



Laboratory Quality Management System

Module 8: Equipment

Venue:

Presenter:

Date:

Introduction

Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable, and timely testing.



Learning Objectives

At the end of this module, participants will be able to:

- list items to consider prior to purchasing equipment for the laboratory;
- manage the selection and acquisition of new equipment;
- describe the requirements for a preventive maintenance program for equipment;
- provide a rationale for developing a preventive maintenance program in your laboratory;



Explain how to retire old or outdated equipment

Module Outline

- Equipment management overview
- Selecting and acquiring equipment
- Getting equipment ready for service
- Implementing an equipment maintenance program
- Troubleshooting, service, repair and retiring of equipment



Equipment maintenance documentation

LQMS/PP/008, Version 1.0, Effective date: 01-Jun-2019



Timely Accurate Diagnostics for a TB-Free Africa

Why Equipment

My lab provides prompt, accurate and validated test results.

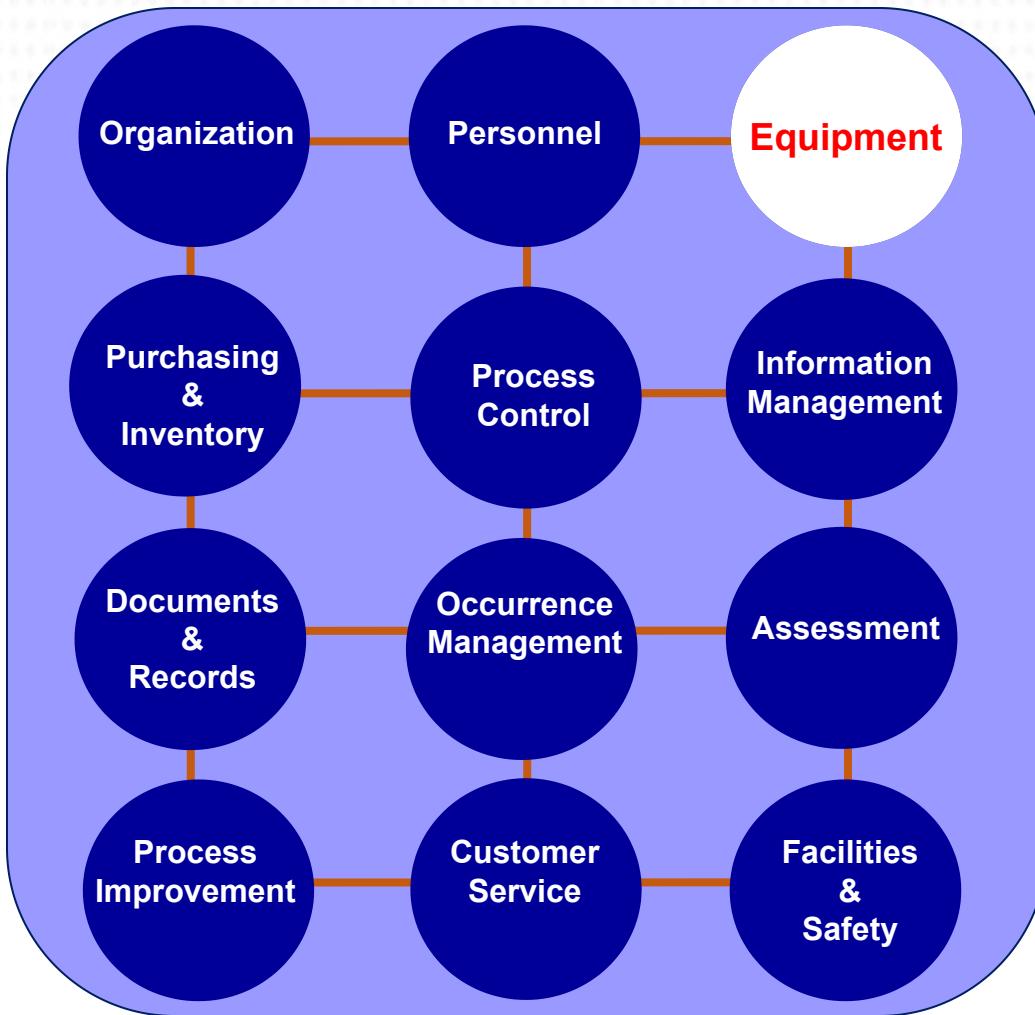


Scenario

“The MGIT machine fails while performing tests. There isn’t a documented procedure for troubleshooting, the maintenance log has not been updated for 6 months, and the manufacturer’s instructions are missing.”

- **What should you do? Why?**
- **What should you have done earlier?**
- **What would you do if this happened in your laboratory?**

The Quality Management System



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UGANDA
Supranational®
Reference Laboratory

Timely Accurate Diagnostics for a TB-Free Africa

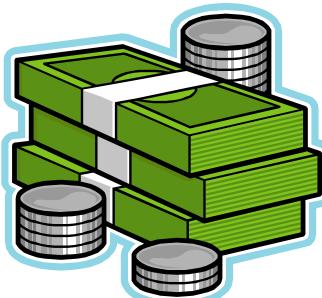
Equipment Management

Benefits

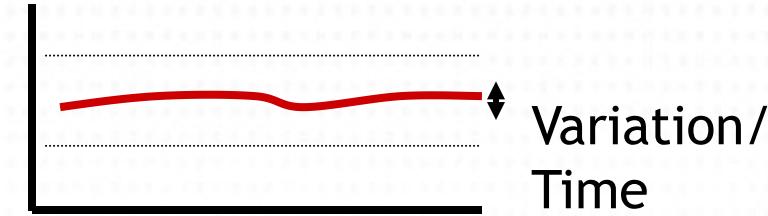
Test results



High Level
Performance



Lowers repair
costs



Lengthens lifespan

Equipment Management Benefits



Reduces
interruption
of services



Greater customer
satisfaction

Increases safety



Equipment Management includes...

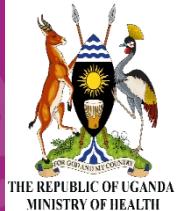
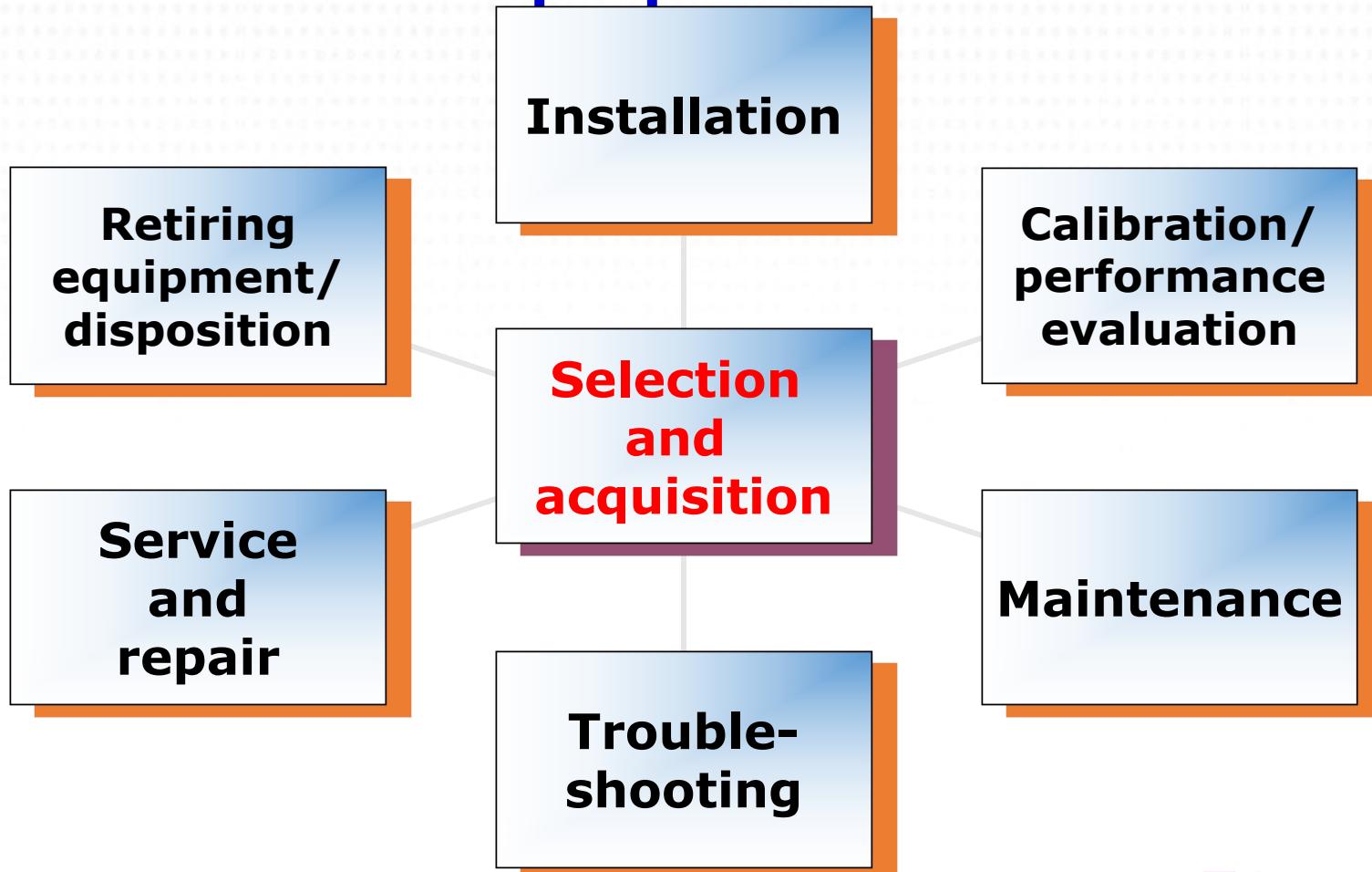
- Assign responsibilities for all activities
- Train all personnel on requirements and maintenance needs
- Monitor equipment management activities:
 - ensure all procedures are followed
 - review all records routinely
 - update procedures as needed



2. Selecting and acquiring equipment



List of Considerations - Equipment



Selecting and Acquiring Equipment



Equipment
needs

Facility
requirements



- performance characteristics
- cost
- reagents

Selecting and Acquiring Equipment

- Easy to use
- Language
- Waranty
- Safety
- Will it fit?



Acquiring Equipment

● Purchase, lease, rent, donations

- 📚 central acquisition

- 📚 bulk procurement

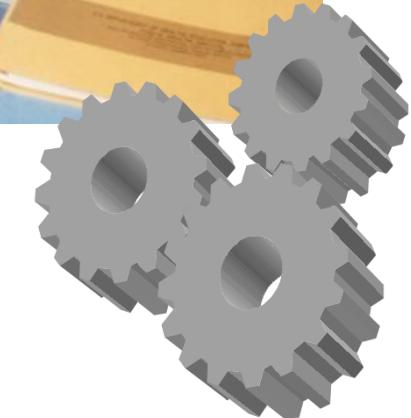
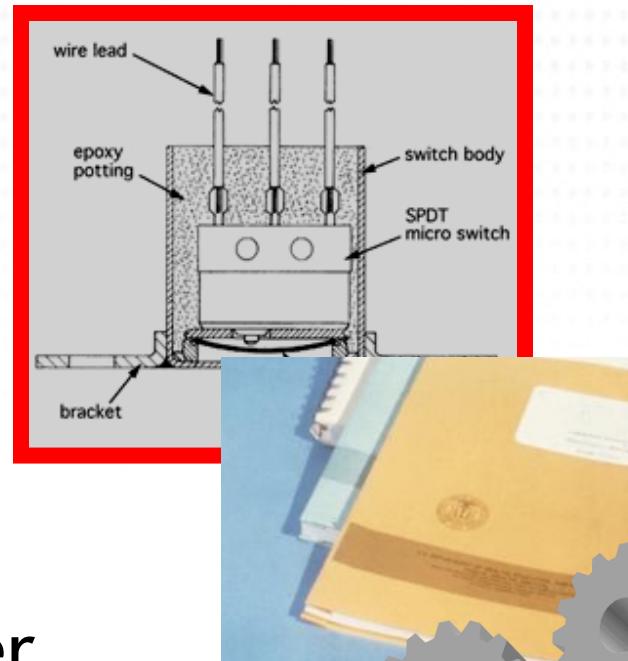
📘 Conditions of contract



Negotiating Equipment Acquisition

Request:

- Wiring diagrams
- Software information
- Parts list
- Operator manual
- Installation by manufacturer
- Trial period
- Warranty



Before Equipment Installation

🌐 Confirm vendor's responsibilities in writing

🌐 Establish checklist



Equipment Installation

- When possible, have manufacturer install and set up
- **Do not** attempt to use prior to proper installation



Equipment Installation

Verify package contents

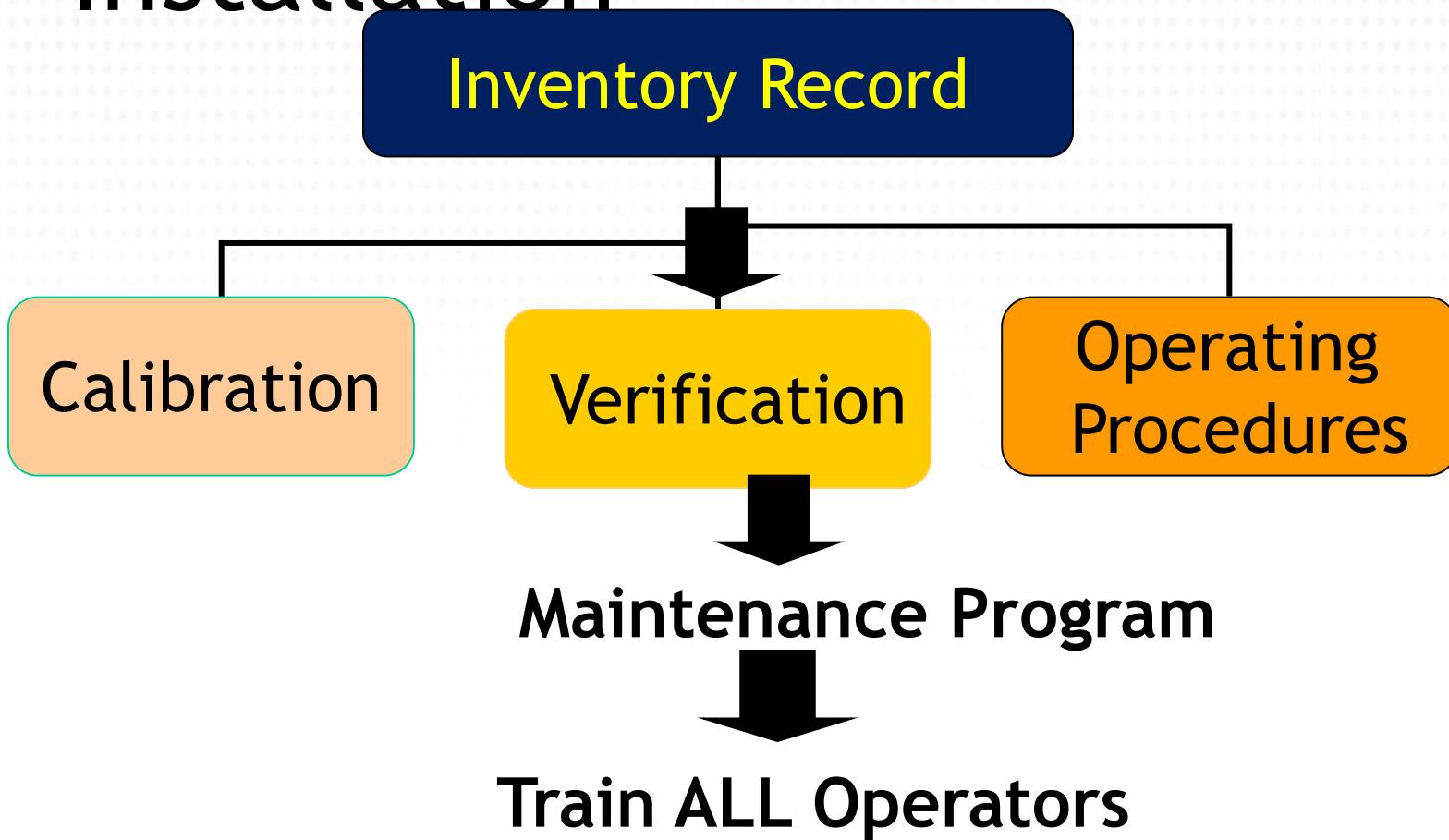
Copy software,
if part of system



3. Getting equipment ready for service



After Equipment Installation



Equipment Calibration

- Perform initial calibration
 - ➲ use calibrators or standards
 - ➲ follow manufacturer's instructions
- Determine frequency of routine calibrations



Performance Evaluation



New Equipment

Test known samples,
analyze data

Establish stability
for temperature-
controlled
equipment

Validate
performance with
parallel samples



Function Checks

Monitor instrument parameters:

- Periodically, daily, weekly, monthly
- After major instrument repair

Examples:

- Incubator temperatures
- Wavelength calibration
- Autoclave temperature change



Validation



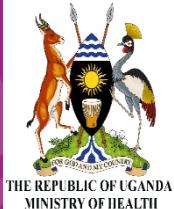
- Confirmation through the provision of objective evidence that the requirements for a **specific intended use** or application have been fulfilled. *[ISO 15189:2012, Terms and Defn, 3.26]*
- The laboratory **shall** validate examination procedures derived from..... *[ISO 15189:2012, Clause 5.5.1.3]*



Why Validation



- Check that the right product is being developed
- Ensures that the product being developed/modified will meet customer's satisfaction
- Establish performance characteristics



When do we do Validation



- a) non-standard methods;
- b) laboratory designed or developed methods;
- c) standard methods used outside their intended scope;
- d) validated methods subsequently modified.

Verification



- Confirmation through the provision of objective evidence that *specified requirements* have been fulfilled. *[ISO 15189:2012, Terms and Defn, 3.27]*

- The laboratory shall obtain information from the manufacturer /method developer..... *[ISO 15189:2012, Clause 5.5.1.2]*

Why Verification



- Confirm manufacturer's claims
- Ensure amount of error in system doesn't affect patient results.
- Ensure effects of shipment and storage didn't affect instrument performance.

Possible indications for Verification

○ Initial acceptance for use of a new method/equipment

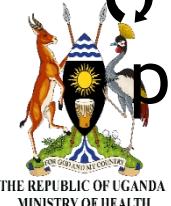


○ Major equipment maintenance/service.

○ Periodic check of existing laboratory processes

○ Movement of equipment from one location to another

○ Requirement for some research protocols



Performance Characteristics



- Claims about performance abilities of a method or equipment
- Specified claims for each examination shall relate to the intended use of that examination
- Preferred claims are from manufacturer, published in authoritative books/peer reviewed journals, international standards, national/regional regulations.



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Performance Characteristics



- () **Accuracy/Bias:** Closeness of agreement between the measured value and the true value.

- () **Precision:** Repeatability or reproducibility of measurement data.

Performance Characteristics



- **Sensitivity:** Ability of a method to identify true positive samples as positive
- **Specificity:** Ability of a method to identify true negative samples as negative

		The Truth	
		Has the disease	Does not have the disease
Test Score:	Positive	True Positives (TP)	False Positives (FP)
	Negative	c	d
		False Negatives (FN)	True Negatives (TN)

$$\text{Sensitivity} = \frac{\text{TP}}{\text{TP} + \text{FN}}$$

Or,

$$\frac{a}{a + c}$$
$$\text{Specificity} = \frac{\text{TN}}{\text{TN} + \text{FP}}$$
$$\frac{d}{d + b}$$

Performance Characteristics

() **Analytical Measurement Range (AMR):** An assessment of the lowest and highest levels at which an analyte can be accurately measured without any type of dilution or concentration.



() **Linearity:** The ability to provide results within a given measurement range that are directly proportional to the concentration (quantity) of an analyte in the test sample

() **Reportable Range:** the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response



Performance

Characteristics



Comparison method			
Method/equipment being verified	Has the disease (Positive)	Doesn't have disease (Negative)	Total
Positive	True Positive (TP)	False Positives (FP)	(TP+FP)
Negative	False Negative (FN)	True Negatives (TN)	(TN+FN)
	(TP+FN)	(FP+TN)	N



Performance Characteristics



- **Sensitivity** =
$$\frac{\text{True Positive (TP)}}{\text{True Positive (TP)} + \text{False Negative (FN)}} \times 100\%$$
- **Specificity** =
$$\frac{\text{True Negative (TN)}}{\text{True Negative (TN)} + \text{False Positive (FP)}} \times 100\%$$

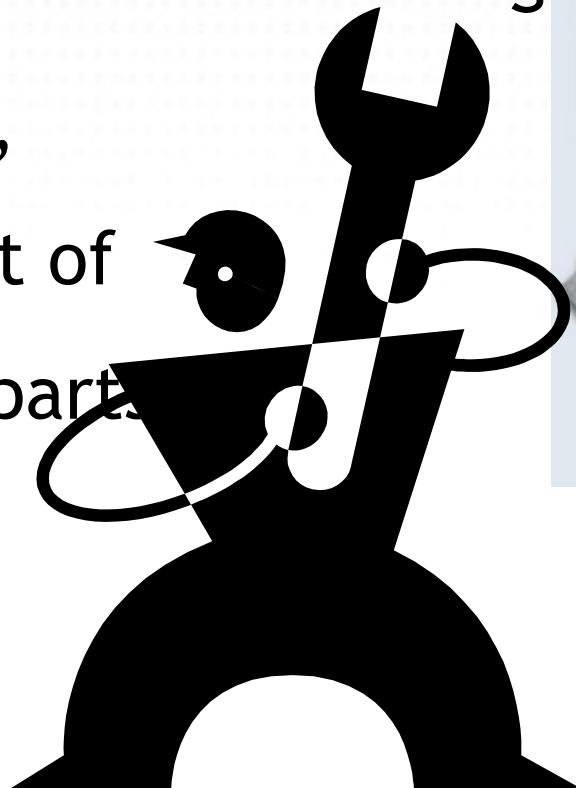
 *The specified requirements for each examination shall relate to the intended use of that examination (ISO 5.5.1.1)*

4. Implementing an equipment Preventive maintenance program



Preventive Maintenance

- Systematic Routine cleaning
- Adjustment,
replacement of
equipment parts



Rationale for developing Preventive Maintenance

Preventive maintenance will ensure that the equipment performs at maximum efficiency and will increase its lifespan

This will also help to prevent:

inaccurate test results due to equipment failure

delays in reporting results

lower productivity



Implementing a Maintenance Program

- Assign responsibility

- Develop written policies and procedures

- Maintain records

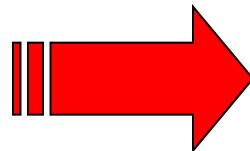
- Train staff



Develop a Maintenance Plan

For each piece of equipment, establish routine maintenance plan to include:

- frequency of all maintenance tasks
- function checks
- routine replacement of parts

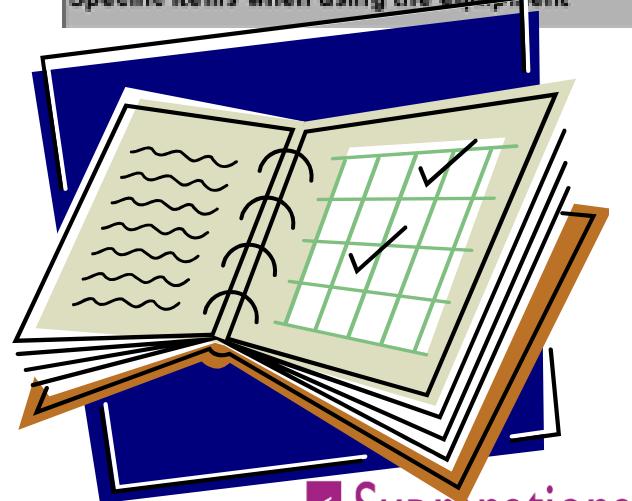


Create an Equipment Inventory Log

Record:

- 📖 Instrument type, model number, serial number
- 📖 Location in laboratory
- 📖 Date purchased
- 📖 Manufacturer and vendor contact information
- 📖 Warranty, note expiration date
- 📖 Spare parts

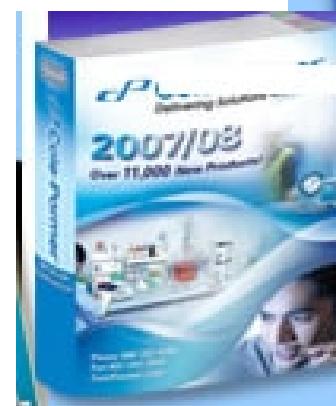
Equipment identification	
Equipment type	
Trade mark	
Type	
Serial#	
Register record#	
Date first use	
Reseller	
Buying type (new, reconditioned, used)	
Equipment performance	
Specific items when using the equipment	



Spare Parts Inventory

Include:

- Record of spare parts
- Log to track stock
- Cost and ordering information



5. Troubleshooting, service, repair and retiring of equipment



Troubleshooting: What is the source of the problem?

- Sample?
- Reagent?
- Water? Electricity?
- Equipment?



Instructions

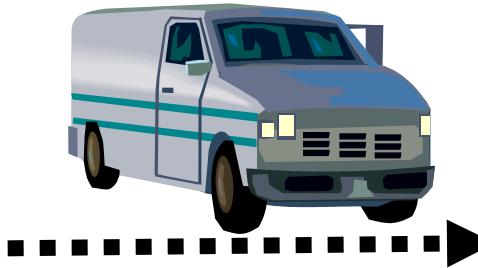


When in-house efforts fail:

- Call manufacturer or other technical expert

- Look for options to continue service

- Obtain back-up instrument from central stores or manufacturer
- Refer sample to nearby laboratory



Do NOT use

Equipment that does not function properly



Service and Repair

● Manufacturers

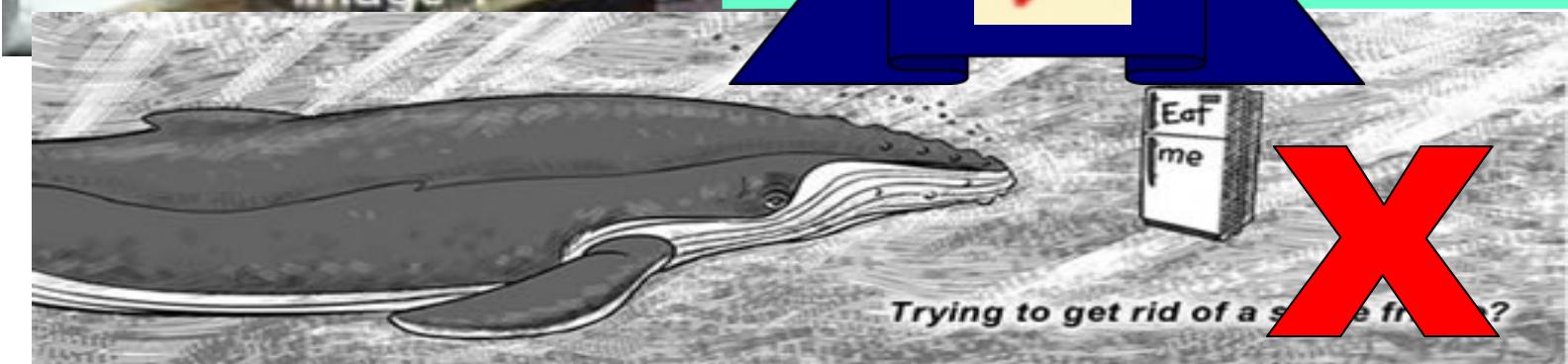
- Laboratory must schedule routine manufacturer's maintenance
- Warranty may require repair handled by manufacturer

● In-house biomedical service technicians



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Retiring Equipment/Disposal





Retiring old equipment

- Policy and procedures for retiring older laboratory equipment.
 - Not functioning and is not repairable
 - outmoded to replaced with new equipment
- Dispose equipment in an appropriate manner.
 - Avoid neglecting in laboratories
 - old equipment accumulates, takes up valuable space and sometimes create hazards.
- When disposing of equipment, salvage any useable parts
 - If the equipment is being replaced with another similar one.
 - consider any potential biohazards, and follow all safety disposal procedures.

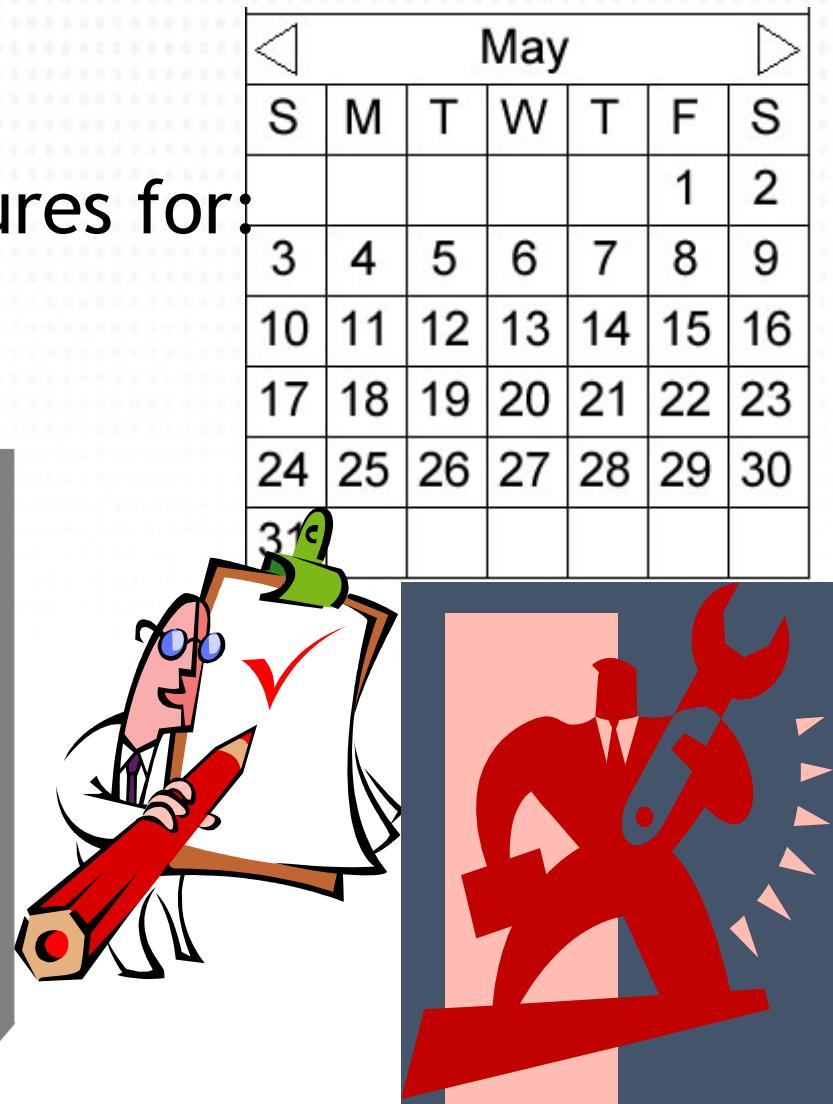


6. Equipment Maintenance documentation

Documents

Develop written procedures for:

- Routine maintenance
 - Function checks
 - Calibration
 - Troubleshooting
 - Manufacturer's service



		May						
S	M	T	W	T	F	S		
							1	2
3	4	5	6	7	8	9		
10	11	12	13	14	15	16		
17	18	19	20	21	22	23		
24	25	26	27	28	29	30		
31								

Dedicated Log Book

Routine maintenance:

- Calibration
- Service repair by manufacturer
- All problems



Function checks



Example of Logbook 1

EQUIPMENT LOGBOOK / EQUIPMENT FOLLOW UP	
Laboratory	
Logbook for	
Establish by	
Date / /	
LOGBOOK FOR	
Equipment identification	
Equipment type	
Trade mark	
Type	
Serial#	
Register record#	
Date first use	
Reseller	
Buying type (new, reconditioned, used)	
Equipment performance	
Specific items when using the equipment	



Example of Logbook 2

Equipment performance	
Specific items when using the equipment	
Documentation available:	
Spare parts available:	
Preventive maintenance activities	
* To be done by end-user	
1/day	
2/week	
1/week	
1/month	
1/3 months	
1/6 months	
* To be done by external assistance (Factory / nature / periodicity)	
 / /
	/

Example of Logbook 3

LOGBOOK FOR	
(Note here all interventions performed on the equipment during preventive or curative maintenance)	
Date / operator	Intervention



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Assessment

1. What considerations should be put in place before acquiring equipment
2. Who is responsible for equipment in the laboratory
3. What measures should be in place to ascertain optimal equipment function



Summary

- An equipment management program will address:
 - equipment selection
 - preventive maintenance
 - procedures for troubleshooting and repair
- Documents and records will include:
 - inventory of all laboratory equipment
 - Information provided by the manufacturer on operation, maintenance, and troubleshooting
 - records of all preventive maintenance and repair activities

Key Messages

A well-organized equipment maintenance program provides:

- High level of performance and greater confidence in the reliability of results.
- Fewer interruptions in test performance, lower repair costs, and elimination of premature replacement of equipment.
- Increased safety for laboratory workers will result from well-maintained equipment.

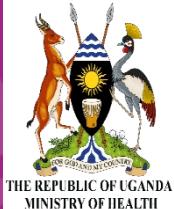
**A major part of equipment maintenance is
PREVENTIVE maintenance**



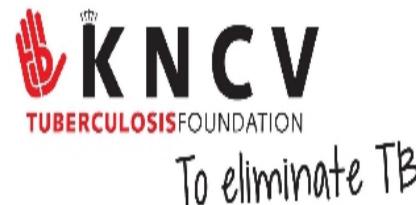
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References

- ~ ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence
« Clause 5.3.1.1 - 5.3.1.7 »
- ~ CLSI
- ~ ASLM



Acknowledgement



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