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DEPARTMENT	Quality Management Unit		
EFFECTIVE DATE	2nd February 2023	Version Number: 02	

Approval and authorizations.

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

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Periodic reviews, approvals and authorizations

Required by: **1st March 2024**

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

Required by: **1st March 2027**

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1.0 PURPOSE:

To guide in determining competence requirement of technical staff, assess their training needs, train on relevant skills and knowledge and assess their competence

2.0 PRINCIPLE:

All technical staff shall be trained on implementation of ISO/IEC 17025:2017, methods of analysis in a specific procedure(s), use of equipment and their competence evaluated by Laboratory Manager before issuance of authorization

3.0 SCOPE:

This procedure describes the process of training and evaluation of competence of new analysts. It also describes the process of identification of training needs for the analysts

4.0 DEFINITIONS:

4.1 Competence- is the ability of an individual to perform a specific task, action or function successfully.

4.2 Quality manager - is the person in charge of ensuring that ISO/IEC 17025:2017 is implemented in Plant health laboratories.

4.3 Analyst- the person authorized to undertake pest diagnosis in the plant health laboratories.

4.4 Laboratory Manager-the overall head of plant health laboratories.

4.5 Head of the laboratory- the person in charge of a specific laboratory or the supervisor of the analysts in the specific laboratory in the plant health laboratories

5.0 RESPONSIBILITIES:

The Laboratory Manager or any other designated personnel shall be responsible for the implementation of training and competence assessment of analysts in the plant health laboratories

The quality manager shall be responsible in ensuring that quality management system is adhered to in accordance to ISO/IEC 17025:2017 certification.

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6.0 PROCEDURES:

I. Training of personnel

1. Identification of training needs is a continuous activity.
2. The basis for the need for training shall be:
 - a. Blind tests – when the results of blind tests are out of range, the Laboratory Manager shall identify the analyst as requiring training in the area that the blind test is covering.
 - b. Internal audits - The internal audit shall assess the competence of the staff during the course of such audits and identify the need for training for staff on such basis.
 - c. Management review meetings and other Laboratory meetings- During these meetings, further needs for training shall be identified by the participants based on weaknesses identified in the entire quality assurance system. In particular, the management review meetings shall assess the needs identified in formulating the training plans under the guidance of the Laboratory Manager
 - d. New methods of testing or sampling – whenever a new method of testing or sampling is introduced in the laboratory, the Laboratory Manager shall identify the staff to be trained in the new method. New methods shall also include methods which were previously used in the lab but have changed.
 - e. New equipments – Whenever new equipment has been introduced in the Laboratory, The Laboratory Manager shall identify the staff to be trained on its operation and maintenance.
 - f. Expansion of scope: Whenever the Laboratory intends to expand its scope of testing/accreditation, the Laboratory Manager shall identify the staff to be trained on the new scope.
 - g. New staff – Any new analyst shall be trained according to the relevant SOPs and related instructions.

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- h. Need for refresher training - during management review meetings, the need for regular refresher training for staff shall be assessed and staff identified for such trainings.
3. Training plan/ projection:
 - a. This shall be developed after the identification of training needs and discussed during management review meetings. The training plan is captured as an [Annex Training projections plan](#).

II. STAFF TRAINING

1. The Laboratory Manager shall give detail of the trainings which the new analyst shall undergo. These include Mandatory and safety training, and in-house task specific training. All personal and professional development training details including formal training, workshops and seminars attended by an analyst shall be recorded in the personal and professional development training form.
2. The quality manager shall nominate a trained staff who shall train the analyst on Mandatory and safety training. The detail of the training done will be recorded in the personal and professional development training form.
3. The Laboratory Manager shall nominate an experienced and authorized staff to train the new analyst (s) on the specific methods and equipment used. This training shall be done in four stages :
 - Stage 1 - Reading relevant instructions (e.g. SOPs)
 - Stage 2 - Observing the task being performed by a trained member of staff
 - Stage 3 - Carrying out the task under supervision
 - Stage 4 - Assessment of competence to carry out the task unsupervised.
4. The detail of the training given shall be recorded in the personal and professional development training form.

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III. COMPETENCE ASSESSMENT

1. KEPHIS Career guidelines gives minimum competence requirements for staff working under its establishments/entities.

Determining competence assessment and supervision

2. The new analyst (s) shall then be assessed for competence by the Laboratory Manager OR her/his supervisor at the end of the training.
3. Competence shall be assessed by allocating at least three blind samples including a positive control/certified reference material and a negative control to the new analyst who will analyze them independently.
4. The experienced trainer may also carry out the analysis on the same samples separately and the results compared.
5. The criteria for assessing competence shall be based on:
 - Comparison of results for the new analyst with results from already trained and experienced analyst. OR
 - Detection and Comparison of positive controls/ reference material and negative control from the same or other samples tested, **Authorization of personnel**
6. If the analyst(s) is deemed competent, the Laboratory Manager shall give a letter of authorization to the analyst to perform the task.
7. If the analyst's incompetence is deemed unsatisfactory, the training shall be repeated and another competence assessment done.

Monitoring of competence

Monitoring of competence shall be done biannually by following the above guideline on III competence assessment.

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7.0 RECORDS

- I. Form No SOP 16-01 - QPHL Personal and professional development training record
- II. Form No SOP 16-02 – QPHL mandatory & safety training record
- III. Form No SOP 16-03 – QPHL in-house task specific on-job training record
- IV. Form No SOP 16-04 – QPHL Training curriculum and Competence assessment form for new analysts
- V. Form No SOP 16-05 - Letter of authorization to perform pest diagnosis

8.0 REFERENCES

- I. Staff job description
- II. Training needs assessment reports
- III. Training policy
- IV. ISO/IEC 17025:2005 standard V.
- V. QPHL quality manual

9.0 ANNEXES:

- I. Personal and professional development training form
- II. Mandatory and safety training form
- III. In-house task specific training form
- IV. Virology training curriculum
- V. Letter of authorization to perform pest diagnosis
- VI. Amendment list form
- VII. Revision list form

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ANNEXES

a) QPHL personal & professional development record

Form Number: **GE-01-01** Version _____ Date Issued: _____

Number :01_____

NAME: _____ P/ No: _____ PAGE NUMBER: _____

Date	Title of training	Duration	Organizer	Certificate code OR Trainer's signature	Analyst signature	Laboratory Manager's Signature
	Give SOP numbers and editions where relevant		To confirm training has been undertaken	To confirm training has been carried out successfully	By trainee	To confirm competence

*** Signifies course attended without certificates**

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b) QPHL mandatory & safety training record

Version Number :01

Date Issued:

Form Number: **No GE-01-02**

NAME:

P/ No :

PAGE NUMBER

Title	Duration	Date	Nature of Training	Trainer's signature	lab Manager's signature
Induction					
Quality management systems (Document Control, Control of Records, Quality System Review, etc..)					
Audits: Planning, Performing, and Reporting Quality Audits					
Non-Conforming Work: Corrective and Preventive Actions					
Handling of Complaints and Positive Feedback					
Health & Safety training	½ day				
Staff training, Competence and CVs					

To confirm that no further training in this topic is required *

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c) QPHL in-house task specific on-job training record

Form Number: **No GE-01-03**

Version Number :01

Date Issued:

.....

NAME:

P/ No:

PAGE NUMBER:

Details of task performed	Date and Duration of training	Nature of Training	Training Stage*	Trainee's signature	Trainer's signature	Date Authorised	Lab Manager's Signature
give SOP numbers and editions where relevant		including records of the tasks undertaken during training Evidence of competence / experience (reference to relevant documents / records)		to confirm training has been undertaken	to confirm training has been carried out successfully	By trainer	to confirm competence

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c) QPHL in-house task specific on-job training record, Cont

Form Number: **No GE-01-03**

Version Number :01

Date Issued:

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Training stages *:

1. Studied task and task documentation
2. Observe procedure
3. Undertake the task under supervision
4. Assessed as competent to undertake the task unsupervised

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d)

Training curriculum and Competence assessment form for analysts

Form Number: No GE-01-04				
Version Number____ :02				
Date Issued:				
Date	Task / Technique	SOP No and Machine ID	Analysts Remarks	Assessors' Comments
	1. Machine / Equipment Operations, Maintenance and General Best practice in virology OR Bacteriology Laboratories			
	2. Sampling procedures for virus or bacterial testing and sample handling			
	3. NCM ELISA method / DAS ELISA method (under either SOP TE 02 or SOP TE 04)			
	☐ Sample preparation			
	☐ Preparation of buffers			
	☐ Testing by NCM and DAS ELISA			
	☐ QC			
	☐ Recording of results/ Results reading and interpretation			
	☐ Report release process			
	4. Introduction to Sweetpotato viruses			
	5. Grafting method / Mechanical Inoculation/ Grow – out tests (under SOP TE 01)			
	☐ Indicator plants available and the viruses they are used to detect			

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	☐ How to maintain the indicator plants in the greenhouses			
	☐ Greenhouse activities and best practices			
	☐ Preparation of buffer for mechanical inoculation			
	☐ Germination tests for indicator plants			
	6. Introduction to Bacterial wilt and <i>Ralstonia</i> spp.			
	7. Detection of <i>Ralstonia</i> spp. by Real time PCR			
	☐ Procedure for Extraction of DNA from potato tubers /stems			
	☐ Real-Time PCR test master mix preparation			
	☐ Convectional PCR setup			
	☐ Convectional PCR reaction mix preparation			
	☐ Results interpretation			
	☐ PCR Setup and operation			
	8. ISO/IEC 17025:2017 principles			
	9. QMS principles			

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d) Training curriculum and Competence assessment form for new analysts Cont'

Date Issued:

.....

Form Number: No GE-01-04

Version Number :01

Final assessment form

Use the following form to enter results (+ ve or – ve) of the three samples provided to you.

Pathogen / test Name	Sample Number	Sample Number	Sample Number
<i>Sweetpotato feathery mottle virus</i> (SPFMV)			
<i>Sweetpotato mild mottle virus</i> (SPMMV)			
<i>Sweetpotato chlorotic stunt virus</i> (SPCSV)			
Tests for <i>Ralstonia</i> spp. by NCM ELISA			
Tests for <i>Ralstonia</i> spp. by Conventional PCR			
Tests for <i>Ralstonia</i> spp. by Real time PCR			

Comments

.....

Analysts signature Date.....

Lab Manager's SignatureDate.....

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e) Authorization to perform pest diagnosis form

Form Number: **No GE-01-05** Version Number :01 Date Issued:

Name of Officer:P/No.....

Procedure(s):

Authorization:

The officer named above has the appropriate qualifications, training and/or experience and has demonstrated to my satisfaction their competence to perform the above procedure(s).

Documentary evidence demonstrating competence was not required/can be found at

Signature..... Date.....

Name.....Position:.....

e) Authorization to perform pest diagnosis form – cont'

Declaration:

I have received appropriate training in the above procedure(s) and consider myself, at this time, to be competent to perform the procedure(s) to the standards to which I have been trained as laid down by QPHL Quality

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Manual..... I have access at all times to Laboratory Quality Manuals and to any other appropriate information or operating procedures prescribed by these manuals to be used in connection with the above procedure(s).

If in future, for whatever reason, I consider that I am not at that time appropriately conversant with any aspect of the above procedure(s), or I do not have access to the prescribed manuals and operating procedures, or I lack the necessary manipulative skills, or I am otherwise unable to carry out a procedure to the prescribed standards, I will inform my Laboratory Manager or Deputy Laboratory Manager as soon as possible and consult with them before carrying out the procedure again.

Signature of Officer:.....Date.....

This sheet is to be kept with the appropriate Training Record.**NOTE: THE OFFICER MUST BE RE-AUTHORISED BEFORE ANALYSING SAMPLES IF THEY HAVE NOT PERFORMED THE ABOVE PROCEDURE FOR A PERIOD OF TWELVE MONTHS.**

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Form

FOR INTERNAL TRAININGS Form Number: No GE-01-06

Version Number: 01

List of participants

Training Type:

Date:

Name	Laboratory section	Signature

Training conducted by: _____ Date: _____ Sign: _____

i) Revision list

Current Version number	Superseded version number	Revision summary	Reviewers name/ Contributors
01	00	New as per the requirements of the new standard ISO17025:2017	George Ngundo, Maureen Mwangangi, Simon Ngare, Sospeter Gachamba
02	01	Edits to suit with current responsibilities in the organogram	George Ngundo, Sospeter Gachamba