GUIDELINES ON MEDICAL EQUIPMENT MANAGEMENT IN NIGERIA

FEDERAL MINISTRY OF HEALTH, ABUJA

AUGUST 2005

GUIDELINES ON MEDICAL EQUIPMENT MANAGEMENT IN NIGERIA

INTRODUCTION

1.0 GENERAL

Medical equipment are devises used in different aspects of health care delivery and designed to aid in the prevention, diagnosis, treatment, rehabilitation etc. of medical problems. It is usually designed with rigorous safety standards. There are several basic types of medical equipment such as: Diagnostic equipment which include medical imaging machines used to aid diagnosis e.g. ultrasound, MRI, CT-scans, PET, and x -ray machines. Therapeutic equipment, infusion pumps, medical lasers, surgical machines etc. Life support equipment is used to *maintain* a patient's bodily function such as medical ventilators, heart-lung machines, ECHO, and dialysis machines. Medical monitors allow medical staff to measure a patient's medical state. Medical laboratory equipment automates or help analyses of blood, urine and genes.

2.0 MANAGEMENT PROCESS

The overall Medical Equipment Management guidelines are based on the monitoring and evaluation of organizational experiences, applicable laws and regulations, and accepted practices. The management process involves a continuous assessment utilizing a design, teaching, implementation, measurement/evaluation, and an improvement cycle encompassing the identification, analysis, resolution, monitoring and evaluation of safety-related issues within the environment.

3.0 MEDICAL EQUIPMENT DOCUMENTATION

When receiving new equipment, all information should be filed with regard to vendor, service provider, etc, to maintain a database of manual and contract details. The inventory must be accurately maintained to obtain adequate property control. A crucial task is to ensure that all information can be found on the Asset Control Form. No field should be left blank. Maintenance Records for each asset should be included in the system.

4.0 EFFECTIVE MEDICAL EQUIPMENT MANAGEMENT

All medical equipment considered to be an “inventory item” should be tagged or labeled for the purpose of inventory as well as for inspection and maintenance records. The title of the user responsible for the operation and management of each piece of equipment should be specified on the tag or the label.

5.0 SELECTION AND ACQUISITION OF EQUIPMENT

5.1 SPECIFICATIONS

Procurement should comply with the International Standard Rules and Regulations on Procurement. All basic information or specifications should be developed by its users based on the latest version of the Medical Equipment Handbook.

5.2 INSTALLATION OF MEDICAL EQUIPMENT

All medical equipment should be installed according to the Manufacturer's specifications as well as Building/ Electrical and Occupational Health and Safety specifications. New equipment should be tested prior to being placed in service and also after any repairs and modifications. Intervals of testing of equipment will be based upon product literature. Installation normally consists of physically attaching the equipment to the building and hooking utilities (plumbing, cables or wiring that had been provided during the preparatory phase). Equipment Users are responsible for any infrastructural changes required for installation.

Upon receipt, a designated administration officer and /or a medical maintenance technician will tag the equipment with the proper inventory code. Once the unit has been accepted, the warranty period commences. Acceptance testing usually consists of testing by users and designated administration officers, including the medical maintenance technician. The manager responsible for use of the equipment will arrange for acceptance testing.

An appropriate and stable power supply system is essential. The electric current will normally be 220 V and 50 Hz, unless otherwise specified, and electric plugs should be 3 pin grounded to avoid electrical hazard or shock. All electric appliances should come with both the UPS (Uninterrupted Power Supply) system and the surge protector to ensure continuous medical support even in the case of a power shutdown or outage. The following details the specific procedures for special Medical Equipment:

i. X- ray Installation: Diagnostic X- ray systems must be installed according to the International regulation. Radiation protection surveys are to be performed on new x-ray installations before they are authorized for human use.

ii. Electrical Equipment: such as ECGs, Defibrillators, etc., must include a grounding system to provide protection against a shock hazard.

iii. Operating Equipment: The installation of gas systems requires the services of an expert. It should not be attempted by a plumber unfamiliar with medical gas systems or anyone not trained in the installation of anesthetic gases and equipment.

iv. Sterilization Equipment:: Upon completion of installation, complete orientation and demonstration, including calibration and the testing processes of the sterilizer should be provided.

5.3 **ORIENTATION AND TRAINING FOR MEDICAL EQUIPMENT USE**RS

Orientation and training on the safe and effective use of medical equipment should be performed for workers or users during installation and servicing. Some specialized training which is not locally available shall be carried out at the manufacturers' training schools.

6.0 MEDICAL EQUIPMENT SAFETY DURING OPERATION

6.1 ELECTRICAL SAFETY:

The hospital's electrical safety programme is designed to provide an electrically safe environment for patients and staff. Scheduled inspections and safety tests are to be performed on all electrically operated equipment at specified intervals and the corresponding limits are to comply with International Occupational Health and Safety Standards.

Upon acceptance of fixed medical equipment, a grounding performance test should be conducted. Electrical equipment commonly includes a grounding system to provide protection against shock hazard if there is an insulation failure, interruption of the leakage current flowing through the ground conductor could pose a shock hazard to patients. A fatal shock could result if the patient is in a weakened condition or unconscious, or if the leakage current is applied to internal organs. The leakage current from frame to ground shall not exceed International Safety Standard, measured from equipment chassis to ground.

It is recommended that all medical facilities have special procedures in place to ensure that medical equipment is turned off/ monitored while switching on generators so that people, as well as equipment, in the medical facility could avoid possible electrical problems including electrical hazard, malfunctioning of equipment and so on.

6.2 RADIOLOGICAL SAFETY

The radiology staffs have the following functions and responsibilities:

i. The leaded apron should be worn for all X- ray work
ii. A dosimeter should be worn outside of the apron at the collar/ neck region, so that exposure to the head, neck, eyes and thyroid can be measured. It is recommended that a second dosimeter be worn under the apron to record possible inner exposure.
iii. Calibrate and maintain all radiation safety equipment used by the Radiology staff.

6.3 ENVIRONMENTAL AND OCCUPATIONAL SAFETY

Equipment and consumables should not negatively influence the local ecology. (See Occupational Health and Safety Guidelines for further information.)

Cell phone usage inside hospitals should be prohibited in operating rooms, radiology department, emergency rooms and Intensive Care Unit, as cell phones transmit signals that interfere with certain types of medical equipment. The Chief Medical Director should advocate adherence to the "no cell phone" policy within the medical facility.

6.4 WORKERS' SAFETY AND INFECTION CONTROL

Safety on the job is everyone's business. Each medical facility worker shall:

i. Ensure that the work is free of safety hazards.
ii. Assist co- workers and verify that all staff wear protective clothing (X- ray protective apron, face mask, etc.)
iii. Be aware of mechanical and electrical hazards (especially in close proximity to high voltage equipment).

The Chief Medical Officer shall:

i. Take appropriate steps to ensure that the Medical Facility complies with all applicable safety standards/procedures/guidelines.
ii. Make every effort to ensure that every activity within the Medical Facility is safe for workers and patients.

The purpose of the Infection Control Policy is to ensure the health and safety of maintenance personnel who may come in contact with potentially infectious materials during the performance of their duties and to safeguard patients, visitors and staff from transmission of infectious agents while installing, servicing or using equipment in clinical or laboratory areas. All personnel assigned to the Medical Facility must be familiar with and comply with the Infection Control Policy.

6.5 MEDICAL GASES SAFETY

Procedures for ensuring safety of gas cylinders shall be as follows:

i. Full and empty gas cylinders shall be separated, and "full" and "empty" signs shall be posted on each cylinder.
ii. Cylinders shall be properly fastened to protect from accidental damage or dislocation.
iii. Cylinder valves shall be tightly closed to prevent gas from escaping.
iv. Cylinder valve caps shall be secured when the cylinders are not in use.
v. Flammable gas cylinders shall be stored separately within the storage area and shall not be stored with oxidizing agents.
vi. Flammable compressed gas storage areas shall be separated from the buildings.
vii. Cylinders shall be maintained separately from medical air compressors and vacuum pumps.
viii. Cylinders shall be isolated from heat sources to avoid being heated to the activation point.
ix. Cylinder wrappers shall be removed prior to storage.

7.0 QUALITY ASSURANCE

7.1 Quality Control recalls/warnings/alert:

The Medical Support Unit is responsible for processing recall/ warning/ alert messages related to medical equipment. The Medical Support Unit shall coordinate actions, disseminate information, and ensure corrective action is taken as required.

An X- ray dosimeter should be worn for monitoring exposure. Personal dosimeters for the operators of x-ray machines should be used and analyzed at least on a quarterly basis. This should be worn for the designated time period, returned to the company for processing/ analysis, and the results reported back to the Medical Facility Unit in written form informing how much radiation (if any) the wearer received.

7.2 **Laboratory External Proficiency Testing Programme**:

The Laboratory must participate in at least one external proficiency- testing programme. Proficiency test samples must be tested in a manner comparable to that for testing patient samples.

8.0 **CALIBRATION OF DIAGNOSTIC EQUIPMENT**

Calibration should be performed on medical equipment to ensure its parameters are within the manufacturer's specifications and to ensure equipment meets applicable regulations. All technical appliances in need of regular calibration come with instructions for such calibration as part of the manual/ other product literature.

8.1 **Audiometer Calibration:**

Calibration of audiometers is provided through scheduled maintenance activities. Audiometers are to be calibrated at least annually and after each repair requiring the exchange of parts.

8.2 **Defibrillator Calibration:**

Calibration of defibrillators is to be accomplished semi-annually using approved test equipment. Only authorized labels and /or forms are to be used for documenting services performed. Forms are to be maintained on file for the life of equipment. The Label (Defibrillator Energy Output Certification) shall be completed and visibly affixed to the equipment.

8.3 **Laboratory Calibration**:

Internal Self-Testing Programme: Calibration shall be done if there is abnormal data. For routine calibration, it is recommended that 1 out of 20 samples be compared with quality controls from the vendor.

8.4 Scale Calibration:

Commercial-type, official scales used for patient weight measurements shall be calibrated annually. Standard- type scales used at medical activities by clinical personnel and designated as the official scales for weight determination shall also be annually calibrated.

8.5 X- ray Calibration:

Only fully qualified personnel shall perform calibration of x- ray equipment. X- ray systems shall be calibrated so that the operation is within the specifications of the manufacturer. Upon completion of calibration of the diagnostic x-ray system, a Medical Equipment Verification/Certification Label must be completed and attached to the x-ray control panel.

9.0 **CONTRACT MANAGEMENT** (including accessories and consumables)

Effective coordination between the Chief Medical Officer, the Procurement Division, the Vendor, Self Accounting Unit and the user/ activity is required to renew or establish an annual maintenance service contract or to develop procurement action for one- time contract services. Consumables should be part of the contract, and re- supply should be done regularly following the standard system for purchase of medical commodities.

All annual medical equipment service contracts shall be reviewed by the Chief Medical Director.

10.0 **ANNUAL EVALUATION**

The Medical Support Unit conducts an annual evaluation of the objectives, scope, performance, and effectiveness of the Medical Equipment Management Plan. Proper documentation must be kept of the inspection, testing and maintenance work carried out on medical equipment on a scheduled or requested basis to ensure compliance with the International Guidelines.

11.0 **PREVENTIVE MAINTENANCE**

Preventive maintenance (PM) can be defined as “the care and servicing by personnel for the purpose of maintaining equipment and facilities in a satisfactory operating condition.” PM is more than an inspection; it is the act of detecting and correcting minor defects before they become major deficiencies.

It is the user’s responsibility to conduct Preventive and User-Level Maintenance in a Medical Facility. The User-level Preventive Maintenance checks include cleaning the equipment, maintaining required replacement supplies and performing operational checks and services.

It is the responsibility of the Chief Medical Director, the designated Administration Officer and a Medical Equipment Technician to establish a detailed maintenance plan for all medical equipment in the facility based on International Guidelines.

12.0 MEDICAL MAINTENANCE DOCUMENTATION

The Hospital must maintain good records for medical equipment for ease of tracking the history and use of the equipment. A similar record must be maintained for calibration and quality control procedures in order to track and identify episodes that may have led to problems.

The maintenance documentation system shall be used to document equipment that passes safety tests. Equipment or systems not passing the safety tests will be taken out of service.

MAINTENANCE CONTRACT MANAGEMENT

When supervisors determine that equipment require repairs that exceed in- house capabilities and the equipment is not covered by an annual service maintenance agreement or under warranty, the request for Commercial Services or Repairs must be submitted to the appropriate authority within the Medical Facility.

DISPOSAL OF MEDICAL EQUIPMENT

Disposal refers to the actions taken to permanently remove the item from inventory and may include scrap, donation or sale following the formal write-off and approval procedure. Disposal may occur because an item is damaged beyond economical repair, it is considered to be obsolete, it is surplus to requirements or simply no longer required in the Medical Facility. Most medical equipment should be disposed of by qualified companies. Policy and procedures should exist locally in this regard.

When the equipment is processed for disposal, International Standards and guidelines should be adhered. Many types of medical equipment used in hospitals are referred as special or hazardous waste and may not be disposed in the “normal” trash. These items contain hazardous components that are restricted from disposal in a routine manner. For example, the items and equipment include:

i. Radiation Equipment: such as X- ray Machine
ii. Electronic equipment containing printed circuit boards/ computers and computer monitors: ECGs, EEGs, Patient Monitors, etc.
iii. Dry-cell batteries, Mercury-containing products: Sphygmomanometer, Thermometer, etc.
iv. Polychlorinated Biphenyl (PCB)- containing products
v. Smoke Detectors
vi. Asbestos- containing equipment
vii.

All unused syringes that have expired should be disposed into medical waste containers to avoid injury or abuse.