Purpose

The purpose of this quality document is to:

- provide guideline for handling, placement, schedule maintenance, performance and calibration of equipment in order to provide quality in testing services
- provide guidelines for procurement of reagents and consumables, their storage and maintaining the record

Application

This procedure applies to all sections of PPHRL involved in testing activities

Procedure

Identification of Equipment's:

Equipment and their accessories should be uniquely identified in all labs of PPHRL. Equipment identification slip will be used for this purpose. This slip includes following information:

Equipment Code: This code will be unique for all equipment's, general syntax of this code is as follow:

AAA/BBB/E/NNN, where

AAA represents Department (two to three letters), i.e.

PPHRL for Laboratory

BBB represents respective laboratories / sections / sub Sections

MIC for Microbiology

HEM for Hematology

HIS for Histopathology

CHE for Chemistry

MOL for Molecular Biology section

E represents equipment

NNN Serial No (001, 002,)

Example: **PPHRL/MIC/E/001**, this identification code represents equipment installed in Microbiology Lab

Equipment Name:

Equipment identification slip must have equipment name.

Location:

This contains the name of lab where equipment is installed

Specimen of Identification slip is:

Equipment Code: _____

Equipment Name: _____

Location: _____

PPHRL will maintain an inventory of its major equipment used to perform testing activities. This includes:

- Information regarding equipment identification
- significant information of the equipment, serial number, vendor, range of measurement (if applicable), year of manufacture, year of operation
- Equipment Log Book Section: A

Each lab will maintain List of Equipment for ready reference.

Equipment Maintenance and Performance Checks

- PPHRL equipment maintenance and performance checks are conducted on a scheduled basis. A schedule, identifying and eliminating potential sources of problems, is established for the servicing of laboratory equipment, such maintenance and performance checks are documented in Equipment Maintenance Log Books to demonstrate that the program is being followed according to schedule.
- The Equipment Maintenance Log Books are compiled and required information is maintained in a readily accessible manner. These log books are placed in a secure and accessible place in respective labs of PPHRL

- Manufacturer's instructions are used for guidance in performing equipment maintenance. In the absence of manufacturer's instructions, instructions are provided in the form of Work Instruction where required.
- Following table labeling "Equipment Maintenance and Performance Requirements" provides information on minimum maintenance requirements for equipment. Laboratories are responsible for developing comparable maintenance schedules for equipment not listed in this table

S/N	Equipment	Requirement	Minimum Frequency
1	Autoclaves	i. Clean ii. Temperature and Time iii. Sterile control all media iv. Spore vials or strips v. Service	i. After spills ii. Daily iii. Each load iv. As per manufacturer of laboratory procedure
2	Balances	i. Clean ii. Mass measurement iii. Service	i. After each use ii. Daily with internal calibration of with a reference weight iii. Annually
3	Centrifuges	i. Clean ii. Sanitize iii. Service	i. After spills or breakages ii. Each month
4	Electrophoresis	i. Refer to instrument manufacturer instructions	i. As recommended by manufacturer
5	Freezers	i. Clean, sanitize and reorganize ii. Temperature	i. As scheduled by laboratory ii. Daily
6	Biohazard safety cabinet	i. Clean ii. Air flow monitor iii. Service (included air flow)	i. After spills ii. Monthly iii. Annually
7	Incubators	i. Clean, sanitize ii. Freezer	i. As scheduled by laboratory

			ii. Daily AM and PM
8	Microscopes	i. Clean objectives and eyepieces ii. Service	i. After each use ii. Annually
9	Ovens	i. Clean ii. Temperature	i. As scheduled by laboratory ii. Daily
10	Pipettes, Petri Dishes, Plastic ware	i. Sterility	i. Each lot
11	Refrigerators	i. Clean and sanitize ii. Temperature	i. As scheduled by lab ii. Daily
12	Water baths	i. Stability and uniformity of temperature	i. At installation ii. Annually
13	Glassware: Non-Class A, Volumetric: pipettes, burettes, and volumetric flasks	i. Accuracy and precision using mass of water	i. Upon receipt
14	Thermometer, Reference	i. Critical points on scale	i. Annually
15	pH meters,	i. pH reading with standard buffer or other known and standardized ionic solutions.	i. Each use
16	Timers	i. National Time Standard	i. Annually
17	Weights	i. Re-certification for accuracy from recognized national or international calibration units	i. Every five years

- Preventive Maintenance of equipment is performed by qualified PPHRL staff, which includes cleaning of equipment after completing the testing activities and conducting general service as per the instructions in respective operation manuals provided by the manufacturer.
- General Service equipment is typically maintained only with cleaning and safety checks.
- Use of outside contractors to perform repairs or maintenance is at the discretion of PPHRL management.

- Instrument and equipment repairs are documented, the documentation includes,
    - Initials of the analyst and the date the problem was observed.
    - Description of the problem/fault
    - Date and initials of the analyst or service representative performing the repair.
- Corrective and Preventive Action Request Form QSP/QF/L4-010 is raised when corrective and / or preventive actions are required for equipment and / or peripherals.

Equipment Calibration

- Equipment installed at PPHRL permanent facility is mostly automated equipment. This equipment has automated procedure and application program for calibration. The supplier has schedule to visit and check calibration of these equipments. Lab personnel working of automated equipments checks calibration of equipment on daily basis. Assurance of calibration includes following activities:
    - Check the calibration status before to execution of examination through automated equipment.
    - Print quality controls chart / calibration charts at least once a week
    - Run standard controls to check the calibration status. It is not in range, run the controls to calibrate the equipment.
    - Reprint the calibration / quality control chart
    - Maintain the record of calibration charts in calibration record file.
    - Calibration error will be automatically adjusted after the calibration has been done
    - If calibration not lies in the range in spite execution the controls. Stop the testing activity, call the vendor to recalibrate.
    - HOD / Technician working over the equipment is responsible to raise the Corrective Action Request to document the activity.
    - Inform FDO to not receive any sample until equipment is not in working order

- Manual equipments like pipettes, weights, thermometer, hygrometer, balances, etc be calibrate from organization traceable to SI
- Maintain the record of calibration certificate in calibration record file, a copy of calibration certificate will be available in respective lab where equipment is installed.
- Adjust the calibration error mentioned in the certificate during the examination of samples. Record of this activity will be maintained in Lab Note Book (where applicable, in case of automated equipments error will be adjusted automatically)
- Bench copy of Calibration Procedure will be available, for equipment (if provided in manual / supplied by the vendor).
- In case of automated / manual equipment inter-laboratory checks will be performed once a week to ensure the calibration (where applicable) and record of this activity will be maintained in the Inter-laboratory Calibration Log Book
- Minimum calibration schedules for the most common types of PPHRL equipment is annual basis for automated equipments lab will follow the instruction provided by calibrating organization or instruction supplied by the vendor.
- Generally, laboratory equipment are categorized as follows:
    - General Service equipment such as grinders, ovens, hotplates, etc.
    - Volumetric equipment such as class A glassware, mechanical and automatic pipettes and burettes; Note: A manufacturer's certificate of graduation accuracy for class A glassware may be accepted. Other volumetric equipment, including pipettes and digital burettes, are calibrated by documented instructions.
    - Measuring instruments such as balances, chromatographs, spectrometers, thermometers; and
    - Physical standards such as reference weights and reference standards.

Unserviceable Equipment

- Equipment is considered "UNSERVICEABLE" as its status, in case of any of the following situation :
    - Out of order

- Damaged
- Does not give correct readings
- Unfit for use due to any reason
- Obsolete
- Awaiting calibration / repair

Such equipment is tagged as “Unserviceable” or “U/S”. An entry must be made in **Unserviceable State** for all unserviceable equipment.

- Equipment that is not operating properly is clearly marked to show that it is out of service.
- When an instrument is discovered to be improperly operating, it is tagged and taken out of service.
- Equipment is not returned to service until performance checks and verification have been performed and documented. Attach such documents with CAR Form raised when equipment become out of order.

Handling, Use, Transport and Storage of Equipment

- The Work Instruction defines the handling and use of the equipment. Main equipment (i.e. high cost & sensitive) in the Lab has instructions for its start-up, operation and shutdown such equipment are identified by the concerned HOD. Equipment is operated by authorized personnel; authorized personnel are identified in Lab Authorization Permits.
- In case maintenance / operation manuals are provided by the equipment manufacturer they are either attached with the Equipment Maintenance Log Book or its reference is mentioned in the said log book. The location of equipment is also recorded in the same.
- If equipment is required to be transferred to another laboratory manufacturer’s instructions for transportation of equipment are followed. Transportation or moving equipment may be performed by the manufacturer/supplier or other service provider or by qualified staff of the sending and receiving laboratory. Equipment is not returned to service until performance checks and calibration have been performed

and documented. The Inventory holder for the equipment is responsible to maintain all requests, records and documentation related to equipment transportation.

- Visitors are restricted to offices and only authorized personnel are permitted in 8the laboratory. Computer software related to equipment is password protected to prevent unauthorized program adjustments. These measures safeguard the equipment, sample security and computer software.

Reagents and consumables

Being a public laboratory, all the reagents and consumables are purchased through the PPRA guidelines. The reagents and consumables are retain under the certain storage condition as are described by the principal vendor. The lab has maintained the details "Reagents & Consumables Record" of reagents and consumables along with their storage condition.

This record includes:

- identity of the reagent or consumable
- manufacturer's name and batch code or lot number
- contact information for the supplier or the manufacturer
- date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service
- condition when received (e.g. acceptable or damaged)
- manufacturer's instructions
- records that confirmed the reagent's or consumable's initial acceptance for use

Related Documents

- List of Equipments
- Monthly Unserviceable State
- Equipment Log Book
- Reagents and Consumable Record