



KENYA PLANT HEALTH INSPECTORATE SERVICE

STANDARD OPERATING PROCEDURE

Department: Planning & Strategy

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SOP FOR CONTROL OF NON-CONFORMING OUTPUTS

SOP/KEPHIS/QMS/04

Issued by: 

DQMR

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

Approved by: 

QMR

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Table of Contents

1.0 Purpose	3
2.0 Scope.....	3
3.0 References	3
4.0 Definitions/Abbreviations.....	3
5.0 Responsibilities	4
6.0 Schematic Representation.....	4
7.1. Non-conformities resulting from Process lapse	5
7.2 Non-conformities resulting from Audit findings	6
8.0 Records	6
9.0 Appendices.....	6
10.0 Review Details.....	8



1.0 Purpose

This procedure details the activities that ensure the outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

2.0 Scope

The procedure covers all non-conformities that occur during day-to-day performance of the corporation's activities. It is applicable to all services offered by KEPHIS Quality management system.

3.0 References

- 3.1 Quality Policy
- 3.2 Quality Manual
- 3.3 ISO 9001:2015 standard
- 3.4 ISO/IEC 27001:2022 standard
- 3.5 Relevant policies, manuals and strategies
- 3.6 Relevant statutory and regulatory requirements
- 3.7 Relevant Standard Operating Procedures (SOPs)
- 3.8 Relevant Work Instructions (WI)
- 3.9 KEPHIS Strategic Plan

4.0 Definitions/Abbreviations

- 4.1 CAP – Corrective Action Plan
- 4.2 CAR – Corrective action request
- 4.3 CNC – Control of Non-conformity
- 4.4 DQMR – Deputy Quality Management Representative
- 4.5 ICT – Information Communication & Technology



- 4.6 ISMS – Information Security Management System
- 4.7 Non-Conformity – Non-fulfilment of a requirement
- 4.8 QMR – Quality Management Representative
- 4.9 QMS – Quality Management System
- 4.10 SOP – Standard Operating Procedure
- 4.11 WI – Work Instructions

5.0 Responsibilities

Directors and deputy directors shall be responsible for the overall implementation of this procedure

6.0 Schematic Representation

Control of Non-conforming Outputs							
Sources of Inputs	Inputs	Activities	Outputs	Receivers of Outputs	Risks	Checks/Controls	Resources
▪ Incidents reports ▪ Audit Reports ▪ Customer Feedback ▪ Relevant procedures ▪ Management reviews ▪ Risk/Opportunity register	▪ Non-conforming output form. ▪ CAR form	▪ Identification of non-conforming output ▪ Ad-hoc committee deliberations ▪ Correction ▪ Root cause analysis ▪ Corrective action ▪ Evaluation of effectiveness of corrective action	▪ Evidence of correction ▪ Minutes of committee deliberations ▪ Duly Filled in Non-conforming output forms ▪ Corrective Action Plans (CAP) ▪ Authorization for acceptance ▪ Communication to customers/interested parties ▪ Updated risk/opportunity registers	▪ Directorates ▪ Departments ▪ Management ▪ Staff ▪ Interested parties	▪ Failure to implement recommendations ▪ Failure to report non-conforming outputs ▪ Loss of credibility to organization ▪ Ineffective corrective actions	▪ Follow-ups ▪ Monitoring of processes ▪ Awareness on reporting non-conformities ▪ QMS Assessment	▪ Personnel ▪ Finance ▪ ICT infrastructure ▪ Stationery ▪ General infrastructure



7.0 Procedure

7.1. Non-conformities resulting from Process lapse

- 7.1 The officer identifies and controls the non-conforming output to prevent any unintended use.
- 7.2 The officer informs the supervisor of the non-conforming output by filling the Non-Conforming Output Form (Appendix 9.1).
- 7.3 The supervisor appoints an ad-hoc committee when necessary to deliberate on non-conforming output(s) within 5 days of receiving the non-conformity form.
- 7.4 The ad-hoc committee makes recommendations on the non-conforming output to the supervisor.
- 7.5 Nonconforming outputs shall be dealt with in the following ways but not limited to:
 - 7.5.1 Correction;
 - 7.5.2 Segregation, containment, return or suspension of provision of product and services;
 - 7.5.3 Informing the customer; and
 - 7.5.4 Obtaining authorisation for acceptance under concession.
- 7.6 Update risks and opportunities determined during planning, if necessary.
- 7.7 The process owner makes changes to the quality management system, if necessary.
- 7.8 Corrected nonconforming outputs are subjected to verification to demonstrate conformity to requirements by the action officer.



7.2 Non-conformities resulting from Audit findings

- 7.2.1 An auditor raises a non-conformity from his/her audit findings through a corrective action request (CAR) form.
- 7.2.2 The auditee develops a corrective action plan (CAP) from the CAR form raised and sends to the lead auditor for agreement within two weeks after the audit.
- 7.2.3 Upon agreement, the corrective action shall be implemented.
- 7.2.4 Update risks and opportunities determined during planning, if necessary.
- 7.2.5 Follow up on effectiveness of corrective actions implemented will be done during QMS/ISMS assessments by the QMR/ISMS Coordinator.
- 7.2.6 The process owner makes changes to the quality management system, if necessary.

8.0 Records

- 8.1 Duly filled Non-Conforming Output Forms.
- 8.2 Duly filled Corrective action request forms.
- 8.3 Duly filled Corrective action plans.
- 8.4 Minutes of deliberations by Ad-hoc Committee.
- 8.5 Communications to customers/ interested parties.
- 8.6 Updated risk/opportunity registers.
- 8.7 Audit report.
- 8.8 Authorization for acceptance.

9.0 Appendices

- 9.1 Control of Non-Conforming Output form.



Appendix 9.1 Control of Nonconforming Output form

KEPHIS/QMS/ FORM/CNC/01

Rev 02 Issue 01

NON-CONFORMING OUTPUT FORM
STATION/ DEPARTMENT:
DETAILS OF NON-CONFORMING OUTPUT
NAME: _____ DATE: _____ SIGN: _____
CORRECTION
ROOT CAUSE(S)
RECOMMENDATION(S)
CORRECTIVE ACTION
APPROVED BY: _____ SIGN _____ DATE _____



10.0 Review Details

REVISION SUMMARY	REASON	DATE	REVISED BY	ISSUE NUMBER	REVISION NUMBER
1. Change Approver of Document	Appointment of new QMR	02/11/2013	QMR	5	3
2. Change title HQA to QMR	The position no longer exists				
3. Grammatical refinement	To ensure procedure is in tandem with practice	03/09/2014	QMR	0	4
4. Deletion of clause 6.1 (c)	The reporting lines in 6.1(c) and 6.2 contradict each other. The deletion will align the reporting lines accordingly	08/07/2016	QMR	1	4
5. Review of entire SOP	To meet requirements of ISO 9001:2015	20/02/2018	QMR	1	5
6. Inclusion of type of nonconformity	To provide clarity on how to handle and address the non-conformity	25/02/2020	QMR	2	5
7. Review of entire SOP	For continual improvement	02/09/2021	QMR	1	6
8. Review of entire SOP	For continual improvement	14/11/2024	QMR	1	7