO 9001. In the context of the standard, this person acts as the interface between the top management and the ISO 9001 registrar. This role is, in fact, much broader than that. The Team Leader should also act as the SUA's "Quality System Champion" who takes on the three responsibilities described below:
    i. Quality System Maintenance. Ensuring that Quality Management System processes are established implemented and maintained.
    ii. Reporting on Quality System performance. Reporting to top management on how well, or poorly, the QMS is performing, including identifying any needs for improvement.
    iii. Promoting customer requirements. Ensuring all employees are aware of customer requirements. It is essential that all employees understand what the

customer needs, and how they can affect how well the company satisfies these needs.

iv. The ISO 9001 Champion Team is designed for ensuring staff learns the standard at pace that allows them to understand and interpret clauses of the Standard and how it applies to a single process or multiple processes at SUA.

6.1.2 Training objectives, topics and expected learning outcomes

The aim of this course is to provide QMS implementation skills to the selected team of Champions. The training is aimed at equipping the team with skills of the requirements of ISO 9001:2015 and ISO/IEC 17025:2015. The course will provide comprehensive set of skills and techniques to plan carry out an Implementation, and which will assist them to implement the system at SUA. The course will help the candidates to develop QMS Manuals, Policies, SOPs, Work Instructions, various tools, develop forms etc. In addition, it will provide a clear and detailed instruction on QMS & LMS requirements. The items to be covered will include:

i. Understanding of ISO 9001 Principles
ii. ISO 9001 Clause interpretation
iii. Implementer's qualities & responsibilities
iv. Process Mapping, scoping, identifying Process inputs, Intermediate products and final outputs.

Course delegates will be able to:

a) Understand the QMS, objectives and benefits of the program.
b) Be confident in interpreting the ISO 9001 standard for application purposes
c) Be aware of QMS requirements and application in the Higher Education System setting, including techniques procedures, Planning and conducting various processes at SUA and its subsidiaries.
d) Apply QMS skills in most industrial areas e.g. Construction, Manufacturing, Service provision, Projects, etc. and finding out how ISO 9001 can apply as a **"Generic Model"** for Quality Management System
e) Identify the most appropriate techniques to employ in various scenarios.
f) Understand the role of Quality Assurance in controlling projects.
g) Be capable of Quality Assuring Projects.
h) Coherently answer questions regarding Quality Management & Laboratory Management System.
i) Be validated and certificated as a Quality Implementers.

6.1.3 Training duration

The training will be conducted in five (5) days. Each day of the training will be broken down into tasks, which will be laid out as a "Daily Training Plan": The detailed training scheduled is attached herein as **Appendix 6**.

6.2 Quality Management Audits

It is critical that due care be taken in selecting staff to perform the role of internal auditor. Individuals who show potential, as auditors should be given formal training by a registered QMS training organization.. Apart from the appropriate training, they should also possess the necessary personal qualities and attitude that enable them to act in accordance with the principles of auditing as outlined in ISO 19011:2018.

6.2.1 Principles of QMS auditing

Guidelines for Auditing Management Systems (ISO 19011:2018) lists six principles of auditing namely integrity, fair presentation, due professional care, confidentiality, independence, evidence-based approach and risk-based approach as briefly described below.

(a) **Integrity**: it is the foundation of professionalism. The individuals managing audit programmed should perform their work ethically with honesty and responsibility undertaking audit activities if competent to do so. They should perform their work in an impartial manner remaining fair and unbiased in all their dealings. They should be sensitive to any influence that may be exerted on their judgment while carrying on audits.

(b) **Fair presentation**: the obligation to report truthfully and accurately. Audit findings, conclusions and reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the individual being audited should be reported.

(c) **Due professional care**: the application of diligence and judgment in auditing. Auditors should exercise care in accordance with the importance of the task they perform and the trust placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

(d) **Confidentiality**: integrity and security of information. Auditors should be prudent in the use and protection of the information acquired in the course of their duties. Auditors should not disclose information without appropriate authority unless there is a legal or professional obligation to do so.

(e) **Independence**: the basis for the impartiality of the audit and objectivity of the audit conclusions

Auditors should be independent of the activity being audited and should be free from bias and conflict of interest, wherever practical. Auditors should maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions are based only on evidence.

(f) **Evidence-based approach**: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process. Audit evidence should be verifiable. It will be based on samples of the information

available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of samplings is closely related to the confidence that can be placed in the audit conclusions.

(g) **Risk-based approach:** this is an approach that considers risks and opportunities. The risk-based approach should substantively influence the planning, conducting and reporting of audits in order to ensure that audits are focused on matters that are significant for the audit client and for achieving the audit objectives.

6.2.2 Selection of Internal Auditors

Selection of Internal Auditors for Auditing of the Quality management System should be done by the University Management. The following elements should be taken into account:

i. The nature of interactions
ii. The complexity of the University
iii. The principles of Process Approach
iv. The size and the composition of the audit team as directed by the ISO 19011:2018
v. The objectives of the audit
vi. Legal and contractual requirements
vii. The geographic location of basic business units
viii. The need of assuring the independence of the audit team regarding the activities to be audit and to avoid conflicts of interests
ix. The capacity of the members of the audit team to effectively interact with the auditee.
x. The audit language and the comprehension of particular social and cultural characteristics of the auditee.

6.2.3 Training of Internal Auditors

The aim of training Internal Auditors is to provide auditing skills against the requirements of ISO 9001:2015. The training will provide comprehensive set of skills and techniques to plan, carry out an audit, and report writing, presentation and audit follow up. The course will help the candidate to develop audit tools e.g. Audit checklists. In addition, it will provide a clear and detailed instruction on quality auditing practices. The training will help participants to:

i. Understand the QMS, objectives and benefits of Internal Auditor program.
ii. Be confident in interpreting the ISO 9001 standard for application purposes
iii. Be aware of Auditor techniques including, adequacy, procedures, Planning and conducting audit process, etc.
iv. Apply audit skills in most industrial areas e.g. Construction, Manufacturing, Service provision, Projects, etc.
v. Identify the most appropriate Auditor techniques to employ in various scenarios.
vi. Understand the role of Quality Assurance in controlling projects.
vii. Be capable of Quality Assuring Projects.
viii. Coherently answer questions regarding Quality Auditing.

ix. Be validated and certified as Quality Auditors

6.2.4 Items to be covered:

During this training the participants of quality audit training are expected to:

i. Understanding of the principles of Quality Management System
ii. ISO 9001 Clause interpretation
iii. Auditors qualities
iv. Roles & Responsibilities
v. Audit scoping
vi. Audit tools
vii. Audit Planning & Sequence
viii. Audit Practice and Techniques
ix. Conducting the Root Course Analysis (RCA)
x. Audit feedback, reporting and closure.

The training will be conducted in five (5) days as outlined in **Appendix 7.**

CHAPTER SEVEN

7.0 GUIDELINES FOR ISO/IEC 17025 ACCREDITATION

7.1Overview

With the right preparation and a good understanding of what is required for **ISO/IEC 17025 Accreditation**, most organizations can expect to achieve certification within 3 to 6 months depending on their size and level of complexity of the laboratory.

At this stage it is vital to have someone (internal or external) who has experience of implementing Laboratory Management Systems and who knows what is needed to achieve Accreditation. Once the groundwork has been done and the **ISO/IEC 17025 Laboratory Manual** has been completed, the libraries will be ready for initial assessment or (Stage 1 Audit). This is aimed at assessing the library's readiness for final audit. The assessor/auditor will check that the written Lab. Management Systems manuals and other documents meet the requirements of the **ISO/IEC 17025 Standard** and match what you are actually doing and highlight any areas of deficiency and potential improvement of the system.

Once any required changes have been made, the organization will be ready for Stage 2 Accreditation Assessment. The assessor/auditor will check that you are working to the requirements of Laboratory Management Systems and the ISO/IEC 17025 Standard. An independent 3rd party shall conduct this.

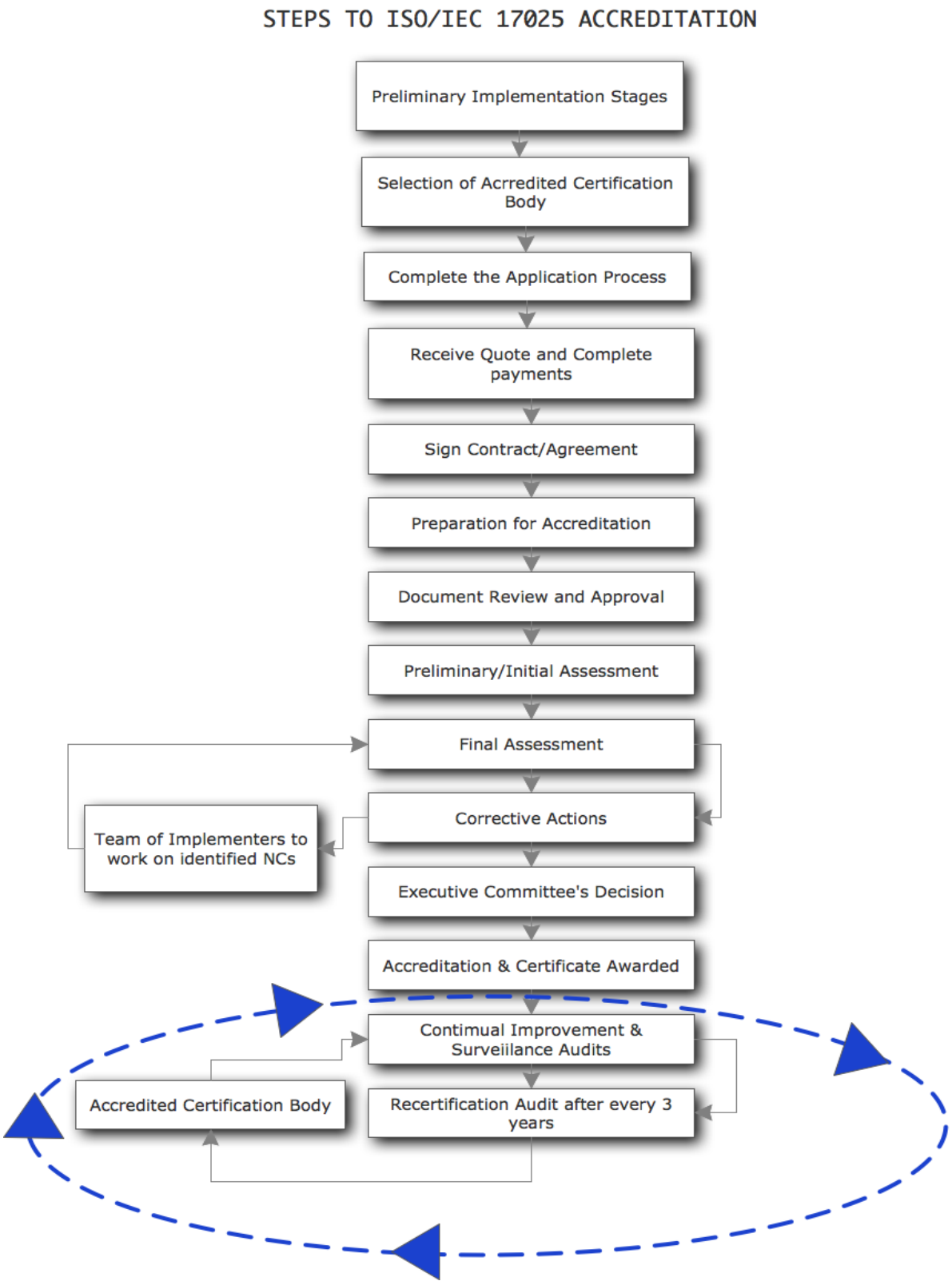

Figure 5: Steps for ISO/IEC 17025 Accreditation

7.2 Implementation Phase

In order to meet the requirements stated above, the SUA should have a clear idea of the objectives and what benefits it will gain by achieving ISO/IEC 17025 Accreditation. The LMS must be prepared to incorporate the Management Systems into every area of the business. All laboratory staff must be aware of what is expected of them and where their areas of responsibility lie, in order to achieve ISO/IEC 17025 Accreditation. A Documented LMS Management System is required, together with the policies and procedures required by ISO 17025. The documentation will define**:**

- The Laboratory structure
- General requirements (Technical Requirements & Management Requirements)
- Impartiality
- Structural requirements
- Resource requirements
- Laboratory personnel
- Facilities and environmental conditions
- Equipment
- Metrological traceability
- Process requirements
- Review of requests, tenders and contracts
- Selection, verification and validation of methods
- Sampling
- Technical Records
- Evaluation of measurement uncertainty
- Reporting of results
- Specific requirements for test reports
- Specific requirements for calibration certificates
- Reporting opinions and interpretations
- Amendments to reports
- Nonconforming work
- Management system requirements

7.3 Management of Documentation

SUA will need to communicate to all of staff, the importance of keeping records and using the correct documentation. Controlling the use of documents to ensure the latest version is

being used is an important part of ISO 17025. SUA will need a system to ensure that old versions are removed and new versions distributed to the various internal departments, together with a system for version control.

7.4 Corrective and preventive measures

Inevitably, processes can go wrong and process owner will need to have a defined process for fixing the problem and identifying where it went wrong, before making changes to prevent it from happening again. Owners should keep records of any actions taken to rectify a problem. Where possible potential problem areas should be identified and set up a system to prevent or minimize their effect before it happens.

7.5 On-going support and training

Staff should be suitably trained to ensure they are capable of carrying out their job function. Records to verify the performance of LMS must be kept for experience, education and training to identify their capabilities. Future training requirements can then be implemented together with any new skills that may be needed as the laboratory evolves. Using this information, LMS will be able to identify any gaps in experience.

7.6 Regular Internal LMS Auditing

Regular Internal LMS Auditing is required. Persons trained within the Laboratory and who are independent of the function being audited may carry the audits. The Internal Auditor will check that procedures in the Laboratory Manual are being followed and will identify any areas of concern to be rectified. A procedure must be established for how audits are to be planned, conducted and recorded.

CHAPTER EIGHT

8.0 RESOURCES REQUIRED FOR IMPLEMENTING ISO 9001 & IEC 17025

8.1 Overview

Before establishing a QMS / LMS it is critical to identify required resources like human resource, financial resources, infrastructure, applicable tools etc. Therefore, SUA should link its Corporate Strategic Plan (2016-2021), human resource related policies (HR Policy), SUA Master Plan, Financial plans, among others. These documents provides future plans which when appropriated synergized, SUA can successful establish and implement QMS within ISO 9001:2015 framework and guidelines.

8.2 Human resource requirement

8.2.1 Quality Manager

As already described in chapter four, SUA is required to allocate and/or employ a Quality Manager solely dedicated with QMS processes. According to the current SUA's Quality Assurance Policy (2017), Quality Assurance Implementation Plan (2018) and Internal Quality Assurance Framework (2018), quality management is under the Quality Assurance Bureau within the office of the Vice Chancellor but implemented throughout the university by Quality Assurance Committees (Chairpersons and members) available in each Department, College/School/Directorate and units in charge of Administration and Services. Currently the Coordinator of Quality Assurance Bureau (QAB) serves as Quality Manager for the University.

8.2.2 QMS Champions

To effectively implement QMS, SUA requires putting in place a team of trained QMS champions who will be involved in establishing and implementing the QMS at all levels of the University. According to the QAP (2017) all university management (VC, DVCs, Principals/Directors/Dean/Heads of Departments are custodians of quality across the University. However, according ISO 9001:2015 Quality Champions should be trained on principles of QMS and other ISO requirements as already discussed before.

8.2.3 QMS Internal Auditors

According to Clause 9.2 of the ISO 9001:2015 organizations should conduct internal audits at planned intervals to provide information on whether the QMS conforms to the organization's own requirements, the requirements of the International Standards (ISO) and legal requirements such as those required by the Tanzania Commission for Universities (TCU). In order to fulfill this requirement, SUA should identify, train and establish a team of QMS Internal Auditors.

8.2.4 Other key requirements

In addition to the requirement for human related resources described in sub-sections 8.2.1-8.2.3, SUA should consider putting in place, improving and/or harmonizing other systems

such as Information and Communication Technology (ICT), physical infrastructure, filling systems, standard operating procedures, financial management systems, human resource systems, students' records and examination systems, among others.

8.2.5 Financial resources required

According to strategic objective number six (i.e. Improve Management and Institutional Governance), strategy number 6.1 and target number 6.1.3 (activities 1 and 2; page 60-61) of the SUA CSP (2016-2021), SUA has budgeted a total of **Four Hundred and Fifty Million (450,000,000/=)** to accomplish the tasks by June 2021. **Appendix 8** shows a detailed breakdown of the required budget to establish and implement QMS in accordance to ISO 9001:2015 QMS certification and IEC 17025:2017 laboratory accreditation.

CHAPTER NINE

9.0 CONCLUSION AND RECOMMENDATIONS

9.1 Conclusion

ISO 9001 has been universally accepted as the quality standard and is well accepted in all types of organizations. ISO 9001 certification is expected to improve the working system at SUA. This is considered to be the biggest motivating factor to staff all carder at the University. The most important motivating factor is 'to improve the quality of products' and "Services". Any firm would expect the quality of product and services to improve once it starts following implementation of ISO 9001 systems.

Other motivation factors may include:

- To increase productivity of labor and machines
- To improve cooperation and coordination between workers and management.
- To increase market share/turnover.
- To boost up morale of employees.
- To reduce cost of running various operations.
- To improve internal and external interactions
- ISO 9001 certification helps in achieving objectives mentioned in the quality policy.
- ISO 9001 certification increases the documentation work.

Conclusions may also be made, with respect to the continuous improvement, maintenance of systems with a view to reduce downtime, evaluation of processes and vendor rating exercise, that majority of the certified companies follow these practices. In addition, the implementation of LMS according to ISO/IEC 17025 SUA will recognize the following benefits among others:

i. Controlled documented methods/Procedures are the basis for training and a stable process.

ii. Increased level control of process applied to the analysis and have channels to implement and complete needed changes.
iii. International recognition
iv. Trust and confidence on test and calibration results
v. Because of corrective action trending and tracking, management within the laboratory identifies and resolves issues related to methods, personnel, and equipment more quickly.
vi. The methods provide a basis for decisions for analytical resources and new method implementation.
vii. Customer survey results show improved satisfaction as a result of the implemented quality system.
viii. Customer requests are more easily met.
ix. Proficiency testing results are shared with customers by request.
x. External audits may be performed by customers (Second Party Audits) prior to testing.

Overall, laboratory business will increase as demonstrated by increased revenue. Implementation of ISO/IEC 17025 provides a system for continuous improvement of daily laboratory practices. Direct benefits include faster identification and resolution of issues, improved customer satisfaction, meeting of quality requirements of specialized customers, and an overall increase in laboratory business.

9.2 Recommendations

For SUA to successfully achieve ISO 9001 certification and ISO/IEC 17025 accreditation, the following chronology of events must be considered the steps discussed in chapter four section 4.2, MUST be strictly followed. This will guide any team player to abide to the process flow hence avoiding any deviation from the path.

In addition, following the size and complexity of Sokoine University of Agriculture, the implementation and certification process can start with some units or processes. After

sometime, the scope can be expanded to other units and finally the whole institution. This approach has several advantages such as:

i. Increasing the ability to control processes such that any error that happens may be corrected before impacting the whole system.
ii. Increasing effectiveness, operational control and enhance efficiency.
iii. Reducing information irregularities
iv. Guiding the implementation efforts from both internal and external partners
v. Monitoring, measurement, analysis and evaluation performance before and after implementation. The lessons learned can be used to improve other processes
vi. Effective resource utilization as financial resources are always scarce. This will help to plan and implement according to the financial capability of the University.

LIST OF APPENDICES

Appendix 1: Job description of a Quality Manager

The role of the quality management section

The fundamental role of the quality management (QM) section is to deliver a comprehensive range of QM services, skills and knowledge. These are to be provided on a cross-cutting and cross-programmed basis to enable the organization to integrate a Quality Management System (QMS) into all facets of product and service delivery and achieve certification of compliance with ISO 9001:2015,Quality Management Systems – Requirements.

Function
The occupant's prime responsibility under the broad policy control and direction from the head of the organization, and in conjunction with top management, is to provide specialist knowledge to the organization on a range of comprehensive QM services, skills, knowledge and advice. The position requires sound knowledge of ISO 9001:2015, Quality Management Systems – Requirements, and competence as a lead auditor of management systems in accordance with ISO 19011:2011, Guidelines for Auditing Management Systems.

The position requires a high level of expertise and management skills, as the occupant will be required to manage the broad range of activities provided by the QM section. These will include analysis and assessment of service and product delivery procedures, planning, training, QMS implementation and internal audits. It will also require strong leadership in assisting and mentoring staff, including top management, through the ongoing audit process and continual improvement of procedures pre- and post-certification.

The position requires high levels of strategic and change management skills. The occupant is required to build cross-programmed partnerships and communicate effectively with organizational staff at all levels. He/she is required to possess a high standard of written and oral communication skills, to be able to effectively manage change and to follow projects through to completion. The occupant is also required to show independent judgment.

Competencies/qualifications
Professional

- A degree or diploma from an internationally recognized educational institution or other comparable qualification that is appropriate to the duties.
- Quality management and auditing skills
- Tertiary studies in the area of QM as part of a degree or diploma from an internationally recognized educational institution. The occupant must be qualified to perform internal audits, and possess a qualification as a lead auditor of management systems (ISO 9001) in accordance with ISO 19011.

Duty statement
Under general direction from the head of the organization, the quality manager will:

- Manage and lead the QM section, providing support to top management;

- Ensure realization of the organization's priorities, including through the coordination of work across the organization;
- Provide strategic input and advise to top management on strategic, operational and tactical issues, risks and solutions;
- Design and undertake appropriate evaluation and performance reporting for the organization;
- Formulate, plan and promote the medium- and long-term strategic direction of quality objectives, policies and systems for the organization;
- Provide expert advice and guidance on QM principles and systems to top management, and engage and collaborate with internal stakeholders to achieve QMS outcomes and facilitate cooperation;
- Lead the planning, design, development and documentation of QMSs for designated sites, functions, products, services and processes that achieve and maintain ISO 9001:2015 certification;
- Build a network of QM practices across the organization by providing professional development, training and mentoring through the ongoing audit process and continuous improvement of procedures pre- and post-certification.

Selection criteria

Applicants are required to possess the following selection criteria:

1. **Demonstrated coordination skills.**
   The ability to coordinate activities throughout their entire life cycle, including feasibility, planning, implementation, evaluation and review. The ability to think and plan strategically in terms of coordinating the management of change and achievement of intended results.

2. **Quality management and auditing**
   Sound knowledge of QMS practices and principles, and sound appreciation of the requirements for third-party certification against the ISO 9001:2015 QM standard. Demonstrated ability to conduct internal audits against ISO 9001:2015 and the demonstrated ability to attain qualifications as a lead auditor of management systems in accordance with ISO 19011:2011.
3. **Corporate governance**
   Demonstrated sound knowledge and experience in the application of corporate governance principles and practices combined with effective decision-making skills.
4. **Delivery of products and services.**
   Demonstrated knowledge of the roles and interactions of the various QMS sections combined with demonstrated knowledge of the delivery of products and services at international, national and regional levels.
5. **Customer focus**
   Commitment to high-quality customer services and ongoing improvement through a focused approach to the QM principles and practices while meeting identified customer needs.
6. **Communication skills**
   Demonstrated ability to communicate clearly across all levels of the organization through oral and written means. Ability to negotiate persuasively and to listen, understand and

adapt to different audiences, particularly top management and broad sectors of the community.

7. Drive and commitment

Demonstrated proactive, decision-making skills and motivation to commit to action. Self-awareness, personal courage, resilience and commitment to personal development.

Appendix 2: Questions for potential quality management consultant/training providers

1. Can you provide an overview of your quality management (QM) background?
2. Are you certified as being compliant against the ISO 9001 QM standard?
3. Do you see the quality management system (QMS) presenting any unique challenges that you have or have not faced previously? If so, what are those challenges and how did you deal with them?
4. Do you believe the drivers to adopt the ISO 9001 QM standard are legitimate?
5. What approach do you believe would be the most appropriate for the organization to achieve certification in accordance with ISO 9001?
6. What would you need from the organization to initiate the project?
7. What strategies do you employ to maintain a close working relationship with the organization and to ensure success while minimizing time and costs?
8. Can you provide examples of work you have previously done for other organizations?
9. If you are selected for or accept the challenge of assisting the organization and it does not achieve certification the first time, what action would you take to ensure that certification is achieved?
10. Do you provide QM training services and, if so, do you have qualified trainers?
11. Are you registered as an internationally recognized training organization?
12. Do you guarantee your services?
13. Can you provide a fixed schedule of charges/fees?

Appendix 3: Gap analysis findings.

Gap analysis findings	
Quality management system (QMS)	
Scope of gap analysis	
Gap analysis time period	
Gap analysis completion date	
Gap analysis conducted by	
Gap analysis participants	
Notes	

4 - Content of the organization				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
5 - Leadership				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*
6 - Planning				
Reference clause in ISO 9001:2015	*Gap identified*	*Proposed remedial action*	*Officer responsible*	*Gap filled date*

Appendix 4: Quality management review meeting template

AGENDA

Date: ---/---/----

Time: ------------

Venue: ------------

Attendees: ------------

Chairperson: ------------

Attendance Sheet				
S/No	**Name of the Participant**	***Department/School/Faculty***	***Position***	***Signature***

S/N	Meeting objective	*Notes: Root causes, decisions, actions*	*Officer responsible*	*Target date*
1	Review the 'QMS' outstanding actions			
2	Report on any changes in external/internal issues relevant to 'QMS'			
3	Report on internal/external audit findings			
4	Update on customer satisfaction and feedback including trends			
5	Update on the progress of 'QMS' objectives			
6	Report on process performance, non-conformities/corrective actions and monitoring/measuring activities			
7	Review performance of external providers and external providers register			
8	Report on adequacy of resources			
9	Update on 'QMS' risks and opportunities for improvement			

Appendix 5: Process matrix template

S/n	*Objectives*				*Key performance indicators (KPIs)*			
	[Insert QMS objectives here]				[Insert KPIs associated with QMS objectives here]			
	Core process	*Purpose*	*Inputs*	*Outputs*	*Process owner*	*Process risks*	*Risk Control*	*Monitors/ measures*
1	[Insert identified core process here]	[Provide a detailed description of the process purpose]	[Detail the inputs and dependencies for the process here]					
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

Appendix 6: The training plan for QMS champions

DAY 1	
Time	**Topic**
08:30 - 09:00	Registration, Welcome & Introduction
09:00 - 10:30	• Introduction to QMS and Terminologies • Background Information of ISO 9001& ISO 17025 • Benefits of QMS
10:30 – 10:45	Morning Break
10:45 – 13:00	• Quality Management System Requirements • QMS Principles • Risk based thinking • The PDCA Cycle • QMS Policy/Objectives
13:00 – 14:00	Lunch Break
14:00 – 17:00	The context of Sokoine University Of Agriculture (SUA)
	• Understanding needs and expectations of interested parties
	• Determining the scope of the quality management system
	• Quality management system and its processes
17:00 – 17:30	• Exercise & end of day 1
	DAY 2
08:30 - 10:45	Registration, Welcome & any question from day 1
	Leadership
	• Leadership and commitment
	• Quality policy
	• Customer Focus
10:30 – 10:45	Morning Break
10:45 – 13:00	• The roles, responsibilities and authorities at SUA
	• Planning for the QMS
	• Actions to address risks & Opportunities
	Lunch Break
14:00 – 17:00	• Quality objectives and planning to achieve them
	• Planning of changes
	DAY 3
08:30 - 10:30	Registration, Welcome & any question from day 2
	Support
	• Resources
	• People
	• Performance Evaluation
	• Continual Improvement
10:30 - 10:45	Morning Break
	• Infrastructure
	• Work Environment
	• Monitoring and measuring resources

	• The Organizational knowledge
13:00 – 14:00	Lunch Break
14:00 – 17:00	• Competence
	• Awareness
	• Communication
	• Documented information
	• Creating and updating
	DAY 4
08:30 - 10:30	Registration, Welcome & any question from day 3
	Operation
	• Operational planning and control
	• Determination of requirements for services
	• Customer communication
	• Design and development of services
	• Design and development planning
	• Design and development Inputs
	• Design and development controls
	• Design and development outputs
10:30 - 10:45	Morning Break
10:45 – 13:00	• Control of externally provided services
	• Control of production and service provision
	• Post-delivery activities
	• Release of products and services
	• Control of nonconforming process outputs, products and services
13:00 – 14:00	Lunch Break
14:00 – 17:00	Performance evaluation
	• Monitoring, measurement, analysis and evaluation
	• Customer satisfaction
	• Analysis and evaluation
	• Internal audit
	• Management review
	Improvement
	• Nonconformity and corrective action
	• Continual improvement
	• Annexes
	DAY 5
08:30 – 16:30	7.5 Documented Information
	• Practical Exercises and Role Plays
	• Review of Documents
	• Policies, SOPs, WIs, etc.
16:30 – 17:00	• Closing Remarks & End of the Course

Appendix 7: The training plan for QMS internal auditors

DAY 1	
Time	**Topic**
08:30 - 09:00	Registration, Welcome & Introduction
09:00 - 10:30	• Introduction to QMS and Terminologies • Background Information of ISO 9001 • Benefits of QMS
10:30 – 10:45	Morning Break
10:45 – 12:45	• Quality Management System Requirements • QMS Principles • Risk based thinking • The PDCA Cycle • QMS Policy/Objectives • The context of the SUA • Leadership and commitment • Planning
12:45 – 13:30	Lunch Break
13:30 – 14:30	• Support & Operation
14:30 – 16:45	• Performance Evaluation & Continual Improvement
16:45 - 17:00	• Exercise & end of day 1
DAY 2	
Time	Topic
08:30 - 09:00	Welcome back and any question from day 1.
09:00 - 10:30	• Review of QMS Requirements • Introduction to ISO 19011:2011 • Terms and definitions • Principles of auditing
10:30 – 10:45	Morning Break
10:45 – 12:45	• Planning an audit program ○ Pre-audit Activities

	○ Performing an audit ○ Opening Meeting ○ Collecting information and audit evidence
12:45 – 13:30	Lunch Break
13:30 – 14:30	• ***Role Play Audit***
14:30 – 16:45	– Audit activities – Conducting and managing an audit program
16:45 - 17:00	Exercise & end of day 2
DAY 3	
Time	Topic
08:30 - 09:00	Welcome back and any question from day 2.
09:00 - 10:30	• Review of ISO 19011:2011 Requirements • Auditor skills • Determining auditor competences • Evaluating and selecting auditors
10:30 – 10:45	Morning Break
10:45 – 12:45	• Audit challenges and barriers • Managing people skills • Handling difficult situations
12:45 – 13:30	Lunch Break
13:30 – 14:30	• ***Role Play Audit***
14:30 – 16:45	– Identifying and defining a nonconformity – Writing a nonconformity statement – Audit report preparation ○ Types of reports and how to prepare
16:45 - 17:00	Exercise & end of day 3
DAY 4	
Time	Topic
08:30 - 09:00	Welcome back and any question from day 3.
09:00 - 10:30	• Any questions from day 3

	• Conducting a closing meeting and who to attend • Audit Report presentation
10:30 – 10:45	Morning Break
10:45 – 12:45	• How to address a nonconformity • Conducting an audit follow up • Role play Audit – Participants to audit the trainer • Homework to participants to be completed in two days
12:45 – 13:30	Lunch Break
13:30 – 14:30	• ***Role Play Audit***
14:30 – 15:30	– Sample Examination
15:30 – 16:30	– Corrections and training summary
	– Receive Homework from participants
16:45 - 17:00	Exercise & end of day 3
DAY 5	
Time	Topic
08:30 - 09:00	Welcome back and any question from day 4.
09:00 - 10:30	• General revision and evaluation for the assignments and tests from Day 1 – Day 5
10:30 – 10:45	Morning Break
10:45 – 12:45	• Discussion for general questions & Final revisions
12:45 – 13:30	Lunch Break
13:30 – 14:30	• ***Self study and final revision for the participants***
14:30 – 16:30	– *Lead Auditor Certified Exam*
16:30 – 17:00	– Closing Remarks & End of the Course

Appendix 8: Detailed budget for the establishment and implementation of ISO/IEC systems

S/n	Target	Activities	Resources Required	Time Frame		KIPs	Budget (Million TZS)	Who will be responsible
				Start	End			
1	Development of framework and guidelines for ISO 9001:2015 certification & ISO/IEC 17025 Accreditation	• Formulate framework and guidelines towards attaining ISO 9001:2015/IEC 17025:2017	Financial resources,	June 2018	Sept. 2018	- Selecting the Consultant - Contract signing - Timely submission of draft 1 and final	38	- QAB - QMS Consultant
2	Implementation Programs	2.1 Conduct Gap Assessment (GA) for understanding the current status at SUA, GA report & action plan developed	Financial resources, Experts, Stationeries	October 2018	December 2018	- GA Planning, execution and reporting	15	- QAB - Consultant
		2.2 Conduct Staff Awareness Training for 100 SUA staff on ISO 9001 & ISO/IEC 17025.	Financial resources, Trainer, Training Materials, Training plan etc.	January 2019	March 2019	- Training delivered, - Training budget - Training records	25	- QAB - Consultant
		2.3 Select and train a team of Champions to be involved in development of the System	30 Selected staff	April 2019 (1st Week)	April 2019 (1st Week)	- Selecting trainees - Training delivered - Training budget established - Training records maintained	25	- QAB - Consultant
		2.4 Documentation, Review & Approval of documented	Review experts (Process owners)	April 2019	July 2019	- Review feedback and comments	30	- QAB - Process owners

			Information, Printing some hard copies for filing and back up for further reference						
		2.5	Conduct 5 days Internal Auditors' Training course (Attend written IRCA exam)	Selected staff, ISO 19011:2018 Standard, Training Material etc.	August 2019 (1st week)	August 2019 (1st week) 7	- Selecting trainees - Training delivered - Training budget - Training records	25	- QAB Consultant
		2.6	Intergradation of all documented manuals into an Intranet web-based program that can be viewed filled and printed on line	IT Consultant (with tools and equipment required)	August 2019	August 2019	- Selecting the consultant - Contract signing - Timely reporting progress - Training and commissioning	15	- QAB - IT Consultant
		2.7	Officially Launch the System for Implementation – Trial Phase (Monitoring & Review).	Team of Implementers , ISO 9001, ISO 17025.	September 2019	September 2019	- The Integrated Management System available	10	- QAB - Implementers - ISO 9001 Consultant
		2.8	Conducting Internal Audit to assess overall implementation and identify any areas of improvement	Internal Auditors, ISO 19011:2018, Manuals, SOPs, WIs, Audit tools, etc.	November 2019	November 2019	- Internal Audit planning, Communication, Approval and execution, - Audit Reports, - Nonconformity reports, - CARs issued to process owners	8	- QAB - Internal Auditors - ISO 9001 Consultant
		2.9	Conduct Management Review for approval and final	The SUA Top Management Team	December 2019	December 2019	MRM Agenda, Planning and communication	5	- QAB - SUA's Top Management

			recommendations					
		2.10	Select of Certification Body (CB), Application for certification, Payment of required fees, Contract signing, CB to conduct pre-assessment audits,	Financial budget, List of CBs, Contract, Top Management (For signing)	January 2020	January 2020	– Contract signing – Pre-assessment and report issued/submitted	15	- QAB - SUA's Top Management - Accreditation Body
		2.11	SUA to implement Corrective Actions & Auditor's recommendation	Implementers (Champions), Financial budget,	February 2020	February 2020	- Submitting CAR reports within the specified time.	3	- QAB - SUA's Top Management - Accreditation Body
		2.12	CB conducts final certification audit, Issue CAR, Addressing NCs, Auditor's recommendation, Certificate issued	Financial budget	February 2020	February 2020	– Audit planning communication and approved – Conducting Audit – Reports submitted on time. – Addressing NCs – Awarding Certificate.	30	- QAB - SUA's Top Management - Accreditation Body
3.0 ISO/IEC 17025 Accreditation		**Steps to Accreditation of two SUA Laboratories:**		- Four laboratories, - Laboratory staff - Financial resources	June 2020	October 2020	Accredited body selected, Contract signed	206	QAB & SUA's Top Management
Total Budget for ISO 9001 Certification and ISO/IEC 17025 Accreditation:								**450,000,000**	