PURPOSE:

To provide an outline of the schedule and requirements for maintenance, performance, calibration, and verification of Molecular Laboratory testing equipment to ensure compliance with DOH requirements.

SCOPE:

Molecular Laboratory Pathologist, All Molecular Laboratory Personnel, BioMedical Engineering Section

PERSON RESPONSIBLE:

All Molecular Laboratory Personnel, BioMedical Engineering Section

GENERAL GUIDELINES:

1 For the purpose of this Standard Operating Procedure, the following terms are to be defined:

1.1 ***Equipment.*** It is a type of a fixed asset used by the company in the business operations for a specific test, like in the laboratory, to perform the COVID-19 RT-PCR tests.

1.2 ***Calibration.*** It is defined as the accuracy and quality of measurements recorded using a piece of equipment. It is often regarded as including the process of adjusting the output or indication on a measurement instrument to agree with value of the applied standard.

1.3 ***Control.*** It can include but not limited to; ventilation, extraction systems, respiratory protective equipment, spillage capture, decontamination units and clean-up procedures.

1.4 ***Installation Qualification***. It verifies the proper installation and configuration of a System. This can include ensuring that necessary files have been loaded, equipment has been installed, the necessary procedures have been approved, or the appropriate personnel have been trained.

1.5 ***Equipment Validation***. It is normally performed as part of an overall equipment and process validation program. An equipment validation program will normally encompass the following:

1.5.1 Establish that the process equipment has the capability of operating within required parameters.

1.5.2 Demonstrate that controlling, monitoring, and/or measuring equipment and instrumentation are capable of operating within the parameters prescribed for the process equipment.

1.5.3 Confirm that over repeated cycles (runs) representing the required operational range of the equipment, that the output or product consistently meets predetermined specifications for quality and function.

1.5.4 Require the implementation of an ongoing monitoring, re-qualification and re-certification of equipment.

PROCEDURE:

Equipment Identification and Records

1. Molecular Laboratory Personnel ensures that all equipment inventory system is labeled with a unique identification number (barcode number/sticker number) by the Logistics Division.
2. Molecular Laboratory Personnel maintains an inventory of its major equipment used to perform regulatory testing.
3. 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 (calibrated daily or calibrated with its use.)
4. Small items with insufficient space to record the information on the label (thermometers) need only be identified with their unique identification number for traceability to their associated records.

Equipment Qualification

1. Molecular Laboratory Personnel elects to purchase Installation Qualification and Operation Qualification from the manufacturer when new equipment is installed. This information is kept with the equipment records.
2. Molecular Laboratory Personnel determines that quality assurance specifications have been met for new equipment.
3. Equipment is not used until it has been qualified and users have been trained in its operation.

Equipment Maintenance and Intermediate Performance Checks

1. Molecular Laboratory Personnel conducts laboratory equipment maintenance and intermediate performance checks on a scheduled basis. A schedule, identifying and eliminating potential sources of problem, is established for the servicing of laboratory equipment.
2. Molecular Laboratory Personnel records such maintenance and performance checks to demonstrate that the program is being followed according to schedule.
3. Manufacturer's instructions are used for guidance in performing equipment maintenance. In the absence of manufacturer's instructions, instructions are provided in the equipment operation procedure.
4. Molecular Laboratory Personnel maintains the maintenance and performance checks records in a logbook.
5. General Service equipment is typically maintained only with cleaning and safety checks.
6. Use of outside contractors to perform repairs or maintenance is at the discretion of the laboratory management.

Equipment Calibration or Verification

1. Molecular Laboratory Personnel maintains calibration and verification records.
2. Data acquired on equipment which fails a parameter are investigated to include items between the failing assessment date and the last successful calibration or verification date. The problems and the investigation are conducted according to

the laboratory's procedures for managing nonconforming work and corrective actions.

Out of Service Equipment:

1. Equipment that is not in use, and therefore has not been calibrated, verified, or not operating properly must be clearly tagged out of service.
2. Out of service equipment must be calibrated or verified prior to use.
3. Equipment is not returned to service until performance checks and verification have been performed and recorded.

Equipment Leaving Direct Control of the Laboratory:

1 Molecular Laboratory Personnel ensures when, for whatever reason, i.e. repair or calibration, equipment goes outside the direct control of the laboratory that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

2 Molecular Laboratory Personnel conducts performance checks and calibration for equipment returned after repair prior to use and recorded to be within the specifications.

3 For equipment returned after calibration, the contractor/vendor calibration certificates are reviewed for the following to ensure the calibration status:

- 3.1 A statement of conformity after calibration/verification.
- 3.2 Item name, type, description
- 3.3 Identification Number
- 3.4 Location
- 3.5 Calibration Interval
- 3.6 Calibration procedure
- 3.7 Date of calibration
- 3.8 Identification of person(s) performing the calibration

4 Any equipment returned after the calibration must be checked for functionality by performing a check of the operation of the equipment. This check must be recorded.

Handling, Use, Storage and Transport of Equipment:

1. Laboratory procedures define the handling and use of the equipment. Each piece of equipment has step-by-step instructions for its start-up, operation and shutdown described in the manufacturer's manuals or per laboratory procedure. Equipment is operated by authorized personnel identified by their respective laboratory.
2. The location of equipment in active use is specified in the laboratory equipment inventory.
3. Transport or move sensitive equipment maybe performed by the manufacturer or other service provider. Equipment is not returned to service until performance checks and verification have been performed and recorded.
4. Only authorized personnel are permitted in the laboratory; non-authorized personnel are escorted. 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.

DOCUMENTATION:

New Policy

DISSEMINATION:

1. Policies and Procedures Manual
2. Unit Orientation
3. Unit Meeting

REFERENCES:

1. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories Section 6.4
2. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements and Pharmaceuticals- An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.
3. FDA Staff Manual Guide (SMG) 2620.2, Procedure for surplus equipment

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**DAVID G. PEDROZA, MD** Associate Pathologist		7/5/22
Verified by:	**TIFFANY B. VILLANUEVA-COO, RMT** Laboratory Manager		7-7-2022
	MONICA B. VILLANUEVA, RN, RMT, PhD Laboratory Director		7-7-2022
	MELANIE ROSE B. ZERRUDO, MD, FPSP Chair, Department of Pathology		7-7-2022
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		7-7-2022
Recommending Approval by:	**ROSARIO D. ABARING, RN, MN, PhD, FPCHA** Ancillary Services Division Officer		07.06.2022
	FREDERIC IVAN L. TING, MD OIC- Total Quality Division		7/8/22
Approved by:	**GENESIS GOLDI D. GOLINGAN** President and CEO		

KEY TASKS	PERSON RESPONSIBLE
Equipment Identification and Records	
1. Ensures that all equipment inventory system is labeled with a unique identification number (barcode number/sticker number) by the Logistics Division.	Molecular Laboratory Personnel
2. Maintains an inventory of its major equipment used to perform regulatory testing.	
Equipment Qualification	
3. Elects to purchase Installation Qualification and Operation Qualification from the manufacturer when new equipment is installed.	Molecular Laboratory Personnel
4. Determines that quality assurance specifications have been met for new equipment.	
Equipment Maintenance and Intermediate Performance Checks	
5. Conducts laboratory equipment maintenance and intermediate performance checks on a scheduled basis.	Molecular Laboratory Personnel
6. Records such maintenance and performance checks to demonstrate that the program is being followed according to schedule.	
7. Maintains the maintenance and performance checks records in a logbook.	
Equipment Calibration or Verification and Equipment Leaving Direct Control of the Laboratory	
8. Ensures when, for whatever reason equipment	

goes outside the direct control of the laboratory that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.	Molecular Laboratory Personnel
9. Conducts performance checks and calibration for equipment returned after repair prior to use and recorded to be within the specifications.	
10. Reviews the contractor/vendor calibration certificates for equipment returned after calibration to ensure the calibration status.	
11. Checks the functionality of any equipment returned after the calibration for functionality by performing a check of the operation of the equipment.	

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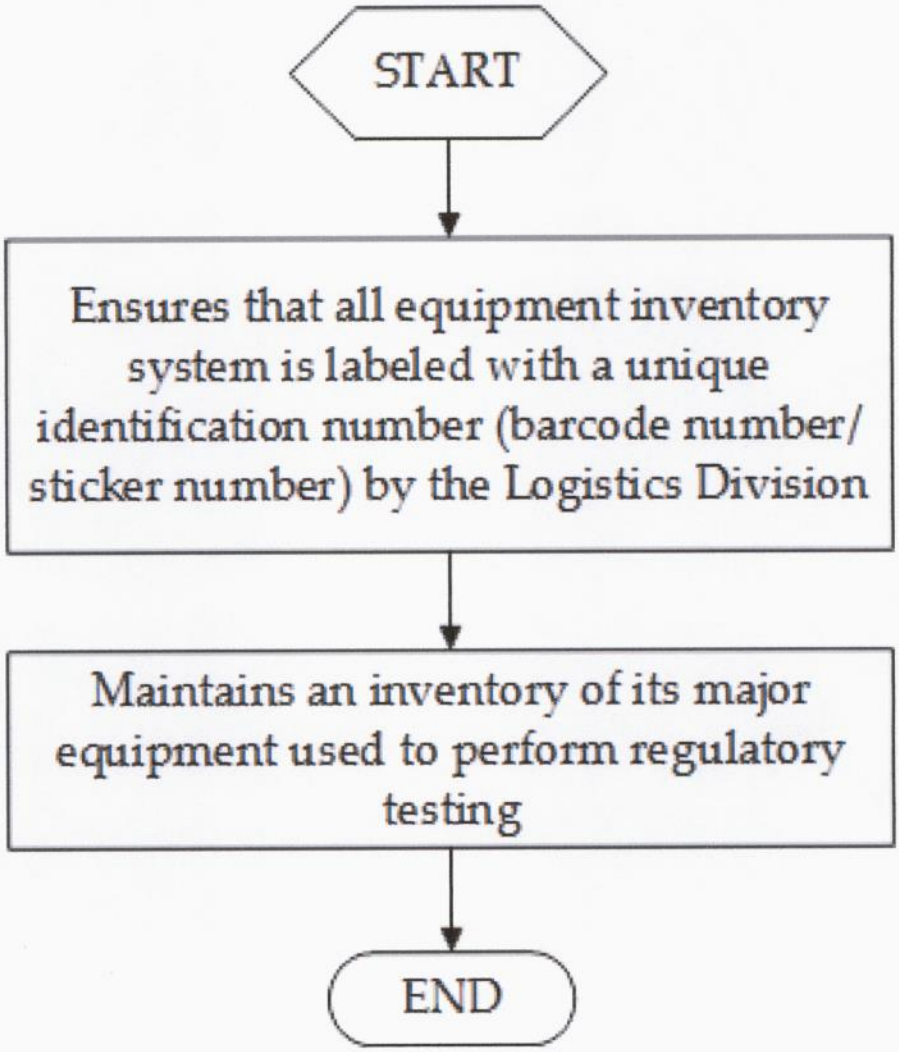
EQUIPMENT IDENTIFICATION AND RECORDS



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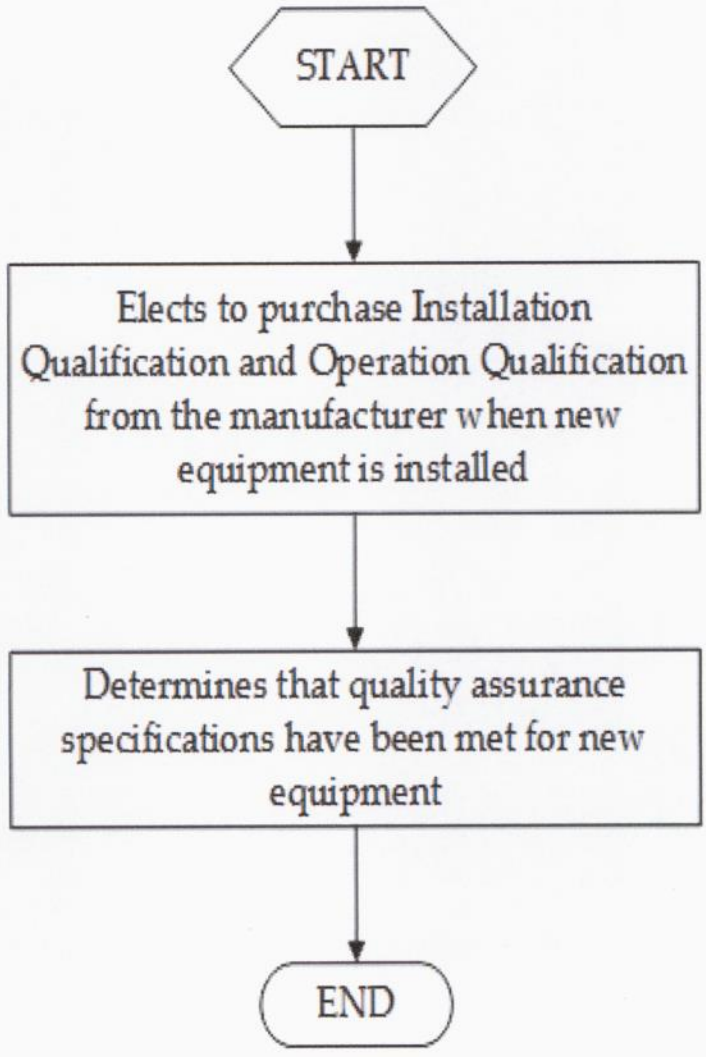
EQUIPMENT QUALIFICATION



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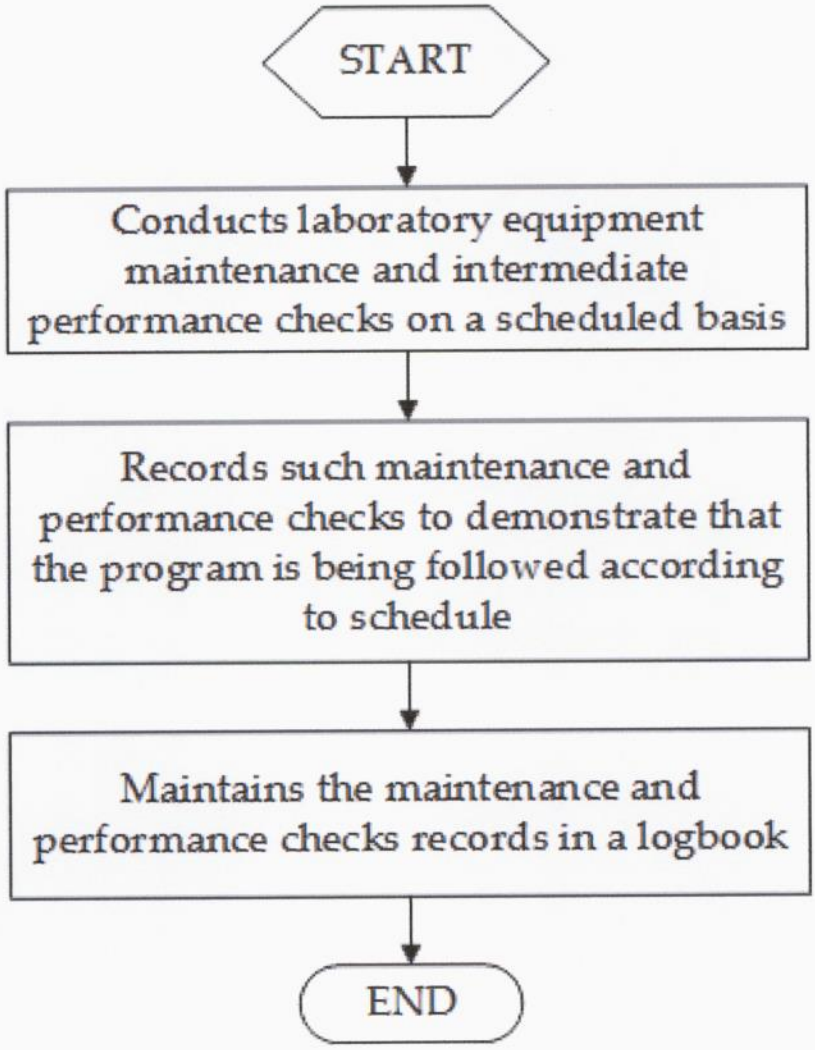
EQUIPMENT MAINTENANCE AND INTERMEDIATE PERFORMANCE CHECKS



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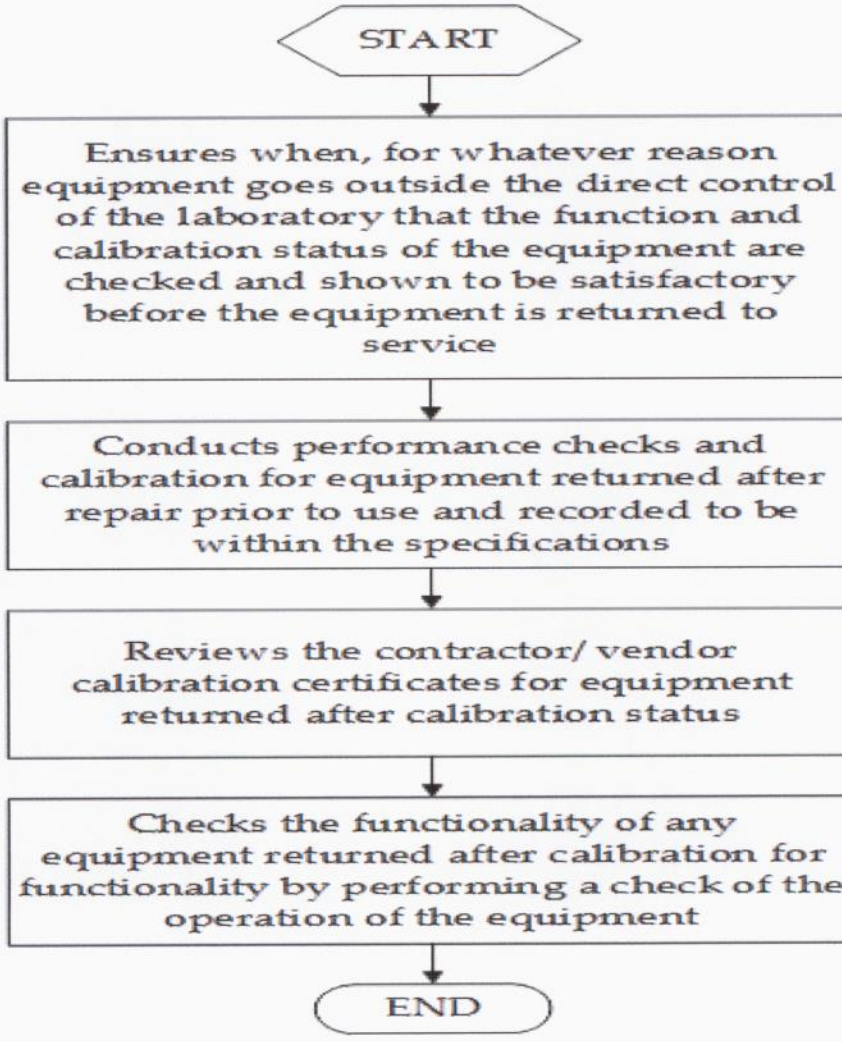
EQUIPMENT CALIBRATION OR VERIFICATION AND EQUIPMENT LEAVING DIRECT CONTROL OF THE LABORATORY



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