



KENYA PLANT HEALTH INSPECTORATE SERVICE

STANDARD OPERATING PROCEDURE

Department: Planning & Strategy

Revision No:07

Issue No:01

SOP FOR INTERNAL QUALITY AUDIT

SOP/KEPHIS/QMS/02

Issued by: 

DQMR

Date...21/11/2024.....

Approved by: 

QMR

Date...21/11/2024.....



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1.0 Purpose

This procedure is implemented to provide information on whether the management system conforms to the organization's own requirements and the requirements of ISO 9001:2015 or ISO/IEC 27001:2022. It also assists to provide information on whether the management system is effectively implemented and maintained.

2.0 Scope

This document describes the procedures to be followed in audit planning, execution, reporting and assessment of audit findings.

3.0 References

- 3.1 Quality Policy
- 3.2 Information Security Policy
- 3.3 Quality Manual
- 3.4 ISMS Manual
- 3.5 ISO 9001:2015 standard
- 3.6 ISO/IEC 27001:2022 standard
- 3.7 ISO 19011:2018 standard
- 3.8 Statement of Applicability (SOA)
- 3.9 Relevant SOPs
- 3.10 Relevant Work Instructions (WI)
- 3.11 Relevant statutory and regulatory requirements
- 3.12 Enterprise Risk Management Framework

4.0 Abbreviations

- 4.1 CAR – Corrective Action Request
- 4.2 DQMR – Deputy Quality Management Representative



- 4.3 ICT – Information Communication and Technology
- 4.4 IQA – Internal Quality Audit
- 4.5 IS – Information Security
- 4.6 ISMS – Information Security Management System
- 4.7 QMR – Quality Management Representative
- 4.8 QMS- Quality Management System
- 4.9 SOA – Statement of Applicability
- 4.10 SOPs – Standard Operating Procedures
- 4.11 WI - Work Instructions

5.0 Responsibilities

The QMR and ISMS Coordinator shall be responsible for implementation of this procedure.

6.0 Schematic Representation

Internal Quality Audit							
Sources of Inputs	Inputs	Activities	Outputs	Receivers of Outputs	Risks	Checks/Controls	Resources
▪ ISO 19011:2018 ▪ ISO 9001:2015. ▪ ISO/IEC 27001:2022 ▪ Quality Manual ▪ Quality Policy ▪ IS Policy ▪ SOPs ▪ WIs ▪ Relevant policies, manuals, strategies	▪ Audit Programme ▪ Agenda- Auditors meeting/opening and closing meetings ▪ Audit checklist ▪ Audit findings	▪ Audit planning ▪ Audit execution ▪ Audit Finding Review ▪ Audit reporting ▪ Audit report review	▪ Audit Notification & Plan ▪ Audit programme ▪ Auditor meeting minutes ▪ Audit reports ▪ CAR forms ▪ Auditor / Auditee Evaluation forms ▪ Assessment report ▪ Audit report review recommendations ▪ Attendance Registers	▪ Management ▪ Auditees ▪ QMR ▪ ISMS Coordinator	▪ Intimidation by auditee/auditor ▪ Biased reporting ▪ Inadequate reporting ▪ Not auditing all processes planned for	▪ Awareness/ training on importance of management systems. ▪ Mechanism for appeal ▪ Rotation of auditors ▪ Sampling of audit areas ▪ Training of auditors	▪ Auditors ▪ Finance ▪ ICT Infrastructure ▪ Stationery ▪ General infrastructure



▪ Relevant statutory and regulatory requirements							
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7.0 Procedure

7.1. Audit Planning

- 7.1.1 The QMR/ ISMS Coordinator draws an annual audit programme to define the scope, purpose, criteria and selection of auditors.
- 7.1.2 The QMR/ ISMS Coordinator calls for a pre- audit meeting to discuss importance of the processes concerned, changes affecting the organization and results of previous audits.
- 7.1.3 The QMR/ ISMS Coordinator sends a general notification to all staff on the impending audit at least 3 weeks before the scheduled audit.
- 7.1.4 Lead auditors shall send specific notifications to stations/departments to be audited at least 2 weeks before the audit.
- 7.1.5 Audit teams shall undertake document review, agree on sampling methods, work documents and reporting.
- 7.1.6 The audit team shall request for necessary resources to be used when conducting the audit.

7.2 Audit Execution

- 7.2.1 The Audit Team shall conduct an opening meeting with members of the department /Region to be audited.
- 7.2.2 The Audit Team shall proceed to conduct the audit by performing interviews, observation, document review, collecting, verifying, generating and communicating audit findings to the auditees.



7.2.3 Upon completion of the audit, the team shall undertake an audit review meeting to review audit findings and draw conclusions.

7.2.4 The Audit findings shall be classified as positive findings, opportunities for improvement and Non-conformities.

7.2.5 Non-conformities will be categorised as either:

- i. Major – The absence of or total systemic breakdown of a management system as specified by the standard or any serious non-compliance to statutory and regulatory requirements.
- ii. Minor - A single system failure or lapse in conformance with a procedure relating to the standard.

7.2.6 The Audit team conducts a closing meeting to communicate and discuss the audit findings with the auditees.

7.2.7 In the event a non-conformity is raised, a timeline of 2 weeks shall be given by the lead auditor for submission of corrective action plan(s).

7.2.8 Signed original copy of the CAR form shall remain with the auditee and a copy sent to the QMR/ISMS Coordinator's office together with the audit report within 7 days.

7.2.9 The lead auditor presents auditee-auditor evaluation forms to the auditee.

7.2.10 The auditee shall evaluate the performance of the auditors using the auditee-auditor evaluation forms (Appendix 9.2) provided and submit to QMR/ISMS Coordinator for analysis.

7.3 Reporting

7.3.1 The Audit team prepares the final report and forwards it to the QMR/ISMS Coordinator and the auditee within 7 days using the format prescribed in appendix 9.4.



- 7.3.2 The auditors shall evaluate the performance of their teams using the auditor-auditor evaluation forms (Appendix 9.3) and submit the forms to QMR/ISMS Coordinator for analysis.
- 7.3.3 The QMR/ISMS Coordinator forms an ad-hoc Audit Finding Review Committee to validate the reports before collating the final report.
- 7.3.4 The ad-hoc committee can adopt or give recommendations for improvements.
- 7.3.5 The QMR/ISMS Coordinator collates the final reports after consideration of 7.3.3 and forwards to management for further action.

8.0 Records

- 8.1 Audit programme
- 8.2 Pre-audit meeting minutes
- 8.3 Audit notification and plans
- 8.4 Audit Reports
- 8.5 Duly filled CAR Forms
- 8.6 Attendance Registers
- 8.7 Assessment Reports
- 8.8 Auditor Evaluation forms and analysis records

9.0 Appendices

- 9.1 Corrective Action Request Form
- 9.2 Auditor-Auditor Evaluation Form
- 9.3 Auditee-Auditor Evaluation Form
- 9.4 Audit Report Template



Appendix 9.1 Corrective Action Request (CAR) Form

KEPHIS/QMS/FORM/IQA/01

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Station:	Area Under Review:
Audit No.	CAR No. OF
Auditors:	Auditee:
Criteria Document:	Audit Date:
Requirement	
Non-Conformity	
Evidence	
Category ☐ Major ☐ Minor	
Signed: Auditee	Signed: Auditor



ROOT CAUSE	
CORRECTION	
CORRECTIVE ACTION	
Signed: Auditee Date..... Signed: Auditor Date.....	
ASSESSMENT (Effectiveness of Corrective Action) Action fully Completed ☐ Action Partially Completed ☐ No Action Taken ☐ Details Was Corrective Action Effective? YES ☐ NO ☐ Remarks Signed: Auditee Date..... Signed: Auditor Date.....	



Appendix 9.2: Auditee – Auditor Evaluation Form

KEPHIS/QMS/ FORM/IQA/02

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Section A: General

Name of the auditor.....

Auditor Responsibilities (Auditor/ Lead Auditor).....

Name of Station(s)/ Department(s) Audited.....

Audit Date.....

Section B: Evaluation

No.	Performance Criteria	Scores				
		5 Excellent	4 Very good	3 Good	2 Fair	1 Poor
1.	Time management					
2.	Open minded					
3.	Communication skills					
4.	Objectivity					

Section C:

Recommendation(s) for improvement

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Thank you



Appendix 9.3: Auditor - Auditor Evaluation Form

KEPHIS/QMS/ FORM/IQA/03

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Section A: General

Name of Auditor.....

Auditor Responsibilities (Auditor/ Lead Auditor)

Name of Station(s)/ Department(s) Audited.....

Date of Audit.....

Section B: Evaluation

No	Element	Performance criteria	Max. score	Score	Brief comments
1	Meetings	Ability to communicate audit aspects effectively	5		
		Ability to convince	5		
		Ability to arrive at good conclusions	5		
2	Auditing	Questioning skills	10		
		Recording of audit findings	10		
		Quality of audit findings	10		
		Quality of nonconformities	10		
		Evaluation of corrections and corrective actions	10		
		Time management	10		
3	Personal attributes	Ethical	5		
		Open minded	5		



		Diplomatic	5		
		Observant	5		
		Perceptive	5		
		Versatile	5		
		Tenacious	5		
		Decisive	5		
		Self-reliant	5		
		Communication skills	5		
4	Reporting	Reporting truthfully and accurately	5		
		Impartiality and objectivity of audit conclusions	5		
		Rationally reaching reliable and reproducible audit conclusions (evidence based)	5		
TOTAL SCORE			140		(Pass mark: Lead auditor=100; Auditor = 80)

Section C: Comments by Evaluator:

1. Recommendation(s) for improvement:

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Name of evaluator

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Signature

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Date



Appendix 9.4: Internal Quality Audit Report Format

KEPHIS/QMS/FORM/IQA/04

Rev 01 Issue 01

- a) Cover Page to include KEPHIS Logo, Report Title, Station, Audit No and Dates of Audit.
- b) Table of Contents
- c) Purpose of the audit
- d) Audit objectives
- e) Scope
- f) Executive Summary
- g) Detailed Report
 - i. Positive Findings
 - ii. Opportunities for Improvement
 - iii. Non-conformities
- h) Conclusion
- i) Appendices to include audit plan, attendance sheets, CAR forms



10.0 Review Details

REVISION SUMMARY	REASON	DATE	REVISED BY	ISSUE NUMBER	REVISION NUMBER
1. Change Approver of Document 2. Change title HQMS to QMR	Appointment of new QMR The position no longer exists	11/09/2013	QMR	5	3
3. Grammatical Refinement 4. Deletion of Clause 6.5 – Quality Audit Records 5. Revision of CAR Form	To ensure procure is in tandem with practice To include Assessment of Corrective Actions and audit follow ups	03/09/2014	QMR	1	4
6. Review of entire procedure	To align to ISO 9001:2015 requirements	20/02/2018	QMR	1	5
7. Introduction of Auditee-Auditor Evaluation form	Opportunity for improvement	01/10/2019	QMR	2	5
8. Review of entire SOP	For continual Improvement	01/09/2021	QMR	1	6
9. Review of entire SOP	For continual Improvement	14/11/2024	QMR	1	7