



Medical Equipment Management Plan

EC.02.04.01 (2009)

EC.02.04.03 (2009)

I PURPOSE

The mission of MCG Health, Inc. (MCGHI) is to improve the health of the people of the State of Georgia, Richmond County and the City of Augusta by providing cost-effective, quality health and hospital services. Consistent with this mission, the Board of Directors, medical staff, and administration have established and provided ongoing support for the Medical Equipment Program described in this plan.

The purpose of the **Medical Equipment Management Plan** is to define the program to manage medical equipment maintenance and safety for patients, visitors, and staff.

II SCOPE

The Biomedical Engineering Department operates between 8:00 am and 5:00 pm with onsite coverage by staff. Biomedical Engineering staff is available on a 24/7 basis by using a formal on call program. Services provided include, but were not limited to: Medical Equipment inventory, Equipment Acquisition, Selection of new equipment, Incoming Medical Equipment inspections, Planned Maintenance, Equipment repair, assistance with Hazard Notifications and Recalls, Documenting user errors, and providing incidental operator training.

III FUNDAMENTALS

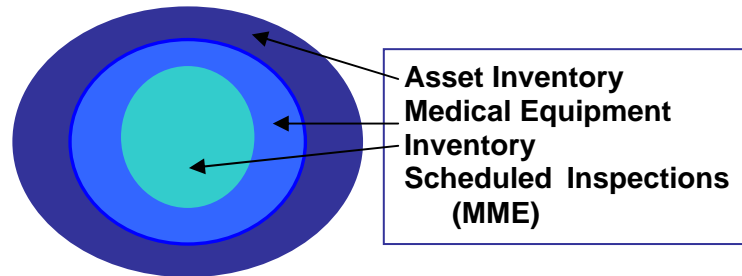
A. Equipment Inventory

The purpose of this policy is to (1) outline components of the medical equipment management program (MEMP) administered by the Biomedical Engineering Department, and (2) to define criteria as well as a risk based assessment process to be used in the development of strategy on how best to define, track and inspect equipment to be included within the program. The risk based assessment is also used to assign initial scheduled maintenance frequencies for a select grouping of devices within the program. Initially proposed equipment inspection frequencies using the criteria should be considered a baseline assessment in the initial development of inspection schedules. These schedules are subject to change based upon the following: equipment type; risk to patient should equipment fail; equipment utilization factors; event history and scheduled maintenance procedures.

Medical equipment will be managed in accordance with the requirements of various regulatory agencies such as The Joint Commission, the GA Department of Health and OSHA.

Not all patient care devices listed within the Biomedical Engineering Department

equipment asset inventory will be included in the MEMP. Additionally, not all items listed within the MEMP will be included in the scheduled inspection program. Graphically, these relationships can be shown as follows:



Non-Life Support Equipment:

PM maintenance for this class of equipment falls into 3 categories:

- 1 PM activity is scheduled for every piece of equipment of this device type. Ninety five percent (95%) of devices defined, as Non-Life Support, should have current PM status. (Target: PM completed within 60 days of date issued) *
- 2 PM history suggests that scheduled PM for every piece of equipment of this device type is not necessary. These device types will be labeled as No PM necessary (NPM), but a 10% sample (SAM) of this equipment will be selected and tested, looking for problems hidden from the user, that might otherwise be missed and could indicate a need to perform PM on every piece of equipment of this device type.
- 3 NPM – No PM required. Items in this category have a very low risk to the patient or staff when they fail, which are repaired only when reported as defective.

Life Support Equipment:

Equipment that is typically (more than 50% of the time) used in life support will have a life support priority group. Equipment in this priority group is included in the MEMP and initially tested for safety and operational performance one or more times/year. This equipment is given the highest priority for testing, calibration, and repair. One Hundred percent (100%) of devices defined as Life Support should have current PM status. (Target: PM completed within 90 days of date issued) *

Items currently risk ranked as Life Support equipment follow:

DEFIBRILLATOR (NON AED)
INCUBATOR, INFANT
MACHINE, ANESTHESIA
PACEMAKER, EXTERNAL
PUMP, BLOOD
SYSTEM, PERSUSION
VENTILATOR
VENTILATOR, ARABELLA
VENTILATOR, INFANT

* NOTE: Devices which are not located or made available for scheduled maintenance within their scheduled inspection timeframes will be defined as overdue for testing, and will remain overdue until documented efforts have been made to locate the specific device, with maintenance performed as soon as the device can be made available. If the device cannot be located within four months of the scheduled date, the inspection work order will be closed out and defined as 'could not locate.' Devices not located or validated to be in active use for a 12 month period will be removed from the active inventory and no longer scheduled for inspection.

All of the included equipment is provided with a durable tag carrying a unique Biomedical Equipment Control (BEC) number.

B. Non-Facility Owned Equipment

Rented equipment, loaned equipment, including that provided for demonstrations, and staff-owned equipment, are all considered for inclusion in the program.

Facility use of patient-owned equipment is discouraged. Exceptions will be considered on a case-by-case basis and only for those items deemed essential to the health and well being of the patient, but not available through the facility or any preferred rental vendors. The patient assumes all risk and liability for the use of personally owned equipment, including timely performance of all required scheduled maintenance activities.

C. Equipment Acquisition

The facility has a formal process for acquiring new capital equipment (defined as items valued at \$5,000 or more). This process requires that a formal requisition be generated and that this requisition be evaluated and considered for approval by the Capital Budget Committee which makes a judgment on the appropriateness of the equipment with respect to the clinical services provided by the institution. The Committee requests support from experts in certain specialized areas when it deems this additional support necessary.

D. Selection of New Equipment

Once it is determined that a new piece of equipment is to be acquired, the facility utilizes a routine selection procedure which involves a formal or informal analysis of quotes or responses from alternate vendors to a written Request for Proposal (RFP) before the purchase decision is made. This process requires assurance from the vendors that the equipment meets appropriate minimum safety and performance standards. Consideration is also given to the equipment's ease of operation and to the ready availability of assistance with on-going user training.

E. Incoming Inspections

All patient care equipment, whether owned, leased or rented is tested for compliance with previously specified minimum safety and/or performance standards before being used for the first time for patient care. The results of this testing are documented and the records are filed on-site in the Biomedical Engineering Department. Similarly, equipment that has been withdrawn from use and placed in storage is also tested to these standards before being returned to service.

F. Planned Maintenance

All of the equipment listed in the facility's Maintenance Monitored Equipment (MME) Inventory is subjected to a carefully controlled regimen of performance assurance and safety testing and scheduled maintenance. This mix of procedures is generally referred to throughout this document as planned maintenance (PM).

$$PM = SM + PA + ST$$

The procedures and intervals for the scheduled maintenance (SM) are initially determined using risk level or manufacturer's specifications and modified based on local experience. The procedures for the performance assurance (PA) and safety testing (ST) have been developed by either the Director of Biomedical Engineering or, in some cases, other service providers. They are based on both the manufacturer's published performance specifications and current, nationally recognized safety standards.

Although the planned maintenance is usually completed on time (within 63 days of the issue date of the computer generated work order), the computerized documentation system includes an exception-reporting feature, which prompts the staff to investigate any incomplete work orders. The primary documentation of the planned maintenance consists of service reports that are kept in electronic form and/or in individual file folders (old history) on-site (one folder for each piece of equipment) and for work performed after July 2007 the primary documentation is electronic and held in our Computerized Medical Maintenance System (CMMS). Computerized summaries of the maintenance work are also available and are used to provide regular status reports to the Department Managers and the Environment of Care/Safety Committee.

G. Equipment Repair Services

The individual making the service call fills out a red DNU "Do Not Use..." tag, if available, noting the time that the service call was made on the tag, and attaches the

tag to the defective equipment item, otherwise less formal notes may be used with contact information and problem description provided. Biomedical Engineering is available in house from 8:00am to 5:00pm by calling 1-2228. Biomedical Engineering is also available for emergency repair service 24 hours a day, 7 days a week by calling 1-8400, for the repair of equipment which is reasonably necessary in order for customer to continue to effectively deliver a vital clinical service, and for which an adequate temporary alternative is not available. When repair services are needed, customer will promptly notify Biomedical Engineering staff and allow full access to equipment.

Equipment Repair Services – (Imaging equipment under service contract)

The individual reporting a problem calls (1-3039) from 8:00am to 4:30pm and provides the problem description and equipment identifier. A call will be placed with the vendor for them. After hours staff may contact the vendor directly and request service, and then leave a message at (1-3039) to allow for timely follow up of the service. Vendor service reports are received and electronically attached to a computerized record keeping system in both the Radiology department and in Biomedical Engineering for tracking purposes.

Equipment Repair Services – (Non-Imaging medical equipment under service contract)

The individual reporting a problem calls the vendor directly and informs Biomedical Engineering (1-2228) of the service call and a Work Order is opened in a computerized record keeping system. An electronic copy of the vendor service report is used to close this tracking Work Order.

H. Hazard Notifications and Recalls

When a written hazard notification/recall involving a medical device, which is in use at the facility, is received from the equipment manufacturer, all of the potential users of the affected device will be notified of the potential problem through the facility's internal hazard notification process. When Biomedical Engineering receives equipment hazard notices and alerts from the facility they will determine whether or not this equipment is in use at the facility and notify the facility.

I. Education and Training of Maintenance Personnel

Biomedical Engineering service technicians are subjected to technical skill assessments during their pre-employment interview, at 12 months after their hire date, and annually thereafter. The education and training needs identified through these assessments are addressed by internal technician cross training, self study of service manuals, or supplemented by appropriate manufacturer/service vendor training.

J. Documenting User Errors and Incidental User In-Services

In the case of repair requests that are handled by Biomedical Engineering personnel, the service event is given a special coding if the call can be attributed to a user error, rather than and equipment malfunction. If it can be confirmed that the user is

unfamiliar with how to operate the equipment properly, the service technician provides the user(s) with an appropriate informal in-service, which is usually limited to addressing the immediate problem. Probable user-related problems (when the service technician can find no evidence of equipment malfunction and a reasonable theory of the reason for the perceived problem is documented) are reported to the Environment of Care/Safety Committee in the next Medical Equipment Safety Report.

K. Education and Training of Equipment Operators/Users

Responsibility for coordinating and implementing the education and training of the equipment users is held jointly by the facility's Education Department, the Medical Director and the department managers. The most common sources of training on specific equipment are the manufacturer's initial in-services, the manufacturer's refresher in-services, the equipment user instruction manual or other audio-visual equivalents, and other staff who have been trained on the proper use of the equipment. Biomedical Engineering technical staff assists in this process whenever they are competent to do so, and on an as-requested basis. Where a specific problem is identified as a result of a service call, Biomedical Engineering staff provides an incidental inservice, usually limited to correcting the user-related problem identified at the time of the service call.

L. Incident Investigations and Medical Device Related Problem Reporting

Events within the facility in which someone is injured, or could have been injured, are reported to the facility's Risk Manager. In situations where an item of equipment is directly involved, or is thought to have been directly involved, the facility has a policy that the equipment be removed from service and impounded with as little disturbance as possible to the settings and other evidence that might aid the investigation. Biomedical Engineering staff act as a resource to the facility and, on request, assists with investigating the circumstances of the incident, or in arranging for others to investigate the incident. Determination of whether or not the incident is reportable pursuant to the Safe Medical Devices Act of 1990 remains with the facility MCGHI Legal or Risk Management Department.

M. Equipment-Related Emergencies

Examples of equipment related emergencies are illustrated in the Attachment to this document.

Nursing departments are requested to provide a copy, to Biomedical Engineering, of their plans outlining how they will manage a failure of what they consider critical equipment.

IV. OBJECTIVES

A. Performance Improvement

In order to maintain an effective performance improvement process, there must be a consistent way of measuring the effectiveness of the program, i.e. how well it is accomplishing its mission.

The following questions are used as frameworks to assess program performance:

- 1) Is the program keeping up with the scheduled maintenance and performance assurance/safety testing workload?
- 2) Have we kept the program services fully compliant with the basic regulatory requirements?

These questions, and other applicable considerations, are addressed in the Annual Program Effectiveness Assessment and Performance Improvement Report. At the time when the Annual Assessment is prepared, areas of weakness that are considered to need improvement are targeted as goals for the following year. Progress with respect to these goals is reported in the quarterly Performance Improvement Report to the facility's quality management committee or quality council Safety Committee.

Based on the last formal assessment, the facility has established the following specific goals for FY 2010:

PI Goal #1: Reduce the average level of "unable to locate for PM" items to below 5%.

PI Goal #2: Increase the % of incidental inservices to above 50% for repairs designated as use errors when specific users can be associated with the equipment being evaluated.

PI Goal #3: Develop the tools to measure baseline response time to urgent or STAT repair requests. In order to use the PDCA process to improve on our response time to urgent or STAT repair requests.

PI Goal #4: Maintain a quarterly PM completion rate for life support equipment of 100%.

PI Goal #5: Maintain a quarterly PM completion rate for non-life support equipment of 95%.

B. Information Management

The heart of the program's maintenance documentation system is the collection of equipment maintenance history data kept in the Biomedical Engineering Department.

There is CMMS computer system that maintains records on all equipment on the Biomedical Engineering inventory. This system has electronic records related to the repair and maintenance of all equipment. A paper file exists which hold paper copies of old history on older equipment. A Quarterly Report documenting the nature of any user-related equipment problems or operator-error trends, equipment failures during patient use, and status of planned maintenance (PM) completion rates, is provided to the Safety Committee.

V. Process of the Medical Equipment Management Plan

a. EC.02.04.01 The organization manages medical equipment risks.

- i. 1. The hospital solicits input from individuals who operate and service equipment when it selects and acquires medical equipment. **A**
 1. See hospital policy 11.02 Capital Equipment: Acquisition
 2. The Director of Biomedical Engineering is a member of the Capital Expenditure Committee
- ii. 2. The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life support equipment) and equipment incident history. The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory. (See also EC.02.04.03, EPs 1 and 3) **C M D**
 1. The active (and inactive) inventory is kept in the Biomedical Engineering CMMS computer system.
 2. The Risk score is maintained within this CMMS as well.
 3. Each new equipment type is evaluated for inclusion in the Medical Equipment Management Program
- iii. 3. The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory. (See also EC.02.04.03, EPs 2 and 3) **C M D**
 1. Each device type that is included by risk in the scheduled maintenance program has an assigned PM procedure in the CMMS
- iv. 4. The hospital identifies, in writing, frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria such as manufacturers' recommendations, risk levels, or current hospital experience. (See also EC.02.04.03, EPs 2 and 3) **A D**
 1. The Biomedical Engineering CMMS contains the frequency of scheduled maintenance based on the risk assessment of the device type.
- v. 5. The hospital monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990. **A**
 1. See hospital policy 11.55 Product Recall & Reporting
 2. See hospital policy 14.92 Safe Medical Devices
- vi. 6. The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment. **A D 3**
 1. See Attachment 1
 2. See Attachment 4

b. EC.02.04.03 The organization inspects, tests, and maintains medical equipment.

- i. 1. Before initial use of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks. (See also EC.02.04.01, EP 2) **C 3**
 1. Medical Equipment that is brought into the hospital or clinics is either brought to Biomedical Engineering for inspection or inspected on location (for larger equipment).
- ii. 2. The hospital inspects, tests, and maintains all life support equipment.

These activities are documented. (See also EC.02.04.01, EPs 3 and 4; PC.02.01.11, EP 2) **A D 3**

1. Activity stored in Biomedical Engineering CMMS computer software.
- iii. 3. The hospital inspects, tests, and maintains non-life support equipment identified on the medical equipment inventory. These activities are documented. (See also EC.02.04.01, EPs 2-4 and PC.02.01.11, EP 2) **C D**
 1. Activity stored in Biomedical Engineering CMMS computer software.
- iv. 4. The hospital conducts performance testing of and maintains all sterilizers. These activities are documented. (See also IC.02.02.01, EP 2) **A D 3**
 1. Maintenance activity is stored in Biomedical Engineering CMMS
 2. Performance testing is performed and documented by the department using the sterilizers as a part of their quality management efforts.
- v. 5. The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented. **A D 3**
 1. Maintenance records for equipment are documented in the Biomedical Engineering CMMS.
 2. Biological testing is documented in the Dialysis unit and copies are entered into the Biomedical Engineering CMMS
- c. **A** indicates scoring category A; **C** indicates scoring category C; **3** indicates direct impact requirements apply; **M** indicates Measure of Success is needed; **D** indicates that documentation is required

Attachments follow:

- Attachment 1 Example Equipment Failures & Basic Personnel Responses
- Attachment 2 Maintenance Priority Level Determination
- Attachment 3 After Hours or Emergency Service Call Procedure
- Attachment 4 Table of Risk Assessment by Device Category with PM Frequency

Attachment 1

Example Equipment Failures & Basic Personnel Responses

**MCG Health
Medical Equipment Emergency Procedures**

Department/Unit: Critical Care Cost Centers: SAMPLE

Medical Device Description	Procedures During Equipment Disruption/Failure	Clinical Interventions During Equipment Failure	Availability of Backup Equipment	How to Obtain Repair Services
Ventilator	Confirm that all connections are secure Confirm that the Ventilator is plugged into emergency power Switch plug to an alternate electrical outlet	Manually bag patient until ventilator function is restored or replaced.	Replacement ventilator available from Respiratory Therapy Dept. Rental of ventilator through Respiratory Therapy Dept	Respiratory Therapy will exchange unit and send to Biomedical Engineering for repair
Oxygen (Wall)	Request additional O2 cylinders from Resp Therapy	Connect O2 tank to ventilator or to regulator for patient	Additional O2 tanks and regulators are available from Resp Therapy	Inform 1-WORK (1-9675) Facilities of the outage
Defibrillator	Bring backup defibrillator to room for use in code	Continue CPR during Code until replacement defibrillator arrives	Back up defibrillator located near room xxxx	Biomedical Eng (1-2228) or Switchboard after hours
Bedside Physiologic Monitor or Modules	Replace lead wires Replace patient cable Exchange module with spare Bring in transport monitor	Provide critical care staff to visually monitor patient until some monitoring is restored.	Spare modules in clean supply room	Biomedical Eng (1-2228) or Switchboard after hours
Physiologic Monitor Central Station	Go to each room and increase the alarm volume to allow room alarms	Staff to circulate every xx minutes to assess patients until central monitoring	Back up Central Station kept in Biomedical Eng, but must	Biomedical Eng (1-2228) or Switchboard after hours

	to be heard	is restored	be configured for specific unit by Biomed before use	
Large volume Infusion Pump	Obtain replacement pump	Switch to manual drip until pump arrives if required	Clean supply room	Biomedical Engineering (1- 2228)
Intra-Aortic Balloon Pump	Request back up unit	Utilize pharmacologic support to optimize patient's preload, contractility and after load	??	Biomedical Eng (1-2228) or Switchboard after hours

Reviewed/Approved by: _____ Date: _____

Attachment 2
Maintenance Priority Level Determination

All of the facility's medical equipment is evaluated for Maintenance Priority using the criteria described below.

A. Risk Criteria (RC)

The following four criteria are used to determine Maintenance Priority.

- 1) Equipment function (F);
- 2) Physical risks associated with the use of the device (A);
- 3) Manufacturer-specified maintenance requirement (M); and
- 4) Equipment incident history (H).

Equipment Function (F).

The numerical value assigned to the device's Function (F) factor is determined by which of the following three classes best describe the device's usual function.

- 5 Medical devices that are used in direct patient care (therapeutic, diagnostic and monitoring equipment).
- 3 Devices whose function is to support items that are used in direct patient care in the clinical environment (e.g. battery chargers and printers).
- 1 Equipment which is not used for direct patient care (e.g. televisions).

Device Application (A).

The numerical value assigned to the device's Application (A) factor is determined by which of the following three classes best describe the physical risks associated with the device's usual clinical application.

- 10 Equipment that is typically (more than 50% of the time) used intended to sustain life.
- 5 Potential for serious injury or patient death.
- 3 Potential for inappropriate therapy or misdiagnosis and consequent injury /illness.
- 1 No significant risk of delay in therapy or diagnosis.

Maintenance Requirements (M).

The numerical value assigned to the device's Maintenance Requirements (M) factor is determined by which of the following three classes best describe the device's generally known or manufacturer-specified level of maintenance requirements.

- 5 Devices that requires frequent or extensive maintenance due to either their design characteristics or specific application.
4. Devices that requires frequent light maintenance due to either their design characteristics or specific application.
- 3 Devices that requires relatively infrequent or light maintenance due to either their design characteristics or the specific application.
2. Devices that requires occasional light maintenance due to either their design characteristics or the specific application.
- 1 Devices require little or no maintenance due to either their design characteristics or the specific application.

Equipment History (EH).

The numerical value assigned after analysis of the device's Equipment History (EH).

- 3 Less than 5% of PM work order noted a problem hidden from the user of the device (e.g. device out of calibration)
- 0 Device has been tracked for problems hidden from the user for less than 1 year, or between 5% and 10%
- 3 More than 10% of PM work order noted a problem hidden from the user of the device (e.g. device out of calibration)

Risk Criteria (RC) Number.

The RC number = F+A+M+EH. It is used to quantify the priority level that should be given to the maintenance monitoring of Medical Equipment in the program.

Equipment with a RC number >18 are classified as Priority Level 1. Level 1 items will be considered life support equipment as defined by The Joint Commission.

MCGHI – MEDICAL EQUIPMENT MANAGEMENT PROGRAM			
Subject:		After Hours or Emergency Service Call Procedure	Page 1 of 1
File Name:		MEMP After Hours or Emergency Service Call Procedure 001.doc	Prepared by: Michael Landis
Effective Date:		8-01-2007	Approved by: Richard Tobias

If the need arises for a piece of medical equipment to be repaired on an emergency basis after hours, on a weekend or holiday, the clinical user shall call the hospital dispatch.

706 721 8400

Hospital dispatch will contact Biomedical Engineering Department on-call pager. On-call Biomedical technician will respond within 30 mins. Escalation process will be initiated if response exceeds 30 Min.

The individual making the service call fills out a red DNU “Do Not Use...” tag, noting the time that the service call was made on the tag, and attaches the tag to the defective equipment item (If no red DNU tag is available, a legible note will suffice). Biomedical Engineering is available in house from 8:00am to 5:00pm (M-F) by calling 1-2228. Biomedical Engineering is also available for emergency repair service 24 hours a day, 7 days a week by calling 1-8400, asking for the switchboard operator to page the Biomedical Engineering Technician On-Call, for the repair of equipment which is reasonably necessary in order for customer to continue to effectively deliver a vital clinical service, and for which an adequate temporary alternative is not available. When repair services are needed, customer shall promptly notify Biomedical Engineering staff and allow full access to equipment.

Equipment Repair Services – (Imaging equipment under service contract)
The individual reporting a problem calls (1-3039) from 8:00am to 5:00pm and provides the problem description and equipment identifier. A call will be placed with the vendor for them. After hours staff may contact the vendor directly and request service, and then leave a message at (1-3039) to allow for timely follow up of the service. Vendor service reports are received and electronically attached to a computerized record keeping system.

Equipment Repair Services – (Non-Imaging medical equipment under service contract)
The individual reporting a problem calls the vendor directly and informs Biomedical

Engineering (1-2228) of the service call and a Work Order is opened in an computerized record keeping system. An electronic copy of the vendor service report is used to close this tracking Work Order.

Approved _____
Richard Tobias, VP Facilities Services
MCG Health, Inc. Date

Attachment 3 shows the current maintenance priority level for supported medical devices