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DEPARTMENT	Quality Management Unit			
EFFECTIVE DATE	02/06/2020			Version Number: 02

Approval and authorizations.

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Periodic reviews, approvals and authorizations

Required by: 1st March 2021

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1 Purpose

This procedure details safe handling, transport, storage, acceptance ,use, planned maintenance and calibration of equipments used in testing to ensure correct performance.

2 Scope

These procedures apply to the equipments used at the laboratory and outside its permanent control which can affect the quality of tests results.

3 Responsibilities

3.1 Technical manager

- 3.1.1 Shall be responsible for ensuring that the laboratory is equipped with the needed instruments and equipment that, at a minimum, meets the specifications of the test methods employed.
- 3.1.2 Ensures availability of resources required for maintenance, servicing and calibration of equipments.
- 3.1.3 Ensures staff are competent in operating the equipments.
Ensures that equipments used at the laboratory are capable of achieving required accuracy.
- 3.1.4 Ensures that equipment maintenance and calibration are conducted and providing support for arranging non-routine instrument repair

3.2 Analysts

- 3.2.1 Responsible for maintaining the equipment records, verifying equipment conforms to specifications prior to use, completing the documentation of this verification and adhering to written equipment operation procedures.

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4 Procedure

4.1 Operation

4.1.1 Only authorized persons are allowed to operate the equipment.

Each equipment shall be operated according to customized work instructions. Practical measures will be taken to prevent unintended adjustments of equipment from invalidating results. All equipment outside the laboratories permanent control shall meet the requirements of the standard.

4.2 Equipment Identification and Records

4.2.1 All equipment in Plant Quarantine Biosecurity Station inventory system is labeled with a unique identification number e.g. PQBS/M/IC/001, meaning identification of incubator at molecular laboratory.

4.2.2 The Laboratory maintains an inventory of each equipment used to perform testing. This inventory contains the following information:

- a) the identity of the equipment and its software or item
- b) the manufacturer's name, type of equipment and serial number or the unique identification
- c) checks that equipment complies with the specification as referenced in individual equipment files.
- d) the current location where appropriate
- e) the manufacturer's instructions if available, or reference to their location
- f) date, results and copies of report and certificates of all calibrations adjustments, acceptance criteria and due date of next calibration maintenance carried out to date.
- g) any damage, malfunction, modification or repair to the equipment.
- h) the calibration and maintenance schedule shall be centrally maintained

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4.2.3 The label or tag found on or near the equipment contains the following information:

- PQBS Laboratories unique identification number
- Date of last calibration (if the equipment affects the quality of test results) and servicing.
- Date of the next calibration.

4.2.4 Equipment that is scheduled to be calibrated daily or with each use, is tagged as above, except that instead of the calibration dates, it is annotated as such (e.g. calibrated daily or calibrated with each use).

4.2.5 Small equipment with insufficient space to record the information on the label (e.g. thermometers) need only be identified with their unique identification number.

4.3 Equipment Qualification

4.3.1 When new equipments are received they shall be verified to conform to the specifications

4.3.2 When new instruments are installed, laboratories will be provided with Installation Qualification (IQ) and Operation Qualification (OQ) from the manufacturer or installer/supplier. This information is kept with the equipment records.

4.3.3 The laboratory shall perform quality control for all new instruments to verify the performance of the equipment as expected. Equipment is not used until this has been completed and users have been trained in its operation.

The decision rule shall be based on the defined acceptance criteria

4.4 Equipment Maintenance

4.4.1 Laboratory equipment maintenance are conducted as per a developed maintenance schedule (EQP/ MNT/01).

4.4.2 Manufacturer's instructions are used for guidance in performing equipment maintenance. .

4.4.3 Preventive maintenance schedule and records shall be retained.

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4.5 Equipment Calibration

4.5.1 A calibration schedule is normally prepared by the technical manager for all critical laboratory equipment affecting performance of tests. Calibrations are done annually for all equipments and before tests for weighing balances and pH meters.

4.5.2 The calibration schedule shall be reviewed and adjusted as necessary. Equipment shall be calibrated by a competent laboratory and ensure measurement results are traceable to the SI units.

4.5.3 Certificates and records of calibration shall be centrally and locally maintained.

4.6 Equipment intermediate and performance checks

4.6.1 Intermediate checks will be carried out periodically when necessary to verify calibration status and recorded in forms SOP-GE-03-02, SOP-GE-03-03, SOP-GE-03-04.

4.6.2 Performance checks will be carried out to verify conformance to specified requirements when machines are new or are returned to service.

4.7 Out of Order Equipment

4.7.1 Equipment that is not in use, and therefore has not been calibrated or verified, is labeled 'out of order' and must be calibrated or verified prior to use.

4.7.2 Equipment that is not operating properly is clearly marked 'faulty' or "not in operation" and must not be used until repaired and calibrated.

4.7.3 For equipment returned after repair, the performance checks and calibration are conducted prior to use and documented to be within specifications.

4.7.4 For equipment returned after calibration, the calibration certificates are reviewed by the technical operator to ensure the calibration status.

4.7.5 Where the equipment is faulty or is not functioning properly, a formal report will be made by the technical operator.

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4.7.6 When equipment is faulty or is not functioning properly the lab shall institute control of non-conforming work.

5 Handling, Use, Storage and Transport of Equipment

- 5.1 Each instrument or piece of equipment has step-by-step instructions for its start-up, handling, operation and shutdown described in manufacturer's manuals or per laboratory procedure.
- 5.2 Transport and storage shall be done according to manufacturer's instructions taking into considerations environmental requirements
- 5.3 Only authorized personnel are permitted to use the equipment; Computer software is write protected and, in most cases, password protected to prevent unauthorized program adjustments. These measures safeguard the equipment, sample security and computer software.
- 5.4 Where equipment has gone outside the direct control of the lab, the lab shall ensure that the function and calibration status of the equipment is checked and shown to be satisfactory before the equipment is returned to service.

6 Definitions

- 6.1 **Calibration** - Calibration is the set of operations, under specified conditions, establishing the relationship between values of quantities by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realized by standards.
- 6.2 **Installation qualification (IQ)** - This is the identification of all system elements, electrical or otherwise. This identification and the subsequent documentation for each installed item details normal operating instructions, routine user maintenance, preventive maintenance and cleaning procedures.
- 6.3 **Operational qualification (OQ)** - OQ is generally described as commissioning. It includes calibration and critical instrument test parameters defined for the use and purpose of the instrument, and may include the definition of upper and lower tolerances.

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6.4 Performance qualification (PQ) - PQ relates to the conformation of the effectiveness of the equipment to meet specifications.

6.5 Measuring instruments – These includes balances, thermometers, electrochemical meters.

6.6 Physical standards - Physical standards includes reference weights and reference thermometers.

6.7 Verification Confirmation - Verification confirmation is through the provision of objective evidence that specified requirements have been fulfilled.

7 Records

- i. Equipment maintenance SOP GE-03-01
- ii. Equipment intermediate and performance checks PH Meter(SOP GE-03-02)
- iii. Equipment intermediate and performance checks Incubators (SOP GE-03-03)
- iv. Equipment intermediate and performance checks Balances (SOP GE-03-04)

8 References

ISO/IEC17025: 2017 General requirements for the competence of testing and calibration laboratories (Section 6.4 Equipment).

9. Revision list

Revision number	Superceded version number	Revision summary	Reviewers name
01	00	New based on ISO17025:2017	Joyce Waithera
02	01	Review reference to records and inclusion of Intermediate checks	Sospeter Gachamba, Jane Wanjiku