

Medical Equipment Management Plan

2017

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, Duke DPCs, Clinical Laboratories, Duke Regional Hospital and Duke 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.

III. Medical Equipment Management

The primary policies for the management of medical equipment are found at:

<https://intranet.dh.duke.edu/dhts/coo/clinical-eng/SitePages/Home.aspx>

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 (EC.02.04.01)

1. *The hospital solicits input from individuals who operate and service equipment when it selects and acquires 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 Buyline 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 hospital maintains a written inventory of all medical equipment.*

The hospital maintains a database documenting all equipment identified in the medical equipment management plan. This includes hospital owned equipment as well as loaner, demo, physician-owned, etc. The database for any patient owned devices can be accessed from the medical record (see EOC.02.04.03 #1).

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. 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 to determine high risk versus routine (non-high risk) equipment. Preventive and Corrective histories as well as equipment inventory, risk level, high risk information are kept in the equipment database. Equipment incident histories with patient information are kept in the Safety Reporting System. (SRS)

3. The hospital identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.

All equipment is evaluated at the time of entry into the medical equipment database using a risk ranking system. The scoring to determine high risk is comprised of a score for equipment function, a score for clinical application and a score for infection control risk. If the total score is greater than or equal to 13, then equipment is identified in the database system as high risk. All equipment with scores totaling less than 13 are considered routine (non-high risk).

4. The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Note: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice. *

Footnote *: An example of standards for a medical equipment program is the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.

All equipment included in the medical equipment management program will receive scheduled maintenance and testing based on manufacturer's recommendations unless otherwise identified for inclusion into the alternative equipment maintenance (AEM) program. The record of this schedule will be included in our database management system. Items included in the AEM will be recommended by Clinical Engineering and be based on records provided by the hospital's contractors, information made public by nationally recognized sources, or records of the hospital's experience over time. Items recommended for inclusion to the AEM will be approved by the Environment of Care committee.

5. The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturer's recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturer's recommendations, or otherwise establishes more stringent requirements
- 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

DUHS will also follow manufacturer's recommendation for items that have been designated as high-risk.

6. A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:

- 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 that equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

The DUHS clinical engineering leadership developed a methodology, based on the above criteria, for the identification of equipment to be included in the alternative equipment maintenance (AEM) program. This methodology was approved by Safety or EOC Committee at each entity. Clinical Engineering leadership will be able to demonstrate the qualifications to make recommendations based on formal education, certification and relevant work experience.

7. The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

DUHS Clinical Engineering will designate in its medical equipment database all items that have been recommended and approved by the Environment of Care committee for inclusion into the AEM program.

8. 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 Device 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 available for reporting medical device issues.

http://vmw-rlrapp2/RL6_Prod/Homecenter/Client/Login.aspx

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 incidents will be reported to the appropriate committee on at least a quarterly basis by Patient Safety/ Risk Management.

9. The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and back-up equipment.

Emergency clinical interventions that are necessary if a piece of medical equipment fails are established by the equipment-using department. 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 below. 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 - DRAH

The Clinical Engineering department is staffed 8:00 AM - 4:30 PM Monday through Friday at Duke University Hospital and the Duke PDCs and DPCs 7:00 AM- 3:30 PM at Duke Raleigh Hospital and Duke Regional Hospital and the Clinical Labs. Emergency coverage is provided on a 24 hour, seven-day-a-week basis, for the hospitals, 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, by entering a request on the Clinical Engineering web portal- include website link, or by calling the on-call pager.

The Clinical Equipment User's Resource Guide contains valuable information specific to equipment backup and can be found at: <https://intranet.dh.duke.edu/dhts/coo/clinical-eng/SitePages/Home.aspx>

The hospital inspects, tests, and maintains medical equipment (EC.02.04.03)

1. *Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.*

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 the equipment management database. Clinical Engineering also performs safety, operational, and functional checks after major repairs or upgrades and these records are also maintained in the equipment management database. (Exception- patient owned and rental equipment)

Use of patient-owned medical devices are discouraged from use and effort should be made to substitute a Duke owned equivalent. If this is not possible, then the caregiver will get the patient to fill out a Non-Duke owned medical equipment release form. An inspection will be performed by the caregiver and the form will be scanned into the medical record. This form includes data on device, manufacturer, model, and serial number.

Rental equipment- if a rental vendor has been reviewed and approved by the Environment of Care committee as meeting all standards of our medical equipment management program, then they may bring in rental equipment directly to the unit and the caregiver will ensure the rental equipment has a valid PM sticker. If they have not been approved, then Clinical Engineering must be notified and

complete the initial inspection. A listing of approved rental vendors can be found on the Clinical Engineering website in the User Resource Guide: <https://intranet.dh.duke.edu/dhts/coo/clinical-eng/SitePages/Home.aspx>

2. *The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.*
Clinical Engineering documents all work performed on all high-risk 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, technician performing the work, a description of the repair, maintenance action, and the time spent on the action. Scheduled maintenance for high-risk medical equipment will have a 100% completion rate which includes documented In Clinical Use and Shipped to Vendor status.
3. *The hospital inspects, tests, and maintains non-high risk equipment identified on the medical equipment inventory. These activities are documented.*
Clinical Engineering documents all work performed on routine (non -high-risk) 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, technician performing the work, a description of the repair or maintenance action, and the time spent on the action. Scheduled maintenance for routine (non high-risk) medical equipment in the AEM program will have a 100% completion rate which includes documented In Clinical Use and Shipped to Vendor status.
4. *The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.*
Central Sterile or Sterile Processing documents performance testing or biological cultures on all sterilizers used. This information is reported at their committee meetings. Engineering and Operations provides maintenance support on sterilizers at Duke University Hospital, the PDCs and Duke Regional Hospital. Clinical Engineering provides maintenance support on sterilizers at Duke Raleigh Hospital.
5. *The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.*
Chemical testing of dialysis RO product water is performed at least annually. Biological and LAL testing of RO systems are 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. At a minimum, corrective action will be taken for any value outside of AAMI limits.
6. *Qualified hospital staff inspects, test and calibrate nuclear medicine equipment annually. The dates of these activities are documented.*
Qualified staff coordinates the inspection, testing and calibration of nuclear medicine equipment. Clinical Engineering is responsible for coordinating inspection, testing and calibration of Nuclear Medicine Cameras. Ancillary and test equipment is the responsibility of the facilities Nuclear Medicine Department.

V. Performance Improvement Standards

Clinical Engineering is responsible for identification of performance improvement indicators, 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.