



KENYA PLANT HEALTH INSPECTORATE SERVICE

STANDARD OPERATING PROCEDURE

Department: Planning & Strategy

Revision No:08

Issue No:01

SOP FOR CONTROL OF DOCUMENTED INFORMATION

SOP/KEPHIS/QMS/01

Issued by: 

DQMR

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

Approved by: 

QMR

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



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1.0 Purpose

The purpose of this procedure is to describe activities involved in creating, updating and control of documented information.

2.0 Scope

The scope includes documented information required by the ISO 9001:2015 and the organization necessary for the effectiveness of the Quality Management System (QMS).

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 statutory and regulatory requirements

4.0 Abbreviations

- 4.1 CDI – Control of Documented Information
- 4.2 DCA – Document Change Application
- 4.3 DQMR – Deputy Quality Management Representative
- 4.4 ICT – Information Communication and Technology
- 4.5 ISP – Information Security Policy
- 4.6 LQP – Laboratory Quality Policy
- 4.7 QM – Quality Manual
- 4.8 QMR – Quality Management Representative
- 4.9 QMS -Quality Management System



4.10 QP – Quality Policy

4.11 SOP - Standard Operating Procedure

4.12 WI – Work Instruction

5.0 Responsibilities

All directors and deputy directors shall be responsible for the implementation of this procedure.

6.0 Schematic Representation

Control of Documented Information							
Sources of Inputs	Inputs	Activities	Outputs	Receivers of Outputs	Risks	Checks/Controls	Resources
- ISO 9001:2015 - ISO/IEC 27001:2022 - Relevant statutory & regulatory requirements	- Document change Application forms - Control Stamps	- Creation and distribution - Updating documented information - Identification - Storage, protection and retrieval - Retention and disposition	- Controlled documented information - Duly filled Document change application forms - Master lists - Policies - Manuals - SOPs - WIs - Forms	- Directorates - Departments - Staff - Other interested parties	- Loss of documented information - Use of obsolete documented information - Use un-controlled documents - Unapproved document changes	- Use of lockable cabinets and rooms/restricting system access - Use of distribution registers - Identification of obsolete documents - Adherence to SOP for control of documented information - Communication of changes	- Personnel - ICT infrastructure - Furniture - Finance - Stationery

7.0 Procedure

7.1 Creation and Distribution of Documented Information

7.1.1 All documented information shall be identified and created by respective directorates and departments. The documents shall be issued, approved and dated prior to use.



- 7.1.2 The Planning & Strategy department is responsible for creating, updating and distributing documented information required by the ISO 9001:2015.
- 7.1.3 All documented information shall remain legible and readily identifiable.
- 7.1.4 All documented information shall be distributed using a distribution register or list which will include the following details:
 - 7.1.4.1 Date of distribution;
 - 7.1.4.2 Document name and reference number;
 - 7.1.4.3 Destination of the documented information;
 - 7.1.4.4 Recipient name, signature and date received.
- 7.1.5 Documented information shall be in hard and/or soft copies.
- 7.1.6 SOPs and WIs shall be accessed through the KEPHIS document repository in the KEPHIS website. Any hard copy shall be deemed obsolete.

7.2 Updating Documented Information

- 7.2.1 All Documented Information shall be reviewed when need arises;
- 7.2.2 A Document change application (DCA) form (Appendix 9.1) shall be used to request for any changes proposed in Policies, Manuals, SOPs, WIs and forms.
- 7.2.3 The change applicant discusses the proposed changes with his/her immediate supervisor and consults the process owner for revision or updating.
- 7.2.4 The process owner recommends, reviews and/or rejects the proposed changes for suitability and adequacy.
- 7.2.5 The process owner forwards the DCA to the QMR for review and approval.
- 7.2.6 The QMR effects the changes in the document(s).



7.2.7 The QMR uploads the reviewed documents in the document repository and communicates the changes to all staff.

7.3 Identification of Documented Information

- 7.3.1 Policies shall be identified by the KEPHIS logo, organization's name, policy name, department name and the reference number - POLICY/KEPHIS/DEPARTMENT/NO.
- 7.3.2 Strategies shall be identified by the KEPHIS logo, organization's name, strategy name, department name and the reference number - STRATEGY/KEPHIS/DEPARTMENT/NO.
- 7.3.3 The Quality Policy, Information Security Policy and Laboratory Quality Policy shall be identified by the KEPHIS logo and referenced as follows KEPHIS/QP, KEPHIS/ISP and KEPHIS/LQP respectively.
- 7.3.4 Manuals shall be identified by the KEPHIS logo, organization's name, manual name, department name and the reference number - MANUAL/KEPHIS/DEPARTMENT/NO.
- 7.3.5 The Quality Manual shall be identified by the KEPHIS logo and reference number KEPHIS/QM.
- 7.3.6 The Standard Operating Procedures (SOPs) shall be identified by the KEPHIS logo, SOP name, organization's name, department name and the reference number – SOP/KEPHIS/DEPARTMENT/NO.
- 7.3.7 The Work Instructions (WI) shall be identified by the KEPHIS logo, WI name, organization's name, department name and the reference number – WI/KEPHIS/DEPARTMENT/NO.
- 7.3.8 The Quality and Information Security objectives shall be identified by the KEPHIS logo and the department's name.
- 7.3.9 All forms including checklists, data sheets and any other forms appropriate for service delivery shall be identified shall be identified



by the KEPHIS logo, department name and the reference number as
KEPHIS/DEPARTMENT/FORM/PROCESSNAME/NO.

7.3.10 Confidential records shall be marked '**Confidential**'.

7.3.11 All documented information shall have an issue and revision number.

7.3.12 All documented information shall have page numbers.

7.4 Obsolete Documented Information

7.4.1 After review of a particular document, the subsequent copy is assigned the next issue and revision number (where applicable).

7.4.2 All hard copies of the previous revision are withdrawn and stamped 'Obsolete' and replaced with the current version.

7.4.3 All soft copies of the previous revision are withdrawn from the document repository, archived in a marked 'Obsolete' folder and replaced with the current version.

7.4.4 Any obsolete documents retained in circulation for reference purposes shall be marked/stamped 'Obsolete'.

7.5 Documented Information of External origin

7.5.1 Documented information of external origin shall be identified and stamped 'External Document'.

7.6 Storage, Protection and Retrieval of Documented Information

7.6.1 Documented information shall be stored in protected and designated areas which may have lockable cabinets, shelves or rooms.

7.6.2 Access of documented information in soft copies shall be controlled.

7.6.3 Documented information shall be readily retrievable.



7.6.4 Documented information in registries shall be stored as per SOP for Registry operations.

7.6.5 All departments shall establish a master list (Appendix 9.2) to control distribution, access, retrieval and use of documented information.

7.7 Retention and disposition of Documented Information

7.7.1 The period of retention shall be guided by the Kenya National archives.

7.7.2 Retention and mode of disposition shall depend on the nature and importance of the documented information.

8.0 Records

8.1 Duly filled Document Change Application Form

8.2 Master list

8.3 Duly filled distribution lists/registers

9.0 Appendices

9.1 Document Change Application Form

9.2 Master List



Appendix 9.1: Document Change Application Form

KEPHIS/QMS/FORM/CDI/01

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Application Date:	
Document Name	
Reference Number	
Change Requested	
Reason	
Change requested by	
Recommendation by immediate supervisor	
Recommendation and approval by process owner	
Recommendation by QMR	

Changed by: Sign: Date:

Effective Date:



Appendix 9.2: Master List

KEPHIS/QMS/FORM/CDI/02

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S/No	DOCUMENT NAME	REFERENCE	LOCATION

Updated by: Sign: Date:

Approved by: Sign: Date:



10.0 Review Details

REVISION SUMMARY	REASON	DATE	REVISED BY	ISSUE NUMBER	REVISION NUMBER
1. Change Approver of Document 2. Change title Head Quality management to QMR 3. Removal Of Appendix 8.3	Appointment of new QMR The position no longer exists The titles are not permanent	11/09/2013	QMR	6	4
4. Grammatical Refinement (Whole document) 5. Amendment of clause - Clause 6.5.9 <i>"All QMS documents shall be reviewed after two years"</i>	To ensure procedure is in tandem with practice	03/09/2014	QMR	0	5
6. Amendment of clause - Clause 6.5.9 <i>"All QMS documents shall be reviewed when need arises"</i>	To ensure Procedure is in tandem with practice	28/10/2014	QMR	1	5
7. Review of entire SOP	To meet requirements of ISO 9001:2015	20/02/2018	QMR	1	6
8. Review of entire SOP	For continual improvement	01/09/2021	QMR	1	7
9. Review of entire SOP	For continual improvement	13/11/2024	QMR	1	8