

KENYA PLANT HEALTH INSPECTORATE SERVICE			Page 1 of 5
Quarantine and Plant Health Laboratory-Muguga			
TITLE AND ID.	SOP FOR VALIDATION/VERIFICATION OF TEST METHODS –GE/07		
DEPARTMENT	Quality Management Unit		
EFFECTIVE DATE	15th February 2021	Version Number: 02	

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>	15th February 2021
Checked by	Quality Manager	<i>Approved</i>	15th February 2021
Approved by	Officer In Charge	<i>Approved</i>	15th February 2021

Periodic reviews, approvals and authorizations

Required by: 15th February 2021

Name /	Job title/role	Signature	Date
Checked by:	Quality Manager	<i>Approved</i>	15th February 2021
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1. Purpose

This procedure give guidelines on validation or verification of test methods to ensure they are precise, accurate and fit for intended use and meet customer needs.

2. Scope

This procedure covers processes involved in validating and verification of non-standard, laboratory developed, and standard methods used outside their intended scope or otherwise modified.

3. References

- i. ISO/IEC 17025: 2017 standard
- ii. Quarantine Plant Health Laboratory Manual

4. Definitions

- i. SOP: - Standard Operating Procedure
- ii. Procedure:-Statements or methods that describe how the work is done and by whom
- iii. Validation – is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled(*ISO/IEC 17025:2005*). .
- iv. Test Method –a definitive procedure that produces a test result that can be either qualitative or quantitative.
- v. Verification- comparison of performance data obtained by the laboratory when performing a standard method with those claimed by the same method.

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5. Responsibilities

5.1 Officer In-Charge

- 5.1.1 Provides the resources required for the method validation and verification processes.
- 5.1.2 Approves requests for method validation.

5.2 The Laboratory Manager

- 5.2.1 Reviews the need for method validation.
- 5.2.2 Plans and Authorizes staff responsible to undertake validation
- 5.2.3 Approves the method for fitness for use upon review of the final validation report.

5.3 Quality manager

- 5.3.1 Ensuring quality procedures are adhered to during validation process. Intergrates new method into the quality management system.

5.4 Section heads

- 5.4.1 Coordinate method validation activities.

5.5 Laboratory staff

- 5.5.1 Undertaking method validation.
- 5.5.2 Ensures quality control and documentation during method validation

6. Procedures

- 6.1 The section head identifies the need to validate the method before it is put into use. The need can be as a result of a newly developed method, non-standard method or changes to a validated method where such changes have been found to affect the original method.
- 6.2 The need is communicated to the laboratory manager who evaluates the need in relevance to customer's requirements and communicates with the Officer-In-Charge for approval.

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- 6.3 Once the approval is made, a plan and the budget is developed for approval by the management. The plan details when, what, how and who will do the validation. The performance characteristics are also described in the plan. Depending on the type of the method (qualitative or quantitative), The laboratory manager will select among the following parameters accuracy, selectivity, repeatability, reproducibility, robustness, limit of detection as well as limit of quantification.
- 6.4 The plan is shared with the implementers for execution.
- 6.5 All data is recorded in the GLP.
- 6.6 Once the validation process is complete, data generated is evaluated for fitness of that method for use and a report is generated, approved/disapproved.

7. Records

- Plan of validation
- Data obtained
- Report
- Method validation/verification checklist

8. Revision list

Revision number	Superseded version number	Revision summary	Contributors name
01	00	New	Sospeter Gachamba, Jane Kamau
02	01	In text amendments after review to include verification.	S. Gachamba, J. Kamau, G.Ngundo, J. Waithera, E.Onkendi