Equipment Management
By Freshwork A

25 April (15 -16:15 KST)

House keeping rules

Please turn off your microphones – this will help with bandwidth and maximize audibility.

Do frequently use the chat function to share your views, comments and challenges. Keep the chat constructive, respectful and on topic!

If you would like to ask questions, please type them in the chat box

Please note that we will record the session to maintain a record of the questions asked and to distribute it to the laboratory team for future reference.

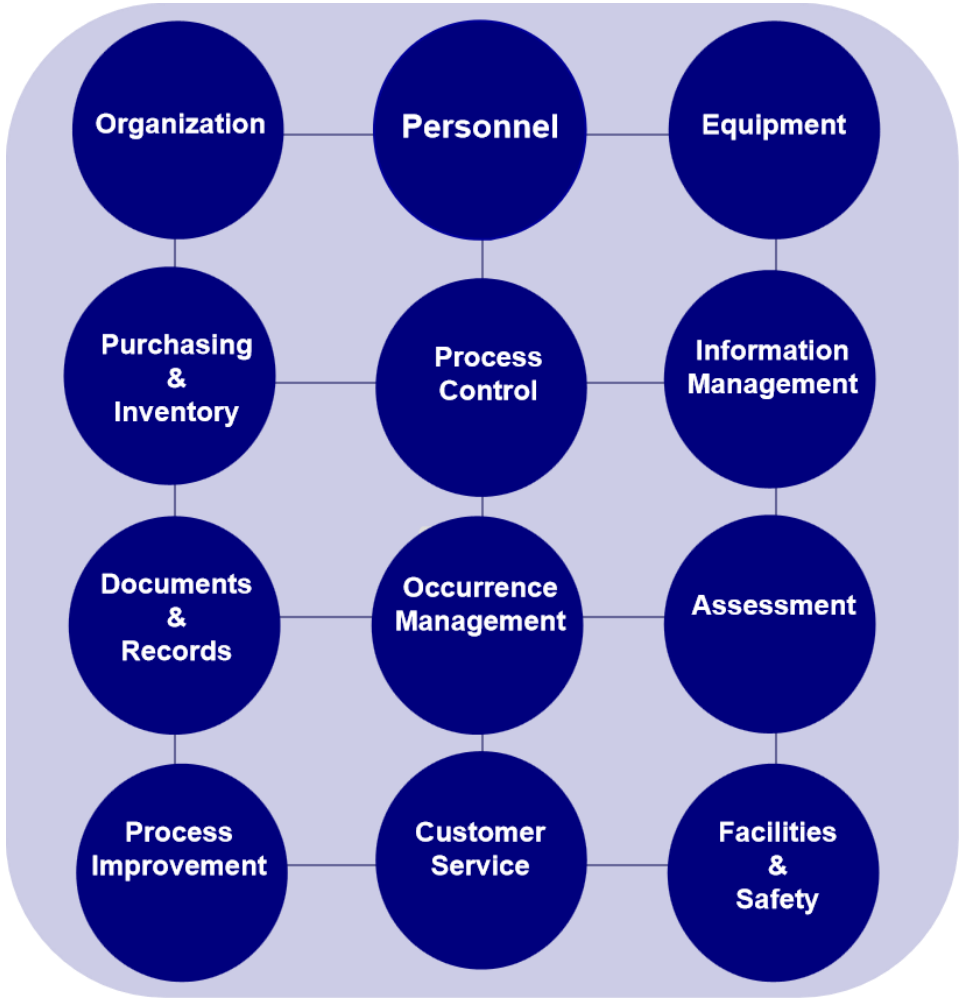
Agenda

S/N	**Topic**	**Time**	**Expected Duration**
1	Welcome	3:00- 3:05 pm	5 min
2	Presentation on Equipment management	3:05-3:45 pm	40 min
3	Quiz questions and case studies	3:45-4:05 pm	10 min
4	Q/A session	4:05-4:15 pm	10 min

Content

- Introduction to Equipment management
- Requirements for selection and acquisition of new equipment.
- Proper installation and qualification (IQ, OQ, PQ) of equipment
- Establishing a preventive maintenance & calibration program.
- Rationale for developing and maintaining such a program.
- Proper procedures for retiring outdated equipment.

Quality Management system



Equipment management

- Equipment management is a crucial component of a quality management system.
- Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable, and timely testing.
- An effective equipment management program:
  - Maintains a high level of laboratory performance
  - Reduce variation in the test result and Increases technologists' confidence in the accuracy of test results
  - Extends the lifespan of instruments
  - Reduces service interruptions due to breakdowns and failures
  - Lowers repair costs as fewer repair will be needed for a well-maintained instrument
  - Increases safety for workers
  - Enhances customer satisfaction

Equipment management

Equipment management oversight

- The laboratory director (or equivalent) is responsible for overseeing all equipment management systems in the laboratory
- This includes ensuring that all personnel using the instruments are properly trained and understand how to operate the equipment and perform necessary routine maintenance.
- Oversight of an equipment management program includes:
  - **Assigning Responsibilities**: Clearly defining responsibilities for all equipment management activities.
  - **Training and Competence**: Ensuring all personnel are trained in the operation and maintenance of equipment.
  - **Monitoring Activities**: Regularly reviewing equipment records, updating maintenance procedures as necessary, and ensuring all procedures are followed accurately.

Equipment management - Lifecycle

Equipment management

1. Selection and acquisition of equipment

- Selecting the most appropriate instrumentation for the laboratory is an important part of equipment management.
- Some basic criteria to consider when selecting laboratory equipment should include:
  - Use- matching equipment with service provided
  - Performance characteristics of the instrument
  - Facility requirements including the requirements for physical space
  - Costs: reagents, spares, maintenance & service, power consumption.
  - Reliability & reputation
  - Supply of reagent (i.e., access to reagents)
  - Ease of operation
  - Availability of instruction in the Language understood by the staff
  - Warranty
  - Availability of manufacturer for technical support and service needs
  - Safety

Equipment management

2. Equipment Installation

- Before installing equipment, ensure that:
  - All physical requirements (such as temperature, humidity, electrical, space, doors, ventilation, and water supply) have been met.
  - Confirm the vendor's responsibilities through a written contractual agreement prior to the start of the installation process.(i.e., delivery, installation, staff training and ongoing technical support)
  - Develop a checklist of expected performance specifications to enable quick verification of equipment performance immediately after installation.

- Whenever possible, it is recommended to have the manufacturer install the equipment. This will likely improve the conditions of the warranty and may ensure that the installation is done properly and quickly

Equipment management

- If equipment is installed by the laboratory the following steps should be taken:
  - Verify that all parts are present in the package.
  - Create a backup copy of any included software.
  - Ensure the equipment is **not used** until installation is complete, performance has been verified, and testing personnel are adequately trained.

Equipment management

Installation Qualification (IQ)

- Proper installation of laboratory equipment is verified by IQ activities
- IQ is a documentable evidence that the equipment is ready, safe, and meets all installation requirements
- The IQ should cover the various aspects and requirements of the installation, including the following:
  - All equipment components have arrived.
  - Equipment is placed and installed at the intended location.
  - All equipment requirements are met (correct environmental temperature, humidity, correct power, water supply is appropriate).
  - Equipment can power-on and off.
  - Laboratory Information System/Laboratory Information Management System (LIS/LIMS) communication, configuration and interfacing is functional.
  - Documents and records are complete

Equipment management

Operational Qualification (OQ)

- OQ is the process to confirm that the equipment is operational for its intended use
- Documented evidence that the equipment is operating correctly
- All functional components of the equipment need to be evaluated to ensure that operational specifications are met.
- Examples of operational attributes used to test the operational functionality of the equipment include:
  - Initial calibration
  - Quality control (QC) testing
  - Functionality check confirmed
  - Security (access controls are working)
  - Data transfer across electronic interfaces

Equipment management

Performance qualification

- Performance Qualification (PQ) is the process of verifying that equipment performs as intended within your specific laboratory environment, including your staff, processes, procedures, and infrastructure.
- PQ provides proof that the equipment produces acceptable results under normal operating conditions and consistent with the manufacturer's claims.
- PQ involves evaluating the performance of new equipment to ensure it is functioning correctly in terms of:
  - Accuracy
  - Precision
  - Sensitivity
  - Specificity
  - Positive and negative predictive value
  - Method comparison

Equipment management

➢Training

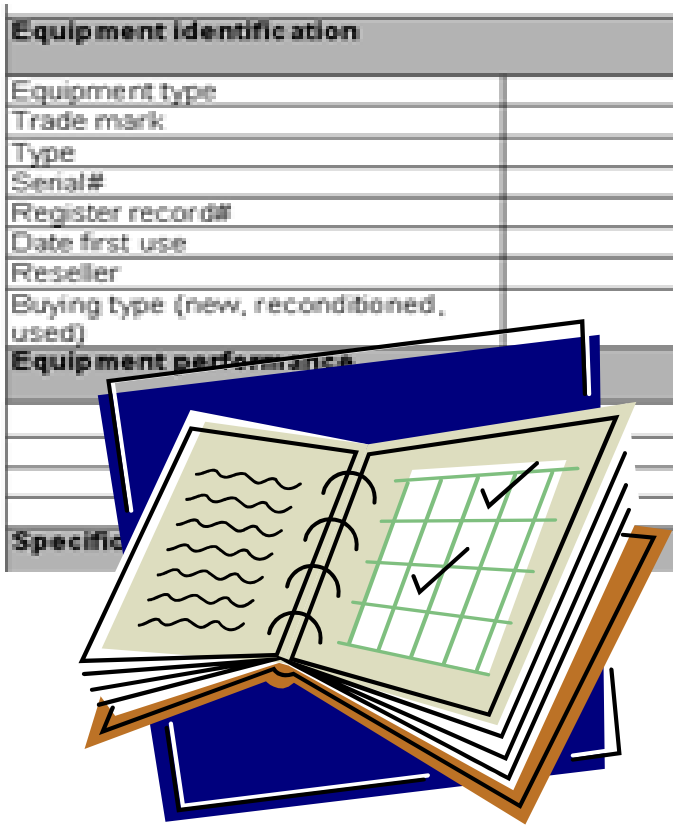
- ➢Detailed training should be provided by a qualified manufacturer’s representative, especially for major equipment installations.
- ➢All operators must be fully trained in the following areas;
  - Start-up & shut-down procedures
  - Cleaning & maintenance
  - Sample preparation & handling
  - QC & calibration procedures
  - Trouble shooting
  - Documentation and use of logbooks

Equipment management

Equipment inventory log

The laboratory should keep an inventory log of all equipment in the laboratory

- This log should include the following details:
  - Instrument type, model number, serial number
  - Location in laboratory
  - Date of purchase and condition at purchase (new, used, or reconditioned)
  - Manufacturer and vendor contact information
  - Warranty's expiration date
  - Spare parts



- The log should be updated to reflect:
  - Newly acquired equipment
  - Equipment that has been retired or decommissioned, along with relevant documentation

Equipment management

Calibration

- Calibration is typically performed initially and at regular intervals *(i.e., ensure equipment remains in a state of continuous calibration),* based on time or usage according to the manufacturer's recommendations (reference user's manual) and any applicable international, national, accreditation, and/or local requirements
- The laboratory needs a documented calibration procedure for each instrument that provides results.
- The calibration procedure should include the following sections:
  - Purpose and scope
  - Frequency of calibration
  - Equipment and calibration materials to use
  - Instructions for performing the calibration
  - Remedial action for out-of-specification results

Equipment management

Calibration Records

- Calibration records must be maintained for each piece of equipment, whether in paper form or within a validated computerized system.
- At a minimum, these records should include:
  - Identification of the instrument or equipment
  - Identification of the calibration standard used (e.g., certified thermometer, certified tachometer, etc.)
  - The date and time when calibration was performed
  - The results of the calibration
  - The identity of the person performing the calibration
  - The acceptability status (pass/fail)
  - Any necessary follow-up actions taken
  - Review and approval details
- Additionally, the laboratory should document the date on which calibration was performed and the next scheduled calibration date for each piece of equipment or instrument.

Equipment management

Preventive maintenance

- Preventive maintenance is intended to minimize unexpected failure of equipment or instruments, so they continue to function as desired.
- Well maintained equipment is critical to the operations of any laboratory by:
  - Assuring that testing is accurate and reliable
  - Prevents instrument failures and prolongs life of the instrument
- Preventive maintenance includes measures such as systematic and routine cleaning, adjustment, and replacement of equipment parts at scheduled intervals
- Examples includes, cleaning optical lenses, thermostat adjustment and changing motor brushes
- Manufacturers generally recommend a set of equipment maintenance tasks that should be performed at regular intervals: daily, weekly, monthly, or yearly

Equipment management

Preventive maintenance records

- At a minimum, preventive maintenance records need to include the following:
  - Instrument or equipment identification
  - Date and time maintenance is performed
  - Maintenance activities performed
  - Identity of the person performing maintenance
  - Any necessary follow-up actions taken
  - Review and approval
- After maintenance has been performed, a label be attached to the instrument indicating the date on which maintenance performed and when the next maintenance or service should be performed.

Equipment management

Maintenance plan

- For each piece of equipment, the laboratory should establish:
  - A routine maintenance plan that specifies the frequency of all maintenance tasks
  - Required function checks
  - Develop list of replacement parts.
- When implementing an equipment maintenance program, the initial steps should include:
  - Assign responsibility for providing oversight.
  - Develop written policies and procedures for equipment maintenance including routine maintenance plans for each piece of equipment that specify the frequency of maintenance tasks
  - Create a format for records, logs, and forms, and establish processes to maintain these records.
  - Train all staff on the correct use and maintenance procedures for equipment.

Equipment management

Function check

- To ensure that equipment is functioning according to the manufacturer's specifications, function checks should be conducted:
  - Initially: Before using the instrument for the first time.
  - Periodically: This can be daily, weekly, or monthly, depending on the equipment and its use.
  - After Major Repairs: Perform function checks following any significant repairs to the equipment
- The laboratory should follow the *manufacturer's instructions* for conducting function checks after each preventive maintenance or repair.
- The results of these checks should be documented and maintained.
- Examples of Function Checks:
  - Daily monitoring of temperature.
  - Checking the speed of a centrifuge.
  - Verifying the indicator paper in an autoclave

Quality Control of Examination (Analytical) Equipment

- The laboratory needs a QC plan for each instrument or piece of equipment that generates examination results to provide ongoing assurance that performance continues to meet specifications.

- The QC Plan Should Include:
  - Frequency of QC testing
  - Personnel responsible for performing, tracking, and trending QC
  - Selection of control materials based on method performance and clinical ranges
  - Acceptance criteria for QC results
  - What is done when out-of-specification results occur
  - Remedial and corrective actions taken for out-of-specification results
  - Procedures for tracking and trending QC data

- When QC Results Are Out of Range:
  - The equipment must be removed from service
  - Troubleshooting must be initiated before further testing
  - No results should be released until QC is within acceptable limits

Equipment management

Proper Use of Laboratory Equipment

- The laboratory must develop an SOP that outlines the correct use of equipment by qualified and trained personnel.
- Equipment must be used in accordance with the manufacturer’s instructions to ensure correct operation, proper maintenance, and user safety.
- When the manufacturer provides updates, the SOP must be reviewed and revised accordingly, and staff must be trained as necessary to incorporate these updates into their routine practices
- During routine use, laboratory personnel must monitor for equipment malfunctions or unexpected results that may require troubleshooting or corrective action.

Equipment management

Trouble shooting

- Despite following a rigorous equipment maintenance schedule, instruments can still malfunction.
- The first step in addressing any nonconforming event is to consult the instrument's operations manual provided by the manufacturer, which includes basic troubleshooting guidance.
- When troubleshooting, consider potential contributors to the nonconforming event:
  - Sample problem
  - Reagent problem
  - Equipment problem
  - Electrical supply issues
  - Water supply issues
- Based on the observed symptoms, make one change at a time . If the equipment is the problem, review the manufacturer's instructions to verify that all procedures are being followed correctly.

Equipment management

Troubleshooting

- Each instrument needs a designated problem log in which a summary of the troubleshooting episode is recorded
- All troubleshooting actions taken are recorded. At a minimum, troubleshooting records should include:
  - Instrument or equipment identification
  - Date of occurrence
  - Description of the problem
  - Date and time troubleshooting was performed
  - Identity of the person performing troubleshooting
  - Any necessary follow-up actions taken
  - Review and approval
- Troubleshooting log data should be reviewed regularly to identify patterns such as recurring, occasional, or isolated issues that may help predict and prevent future equipment failures.

Equipment management

Unscheduled Service and Repair

When equipment fails and troubleshooting does not resolve the issue:

- Repair order should be initiated with the designated service provider
- Continue testing using alternative options until the equipment can be repaired
  - Refer to near by laboratory
  - Obtain backup instrument if available and validated
  - Store samples appropriately (if possible) for future analysis

- The manufacturer's service engineer or facility personnel trained by the manufacturer will perform necessary repairs and generate a service record.
- **DO NOT** use equipment that does not function properly
- Place a malfunction notice on the equipment so all staff are aware that it is not in use.

Equipment management

Service and Repair record

At a minimum, the service/repair record needs to include the following:

- Instrument or equipment identification
- Date and time the service/repair was performed
- Description of the service/repair performed
- Identity of the person performing the service/repair
- Follow-up action, if needed
- Review and approval

Equipment management

Scheduled service and repair

- Scheduled service must be periodically performed by the manufacturer to ensure reliability and extend equipment lifespan.
- In large facilities, in-house biomedical service technicians may also carry out equipment maintenance and repair.
- This service schedules should be planned carefully to minimize disruption to the laboratory workflow and operations.

Equipment management

Retiring and disposing of equipment

- It is crucial to have a policy and procedures in place for retiring older laboratory equipment.
- Equipment retirement should be initiated under the following conditions:
  - When experts indicate the equipment is not repairable.
  - The equipment is outdated and should be replaced with new, updated models.
  - To prevent inaccurate results.
  - To free up valuable space.
  - To prevent potential hazards.

- Before disposal, all retired equipment must be decontaminated according to the manufacturer's guidelines.
- This step is critical to protect personnel, the environment, and the public from any residual hazards during transport or disposal.

Equipment management

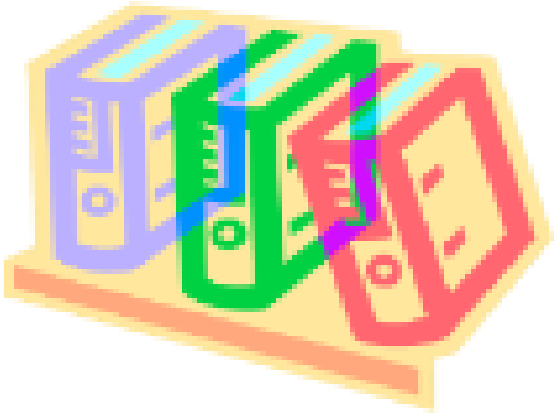
Equipment Maintenance Documentation

- Each major piece of equipment will have its own equipment maintenance document
- An equipment maintenance document should include:
  - Step-by-step instructions for routine maintenance,
  - Instructions for carrying out function checks,
  - Directions for calibrating the instrument;
  - A guide for troubleshooting;
  - Any required manufacturer’s service and repair;
  - List of any specific items needed for use and maintenance, such as spare parts.

Equipment management

Operator's Manual

- A document provided by the manufacturer that contains essential instructions for safe and effective equipment use, maintenance, and troubleshooting.
- The manual includes:
  - Preventative maintenance procedures and schedules
  - Maintenance logs that can be photocopied
  - Step Step-by -step instructions to perform maintenance, system checks and basic troubleshooting.
  - Explanation of error codes and alerts



- *The operator's manual should be kept accessible near the equipment—it's your first point of reference for routine tasks and troubleshooting*

Equipment management

Dedicated Logbook

- Each piece of equipment should have a dedicated logbook documenting all characteristic and maintenance elements including:
  - Preventive maintenance activities and schedule;
  - Recording of function checks and calibration;
  - Any maintenance performed by the manufacturer;
  - Full information on any problem that the instrument develops, the subsequent troubleshooting activity, and follow-up information regarding resolution of the problem
- The logbook should be available for review during the entire life of the equipment.

Quizzes and case studies

Quiz 1(1 minute)

1. What is the primary goal of an equipment management program?

a) Increase in laboratory expenses

b) Extend equipment lifespan and ensure accurate testing

c) Minimize staff training requirements

d) Eliminate the need for maintenance

Quiz 2 (1 minute)

3. Which phase includes comparison to previous methods, verifying accuracy, precision, and linearity?

A) Installation Qualification (IQ)

B) Operational Qualification (OQ)

C) Performance Qualification(PQ)

D) None of the above

Quiz 3 (1minute)

4. When should a function check be performed on equipment?

a) Only when equipment breaks down

b) After major repairs, periodically, and before first-time use

c) Once every five years

d) Only when results are inconsistent

Quiz 4(1minute)

5. What is the purpose of maintaining a troubleshooting log for laboratory equipment?

a) To track recurring problems and anticipate future failures

b) To assign blame for equipment failures

c) To avoid manufacturer inspections

d) To keep lab records cluttered

Quiz 5(1minute)

2. What is an important step before retiring and disposing of outdated laboratory equipment?

a) Throwing it away without documentation

b) Decontaminating the equipment following manufacturer guidelines

c) Selling it to any available buyer

d) Ignoring safety protocols

Case study 1(1minute)

1. An autoclave in a microbiology lab had not been maintained per the manufacturer's recommendations. When a technician loaded a batch of culture media, the autoclave failed to reach the correct temperature, leading to contamination risks

What is the most likely cause of the autoclave failure?

a) Operator didn't close the door properly

b) Electrical power fluctuation

c) Lack of routine preventive maintenance

d) Wrong type of media used

Case study 2(1 minute)

2. You are running ELISAs when the plate reader fails. The lab lacks a documented troubleshooting procedure, the maintenance log hasn't been updated for two years, and the manufacturer's instructions are missing.

What is the most appropriate immediate action?

a) Try different settings on the reader and continue the test

b) Restart the reader and re-run the test from the beginning

c) Stop using the equipment, label it as "Out of Order," and escalate the issue to the lab manager

d) Use the equipment based on memory and experience until the test is completed

Case study3 (1minute)

3.You are the Laboratory Manager in a Microbiology Laboratory. Your MALDI-TOF instrument (used for bacterial ID) required a laser replacement. The manufacturer's technician came in and replaced the laser, but due to time constraints, no documentation was left regarding the repair or calibration. The engineer said paperwork would be emailed later. Later that evening, staff ran 25 patient samples and reported results directly from the MALDI-TOF system. The next morning, a physician called questioning three identifications that didn't correlate clinically. There were no notes or logs showing the equipment had passed verification or calibration after the laser replacement.

3.1 What factors could have contributed to this incident?

a. Lack of post-repair verification
b. Absence of repair documentation before sample processing
c. The laser was replaced but calibration was not done
d. All

Case study 3 cont.(1 minute)

3.2. After the MALDI-TOF laser replacement, what critical step was missing before using the equipment for patient testing?

a) Cleaning the equipment housing

b) Documentation of sample results

c) Function check , QC and calibration of the instrument

d) Informing the physician about the repair

Case study 3 cont.(1 minutes)

4. As the Laboratory Manager, what measures will you put in place to prevent this from recurring?

   a) Use the incident as an opportunity for improvement

   b) Arrange for staff training for post repair verification procedures

   c) Clarify the contract with the vendor and spell out the scope of work

   d) Establish a policy that prohibits the use of equipment post-maintenance until verification is completed and documented

   e) All

QUESTIONS ???

Thank you