Massachusetts General Hospital

Medical Equipment Management Program

Policies and Procedures

2019

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1 PURPOSE

The purpose of the Massachusetts General Hospital Medical Equipment Management Program is to ensure that medical equipment is used safely and appropriately, performs properly, and is managed cost-effectively in the environment of care for which it is intended.

2 SCOPE

The medical equipment management plan is applicable to all licensed MGH facilities and includes equipment of all ownership statuses.

3 OBJECTIVE

The objective of the program is to minimize the risk of using medical equipment through inspection, preventive maintenance and education of those who use and maintain the equipment. The Medical Equipment Management Committee at Massachusetts General Hospital (MGH), as designated by the Hospital Safety Committee, shall define the Medical Equipment Management Program (MEMP) for the use and maintenance of medical devices for all departments involved with medical equipment. Responsibility for carrying out the MEMP is delegated to various departments responsible for medical equipment management, referred to as designated technology management groups (DTMG). Any department or individual clinician using medical equipment at MGH must ensure that the equipment conforms to this program.

4 RESPONSIBILTY FOR MANAGING MEDICAL EQUIPMENT

4.1 Program Management

The Medical Equipment Management Committee (MEMC) has primary responsibility for ensuring the proper implementation of this management program. There are two types of representatives involved in the MEMC:

DTMG Representative – An appropriate person to present equipment issues to the MEMC for their DTMG;

MEMC Advisor – A representative from a department, which may not be directly responsible for the management of medical equipment, but may provide important expertise to the committee (Partners Recall Officer, Infection Control, Clinical Laboratories, etc).

The MEMC has been delegated sufficient authority to carry out the following responsibilities:

- ensuring that the MEMP is properly reviewed and revised as necessary;
- ensuring proper implementation of the MEMP;
- ensuring that appropriate performance standards are established and maintained;
- ensuring that user departments are aware of their responsibilities for implementation and record maintenance of staff orientation and education programs;
- ensuring that DTMGs are aware of their responsibility for implementation and maintaining records of equipment-maintainer orientation and in-house personnel education programs.

Partners Materials Management Department has the responsibility for ensuring that MGH fully complies with the medical device recall program run by the Partners Recall Officer.

The Office of Corporate Compliance has the responsibility for ensuring that MGH fully complies with the Safe Medical Devices Act of 1990.

The MGH Medical Equipment Management Program is evaluated annually by the Medical Equipment Management Committee to ensure that it meets the stated objectives, is current and appropriate in scope and content, is effective, and continues to comply with all regulatory requirements and industry standards.

4.2 General DTMG Responsibilities

Various departments at MGH share the responsibilities for technology management and for assuring the safety and efficacy of medical equipment. These departments are responsible for managing specific types of medical equipment included in the MEMP and consistent with their mission and staffing. Department managers are responsible for ensuring that the following medical equipment management activities are properly implemented for medical equipment assigned to their areas of responsibility:

- ensuring compliance with the MEMP;
- sending an appropriate representative to the MEMC meetings;
- establishing guidelines for equipment acquisition, education and training of users and maintainers of their medical equipment, performance improvement, maintenance and risk management, the inspection, testing, maintenance and repair of medical equipment and related devices, and systems assigned to their area of responsibility;
- providing annual quality improvement (QI) and performance reports to the MEMC including scheduled maintenance compliance, at least one tracked QI indicator, and other medical equipment issues like critical events, inventory changes and training documentation;
- implementing and recording employee participation in orientation and education programs;
- ensuring compliance with the MGH medical device recall program;
- working with the Director of Corporate Compliance and the Center for Quality and Safety to ensure compliance with the Safe Medical Devices Act of 1990;
- informing users of how to report the need for repair or inspection of each item of equipment for which the DTMG is responsible.

4.3 DTMG areas of responsibility for equipment included in MEMP

- Biomedical Engineering (BME) is responsible for the management of all medical equipment except those types of devices and systems that are specifically assigned to other MGH departments as DTMGs including the Dialysis Water Treatment System.
- Perioperative Clinical Engineering, in the Department of Anesthesia, manages medical equipment in operating room areas, including anesthesia technologies in some remote locations where anesthesia is administered.
- Respiratory Care Services manages respiratory care technologies.
- Radiology manages imaging technology not managed by Biomedical Engineering within its clinical areas.
- Patient Care Services are responsible for the management of beds.
- The Vascular Lab is responsible for management of all vascular imaging equipment and any medical equipment not managed by Biomedical Engineering within its clinical area.
- Obstetrics/Gynecology is responsible for management of ultrasound equipment and any medical equipment not managed by Biomedical Engineering within its clinical areas.
- Radiation Oncology is responsible for management of radiation treatment equipment and any medical equipment not managed by Biomedical Engineering within its clinical area.
- Cardiology is responsible for the management of unique systems related to specialized cardiology areas such as Cardiac Ultrasound, Holter and Cardiac Rehabilitation, Cath Lab, EP Lab.

4.4 Other areas of responsibility for equipment not included in the MEMP

- The Clinical Laboratories are responsible for managing service, regulatory compliance and other issues associated with instrumentation used in their laboratories, including point-of-care devices. Service is provided in various ways, either by staff members within the individual departments, or by outside vendors on a contractual or as-needed basis.

5 PROGRAM COMPONENTS

5.1 Selection and Acquisition of Equipment

5.1.1 Equipment Procurement

Prior to a proposed purchase or lease of a new type of technology or medical equipment (e.g., a device type or manufacturer which is not in the inventory), the equipment shall be evaluated for:

- risk;
- appropriateness of its intended use;
- electrical and mechanical safety;
- effectiveness of use in the intended environment of care;
- possible problems associated with improper use or atypical conditions;
- provision of maintenance service for the life of the equipment;
- plan for orientation and training of all appropriate clinical staff;
- compliance with Joint Commission National Patient Safety Goals ;
- compatibility with other equipment in the hospital including disposables/accessories.

5.1.2 Selection

The selection of the most appropriate device or system shall be made through collaboration between the clinical department, the Purchasing Division of Partners Materials Management, and the DTMG. Effort will be made to consider the strategic plans of the hospital when making such decisions.

5.1.3 Pre-purchase Planning

The DTMG shall assist with the following activities as required prior to the purchase of new medical equipment:

- negotiation of warranty terms
- planning for the installation of the equipment
- coordination of user in-service education
- negotiation of technical staff training
- assuring special supplies are budgeted and ordered.

5.1.4 Purchase

Requisitions for capital equipment should be reviewed by the DTMG for technical accuracy, cost optimization, and avoidance of potential duplication. Contracts with new vendors should be negotiated through the Contracts, Purchasing Department.

5.1.5 Incoming Inspection

All medical equipment must be inspected for safety and performance by the DTMG or by the manufacturer (or qualified third-party vendor) prior to initial use. This requirement includes all equipment located in an MGH facility.

Under certain circumstances, a modified incoming inspection may be appropriate. When a large quantity of the same device is received by the hospital, a statistical sample of the devices may be selected for incoming inspection, provided that the following conditions are met:

The manufacturer thoroughly tests each device prior to shipment and copies of testing procedures and records are obtained;

The manufacturer provides data on failure rates of new devices upon delivery and the data are deemed acceptable;

The DTMG has sufficient experience with the device type to judge that the risk to the patient of failure is acceptable;

The Medical Equipment Management Committee approves the modified inspection. The MEMC can give approval for modified inspection for generic types of equipment of devices.

5.1.6 Notification of Arrival

When new medical equipment is received by MGH, the appropriate DTMG must be notified immediately.

The appropriate incoming inspection procedure shall be performed to ensure that the equipment is safe and functioning properly before being put into service.

5.1.7 Inspection Failure

If the equipment fails inspection, one of the following actions is recommended:

The equipment is returned to the manufacturer as unsafe for patient care use.
OR
The equipment is modified to make it safe (e.g., adding an isolation transformer) at the expense of the manufacturer.
AND/OR
The problem is referred to the Office of Corporate Compliance/Center for Quality and Safety if failures need to be reported to the FDA.

5.2 Inclusion Criteria and Risk Classification

5.2.1 Program Inclusion Criteria

All medical equipment shall be included in the MEMP. Equipment not meeting the inclusion criterion may be included in the equipment inventory at the discretion of the DTMG.

5.2.2 Risk Classification

All medical equipment in the MEMP shall be identified as High Risk if there is a risk of serious injury or death to a patient or staff person should the equipment fail. This risk classification is determined by evaluating the severity to the patient or staff person as a consequence of failure. See Appendix B: Risk Classification/Severity Assessment. Low Risk devices are defined as those devices where the Severity is Level 1 (Negligible) and Normal Risk devices are defined as those devices where the Severity is Level 2 (Marginal).

5.3 Maintenance Strategies

Medical Equipment manufacturer recommendations for maintenance activities and associated frequencies shall be followed for:

- Medical laser devices
- Imaging and radiologic equipment, whether used for diagnostic or therapeutic purposes
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies
- Equipment subject to federal or state law or Medical Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements.

Maintenance history includes any of the following documented evidence:

- Records of the hospital's experience over time
- Information made public by nationally recognized sources
- Records provided by the hospital's contractors

5.3.1 Maintenance Intervals

All equipment in the MEMP shall follow manufacturers' recommended maintenance intervals unless the equipment is on an AEM program. If manufacturers' recommended maintenance intervals are not available, the interval shall be determined following the guidance of ANSI/AAMI EQ89.

5.3.2 Scheduled Maintenance Procedures

Scheduled maintenance procedures shall follow manufacturers' recommended procedures unless the equipment is on an AEM program. If manufacturers' recommended maintenance procedures are not available, the interval and activities shall be determined following the guidance of ANSI/AAMI EQ89.

5.3.3 Non-hospital-owned Medical Equipment

Non-hospital-owned equipment is defined as equipment that is brought in to the Hospital for various reasons, but is not owned by the Hospital.

Regardless of ownership, all medical equipment shall follow the policies and procedures set forth by this MEMP. Specifically, this includes being entered into the inventory and following the maintenance activities whether they are manufacturer recommended procedures or an AEM program approved by the hospital.

Rented/leased

Rented/leased equipment must conform to the same standards as hospital-owned equipment.

All rented/leased equipment shall receive functional testing on site prior to patient use at the hospital. Additional inspection may be required for high-risk equipment. On-site inspections are not required if all of the following conditions are met:

- equipment is inspected prior to transport;
- inspection documentation provided on delivery of equipment;
- equipment is transported and delivered by the vendor.

Rented/leased equipment shall be assigned a control number, entered into an equipment management database, and assigned a schedule for routine maintenance. The rented/leased equipment will be differentiated as such by either a special control number or special status in the database.

Scheduled maintenance and repair of rented/leased equipment shall be performed either by the DTMG or the rental/leasing company. If the latter, the DTMG must evaluate the rental/leasing company's qualifications and ensure that maintenance procedures comply with the manufacturer's or MGH's specifications.

Physician-owned

If a physician chooses to use privately owned instrumentation for patient care, it must first be examined by the DTMG and pass any applicable performance and safety testing.

If the equipment is substantively different from any already in common use in clinical practice, approval should be sought by the appropriate committee, e.g., Subcommittee on Human Studies, department practice committee, prior to use.

If clinicians other than the owner are expected to use the equipment, in-service training shall be arranged in advance.

Loaned Medical Equipment

Equipment may be on loan from a manufacturer for the purpose of clinical evaluation or as a replacement for equipment that is out of service for repair.

Acquisition of equipment on loan to the hospital should be documented via a no-charge purchase order. It is the obligation of the user to ensure that any new equipment that is on loan to the hospital for clinical evaluation is inspected for electrical safety and functional testing. The equipment must be supplied to the DTMG with an operator's manual and preferably a service manual.

Patient-owned medical equipment and home health care medical equipment

Patient-owned electrically powered medical equipment is not permitted, with the following exceptions:

- Patients may bring their own CPAP (nasal continuous positive airway pressure) machines or BiPAP (bi-level positive airway pressure) machines to the hospital. The device must be inspected by the appropriate DTMG upon the patient's admission to the hospital.
- The patient owns and requires a unique device that is not in the hospital's inventory and is not easily obtainable. The device must be approved by the patient's physician and nursing staff and inspected and approved by the appropriate DTMG with consideration for training that may be required by users/clinicians.

Patient-owned medical equipment must meet electrical safety standards to be used in the hospital.
If the patient-owned medical device does not have a hospital-grade three-prong plug on it, an isolation transformer will be attached to it. Exception: If the DTMG determines that the device is double-insulated, a two-prong plug shall be permitted. [Refer to Chapter 10 (10.2.2.1.2) of Health Care Facilities, NFPA 99 2012 edition, for more information on this issue.]

Whenever there is a request to use a patient-owned medical device that fits the above criteria, the form "Use of Personally Owned Medical Equipment" will be completed. The DTMG technician will inspect the device, note the results of the test on the form, and sign and date the form. The form will then be signed by the patient and filed in the patient's record.

A "Patient Owned Device" label will be placed on the device, which indicates whether the device passed or failed inspection, the date of the inspection, and the initials of the technician who performed the test. The inspection expires in 30 days or when the device leaves the hospital.

A control number will be assigned to the device but a control number label does not need to be affixed to it. The inspection results will be documented in the database with a work order.

5.3.4 Devices used in Clinical Trials

Devices undergoing clinical trial or used only in conjunction with a clinical trial may require special attention to ensure safety.

Partners Investigational Review Board (IRB) is responsible for the approval of all clinical trial protocols at MGH and may set policies for management of devices for clinical trial. Partners IRB protocols are maintained on the Partners Research Administration electronic database.

The IRB classifies each device as being "Significant Risk" or "Non-Significant Risk". A Significant Risk device requires an FDA Investigational Device Exemption (IDE) before it can be reviewed by a DTMG.

IRB protocols that use medical equipment will be reviewed by the appropriate DTMG(s). The review shall include an assessment of the maintenance requirements for the device, following the guidelines set forth in this MEMP.

Once approved by the DTMG, a work order will be generated associated with the approval of any protocol/equipment review. The medical device(s) will be assigned control number(s) and entered into the database as Equipment Class = IRB Device and will henceforth be subject to the policies and procedures of the

MEMP until the device(s) is/are retired. The Principal Investigator (PI) is ultimately responsible for ensuring that the device(s) is/are in compliance with the MEMP.

When the clinical trial has concluded and the IRB device is discontinued from use in the hospital, the user shall ensure that the DTMG is notified and that hospital-applied labels are removed.

5.3.5 Modification and Fabrication of Clinical Devices

To implement a needed safety or performance improvement to medical equipment or system, and if an affordable, clinically or technically acceptable, commercially available solution cannot be obtained, equipment may be modified or fabricated as needed for use only in MGH.

A physician's order is required to fabricate or modify equipment to meet the needs of a specific patient.

A project manager shall coordinate development, engineering review and documentation of the project. Final approval of the modified or fabricated equipment for clinical use and the associated project documentation rests with the director of the DTMG or Hospital Risk Manager.

All fabricated equipment shall be enrolled in the equipment database and assigned control numbers. Device types, model numbers and scheduled maintenance intervals shall be identified. A scheduled maintenance procedure shall be developed. The process of development of the equipment shall be documented. A copy of all final project documentation shall be maintained by the DTMG.

5.4 Alternative Equipment Maintenance (AEM) Program

5.4.1 AEM Definition

Any difference between the manufacturer's recommended activities and/or frequency and those followed by the hospital constitutes an alternative equipment maintenance (AEM) program for that medical equipment.

An AEM program may be considered for medical equipment if the following criteria are met:

- There is sufficient maintenance history for a medical equipment device type/model.
- Any changes made pose no anticipated consequential risk of harm to patients or staff members who use the medical equipment ~~as result of these changes~~.
- Any changes made do not result in degraded performance of the medical equipment.

5.4.2 AEM Analysis

An analysis shall be performed by qualified personnel (as defined by the responsible DTMG) before medical equipment is placed on an AEM program. While each case is evaluated separately and on its own merits, the following factors considered as part of the analysis include:

- How the equipment is used, including the seriousness and prevalence of harm during normal use.
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm.
- Availability of alternative or back-up equipment in the event the equipment fails or malfunctions.
- Incident history of identical or similar equipment.
- Maintenance requirements of the equipment.

For all new AEM's after July 1, 2014[1], maintenance histories should be used to support the analysis. Risk can be assessed by using the formula (see Appendix D: Assessing Risk for an AEM Analysis):

Risk = Severity x Probability

All Low Risk devices that are not exempted from the AEM program (see Section 4.7 Maintenance Strategies), are considered to be on an AEM program. Individual AEM Analyses for each device type/model are not required as the Risk = Severity x Probability is low for the entire category and considered acceptable, regardless of the Probability of Failure.[2]

5.4.3 AEM Maintenance Strategies[3]

The following are acceptable types of maintenance strategies that may be followed in an AEM program. Maintenance activities that combine the different strategies are also acceptable.

Preventive Maintenance (Time-Based Maintenance): A maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. It may be an "interval-based maintenance" where the activities are performed at fixed time intervals or "metered maintenance" where the activities are performed according to metered usage of the equipment. This maintenance strategy is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a defibrillator battery every six months.

Predictive Maintenance (Condition-Based Maintenance): A maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a defibrillator battery twelve months after the manufacturer's recommended interval, based upon historical monitoring that showed battery capacity does not tend to fall below the required performance threshold before this extended time.

Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance): A maintenance strategy where maintenance or replacement is performed only after equipment fails or experiences a problem. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement battery readily available.

Reliability-Centered Maintenance: A maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Example: Replacing a defibrillator battery used in the Cardiac OR more frequently than one used in an Ambulatory office because of the higher frequency of use in the Cardiac OR.

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[1] July 1, 2014 is the date when TJC changed their regulations to reflect changes in the CMS regulations and where Alternative Equipment Maintenance programs are first mentioned.

[2] [2] In other words, even if the Probability of Failure were to be Probable (4), the maximum Risk = Severity x Probability would be Risk = 1 (Negligible) x 4 (Probable) = 4, which is within the acceptable risk range (see Appendix D).

[3] CMS Manual System, Publicaton 100-07 State Operations Provider Certification. Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS).

5.4.4 AEM Maintenance for Low Risk Devices

Since, by definition, Low Risk devices can reasonably be expected to have no adverse health, financial, or operational effect were the device to fail, the AEM maintenance strategy that Low Risk devices will follow is a Reactive, or Run-to-Fail, Maintenance strategy.

5.4.5 Identification of Equipment

Equipment on an AEM program shall be identifiable.

5.4.6 Identifying a Problem

Should an AEM-program device failure be found that may have resulted from the AEM program, a safety report shall be filed. This action will trigger a formal investigation.

5.4.7 Evaluating the Safety and Effectiveness of the AEM Program

The DTMG is responsible for monitoring the safety and effectiveness of the AEM program.

5.5 Management of Hazard Notices and Recalls of Medical Equipment

Device recalls and hazard alerts are coordinated by the Partners Recall Officer in Partners Materials Management. See "HAZARD NOTIFICATION/MEDICAL DEVICE-PRODUCT" located in the MGH Safety Manual, Part 05 Specific Standards, Section 7 (link http://phsweb23/CUSTOMFS/POLICY.ASP?HU=http:++healthcare.partners.org+mgh+policies+default.htm).

5.6 SMDA Reporting, Quality Improvement Indicators, and Equipment Failure Monitoring

5.6.1 SMDA Reporting

The MGH Director of Corporate Compliance is responsible for administration of the SMDA. A procedure shall be maintained for investigating and reporting problems with medical devices in compliance with the Safe Medical Devices Act of 1990 (SMDA). This procedure can be found in the Medical Device Failure Investigation and Reporting Manual, which is currently under the authority of Biomedical Engineering and located in the department's main office.

5.6.2 Monitoring of Quality Improvement Indicators

The DTMG routinely shall monitor performance indicators, e.g., scheduled maintenance, repairs, and use errors. These reports shall be reviewed for trends, potential problems and areas for improvement.

The DTMG routinely shall monitor medical equipment related problems to look for trends in types of repairs and notify the appropriate department when trends indicate a need for replacement of the medical equipment, user education, etc.

5.6.3 Equipment Failures

Medical equipment shall be referred for repair to BME or the DTMG when there is a suspected malfunction.

If it is determined that medical equipment must be removed from service in order to be repaired, the DTMG

shall notify users and provide assistance for maintaining operations during the equipment's absence, i.e., provide back-up equipment whenever possible.

For urgent equipment problems requiring immediate attention, a service call should be placed to the DTMG.

For non-urgent equipment repairs, the device should be discontinued from use, removed from service and tagged with a repair tag if possible. The DTMG should be notified.

Equipment with suspected or known problems shall not be used until it is inspected and/or repaired unless it is needed urgently and is deemed safe by the user.

The DTMG will notify a responsible person before clinical equipment is removed from service.

Upon completion of any repair or upgrade requiring the disassembly of the equipment or upon return from outside service, the appropriate maintenance procedure shall be performed to ensure functionality and safety.

Successful completion of a repair, including any associated scheduled maintenance procedure, shall be documented in a work order, which is stored in the database.

The DTMG shall keep its customers informed about the status of equipment that is out of service for repair.

In the event that a device is serviced by an entity other than the DTMG, the DTMG shall be responsible for records of repairs and for ensuring that the equipment is appropriately and safely returned and placed back into service.

5.6.4 Incident Investigation and Follow-up

If a medical device is involved in an incident, the following procedure shall be followed:

1. The device shall be sequestered with all its disposables,
2. A repair tag shall be completed and the "Involved in Incident/Near Miss" checkbox shall be checked,
3. A Safety Report shall be completed (see below) and its number recorded on the repair tag, and
4. The responsible DTMG shall be called immediately to retrieve the device.

Massachusetts General Hospital has developed programs for reporting and investigating problems, accidents and incidents that involve medical equipment at the hospital (Clinical Policy & Procedure Manual, Adverse Events and Medical Errors). Such events are reported in the hospital's online Safety Reporting System, RL Solutions. Reports submitted involving medical equipment are forwarded to Biomedical Engineering or the appropriate DTMG for investigation and follow-up.

5.7 Emergency Procedures for Medical Equipment

MGH has developed emergency procedures to address a variety of medical equipment incidents. These include procedures for responding to medical equipment incidents and system failures, emergency clinical intervention when medical equipment fails, availability and access to spare equipment for use when equipment fails, and procedures for emergency repair of medical equipment.

5.8 Inventory Documentation

All medical equipment shall be uniquely maintained in an accurate inventory managed by the appropriate DTMG. The database (can be electronic or paper) shall also contain service histories for the devices listed to be used in the program's maintenance and quality improvement activities. Information from the database shall be available for equipment planning, recall, incident investigation, and regulatory activities including SMDA compliance.

Records of scheduled maintenance activities shall be maintained by the DTMG and entered into the equipment database.

Accuracy of equipment information shall be verified when equipment is seen for routine reasons, e.g., scheduled maintenance, repair. The equipment database should include an audit trail, i.e., every transaction for each device shall be recorded.

5.8.1 Equipment Retirement

When equipment becomes obsolete, no longer meets clinical needs, and is replaced by newer, more suitable technology, it must be retired from clinical use so that it does not become a maintenance and user training problem.

When equipment is officially retired, it must be physically removed from the clinical area, have its control number and inspection labels removed, and have its status changed to "retired" in the equipment database. Disposal of the equipment is addressed in 4.12.8 of the MGH Medical Equipment Management Program.

5.8.2 Control Numbers

Each DTMG shall assign a unique number to each medical device for inventory and maintenance history tracking unless it falls into one of the following exceptions:

Under certain circumstances, a unique number may be assigned to a system, rather than the individual components. System Control Numbers should be created for patient monitoring systems and large-scale data acquisition systems. Each piece of equipment associated with the system may or may not have an assigned Control Number.

Large volume items that are low cost and/or low risk, such as regulators and flow meters, may be grouped together and assigned a control number for the entire group.

5.8.3 Inspection Labels

An inspection label shall be placed on equipment included in the Medical Equipment Management Program. At the discretion of the DTMG, exceptions can be made on the low risk and/or low cost, high volume devices.

The label on devices requiring scheduled maintenance shall include the date of last inspection as well as the date for re-inspection. The label shall indicate whom to contact in the event of a problem, need for repair, or question regarding use.

The label on low risk devices does not include any inspection date (need for re-inspection only after servicing).

5.8.4 Missing and Inactive Medical Equipment

When equipment is classified as "Missing", it is removed from maintenance scheduling and compliance reporting in the database.

Missing Medical Equipment with a fixed location and definitive user group

When equipment meeting these criteria is due for scheduled maintenance, a thorough search, consisting of a physical inspection of the area and inquiry to users regarding whereabouts, will be made. If the equipment cannot be located, the users will be notified that they must contact the appropriate testing group when the equipment is found. The leadership of the owner department will be given an inventory by control numbers of all such devices. The equipment will be classified as "missing" until it is located. If it is not located within three scheduled maintenance cycles, it will then be classified as "retired". Equipment having only a 2-year Inventory cycle is classified as missing at time of inventory. If not located by the next inventory cycle (2 years) the device will be classified as retired.

Missing Medical Equipment that is not assigned to a specific location or user group but may be used in various locations throughout the hospitals

When equipment meeting these criteria is due for scheduled maintenance, effort must be made to locate and inspect it. If it is not located after one year of active searching, it will be classified as "missing" until it is located. If it is seen for any reason within that year, including repair or inventory, it cannot be designated as missing. If it is not located within three scheduled maintenance cycles, it will then be classified as "retired". Reasonable exceptions to this policy can be made for equipment with special distribution patterns with the approval of the DTMG.

5.8.5 Equipment that is temporarily removed from clinical use

Equipment that is intentionally removed from clinical use for reasons other than service will be classified as "inactive". This equipment will be excluded from scheduled maintenance scheduling and compliance reports.

5.8.6 Re-Activating Medical Equipment

Equipment that is found after it was designated as missing or equipment that is re-activated after being designated inactive must be inspected before being put back into service.

5.8.7 Equipment that is permanently removed from clinical use

Equipment that is permanently removed from clinical service will be classified as "retired". This equipment will be excluded from scheduled maintenance scheduling and compliance reports.

5.8.8 Disposal of Obsolete or Discontinued Equipment

Retirement of obsolete medical equipment must be coordinated through the DTMG for the purpose of maintaining database accuracy.

The equipment shall be removed from the clinical area and designated as retired in the inventory. Hospital labels shall be removed.

Partners Materials Management is responsible for the appropriate sale, transfer, or disposal of such equipment. When any non-hospital-owned medical equipment is discontinued from use in the hospital, the user shall ensure that the DTMG is notified. Hospital-applied labels shall be removed and change of status documented in the inventory record.

5.9 Incoming Equipment Documentation and Labeling

The risk classification of all devices must be verified and recorded in the database. If the manufacturer or model number is not currently in the inventory, the device must be classified using the risk classification assessment (See Appendix B – Risk Classification/Severity Assessment).

All relevant information regarding the device must be entered into inventory and a control number obtained.

A control number label must be affixed to the device for inventory tracking.

The appropriate inspection label, which includes the phone number of the DTMG or an appropriate contact phone number for maintenance issues (for example: manufacturer service, service contract or IRB Principle Investigator), must be affixed to the device.

5.10 Equipment Maintenance Documentation

A record is maintained in a database for all equipment requiring periodic maintenance in accordance with the hospital's maintenance strategies. Completed scheduled maintenance records shall indicate that the device passed the required maintenance and testing procedure. If a device fails any part of the maintenance procedure, appropriate corrective measures (e.g. repair, calibration, etc.) will be taken and the device retested prior to completion of the record and return of the device to service. If corrective measures are unsuccessful, the failure shall be noted in the record and the device permanently removed from service (retired from the database).

5.11 Maintenance Tools and Test Equipment

DTMGs will provide service technicians the necessary and appropriate tools to maintain medical equipment. Test equipment, if applicable, shall be calibrated on an annual basis and these maintenance records shall be maintained by the DTMG.

5.12 Sterilizer Documentation

Hospital Departments with sterilizers record documentation of biological testing and sterilization parameters and maintain them within their departments for three years. Biomedical Engineering and Anesthesia Clinical Engineering maintain documentation for the inspection, testing and maintenance of sterilizers.

5.13 Hemodialysis Water Quality Documentation and Equipment Maintenance

The Biomedical Engineering Department maintains records of all chemical and biological testing of renal dialysis water. The department maintains trend reports on all chemical and biological testing of renal dialysis water. Inspection, testing and maintenance of hemodialysis equipment are provided by the DTMG or by the manufacturer (or a qualified 3rd party vendor) according to manufacturer recommendations and AAMI/ANSI Standards for Hemodialysis Systems: RD5 (Hemodialysis Systems), RD52 (Dialysate for Hemodialysis) and RD62 (Water Treatment Systems for Hemodialysis Applications).

6 QUALIFICATIONS AND TRAINING

6.1 Qualifications of Personnel Maintaining and Supporting Medical Equipment

Each DTMG shall determine the qualification standards for its employees who maintain, manage, support, plan, analyze, and implement medical equipment and systems for the hospital. Records of staff qualifications shall be maintained by the DTMG.

The DTMG shall also ensure that third party service providers are qualified.

6.2 Training of Equipment Maintainers

Each DTMG shall develop a program to assess the competency of staff that repair and maintain equipment. This assessment shall occur during orientation of new employees and periodically thereafter.

6.3 Training of Equipment Users

Training on the use and maintenance of medical equipment shall be provided via the orientation and training programs of the various departments. Responsibility for the provision and documentation of training is distributed between the DTMGs and user departments. The objective of these programs is to ensure that the staff members possess knowledge in the following areas, as required by their job functions:

- medical equipment capabilities;
- limitations, and special applications for users;
- basic operating and safety procedures;
- emergency procedures for equipment failure;
- equipment maintenance information and maintenance skill requirements;
- systems for reporting equipment problems, failures, and user errors.

When new equipment is purchased by the hospital, arrangements shall be made by the DTMG and the user group to provide in-service training on the use and maintenance of the equipment. This training may be provided by a representative from the equipment manufacturer or vendor. However, the representative must limit training to knowledge necessary to operate the equipment and may not provide clinical instruction to clinical personnel.

7 WAIVERS OR MODIFICATIONS

The above policies may be waived or modified under special circumstances with the approval of the hospital safety committee or other appropriate hospital authority and, when applicable, the consent of the affected clinical area(s).

Sufficient data or rationale justifying the waiver or modification must be presented to ensure that safety is not compromised.

APPENDIX A – GLOSSARY AND DEFINITIONS

AEM: Alternative equipment maintenance: maintenance activities and/or maintenance frequencies that differ from manufacturer recommendations.

BME: Biomedical Engineering

CLIA: Clinical Laboratory Improvement Amendments

CMS: Center for Medicare and Medicaid Services

DTMG: Designated Technology Management Group: an area or department(s) within the hospital responsible for medical equipment management.

Low Risk Device: Medical equipment whose Severity Level is 1 (Negligible) such that failure could reasonably be expected to have no adverse effect (health, financial, operational)

MEMC: Medical Equipment Management Committee

MEMP: Medical Equipment Management Program

MTBF: Mean-time-between-failure

Normal Risk Device: Medical equipment whose Severity Level is 2 (Marginal) such that failure could reasonably be expected to have reversible adverse effect (health, financial, operational)

SM: Scheduled Maintenance

SMDA: Safe Medical Devices Act

TJC: The Joint Commission

Patient Care Equipment or Medical Equipment: devices that provide direct life support, deliver energy to a patient, gather diagnostic information or monitor physiologic condition. The device can also control a body function, deliver a drug or require invasive connection. The device may or may not be electrical.

Scheduled Maintenance: any routine maintenance, testing or inspection that is performed at predetermined intervals to ensure that equipment is electrically safe, that it is functioning properly, or to take actions to prevent failures. Scheduled maintenance may include any or all of the following: visual inspection, electrical safety testing, functional testing, preventive maintenance.

Visual Inspection: an examination of equipment and its environment to check for obvious signs of physical damage, contamination, or misuse.

Electrical Safety: testing the electrical integrity of equipment according to the standards for electrical testing of

medical equipment established by NFPA 99. (Refer to Healthcare Facilities Handbook by the National Fire Protection Agency, 2012)

Functional Testing: the process of ensuring that equipment is performing according to manufacturers' specifications.

Preventive Maintenance: activities intended to reduce the likelihood of future malfunctions, including parts replacement, cleaning, and vacuuming.

APPENDIX B: RISK CLASSIFICATION/SEVERITY ASSESSEMENT

All medical equipment shall be evaluated for the severity to the patient or staff person should the medical equipment fail.

The following severity levels are used:

Severity Levels and Definitions

Severity	Definition
1: Negligible	Failure could reasonably be expected to have no adverse effect (health, financial, operational)
2: Marginal	Failure could reasonably be expected to result in reversible adverse effect (health, financial, operational)
3: Critical	Failure could reasonably be expected to result in permanent adverse effect (health, financial, operational)
4: Catastrophic	Failure could result in loss of life, total financial loss, and/or cessation of all operations

Medical equipment falling into Levels 3 (Critical) and 4 (Catastrophic) shall be identified as High Risk devices.

Medical equipment falling into Level 2 (Marginal) shall be identified as Normal Risk devices.

Medical equipment falling into Level 1 (Negligible) shall be identified as Low Risk devices.

APPENDIX C: PROBABILITY OF EQUIPMENT FAILURE

For the purpose of assessing the risk of putting a medical equipment on an AEM program, only the probability of maintenance-related failures should be considered, i.e. failures resulting from inadequate or insufficient testing, inspection or preventive maintenance. When maintenance-related failure data cannot be separated out, the Meantime Between Failure (MTBF) should always reflect a more conservative number by over-estimating the failures rather than under-estimating the failures.

Meantime Between Failure is calculated using the formula:

MTBF = Total Device-Years / Total Number of Failures During Those Years

The following probability levels are used:

Probability of Failure and Definitions

Probability	Definition
1: Improbable	Failure is extremely unlikely to occur in a device or system (e.g. MTBF > 20 yr)
2: Remote	Failure is unlikely, but possible to occur in a device or system (e.g. MTBF > 20 yr and < 10 yr)
3: Occasional	Failure is likely to occur sometime in a device or system (e.g. MTBF > 5 yr and < 10 yr)
4: Probable	Failure is likely to occur several times in a device or system (e.g. MTBF <5 yr)

Appendix D: Assessing Risk for an AEM Analysis

The following tool is used to assess the risk associated with maintenance-related failures of equipment. It can be applied globally on an entire device type/model, or more specifically towards a particular change affecting a component or subsystem of a device.

The risk is calculated as a function of severity and probability using the following formula:

Risk = Severity x Probability

Where,

Severity takes into consideration the potential for adverse effects on the patient or staff person should the equipment fail (see Appendix B: Risk Classification/Severity Assessment).

Probability looks at the probability of maintenance-related equipment failures due to inadequate or insufficient testing, inspection or preventive maintenance (see Appendix C: Probability of Equipment Failure).

The resulting risk score can be summarized in the following table:

			Probability of Maintenance-Related Failure			
			Improbable 1	Remote 2	Occasional 3	Probable 4
Severity of Failure	Catastrophic	4	4	8	12	16
	Critical	3	3	6	9	12
	Marginal	2	2	4	6	8
	Negligible	1	1	2	3	4

Depending on the results of the risk score obtained using the above formula, approval is required as outlined below:

Risk Score Range	Required Approval Level
Low Risk Score: 1-4	No special approval required
Moderate Risk Score: 5-7	Risk & AEM Analysis must be approved by the DTMG through a process established by the DTMG
Serious Risk Score: 8-11	Risk & AEM Analysis must be approved by the MEMC
High Risk Score: 12-16	Risk & AEM Analysis must be approved by the Hospital Safety Committee