Kenya Bureau of Standards

Standards for quality life

2
AUDIT FORMS

Audit Forms: ISO 9001:2015 QMS Internal Audit Course

FORM 1: CHECKLIST

ORGANIZATION:	**Audit No**: **Audit date:**
Location to be audited:	

NO	Aspect of system to be checked (question)	Reference	Remark (A/U *)

* A – acceptable U – unacceptable

Name of Auditor …… Signature …… Date……

FORM 2: ATTENDANCE REGISTER

ORGANIZATION:				
AUDIT NUMBER:				
SN	NAME	DESIGNATION	SIGNATURE	
			Opening Meeting Date: ……	Closing Meeting Date: ……..

FORM 3: CORRECTIVE ACTION REQUEST (CAR) FORM

CAR NO._____OF_____

ORGANIZATION:	
AUDIT DATE:	AUDIT NO:
Area under review:	Clause of criteria document:

Requirement:

Nonconformity/evidence:

Signed: Auditor_____ Auditee _____

Category: ☐ MAJOR ☐ MINOR

Root Cause:

Correction (as applicable):

Corrective action to be taken to prevent recurrence:

Signed: Auditee_____ Auditor _____

Date of completion _____

Follow up (to be completed by the auditor):

Action fully completed ☐

Action partially completed ☐

No action taken ☐

Details:

Signed…… …… ……
Auditor Name Date

Signed…… …… ……
Auditee Name Date

Effectiveness of corrective action (to be completed during the next audit by auditor):

Was the corrective action taken effective? ☐ YES NO ☐

Details (as necessary):

Signed…… …… ……
Auditor Name Date

Audit Forms: ISO 9001:2015 QMS Internal Audit Course

FORM 4: AUDIT FINDINGS REPORT

DEPARTMENT		Name of auditor	
KS	Date	Audit number	
1	2		
Sno	Findings	Name/Signature of auditee	Relevant Clause
	Location _____		

FORM 5: AUDIT REPORT

1.0 1.0 Introduction

1.1 Audit objectives

1.2 Audit scope

1.3 Audit criteria

1.4 Audit team

1.5 Auditee (department, representative)

2.0 Executive Summary

3.0 Detailed Report

3.1 Department A
3.1.1 Positive findings
i) ..

3.1.2 Opportunities for improvement
i) ...

3.2 Department B
3.2.1 Positive findings
i) ...

3.2.2 Opportunities for improvement
i) ...

3.3 Department C
3.3.1 Positive findings
ii) ...

3.3.2 Opportunities for improvement
ii) ...
3.X Other issues

3.X.1 Handling of Customer Complaints
……

3.X.2 Evaluation of effectiveness of previous corrective actions

3.X.3 Unresolved issues

….

…

4.0 Conclusion

……..

Signed …… Date……

Lead Auditor

Appendix 1
Timetable of the audit

Appendix 2
Nonconformity forms (CAR forms)

Appendix 3
Attendance registers (opening and closing meetings)

Logo

ISO 9001:2015

INTERNAL AUDIT REPORT
Lavender Company (*Name of Organization*)
XXXXXXXXX (name of department(s), regions etc)

Audit No. XYZ/2016

TABLE OF CONTENTS

1.0 Introduction

ISO 9001:2015 audit for ***Lavender Company, department XYZ*** was carried out on 9/6/2016 at the company in Nairobi's Industrial area (physical location). Below is the detailed report.

1.1 Audit Objectives

- To establish continued conformity and continual improvement of the organization's quality management system to ISO 9001:2015
- To determine the ability of the system to meet statutory, regulatory and contractual commitments
- To evaluate effectiveness of the QMS

1.2 Audit Scope

The **scope of the audit** was ***manufacture and sale of detergents*** as per the timetable in Appendix 1. All the areas planned for audit were audited.

1.3 Audit Criteria

The **audit criteria** was ISO 9001:2015 standard and the organization's QMS documentation, as well as the relevant statutory and regulatory requirements.

1.4 Audit Team

The audit was carried out by the following **auditors**:

- XXXXX– Audit team leader
- XXXXX - Auditor

1.5 Auditee representative

The **auditee** representative was XXXXX.

The details of the audit are included below.

2.0 Executive Summary

During the audit the auditor(s) was/were given the necessary cooperation allowing the collection of audit evidence and the evaluation of this evidence to come up with the audit findings and conclusions in this report.

The auditor(s) found that:

- (general positive findings)

However the auditor also found that:

- (general opportunities for improvement)

In addition the auditor recorded **XXXXX** nonconformities classified as **XX** major and **XXX** minor. The nonconformities are attached to this report.

3.0 Detailed Report

3.1 Human Resource

3.1.1 Positive findings

i) ..

3.1.2 Opportunities for improvement

i) ...

3.2 Procurement

3.2.1 Positive findings

i) ...

3.2.2 Opportunities for improvement

i) ...

3.3 Manufacturing

3.3.1 Positive findings

ii) ...

3.3.2 Opportunities for improvement

ii) ...

3.X Other issues

3.X.1 Handling of Customer Complaints

3.X.2 Evaluation of effectiveness of previous corrective actions

The evaluation of effectiveness of the corrective actions for the 3 NCs recorded during the audit of 17th July 2015 was carried out. All corrective actions were found to be effective.

3.X.3 Unresolved issues

i) It was not possible to audit the procurement department because they were in an emergency meeting. This to be done at the next audit.
ii) The next audit to also address the security procedures.

4.0 Conclusion

Based on the findings above, it is the opinion of the auditors that the quality management system …….

The auditor therefore recommends ....

Signed …… Date:

Audit Team Leader

Appendix 1
Timetable of the audit

Appendix 2
Nonconformity forms (CAR forms)

Appendix 3
Attendance registers (opening and closing meetings)

Kenya Bureau of Standards

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National Quality Institute

Entrenching a culture of quality in the Kenyan society

3
EXERCISES

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

This section contains the exercise that shall be used for the entire course. The exercises are designed to provide students with the opportunity to practice what they learn during the tutorial sessions. Generally the exercises involve team work. Each exercise describes the purpose, instructions and the allotted time for completion.

Table of Contents

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 1 Part 1 and Part 2: REVIEW OF ISO 9001:2015

The purpose of this exercise is to give the participants practice in identifying audit evidence needed to demonstrate conformity.

Directions:
Clause 4 of ISO 9001:2015 will be done as a class with guidance from the course facilitator.

Part 1: Read ISO 9001:2015 clauses 5 to 7. Identify the requirements and audit evidence needed to demonstrate conformity to the given requirements.

Part 2: Read ISO 9001:2015 clauses 8 to 10. Identify the requirements and audit evidence needed to demonstrate conformity to the given requirements.

Time:
Group discussion: 1 hour 30 minutes
Class discussion: 1hour 30 minutes

Note: Each part is to take the allocated time above

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 2: CREATING AN AUDIT PLAN

Purpose:
To provide practice in audit preparation and creating an audit plan/timetable

Directions:

Determine the necessary number of audit days for your team to perform a scheduled internal audit for your organization.

Using the guidelines given in class, the documentation provided and the clauses of ISO 9001:2015 allocated to each group by the course facilitator, create an audit plan for the audit. Present your plan to the rest of the class.

Time:
Group discussion: 30 minutes
Class discussion: 15 minutes

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 3: CREATING AN AUDIT CHECKLIST

Purpose:

To give practice in the preparation of an audit checklist

Directions:

Using the audit plan from the previous exercise, develop a checklist that would enable you to conduct an effective audit. Refer to the relevant clauses of ISO 9001:2015

The group should agree on a checklist to be presented to the rest of the class.

Time:
Group discussion: 30 minutes
Class discussion: 30 minutes

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 4: REVIEWING THE QMS SCOPE, QUALITY POLICY & QUALITY OBJECTIVES OF MIGINGO SHIPS

Purpose
To audit for the required elements in the QMS scope, quality policy and quality objectives as part of document review (stage 1) audit.

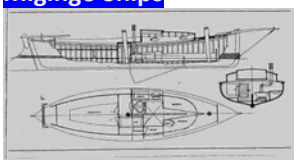
Time:
Group discussion: 30 minutes
Class discussion: 30 minutes

Directions:
Each group will be assigned a topic from the Migingo ships case study provided below. The group shall then review it against the requirements of clauses 4.3, 5.2 and 6.2 of ISO 9001:2015.

1. What are the requirements of clauses 4.3, 5.2 and 6.2 of ISO 9001:2015
2. Where does the scope, policy and objectives meet or fail to meet the requirements of clause 4.3, 5.2 and 6.2 of ISO 9001:2015

Case Study- Migingo Ships (MS)

Migingo Ships



MS-QMS SCOPE
The scope of ***Migingo ships'*** QMS covers construction and maintenance of ships at our head office in Mombasa- Kenya and branches in Kisumu-Kenya and regional office in Jinja Uganda. Our scope does not include internal quality audits.

MS- QUALITY POLICY

We shall produce quality ships at a profit if we can, at a loss if we must. But we shall always produce quality ships

MS- QUALITY OBJECTIVES

1. To increase our revenue in 2017
2. To reduce customer complaints in 2017
3. To reduce turn-around time for ship repairs

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 5: DOCUMENTING NON CONFORMITY STATEMENTS

The purpose of this exercise is to help participants develop skills for raising statements of non-conformities effectively

Time:
Group discussion: 30 minutes
Class discussion: 45 minutes

Directions:

Each group will be assigned a scenario (s) to study from the scenarios below. The group shall then identify non conformities, **if any,** and record them in the given non-conformity forms. The group should also use exercise 4 above to raise non-conformity statements.

Scenario 1
You ask a Human resource specialist in the Human Resource Department about the QMS policy at TWM manufacturing company. "I don't' know!, our department doesn't deal with customers and that stuff doesn't apply to us'".

Scenario 2
You are watching an operator take pH measurements at one of the production sites at TWM manufacturing facility. The operator has the latest procedure with him and appears to be doing everything according to the procedure. You notice that the procedure requires three measurements and the results are to be recorded on form FM-001. The form that the operator is using only has two columns for measurement data. As such, the operator pencils in another column and records the third measurement.

Scenario 3
While auditing the laboratory department of Nairobi dairy industry, you notice that determination of milk fats is not done due to lack of competence. On further inquiry, you notice that the head of lab had requested for training of his staff six months ago but the training department has not taken any action.

Scenario 4
While interviewing a nurse at one of the hospitals, you ask what ISO 90001 means to her, and she states, "I' m focused on making sure that I follow my procedures that I'm not really sure about ISO 9001. We've had several negative issues affecting our patients in the past and management is really driving 100% conformance at ALL times-or else. We really don't have time for all the other extras around here. I can't afford to lose my job as a result of those negative issues".

Scenario 5
While reviewing the management review records, you notice the last management review was conducted 4 months ago. The record shows that internal and external audit results were presented during the review, which included ten major nonconformities issued by the internal auditors and 5 major nonconformities issued by the certification body. There was no evidence that the management reviewed the effectiveness of corrective actions that had been proposed.

Scenario 6

One of the quality objectives at the TWM Company is to "reduce errors by 20% by the end of the year." You request to review the plan put in place to achieve this objective. You notice that the plan to achieve this quality objective does not indicate what will be done, what resources will be required and how the results will be evaluated.

Scenario 7

While auditing the internal audit process, you notice that TWM Company develops an annual audit programme and audit plan during January of each year. You ask about the criteria used to determine what is to be audited each year and the Quality manager replies, "We've decided to integrate the environmental and quality management system audits. So, now we include QMS every time we do an EMS audit".

EXERCISE WORK SPACE

QMS-NCR

NON CONFORMITY REPORT

Organization: _____ CAR No. _____

Area under review: _____ ISO 9001 clause: _____

Category ☐ MAJOR ☐ MINOR

Requirement:

Nonconformity/evidence:

Auditor_____ Auditee _____

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

QMS-NCR

NON CONFORMITY REPORT
Organization: _____ CAR No. _____

Area under review: _____ ISO 9001 clause: _____

Category ☐ MAJOR ☐ MINOR

Requirement:

Nonconformity/evidence:

Auditor_____ Auditee _____

QMS-NCR

NON CONFORMITY REPORT
Organization: _____ Incident No. _____

Area under review: _____ ISO 9001 clause: _____

Category ☐ MAJOR ☐ MINOR

Requirement:

Nonconformity/evidence:

Auditor_____ Auditee _____

EXERCISE 6: EVALUATION OF CORRECTIVE ACTIONS

Purpose:
To help participants gain understanding of the corrective action processes

Directions:
In your groups, choose one of the non-conformities raised in exercise 5 above and develop a corrective action plan for it. Use the format presented in class.

Present your plan to another group and you will have a plan presented to you. As a team of auditors, determine if the corrective action plan presented to you would be effective when implemented.

Time:
Group discussion: 30 minutes
Class discussion: 45 minutes

Directions:

Each group will be assigned a scenario (s) to study from the scenarios below. The group shall then identify non conformities, **if any,** and record them in the given non-conformity forms. The group should also use exercise 4 above to raise non-conformity statements.

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 7 A and B: AUDIT PRACTICALS/ROLE PLAYS

Purpose:

1. To practice conducting an actual audit OR
2. To simulate an audit situation using interview techniques and role plays

Time:

Group preparation:	45 minutes
Actual Audit:	120 minutes
Role plays:	120 minutes
Class discussion:	45 minutes

Directions:

For this exercise, you will either conduct an actual audit (Exercise 7 A)or a role play (Exercise 7 B)

Exercise 7 A: Practical Audit:

For the practical audit, you will rely on documents from your organization to be audited and the ISO 9001:2015 standard. You will prepare for the practical audit as directed by the course facilitator.

Time:

Group preparation:	45 minutes
Actual Audit:	120 minutes
Class discussion:	45 minutes

Exercise 7 B: Role Play on Conducting the Audit

For this exercise , you will rely on the Maendeleo Case study. Four scenarios have been developed to help you perform a simulated audit of Maendeleo.

Before the scenarios begin, you shall be given 60 minutes to prepare for your roles as either auditor or auditee.

When **it is NOT** your turn to act as auditor or auditee you should take thorough notes on any non-conformities identified. Listen carefully to the auditor's interview questions and the responses from the auditee. After the scenarios, the instructor will lead a class discussion on the non-conformities (or lack of non-conformities) observed during the audit. The information will be used to document an audit report

Directions for auditees

You shall be assigned to play the roles of any of the following Maendeleo employees:

- Managing Director
- Management representative/Quality Director
- Training Manager

- Human Resources manager
- Procurement Manager
- Finance Director

For different Scenarios, the facilitator may assign different students to role play the same Maendeleo employee. To help you get into character, the instructor will hand out scenario preparation sheets that will help you assume different roles for each of the auditees. In some scenarios you will need to provide specific documents to the auditor, if asked. Don't be afraid to immerse yourself into your role as the auditee.

Directions for auditors
The instructor will assign the roles of the various auditors for each scenario.

Auditors will need to plan the questions they will ask the auditees. But you will have to be alert when auditing in case you come across any potential audit training. Just like in real audit situations the auditee may not be cooperative. You should ask when necessary to see specific QMS documentation. If the auditee cannot provide you with the necessary documents, this may be a further audit trail for you to examine.

Time:
45 minutes preparation for both auditors and auditees
45 minutes for the role plays
45 minutes for class discussion and debriefing

SCENARIOS:

Scenario 1: Auditing the record control process

Auditees: Management representative and Training Manager

Preparation documents: Control of records procedure
Maendeleo Institute Quality Manual
Customer complaints procedure

Scenario 2: Auditing Training and awareness process

Auditee: Human resources Manager

Preparation Document: Training needs identification procedure
Training record log
Maendeleo Institute Quality Manual

Scenario 3: Auditing the Management review Process

Auditees: Managing Director, Management representative and Finance Director

Preparation documents: Maendeleo Institute Quality Manual

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

Records of management review

Scenario 4: Auditing the Internal audit process

Auditees: Management representative

Preparation Documents Internal audit procedure
Maendeleo Quality Manul

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

EXERCISE 8: PREPARING THE AUDIT REPORT AND CONDUCTING THE CLOSING MEETING

Purpose:

To gain an understanding of audit reporting and closing meeting possesses.

Directions:
Each team is to prepare an audit summary report and present it during a closing meeting to the management of the auditee organization (to the participants). This report should be based on the results of previous exercises.

The report must address all the relevant topics covered in during the training. The teams shall agree on an acceptable format for the report.

Remember the purpose of the audit is to verify conformity with requirements; do not neglect to include this in the report as well as the non-conformities.

The team shall be reviewed against the following criteria:

- content and accuracy of the written summary report
- contribution of each member to the preparation work
- for the team leader, a clear, logical presentation of the audit summary, effective dealing with manager concerns and summation/closure and ability to handle difficult situations
- For team members, clear presentation of the NCR and dealing logically with the auditee concerns and reaching an understanding on corrective action responsibility/timing

Time:
Group discussion: 30 minutes
Class discussion: 15 minutes

EXERCISE WORK SPACE

Course Exercises: ISO 9001:2015 QMS Internal Auditors' Course

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4
CASE STUDY

MAENDELEO QUALITY INSTITUTE

QUALITY POLICY MANUAL

TABLE OF CONTENTS

0.1 FOREWORD

The Maendeleo Quality Institute is a Management Development Institute (MQI) established to provide training, research and consultancy services. In pursuing this mandate, the Institute has embraced modern and recent trend in management.

The adoption of a quality management system is a strategic decision to help achieve the vision of becoming a model institute in provision of training research and consultancy.

Achieving ISO 9001:2015 certification is a milestone which will enhance our name in training and be counted as one of the few premier MQI's which are ISO 9001:2015 certified.

I take this opportunity on my own behalf and on behalf of the top management to give unqualified support to the implementation of the Quality management System in terms of management commitment to the process, training requirements of our customers, establishment and implementation of quality policies and attaining quality objectives.

The QMS will lead to higher productivity and clarity of tasks and to our students and their sponsors; we will give you assurance that we shall exceed your training needs. Equally, other stake holders will benefit from increased efficiency and mutual beneficial relationships with our suppliers among others.

To become a model MQI and in the spirit of continual improvement, embraced by the QMS, we welcome your feed back, compliments or complain on our services.

Kiboko Kubwa
Managing Director

0.2 CIRCULATION LIST

This quality policy manual will be distributed on controlled basis to the following:-

COPY NO.	RECIPIENT	SECTION
1.		

0.3 AMENDMENT RECORD SHEET

Ref No	Revision No	Subject Of Review	Revision Date	Prepared By	Approved By

1.0 SCOPE

1.1 General

This QM defines the QMS of Maendeleo Quality Institute. It gives policies for the QMS in order to address customer needs and regulatory requirements and also enhance customer satisfaction.

2.0 REFERENCES

ISO 9001:2015; Quality management systems-requirements

3.0 TERMS AND DEFINITIONS

NONE

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Maendeleo Quality Institute has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. Issues include political, social, economic, environmental, legal among others. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing Maendeleo Quality Institute and its interested parties. “Maendeleo Quality Institute has determined the interested parties relevant to the QMS and the requirements of the identified interested parties.

4.3 Determining the Scope of the Quality Management System

In establishing the QMS, Maendeleo Company has identified three processes of training, research and consultancy to be under the QMS. A monitoring, measurement and analysis system has been put in place. From time to time we shall choose to outsource processes. However these processes will be outside the scope of the QMS.

4.4 Quality Management System and Its Processes

Maendeleo Quality Institute has adopted a process approach for its management system. The QMS is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review. The Institute has developed procedures that support the achievement of the requirements of the standards for each process steps. We retain records to provide documented information substantiating the process inputs and outputs have been accomplished as planned.

5.0 Leadership & Commitment

5.1.1 General

Management is actively involved in implementing the QMS, and is accountable for its overall effectiveness. Management has initiated and fully supports the vision and strategic direction for the continued sustainability and enhancement of the QMS. The Managing Director has initiated and fully supports the quality policy and quality objectives. Management is committed to the development and implementation of the QMS and to support continually improving its effectiveness. Management provides direction to the integration of the QMS requirements into each business process of the organization and is committed to promoting the use of the

process approach and risk based thinking, as well as the management and motivation of our employees throughout our QMS.

5.1.2 Customer focus

In order to enhance customer satisfaction, the management shall ensure that customer requirements are determined, through the Business Development Division activities according to documented procedure Marketing and Function Coordination. All product and development activities will aim at meeting the customer specified requirements.

5.2 Policy

The quality policy is shown below. All employees shall be required to understand their roles in ensuring the implementation of the policy, which is communicated to them through notice boards and staff briefings.

"We are committed to improve service delivery by providing quality training, research and consultancy services. We commit to help our customers develop their capacity and analyze their training needs and continually improve quality management system".

We aim to:

- Provide world-class training that is based on a defined customer service charter and uses the latest available technology
- Accreditation to and partnering with Management Development Institutes (MQI's)
- Recruitment & development of a well-trained & motivated faculty and other work force
- Careful selection, evaluation and re-evaluation of suppliers based on specified criteria
- Efficient and effective maintenance of all our facilities and equipment
- Increase in infrastructure and capacity to delivering our mandate
- Effective and efficient internal and external communication
- Continuous growth and profitability of the business

5.3 Organizational Roles Responsibilities and Authorities

While all managers have the responsibility of providing the leadership, motivation and direction to their respective staff and for the preparation and monitoring their departmental budgets, they have specific responsibilities which depend on the section concerned.

In addition, the following overall QMS responsibilities and authorities are assigned as follows:

Responsibility	Assigned To
Ensuring that the management system conforms to applicable standards	Director Technical Department
Ensuring that the processes are delivering their intended outputs	Applicable process owner
Reporting on the performance of the management system and providing opportunities for improvement for the management system	Director Technical Department
Ensuring the promotion of customer focus throughout the organization	Director Technical Department
Ensuring that the integrity of the management system is maintained when changes are planned and implemented	Director Technical Department

6.0 Planning

6.1 Actions to Address Risks and Opportunities

Maendeleo Quality Institute has taken into consideration potential issues and has determined the risks and opportunities that need to be addresses to:

- Provide assurance that the QMS can achieve its intended result
- Enhance desirable effects
- Prevent, or reduce, undesired effects
- Achieve improvement

Maendeleo Quality Institute has planned actions to address the above risks and opportunities and has initiated appropriate procedures to integrate and implement appropriate actions into our QMS including the evaluation of the effectiveness.

6.2 Quality Objectives and Planning to Achieve Them

The management has defined measurable objectives, which are translated into lower objectives at relevant functions and levels within the organization. The objectives include those needed to meet product and service quality requirements and are consistent with the quality policy. A procedure is established to address reviewing of programmes for achieving existing objectives and establishing of new objectives:

6.3 Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per the procedure for change management.

7.0 Support

7.1 Resources

7.1.1 General

On a regular basis but not less than once a year, the heads of sections will prepare work plans during which the sectional resource needs will be established. Included within the definition of resources are personnel, facilities, equipment, and funding available through state appropriations and other sources. Based on the results of the periodic review, the management will determine the priority of needs and will identify appropriate resources to address these requirements. Once the priorities have been determined, an open budget hearing will be held to communicate these to the Council and staff. Resource determination and budgeting is conducted in a controlled manner through a documented procedure with procedure, Budget Preparation and Implementation Process.

The resources requirements determined during the budgeting item shall be monitored and reviewed as necessary on a continuous basis. Heads of section shall ensure staff involvement and participation in identifying the needed resources in their areas of work.

7.1.2 People

Maendeleo Quality Institute ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

Maendeleo Quality Institute will ensure that all employees are competent as documented in the respective Job description, which also specify the job requirements, broad responsible and authority levels. Specific and relevant responsibilities and authority levels are defined in the respective procedures

7.1.3 Infrastructure

Maendeleo Quality Institute management shall determine, provides and maintains appropriate and adequate infrastructure needed to ensure product and service conformity. These shall include the office space, class rooms, hotels and furniture, facilities, equipment, including computers, LCD projectors, telephone facilities and other communication equipment. Adequate computer hardware and software shall be provided for data capturing and process monitoring and control.

Other support services such as transport and communication shall also be provided as needed to ensure product and service conformity to the specified requirements.

Review of the adequacy and appropriateness of the infrastructure is done on a continuous basis by the heads of department as part of resource management. Systems are in place to ensure the security, adequacy and maintenance of the facilities and equipment.

7.1.4 Environment for the Operation of Processes

Maendeleo Quality Institute will provide safe, convenient, barrier-free, attractive environment that welcomes, inspires and enables staff to perform at their fullest potential. Standards have been defined to ensure a conducive work environment that includes health, safety, and environment and security systems.

7.1.5 Monitoring and Measuring Resources

This clause does not apply to Maendeleo Quality Institute.

7.1.6 Organizational Knowledge

Maendeleo Quality Institute also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Maendeleo Quality Institute shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competence

Maendeleo Quality Institute shall ensure that job requirements are evaluated from time to time to reflect the changing needs and expectations of the customers. This shall be done through reviews of job descriptions of the various jobs within the organization structure.

The current job requirements shall be met by all employees at the recruitment stage and thereafter, through training or other appropriate action. Competence gaps shall be identified and the Institute shall provide the necessary training or takes other action as necessary.

7.3 Awareness

Training and subsequent communication ensure that staff are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the management system, including the benefits of improved performance;
d) the implications of not conforming with the management system requirements.

7.4 Communication

Both internal and external communication will be conducted in a controlled manner. There are procedures in place to guide telephone communication and communication through meetings. At the beginning of every calendar year, all the section heads submit a schedule of planned departmental meetings.

7.5 Documented Information

The management system documentation includes both documents and records.

The documented information include, manuals, procedures, standards, Acts of parliament and records.
Documents required for the management system are controlled in accordance with procedure ***for control of documents.*** The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented procedure ***for control of records*** has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

8.0 Operation

8.1 Operational Planning and Control

Maendeleo Quality Institute has planned and developed the processes needed for all its operations.
The required verification, validation and pilot trials, monitoring, inspection and checking activities specific to the product and service, and the criteria for product and service acceptance are defined in the various checklists and related work instructions.

The records to be maintained for evidence of conformity of processes, products and services are defined in the relevant procedures.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Maendeleo Quality Institute shall establish effective communication with all customers regarding;

- All product delivery and service information
- Enquiries, contracts or admission processing; including amendments
- Customer feedback, including complaints.

Product delivery and service information is communicated personally and in writing to the customer by the concerned staff, usually during a meeting.

Customer feedbacks, including complaints, are received and handled according to a documented procedure, which also defines the responsibilities for these activities and ensures that customer complaints are resolved as procedure for Admission**.**

8.2.2 Determining the Requirements Related to Products and Services

Maendeleo Quality Institute has established procedures to ensure that the following are determined:

- Requirements specified by the customer, including those for product and service delivery and follow-up activities.
- Statutory and regulatory requirements related to the product or service delivery which are determined at the product design and development stages, or when such requirements are introduced by the imposing authorities.
- Maendeleo Quality Institute own requirements related to the product or service delivery.

After every training, participants will be required to provide feedback which will be used to analyze customer requirements and whether the customer's specified requirements have been met.

8.2.3 Review of Requirements Related to Products and Services

Before acceptance of any booking, the stated customer requirements are reviewed to ensure clarity, completeness and that there are no ambiguous requirements. The reviews also ensure that:

- The requirements are acceptable, adequately defined, understood and documented.
- Contract or booking changes are understood and resolved with the customer
- Maendeleo Quality Institute has the capacity to deliver the required product or service. No unusual bookings are accepted before Maendeleo Quality Institute reviews its internal capability to meet the stated requirement.

8.2.4 Changes to Requirements for Products and Services

Maendeleo Quality Institute updates all relevant requirements and documents when the requirements are changed, and ensures that all appropriate staff are notified.

8.3 Design and Development of Products and Services

Maendeleo Quality Institute develops curriculum for any training carried out at our Institute.

For new designs (new courses), Maendeleo Quality Institute ensures the translation of customer needs and requirements into detailed design outputs. These address performance, reliability, maintainability, testability, and safety issues, as well as regulatory and statutory requirements.

This process ensures:

a) Design planning is conducted
b) Design inputs (requirements) are captured
c) Design outputs are created under controlled conditions
d) Design reviews, verification and validation are conducted
e) Design changes are made in a controlled manner.

8.4 Control of Externally Provided Processes, Products and Services

Maendeleo Quality Institute maintains a procurement system that ensures that purchased inputs conform to specified requirements. Documented procedures are established to control procurement activities. Suppliers are evaluated and selected on the basis of their ability to meet specified requirements. Documented criteria for selection, evaluation and re-evaluation of suppliers are defined and approved Suppliers List is maintained. Any supplier who fails to quality during the re-evaluation process is removed from the list.

Purchasing is initiated through a Material Requisition, which describes the specified requirements. The purchasing documents, which clearly describe the products and services required, are then raised based on the requisition after supplier selections. Both requisition and purchase orders are reviewed for accuracy, adequacy and completeness of the specified purchase requirements prior to approval and their communication to the supplier.

Purchasing documents are considered valid on the basis of appropriate approval according to the documented purchase authorization levels the purchasing documents cover the following information as applicable:

- Requirement for approval of product , procedures, processes and equipment
- Requirement for qualification of personnel
- Management system requirements

All purchased goods are subjected to incoming verification before acceptance while purchased services are

verified after delivery before payments are made.

Where certain services or products are outsourced from a strategic partner, and when our customer requires to verify such services or products, Maendeleo Quality Institute will facilitate such verification, including at the strategic partner's premises, if necessary.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Maendeleo Quality Institute plans and carries out operations and service delivery under controlled conditions which include the following:

- Availability of information, including detailed service standards, which describe product and service characteristics.
- Availability of work instructions that define manner of work and service delivery as
- Follow-up on product and service delivery and post-delivery activities.

The concerned manager is responsible for the determination of the optimal process and for ensuring that the service delivery conditions are met for all functions.

8.5.2 Identification and Traceability

Maendeleo Quality Institute maintains a system for identification and traceability of the courses/products provided and certificates issued.

8.5.3 Property Belonging to Customers or External Providers

All products handled by Maendeleo Quality Institute that belong to customers and external providers and which shall be used by Maendeleo Quality Institute to facilitate provision of a service shall be verified and recorded during receipt. These include participant's documents, materials, identification paper, projects or intellectual properties. All products supplied by the customer are identified, protected against loss or damage up to delivery to customer. Any customer property that is lost or damaged is recorded and reported to the customer pending a mutually agreed action.

Records are maintained of any customer or Maendeleo Quality Institute supplied products that are lost, damaged or otherwise found unsuitable for use.

8.5.4 Preservation

Maendeleo Quality Institute ensures the integrity of the certificates issued and maintains a system for ensuring the quality of the certificates is maintained during printing editing and processing up to delivery to participants. The perseveration of the integrity of the courses provided is ensured through effective curriculum development & course delivery.

8.5.5 Post-Delivery Activities

Maendeleo Quality Institute maintains documented information of all services delivered to our customers. The extent of post-delivery activities includes consideration of our customer's requirements and received feedback.

8.5.6 Control of Changes

Maendeleo Quality Institute reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Management reviews and monitors changes that affect service provision and ensures change documentation and information is distributed and controlled. Records of results of the review of changes, the person authorizing the change, and any necessary actions arising from the review are maintained in accordance with applicable procedures.

8.6 Release of Products and Services

Acceptance criteria for our services are defined in appropriate departmental procedures. Reviews and inspections are conducted at appropriate stages to verify that the requirements have been met.

8.7 Control of Nonconforming Outputs

Maendeleo Quality Institute controls all non-conforming outputs. Such non-conforming output is appropriately identified and segregated or any other appropriate action taken to prevent unintended use or continued delivery.

Non-conforming output is detected through monitoring and checking activities, audit activities, and customer feedback. Whenever non-conformity is detected, a decision will be made to address whether to:

- Rectify the non-conformity immediately to meet specified requirements
- Accept by concession from the customer
- Stop the service delivery

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Maendeleo Quality Institute plans and carries out inspection, verification, measurement, analysis and improvement processes needed to:

- Demonstrate that products and services meet defined requirements.
- Sustain the effectiveness of the management system
- Continually improve the effectiveness of the management system.

9.1.2 Customer Satisfaction

Maendeleo Quality Institute monitors information relating to customer perception as to whether the

organization has met customer requirements. The Institute solicits customer feedback on a continuous basis during and after completion every training as per the documented procedure and monitors complaints and customer enquiries as a means of obtaining such information. Reports are prepared by the Research and Consultancy staffs who also distribute them to the respective heads of sections for both corrective action and preventive action. The information obtained from the analysis is also used to drive improvements.

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

Maendeleo Quality Institute analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

a) conformity to product and service requirements
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

9.2 Internal Audit

We plan and conduct internal audits to evaluate the effectiveness of the management system. The evaluation aims to determine whether the management system conforms to the planned arrangement, whether the system is implemented and whether it is effective in achieving the specified objectives. Audit schedules identify staff who audits areas that are independent of their functions within the organization. All auditors are trained and certified by a competent body.

The results are brought to the attention of the management responsible for the area being audited that must ensure that actions are taken without undue delay to eliminate identified non-conformities and their causes.
Audit follow-up verifies actions taken and the reporting of the results. The Director Technical Department (Management Representative) is responsible for planning and implementation of quality internal audits.

9.3 Management Review

The top management shall undertake planned reviews of the ISO 9001:2000 QMS to evaluate suitability and effectiveness of the system. The meetings, which shall be held at least twice a year, shall also assess opportunities for improvement and the need for changes to the system, including the quality policy and quality objectives

The agenda of the management meetings include the following:

- Service and product delivery and conformity to customer requirements
- Status of corrective and preventive actions
- Follow-up actions from previous management reviews
- Changes that could affect the management system

The minutes shall detail decisions and actions from the management meetings which shall translate into the following:

- Improvement of the effectiveness of the management system and its processes
- Improvement of product and services, with special emphasis to customer and stakeholder requirements
- Resources needed to implement the system.

10.0 Improvement

Maendeleo Quality Institute continually improves the effectiveness of the management system through the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management meetings. To drive continuous improvements, the following occur:-

- The quality policy establishes our commitment to continuous improvement while the improvement objectives establish measurable goals.
- Through the audits, the effectiveness of the QMS is assessed while information regarding specified issues is analyzed and understood.
- Customer feedback is gathered and customer complaints are reviewed.
- Non-conforming product is controlled and recorded.
- Records demonstrating the performance of the system are maintained.
- Corrective and preventive actions are taken to eliminate the causes of actual and potential non-conformities.

The improvements of the management system shall cover the following:

- Refinement of the Policy Manual, quality policy and quality objectives.
- Attention to documented procedures, document control and record keeping.
- Clarification of responsibility and authority.
- Increased understanding of the human resource needs.
- Renewal of the organization's infrastructure.
- Enrichment of customer communication.
- Ensuring that developments meet customer needs.
- Use of more suitable suppliers and specific supplies.
- Increased effectiveness of operations.

10.2 Nonconformity and Corrective Action

This clause does not apply to Maendeleo Quality Institute.

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, Maendeleo Quality Institute works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

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1. TITLE

Procedure for control of documents in MQI

2. PURPOSE

To ensure documents are controlled

3. SCOPE OF APPLICATION

This internal procedure is applicable to all quality system Documents

4. REFERENCE

ISO 9001: 2015 Standard clause 7.5

5. DEFINITIONS

5.1 MQI – Maendeleo Quality Institute.

5.2 HOD- Heads of department

5.6 MD – Managing Director.

6. RESPONSIBILITIES.

6.1 Management Representative and HOD shall be responsible for implementation and maintenance of this procedure.

7.0 METHOD

7.1 Quality system documents required for the effective functioning of the quality management system shall be prepared by process owners in consultation with MR. This shall be done prior to writing or during preparation of the documents.

7.2 Documents shall remain legible by clearly printing in Calibri font 12.

7.3 Standard format for the Quality System Manual shall bear the table of contents and the header.

7.4 Standard format for operating procedures shall be adopted that incorporates header, title, purpose, scope, definitions/terms, responsibility, method, key performance indicators, and appendices.(See appendix 2).

7.5 Standard format for work instruction shall have the header and method.

7.6 Documents thus prepared shall be typed in computer with clear identification such as department/section, title/ process, document number, issued by, Approved by , page number of, issue number and revision number. (See appendix 2).

7.7 The process owner shall give the name and number of the document.

7.8 The process owner shall sign the page(s) of the amended document (procedures) to evidence its review and re-approval prior to issue and use.

7.9 Process owners shall store the documents after binding or filing in clean and dry cabinets or shelves.

7.10 **DOCUMENTS OF EXTERNAL ORIGIN**

7.10.1 A master list of all the documents of external origin shall be prepared by the Process owners. It shall reflect the details such as title, reference number, version and date.

7.10.2 The process owners shall request for information from the concerned body on the revision/ amendment.

7.10.3 The amended / new edition shall be procured by MQI and the master list shall be updated as necessary by process owners.

7.10.4 The process owners shall distribute and control these documents.

7.10.5 The obsolete version of the standard shall be filled separately in a file labelled 'Obsolete Document of external origin' and sent to company archives.

7.11 DISTRIBUTION

7.11.1 Only approved versions of applicable document shall be available at their points of use.

7.11.2 The Quality System Manual and Compulsory procedures shall be controlled and therefore their circulation shall be restricted to persons whose job titles or names appear in the TOD form determined by the MR.

7.11.3 Recipient staff shall receive the document and acknowledge the receipt of the document in the transmittal of documents form. The acknowledged TOD form shall be filed by the MR. see Appendix 1.

7.11.4 Uncontrolled copies of the quality system manual and operating procedures can be given to the customers or external interested parties for information on the quality system management of the organization. The uncontrolled copies shall be identified with a stamp 'uncontrolled' and not to be subjected to updating whenever there is an amendment. The MR shall seek consent of the MD before giving the uncontrolled copy of the manual to customers or interested parties.

7.11.5 Obsolete version of the document(s) shall be withdrawn from the holders and shredded. The obsolete version of the document(s) with the process owner shall be filed separately. The file shall be labelled by the name of the document and sent to the company Archives.

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1. TITLE

Procedure for control of records

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2. PURPOSE

This document defines the specific procedure to be followed related to control of quality records of MQI and to ensure their establishment and maintenance.

3. SCOPE

This procedure is applicable to all quality system records.

4. REFERENCE

ISO 9001:2015 standard, clause 7.5

5. DEFINITIONS.

5.1 TOD - Transmittal of documents
5.2 MQI - Maendeleo Quality institute
5.3 MR - Management representative
5.4 HOD - Head of department
5.6 MD - Managing Director
5.7 Process owner; - A person directly having responsibility and accountability for implementation of a quality management process in a given unit of operation within a department.

6. RESPONSIBILITIES.

6.1 Management representative and Heads of departments are responsible for implementation and maintenance of this procedure.

6.2 Managing Director shall authorise this procedure prior to issue and use.

7.0 METHOD

7.1 Identification.

7.1.1 All quality records shall be identified with a label indicating the title /reference number/department/section name by concerned department/section.

7.1.2 A master list of all the records shall be maintained by the MR and update it as and when the records are added into the system.

7.1.3 Departmental list of records shall also be maintained by the HOD and update it as and when the records are added into the system.

7.1.4 All the files / registers shall be labelled indicating the Department the record belongs to / title of the record/ valid period.

7.2 Collection

7.2.1 Quality records shall be generated by trained personnel only.

7.2.2 The entries shall be in ink and legible cancellations, erasers are discouraged. Any cancellation must be counter signed.

7.3 Filing

7.3.1 During filing the latest document by date shall be placed on the top.

7.3.2 All files shall bear a label with identifying information and logical sequential serial number.

7.3.3 Filling of the documents shall be carried out within 48 hours of the transaction.

7.6 Retention time/storage/protection.

7.6.1 All quality records shall be stored in designated safe areas and shall have a stated retention time as determined by the process owner.

7.6.2 Files borrowed shall be returned to the holder immediately after use files /register/log books shall be kept in the designated areas by process owners

7.6.3 Access to quality records on computer shall be protected by having a password or ready only

7.6.4 Records held on computer shall have back up copies as means of reconstruction in case of file damage or loss.

7.6.5 MR shall keep quality records in designated safe areas and shall have retention time as stated below.

7.7 Maintenance

7.7.1 HODs shall ensure that all records for their department are properly maintained.

7.7.2 Storage rooms /racks/ cabinet/ shelves shall be kept clean.

7.7.3 Obsolete records shall be identified by the expiry of the stated storage period.

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1. TITLE

Procedure for Staff Training and Development

2. PURPOSE

To meet the organization's staff need based skills of employees who are involved in the quality of products and services, through manpower training and development.

3. SCOPE

This procedure shall apply to all staff of MQI.

4. REFERENCES

N/A

5. DEFINITIONS

5.1	MQI	- Maendeleo Quality Instituite
5.2	TO	- Training Officer
5.3	HOD	- Heads of Department
5.4	MD	- Managing Director
5.5	HRM	- Human Resources Manager
5.6	TNA	- Training Needs Assessment

6. RESPONSIBILITY

6.1 The Human Resources Manager shall verify and confirm the Training Plan.

6.2 The Training Officer shall ensure Training Plans are implemented as per the authorised Programmes

6.3 The Managing Director shall approve the training plan.

6.4 The Heads of Departments shall be responsible for identifying the training needs of all personnel working in their respective Department/Section.

7. METHOD

7.1 The HODs shall identify the training needs of through period performance appraisals, TNA of their staff and recommend action to address training gaps to the TO through the HRM.

7.2 The TO shall develop the Training Plan in conformance with the identified training needs and submit to the HRM.

7.3 The HRM shall forward the Training Plan to the MD for approval.

7.4 Depending on the availability of materials and resources the MD shall approve the Training Plan.

7.5 Training Officer shall implement the approved Training Plan.

7.6 The Training Officer shall implement training evaluation for the individuals after a period of one year to assess effectiveness.

7.7 The Training Officer shall update employee records.

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1. TITLE: Procedure for internal quality audit

2. PURPOSE: To ensure effective conduct of internal audits

3. SCOPE: This procedure applies to all internal quality audits

4. REFERENCES

ISO 9001:2015 Standard clause 9.2

5. DEFINITIONS

5.1 MR – Management Representative
5.2 MD - Managing Director

6. RESPONSIBILITIES

6.1 Management Representative is responsible for ensuring that internal audit programme is prepared and implemented. The programme will provide for allocation and training of internal auditors and for preparing the internal audit schedule.

7.0 METHOD

7.1 AUDIT PLANNING

7.1.1 The MR shall prepare internal audit schedule and post on the notice board.

7.1.2 The internal audit schedule shall cover all aspects of the Quality Management System at least once a year.

7.1.3 The schedule shall leave time for unscheduled audits in response to the following:

a) Unanticipated problem areas
b) Actual problems
c) Requests from management
d) Unforeseen changes in circumstances

7.1.4 The schedule shall define for each audit:

(a) The auditor
(b) The auditee
(c) The date

7.2 AUDIT PREPARATION

7.2.3 From the audit schedule, the audit team leader shall prepare an audit plan for the area to be audited.

a) Shall assign individual auditors tasks.
b) Ensure working documents are prepared
c) Lead audit team

d) Chair opening and closing meeting.
e) Ensure audit progress as per plan

7.3 AUDITING:
The auditor shall be accompanied by a representative of the audited process area as part of the audit team. During the audit, the auditor shall do the following:

7.3.1 Shall have an opening meeting with the auditee(s) to highlight the agenda

7.3.2 Shall make notes to aid the writing of audit report.

7.3.3 Shall collect documentary evidence of conformity or nonconformity.

7.3.4 Shall conduct the audit in accordance with the audit schedule using prepared lists and questions.

7.3.5 Shall convene an audit team strategy meeting to record nonconformities, and prepare a summary report and form a corporate opinion that shall be presented at the closing meeting

7.3.6 Shall keep the auditee informed as to the progress of the audit and findings during the closing meeting.

7.4 REPORTING AND ANALYSIS OF AUDITS.
As soon as practical audit is done the auditor shall prepare an audit report which classifies the findings of the audit as follows:

7.4.1 Shall use the standard proforma for the reporting of the audit

7.4.2 Shall ensure that major and minor failure are summarized/captured

7.4.4 Shall observe and highlight the area of weakness that could be improved.

7.4.5 Shall record positive observations as well as negative observations.

7.4.6 Shall clearly define the areas where corrective actions are required

7.4.7 The report shall be signed by the auditee and the audit team leader as being a true and accurate representation of the facts.

7.4.8 Ensure audit results are reported clearly, conclusively and without undue delays and submit the audit findings to the MR

7.5 FOLLOW-UP AUDIT

7.5.1 The auditor shall make a follow up audit of the actions taken after an agreed period of time.

7.5.2 Corrective actions resulting from the audit shall be reported to the Managing Director if the necessary action has not been within the agreed period of time.

7.5.3 The audit and follow up findings shall be discussed in the management review meeting.


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