PURPOSE:

This procedure specifies the schedule and requirements for maintenance, performance, calibration, and verification of Molecular Laboratory testing equipment to ensure compliance with DOH requirements. Meeting the criteria in this procedure demonstrates control of the equipment maintenance and calibration parameters needed to achieve accurate test results for SARS-C0V-2.

LEVEL:

Molecular Laboratory Pathologist, All Molecular Laboratory Personnel, BioMed

DEFINITION OF TERMS:

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.

2 ***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:

- 2.1 Establish that the process equipment has the capability of operating within required parameters.
- 2.2 Demonstrate that controlling, monitoring, and/or measuring equipment and instrumentation are capable of operating within the parameters prescribed for the process equipment.
- 2.3 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.
- 2.4 Require the implementation of an ongoing monitoring, re-qualification and re-certification of equipment.

3 ***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.

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

5 ***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.

POLICY:

Equipment Identification and Records

1. All equipment inventory system is labeled with a unique identification number (barcode number/sticker number) by the Materials Management Department.
2. Each laboratory maintains an inventory of its major equipment used to perform regulatory testing. This inventory contains the following information:
3. The label or tag found on or near the equipment contains the following information:
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 (calibrated daily or calibrated with its use.)
5. 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.
6. Detailed guidance on equipment records is provided.

Equipment Qualification

1. When new equipment is installed, laboratories may elect to purchase Installation Qualification and Operation Qualification from the manufacturer. This information is kept with the equipment records.
2. For new equipment, the laboratory may determine that quality assurance specifications have been met.

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. Laboratory equipment maintenance and intermediate performance checks are conducted on a scheduled basis. A schedule, identifying and eliminating potential sources of problem, is established for the servicing of laboratory equipment.
2. Such maintenance and performance checks are recorder 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. The maintenance and performance checks records may be maintained in a logbook.
5. Preventive maintenance procedures, other than basic cleaning, are developed for each equipment item, unless they are already described elsewhere.
6. General Service equipment is typically maintained only with cleaning and safety checks.
7. Use of outside contractors to perform repairs or maintenance is at the discretion of the laboratory management.

Equipment Calibration or Verification

1. A calibration or verification procedure is prepared by the testing laboratory for all critical laboratory equipment where the laboratory personnel perform the COVID-19 RT-PCR testing
2. Calibration and verification records are maintained.
3. 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 When, for whatever reason, i.e. repair or calibration, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

2 For equipment returned after repair, the performance checks and calibration identified are conducted 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:

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories Section 6.4

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.

FDA Staff Manual Guide (SMG) 2620.2, Procedure for surplus equipment

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