

KENYA PLANT HEALTH INSPECTORATE SERVICE		 Page 1 of 8
Quarantine and Plant Health Laboratory-Muguga		
TITLE AND ID.	SOP FOR CONTROL OF RECORDS AND DATA MANAGEMENT—GE/11	
DEPARTMENT	Quality Management Unit	
EFFECTIVE DATE	1st February 2019	Version Number: 1

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>	1 st February 2019
Checked by	Quality Manager	<i>Approved</i>	1 st February 2019
Approved by	Officer In Charge	<i>Approved</i>	1 st February 2019

Periodic reviews, approvals and authorizations

Required by: **1st February 2021**

Name	Job title/role	Signature	Date
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Periodic reviews, approvals and authorizations

Required by: **1st February 2024**

Name	Job title/role	Signature	Date
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1.0 Purpose

To assure that records used by the Quarantine Plant Health Laboratory employees are properly managed and identified. Records include reports, correspondence quality records and technical records. Quality records include the following: internal audit reports, management reviews, corrective and preventive actions. Technical records include forms, worksheets, inspection reports, workbooks (GLPs) and test reports.

2.0 Scope

This SOP applies to all records internally or externally generated both in hard copy and/or electronic form. This procedures covers identification, collection, indexing, access, filling, storage, maintenance, archiving and disposal of records.

3.0 References

- 3.1 Quarantine Plant Health Laboratory Manual
- 3.2 ISO/IEC 17025 Standard
- 3.3 KEPHIS ICT Policy
- 3.4 Best Practice Guide for water laboratories

4.0 Definitions

- 4.1 Data file – A data file is related numeric, graphic or textual information that is organized in a strictly prescribed form and format.
- 4.2 Electronic record – An electronic record is information recorded in a form that only a computer can process. Electronic records include numeric, graphic and textual information.
- 4.3 Form – A form is a document with a fixed arrangement of captioned spaces designed for entering and extracting prescribed information. Forms become a record once filled out.
- 4.4 Non-record – Non-records are copies of memoranda or letters sent to an office or an employee for information only and for whose filing or maintenance no one in the office is responsible.
- 4.5 Records – Records are materials created or received by an agency and that are preserved as evidence of the activities of the agency or for its information value.
- 4.6 Technical records – Technical records are accumulations of data and information which result from carrying out tests or calibrations and which indicate whether specified quality or process parameters are achieved.

5.0 Responsibilities

5.1 Laboratory Manager

- a) Ensures resources are available for record keeping.

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- b) reviews test reports for completeness

5.2 Quality manager

- a) implements record management system
- b) ensures proper forms and worksheets are used in respective laboratory sections
- c) ensures implementation of a record management system
- d) ensures storage areas for records are within resources,
- e) Periodically assess the effectiveness of the record management system.
- f) maintains record system for quality records,
- g) Implements established record storage and disposal.

5.3 Laboratory Analyst:

- a) Recording and checking of correctness of data when transferring into records during tests
- b) Responsible for using the proper and approved forms and worksheets,
- c) Responsible for following record management guidelines, and securing records in their possession.
- d) Responsible for archiving record and disposal of quality records as established by record schedule
- e) verifies adequacy and accuracy of forms and worksheets used in their area

5.4 IT Staff

- a) IT staff will be responsible for regular back up and archiving of data stored in electronic form.

6.0 Procedure

6.1 Record Identification

6.1.1 Records shall be identified by a unique number referencing the identifiable procedure and category and laboratory process initials (first three letters) in the format eg. SOP-GE-01/CAL/1 where SOP-standard operating procedure General SOP, 01-SOP number, CAL-Calibration and 1-series number.

6.1.2 Records are dated, given a version number and identifies by initials of the person who establishes the record.

6.1.3 All record shall have a KEPHIS logo to the left to header region

6.2 Recording and Error Correction

6.2.1 All work performed is recorded legibly in appropriate workbooks. Work is recorded in such a manner that another individual, competent in the same field, may repeat the work

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described solely from the description written without additional explanation.

- 6.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the test or task.
- 6.2.3 Entries contain the date, initials of person performing the work, results, signed and dated.
- 6.2.4 Entries are made in ink. No erasures are made. Space not used will be indicated with a line.
- 6.2.5 Corrections will be made by drawing a single line through the incorrect entry, enter the correct information, counter signed and dated.
- 6.2.6 Where there is need for amendment of records, this shall be authorized by the section head, and shall be tracked to previous versions or original observations. Both the original and amended data shall be retained including the date of alteration, altered aspects and personnel responsible for the alterations.
- 6.2.7 The following information should be available in laboratory data sheets:
 - a) date of receipt of sample and date of analysis,
 - b) laboratory and persons responsible for performing analysis,
 - c) identification of sample as to whether it is a routine or a control ,
 - d) analytical technique and method used and quality control data, and
 - e) Results of analysis.

6.3 Electronic Records

Electronic records and data files are backed up on a regular basis to safeguard against the loss of information due to equipment malfunctions or human error.

6.4 Access

- 6.4.1 There is restricted access to all records to prevent unauthorized use and amending of information.
- 6.4.2 Access to the Quarantine Plant Health Laboratory records is restricted to authorized personnel.

6.5 Filing and Storage

- 6.5.1 Records are stored in dry and clean rooms. Storage areas and cabinets are labeled.

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- 6.5.2 Records and other quality documents may not be stored in private desk drawers or other obscure locations that are not generally known.
- 6.5.3 Records pertaining to completed inspections and applications are filed in the respective laboratory section offices.
- 6.5.4 Records are filed by test or service given (e.g. Virology analysis Reports,) or by title of record.
- 6.5.5 Quality records (e.g. audits, archived procedures and work instructions, corrective action and problem reports) are filed in the Quality Manager's office.

6.6 Record Retention

- 6.6.1 Quality records will be retained for a minimum for ten years.
- 6.6.2 Reports will be stored in a secure location with limited access. Computer based files are archived and stored for record keeping.

6.7 Disposal of records

- 6.7.1 Disposal of records shall be done as outline in the SOP-01, Control of documents.

6.8 Archival of Quality Records

6.8.1 Hard copy records

Records shall be held in the laboratory or respective work areas until the respective files capacity to hold is reached. The respective section head shall withdraw records in such files while retaining the current copies or as it may be deemed necessary, package them together (using rubber band or tape) and move them to the archive room for storage. An "Archive sheet" duly filled by the section head shall be placed on the top of the package. An archive register shall then be filled with details of the archive, date of archive and record name. Archived documents shall be retained for a period of 10 years.

7.0 Appendices

- 7.1 Archive sheet
7.2 Archive register

8.0 Revision list

Current Version number	Superseded version	Revision summary	Reviewers name

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	number		
01	00	New based on ISO17025:2017	S.Gachamba

Appendices

7.1 Archive sheet

Date of archive	
Laboratory section	
Record Name	
Archived by	Name : Signature :

7.2 Archive register

Date of archive	Record or document name	Laboratory section	Archiver name	Signature

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01	00	New	Sospeter Gachamba