Medical Equipment Management Plan
2009

I. Introduction, Mission Statement, and Scope

The Medical Equipment Management Plan defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients. The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment. The mission is to ensure that equipment used in patient care is safe, available, accurate, and affordable. The scope of this plan is Duke University Health System including Duke University Hospital, Duke PDC's, Clinical Laboratories, Durham Regional Hospital and Duke Health Raleigh Hospital.

II. Organization of Participants

- The administration and oversight of medical equipment management is the responsibility of Clinical Engineering.
- Management of medical device incidents is the primary responsibility of Risk Management.
- Management of equipment hazard notices and recalls is the primary responsibility of Procurement Services.

III. Medical Equipment Management

The primary policies for the management of medical equipment are found at www.duhsclinicalengineering.org.

Additional information pertaining to the management of medical equipment can also be found in the Clinical Engineering User's Resource guide located on the above website.

IV. Medical Equipment Management Activities (EC.02.04.01 and EC.02.04.03)

Managing medical equipment risks

1. **Selection and acquisition of medical equipment**

   Clinical Engineering provides guidance and direction in the selection of medical equipment through active involvement in the Duke University Health System capital process. Clinical Engineering also works with department managers and Procurement Services to assist in the selection and purchase of non-capital medical equipment. During this process, input is solicited from individuals who operate equipment. Clinical Engineering works with departments to provide average life expectancy, inventory, and information on equipment that has had extensive repairs or is no longer supported by the manufacturer. Duke University Health System also subscribes to MD Byline research agency specializing in medical equipment. This service provides valuable research and comparative tools for use in requesting medical equipment.

   Clinical Engineering assists in the incoming inspection process and acts as a resource to the hospital's education department to ensure users are trained prior to the use of the equipment.

2. **The organization maintains a written inventory of selected equipment categorized by physical risk associated with risk (including all life support equipment) and equipment incident history. The organization evaluates new types of equipment before initial use to determine whether they should be included in the inventory.**

   The hospital maintains a database documenting all equipment identified in the medical equipment management plan. Items are inspected prior to use in accordance with all applicable policies and procedures. This includes hospital owned equipment as well as loaner, demo, physician-owned, etc. Identification of medical equipment with clinical alarm systems is also completed during the initial inspection process to ensure proper placement in the medical equipment management program. Procurement Services requests that all medical equipment be delivered to Clinical Engineering, with the exception of large installed pieces, e.g., Radiology rooms, Lab Analyzers. Clinical Engineering ensures an

incoming inspection on equipment includes verification of accessories, manuals, electrical safety, and operation in accordance with all applicable policies. At this time, Clinical Engineering will also assess the piece of equipment or system for inclusion in the equipment management program. Using risk-based criteria including equipment function and failure risk and corrective history, Clinical Engineering assigns equipment to a Tier Level of 1, 2, or 3. Items in Tiers 1 and 2 are included in the equipment management program and will receive annual or greater preventive maintenance. Tier 3 items are those items that have been excluded from the program and receive no annual preventive maintenance. Preventive and Corrective histories as well as equipment inventory, risk level, life support/ non – life support information are kept in the equipment database. Equipment incident histories with patient information are kept in the Safety Reporting System. (SRS)

3. **The organization identifies the activities in writing for maintaining, inspecting and testing for all medical equipment on the inventory. The organization uses different strategies for different items as appropriate. For example, strategies such as predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance may be selected to ensure reliable performance.**

   Clinical Engineering uses a combination of maintenance strategies on equipment included in the medical equipment management program. Clinical Engineering uses predictive maintenance for repairs such as battery replacement. Clinical Engineering uses interval-based inspections (scheduled preventive maintenance) for those items that are identified to be Tier Levels 1 or 2. Clinical Engineering uses metered maintenance, based on hours of use, for items such as ventilators or dialysis machines. Clinical Engineering also performs corrective maintenance as requested by user departments or as required because of discoveries during scheduled preventive or metered maintenance.

4. **The organization indentifies the activities in writing frequencies for inspecting, testing and maintaining medical equipment on the inventory based on criteria such as manufacturer's recommendations, risk levels, and current organization experience.**

   Clinical Engineering sets intervals for inspecting and testing equipment included in the management program by determining a risk ranking and assigning a Tier Level. That risk ranking is comprised of a score for equipment function, failure risk, and corrective history. Tier Level 1 represents those items that have maintenance scheduled at least annually according to the recommendations set forth by the manufacturer, the user department, Clinical Engineering and / or the appropriate Safety or Environment of Care Committee. Tier Level 2 represents those items that are lower in overall risk ranking and are scheduled typically for annual or greater preventive maintenance. Testing of clinical alarms for proper function and audibility (if applicable) occurs during each preventive maintenance inspection. Clinical Engineering, in conjunction with the appropriate Safety or Environment of Care Committee, may decide to adjust the Tier level based on equipment history. Frequencies of maintenance are documented in the equipment database.

5. **Monitoring and reporting incidents in which a medical device 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**

   The Director of Risk Management will have the overall responsibility of implementing and managing the hospital's medical device reporting program. This includes establishing and maintaining a hospital-wide system for documenting medical device incidents, reviewing and analyzing all reportable incidents, and completing and submitting appropriate reports to outside agencies. Following an incident, DUHS personnel will attend to the injured patient or employee as appropriate and sequester all equipment involved in the incident including accessories, packaging, etc. DUHS personnel will report the incident to their immediate supervisor and notify Risk Management.

   The **Safety Reporting System (SRS)** is also available for reporting medical device issues.

   DUH/ PDC/ Clinical Labs - http://srs.duhs.duke.edu.

   DRH - http://srs.drh.duhs.duke.edu/

   At Durham Regional Hospital, employees should page Risk Management.

DRAH - http://srs.dhrh.duhs.duke.edu/

At Duke Health Raleigh Hospital employees should contact Risk Management at 954-3123 during normal operating hours, after hours employees will contact the Clinical Administrator at 954-3292.

Clinical Engineering will assist Risk Management in conducting an investigation, evaluating the safety of the device, and determining whether the device should be impounded, repaired, further investigated, or returned to service. A summary of significant medical device incidents will be reported to the appropriate Safety or Environment of Care Committee on at least a quarterly basis.

Monitoring and acting on equipment hazard notices and recalls

All equipment hazard notices and recalls are coordinated through Procurement. Information on hazard notices or recalls that apply to medical equipment are sent electronically. Clinical Engineering will follow all applicable policies and procedures, including checking the Clinical Engineering database to determine the presence of affected equipment and completing and documenting any appropriate work.

6. **Written procedures that address when medical equipment fails:**

    1. including clinical interventions
    2. backup equipment

Emergency clinical interventions that are necessary if a piece of medical equipment fails are established by the equipment-using department. The Clinical Engineering department is staffed 8:00 AM - 4:30 PM Monday through Friday at Duke University Hospital, Durham Regional and the Clinical Laboratories; 7:00 AM- 3:30 PM at Duke Health Raleigh Hospital. Emergency coverage is provided on a 24 hour, seven-day-a-week basis through use of on-call pagers. Users of medical equipment have several different methods of obtaining repair services. Users may notify Clinical Engineering of the need for service during regular rounds performed by the Clinical Engineering department, by calling the main shop phone number, by bringing the piece of equipment to the Clinical Engineering department, or by calling the on-call pager. Should a piece of medical equipment malfunction or fail, hospital staff should first ensure the safety of the patient, remove the piece of equipment from service, label it, and notify Clinical Engineering through one of the methods listed above. The user establishes when and how to perform emergency clinical interventions when medical equipment fails. Backup equipment is available for many types of equipment within the user department, through loaners or spares maintained by Clinical Engineering. Or through such departments as:

Equipment Distribution – DUH
Electronic Flow Control – DRH
Patient Care Equipment Department - DHRH

The Clinical Equipment User's Resource Guide contains valuable information specific to equipment backup and can be found at www.duhsclinicalengineering.org.

Inspection, testing and maintenance of medical equipment

1. **The organization performs safety, operational, and functional of medical equipment identified in the medical equipment inventory before initial use.**

Clinical Engineering is notified by Procurement Services, Materials Management, or user departments when equipment is received into the hospital. Clinical Engineering performs an initial inspection including testing of clinical alarms and an electrical safety inspection (where applicable) in accordance with all applicable policies and procedures before initial use. Information from these inspections are electronically documented and entered into a database.

2. **The organization inspects, tests, and maintains life support equipment**

Clinical Engineering documents all work performed on life support equipment included in the medical equipment inventory plan in accordance with all applicable policies and procedures. Information included

on the work order includes at a minimum: the asset ID (CE# or serial number), a description of problem, the department, the technician performing the work, a description of the repair or maintenance action, and the time spent on the action.

3. **The organization inspects, tests, and maintains non life support equipment**

   Clinical Engineering documents all work performed on non life support equipment included in the medical equipment inventory plan in accordance with all applicable policies and procedures. Information included on the work order includes at a minimum: the asset ID (CE# or serial number), a description of problem, the department, the technician performing the work, a description of the repair or maintenance action, and the time spent on the action.

4. **The organization documents performance testing of all sterilizers used.**

   Central Sterile or Sterile Processing documents performance testing or biological cultures on all sterilizers used. This information is reported at their respective Quality Improvement Committee or Infection Control meetings. Engineering and Operations provides maintenance support on sterilizers at Duke University Hospital, the PDCs and Durham Regional Hospital. Clinical Engineering provides maintenance support on sterilizers at Duke Health Raleigh Hospital.

5. **The organization documents chemical and biological testing of water used in hemodialysis.**

   Chemical testing of dialysis RO product water is performed at least annually and biological testing of the RO system is completed monthly. Each machine has biological testing performed on a scheduled basis. Results are reported to the applicable Quality Improvement, Infection Control or Safety / Environment of Care Committee. Corrective action will be taken for any value outside of AAMI limits.

V. Performance Improvement Standards

Clinical Engineering is responsible for identification of performance improvement indicator, which is based on priorities identified by the department, users of medical equipment, and the appropriate Safety or Environment of Care Committee. The Safety or Environment of Care Committee has the responsibility for approving the monitors and thresholds on an annual basis. All PI activity and quality indicators are reported at least quarterly to the Safety or Environment of Care Committee. This information is provided to the Governing Body through the routine reporting channels. All elements of the PI program are subject to change at any time based on Institutional experience, regulatory change, or administrative input.

VI. Management Plan Evaluation

The Senior Director of Clinical Engineering will evaluate the Medical Equipment Management Plan annually for its scope, objectives, performance, and effectiveness. Any changes in scope will be addressed in the annual update of the plan, and any changes in the range of application or interaction will be incorporated into the plan. Annual planning objectives will be developed through interactions with Safety or Environment of Care Committee members and hospital administration. These objectives will address primary operational initiatives for maintaining and enhancing the safety of the Environment of Care. Progress toward accomplishing these objectives will be reported at least annually to the appropriate Duke University Safety or Environment of Care Committee demonstrating effectiveness of the management plan. The performance of the plan will be assessed through progress in achieving the Performance Improvement Standards defined within the plan. The annual evaluation of the plan will be presented to the applicable Safety or Environment of Care Committee during the first quarter of the new calendar year. This information will be reported to the Governing Body through the routine reporting channels.