UMass Memorial Medical Center

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| Procedure Name: Medical Device Management Plan | |
| Developed By:  DeparmtnetClinical Engineering | Effective Date: 3/5/2008  Reviewed Date: 10/30/2014  Approved by: Chirag Pujary |
| Applicability: The Medical Device Management Plan applies to all patients, employees, physicians/residents, students, volunteers, and visitors of UMass Memorial Medical Center, including University, Ambulatory Care Center, Memorial and Hahnemann campuses as well as satellite (ie: TriRiver, Barre, Plumbley, Westborough, ,Southborough, Shrewsbury, Home Health, Outreach Lab, Ventures Labs, 21 Eastern Ave endoscopy center, Worc Queen St/PTRC etc.). This program also covers UMass Memorial Community Medical Group sites (CMG), Clinton Hospital, and HealthAlliance imaging/ventilator device service management. | Associated Policies:  #1083 Adverse Medical Device Occurrence Reporting Policy;  #1084 Product Recall/Alerts and Device Tracking policy;  #1140 Personal Wireless (RF, Radiofrequency) Communication Device Usage Guidelines  #1180 Occurrence (Incident) Reporting Policy;  #1304, Capital Requisition and Approval Process;  #1358 New Medical Products and Devices  #2046 Clinical Alarm Systems  #2201 Medications and Medication Devices Obtained from Sources other than the Hospital  #2508 Daily and Alert CheckPoint™ Monitoring  #2515 Temperature Settings for Solution and Blanket Warming Cabinets  #6005 Hazard Surveillance, Environmental Quality Rounds Policy;  # 6021Furnishings and Non-medical Equipment Guidelines**;**  #6605 Laser Safety  UMMS- Standard Operating Procedures for Investigational Devices |
| Keywords: Medical Device, Medical Equipment, Wireless, Clinical Engineering, BioMed, Health Technology, Investigational Devices | |

**Purpose:**

The purpose of the Medical Device Management Plan is to establish and maintain a medical device management program to promote the safe and effective use of all medical devices used at UMass Memorial Medical Center, and other covered facilities as defined in applicability/scope statement.

Through this program, the Medical Center plans to establish and maintain a physical environment free of hazards and manage staff activities to ensure systems for the safety of patients, workforce members, students, volunteers, and visitors. The Medical Device Management Plan is implemented under the direction of the Clinical Engineering Management team. In addition, there is an Environment of Care Committee, a multi-disciplinary oversight group that promotes safety awareness and serves as a clearinghouse for issues related to the quality of the environment of care. The effectiveness of this plan is measured through multiple different data collection tools and follow-up action plans are developed and implemented based on established goals/objectives created for the plan.

**Scope:**

The Medical Device Safety Program applies to all patients, employees, physicians/residents, students, volunteers, and visitors of UMass Memorial Medical Center, including University, Ambulatory Care Center, Memorial and Hahnemann campuses as well as satellite (ie: TriRiver, Barre, Plumbley, Westborough, ,Southborough, Shrewsbury, Home Health, Outreach Lab, Ventures Labs, 21 Eastern Ave endoscopy center. Worc/Queen St PTRC. etc.). This program also covers UMass Memorial Community Medical Group sites (CMG), Clinton Hospital, and HealthAlliance imaging service contract management. It does not include implantable medical devices, disposable medical devices, accessories, or catheters. All equipment included in the Medical Device Management Plan will be identified with a unique hospital inventory tag provided through the Clinical Engineering Department.

Non-medical devices such as, but not limited to, radios, typewriters, coffee makers, microwave ovens, toasters, food-storage refrigerators, as well as personal electrical equipment (i.e.: hair dryers, CD/MP3 players, laptop computers, personal digital assistants (PDAs), etc.) are not included in the medical device management program. Non-medical, patient accessible, equipment will be reviewed annually for safety and reported by exception only by the Clinical Engineering Department. Please refer to policy #6021 for specifics on furnishings and non-medical equipment maintenance guidelines.

**Definitions (If applicable):**

Medical Device – A health care device intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or for the monitoring, and care of patients. Examples of medical devices include but are not limited to: hospital beds, ventilators, monitors, defibrillators, thermometers, etc. This policy does not apply to implants or in vitro reagents, which are devices under the Food and Drug Adminstration definiton

Investigational device: A health care device that may not have received approval for marketing by the US Food and Drug and/or is being tested for safety or efficacy in a new indication.

Personal Electrical Devices (or patient-owned non-medical devices) – Devices used for the patient’s convenience or entertainment

Patient-Supplied Medical Devices – Any medical device that is owned or rented by the patient

IEC 60601 – International Electrotechnical Commission, medical device safety requirements

NFPA 99 – National Fire Protection Agency for healthcare facilities

Workforce Members – All employees, contractors, volunteers, trainees (including medical students, interns, residents, allied health professional and business students), members of the medical staff (including employed and private physicians), temporary employees, and other persons employed, credentialed or under the control of UMMMC whether or not they are paid by UMMMC.

Equipment Management Program (or Computerized Maintenance Management System/CMMS) – Database used to track the inventory and service histories of all medical devices included in the Medical Device Management Plan.

**Responsibilty:**

Development, implementation, & oversight of medical device management plan are the responsibility of the director of clinical engineering.

Hospital Leadership: Through the Environment of Care Committee and Clinical Engineering Management Team, hospital leadership receives summary reports of Performance Monitoring and other activities related to the Medical Device Management Plan on a regular basis.

Chair, Clinical Engineering Management Team: Coordinates the development, implementation, and monitoring of the Medical Device Management Plan. Ensures that reports flow from the Clinical Engineering Management Team to the Environment of Care Committee on a regular basis and that reports of program performance monitoring are given to the Environment of Care Committee as needed.

Clinical Engineering Management Team: Meets to analyze medical device management issues, collaborates with other teams and subcommittees as required, and develops recommendations for resolving them to improve Medical Device Management Performance.

Environment of Care Committee: Reviews activities of the Clinical Engineering Management Team and develops recommendations for improvement as appropriate.

Chair, Laser Safety Committee: Coordinates the development, implementation, and monitoring of the Laser Safety Committee activities. Serves as the clinical certified laser safety officer.

Laser Safety Committee: Meets to analyze laser use issues and develops policies and recommendations for resolving them to enhance the safe use of lasers in the clinical environment. All committee activity is discussed in the Clinical Engineering Management Team.

Department Managers: Responsible to ensure that workforce members are ready to act appropriately for medical device management situations.

* + 1. Provide orientation to new workforce members in their department including job and area specific procedures related to the Medical Device Management Plan.
    2. Maintain appropriate department specific Medical Device Management Plans and Procedures.
    3. Ensure that staff receives appropriate training as necessary to know their role in a Medical Device Management situation (i.e., preventive maintenance, repair service request, in-house device incident involving patient/visitor/employee, medical device user training, medical device recall, etc.).
    4. Monitor competency of workforce members with respect to medical device operations.
    5. Communicate issues and concerns related to Medical Device Management to the Chair, Clinical Engineering Management Team, Clinical Engineering Management Team or Environment of Care Committee as appropriate.

Employee: Workforce members are knowledgeable with regard to the Medical Device Management Plan.

* + 1. Learn and understand their specific role in a Medical Device Management situation.
    2. Ensure that appropriate training and education is received.
    3. Understand their department’s role in a Medical Device Management situation.
    4. Report any concerns related to Medical Device Management to their supervisor.

Facilities Engineering: Facilities Department maintains the refrigerators/freezers, ice machines, blanket warmers, equipment boom arms and surgical lights at Memorial/Hahnemann campuses. Line isolation monitors, translogic pneumatic tube system, public address system, and refrigerators/freezers are maintained through University Campus Facilities. Reverse osmosis system is maintained by Facilities in the Memorial campus Renal Dialysis/Sterile Processing unit, and the University campus Sterile Processing unit only.

Universal Hospital Services (UHS): Contracted entity which manages, disinfects, and distributes mobile medical devices throughout the UMass Memorial Medical Center campuses. UHS also owns and maintains all general infusion pumps and patient controlled analgesia pumps. This program oversight is managed by the Clinical Engineering Department. The performance metrics are reported to the Safety Committee and senior administration for review.

Institutional Review Board of UMass Medical School: Reviews and approves protocols for the use of investigational devices with human subjects and has the responsibility of determining FDA regulatory classification of the proposed use of the device in research with human subjects.

Principal Investigators (PI): Must adhere to the UMass Medical School standard operating procedure for investigational devices. The PI will identify, along with the unit manager, employees whose job roles and responsibilities may be affected by use of the investigation device; and ensure training of those individuals. PI must track investigational device, from shipment through return to sponsor, if appropriate, and be responsible for proper storage and handling of the device

**Program Planning**

Procurement of Medical Device – Procedures for selecting and acquiring medical device.

Refer to administrative policy #1304, Capital Requisition and Approval Process. Refer to administrative policy #1358, Request for Review of Medical Devices and Products Prior to Use in Clinical Care.

Inventory of Medical Devices

Refer to Clinical Engineering Department (508-334-1111) – Medical Device Inventory.

Inspection - Incoming Medical Devices

All medical devices with power sources regardless of ownership shall be inspected for safety, including grounding and minimal current leakage as necessary, prior to being placed in service. The Clinical Engineering Department Electrical Safety Inspection protocol shall be used as the inspection procedure. All measurements shall meet the NFPA 99, IEC 60601 healthcare standards for electrical safety.

Each department that receives new equipment shall notify the Clinical Engineering Department, at 508-334-1111 directly, or through the Materials Management Department, upon delivery of said equipment regardless of the purchase rental, loan, lease, evaluation, or demonstration arrangement. The outside manufacturers/ contractors are responsible for the quality and performance of all rented, leased, contracted, or equipment on evaluation.

The Clinical Engineering Department will inspect the incoming equipment and, if applicable, coordinate and monitor manufacturer’s installation. The Incoming Equipment Inspection Form will be used to document the inspection results. All results will be kept in the Clinical Engineering Department.

Incoming equipment deemed not acceptable following function/electrical safety inspection shall be tagged as such by the clinical engineering technician and arrangements made through the Materials Management Department for repair or replacement by manufacturer or his/her agent prior to putting into use.

The department who rents, leases, or contracts any reusable medical device will be responsible for proper cleaning, disinfecting and for sterilizing the items prior to use.

Environmental Quality Improvement (EQI) Rounds will collect data in regards to the presence of inspection stickers on all medical devices located in clinical departments. Refer to #6005 Hazard Surveillance, Environmental Quality Rounds Policy.

Equipment information and service history will be established and maintained in the Clinical Engineering Department for future record of analysis. A duplicate set of records may be maintained by the department head at his/her option.

For investigational devices, all devices with an power source (internal or external) must be inspected by Clinical Engineering prior to patient use. Software which modifies the function of an existing electrical device approved for sale and distribution in the US is not considered an electrical device (eg, software applications used in mobile phones).

Medical Device User Training

The equipment users or operators shall be properly trained on the safe use of the equipment. For approved medical devices, it is the department head’s responsibility, through collaboration with nursing education department, to coordinate the initial and continued in-service training. All attendance documentation, whether it is for new devices or continuing education on the function and safety of existing devices, should be kept within the department that possesses the equipment. The existence of staff in-service programs for patient care devices will be monitored through periodic review of the Clinical Engineering Management Team

Clinical users of medical devices will include the proper use of devices as part of their departmental competency assessment as appropriate.

The Safety Education Program offers a module that is reviewed annually within each department regarding the safe use of electrically operated patient care equipment.

The Clinical Engineering Department will provide and/or coordinate in-services upon request regarding patient care equipment, electrical safety, functional safety, theoretical operation/performance, or incident investigation.

For investigational devices, the PI or designee must work with the department head to train staff who are affected by use of the investigation device, as per the UMMS SOP on Investigational Devices.

Medical Device Service Contract

The decision to secure equipment service either from Clinical Engineering or an outside service agency, i.e., "Service Contract", is to be considered at the time new equipment is budgeted. After the manufacturer’s equipment warranty expires (generally after the first year), the decision is to be made jointly by the department head, clinical engineering business manager, and director of clinical engineering during the operational budgeting process for inclusion in the Supply and Expense budget. It is the responsibility of the department head to request the advice of clinical engineering business manager and director of clinical engineering.

Additionally, should a service or maintenance contract be desired at any other time, the advice of the clinical engineering business manager and director of clinical engineering should be solicited by the responsible department head.

All service contract agreement information is kept in the Clinical Engineering Department, and in the McKesson/Pathways materials management system.

Risk Based Preventive Maintenance Criteria for Medical Devices:

Clinical Engineering has implemented and deployed a risk based preventive maintenance (PM) inclusion procedure based on the American Hospital Association (AHA) risk model.

Environmental devices are devices in patient care locations, which without maintenance other than the user’s usual care, are reasonably free from avoidable hazard. The decision to classify a device as "environmental" will be made by the Clinical Engineering Management Team on a case by case basis, based on service history and results from the risk table. Based on the preventive maintenance schedule, the environmental devices are examined as part of the overall area inspection. No device specific preventive maintenance (PM) records are maintained within the Equipment Management Program.

Preventive Maintenance, Function Testing and Electrical Safety Inspection of Medical Devices

All patient care equipment is tested for safety and performance prior to initial use and periodically thereafter to permit proper and safe use.

Clinical Engineering Department is responsible for the coordination of the preventive maintenance program for all patient care equipment. In-house preventive maintenance is scheduled and performed by the clinical engineering staff at intervals approved by the Clinical Engineering Management Team, in accordance with Center for Medicare and Medicaid Services, the Joint Commission and ECRI standards. Preventive maintenance performed by outside contractors shall be monitored by the Clinical Engineering Department for maintenance frequency, performance and equipment service records.

Equipment technical performance is verified against the manufacturer’s specifications. The Clinical Engineering Electrical Safety Inspection Protocol is used as the safety inspection procedures.

After each preventive maintenance procedure a sticker is affixed to the equipment. The sticker includes the last inspection date and the date of the next inspection. To ensure patient safety, these stickers should be checked by the equipment operator prior to each use, particularly in those areas where equipment is subject to inter-department inter-unit transfers. Any equipment that lacks an “up-to-date” sticker should be reported to the Clinical Engineering Department and not used until it has been inspected.

A visual inspection should be made by the equipment operator before each use that could identify presence of such deficiencies as frayed cords, overheating, damaged or missing components or accessories, fluid leaks, etc.

All clinical users of medical device should be knowledgeable regarding appropriate and necessary clinical intervention in the event of a device malfunction.

The Clinical Engineering Management Team will monitor and report, on a bi-monthly basis, to the Environment of Care Committee, information on preventative maintenance pending/ completed. All maintenance activities including measurements, analysis, action taken, and parts used are maintained in the Clinical Engineering Department for future analysis. A duplicate set of records may be maintained by the department head at his/her option.

For investigational devices, Clinical Engineering shall determine the appropriate frequency of monitoring and inspection based on the characteristics of the device.

Medical Device Repair, Emergency Service, Product Recall

Any actual or potential medical device or equipment malfunction will be managed as per UMMMC policy “Adverse Medical Device Occurrence Reporting Policy #1083”.

All requests for maintenance or service for patient care equipment will be directed by phone to the Clinical Engineering Department 508-334-1111 during the normal working hours. After normal working hours, emergency repair calls to the Cheshire Help Desk/Call Center (through 508-334-1111 Clinical Engineering’s forwarded line), where an emergency on-call program is established for Clinical Engineering Services or the Clinical Engineering on-call technician and contact information can be accessed through UMMMC OurNet intranet on-call schedule.

Bright red "DEFECTIVE - DO NOT USE" tags shall be affixed so that medical/nursing staff may identify faulty/malfunctioning equipment for removal and/or repair by Clinical Engineering personnel. The "DEFECTIVE - DO NOT USE" tag shall only be removed by Clinical Engineering after the equipment has been repaired and safety tested.

All equipment malfunctions, including rental, leased, loaned and demo equipment shall be reported to Clinical Engineering and arrangements made with Materials Management Department for repair or replacement by manufacturer or his/her agent. Further information and instructions are contained in policy #1083 Adverse Medical Device Occurrence Reporting Policy.

An electrical safety test shall be performed by Clinical Engineering after each repair.

When a device becomes obsolete, has had repetitive extensive repairs, or is in need of replacement or modification due to equipment recall, the Clinical Engineering Department, will advise the affected departments to plan for equipment replacement.

Arrangements for equipment needed as back-up in an emergency situation should be coordinated through the Materials Management and/or Clinical Engineering Department.

All repair activities including measurements, analysis, action taken, and parts used are maintained in the Clinical Engineering Department for future analysis. A duplicate set of records may be maintained by the department head at his/her option.

In the event of receipt of a Product Recall, Refer to #1084 Product Recall/Alerts and Device Tracking policy.

Medical Devices Not Owned, Rented or Leased by UMass Memorial Medical Center

The use of non-hospital owned furnished electrical/battery-operated medical equipment is generally discouraged, except IRB approved investigational devices. However, if such equipment or appliances are deemed necessary for medical reasons, the attending physician’s written authorization is required. The patient must confirm that all necessary maintenance recommended by the manufacturer has been performed. The Hospital should also receive the operator instruction manual. Clinical Engineering shall be contacted for electrical safety inspections before the equipment may be used, if possible. Specific guidelines and forms have been developed for use when patients utilize equipment not provided by the hospital. Please contact Clinical Engineering for further guidance on the use of medical devices not furnished by the hospital as well as the approved forms that must be completed.

For all concerns related to non-Medical Devices not owned, rented or leased by the hospital (i.e., patient/visitor/employee-owned non-medical devices, refer to #6021 Furnishings and Non-medical Equipment Guidelines or UMMS-Standard SOP for Investigational Devices, as appropriate.

Prohibited Equipment and Appliances

The following types of equipment are prohibited from use:

The use of electrical extension cords, except in an emergency situation, which is defined as a situation where patient safety or patient care would be jeopardized; if deemed necessary, an authorized extension cord, i.e. approved by facilities engineering or clinical engineering, may be requested by contacting either department. Facilities engineering will maintain a supply of approved 16-gauge extension cords for emergency situations.

The use of plug adapters (i.e., cheater plugs) that disrupt or bypass the ground connection; Two-wire devices of any sort are strictly forbidden unless polarized and double-insulated.

* Portable space heaters;
* Two-wire electric heater pads;
* Unprotected lead wires/cables used with the following medical devices:
  + - * cardiac monitors;
      * electrocardiographs (ECGs);
      * electroencephalographs (EEGs);
      * electromyographs (EMGs);
      * electrophysiology equipment;
      * multiparameter patient monitors;
      * muscle stimulators;
      * nerve stimulators;
      * neurostimulators;
      * respiratory monitors/apnea monitors;
* Cellular phone use in patient care areas may be restricted; refer to policy # 1140 Personal Wireless (RF, Radiofrequency) Communication Device Usage Guidelines
* Bed/mattress combinations that would compromise patient safety.

Medical Device Malfunctions Involving Patient Injury

Any patient care equipment malfunction involving patient injury should be managed in accordance with Policies regarding:

* + 1. #1083 Adverse Medical Device Occurrence Reporting Policy
    2. #1180 Occurrence (Incident) Reporting Policy
    3. #1073 Mandatory Reporting of Adverse Events to External Regulatory Agencies.

Medical Device users should not call manufacturers’ representatives. Follow-up action will be coordinated through Risk Management and Clinical Engineering directly.

For investigational devices malfunction, the UMass Medical School Investigators Manual details applicable policies and procedures related to reporting of adverse events in clinical studies.

Medical Device User Function Testing

The department head or nurse manager is responsible for ensuring that identified lists of devices are tested at regularly scheduled intervals.

Emergency equipment such as code carts and defibrillators are to be checked at least daily for their availability and proper functioning, or more often if the department head/nurse manager deems necessary. Documentation on appropriate forms will be maintained in the area per coinciding policy and regulatory agency requirements.

Other equipment such as intubation carts or boxes, transport boxes, doptones, closets of assembled equipment needed for certain procedures, etc. are to be checked as frequently as determined by the department head/nurse manager.

Examples of equipment and their components that must be inspected daily are:

* + Code cart – lock
  + Defibrillator - charging, discharge on battery power, paddle condition, all necessary accessories available -internal paddles, i.e., multifunction cable/pads, ECG cable/leads and any other standard patient care equipment kept on unit.

**Monitoring/Reporting**

Data collection for performance measurement of the effectiveness of the Medical Device Management Plan is provided by Environmental Quality Inspection Rounds, and the Clinical Engineering database. The data is reviewed bi-monthly through the Clinical Engineering Management Team and the Environment of Care Committee. Improvement actions are recommended when the minimal performance requirements are not met. Reporting also includes and summarizes trends, medical device related abuse, operator errors – both departmental and equipment type, as well as financial performance of medical device service contractual agreements, as well as general parts service expenditures.

Annual Evaluation of Effectiveness

Annual evaluation contains the following information:

* Performance monitoring standards and measurement of effectiveness
* Scope, Goals and objectives for the coming year

Recommendations for improvement action and follow-up on unachieved performance measurements