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Approval and authorizations.

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

Name	Job title/role	Signature	Date
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Approved by	Officer In Charge	<i>Approved</i>	15 th January 2024

Periodic reviews, approvals and authorizations

Required by: 1st February 2024

Name	Job title/role	Signature	Date
Checked by	Quality Manager	<i>Approved</i>	15 th January 2024
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Periodic reviews, approvals and authorizations

Required by: 1st February 2027

Name	Job title/role	Signature	Date
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1.0 Purpose

The purpose of this SOP is to lay down a procedure to verify that the laboratory operations continue to comply with the requirements of quality management system and ISO/IEC 17025:2017 standard and whether it is effectively implemented and maintain. QPHL has established and implemented arrangements for auditing the day-to-day operation of the processes required by the quality system and for reviewing the effectiveness of the overall management system. The audit process gathers information about the quality system so that QPHL can assess its strengths and weaknesses and can therefore improve.

2.0 Scope

This document shall be used to describe the procedure to be followed in conducting internal audits, how they are planned, carried out, reported and followed up in QPHL.

3.0 References

- 3.1 Quality Manual
- 3.2 ISO/IEC 17025:2017 standard

4.0 Definitions

- 4.1 QMS- Quality Management Systems.
- 4.2 QHPL-Quarantine Plant Health Laboratory.
- 4.3 SOPs – Standard Operating Procedures.
- 4.4 Internal Audit- A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled according to the ISO/IEC 17025:2017 standard.
- 4.5 Non conformity- situations that differ from the standard.
- 4.6 Corrective Actions (C.A) - those actions that are implemented to eliminate causes of non-conformity.
- 4.7 Internal Auditor/team- Independent and trained person(s) who undertake internal audit.

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5.0 Responsibilities

- 5.1 Quality Manager** -Prepares and communicates on the internal audit schedule, plans and organizes internal audits, ensures that summary reports are prepared and presented to management, monitor audits to ensure activities take place as planned.

6.0 Procedures

6.1.Audit Planning

- 6.1.1 The Quality Manager shall draw an audit plan (Plan/SOP/GE/12/01) and programs to cover the required period to ensure that audits are carried out at the appropriate frequency. Internal audit shall be done at least once in every year.
- 6.1.2 The Quality Manager will appoint an audit team and a team leader from among certified or trained auditors. Wherever resources permit, the team members shall be independent of the activity to be audited.
- 6.1.3 Unscheduled, non-notified and outsourced audits can also be carried out to supplement the pre-determined audit schedule where need arises. If an audit is not to be conducted as per the schedule, the reason for this shall be communicated. The audit shall then be rescheduled and the audit program shall immediately reflect the new rescheduled time. Rescheduled audits shall be within fourteen to twenty days. All auditors, auditees and Laboratory Manager shall be notified via e-mail of the re-scheduled audit time.
- 6.1.4 The internal audit schedule shall address all applicable elements of the ISO/IEC 17012:2017 standard.
- 6.1.5 A flow diagram covering the audit process is given in [GE/12/Annex/1](#).

6.2 Initiating the audit

- 6.2.1 A lead auditor shall be appointed to coordinate the audit. He or she will use the [Internal Audit Checklist- GE/12/Form/001](#) - [GE/12/Form/001](#) which will include a brief description of the scope with a checklist

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of the areas, workflows, procedures and equipment that will be audited. In addition, the [Internal Audit Checklist- GE/12/Form/001](#) will provide the opportunity to include the auditor's notes as an attachment.

6.3 Audit preparation

6.3.1 The auditee shall arrange a suitable time to conduct the audit and provide relevant documentation. The details of the audit will be decided at that point. Where necessary, documentation will be inspected prior to the audit. The areas to be audited shall ensure that responsible staff are available for the audit facilitation.

6.4 Conducting an opening meeting

6.4.1 Quality manager shall organize for an opening meeting with the auditee .

The agenda for the opening meeting shall contain the following;

- i. Introduction and Registration of participants
- ii. Audit Purpose, Scope and Criteria
- iii. Methodology of the Audit
- iv. Audit Plan
- v. Communication – Channels, Language
- vi. Confirmation of Health, Safety, Emergency and Security Procedures
- vii. Emphasis on Confidentiality
- viii. Commitment of non-victimization of any staff because of Audit Findings
- ix. Request for Resources
- x. Confirmation of Closing Meeting
- xi. A.O.B

6.5 Collection and verification of information

- a) 6.5.1 An [Internal Audit Checklist- GE/12/Form/001](#) shall be used to gather audit information/data. The following sources of information will be used: Discussions with staff
- b) Reviews of past audit reports and non-conformances that were highlighted during the last audit of that area

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- c) Documents covering policy, objectives and procedures
- d) Observation of activities and testing
- e) Records
- f) Indicators of performance

6.5.2 The audit shall be conducted in a manner that causes minimal disturbance to work programs.

6.6 Recording audit findings

6.6.1 Notes of audit findings shall be documented in details. The records shall provide adequate evidence to support the auditors' verdict.

6.6.2 Audit findings shall be recorded as per the audit checklist.

6.6.3 Any systems failures that impact directly on the quality of the service offered shall be identified and clearly marked as such on the audit report. The non-conformances will be reviewed with the auditee to ensure that the audit evidence is accurate and that any non-conformances are understood.

6.6.4 After the audits, the auditors will meet to prepare the audit report.

6.7 Conducting a closing meeting

- i. Introduction/Registration of participants
- ii. Reiteration of purpose of the Audit and the basis
- iii. Emphasis on confidentiality
- iv. Summary of Audit results (Positive and negative findings)
- v. Report on Non Conformities
- vi. Discussions.

Any other issues arising12.1 A closing meeting will be scheduled between the auditors and the auditee to discuss the audit findings. If any nonconformance are pointed out, corrective action will be discussed and agreed upon.

6.8 Preparing the audit report

6.8.1 The report shall reflect the data recorded in the checklist and with reference to the ISO 17025:2017 standard.

- a) Area audited
- b) Auditor name(s)

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- c) Audit number
- d) Date(s) of audit
- e) Date of Report issue
- f) Auditee
- g) Audit topic and objectives including the specific areas or records to be audited: Training Records, **CVs**, Procedures, Workflows, Equipment use, Environments, Competence and Test Witnessing of ISO activities
- h) Audit findings, observations and non-conformances. For further clarity, the reference clause number for non-conformances/quality improvement shall be included in the [corrective action form\(GE/12/Form/002\)](#)
- i) Areas not covered that are within the original scope of the audit
- j) Total number of non-conformances,
- k) The audit report will also include the positive observations by mentioning achievements and advances since the previous audit. This has the dual purpose of putting the non-conformances into a fuller quality context and adding breadth and depth to the audit.

The report shall begin with an executive summary of the whole report which shall list the number of NCs and the final audit conclusion.

This shall be followed with background information, then the body of the report with segmented sections starting with effectiveness of implemented corrective actions from the previous audits, then followed with observations (positives and areas of improvements) from the audited clauses.

6.8.2 A detailed report of the audit will be produced.

6.9 Follow up action for the auditee

Corrective action form shall be filled separately for any raised NC. This form shall gather information related to NC raised, clause violated, observation.

The auditee shall provide information about

6.9.1 Root cause analysis

6.9.2 The actual action taken [/003](#)).

6.9.3 Corrective action action deadline together with evidence or reference.

6.9.4 The clearance of non-conformances and the completion of preventive/corrective actions shall be implemented within the agreed time frames.

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6.9.5 Monitoring of the corrective actions shall be done as per implemented monitoring schedule [GE/12/Form/004](#).

6.10 Follow up action for auditor

6.10.1 Corrective actions associated with major systems failure shall be confirmed by the auditor as having been effectively carried out.

6.10.2 The Lead Auditor shall determine whether the action has been cleared satisfactorily and assesses the effectiveness of the action taken by reference to objective evidence supplied by the auditee.

6.10.3 The Lead auditor shall complete and date the [corrective action form\(GE/12/Form/002\)](#) within a two-week period after the [corrective action](#) has been completed by the auditee. Completed clearance reports shall be maintained electronically to auditors and auditees.

6.10.4 If the action has not been cleared satisfactorily before the agreed action deadline then a revised date shall be agreed between the auditor and the audit recipient.

6.11 Escalating outstanding actions

9.0.1 If the nominated recipient will not have returned the completed [corrective action form \(GE/12/Form/002\)](#) the time of the action deadline + 1 week, then a 'One week overdue audit prompt' e-mail will be sent to the nominated recipient and the Lead Auditor. If the nominated recipient does not respond within another week, an 'Outstanding audit responses – 2 weeks overdue' e-mail will be sent to the Deputy Quality Manager/QA Manager who will then email the recipient. If the audit responses have not been received within a further week, an 'Outstanding audit responses – 3 weeks overdue' e-mail is sent to the Deputy Quality Manager/Quality Manager who will then email the recipient and the next level of line management shall be informed to ensure action.

6.11.2 Copies of all actions and deadlines follow-up correspondence shall be retained on the relevant audit file.

7.0 Audit program monitoring and review

7.1 The results of internal audits shall be reviewed during staff meetings and annually during the Management Review process.

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8.0 Records

- 7.1 Audit Schedule
- 7.2 Internal Audit [corrective action form \(GE/12/Form/002\)](#).
- 7.3 Internal Audit Checklist- GE/12/Form/001
Internal audit action plan (GE/12/Form/003)
Corrective action monitoring schedule

9.0 Revision list

Current Version number	Superseded version number	Revision summary	Reviewers name/ Contributors
01	00	New based on ISO17025:2017	Sospeter Gachamba
02	01	Reviewed audit dates, and inclusion of witnessing of tests	Sospeter Gachamba, Jane Wanjiku
03	02	Typos and inclusion of agenda for opening and closing meeting	Sospeter Gachamba, Jane Wanjiku
04	03	Typos	Sospeter Gachamba

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Internal audit action plan (GE/12/Form/003)

Clause	Observation	Root cause	Correction required	Preventive/corrective action required	Date of completion	Responsible person and dates	Evidence required	Remarks on effectiveness and date.

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ISO 17025:2017 INTERNAL AUDIT PLAN TEMPLATE

Dates:

Audit Scope	Bacteriology, Virology, Molecular, QMS	
Audit Objective	Determine Conformance to requirements of ISO 170025:2017 Establish effectiveness of the Quality Management System	
Audit Criteria	- ISO 17025:2017 - QPHL Manual - SOPs and Work Instructions - Legal & Statutory Requirements	
Requirements (indicate applicable clauses) on	May 2019	
1. General requirements	√	
2. Structural requirements	√	
3. Resource requirements	√	
4. Process requirements	√	
5. Management requirements	√	
6. Witnessing of tests	√	

Prepared by SignDate

DQMR

Approved By Sign.....Date.....

QMR