

MASENO UNIVERSITY

DOCUMENT TITLE	PROCEDURE FOR INTERNAL QUAI	LITY AUDIT	
DOC. NO:	MSU/VC/MR/OP/02	ISSUE NO:	2
DATE OF ISSUE	10 TH MARCH, 2023	REV. NO:	1
AUTHOR	MI	R	
AUTHORIZED BY:	VICE-CHANCELLOR R S	ISSUED BY:	MR
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0.1 DOCUMENT CHANGES

#	Date	Details of Change		Authorization
	(dd-mm-yy)	Page	Clause/sub clause	Title
1	06/03/2023	1	Change of signature to reflect the current Officer in charge.	VC
2	06/03/2023	2	3.0. Reference to ISO 10013:2021 and ISO 19011:2018.	VC
			July	
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0.2 DOCUMENT DISTRIBUTION

This quality management procedure is available on Maseno University Website for authorized users.

1. PURPOSE

The purpose of this procedure is to ensure that Internal Quality Audits are effectively carried out in order to ensure continual improvement of Quality Management System in the University.

2. SCOPE

The procedure covers audit scheduling, preparation, execution, audit follow-up and reporting

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3. REFERENCES

- 3.1 Maseno University Quality Manual
- 3.2 MSU/VC/MR/OP/01 Procedure for Control of Documented Information
- 3.3 ISO 9001-2015 Quality Management System requirements Clause 9.2
- 3.4 ISO 9000:2015, Quality Management systems –Fundamentals and vocabulary
- 3.5 ISO 10013:2021, Guidelines for Quality Management System Documentation
- 3.6 ISO 19011:2018-Guideliness on QMS Auditing

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4. DEFINITIONS OF TERMS/ABBREVIATIONS

4.1 Definitions of Terms Used:

For the purpose of this procedure the following terms shall apply in addition to those defined in the Maseno University Quality Manual, ISO 9000:2015 and ISO 19011:2011.

- 4.1.1 Audit Systematic and independent assessment of quality activities to determine the extent to which they meet requirements and are effective
- 4.1.2 Auditee: This is a specific functional department or section to be audited under the responsibility of the respective Head
- 4.1.3 Audit team leader: An internal quality auditor designated or appointed to lead an audit.
- 4.1.4 Audit team: One or more internal auditors selected to conduct an audit
- 4.1.5 Audit scope: This is the extent or boundaries of an audit which may include a defined physical location, functional positioning, activities and processes as well as time period for performance of an audit.

4.2 Abbreviations and Acronyms

4.2.1 **CAR** : Corrective Action Request

4.2.2 **CAP**: Corrective Action Plan

4.2.3 **MSU**: Maseno University

4.2.4 VC : Vice-Chancellor

4.2.5 QMS: Quality Management System

4.2.6 MR : Management Representative

5. RESPONSIBILITIES

The MR has the overall responsibilities for planning, coordinating, executing and monitoring internal audits to provide information that ensures conformity, effective implementation and maintenance of the QMS. This includes drawing up of annual audit programme, audit notification, appointment of auditors, follow up of corrective actions, and presentation of overall audit reports to the top management.

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6. METHOD

6.1 Planning and execution of Internal Quality Audits

The MR shall be responsible for:

- 6.1.1 Planning and Scheduling of internal quality audits and ensuring that internal audits are conducted as scheduled.
- 6.1.2 Planning internal quality audit programmes which shall be carried out bi annually, however, the MR can schedule special quality audit when necessary.
- 6.1.3 Nominating audit team for scheduled audits.
- 6.1.4 Establishing quality audit criteria, scope and frequency.
- 6.1.5 Selecting auditors to facilitate objectivity and impartiality by ensuring that auditors do not audit their own work.
- 6.1.6 Retaining documented information of internal quality audits.
- 6.1.7 Coordinating follow up on corrective actions including verification of actions taken and reporting verification results.
- 6.1.8 Ensuring that internal quality auditors carrying out audits are trained and have necessary competence as auditors.
- 6.1.9 Retaining documented information on training of internal quality auditors and list of trained internal auditors.
- 6.1.10 Presenting internal audit reports to management review meetings.

6.2 Responsibility of Auditee during QMS audits Auditee shall be responsible for:

- 6.2.1 Ensuring that audits scheduled for their departments are carried out as planned.
- 6.2.2 Signing for identified nonconformities recorded on the audit CAR forms during internal audits.
- 6.2.3 Ensuring that CARs raised during internal quality audits are implemented within the agreed upon timeline without undue delay and that the CARs are closed out by Auditors.

6.3 Responsibility of Internal Quality Auditors during Internal

Audits Internal auditors shall be responsible for:

6.3.1 Obtaining from the MR the audit basis/documents and preparing audit checklist questions.

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- 6.3.2 Preparing audit notifications and audit Plan for assigned areas as per audit schedule, criteria and scope.
- 6.3.3 Formally notifying the auditee of the audit in writing, at least five working days in advance.
- 6.3.4 Conducting audits as per audit principles outlined in ISO 19011:2011 Standard.
- 6.3.5 Generating audit findings and CARs as applicable and ensuring they are completed and signed by the Auditee.
- 6.3.6 Ensuring initial audit follow-ups on dates agreed with the Auditee and filling follow-up review reports in the CARs.

6.4 Audit scheduling

- 6.4.1 The MR shall develop a corporate schedule of audits at the beginning of each year.
- 6.4.2 The MR shall take into consideration the status and importance of departmental activities when scheduling audits.
- 6.4.3 The audit areas shall include Divisions/Departments/Sections/Units

6.5 Execution of audit

The audit team shall hold an opening meeting with the auditee in which the following agenda shall be covered:

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- i. Introduction
- ii. Registration of attendance
- iii. Confirmation of the Audit basis, documentation to be used, audit scope and purpose
- iv. Confirm audit plan
- v. Assurance of confidentiality
- vi. Clarify circumstances under which the audit can be terminated.
- vii. Language and audit methodology.
- viii. Safety measures and requirements.

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6.6 Actual Audit

- 6.6.1 During the actual audit, the auditor shall use a checklist prepared to obtain objective evidence
- 6.6.2 The auditor shall record the evidence on the audit findings form.
- 6.6.3 The auditor shall read the findings to the auditee and request them to sign.

6.7 Review Meeting

- 6.7.1 The auditor shall evaluate the audit findings against audit criteria and categorize the findings into positives, risk and opportunities and nonconformities as applicable.
- 6.7.2 The auditors shall classify non-conformities into major or minor non-conformities and fill in the CAR forms to be filled by auditees during the closing meeting.

6.8 Closing Meeting

- 6.8.1 The auditor shall ensure registration of the attendees
- 6.8.2 The auditor shall thank the auditee.
- 6.8.3 The auditor shall clarify the purpose and scope of the audit
- 6.8.4 The auditor shall reassure the auditee of confidentiality of the auditee findings
- 6.8.5 The auditor shall present the overall summary and conclusions, starting with the positives.
- 6.8.6 The auditor shall give non-conformities in detail if applicable
- 6.8.7 The auditor shall allow discussion on the findings.
- 6.8.8 The auditor shall request the auditee to sign the CARs if applicable.
- 6.8.9 The auditor shall request for corrective action dates
- 6.8.10 Agree on the follow up dates.

6.9 Audit Reports

6.9.1 The auditors shall prepare audit report and forward it to MR including the notification, checklists, attendance registers, audit findings and CAR, within one week after the audits.

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- 6.9.2 MR compiles audit reports and present to the auditors meeting within a week after receiving reports.
- 6.9.3 Audit report shall be sent to the auditees within three weeks after the audit.

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- 6.9.4 The auditors shall follow up on the agreed corrective action on the agreed dates within 30 days after the audit to establish whether the corrective actions have been effectively done.
- 6.9.5 Nonconformities shall be closed within 30 days.
- 6.9.6 Effectiveness of nonconformities shall be confirmed in the subsequent quality audits.

