

# **Division of Blood Transfusion Services**

**Ministry of Health and Family Welfare**



# Equipment Management & Calibration



# Learning Objectives

- To know the importance of equipment management program
- To be able to select, procure, install and maintain the lab equipment
- Proper maintenance of equipment records
- Proper equipment disposal & condemnation



# Importance of Equipment Management Program

- Maintain a high level of performance
- Lengthen life of equipment
- Reduce interruption of services due to breakdowns and failures
- Improve customer satisfaction
- Improve the technologist's confidence and knowledge



# Equipment Management

- Need assessment
- Selection
- Procurement
- Installation
- Calibration / Validation
- Maintenance
- Troubleshooting
- Service and repair
- Retiring equipment / disposition



# Need Assessment

- Blood centre has requisite equipment as per their scope of activities/ services
  - Example – BCSU, Storage Center
- Should have policies, processes and procedures for:
  - Assessment of present needs
  - Assessment of future needs

# Selecting an Equipment

- Platform & test methods.
- Physical space and electrical requirements.
- Back up method.
- Quality control requirements.
- Cost of operation.
- Ease of operation.



# Selecting an equipment

- LIS/HIS interfacing.
- Training requirements and cost.
- Vendor assistance and validation.
- Maintenance and service agreements.
- Mean time between failures.
- Sensitivity and Specificity.
- Facility needs and resources.





# Selection Criteria

- Use co-efficient index
- Performance characteristics
  - Accuracy / precision / sensitivity / specificity
- Facility requirements
  - Electrical, drains, plumbing
- Cost
- Supply of reagents
- Ease of operation
- Warranty
- Availability of manufacturer technical support
- Service Contracts



# Utilization Index

- **Utilization Index**

- Parameter to assess productivity of service of an equipment

- **Use Co-efficient Index**

- $N / M \times 100$
- N = average number of hours the equipment is used / day
- M = Maximum number of hours the equipment can be used per day
- < 50% considered to be under utilized

# Selection & Validation of Equipment

- Blood bank/ Blood centre has a policy for selection, procurement and installation
  - Design qualification
  - Installation qualification
  - Operational qualification
  - Performance qualification
  
- Blood centre should have a policy and procedure for calibration and validation of equipment to achieve the required performance that complies with standards.
  - What is calibration?
  - What is validation?



# Validation

- WHO defines validation as the action (or process) of proving that the procedure, process, system, equipment , or method used works as expected and achieve the intended result. (WHO-BS/95.1793)

## Components of validation

- Quality control
- Proficiency testing
- Validation of employee competency
- Instrument calibration
- Correlation with clinical findings



# Design Qualifications (DQ)

Documented verification that the design (specifications) of the equipment and its components is adequate for your requirements



# Equipment Specifications

- Description of a set of requirements to be satisfied by a product, material, or process
- Specifications are often in the form of written descriptions, drawings, professional standards, and other descriptive references.



# Specification Documents

- Specification documents define how the equipment or system should be installed and operate, & how the equipment or system should perform during regular use in its normal operating environment.
- The wide variety of specifications required to clearly define the installation, operation and performance are most often grouped into the following specifications;
  - Design Specification,
  - Functional Specification &
  - User Requirement Specification.
- Each of these documents provides the foundation to support validation protocols.



# Procurement and Reception of Equipment

- At time of delivery the equipment is inspected as per specifications given in the supply order by the user department.
- On satisfactory receipt, installation and commissioning of the equipment a certificate to that effect is given by user department.
- The operational manual is available to the User department.



# Installation Qualification (IQ)

Installation qualification demonstrates that the equipment is properly installed in environmental conditions that meet the manufacturer's specifications



# Installation

## ■ Prior to installation:

- Verify physical requirements have been met
- Safety checks, electrical, space, ventilation, water supply, ambient temperature, etc.
- Confirm responsibility for installation

## ■ Upon receipt:

- Verify package contents
  - Do not attempt to use prior to proper installation
- If required, ensure the equipment is installed by the manufacturer



# Installation Qualification (IQ) – (contd...)

- IQ testing and documentation typically includes:
  - verification of the manufacturer
  - model no.
  - equipment no.
  - equipment calibration status,
  - equipment SOP verification &
  - verification of critical installation parameters e.g. equipment location,
  - major components and utilities

## Installation Qualification

<b>Instrument Type :</b>	<b>Manufacturers Name:</b>	
<b>Model Name:</b>	<b>Supplier Name:</b>	
<b>Installation report</b>		
<b>Name of the Customer:</b>	<b>Instrument Type:</b>	
<b>Model No.:</b>	<b>Serial Number:</b>	
<b>Date of Receipt:</b>	<b>Date of Installation:</b>	
Power check		
Power supply		
Plug Top		
Earth voltage		
Environmental Parameters		
Parameter	Working Range	Site condition
Physical Check of Equipment:		
Check for damage	Checked	No damage found
Visual and functional inspection	Checked	OK
No damage on internal assembly	Checked	No damage found
System configuration check:		
Positioning of Equipment on flat stable surface	Checked	Found OK
Adequate space around the equipment	Checked	Found OK
Interference to other equipments	Checked	No interference
Results:		
Installed the equipment satisfactorily and is ready for operational verification		
Installed By:	Checked By:	
Signature:	Signature:	
Date:	Date:	

# Installation (contd...)

## ■ After installation

- Establish inventory record
- Define conditions
- Develop and implement protocols for calibration, performance verification, and operating procedures
- Establish maintenance program
- Provide training for all operators



# Labeling of Equipment

- Blood centre maintains labels on each equipment with the following details:
  - Identification (YY – lab code- 0001, 2011-IH-012)
  - Serial number / Model number
  - Date of last calibration
  - Due date of calibration
  - Contact details of the service engineer



## Example: Equipment label

# DF-3

**Deep Freezer (-40°C)**

**Make :**

**Model:**

**Serial No.**

**Date of Installation :**

**File No. in Office :**

**Purpose: Quarantine Storage for Plasma Components**

**Name of Hospital**  
**Calibration/Service Tag**

Equipment DTM No. \_\_\_\_\_

Serial No. \_\_\_\_\_

**Calibration/Service**

Done On \_\_\_\_\_

Due Date \_\_\_\_\_

**Name & Signature of Service Eng.**

Contact No. \_\_\_\_\_

## **Alarms available in the equipment**

	Audio	Visual
Power failure		
High Temperature		
Low Temperature		
Door Ajar		

# Equipment Record, Unique Identification

- Blood centre maintains records for each equipment for life span or for any time period required by regulations and may include:
  - Identification
  - Manufacturer's name, type, serial no./ other unique id
  - Manufacturer's contact person and telephone number
  - Date of receiving and date of putting into a service
  - Current location, where appropriate
  - Condition when received (new, used or reconditioned)
  - Manufacturer's instructions,
  - Equipment performance records that confirm the equipment suitability for use
  - Maintenance carried out and that planned for the future
  - Damage to or malfunction/modification/repair of equipment





# Operational Qualification (OQ)

- An Operational Qualification is a validation protocol that provides documented verification that equipment or a system functions according to written & pre-approved specifications.
- It demonstrates that the installed equipment operates as intended.
- It focuses on the capability of the equipment to operate within the established limits and specifications supplied by the manufacturer.



# Operational Qualification (OQ) (contd...)

- OQ testing and documentation typically includes
  - verification of the Operator Interface,
  - Screen Menus,
  - Alarms,
  - Inputs and Outputs,
  - Print Functions,
  - Eventful & Uneventful Functions

# Operational Qualification

<b>Instrument Type :</b>	<b>Manufacturers Name:</b>
<b>Model Name:</b>	<b>Supplier Name:</b>
<b>Installed on:</b>	<b>Service Engineer:</b>

## Operational verification Report

<b>Name of the Customer</b>	<b>Instrument Type</b>
<b>Model No.</b>	<b>Serial Number</b>
<b>Date of Receipt</b>	<b>Date of Installation</b>

### Operational Check

<b>Parameters</b>	<b>Result</b>

### Results

Operational verification of equipment has been completed satisfactorily and it is ready for performance verification.

<b>Operation performed by:</b>	<b>Checked By:</b>
<b>Signature:</b>	<b>Signature:</b>
<b>Date:</b>	<b>Date:</b>

# Interfacing

- Definition
- Provision of interfacing in all equipments
- Compatible with the transfusion services software.
- each interfacing should be unique and “plug and play”
- Changes in computer system to accommodate automated testing. (compatible software)
- For each equipment specific test should be traceable.
- LIS should be able to identify the results are coming from specific equipments.



# Interfacing...

- LIS/HIS should interpret the results.
  - Individual results should be sent to LIS, interpretation is controlled by laboratory not by vendors.
- Eg weak D testing in patients: equipment may give D+ to weak D, whereas transfusion services may have a protocol to give D negative to patients.
- Validation strategy is affected.



# Type of interface

- **Unidirectional:** Test results are uploaded after completion.
- **Bidirectional:** downloads data on ordered test and after completion uploads the results.
- Middleware may be needed to translate the information sent by equipment to LIS.
- Process flow changes should be monitored when entering data manually.

# Training of User Staff

- All relevant staff are trained on the use of equipment.
- Training should include the following modules:
  - Use & practice of equipment including proper handling of equipment
  - Preventive maintenance and trouble shooting
  - Following instruction manual in day-to-day use of equipment
  - Common and recurrent causes of break-down



# Training of User Staff (contd...)

- Training should include the following modules (contd...)
  - Inspection and routine maintenance
  - Calibration
  - Testing and safety guidelines
  - Basic concepts of physics and electronics as relevant to equipment
  - Documentation of procedures (SOPs)
- Refresher training when new equipment is procured, is provided.





# Performance Qualification (PQ)

- PQ demonstrates that the equipment performs as expected for its intended use in the processes established by the blood center and that the output meets the center's specifications.
- It evaluates the adequacy of equipment for use in a specific process that uses the blood center's personnel, procedures, and supplies in a normal working environment.
- PQ testing and documentation typically includes
  - Verification of the operator training,
  - SOP approval
  - Equipment or system process parameters.



# Performance Qualification

<b>Instrument Type :</b>	<b>Manufacturers Name:</b>
<b>Model Name:</b>	<b>Supplier Name:</b>
<b>Installed on:</b>	<b>Service Engineer:</b>
<b>Placed in service from</b>	

## Performance Verification Report

<b>Name of the Customer:</b>	<b>Instrument Type:</b>
<b>Model No.:</b>	<b>Serial Number:</b>
<b>Date of Receipt:</b>	<b>Date of Installation:</b>

### Performance Check

Parameters	Result

### Results:

**Performance verification of equipment is done. Equipment is validated for routine use.**

<b>Operation performed by:</b>	<b>Checked By:</b>
<b>Signature:</b>	<b>Signature:</b>
<b>Date:</b>	<b>Date:</b>

# Calibration



# Calibration

- A set of operations which establish relationship between values by a measuring equipment and that of a reference standard.
- “Comparison of measurement system with known standards”
- equipment, apparatus and recording devices calibrated and checked under established protocols that specify periodicity.

**Unnoticed volumetric deviations can have a serious effect on the quality of your product**



# Definitions

## Calibration

Comparison of measurements performed by an equipment to those made by a more accurate equipment (standard) for the purpose of detecting, reporting & eliminating errors in measurement

## Monitoring

Continuous observation & measurement of a variable, to check on a given condition.

# Equipment Calibration

- Perform initial calibration
  - Calibrators or standards
  - Follow manufacturer's instructions
- Determine frequency of routine calibrations

<b>Equipment</b>	<b>Performance</b>	<b>Frequency</b>	<b>Frequency of Calibration</b>
<b>Temperature Recorder</b>	Compare against thermometer	Daily	As often as necessary
<b>Refrigerator</b>	-	Daily	Keep printed temp. record
<b>Lab Centrifuge</b>	-	Standardize speed before initial use & after prepare	Record
<b>Blood weighing device</b>	Standardize against container of known weight	Each day of use	As often as necessary
<b>Water Bath</b>	Temp.	Daily	As often as necessary



Equipment	Performance	Frequency	Frequency of Calibration
Auto-Clave	-	Check temp & pressure gauge with each time use	Record
Laboratory Thermometer	-	Each day of use	Before initial use
Electronic Thermometer	-	Monthly	Before initial use
ELISA	-	Run daily 1- Negative & 2- Positive Control	Record

# Program for Calibration and Maintenance of Equipment

- Centre should have established or implemented procedure for calibration and regular monitoring
- Procedure also include program of preventive maintenance which contains recommendations of manufacturers / service report.
- Frequency of calibration of equipments is as per recommendation of manufacturer, or as per prevalent standards.
- Equipment that is used more frequently, should be calibrated more frequently and vice versa.



# Use of Equipment

- There are mechanisms to ensure that the equipment is operated only by authorized personnel
- Instructions for use and daily maintenance of all equipment are available to personnel.
- Equipment used in collection, processing, testing, storage & distribution of blood components are kept in a clean and proper manner and amenable for cleaning, disinfection & maintenance.



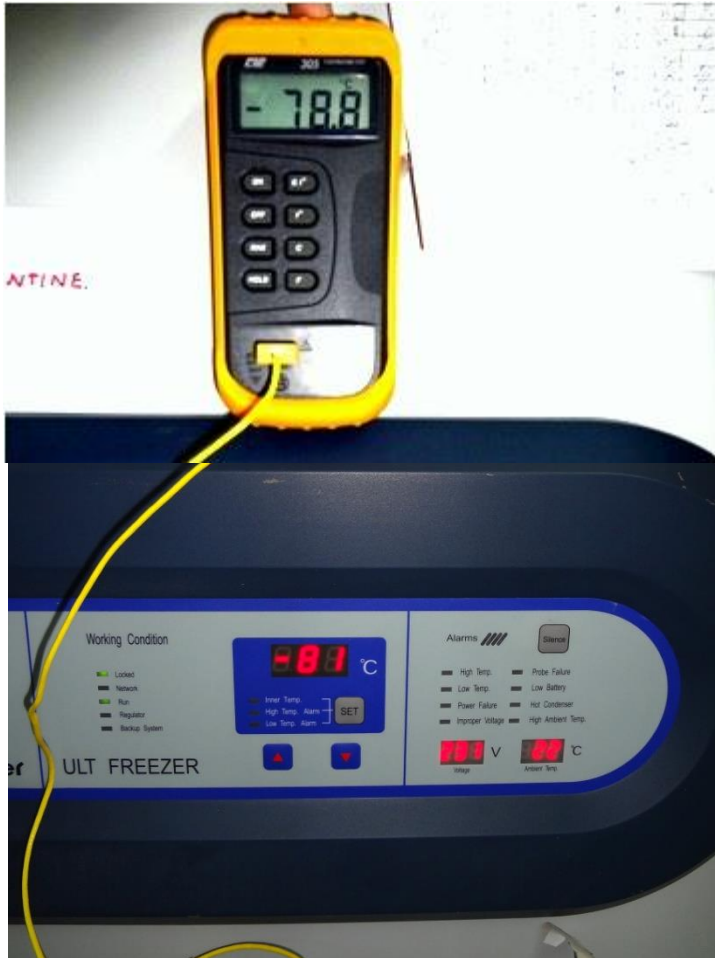
# Quality Evaluation

- A record of incidence of defects and failures in equipment is maintained.
- The response time to reported defects is monitored
- A regular evaluation of performance of equipment (equipment audit) should be carried out with the help of the history sheet of the equipment.

# Implementing a Maintenance Program

- Assign responsibility
- Oversight of all laboratory equipment
- Individual responsibilities
- Develop written policies and procedures
- Train staff
- Keep records

# Calibrated Digital Thermometer for blood storage equipments



# Example: Maintenance and Calibration schedule

## Blood Bank Refrigerator

### **Daily Checks** (Responsibility : Designate staff)

- Temperature display
- Thermograph assembly
- Cleanliness
- Manual recording of temperature three times in a day (9 am, 5pm, 11pm)

### **Weekly Check** (Responsibility : Designate staff)

- Check the internal temperature of refrigerator with external calibrated digital thermometer.
- Check that temperature probe of Refrigerator is properly placed in 10% glycerol solution.
- Check for alarms (Door ajar, Power failure alarm and temperature high and low alarm)
- Change the thermograph or take print out of data logger reading and paste in the log book.
- All the shelves should be cleaned with 10% vol/vol Echosheild( Hydrogen peroxide solution)

### **Six monthly check** (Responsibility : Service engineer)

- Preventive maintenance visit of service engineer.



# Example: **Maintenance and Calibration schedule**

## **Deep freezer**

### **Daily Checks** (Responsibility : Designate staff)

- Temperature display
- Thermograph assembly
- Cleanliness
- Manual recording of temperature three times in a day (9 am, 5pm, 11pm)

### **Weekly Check** (Responsibility : Designate staff)

- Check the internal temperature of Deep freezer with external calibrated digital thermometer.
- Check for alarms (Door ajar, Power failure alarm and temperature high and low alarm)
- Change the thermograph or take print out of data logger reading and paste in the log book.

### **Monthly Check** (Responsibility : SR)

- Deep freezer should be defrosted and all the shelves should be cleaned with 10% vol/vol Echosheild( Hydrogen peroxide solution)
- Check that temperature probe of Deep freezer is properly placed in 100% glycerol solution.

### **Six monthly check** (Responsibility : Service engineer)

- Preventive maintenance visit of service engineer.





# Implementing a Maintenance Program: Documents

- **Develop written procedures for all equipment**
  - Step-by-step instructions for performing maintenance and function checks
  - Include guide for troubleshooting
- **Develop a problem log record for each piece of equipment**
  - Date problem occurred, removed from service
  - Reason for breakdown or failure
  - Corrective action taken
  - Date returned to use
  - Change in maintenance or function checks

# Proforma for repairing of an equipment

<b>Name of the equipment</b>	
<b>Model No.</b>	
<b>Manufacturer</b>	
<b>Date of fault reported</b>	
<b>Description of fault/malfunction</b>	
<b>Date of information to the vendor</b>	
<b>Date of visit by service engineer</b>	
<b>Details of repairs to be done</b>	
<b>Estimate of repairs</b>	
<b>Date of reporting to TEMD</b>	
<b>Repairs done on</b>	
<b>Duration of breakdown of the equipment</b>	
<b>Status of equipment after repairs</b>	
<b>Calibration &amp; Validation</b>	
<b>Remarks</b>	



# Pro forma for History Sheet of the Equipment

<b>Name of the equipment</b>	
<b>Model No.</b>	
<b>Manufacturer</b>	
<b>Name of supplier with contact No.</b>	
<b>Mode of purchase</b>	Hospital supply/NACO/SACS/Other
<b>Cost of equipment</b>	
<b>User manual</b>	
<b>List of accessories</b>	
<b>List of repairs</b>	
<b>Warranty</b>	
<b>AMC</b>	
<b>Date of installation &amp; demo</b>	
<b>Calibration</b>	
<b>Validation</b>	
<b>Operational qualification</b>	
<b>Performance qualification</b>	
<b>Status of the equipment</b>	



# Annual Maintenance Contract

- The Annual Maintenance Contract should include:
  - Regular service and maintenance after the warranty period
  - Warranty with spares
  - Continuous supply of consumables
  - Training of staff to handle the equipment
  - Reliable and prompt after-sale service
  - Suppliers contact details and emergency telephone number is available in Blood Bank.
  - Breakdown time / Uptime / Penalty clause



# Preventive/planned maintenance

- Written procedures exist for planned maintenance of blood bank equipment.
- Warranty of new equipment is for a sufficient time period to test performance of equipment.
- Safeguards for electronic equipment e.g. voltage stabilizer automatic switch over for emergency (generator) are ensured.
- Periodic checks and repairs are done according to guidelines provided in the operational manual.
- A logbook for all critical equipment is kept.



# Preventive Maintenance Schedule of Equipment

<b>Name of the equipment</b>	
<b>Manufacturer &amp; Model No.</b>	
<b>Name of supplier with contact No.</b>	
<b>Name of company to whom AMC given</b>	
<b>Contact person with phone no.</b>	

Visit for AMC on	Status of equipment on visit	Any recommendation	Equipment checked by	Next AMC due on

# Benefits of a Equipment Maintenance Program

- Safety
- Fewer interruptions of work
- Lower repair costs
- Elimination of premature replacement
- Less standby equipment
- Identification of high maintenance cost
- Reduction of variation in test results
- Greater confidence in the reliability of results



# Breakdown of the Equipment

- Blood centre has SOP for replacement/ repairing of defective equipment.
- The defective equipment is labeled and taken out of service.
- Once repaired it should be calibrated before put in use and the procedure is specified in a laid down SOP .
- For equipment which are non-functional a prominent label stating ‘OUT OF ORDER’ is affixed.
- For equipment not in use a prominent label stating ‘CURRENTLY NOT IN USE’ is affixed.
- Blood bank has a back up policy for shifting and storage of blood components in the event of breakdown of equipment.



# Corrective Maintenance

- There is a system for communicating defects in equipment which is known to all staff.
- Written procedures exist for corrective maintenance of all essential blood bank equipment
- Procedures are described for repair of equipment by outside agencies and in house are maintained.
- Records of external repair workshops are kept.
- Response time of the supplier in case of repairs necessary is recorded.



# Condemnation of Equipment

- Procedures for condemnation and disposal of obsolete equipment are laid down.
- Criteria for condemnation and disposal of equipment should be defined, such as:
  - Non-functional and beyond economical repair
  - Non-functional and obsolete
  - Functional but obsolete
  - Functional but hazardous
  - Functional but no-longer required

# Pro forma for Equipment Disposal & Condemnation

Asset Register no.	Identification no.	Serial no.	Equipment	Reason for disposal	Disposal method	Disposal date

# Learning Outcomes

- You should be able to plan an equipment management program at your centre
- Be able to prepare worksheets, proformas etc. for different areas
- Be able to plan and execute the process of procurement, AMC and condemnation

