

KENYA PLANT HEALTH INSPECTORATE SERVICE		
Quarantine and Plant Health Laboratory-Muguga		
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EFFECTIVE DATE	15th January 2024	Version Number: 03

Approval and authorizations.

Completion of the below signature blocks signifies the review and approval of this document.

Name	Job title/role	Signature	Date
Authored by	Deputy Quality Manager	<i>Approved</i>	15 th January 2024
Checked by	Quality Manager	<i>Approved</i>	15 th January 2024
Approved by	Deputy Director	<i>Approved</i>	15 th January 2024

Periodic reviews, approvals and authorizations

Required by: 1st February 2025

Name /	Job title/role	Signature	Date
Checked by	Quality Manager	<i>Approved</i>	15 th January 2024
Approved by	Deputy Director	<i>Approved</i>	15 th January 2024

Periodic reviews, approvals and authorizations

Required by: 1st February 2028

Name	Job title/role	Signature	Date
Checked by			
Approved by			

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1.0 Purpose

The purpose of this procedure is to assure that quality system documents used in Quarantine Plant Health Laboratories are properly developed, approved, reviewed, active and easily retrieved. . Management system documents shall comprise both internally and externally generated documents and includes; manuals, procedures, methods, policies and regulations.

2.0 Scope

This SOP applies to all documents both in hard copy and/or electronic form. It will apply to all documents required by the quality management system that covers requirements of the ISO17025 standard

3.0 Responsibilities

Deputy Quality Manager

3.1 Deputizes head of quality management system

3.2 Implements and maintains document control system

4.0 Accountability

Quality Manager (QM):

4.1 Is the head of quality management system

4.2 Ensures the document is authenticated

5.0 Procedures

5.1 Document Changes

5.1.1 Only authorized staff member will initiate need for change of document which is documented by the Quality Manager in the SOP revision log book. Documents shall be reviewed periodically and updated when needs for changes are identified. Where changes are not necessary, review for adequacy will be conducted after every 3 years.

5.1.2 The Laboratory Manager reviews the adequacy of the change and makes comments on the changes and forwards the revision log book to the Quality

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Manager who reviews proposed modification who aligns them to be consistent with standard requirements.

5.1.3 A summary of changes on the revision is done on the document before submission for approval and issuance to the user.

5.1.4 The document is distributed and the master list is updated.

5.2 Procedure format and numbering

5.2. 1 Title/Classification

The document shall have a concise title and identification number to help end users easily identify the scope of the document e.g. SOP for Control of Documents- GE/01. The numbering format will be as follows -GE/01. Where GE is the abbreviation for the Standard Operating Procedure categorized as General, and TE/01 for technical standard operating procedures. Equipment's operation procedures shall have EQ/01 in series.

5.2.2 Versions are numbered sequentially. The version number followed by a second sequential number (i.e. 1.1) notes minor revisions. Major revisions will result in a new version number, which will be the next sequential number (i.e. 2.0).

5.2.3 Drafts, if used, are identified as DRAFT .Drafts may be identified with a watermark or noted as "DRAFT" in the header. Drafts are not to be logged or tracked.

5.2.4 The Quality Manager assigns and maintains the document numbers.

5.3 Documents identification

5.3.1 All Documents used in the laboratory shall either be in Hard (Paper form) or soft (Electronic) form.

5.3.2 Identification and control of Hard copies shall be entirely be coordinated by Quality Manager.

5.3.3 Identification and control of soft copies shall be by password, software and any other IT tools as shall be deemed necessary.

5.3.4 The following identification is used to identify all documents generated at the laboratory

5.4 Quality manual and Technical procedures

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5.4.1 KEPHIS logo

5.4.2 Corporate Name in Full

5.4.3 Document title (in full)

5.4.4 Document title alphanumeric identification e.g. GE/01.

5.4.5 Department of use

5.4.6 Document Revision number e.g. Rev. No. 1

5.4.7 Effective Date e.g. 20th July 2011

5.4.8 Prepared by

5.4.9 Authorized by

5.4.10 Verified by

5.4.11 Issue date

5.4.12 Version number

5.4.13 Page number in the format - Page x of y

Records and Forms

5.4.14 Title of the record

5.4.15 Unique Form Number (from the relevant SOP e.g. SOP/01/Form Initials/Number Series)

5.4.16 Date of issuance

5.4.17 Issued by

5.4.18 Issue date

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5.5 Document review

- 5.5.1 The Quality Manager maintains the listing (Master list-GE/01/ML/01) of all quality documents which include the date prepared, date revised, date reviewed and due date for next scheduled review for continuing relevance.
- 5.5.2 The Quality Manager tracks and review of all documents that are due for review.
- 5.5.3 Documents are reviewed periodically and updated as necessary.
- 5.5.4 A history of revision shall be documented as per table in revision section of each document. The table of revision shall contain; Reason for review, date of review and reviewer names.

5.4 Obsolete Documents

- 5.4.1 After revision of a particular document, all copies of the previous revision are withdrawn and marked/Stamped 'Obsolete' by the Quality Manager or his designee and replaced with the new version.
- 5.6.2 The documents shall then be stored in a designated archive area. The date of archiving document is recorded in the archive register.
- 5.6.3 Documents e.g. data sheets that are continually generated in the laboratory shall be stored in the respective sections and archived quarterly by submitting them to the Quality Manager.
- 5.6.4 Documents shall be archived for 15 years. Destruction of documents will be done with consultation and approval of methods by the Kenya National Archives Document Disposal office. Records for preservation shall be transferred to the National Archives and any other institutional archives approved as a place of deposit by the Director, KNADS. Confidential records shall not be destroyed.

5.7 Document Issue;

Reviewed documents shall bear the name of the reviewer, checker and approver.

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5.8 External documents

External documents, required by the Quality management System and having an impact on work output, are controlled locally. Examples of relevant external documents would include regulations, published protocols and standards. External documents will be stamped “External’ and listed for traceability to the point of use.

5.8 Documents maintained in computerized systems

Where documents are maintained in a computerized system and review is necessary, the procedure in item 5.5 above shall be followed.

Once the approval of changes is approved by the Quality manager in the document revision log book, the quality manager shall access the document in electronic form and amend as requested. The document shall then be taken to the reviewer and approver for approval. The quality manager produces an equivalent copy in electronic form by scanning, and posts it back to its previous location. The old copy is archived in designated archive folder.

6.0 Abbreviations

6.1 SOP: - Standard Operating Procedure

6.2 QMS:-Quality Management System

7.0 Definitions

7.1 Controlled Document: - These are formally identified, registered and regulated items.

7.2 Internal Documents: - These are documents generated within limits of the defined Administrative system.

7.3 External documents: - These are documents generated outside the limits of KEPHIS administrative system.

7.4 Master List:-This is a list that contains relevant information related to all documents revision status and distribution.

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7.5 Mandatory SOPs: - These are QMS controlled documents generated by the QM e.g. Management review, control of document, control of records, internal audit, corrective action etc.

7.6 Requestor:- A staff who initiates a need for change of document.

7.7 Approver: - A designated officer who approves quality management documents e.g. laboratory manager

7.8 D-Distribution

7.9 DAR-Document Archival Register

7.10 R-Review

8.0 References

8.1 ISO/IEC 17025: 2017 standard

8.2 Quarantine Plant Health Laboratory Manual

8.3 KEPHIS ICT Policies

9.0 Revision History

Current Version number	Superseded version number	Revision summary	Revision by
01	0	New	S.Gachamba,
02	01	Minor changes	S.Gachamba,

10.0 Annexes

10.1 Distribution List GE/01/D/01

10.2 Masterlist GE/01/ML/01

10.3 Document Revision log book GE/01/R/01

10.4 Document Archive log book GE/01/DAR/01

10.5 Revision history

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Annexure10.1: DISTRIBUTION MASTER LIST

Doc. Title	Revision Number	Location	Recipients name	Signature	Date of issue

Annexure10.2: Document Issuance Log book

Doc. Title and ID	Revision Number	Location	Issued by name signature and date	Recipients name signature and date
	Copy No			

Annexure10.3 Document Revision log book

Date	Doc. Title and ID	Proposed changes	Raised by	Checked by	Approved /Not approved by

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Annexure10.4 Archive registers

Document title	Date of archive	Reason for archive	Archiving officer name and sign	Archive location

Annexure10.5 Approved list of document signatories.