



**FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA**  
**MINISTRY OF HEALTH**

# **ETHIOPIAN HOSPITAL SERVICES TRANSFORMATION GUIDELINES**

**CHAPTER 15: Medical Equipment Management**  
**Ethiopian Hospital Management Initiative**  
**August, 2017**  
**Version 1.0**





**FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA  
MINISTRY OF HEALTH**

# **ETHIOPIAN HOSPITAL SERVICES TRANSFORMATION GUIDELINES**

## **CHAPTER 15: Medical Equipment Management Ethiopian Hospital Management Initiative**

**Version 1.0  
August, 2017**

## Forward

The earliest modern efforts to improve the quality of government hospitals throughout Ethiopia began in 2006 with the Ethiopia Hospital Management Initiative (EHMI), envisioned by the then Minister of Health, Dr. Tedros Adhannon, and supported by the Clinton Health Access Initiative in collaboration with the Yale Global Health Leadership Institute. The EHMI resulted in the creation of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG), which built on both the Business Process Reengineering (BPR) and Hospital Blueprint efforts, as well as the Masters in Hospital and Healthcare Administration (MHA) degree program. Subsequently, the country developed a hospital performance monitoring system based on achievement of key performance indicators (KPI) and the Ethiopia Hospital Alliance for Quality (EHAQ) to spread best practices and promote collaborative learning in government hospitals nationally. EHAQ has focused on patient satisfaction, labor and delivery management, and provides a national framework for continuous quality improvement in hospitals across Ethiopia.

The Ethiopian Hospital Services Transformation Guidelines (EHSTG) build on and expand the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) and are consistent with the Health Sector Transformation Plan (HSTP). The EHSTG, which is consistent with the national focus on quality improvement in health care, contains a common set of guidelines to help hospital Chief Executive Officers (CEOs), managers, and clinicians (care providers) in steering the consistent implementation of these transformational systems and processes in hospitals throughout the country. The EHSTG focused on selected management and clinical functions, including new individual service specific chapters for Emergency Medical, Outpatient and Inpatient Services, Nursing and Midwifery, Maternal, Neonatal and Child Health and Teaching Hospitals' Management. These guidelines also incorporate recent lessons from the operationalization of the EHRIG, as well as, new national initiatives such as the Guidelines for the Management of Federal Hospitals in Ethiopia, Hospital Development Army (HDA), Clean and Safe Hospital (CASH), and Auditable Pharmaceutical Transaction and Service (APTS).

It is expected that the guidelines will continuously evolve as new evidence emerges regarding improved hospital care and practices that are better tailored to needs and circumstances of different tiers of public hospitals. We are grateful to all partners that have participated in the production of these guidelines. Special thanks go to our colleagues at the Clinton Health Access Initiative for their substantial contributions and support throughout the development of these guidelines as well as their dedicated efforts in support of our health reform efforts in so many other capacities.

Hon. Minister Kesetebirhan Admasu (MD, MPH)  
Minister of Health, Federal Democratic Republic of Ethiopia

## Acknowledgements

The Federal Democratic Republic of Ethiopia Ministry of Health would like to acknowledge the following individuals and their organizations for their participation in technical working groups and contributions in the development of this document.

Mulugeta Mideksa	CHAI
Dr. Frehiwot Woldehanna	AAU-AAIT. CBM
Bereket Endrias	FMOH
Demeru Yeshitila	JPIEGO
Wondafrash Million	FMOH

## Medical Equipment Management chapter proofreaders (Alphabetically listed)

1. Lemlem Degafu      Pharmaceutical and Medical Equipment Management Directorate, FMOH
2. Miraf Tesfaye      Pharmaceutical and Medical Equipment Management Directorate, FMOH
3. Rahe Desta      Pharmaceutical and Medical Equipment Management Directorate, FMOH

## Table of Contents

Forward	II
Acknowledgments	IV
Table of contents	V
List of Tables	VI
List of Figures	VI
List of Boxes	VI
Abbreviations	VII
<b>Section 1</b> Introduction	I
<b>Section 2</b> Operational Standards for Medical Equipment Management	2
<b>Section 3</b> Implementation Guidance	3
3.1 Medical Equipment Management Unit	3
3.2 Medical Equipment Management Committee	5
3.3 Medical Equipment Maintenance Workshop	6
3.4 Medical Equipment Inventory	6
3.4.1 Equipment Risk Classification	10
3.4.2 Spare Parts Inventory	11
3.5 Equipment History File	12
3.6 Model Medical Equipment List	12
3.7 Medical Equipment Development Plan	13
3.8 Accusation /Procurement of Medical Equipment	14
3.9 Equipment Donation	15
3.10 Preparing for Equipment Delivery and Commissioning	16
3.11 Acceptance Testing and Installation	18
3.12 Standard Operating Procedures	21
3.13 Calibration, Inspection, Testing and Maintenance	21
3.14 Disposal of Medical Equipment	28
3.15 Training in equipment use and maintenance	28
3.16 Budgeting for Medical Equipment Management	32
3.16.1 Budget Submission	34
3.17 Medical Equipment Incident Reporting	35
<b>Section 4</b> Implementation Checklist and Indicators	35
4.1 Assessment Tool for Operational Standards	35
4.2 Implementation Checklist	35
4.3 Indicators	37

<b>Source Documents</b>	39
-------------------------	----

<b>Appendices</b>	42
-------------------	----

Appendix A	Sample Inventory Data Collection Form	42
Appendix B	Typical Equipment Lifespan	44
Appendix C	Sample Medical Equipment Risk Assessment Form	49
Appendix D	Sample Bin Record Card for Spare Parts	53
Appendix E	Sample Stock Record Card for Spare Parts	54
Appendix F	Common Site Preparation Steps for Installation of Medical Equipment	55
Appendix G	Guidance for Unpacking and Inspecting Equipment Orders	57
Appendix H	Sample Acceptance Test Log Sheet	59
Appendix I	Sample Planned Preventive Maintenance Log Sheet	70
Appendix J	Good Practice Checklist for Corrective Maintenance	71
Appendix K	Sample Corrective Maintenance Report	75
Appendix L	Sample Work Order Form	76
Appendix M	Sample User Training Verification Form	78
Appendix N	Principles behind Replacement Cost Calculation	79
Appendix O	Biomedical Equipment Maintenance workshop layout For General and Referral Hospital	80

**Tables**

Table 1	Sample Template for Equipment Development Plan	14
Table 2	Steps to Develop an Equipment Training Plan	30
Table 3	Medical Equipment Management Checklist	36
Table 4	Medical Equipment Management Indicators	37

**Figures**

Figure 1	The Medical Equipment Management Cycle	2
Figure 2	The Hidden Costs of Medical Equipment Management	33

**Boxes**

Box A	Definition of Medical Equipment	8
-------	---------------------------------	---



## Abbreviations

AAMI	American Advanced Medical Instruments
ACCE	American College of Clinical Engineering
BME	Biomedical Engineer
BMES	Biomedical Engineering Service
BMET	Biomedical Equipment Technologist
BMT	Biomedical Equipment Technician (level 4 & 5)
CEO	Chief Executive Officer
CHAI	Clinton Health Access Initiative
CMMS	Computer Maintenance Management System
EDP	Equipment Development Plan
FAMU	Fixed Asset Management Unit
FMOH	Federal Ministry of Health
HT	Healthcare Technology
HTA	Healthcare Technology Assessment
HTM	Healthcare Technology Management
LIS	Lab Information System
MEC	Medical Equipment Committee
MEMU	Medical Equipment Management Unit
MSGD	Medical Service General Directorate
NGO	Non-Government Organization
PACS	Picture Archive Communication System
PHID	Public Health Infrastructure Directorate
PPM	Planned Preventive Maintenance
RHB	Regional Health Bureau
RIS	Radiography Information System
SOP	Standard Operating Procedure
TA	Technical Advisor
TOR	Terms of Reference
WHO	World Health Organization

## Section.I Introduction

There is a recognition that health technology management, including medical equipment, is among areas included in the Healthcare Sector Transformation plan (HSTP) for the next 5 years (2015/16-2019/20(2008-2012 EFY)). Specific areas that require improvement in the coming years include the development of local innovative healthcare technologies through technology transfer and increased local production capabilities.

In Ethiopia, lack of proper management of medical equipment has limited the capacity of health institutions to deliver adequate health care. It is estimated that only 72% of medical equipment found in Addis Ababa public hospitals are functional and in some hospitals in the regions functional equipment are near to 50%.

The rising number of these non-functional equipment are due to Poor equipment handling and utilization, frequent power surges, the age of the equipment, lack of operator training, lack of preventive maintenance, lack of spare parts, lack of maintenance capacity, and minimal knowledge regarding sophisticated equipment.

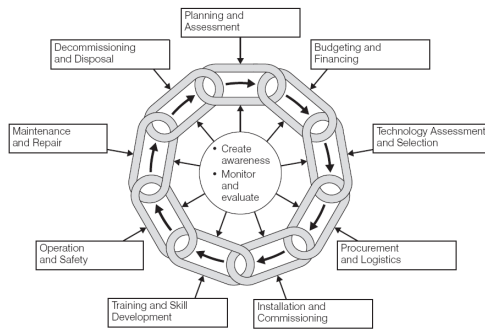
As healthcare delivery continues to expand and improve in Ethiopia, and an increasing number of sophisticated medical equipment is introduced, a system capable of supporting and managing these medical technology must be in place. It is very crucial to implement Medical Equipment Management in the hospitals to manage and coordinate the medical equipment management cycle which includes planning and assessment of needs, procurement, training, operation, maintenance, decommissioning and disposal.

To realize this medical Equipment management in all public hospitals, FMOH introduced the previous Medical Equipment Management Guideline and has tried to implement in some hospitals. Although due to different reasons the implementation was not as it was expected, the introduction of the guideline has created a good understanding on the importance of Medical Equipment management for hospital managers and professionals. To enhance the implementation of the Medical Equipment management chapter and

to include the components of HSTP agendas the revision of the previous document became important.

This chapter outlines procedures that hospitals should undertake to appropriately manage their medical equipment, allowing for the extension of services while ensuring the safety of its patients.

**Figure 1.** The Medical Equipment Management Cycle



Source: Bird, Caroline, et al. 'How to Manage' Series for Healthcare Technology, Guide 1: How to Organize a System of Healthcare Technology Management. Hertfordshire, UK: TALC, 2005.

## Section 2 Operational Standards for Medical Equipment Management

The Hospital has in-house biomedical Engineering department or directorate or unit to oversee the entire Medical Equipment Management system that has operational plan as well as a necessary structure and staff

1. The hospital has appropriate medical equipment maintenance workshop as per the national standard, proper calibration, maintenance and measuring tools in adequate manner.
2. The Hospital has a Medical Equipment Management Advisory Committee from multi-disciplinary team to update the hospital's core Medical equipment list and make decision on disposal of Medical equipment as well as to share ownership
3. The Hospital has computer-based or automated inventory

management system that tracks all equipment and spare parts included in the equipment management program.

4. An Equipment History File is maintained for all medical equipment containing all key documents.
5. Equipment acquisition is carried out after proper planning and need assessments including technical specifications development, procurement and pre-installation inspection/ proper site readiness assessment.
6. All new equipment are installed and commissioned in accordance with the manufacturer's specifications and undergoes acceptance testing prior to its initial use to ensure the equipment is in good operating condition.
7. There is a schedule for inspection, testing and preventive maintenance for each piece of equipment as per the service manual and that schedule is appropriately implemented on daily, weekly and monthly basis.
8. All equipment operators and personnel are trained and re-trained on proper application, safety, and maintenance of medical equipment.
9. There is a notification and work order system for corrective maintenance and calibration of medical equipment based on their risk level.
10. The hospital ensures decommissioning including relocation, uses as spare, donation or safe discarding. Proper disposal of medical equipment is carried out according to international, national and regional legislations.

## Section 3 Implementation Guidance

### 3.1 Medical Equipment Management Unit

Each hospital should establish a Medical Equipment Management Unit / MEMU/that is appropriately staffed and led by trained biomedical personnel, with the following activities;

- The hospital should have a Medical Equipment Maintenance workshop separately from the General Maintenance Workshop equipped with the necessary testing, calibration, measuring instruments, maintenance

tools, personal protective equipment, computer, printers, reference books, operator and service manuals, and internet access needed to carry out the overall medical equipment management services

- Establish and maintain paper or computer based medical equipment inventory
- Develop and maintain Equipment History Files for all equipment
- Establish SOPs for equipment use, safety, PPM and troubleshooting procedures
- Establish PPM schedules
- Conduct in house medical equipment maintenance and manage outsource medical equipment maintenance when necessary
- Conduct acceptance testing and installation of new equipment
- The unit Perform Medical Equipment after sales contract management based on the suppliers procurement agreement
- Provide staff in-service training on the correct and safe use of equipment and basic troubleshooting and preventive maintenance measures
- Track equipment inventory, service history and work orders
- The unit ensures the hospital allocates sufficient funds for regular and incident based maintenance budget, including spare parts.
- The unit develops and maintains a written procedure describing the processes for managing risk, improving safety and quality of technologies.
- The unit establishes automated and centralized documentation system that tracks all equipment and spare parts for planning, budgeting, requisition, reporting and other purposes.
- The unit participates on equipment planning, purchase, installation, maintenance, troubleshooting, and technical support.
- The unit works towards national and international service accreditations.

The number and skill mix of staff within the medical Equipment Management Unit will depend on the size of the hospital. Larger hospitals should employ skilled biomedical Engineers and technicians who are able to undertake corrective maintenance on both small, larger and more complex equipment. However, for smaller hospitals it may be more cost effective to perform

simple preventive and corrective maintenance and sophisticated or more complex equipment should be linked with the referral system to get support from the next high level hospital Medical equipment Management unit or outsource larger and more complex maintenance work to an external company if needed.

A well-balanced mix of in-house and external service providers is technically and financially sound, particularly in settings with limited resources. Even the smallest biomedical maintenance departments should oversee the condition and operation of all medical equipment, be the contact point for all equipment and maintenance matters, be responsible for finding the correct solution (calling in technical support from external service providers) and possibly undertake PPM and repair themselves (if properly trained).

The Head of Medical Equipment management unit should be a member of the Hospital management, participate in the overall hospital planning and evaluation of the hospital performance and also conduct weekly work-planning meetings of MEMU to assess, prioritize and assign outstanding jobs based on the Work Order File.

### **3.2 Medical Equipment Management Committee**

Each hospital should establish a Medical Equipment Committee (MEC) that advises the management of medical equipment in the facility. The MEC is chaired by the medical director of the hospital and the head of medical equipment management unit should be the secretary. Depending on the equipment being discussed by the MEC, specialists from the associated department/case team may also participate on an ad hoc. The MEC should be composed of the hospital medical director and representative of nurses, pharmacists, administrative, laboratory and biomedical personnel. The selection of members of the MEC should be a clear and transparent process. The Committee should establish Terms of Reference (TOR) that clearly outline the roles and responsibilities of the committee members and should meet on a regular basis as defined in the TOR and as-needed in emergency situations.

The MEC is responsible to:

- a. oversee establishment of a medical equipment inventory
- b. develop a model medical equipment list
- c. monitor the implementation of policies, standards and guidelines for:
  - i.Planning and procurement of medical equipment
  - ii.donation of medical equipment
  - iii.Disposal of medical equipment
  - iv.Review incident reports related to medical equipment

### **3.3 Medical Equipment Maintenance Workshop**

#### **Medical Equipment Maintenance Workshop**

Hospitals should establish a medical equipment maintenance workshop based on their level (see the Appendix O Workshop Minimum standard layout) that consists of the following:

Maintenance workshop including space for:

- Administration offices
- Electrical/Electronic Work Area
- Biomechanical Work Area
- Test , Measuring equipment, Tools, Spare parts, and Personal Protective Devices Store
- Staff Training Room

### **3.4 Medical Equipment Inventory**

An inventory of Medical device is a detailed itemized list of medical equipment held by the hospital and:-

- Must be continually maintained and updated to reflect the current status of each Medical equipment
- Depending on the level of the hospital and its Medical equipment, different details are tracked and updated as changes occur
- Medical equipment inventory is a list of the technology on hand, including details of the type and quantity of equipment and the current operating status

- Accessories, consumables and spare parts inventories are directly correlated with the main medical equipment inventory

Data included in Hospital medical equipment inventory are:-

- Inventory identification number
- Type of equipment/item
- Brief description of item
- Manufacturer
- Model/part number
- Serial number
- Power requirement
- Physical location within facility
- Condition/operating status
- Operation/service requirements
- Date inventory updated
- Maintenance service provider
- Purchase supplier
- Year of Manufacturing and purchased
- Equipment risk classification
- Estimated life span
- Availability of trained user and technicians
- Other information as needed

Before establishing a medical equipment inventory the MEC/MEMU should determine which items should and should not be included in the inventory and medical equipment management program based on standard inclusion and exclusion criteria. This should be based on the definition of medical equipment that is presented in Box A. However, the MEC/MEMU may decide to exclude smaller, less expensive and easily replaceable items from the medical equipment inventory and program (for example sphygmomanometers, stethoscopes, etc.) since the effort required to record, maintain and repair these smaller items may not be worth the required manpower and financial resources. The Medical Equipment Strategy should



give a clear definition of medical equipment that should be included in the medical equipment inventory and program, and should also state exclusion criteria for items that should not be included.

**Box A Definition of Medical Equipment**

Medical equipment can be defined as “any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is used for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means.”

**Source:** *GHTF/SG1/N29R16:2005, Global Harmonization Task Force, 2005*

Each hospital should establish an inventory of all medical equipment following the inclusion and exclusion criteria described in the Medical Equipment guidelines. A small team should be established to set up the initial inventory of medical equipment. The team should be led by the Head of Medical Equipment management unit who is ultimately responsible to establish and maintain the equipment inventory. Additional equipment maintenance personnel or other staff assigned by hospital management should also form part of the inventory team. Additionally, one or more department/case team representatives should participate in the inventory of their respective department/case team.

The inventory team is responsible to visit every department and record every item of medical equipment. A sample Inventory Data Collection Form is presented in Appendix A.

Items that are obsolete, that cannot be repaired or that are not of use to the hospital should be removed and transferred to a storage area at the time of the inventory and the formal disposal process should be started. An inventory code number should be assigned to each piece of equipment. This can be done sequentially from number 1 upwards. Each new item is assigned the next number, with no regard to type of equipment, location etc. Alternatively, a 'speaking numbers' inventory system can be used. This system indicates the location, the type of equipment and the individual number of the equipment. With a 'speaking number' system each room/department in the hospital is assigned a location code and each type of equipment is assigned an equipment type code – for example "T1 99 02" where T1 is Theatre number 1 in the operating suite, 99 indicates the item is suction pump and 02 is the individual number of machine.

Although the 'speaking numbers' inventory system is more complex to establish, it has the advantage that it is easy to identify the location of each item and to organise the equipment inventory by each department. An inventory database should be established to record and manage all items of equipment. This can be paper based or computerized, with paper back up. The following should be documented in the Inventory for each item of equipment:

Information gathered as part of the inventory of medical equipment should be included in the overall fixed asset inventory of the hospital. Further guidance on the fixed asset inventory process is provided in Chapter 18 Health Financing and Asset Management

The inventory should be reviewed and checked annually, with regular updates during the year when new equipment arrives or is removed from service. Additional inventory checks may be conducted at regular time intervals throughout the year, as determined by the MEC and hospital management. When an item is discarded it should be removed from the Inventory Database. A record should be kept in a separate file of all discarded equipment for future reference and audit purposes.

All equipment should be labelled with its inventory number preferably using a water proof PVC sticker.

Hospital policy should prohibit use of medical equipment without inventory tags/stickers. This is to ensure that all equipment in use has undergone 'acceptance testing' and receives regular preventive maintenance, hence minimizing risks to patients and staff from faulty equipment.

### **3.4.1 Equipment Risk Classification**

As part of establishing an inventory an assessment should be undertaken to classify each item of equipment as 'high', 'medium' or 'low' risk. This level of risk determines the priority with which equipment should be repaired and maintained or replaced if no longer operable. For example if a 'high risk' item (such as an anaesthesia machine) is broken this should generally be repaired before a 'low risk' item even if the 'low risk' item has been broken for longer, except under special circumstances.

Additionally, when implementing the guidance in this chapter (such as developing standard operating procedures (SOPs), setting maintenance schedules, training staff in equipment use etc.) the 'high risk' items should be dealt with first.

The assessment of risk should be done based on:

- Function of the equipment: For example whether the equipment is used for life support, routine treatment, diagnosis or monitoring
- Risk which may associated with equipment failure
- Preventive maintenance requirements: The frequency with which preventive maintenance is required to minimize breakdown and ensure safety
- Main area of equipment use: For example use in anaesthesia or surgical areas, use in general care areas etc.
- Likelihood of equipment failure: This is measured as the 'mean time between failures' calculated from previous use or service records

Appendix C presents a Sample Medical Equipment Risk Assessment Form for assigning the risk category to medical equipment.

A Medical Equipment Risk Assessment Form should be completed for all items in the equipment inventory. The risk category should be entered on the Inventory Index Card, and the Risk Assessment Form should be filed in the Equipment History File (see Section 3.5 below). Any new item of equipment should be assigned a 'risk category' when it is received by the hospital and entered into the inventory.

### **3.4.2 Spare Parts Inventory**

The equipment maintenance department should maintain a stock of the most commonly replaceable spare parts for the different types of equipment in the hospital. Items should be kept in a locked room with a stock control system in place. Spare parts should be stored according to manufacturer's instructions and should not be used beyond the expiration date.

The inventory of spare parts should be managed using a 'stock and bin card' system.

#### **Bin Card**

A Bin Card should be prepared for each spare part stored in the maintenance department. The Bin Card should be kept with the product inside the store. All transactions of the product to or from the store should be recorded on the Bin Card. The Bin Card should also include a column for the loss/adjustment of stock and a column for the stock balance. The stock balance should be updated after each and every transaction or adjustment.

#### **Stock Card**

The Stock Card is similar to the Bin Card but is used to track stock based on issuing and receiving orders. The Stock Card should be maintained by the Head of the Maintenance Department. Whenever Stock Cards are updated the totals should be checked against those on the Bin Card and any discrepancies should be investigated.

A combined Bin/Stock Card System provides a measure of internal control

that helps to minimize leakages of stock due to theft or loss.

Paper based or electronic Stock Cards can be used. If an electronic system is installed, there should be regular back up of data.

Sample Bin and Stock Record Cards are presented in Appendices D and E.

### 3.5 Equipment History File

An individual file/folder should be established for each item of equipment. This file should be held in the equipment maintenance department. The file should contain:

- Inventory Data Collection Form (Appendix A)
- The address of the manufacturer
- The address of the supplier and local agents
- Details of any maintenance contract and maintenance contractor (if relevant)
- Copy of warranty (if relevant)
- Price paid/Copy of invoice
- List of consumables required to run machine and recommended spare parts
- Acceptance test log sheet (Appendix H)
- Medical Equipment Risk Assessment Form (Appendix C)
- SOPs for operation and maintenance of the item
- Planned preventive maintenance schedule
- Corrective maintenance reports (Appendix K)

Operator, service and other relevant manuals for all equipment items should be stored in the workshop library. Copies should be made and distributed to users and other interested parties as necessary.

### 3.6 Model Medical Equipment List

Each hospital should establish a model medical equipment list that describes the 'ideal' number and types of equipment required by the hospital. A multi-disciplinary team brought together from across all the departments/case teams should develop an outline of the Essential Service Package for

the hospital that describes the core functions and services provided. This Essential Service Package will determine the corresponding Model Equipment List of all items that are necessary to provide each service. Each discipline will decide the type of equipment required to provide the healthcare interventions described in the Essential Service Package. National standards for medical equipment for each type of service or hospital (Primary, General and Specialized), where these exist, should be the minimum requirements of the Model Equipment List, but these may be expanded upon as determined by the multi-disciplinary team.

The Model Medical Equipment List should be approved by the MEC.

### **3.7 Medical Equipment Development Plan**

The Equipment Development Plan (EDP) is a plan to define goals for acquisition, maintenance, and replacement of equipment in the short term and long term. The equipment development plan should be developed taking into consideration the current equipment inventory and the 'model equipment list'.

The medical equipment development plan (EDP) brings attention to:

- Current stock and condition of equipment: which pieces need to be replaced or rehabilitated, which pieces need to be disposed
- Shortfalls in equipment: missing equipment that needs to be purchased
- What action is needed to rehabilitate, replace or purchase equipment
- Short-term (1 year) and long-term (2-5 year) goals to ensure that the hospital has all necessary equipment for current and future services

The EDP should be developed by the MEMU and approved by hospital management. The plan is the basis for the annual equipment budget. The Head of Equipment Management Unit is responsible to implement the plan, with the assistance of other departments where relevant (for example administration and finance). He/she should present quarterly reports to the hospital management on the status of implementation of the MEMU plan. The plan should be updated annually. A sample template for an EDP is presented in Table 1 below.

Table 1 Sample Template for Equipment Acquisition Plan					
Department/Room:					
Equipment	Condition	Short Term Action	Short term cost estimate	Longer Term Action	Long term cost estimates
(type and inventory number)	For example age and expected life; working condition (good, fair, poor, needs repair, damaged beyond repair, obsolete)	(1 year)  For example: repair needed; replacement needed; user training needed; first time purchase needed		(2-5 years)  For example: replacement needed; first time purchase needed	
A. Existing equipment					
a. b. c. etc.					
B. Additional equipment required (based on Model Equipment List)					
a. b. c. etc.					

3.8 Accusation /Procurement of Medical Equipment

The accusation / procurement of medical equipment should be undertaken in accordance with the Ethiopian government/ MOFED/BOFAD directives. Medical Equipment may inter in to the hospital through one of the following means.

1. Purchasing
2. Donation
3. Leasing and Renting
4. Cluster based equipment sharing

- In Medical equipment Procurement process the following steps should be considered.
- Need assessments and Justifications
- Planning and Budgeting
- Technology Assessment, preparation of technical specification and Selection
- Cost of ownership( Maintenance, Spare part, consumable etc)
- After sale services
- Human resource
- Procurement

When purchasing new equipment enough spare parts and accessories to last at least 2 years should also be purchased.

Further guidance on the procurement process and development of a procurement policy is presented in Financial and Asset Management Chapter.

### **3.9 Equipment Donation**

The hospital MEMU should strictly follow National Medical Equipment Donation Directive for the receipt of donated medical equipment. The directive describes the conditions under which donated medical equipment will be accepted by the hospital. For example:

- Donated equipment must be in good working order
- Equipment will only be accepted if the item is needed by the hospital and is described in the Model Equipment List and associated annual Equipment management Plan
- Instruction manuals, in English, should be supplied with the donation
- Supplies, consumables and spare parts for the equipment should be readily available in Ethiopia. If that is not possible, at least 1 to 2 years of needed consumables and spare parts should be supplied by the donor



with the donated equipment

- Expertise for the maintenance and repair of the equipment should be available in Ethiopia
- The equipment must be compatible with other medical equipment system in the hospital.
- The equipment must not require any special storage or operating conditions that the hospital cannot provide (for example air conditioning, humidity control etc.)
- The donor should provide training in the regular use and preventive maintenance of the equipment, if relevant, and
- The donor should provide follow up support regarding use of the equipment, where necessary.

When items are donated the hospital and donor must agree who is responsible for customs clearance, including approval of the item by the regulatory authority if necessary.

The MEMU should establish a list of desired equipment that is based on the Model Equipment List and associated Equipment annual Plan. The list of desired items and donation policy should be given to all individuals/organizations that are willing to make a donation to the hospital.

All equipment donations should be reviewed by MEMU and approved by the hospital management before acceptance.

### **3.10 Preparing for Equipment Delivery and Commissioning**

When an order has been placed to purchase a new item of equipment, or a donation has been accepted, preparations must be made for receipt of the item. This is to ensure quick and efficient installation, commissioning, training, and eventually placement into service. Pre-installation work involves the following:

#### **A. Site Preparation**

Site preparation is often required to ensure that the location where the new equipment to be installed is suitable. This may require new connections for

electricity, water, drainage, gas or waste and may even require construction work.

Preliminary considerations to think about include:

- Is there sufficient access to the room/space (door entry sizes, elevator capacity)?
- Is the room/space large enough?
- Is the position and layout of the room/space suitable?
- Are the required work surfaces and service supply points available?
- Is the environment adequate for the purpose? (Is it dust-free? Away from running water? Air conditioned, if necessary?)
- Site preparation tasks may include:
  - Disposing of the existing item that is to be replaced
  - Extending pipelines and supply connections to the site
  - Upgrading the type of supply, such as increasing voltage or pipeline diameters
  - Providing new surfaces, such as laying concrete or providing new worktops
  - Creating the correct installation site, such as digging trenches, building a transformer house or a compressor building

Appendix F presents a list of Common Site Preparation Steps to follow when preparing a site to receive a new piece of equipment.

## **B. Organizing Lifting Equipment**

Large or heavy items will need to be lifted and moved upon arrival. Plans should be made ahead of time to arrange proper lifting/moving equipment before the new equipment arrives.

## **C. Organizing Warehouse Space**

If goods need to be stored before they can be unpacked or installed, space should be made available for these items before they arrive.

## D. Preparation for Acceptance Testing and Installation

Any preparations that need to be made for acceptance testing and installation, including ensuring that appropriately trained personnel to do the testing are available, gathering or acquiring materials, working/storage space and/or test instruments should be done before the item arrives.

## E. Preparation for User Training

The details of training should already have been decided when drawing up the purchase contract or donation acceptance document. During delivery time, any preparations that need to be made (including preparation of training materials, training space, equipment, etc.) should be finalized in order to ensure training can commence when the equipment is delivered.

### 3.11 Acceptance Testing and Installation

- i. All medical equipment, purchased or donated, should be inspected upon delivery and tested prior to initial use. This is known as acceptance testing and ensures that delivered medical equipment is complete, undamaged, in good operating condition, accompanied by manuals and spare parts, satisfies safety criteria, and meets specifications of the purchase order. A competent individual must assess the functionality of the equipment to prevent any harm to the operator or patient upon use. Guidance for unpacking and inspecting equipment is presented in Appendix G.

The main steps in the Acceptance Testing process are described below:

Determine what personnel should be involved by asking the following:

- **How complex is the equipment?** The more complex the device, the more likely the manufacturer will need to be involved.
- **Do the hospital staffs have the necessary technical skills?** If the staff cannot perform the job, then an outside vendor should be contracted.

- **Are you buying a single item or in bulk?** If purchasing in bulk, it is often worthwhile to contract the manufacturer to perform this process on all the equipment. For a single unit, the in-house staff may be able to manage with guidance from the manufacturer.
- ii. Isolate the equipment until it has undergone acceptance testing. Once equipment arrives, set it aside by isolating the equipment in a special holding area and by labelling it as “not for use” to ensure that the equipment will not be used. The only exception is for large items that may be delivered to where they will be installed but should still be clearly marked as “not for use” until the acceptance process is completed.
  - iii. Undertake acceptance testing and complete Acceptance Test Log Sheet (see Appendix H)
 

Acceptance testing should include:

    - Checking the delivered equipment matches as per the details of the purchasing order (model, vendor, quantity, technical requirements, etc)
    - Checking the equipment is accompanied by operation and service manuals and necessary paperwork (e.g. warranty, if applicable) as per the purchase order.
    - Checking that appropriate spare parts and consumables are included as per the purchase order
    - Installation and commissioning of the equipment. Installation is the process of fixing the equipment into place. Depending on the complexity of the equipment, this can range from simply plugging the equipment into an electrical socket to building it into the fabric of the room. Commissioning is performing a series of tests and adjustments that will check whether the new equipment is functioning correctly and safely, and ensuring that any adjustments are made, before the equipment is accepted.
  - iv. Accept the equipment and Establish Equipment History File

- V.** If the equipment passes the safety, calibration and function tests and commissioned then the hospital can officially accept the equipment. An acceptance Test Log Sheet (Appendix H) should be completed, signed and filed in the Equipment History File.
- Vi.** Enter equipment into the equipment inventory
- Vii.** After the item has undergone acceptance testing and commissioned it should be entered into the hospital inventory. The assigned inventory number should be marked onto the item of equipment
- Viii.** Prepare Standards Operating Procedures and assign Planned Preventive Maintenance Schedule(see sections 3.12 and 3.13 below)
- ix.** Provide training for equipment users and maintainers as appropriate. This will ideally occur immediately but sometimes, due to availability of trainers (in-house, vendor, other), training may occur at a later date. In this case the MEMU will have to decide if it is safe to hand over the equipment before training the staff. Placing the equipment into operation without training should only be done when the equipment type has been used before and the staffs are familiar with proper operation. Installation and commissioning should be carried out in the presence of the user as well as engineering support team. Demonstration of the device indicating all its functions should be carried out to the satisfaction of the user and biomedical engineering team. Training on operation and maintenance should be included in specifications indicating the type, duration, location (on-site/off-site, local/overseas), target personnel i.e. doctors, nurses, maintenance personnel, since differing types and levels of training needs to be provided for each staff category. User training should be provided by an application specialist, especially training for sophisticated or complex devices.
- x.** Handover equipment to appropriate department/users.
- xi.** Make an order or recommendation for final payment

Final payment should be made after the item has undergone acceptance testing, commissioned and all agreed services (e.g. installation or training) have been provided.

Payment should be pending if the equipment does not pass the acceptance test /not commissioned or the services provided are unsatisfactory as per the procurement agreement. In such circumstances the MEMU must work with the supplier to rectify the situation as quickly as possible.

### 3.12 Standard Operating Procedures

To ensure that equipment is used correctly and safely Standard Operating Procedures (SOPs) should be developed and attached to each item of equipment. The SOP should be a simple 'how-to' guide that describes how to use the equipment, instructions for care of the equipment, and basic safety and troubleshooting procedures. The SOP should be based on the manufacturer's user manual (if available). SOPs should be kept attached or adjacent to the item and a copy should be included in the Equipment History File that is stored in the Medical Equipment Maintenance Department.

All staff, including maintenance technicians, should be trained to follow the SOPs and should follow infection prevention procedures when handling medical equipment. (For further guidance on infection prevention see *Infection Prevention and Patient Safety Chapter*).

### 3.13 Calibration, Inspection, Testing and Maintenance

Medical devices may cause life threatening problem if it is not managed properly. Therefore, it is important to have a well-planned and managed maintenance program to ensure medical equipment are reliable, safe and available all time when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients. In addition, such activities prolong the useful life of the equipment and minimize the repair related cost of equipment.

- Disinfection and sterilization of equipment and tools is required.
- Incident report is performed
- There is a schedule for regular inspection, testing and preventive maintenance for each piece of equipment as per the manufacturer's service manual.
- Corrective maintenance is performed whenever medical equipment

breaks down.

- There is a schedule for calibration of medical equipment (for high risk equipment) as per the manufacturer's service manual.

### **a. Planned Preventative Maintenance**

All medical equipment should be inspected and tested prior to use (acceptance testing) and thereafter should undergo regular planned preventative maintenance (PPM) to ensure that the equipment is working properly and to prolong its expected lifetime. Safety and calibration testing should also be performed regularly to ensure the equipment is safe to use and is operating within expected specifications (or to adjust if it is not).

Preventing equipment failure is more efficient than repairing equipment after breakdown occurs. PPM should be carried out by both equipment users (for simple, easy, everyday tasks) as well as biomedical technicians from the maintenance department (for more complex tasks requiring special skills and/or tools). For some equipment PPM should only be carried out by certified service engineers.

SOPs for each item of equipment should include instructions on simple PPM and troubleshooting that can be performed by users of the item.

For each item of equipment there should be a plan for preventive maintenance, safety and calibration testing that is documented and at a minimum follows manufacturer's recommendations. If the manufacturer's manual is not available then inspection, testing and preventive maintenance should be conducted at a minimum every six months.

The preventive maintenance plan should include:

- A description of and guidelines for the tasks to be conducted including:
  - Care and cleaning
  - Safety procedures
  - Functional and performance checks
  - Calibration testing
  - Preventive maintenance checks
- A statement on who is expected to perform each of the above tasks
- The frequency with which each of the tasks should be conducted

For each item of equipment a timetable/schedule for each of the tasks above should be established together with a log file to document all maintenance activities. The maintenance plan and schedule should be developed collaboratively between the Medical Equipment Maintenance Department and the Head of the Department/Case Team where the item is located. The maintenance plan, schedule and log sheet should be attached or kept adjacent to the equipment item. A copy of the plan and schedule should be kept in the Equipment History File that is held in the Equipment Maintenance Department.

A sample Preventive Maintenance Log Sheet is presented in Appendix I. The Head of the Equipment Maintenance Department should establish a system to check all Maintenance Log Sheets to ensure that all PPM tasks are conducted in accordance with the schedule for each item of equipment, and should address any instances where PPM is not conducted in accordance with the schedule.

### **b. Calibration**

Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analyzers, etc.) also require periodic calibration.

### **c. Safety Inspections**

These are performed to ensure the device is electrically and biomechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to the manufacturer's specifications. The frequency of safety inspections may be different than planned

Maintenance and performance inspections are usually based on regulatory requirements periodic calibration to ensure accuracy compared to known standards.



#### **d. Corrective Maintenance**

Corrective maintenance involves equipment repair and replacement of parts. Instrument operators can follow SOPs to perform simple corrective maintenance such as replacing blown out fuses or simple troubleshooting. However, most corrective maintenance must be performed by a qualified technician. A 'Good Practice Checklist' for corrective maintenance technicians is presented in Appendix J.

Whenever corrective maintenance is performed a Corrective Maintenance Report should be completed and stored in the Equipment History File. A sample Corrective Maintenance Report is presented in Appendix K.

NB: Only engineers that are certified by the supplier can perform corrective maintenance on instruments still under warranty.

If a large piece of equipment requires major rehabilitation an assessment should be done to determine whether it is worthwhile repairing the item or whether it would be better to purchase a new one. Generally, if purchasing separately all the parts that make up a piece of equipment it would cost 3-4 times the price of the equipment. Rehabilitation may be cheaper in the short term, but if this only adds a short additional lifespan to the item or if it is continually necessary to replace different parts, then it may be more cost effective to purchase a new item.

#### **e. Work Orders and Reports**

Whenever an item of equipment is faulty this should be reported immediately to the medical equipment maintenance department using a Service Request/Work Order Form. Requests for maintenance to be undertaken by technicians should also be documented on a Work Order Form. In urgent cases the request for repair can be made by a telephone call or other verbal means of reporting, however this must always be backed up with a written request on the Work Order Form. A sample Work Order Form is presented in Appendix L.

Three copies of the Work Order Form should be prepared (using carbon copy paper):

- The first copy should be kept by the user department and filed in a 'Maintenance Pending File'. This file is best organized by date submitted, with the most recent request at the top. The 'Maintenance Pending File' should be checked regularly by the Head of Department/Case Team to ensure that Work Orders are being carried out in a timely manner. When the work is completed and the item is returned to service the Work Order Form should be signed by the user (Department/Case Team Head or representative) and the Work Order Form should be transferred to a 'Maintenance Completed File'
- The second two copies of the Work Order Form should be submitted to the Equipment Maintenance Department together with the broken item (if it is feasible to move the item). Whenever a Work Order is received by the Equipment Maintenance Department this should be reviewed by the Department Head and the duty should be assigned to the appropriate individual (or outside service provider). The name of the person who is assigned to undertake the repair should be written on both copies of the Work Order Form. In the event that several items required repair at the same time then 'High priority' equipment should be repaired before 'Medium' or 'Low Priority' equipment.
- Within the Equipment Maintenance Department one copy of the Work Order should be entered into a 'Work Order Pending' File held by the Head of Equipment Maintenance. This file is best organized by date submitted, with the most recent request at the top. When the work is completed the Work Order should be transferred to a 'Work Order Completed' File and kept as a permanent record of the work undertaken
- The final copy of the Work Order Form should be given to the responsible medical equipment technician who is assigned to undertake

the repair. Upon completion of the task the final section of the Work Order Form and a Corrective Maintenance Log should be completed. The item should be returned to the user. The completed Work Order Form and Corrective Maintenance Log should be filed together in the Equipment History File,

#### **f. Outsourcing of Technical Services**

When the equipment maintenance department is unable to perform PPM or corrective maintenance of a particular item of equipment, support from external maintenance contractors will be required. Work may be outsourced to the National Scientific Equipment Centre, the manufacturer's local agent, the manufacturer, private maintenance companies, individuals such as electricians or plumbers or the Ethiopian Health and Nutrition Research Institute for laboratory equipment. The Ethiopian Biomedical and Laboratory Equipment Engineers Association could be a good source for finding qualified individuals or companies. Support may also be provided by the relevant Regional Health Bureau.

When making the decision to outsource a service, the hospital must consider the task at hand and the qualifications needed to perform the task. In order to do this, the Medical Equipment Committee should register all potential individuals and companies that they would consider as a supplier of maintenance services. The MEMU should prepare a list of requirements that each company should meet in order to be contracted by the hospital and a team of suitable staff chosen to visit these registered suppliers when possible to ensure that the suppliers meets the requirements and are qualified to provide the services they offer.

Once the appropriate companies or individuals have been identified and registered, the MEMU should determine the type of arrangement they would like to have with the particular organization. The arrangement used depends on the sophistication of the equipment and the number of maintenance options available.

The most common arrangements encountered are:

1. Agents' Maintenance Contracts – typically for sophisticated

equipment that is covered by a warranty for a certain period of time. The contract would be for service post-warranty and negotiated at the time of equipment purchase.

2. Annual Contracts – for particular types or groups of equipment that can be maintained by an external company for a period of one year. A formal tendering process should take place to select the best company to provide these services.
3. Annual Standby Registration – these companies or individuals can be called upon as needed to provide maintenance services for certain equipment although they must submit tenders at the time a job becomes available
4. One-off Jobs – in this case, the expertise needed may not be on the registered list and the MEMU must look for individuals or companies that might be able to undertake this one-time only task.

Having such arrangements allows the hospital to gain from the benefits of bulk purchasing (e.g. one company can cover many different maintenance jobs), gain from the benefit of fixed period contracts; ensure that appropriate contractors are chosen and that the quality of work is high. Therefore, when a repair requiring external support becomes necessary, the Head of the Equipment Maintenance Department can refer to the registered list of companies and/or contracts to outsource the work.

The MEMU should follow national guidelines for the use of outside contractors including:

- Staff from the maintenance department must accompany outside consultants at all times
- Contractor must provide feedback on progress of job
- Contractor must sign-out after each service visit
- Contractor will provide a report at the completion of the service to be placed in the equipment file

Hospitals may also collaborate together to enter joint service contracts in order to minimize costs and benefit from bulk purchasing.

### 3.14 Disposal of Medical Equipment

The hospital should establish Medical Equipment Disposal Committee to oversee the disposal of all medical equipment that are no longer required by the hospital, including medical equipment. Items may be disposed when they are no longer required by the hospital, cannot be repaired, or have reached the end of their useful lifespan (see Appendix B). A policy for the disposal of fixed assets should be established by the hospital and approved by hospital management.

Whenever an item of medical equipment is disposed it should be removed from the hospital inventory and a record should be entered into the Equipment History File to indicate that the item has been disposed. The Equipment History File should then be moved to a separate storage location for 'inactive' equipment items.

Further guidance on the disposal of hospital assets, including medical equipment is presented in Financial and Asset Management Chapter.

### 3.15 Training in Equipment use and Maintenance

Proper use of medical equipment is essential to maintain optimal performance of medical devices and preserve the safety of patients as well as the staff operating the devices. Given the variation in technical characteristics of medical equipment, all clinical staff should be trained to operate each medical device that they use. The MEMU is responsible for overseeing all user training for medical devices, whether in-service or conducted by suppliers/external parties.

Training should be conducted at various times throughout a staff member's career:

- Induction training – when staff are newly placed in post, move to a new department or facility, or to a new location with different responsibilities
- Training at the commissioning of equipment – when new equipment first arrives
- Refresher training – to update and renew skills throughout the working life of staff

Building the capacity of biomedical engineers, technologists, and technicians is

always one of the major activities of the Biomedical Engineering Directorate/case team. This can be realized through regular short-term training programs, Supplier Company's training, and formal credit programs in higher education institutions, local and abroad. All such training programs are accompanied by certifications.

The hospital plans annually at least one-week long in-house refresher training program for its staffs. Participation in such refresher programs is mandatory and is part of the annual performance evaluation.

User training should cover:

- Equipment capabilities
  - Purpose and capabilities of device
  - Awareness of different models and operational differences
  - Awareness of the expected life of medical device and need for replacement
  - Knowledge of where/how to access user manuals and receive equipment updates
- Operating procedures
  - How to assemble the device and connect accessories
  - How to operate the device effectively and safely
  - How to link device to patient safely, causing minimal discomfort to patient
  - How to set/change controls
- Protocol for equipment failure
  - How to recognize malfunction (or correct if possible)
  - Who to contact to report damage and adverse incidents and to do so promptly
- Emergency and safety procedures
  - How to safely shut down/disassemble
  - How to clean/decontaminate device and maintain equipment in good operating condition
  - Basic safety protocol:
    - Always visually inspect equipment before each use.
      - Check for signs of damage or incorrect settings

- Make sure all necessary parts are in place
- Do not use equipment unless properly trained
- Ask senior staff or other trained personnel when in need of assistance
- Maintenance procedures
  - How to perform basic, routine maintenance (if applicable)
  - How to request equipment maintenance (work order)
  - How to keep track of consumables and reorder when necessary

The MEMU should establish an Equipment Training Plan that describes the training needs of hospital staff for the use of medical equipment. Table 2 describes the steps to develop an Equipment Training Plan.

Table 2 Steps to Develop an Equipment Training Plan		
Process		Activity
The MEMU (or its training sub-group):		
Identify existing needs		<div>Refers to:</div> <ul style="list-style-type: none"><li>• Any record the Maintenance Manager made when analyzing the Equipment Inventory that training was required</li><li>• Any prompts, triggers or requests for training reported/submitted</li></ul>
Identify new needs		<div>Study the Equipment Development Plan (EDP) and identify the training required to handle:</div> <ul style="list-style-type: none"><li>• Planned equipment replacements</li><li>• Planned new equipment purchases/donations or additional services</li><li>• Problems with equipment operation, maintenance or management</li></ul>

Determine the range of training that will satisfy the needs	<p>Consider:</p> <ul style="list-style-type: none"> <li>• The eight different areas for equipment-related skill development: basic handling, operation, application, care and cleaning, safety, user PPM, PPM and repair for maintainers, associated skills (procurement, stock control, financial management, etc.)</li> <li>• The three types of training required at different times in the working life of staff (induction, at commissioning and refresher training)</li> </ul>
Determine the source that will provide the needs	<p>Consider:</p> <ul style="list-style-type: none"> <li>• The various sources of training which provide the option for on-the-job or external courses</li> <li>• Any initiatives organized and provided by the central health service provider organization and donor programs</li> </ul>
Prioritize across the needs	Prioritize the short-term and long-term actions
Prepare an overall Equipment Training Plan	Cover all aspects listed above for equipment-related skill development.

Training can be provided either on site or off site. When purchasing new medical equipment, the hospital can request that suppliers provide in-service training for equipment use, maintenance, and repair. The Hospital can also send staff to the manufacturer. The MEMU should assess the quality of the manufacturer's user training to ensure it is practical and provides adequate training for equipment use. The hospital can also send staff to be trained at other facilities where employees are already trained and using the particular item of medical equipment.

The Hospital can hold in-service trainings if it has staff that are professionally trained to operate and repair the specified medical equipment and has other needed resources to conduct the training (see below).

For in-service trainings the hospital should provide:



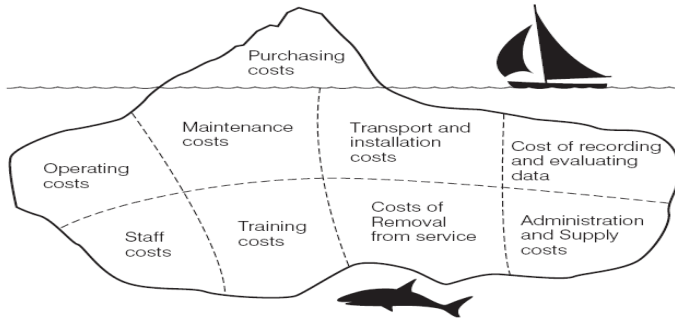
- Trainer (professionally trained expert in use, maintenance, and repair of medical equipment)
- Training materials specific to the piece of medical equipment
- Adequate space to conduct the training
- Sample equipment and supplies to practice/conduct the training
- Test and calibration instruments to test performance and safety
- Spare parts for maintenance training
- User and service manuals
- Formal method of testing and method of certifying trainees (e.g. give exam and issue certificate)

The Human Resource Department and MEMU are responsible for keeping records of all user trainings. Training records should specify the name of the person trained, the trainer, the date of the training, the medical device for which training was conducted, its manufacturer and model. If possible, the content of the training should be appended or briefly described in the user training form. A sample User Training Verification Form is presented in Appendix M

### **3.16 Budgeting for Medical Equipment Management**

To effectively manage all medical equipment careful planning and budgeting is essential. As illustrated in Figure 2 below, there are a variety of costs to medical equipment. It is essential that entirety of costs for all medical equipment existing and planned purchases are considered when planning and budgeting.

Figure 2 The Hidden Costs of Medical Equipment Management



Source: Temple-Bird, C., KaurManjit, LenelAndreas, and WilliKawohl. (2005). *Guide 2: How to Plan and Budget for your Healthcare Technology*. In 'How to Manage' Series for Healthcare Technology. p.58 Hertfordshire, UK: TALC.

The first step in preparing a budget for the management of medical equipment is to determine the value of existing stock. This is known as the 'Stock Value Estimate'. This should indicate the up-to-date replacement cost of all items in the Equipment Inventory. The up-to-date replacement value can be estimated from purchase contracts, supplier information, data from service contracts, manufacturer's websites etc. With the above information it is possible to calculate an annual equipment budget. This should be based on the Equipment Development Plan and should include:

- Replacement costs for current equipment
- Maintenance and repair costs
- Costs for new purchases for expansion of services
- Installation costs of new equipment
- Training costs

#### a. Replacement costs for current equipment

An annual replacement budget covers equipment likely to reach the end of its usefulness by the end of the year. A quick estimate of an annual replacement

budget can be made using the Stock Value Estimate as follows:

Annual replacement budget = Stock Value Estimate/ average lifetime of all equipment

Further guidance on the calculation of replacement costs is presented in Appendix N.

#### **b. Maintenance and repair costs**

As an approximation, maintenance and repair costs for medical equipment are generally between 5-6% of the 'new' stock value. Hence the Stock Value Estimate can also be used to estimate the budget required for maintenance and repair.

#### **c. Costs for new purchases for expansion of services**

The Equipment Development Plan guides the purchase of new equipment for the hospital. The cost of items that are due to be purchased in the Financial Year should be calculated and included in the Medical Equipment Budget.

#### **d. Installation costs of new equipment**

As described above, there may be costs associated with the installation of new items such as renovation, installation of plumbing etc. The equipment development plan should include a description of any installation work that is required. These costs should be estimated and included in the budget.

#### **e. Training costs**

The equipment training plan is the basis for the estimate of training costs associated with medical equipment use and maintenance.

### **3.16.1 Budget Submission**

The equipment management budget that is prepared by the MEMU and MEC should be submitted to the CEO for inclusion in the hospital's annual budget plan. The CEO should allocate items to capital or recurrent budget lines as appropriate.

### 3.17 Medical Equipment Incident Reporting

The hospital should establish a process to report and investigate all critical incidents, including incidents that arise from the use of medical equipment. An Incident Officer should be assigned to investigate all incidents and to ensure that any required follow up action is implemented. Further guidance on Incident Reporting and a sample Incident Report Form are presented in Quality Management & Clinical and Patient Safety Chapter.

## Section 4 Implementation Checklist and Indicators

### 4.1 Assessment Tool for Operational Standards

In order to determine if the Operational Standards for Medical Equipment Management have been met by the hospital an assessment tool has been developed which describes criteria for the attainment of a Standard and a method of assessment. This tool can be used by hospital management or by an external body such as the RHB or FMOH to measure attainment of each Operational Standard. The tool is presented in Appendix E of Chapter 20 Monitoring and Reporting.

### 4.2 Implementation Checklist

The following Table can be used as a tool to record whether the main recommendations outlined above have been implemented by the hospital. The Table does not measure attainment of each Operational Standard but rather provides a checklist to record implementation activities.

**Table 3 Medical Equipment Management Checklist**

		<b>Yes</b>	<b>No</b>
	A Medical Equipment Management Unit has been established		
	Medical Equipment Management unit have workshop that meets the minimum workshop standard lay out		
	Medical Equipment Management unit with an operational plan		
	Medical Equipment Management unit with required staff and led by a Biomedical Engineer/HTM/Clinical Engineer/Senior Biomedical Technician personnel		
	A Medical Equipment Management committee has been established		
	Terms of reference for the Medical Equipment Committee are defined		
	An inventory management system to manage medical equipment has been established		
	An inventory management system to manage spare parts of medical equipment has been established		
	An Equipment History File system has been established		
	There are policies and procedures for medical equipment acquisition		
	There are policies and procedures for medical equipment commissioning and decommissioning		
	There are policies and procedures for medical equipment donations		
	There are policies and procedures for medical equipment disposal		
	There are policies and procedures for outsourcing of medical equipment servicing		
	A maintenance notification and work order system has been established		
	Preventive maintenance of medical equipment is scheduled and conducted		
	Inspection and testing of medical equipment is scheduled and conducted		
	All new equipment undergoes acceptance testing		
	Identify Equipment those need regular Calibration and made calibration as per the manufacturer recommendations		
	Are all newly procured medical equipment under goes contract / Procurement agreement management		

### 4.3 Indicators

In addition, the following indicators may be monitored on a regular basis to assess the effectiveness/outcomes of implementation of the recommendations provided in this chapter.

<i>Table 4 Medical Equipment Management Indicators</i>				
<b>S/N</b>	<b>Indicators</b>	<b>Formula</b>	<b>Fre- quency</b>	<b>Com- ment</b>
	% of medical equipment undergoes inspection, commissioning and entered in to inventory data	Total number of Medical Equipment undergoes Inspection, commissioning and entered in to inventory data / Total Number of Medical entered in to the Hospital	Quarterly	
	Percentage of medical equipment identified on model medical equipment list that is in use at the hospital	Total number of medical equipment identified on model equipment list that is in use at the hospital/ Total number of medical equipment identified on model equipment list *100	Quarterly	

	% functional medical equipment	Total number of medical equipment that is functional/ total number of medical equipment *100	Quarterly	
	a) Number of donated medical equipment  b) % of donated items that are functional	a)Total number of donated medical equipment  b) total number of donated medical equipment that is functional/ total number of donated medical equipment*100	Quarterly	
	a) Number of work orders received  b) Number work orders completed  c) % of work orders completed	a) Total number of work orders received for repair of medical equipment  b) Total number of medical equipment work orders completed  c) total number of medical equipment work orders completed/ Total number of work orders received for repair of medical equipment	Quarterly	

	Average time to completion of work order	of time taken to complete work order/ total number of work orders completed	Quarterly	
	Actual expenditure on medical equipment as % of budget allocated to medical equipment	Actual expenditure on medical equipment / total budget allocated to medical equipment *100	Quarterly	
	Number of incident reports related to medical equipment malfunction	Total number of incident reports received related to medical equipment malfunction	Quarterly	

## Source Documents

1. Abington Memorial Hospital Department of Biomedical Engineering, Medical Equipment Management Program. Abington Memorial Hospital Policy and Procedure for Biomedical Equipment Class/Risk Classification.
2. Association for the Advancement of Medical Instrumentation. AAMI Equipment Management Committee. (1999). ANSI/AAMI EQ56: 1999. Recommended practice for a medical equipment management program. Arlington, VA.
3. The Australian Council on Healthcare Standards. EQuIP Standards, 3<sup>rd</sup> Edition. Safe Practice and Environment, pp. 4.
4. Baldinger, P. and Ratterman, W. (2008). Powering Health. Options for Improving Energy Services at Health Facilities in Ethiopia. Washington DC: United States Agency for International Aid.
5. Bekele, H. (2008, August). Assessment on Medical Equipment Conditions. Ethiopian Science and Technology Agency. National Scientific Equipment Centre.



6. Egyptian Ministry of Health and Partners for Health Reformplus. (2004, December). Egyptian Hospital Accreditation Program: Standards. 6. Environmental Safety, pp. 31.
7. Hospital Standards for Accreditation for Afghanistan. Section 5: Administration and Management. Maintenance of Hospital Facilities and Equipment.
8. Joint Commission International. Joint Commission International Accreditation Standards for Hospitals, 2<sup>nd</sup> Edition. Facility Management and Safety. pp. 135, 140-1.
9. Mavalankar, D., Raman, P., Dwivedi, H., Jain, M.L. (2004). Managing Equipment for Emergency Obstetric Care in Rural Hospitals. International Journal of Gynecology and Obstetrics. (87): 88-97.
10. Temple-Bird, C., KaurManjit, LenelAndreas,andWilliKawohl. (2005). Guide 1: How to Organize a System of Healthcare Technology Management. In 'How to Manage' Series for Healthcare Technology. Hertfordshire, UK: TALC.
11. Temple-Bird, C., KaurManjit, LenelAndreas,andWilliKawohl. (2005). Guide 2: How to Plan and Budget for your Healthcare Technology. In 'How to Manage' Series for Healthcare Technology. Hertfordshire, UK: TALC.
12. Temple-Bird, C., KaurManjit, Lenel Andreas, TrondFagerli, and WilliKawohl. (2005). Guide 3: How to Procure and Commission Your Healthcare Technology. In'How to Manage' Series for Healthcare Technology. Hertfordshire, UK: TALC.
13. Temple-Bird, C., KaurManjit, Lenel Andreas, and WilliKawohl. (2005). Guide 4: How to operate your healthcare technology effectively and safely. Management Procedures for Health Facilities and District Authorities. In'How to Manage' Series for Healthcare Technology. Hertfordshire, UK: TALC.
14. Temple-Bird, C., KaurManjit, Lenel Andreas, and WilliKawohl. (2005). Guide 5. How to organize the maintenance of your healthcare technology.Management Procedures for Health Facilities and District Authorities.In'How to Manage' Series for Healthcare Technology. Hertfordshire, UK: TALC.

15. Wang, B. (2003). A Framework for Health Equipment Management in Developing Countries. Business Briefing: In Hospital Engineering & Facilities Management. International Federation of Hospital Engineering. Retrieved from: [http://www.abeclin.org.br/comissoes\\_arquivos/A%20Framework%20for%20Health%20Equipment%20Management%20in%20Developing%20Countries.pdf](http://www.abeclin.org.br/comissoes_arquivos/A%20Framework%20for%20Health%20Equipment%20Management%20in%20Developing%20Countries.pdf).
16. World Health Organization Regional Office for the Western Pacific. (1998).Section 2.6.Training of Technicians for Medical Equipment Maintenance. In District Health Facilities: Guidelines for Development and Operations. WHO Regional Publications, Western Pacific Series No. 22. Retrieved from: [www.wpro.who.int/internet/files/pub/297/partI\\_2.6.pdf](http://www.wpro.who.int/internet/files/pub/297/partI_2.6.pdf).
17. World Health Organization. (1998). District Health Facilities Guidelines for Development and Operations. Part I, section 2.4 Management of Medical Equipment pgs.150-154. WHO Regional Publications, Western Pacific Series No. 22, pp 150-3.
18. World Health Organization. (2000). Guidelines for Health Care Equipment Donations. WHO/ARA/97.3. Geneva: World Health Organization.
19. Doncaster and Basset Law Hospitals. NHS Foundation Trust. Medical Equipment Training for Trust Staff. Volume 3. Retrieved from:[http://www.dbh.nhs.uk/Library/Corporate\\_Policies/CORP%20RISK%202%20v.3%20-%20Medical%20Equip%20Training%20for%20Staff.pdf](http://www.dbh.nhs.uk/Library/Corporate_Policies/CORP%20RISK%202%20v.3%20-%20Medical%20Equip%20Training%20for%20Staff.pdf).
20. Duke University Clinical Engineering Policy CE-020. (2007, January). Retrieved from: [http://clinicalengineering.duhs.duke.edu/wysiwyg/downloads/CE020-Equipment\\_Management\\_Program.pdf](http://clinicalengineering.duhs.duke.edu/wysiwyg/downloads/CE020-Equipment_Management_Program.pdf).

# Appendices

## Appendix A Sample Inventory Data Collection Form

Inventory # \_\_\_\_\_

Type of Equipment: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Model: \_\_\_\_\_ Serial #: \_\_\_\_\_

Country of Origin: \_\_\_\_\_ Year of Manufacture: \_\_\_\_\_

Power Requirement:  
☐ 220V      ☐ 110V

Current State/Condition:  
☐ Operable and in service  
☐ Operable and out of service  
Reason out of service: \_\_\_\_\_

☐ Needs maintenance

☐ Not repairable

Needs to be discarded?    ☐ Yes    ☐ No

Spare parts available?    ☐ Yes    ☐ No

If yes, what, how many, and where are they located? \_\_\_\_\_  
\_\_\_\_\_

Manuals Available:

<input type="checkbox"/> User manual	# of copies _____	Location _____
<input type="checkbox"/> Service manual	# of copies _____	Location _____
<input type="checkbox"/> Other (specify)	# of copies _____	Location _____

Equipment Users:

☐ Doctors    ☐ Nurses    ☐ Lab Technicians  
☐ Students    ☐ Residents    ☐ Other (specify) \_\_\_\_\_

Equipment owner (department), if any: \_\_\_\_\_  
 \_\_\_\_\_

Contact Person and Telephone numbers: \_\_\_\_\_  
 \_\_\_\_\_

Current location of equipment: \_\_\_\_\_  
 \_\_\_\_\_

Will it move from here?      No      Yes    If so, where? \_\_\_\_\_  
 \_\_\_\_\_

Other notes (use back of paper if more room is needed: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

## Appendix B Typical Equipment Lifespan

The following is a list of typical equipment lifetimes developed by the American Hospital Association. The list reflects how equipment lasts within the United States healthcare system, whether it was manufactured in the U.S. or abroad. While this may not be directly applicable to the Ethiopian context, it is useful to have and use as a reference.

### *Diagnostic and Treatment Departments*

Item	Years	Item	Years
Accelerator	7	Blood gas analyzer	5
Alternating pressure pad	10	Blood gas apparatus, volumetrics	8
Amino acid analyzer	7	Blood transfusion apparatus	6
Amplifier	10	Blood warmer	7
Anacrobe chamber	15	Blood warmer coil	7
Analyzer, haematology	7	Bone surgery apparatus	3
Anatomical model	10	Breathing unit, positive-pressure	8
Anesthesia unit	7	Bronchoscope	
Ankle exerciser	15	Flexible	3
Apnea monitor	7	Rigid	3
Apron, lead-lined	47	Carbon monoxide recorder/detector	10
Arthroscope	5	Cardiac monitor	5
Arthroscopy instrumentation	3	Cardioscope	8
Aspirator	10	Cart	
Audiometer	10	Emergency-isolation	10
Autoclave	10	Medicine	10
Autoscaler, ionic	10	Caspar ACF instrument and plate system	7
Bacteriology analyzer	8	Cassette changer	8
Baci incinerator	5	Cautery unit	
Balance		Dermatology	7
Analytical	10	Gynecology	7
Electronic	7	Cell freezer	7
Precision mechanical	10	Cell washer	5
Basal metabolism unit	8	Centrifuge	7
Bath		Centrifuge, refrigerated	5
Fluidotherapy	7	Cerebral function monitor	7
Paraffin	7	Child immobilizer	15
Serological	7	Chloridimeter	10
Water	7	Chromatograph, gas	7
Biochemical analysis unit	7	Clinical analyzer	5
Biochromatic analyzer	7	Clopay wrapping machine	10
Biofeedback machine	8	Coagulation analyzer	5
Biomagnetometer	7	Cold-pack unit, floor	10
Bipolar coagulator	7	Colonoscope	3
Blood cell counter	5	Colorimeter	7
Blood chemistry analyzer, automated	5	Colposcope, with floor stand	8
Blood culture analyzer	8	Computer, clinical	5

Item	Years	Item	Years
Computer-assisted tomography (CT) scanner	5	Exercise equipment, outdoor	10
Conductivity tester	5	Exercise system, computer assisted	5
CO-oximeter	10	Excitator, orthotron	10
Cryopthalmic unit, with probes	7	Eye surgery equipment (phacoemulsifier)	7
Cryostat	7	Fibreoptic equipment	5
Cryosurgical unit	10	Fibrometer	7
Cyclotron	7	Film changer	8
Cystic fibrosis treatment system	10	Film viewer	10
Cystometer	10	Flow cytometer	5
Cystomegogram unit	10	Fluid sample handler	5
Cystoscope	3	Fluorimeter	10
Decalcifier	10	Fluoroscope	8
Deionized watersystem	7	Frame, turning	15
Densitometer, recording	5	Fumace, laboratory	10
Dental drill with syringe	3	Gamma camera	5
Dermatome	10	Gamma counter	7
Diagnostic set	10	Gamma knife	10
Diarthomy unit	10	Gamma well system	7
Digital fluoroscopy unit	5	Gas analyzer	8
Digital radiography unit	5	Gastroscope	5
Diluter	10	Geiger counter	10
Dispenser, alcohol	10	Generator	5
Distilling apparatus	15	Gloves, lead-lined	3
Doppler	5	Hand dynamometer	10
Dose calibrator	5	Heart-lung system	8
Dryer, sonic	10	Heat sealer	5
Duodenoscope	3	Hemodialysis unit	5
Echocardiograph system	5	Hemoglobinometer	7
Echoview system	5	Hemophotometer	10
Electrocardiograph	7	High-density mobile film system	10
Electrocardioscanner		Holter	
(Holter monitor scanner)	7	Electrocardiograph	7
Electroencephalograph	7	Electroencephalograph	7
Electrolyte analyzer	5	Homogenizer	10
Electromyograph	7	Hood, exhaust or Bacti	10
Electrophoresis unit	7	Hydrocollator	10
Electrosurgical unit	7	Hydrotherapy equipment	15
Ergometer	10	Hydrator	10
Evaporator	10	Hyperbaric chamber	15
Evoked potential unit	10	Hypothermia apparatus	10
Exercise apparatus	15	Image analyzer	5

Item	Years	Item	Year
Image intensifier	5	Nebulizer	
Immunodiffusion equipment	10	Pneumatic	10
IMX analyzer	7	Ultrasonic	10
Incubator, laboratory	10	Nephroscope	7
Inhalator	10	Neurological surgical table headrest	10
Intraarterial shaver	10	Neutron beam accelerator	8
Iontophoresis unit	8	Noninvasive CO2 monitor	7
Isodensitometer	7	Optical readers	5
Isolation chamber	12	Orthotron system	10
Isotope equipment	7	Orthourological instruments	10
Isotope scanner	7	Oscilloscope	7
Kiln	10	Oven	
K-pads	5	Paraffin	10
Kymograph	10	Sterilizing	10
Lamp		Oximeter	10
Deep-therapy	10	Oxygen analyzer	7
Infrared	10	Oxygen tank, motor, and truck	8
Mercury quartz	10	Pacemaker, cardiac (external)	5
Slit	10	Pacing system analyzer	7
Laparoscope	3	Panendoscope	10
Laryngoscope	3	Parallel bars	15
Laser, coronary	2	Pelviscope	7
Laser, surgical	5	Percussor	5
Laser positioner	5	Perforator	10
Laser smoke evacuator	5	Peripheral analyzer	10
Lifter, patient	10	pH gas analyzer	10
Linac scalpel	5	pH meter	10
Linear accelerator	7	Phonocardiograph	8
Lithotripter, extracorporeal shock-wave (ESWL)	5	Photocoagulator	10
Magnetic resonance imaging (MRI) equipment	5	Photography apparatus, gross pathology	10
Mammography unit		Photometer	8
Fixed	5	Physioscope	10
Mobile (van)	8	Pipette, automatic	10
Marograph	7	Plasma freezer	10
Mass spectrophotometer	7	Platelet rotator	20
Microbiology analyzer	8	Positron emission tomography (PET) scanner	5
Microscope	7	Proctoscope	3
Microtome	7	Prothrombin timer, automated	8
Microtron power system	7	Proton beam accelerator	7
Mirror, therapy	15	Pulmonary function analyzer	8
Muscle stimulator	10		

Item	Years	Item	Years
Treadmill, electric	8	Wheelchair	5
Tube dryer	10	X-ray equipment	
Tube tester	10	Developing tank	10
Ultrasound, diagnostic	5	Film dryer	8
Ultrasound unit, therapeutic	7	Film processor	8
Vacurette	10	Furniture	15
Ventilator, respiratory	10	Image intensifier	5
Vial filler	10	Intensifying screens	5
Vibrator	10	Silver recovery unit	7
Video		X-ray unit	
Camera	5	Fluoroscopic	5
Light source	5	Mobile	5
Monitor	5	Radiographic	5
Printer	5	Superficial therapy	5
		Tomographic	5
		Wiring	5

### *Nursing Departments*

Nursing departments consist of cardiac care, chemical dependency, intensive care, medical/surgical care, neonatal intensive care, nursery, pediatrics, pediatric developmental disabilities, and psychiatric units.

Item	Years	Item	Year
Bassinet	15	Cabinet	
Bath		Bedside	15
Sitz	10	File	15
Whirlpool	10	Instrument	15
Bed		Metal or wood	15
Birthing	15	Pharmacy	15
Electric	12	Solution	15
Flotation therapy	10	X-ray	15
Hydraulic	15	Central supply furniture	15
Labor	15	Chair	
Manual	15	Blood drawing	10
Orthopedic	15	Dental	15
Bench, metal or wood	15	Executive	15
Bin, metal or wood	15	Folding	10
Blood pressure device, electronic	6	Geriatric	10
Bookcase, metal	20	Hydraulic, surgeon's	15



Item	Years	Item	Years
Chair (continued)		Operating stool	15
Kinetic	15	Ophthalmoscope	10
Podiatric	15	Osmometer	7
Shower/bath	10	Otoscope	7
Specialist's	15	Ottoman	10
Chart rack	20	Patient monitoring equipment	10
Chart recorder	10	Phototherapy unit	10
Clothes locker		Physicians' in-and-out register, portable	10
Fibreglass or metal	15	Physiological monitor	7
Laminate or wood	12	Pump, breast	10
Computer, central output	5	Scale, baby	15
Credenza	15	Settee	12
Crib	15	Sheaving, portable, steel	20
Croupette	10	Sofa	12
Defibrillator	5	Stall Bar	15
Desk, metal or wood	20	Table	
Doppler	5	Anaesthetic	15
Dresser	15	Autopsy	20
Food service furniture	15	Electrohydraulic tilt	10
Frame, tuming	15	Examining	15
Housekeeping furniture	15	Folding	10
ICU and CCU furniture	15	Food preparation	15
Infant care center	10	Fracture	15
In-service education furniture	15	Instrument	15
Insufflator	5	Light	15
Labor and delivery furniture	15	Metal	15
Laboratory furniture	15	Obstetrical	20
Lamp		Operating	15
Bilirubin	10	Orthopedic	10
Emergency	10	Overbed	15
Lawn and patio furniture	5	Pool	10
Light		Refrigerated	10
Delivery	15	Therapy	15
Examining	10	Traction	10
Portable, emergency	10	Urological	15
Natural childbirth backrest	10	Wood	15
Nursing service furniture	15	Telemetry unit, cardiac	5
Operating room furniture	15	Thermometer, electric	5
		Ultrasonic fetal heart monitor	7
		Work station	10

## Appendix C Sample Medical Equipment Risk Assessment Form

All medical equipment should be assessed to determine the risk associated with equipment use and failure. This guides the priority that should be assigned to each item for maintenance and repair and replacement when the item can no longer be repaired.

### Step 1 Assign a Score to Each item of Equipment

Each item of equipment should be scored in each of 5 categories:

Category A	Equipment function
Category B	Risk associated with equipment failure
Category C	Preventive maintenance requirements
Category D	Main area of equipment use
Category E	Likelihood of equipment failure (mean time between failures)

Note: Category E, the 'mean time between failures' can be calculated based on equipment service and incident history. If this is not known then an estimate should be made.

### Step 2 Calculate Total Score and Risk Category

The most important categories in the assessment are (A) Equipment Function and (B) Risk Associated with Equipment failure. Because these are the most important categories these are given greater weight when the total score is calculated. Hence the total score is calculated as follows:

$$\text{Total score} = A + B + (C+D+E)/3$$

The total score will range from 3 to 20.

Medical equipment should be categorized as follows:

***High risk (score 18 – 20):***

Equipment should be tested at least twice per year and should be given highest priority for repair and routine testing and calibration.

***Medium risk (score 15 – 17):***

Equipment should be tested at least annually and should be repaired or undergo routine testing and calibration after this has been done for 'high priority' equipment.

***Low risk (score 12 -14):***

Equipment should be tested at least annually and should be repaired or undergo routine testing and calibration after this has been done for 'high and medium risk' equipment.

***Hazard surveillance (<12):***

Equipment in this category should undergo annual inspection.

Equipment Type:	Inventory Number:
Name and signature of assessor:	Date of assessment:
Assessment Criteria	Score (circle as appropriate)
<b>A. Equipment Function</b>	
Therapeutic – life support	10
Therapeutic – surgical or intensive care	9
Therapeutic – physical therapy or treatment	8
Diagnostic – surgical or intensive care monitoring	7
Diagnostic – other physiological monitoring	6
Analytical – laboratory analytical	5
Analytical – laboratory accessories	4
Analytical – computer and related	3
Miscellaneous – patient related	2
Miscellaneous – non-patient related	1
<b>B. Risk associated with equipment failure</b>	
Potential patient death	5
Potential patient injury	4
Inappropriate therapy or misdiagnosis	3
Equipment damage	2
No significant identified risk	1

C. Preventive maintenance requirement	
Monthly	5
Quarterly	4
Semi-annually	3
Annually	2
Not required	1
D. Likelihood of failure (mean time between failures)	
Less than three months	5
Approximately 4 – 6 months	4
Approximately 7 months to 1 year	3
Approximately 1 to 3 years	2
Approximately > 3 years	1
E. Main area of equipment use	
Anesthesia/Surgical care locations	5
Critical/Intensive care locations	4
Labs/Exam areas	3
General care areas	2
Non-patient areas	1
Total Score = A + B + (C+D+E)/3	
Inventory Classification Result	(tick appropriate box below)
High risk (score 18 to 20)	
Medium risk (score 15 to 17)	
Low risk (score 12 to 14)	
Hazard surveillance (<12)	



Appendix E    Sample Stock Record Card for Spare Parts

Item Description:

Item Code Number:

Unit pack size:

Maximum stock level:

Minimum re-order level:

Lead time:

Order quantity:

Date	Doc. No. (Receiving or Issuing	Received from or Issued to	Quantity				Unit Price		Price		Expiry Date	Remarks
			Received	Issued	Loss/Adj	Balance	Birr	Cent	Birr	Cent		




## Appendix F Common Site Preparation Steps for Installation of Medical Equipment

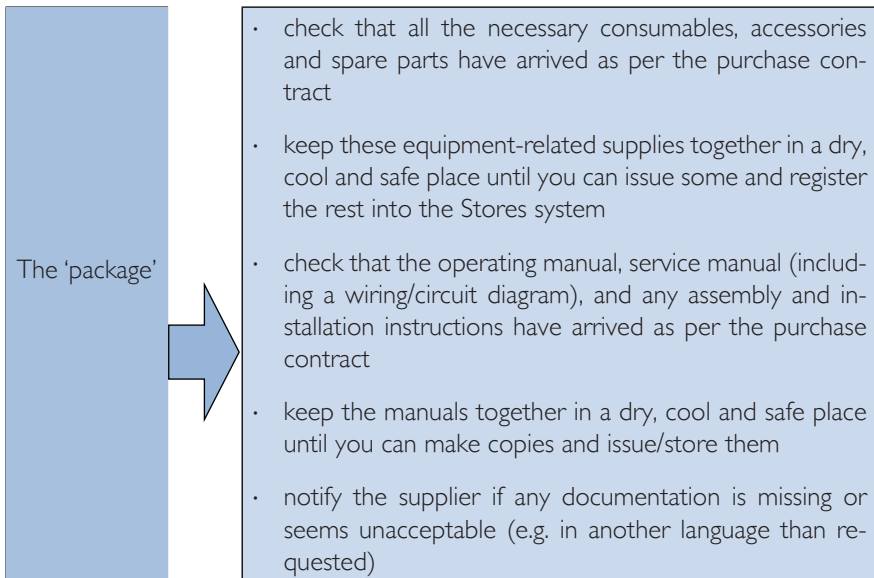
Step	Activity
Review technical needs	<ul style="list-style-type: none"> <li>• Study the manufacturer's site preparation instructions</li> <li>• Use experience and common sense</li> </ul>
Remove existing equipment	<ul style="list-style-type: none"> <li>• Cut supply connections and remove the existing item</li> <li>• Cannibalize the existing item for parts</li> </ul>
Construct or alter building	<ul style="list-style-type: none"> <li>• Build any special construction required, such as a transformer housing, lead screening, room extension</li> <li>• Make any special modifications necessary, such as enlarging the doorway, or building a worktop</li> <li>• Remove any scrap or other items from the room</li> </ul>
Provide electrical requirements	<p>Undertake the work required to provide (as necessary):</p> <ul style="list-style-type: none"> <li>• A new transformer</li> <li>• A new or upgraded generator</li> <li>• A single phase or three-phase supply at the site of installation</li> <li>• A special circuit breaker</li> <li>• A special socket outlet</li> <li>• An electrical circuit with sufficient capacity</li> </ul>
Ensure the electricity installation is safe	<p>Undertake:</p> <ul style="list-style-type: none"> <li>• An exercise to ensure that all relevant electrical installations are properly grounded and tested</li> <li>• Any remedial works as required</li> </ul>



Provide water and drainage requirements	<p>Undertake the work required to provide (as necessary):</p> <ul style="list-style-type: none"> <li>• Adequate water pressure</li> <li>• Water treatment</li> <li>• Increased pipeline diameter</li> <li>• Proper drainage</li> <li>• Appropriate connection points</li> </ul>
Provide steam supply requirements	<p>Undertake the work required to provide (as necessary):</p> <ul style="list-style-type: none"> <li>• A steam supply at the proposed site</li> <li>• Increased pipeline diameter</li> <li>• A boiler which can accommodate the increased load</li> <li>• Appropriate connection points</li> </ul>
Provide gas supply requirements	<p>Undertake the work required to provide (as necessary):</p> <ul style="list-style-type: none"> <li>• Relevant gas supplies at the proposed site</li> <li>• Appropriate connection points</li> </ul>
Provide extra specific requirements for installing the equipment	<p>Depending on specific guidelines for certain types of equipment (as detailed by the equipment supplier), provide:</p> <ul style="list-style-type: none"> <li>• Bolts in the ceiling for attaching operating lights in theatres</li> <li>• Trenches for supply lines to dental suites</li> <li>• Trenches for waste water for washing machines, etc.</li> </ul>
Provide any additional equipment needs	<p>Provide any associated items as necessary for the equipment or installation, such as:</p> <ul style="list-style-type: none"> <li>• An uninterruptible power supply (UPS)</li> <li>• A water pump</li> </ul>

## Appendix G Guidance for Unpacking and Inspecting Equipment Orders Checks Activities

For damage		<ul style="list-style-type: none"> <li>• systematically open one crate at a time</li> <li>• check the boxes/packages inside each crate for possible damage</li> <li>• systematically open one package at a time and note what you find on the relevant documents (see Appendix H)</li> <li>• Keep all packaging, supports, labels and booklets, as you may have to re-pack the equipment to return it for repairs.</li> <li>• unpack the equipment carefully</li> <li>• ensure that the equipment and its associated supplies do not appear to be damaged</li> <li>• if anything appears damaged, take a photograph if possible, and notify the supplier</li> </ul>
Against documentation		<ul style="list-style-type: none"> <li>• check that the delivery matches the packing list(s)</li> <li>• check that the contents comply with the specifications in the purchase order – in other words, check the type and model of all equipment and supplies</li> <li>• check that the quantities are according to the purchase order</li> </ul>
Technical requirements		<ul style="list-style-type: none"> <li>• ensure that the voltage shown on the packing list (or on the packing case) for electrical equipment is compatible with your power supply</li> <li>• check that the equipment data plate matches your order and the packing case/list and, for electrical equipment, that the voltage stated is correct</li> <li>• for electrical equipment, ensure the mains lead and battery charger, where applicable, is included</li> </ul>



## Appendix H Sample Acceptance Test Log Sheet

Only when this form has been satisfactorily completed should the Registration Box be filled in by the Head of Medical Equipment Maintenance.

### REGISTRATION BOX

ALLOCATED INVENTORY NUMBER .....  
 EQUIPMENT TYPE .....  
 DESTINATION LOCATION .....  
 ACCEPTANCE DATE .....  
 MAINTENANCE CONTRACT WITH .....

HEALTH FACILITY .....

NAME OF EQUIPMENT .....

TYPE/MODEL .....

ORDER NUMBER ..... SERIAL NUMBER .....

COST..... DATE RECEIVED .....

MANUFACTURER ..... SUPPLIER/AGENT .....

ADDRESS ..... ADDRESS .....

PHONE ..... PHONE .....

FAX ..... FAX .....

DETAILS OF ALL ACCESSORIES, CONSUMABLES, SPARE PARTS AND  
 MANUALS RECEIVED ARE LISTED ON THE FOLLOWING PAGE OF  
 THIS FORM

ACCEPTANCE CHECKS

I. DELIVERY

Undertaken by: .....

Witnessed by:   Name .....                      Position .....

                    Date .....

	Yes/done	No/not done	Corrected if applicable
a) Representative of supplier present?	.....	.....	.....
b) Correct number of boxes received?	.....	.....	.....
c) After unloading, visible damage to the boxes?	.....	.....	.....
d) If damaged, has this been stated on the delivery note and senior management informed?	.....	.....	.....

Comments .....

.....

2. UNPACKING (refer to invoices and shipping documents)

Undertaken by: .....

.....

Witnessed by:   Name .....                      Position .....

..                      Date .....

	Yes/done	No/not done	Corrected if applicable
a) Visible damage to the equipment?	.....	.....	.....
b) Equipment complete as ordered?	.....	.....	.....
c) User/operator manual as ordered?	.....	.....	.....
d) Service/technical manual as ordered?	.....	.....	.....
e) Accessories as ordered?	.....	.....	.....
f) Consumables as ordered?	.....	.....	.....
g) Spare parts as ordered?	.....	.....	.....

Comments .....

.....

.....

### 3. ASSEMBLY (refer to manuals)

**Undertaken by:** .....

**Witnessed by:** Name ..... Position .....

Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Are all parts available?	.....	.....	.....
b) Do they fit together?	.....	.....	.....
c) Mains lead with plug included?	.....	.....	.....
d) Do all the accessories fit?	.....	.....	.....
e) Are markings and labels OK?	.....	.....	.....
f) Any damage?	.....	.....	.....

Comments .....

.....

.....

#### 4. INSTALLATION (refer to manuals)

**Undertaken by:** .....

**Witnessed by:** Name ..... Position .....  
Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Was the work carried out satisfactorily?	.....	.....	.....
b) Were technical staff present as learners?	.....	.....	.....

Comments .....

## 5. COMMISSIONING/TESTING

**Undertaken by:** .....

**Witnessed by:** Name ..... Position .....  
Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Were electrical, mechanical, gas, radiation safety tests and performance checks carried out in accordance with the test sheets on pages 7 to 9 of this form?	.....	.....	.....
b) Was the work carried out satisfactorily?	.....	.....	.....
c) Were technical staff present as learners?	.....	.....	.....
d) Were operators present as learners?	.....	.....	.....

Comments .....

## 6. ACCEPTANCE – to be certified by the Head of Equipment Maintenance only

	Yes/ done	No/not done	Corrected if applicable
a) Is the equipment accepted?	.....	.....	.....
b) If rejected, have the shortcomings been summarized on page 10 of this form	.....	.....	.....
c) If so, has a report gone to senior management and formal complaints procedures started?	.....	.....	.....
d) Should payment be withheld pending corrections?	.....	.....	.....
e) Is payment approved?	.....	.....	.....

Comments .....

.....

.....

## 7. TRAINING

**Undertaken by:** .....

**Witnessed by:** Name ..... Position .....  
Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Were the expected training courses given?	.....	.....	.....
b) Were the training courses satisfactory?	.....	.....	.....



c) Were suitable operators present?	.....	.....	.....
d) Were suitable technical staff present?	.....	.....	.....

Comments .....

.....

.....

**8. REGISTRATION** – to be undertaken by the Head of Medical Equipment Maintenance

	Yes/ done	No/not done	Corrected if applicable
a) If accepted, has an inventory number been allocated?	.....	.....	.....
b) Has the Registration Box on Page I of this form been filled in?	.....	.....	.....
c) Has the Stores Controller been provided with the location for the equipment and all necessary data, so that the Stores Receiving Procedure can be followed and a Goods Received Note completed?	.....	.....	.....
d) Have the accessories, consumables, spare parts, and muals all been issued to the correct holding authorities?	.....	.....	.....

NAME.....

SIGNATURE.....

DATE.....

NOW PLACE THIS FORM AS THE FIRST RECORD IN THE  
EQUIPMENT FILE/SERVICE HISTORY

Describe and quantify all items received, and complete a Register of New  
Stocks form:

<b>ACCESSORIES RECEIVED</b>			
1.		2.	
3.		4.	
5.		6.	
7.		8.	

<b>CONSUMABLES RECEIVED</b>			
1.		2.	
3.		4.	
5.		6.	
7.		8.	

<b>SPARE PARTS RECEIVED</b>			
1.		2.	
3.		4.	
5.		6.	
7.		8.	

<b>MANUALS RECEIVED</b>			
1.		2.	
3.		4.	

**COMMISSIONING/TESTING PROCEDURES** (see manuals and relevant technical standards)

**i. ELECTRICAL INTEGRITY TESTS**

**Undertaken by:** .....  
.....

**Witnessed by:** Name ..... Position .....  
..... Date .....

**Classification (applies to medical equipment only)**  
**Fill as applicable**

a) Class I - II - III?
b) Type B - BF - CF?
c) Type AP - APG?

	Yes/ done	No/ not done	Corrected if applicable
Mains Connection			
a) Are cables and plugs intact?	.....	.....	.....
b) Is cable color code correctly connected?	.....	.....	.....
c) Are connectors intact?	.....	.....	.....
d) Are the fuses correct?	.....	.....	.....
e) Is equipment protection correct?	.....	.....	.....
f) Is voltage setting correct?	.....	.....	.....
g) Is there an earth terminal?	.....	.....	.....
Electrical Measurements with Safety Tester			
a) Is protective earth continuity correct?	.....	.....	.....
b) Is insulation resistance correct?	.....	.....	.....
c) Are the leakage currents correct?	.....	.....	.....
d) Is the voltage measurement correct?	.....	.....	.....

Comments .....  
.....  
.....

**ii. MECHANICAL INTEGRITY TESTS****Undertaken by:** .....**Witnessed by:** Name ..... Position .....

Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Are knobs and switches intact?	.....	.....	.....
b) Do the wheels/castors move?	.....	.....	.....
c) Are the handles intact?	.....	.....	.....
d) Are the mechanical movements okay?	.....	.....	.....

Comments .....

.....

**iii. GAS INTEGRITY TESTS****Undertaken by:** .....**Witnessed by:** Name ..... Position .....

Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Are the cylinders full?	.....	.....	.....
b) Are appropriate gauges available?	.....	.....	.....
c) Is there a cylinder key?	.....	.....	.....
d) Is the pressure reading correct?	.....	.....	.....
e) Is the cylinder colour code correct?	.....	.....	.....
f) Are the hoses and fittings correct?	.....	.....	.....
g) Is the system leaking?	.....	.....	.....

Comments .....

.....

iv. RADIATION INTEGRITY TESTS

Undertaken by: .....

Witnessed by:      Name .....      Position .....

                                         Date .....

	Yes/ done	No/not done	Corrected if applicable
a) Is the kV calibration correct?	.....	.....	.....
b) Is the mAs calibrated correctly?	.....	.....	.....
c) Was the line voltage compensation performed?	.....	.....	.....
d) Was the exposure test correct?	.....	.....	.....
e) Were the step wedge test results correct?	.....	.....	.....
f) Were the small and large focus calibrations done?	.....	.....	.....

Comments .....

.....

.....

.....

v. PERFORMANCE TESTS (see manuals for manufacturer's recommendations)

Undertaken by: .....

Witnessed by:      Name .....      Position .....

                                         Date .....

	Yes/done	No/not done	Corrected if applicable
Note: carry out all operational tests as specified by the manufacturer			
a) Are the function verification tests correct?	.....	.....	.....
b) Is the equipment calibration acceptable?	.....	.....	.....

Comments .....

.....

**FAULT REPORT** (describe any shortcomings with the equipment or services provided)

.....  
.....  
.....  
.....  
.....  
.....

NAME .....

SIGNATURE .....

DATE .....

Appendix I Sample Planned Preventive Maintenance Log Sheet

Equipment:					Inventory #:								Location:								Month:											
Task	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	
Daily Tasks																																
Daily Task 1																																
Daily Task 2																																
Daily Task 3																																
Daily Task 4																																
Daily Task 5																																
Weekly Tasks																																
Weekly Task 1																																
Weekly Task 2																																
Monthly Tasks																																
Monthly Task 1																																
Monthly Task 2																																
Quarterly Tasks																																
Quarterly Task 1																																
Quarterly Technical PM																																
Semi-Annual Tasks																																
Semi-Annual Technical PM																																
Annual Tasks																																
Annual Technical PM																																

## Appendix J Good Practice Checklist for Corrective Maintenance

### Step 1

Resist the temptation to dive straight in. Do not immediately open up the machine and plunge in with a screwdriver.

### Step 2

Listen to the equipment users. Talk to the user – they can help you to discover the symptoms of the fault. Ask the users lots of questions – they often don't realize how much they know.

### Step 3

Look up the equipment's service history. Each individual piece of equipment should have a record of its service history. Use this to make yourself aware of the particular machine's past fault.

### Step 4

Check the main incoming supply. Ensure that the electricity/gas/water supply is reaching the wall outlet/socket – if it isn't, check the relevant main circuit breakers/valves/taps controlling the service supply.

### Step 5

Inspect the main incoming connection. Check the plug, connector, and mains/incoming lead to see if electricity (or other supply) is reaching the machine.

### Step 6

Inspect the machine's external supply connection point. Check the main external fuses/taps/regulators for the machine.

### Step 7

Refer to the operator's manual. Familiarize yourself with the instructions on how the equipment is meant to work.

### Step 8

Check the accessories. Ensure that the correct accessories are attached to the correct inlets.



### **Step 9**

Watch the machine in operation. Ask the users to describe what steps they usually take to put the machine through a normal operational cycle. Watch them do this, and observe what happens.

### **Step 10**

Refer to local sources of advice. Consult the service manual, training resources, PPM schedules and any other technical personnel. Take note of any possibility of remote diagnostics where, for complex equipment such as CT scanners, the manufacturer's computer may be able to log into the equipment and diagnose the fault.

### **Step 11**

Only at this point, consider opening the machine. Decide whether it is best to take the machine back to the workshop before opening it.

### **Step 12**

Inspect the machine's internal supply connection points. Check the main internal fuses/taps/valves for the machine, and then check the on/off switch.

### **Step 13**

Go through the troubleshooting or fault-finding steps provided in the service manual. BEWARE: It is very common for maintainers to guess the problem and act on it without verification. This leads to frustration when the diagnosis turns out to be incorrect. Thus, always take steps in the following order:

1. Determine the problem to a high degree of certainty by testing
  - Alter and adjust the equipment as little as possible during this stage
  - Never guess a problem or make an alteration that cannot be reversed
  - Always record adjustments as the work progresses (for example, on a notepad)
2. Correct the problem.

**Step 14**

Contact more experienced colleagues. Ask the in-house team of another health service provider (for example at a neighboring public or private hospital), or ask the national service provider (National Scientific Equipment Center).

**Step 15**

Ask the manufacturer or their representative for help. Contact them for discussions and fault-finding by phone, fax or email. Email is the cheapest and often the most effective way to get in contact with the manufacturer. Try to get some hints, but be sure to clarify whether you are being charged for this advice.

**Step 16**

Call in support from the private sector when the work is beyond your capabilities. Call in the private maintenance contractor, if there is one, for faults that cannot be handled by the in-house team. Ensure that the hospital management or Medical Equipment Service has the funds to cover this.

**Step 17**

If the work is within your capabilities, only at this point consider taking corrective action. When a fault is found that the in-house team has the skills and authority to pursue, follow the corrective action or parts replacement steps provided in the service manual.

**Step 18**

Use the correct materials. Select only the correct maintenance materials and spare parts relevant to the machine.

**Step 19**

Work carefully. Handle the spare parts and maintenance materials carefully so as not to damage them or the machine.

### **Step 20**

Make a record of your work. Fill in the Work Order form to record the problem reported, fault found, corrective action taken, parts used, time taken, etc.

### **Step 21**

Ensure the equipment is safe to use. Always safety test the equipment with the correct test equipment before returning it to the users.

### **Step 22**

Repeat step 9. Ensure that the operators can make the equipment function properly during a normal operational cycle.

### **Step 23**

Reduce the likelihood of problems in the future. Ensure in the future that planned preventive maintenance (PPM) is carried out on the equipment.

## Appendix K Sample Corrective Maintenance Report

Work order number:	
Equipment type	Inventory Number
Model	Serial No.

Description of equipment failure
Cause of equipment failure (if known)
Part of machine / equipment to be maintained

Corrective action		
Time required		
Spare parts replaced		
1.	2.	3.
4.	5.	6.
Engineer 1	Signature 1	Date
Engineer 2	Signature 2	Date

User comments		
Date	Signature	Date

Appendix L Sample Work Order Form

Note: this is a triplicate form	
<ul style="list-style-type: none"><li>• 1st sheet is the User File copy</li><li>• 2nd sheet is the Maintenance Progress File copy</li><li>• 3rd sheet is the Equipment History File copy</li></ul>	
SECTION A: To be completed by user	
Equipment Type:	Inventory Number:
Item Location:	
Name of person making request:	Date:
Description of Problem:	
Troubleshooting performed (if relevant):	
SECTION B: To be completed by Head of Equipment Maintenance	
Date request received:	Work order number:
Priority of task (high/medium or low):	Task allocated to:
SECTION C: To be completed by Maintenance Technician	

Was item repaired?	
Yes	No
<p>If Yes, complete Maintenance Report Form. Return Item to User.</p> <p>Equipment _____ returned</p> <p>Date _____ returned</p>	<p>If No, state reason work not completed and return Work Order Form to Head of Equipment Maintenance for follow up and completion of Work Order (by assigning another technician or outsourcing):</p>
<p>Name of Maintenance Technician _____</p> <p>Signature: _____</p>	
<p>After corrective maintenance is completed the Work Order Form and Corrective Maintenance Log Form should be filed together in the Equipment History File.</p>	

Appendix M Sample User Training Verification Form

<b>Name:</b>		<b>Position:</b>	
<b>Department/ward:</b>		<b>Date employment commenced:</b>	

Medical Device	Manufacturer/ Supplier	Model	Trained By	Date of training	Assessment/ Review date	Comments

## Appendix N Principles behind Replacement Cost Calculations

### A. Basic Principle

Assuming Your equipment stock value is, for example, US\$2,500,000 (Note: This is not based on what is purchased each year, but upon the value of all the items already owned.)

And All the equipment only had a 'life' of one year

Then US\$2,500,000 would be needed each year to replace equipment

### B. Taking Equipment 'Life' Into Account

But If the 'life' of the equipment is, in fact, five years

Assume The equipment will not all reach the end of its life at the same time

Then The replacement budget can be spread over the lifetime of the equipment, as follows:

Replacement budget each year = value of stock  
Lifetime

For example:  $\text{Replacement budget per annum} = \$2,500,000/5 = \$500,000 \text{ p.a.}$

### C. Averaging Across All Stock

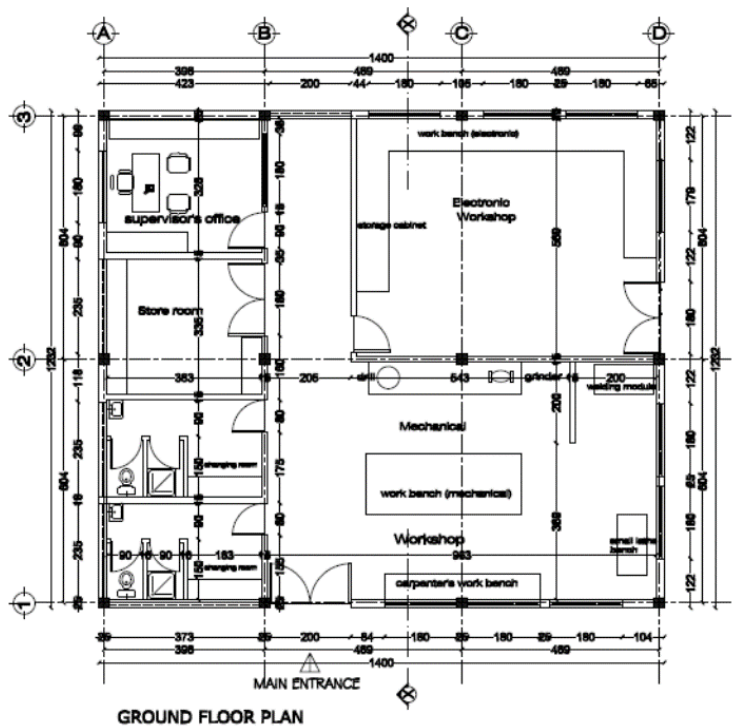
In fact, stock will actually be made up of different types of equipment with different lifetimes – some 5 years, some 10, some 15, etc. Based on such lifetimes, an average lifetime is often taken to be 10 years. Thus, a rough estimate of the replacement budget will need to be 10% of the equipment stock value each year:

Replacement budget each year = total stock value  
Average lifetime

**For example:**  $\text{Replacement budget per annum} = \$2,500,000/10 = \$250,000 \text{ p.a.}$



Appendix O Biomedical Equipment Maintenance workshop layout For General and Referral Hospital



This publication is produced by the generous support of the American people through the United States Agency for International Development (USAID), the United States President's Emergency Plan for AIDS Relief (PEPFAR), and the President's Malaria Initiative (PMI). The content is the responsibility of the Ministry of Health of the Federal Democratic Republic of Ethiopia and the USAID Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) project in Ethiopia and does not necessarily reflect the views of USAID, PEPFAR, PMI or the United States government.



**USAID**  
FROM THE AMERICAN PEOPLE



U.S. President's Malaria Initiative