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Medical Equipment Management Plan
2025

I. Introduction, Mission Statement, and Scope

The Medical Equipment Management Plan (MEMP) outlines the strategies and procedures for the effective management, maintenance, and utilization of medical equipment across Duke Health facilities.

This plan aims to ensure the safe and reliable operation of medical devices, promote regulatory compliance, and support the delivery of high-quality patient care without incurring unnecessary expenses.

The Medical Equipment Management Plan encompasses all aspects of managing medical devices across Duke Health facilities, including Duke University Hospital, Duke Regional Hospital, Duke Raleigh Hospital, Duke Primary Care, Duke Health Integrated Practice, and Clinical Labs. This plan applies to medical devices used in patient care for diagnosis, treatment, and monitoring.

II. Organization of Participants

The administration and oversight of medical equipment management is the responsibility of Clinical Engineering.

III. Medical Equipment Management

The primary policies for the management of medical equipment are reviewed annually and stored digitally within the Duke Health Policy Center. These policies are listed under DHTS Clinical Engineering.

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

EC.02.04.01: The hospital manages medical equipment risks.
EP2 - 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. The “DHTS Clinical Engineering – Inspection of Patient Related Equipment” policy, located in the Duke Health Policy Center, was created to fulfill this element of performance.

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.

Refer to the following policies for more information:

- "DHTS Clinical Engineering – Inspection of Patient Related Equipment"
- "DHTS Clinical Engineering - Incoming/Outgoing Inspection and Disposal Policy"

EP3 - 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).

Refer to the following policies for more information:

- "DHTS Clinical Engineering – Inspection of Patient Related Equipment"

EP4 - The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory.

All equipment included in the medical equipment management program will receive scheduled maintenance and testing based on manufacturer's recommendations unless otherwise identified, and approved, for inclusion into the alternative equipment maintenance (AEM) program.

EP5 - 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 manufacturers' recommendations, or otherwise establishes more stringent maintenance 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*

Note: Maintenance history includes any of the following documented evidence:

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

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

EP6 - 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. Safety or EOC Committee previously approved this methodology 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.

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.

EP7 - The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

These devices will be identified in the computerized maintenance management system.

EP9 - The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and back-up equipment.

Should a piece of medical equipment malfunction or fail, hospital staff should remove the piece of equipment from service, label it, and notify Clinical Engineering through one of the methods listed below. The clinical 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, DHIP, and DPC
- 7:00 AM- 3:30 PM at Duke Raleigh Hospital and Duke Regional Hospital and the Clinical Labs.
- Emergency coverage is provided to the hospitals through use of on call pagers for off hours, including all nights, weekends, and holidays.

The Clinical Engineering department has adopted a standard work order system for all departments requesting maintenance on clinical equipment. When a malfunction occurs with a piece of clinical equipment that is encompassed within the program of the Clinical Engineering department, the using department shall notify Clinical Engineering during rounds, by telephone (see "DHTS CE007 On Call and Work Hours" policy), by on-line web request, or by bringing the device to the Clinical Engineering office. More information can be found in the "DHTS Clinical Engineering – Work Order Repair Requests" policy on the Duke Health Policy Center.

EP10 - The hospital identifies quality control and maintenance activities to maintain the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. The hospital identifies how often these activities should be conducted.

Quality Control activities are the responsibility of the Medical Imaging Physics group and the medical physicists. They conduct a performance examination on all CT, PET, MRI and nuclear medicine devices at least annually. They produce a formal report with any deficiencies that may have been identified. The departments will then work with the physicists, clinical engineering and the vendors to correct any deficiencies.

EP11 - The hospital monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.

Equipment incident histories are kept in the Safety Reporting System(SRS). This process is explained in the "DHTS – Clinical Engineering Incident Procedure" policy on the Duke Health Policy Center.

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

EP1 - 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.

EP2 - The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.

EP3 - The hospital inspects, tests, and maintains non-high risk equipment identified on the medical equipment inventory. These activities are documented.

Procurement Services, Materials Management, or user departments notify clinical Engineering 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 is 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.

Refer to the following policies for more information:

- "DHTS Clinical Engineering – Inspection of Patient Related Equipment"
- "CE013 Clinical Engineering Work Order Documentation"
- "DHTS Clinical Engineering - Periodic Maintenance"

EP4 - 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, Duke Regional Hospital, and Duke Raleigh Hospital.

EP5 - The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

Refer to the following Policies:

- "DHTS Clinical Engineering - RO Water System Culture and Endotoxin Sampling"
- "DHTS Clinical Engineering - Dialysate Fluid Culture and Endotoxin Sampling"
- "DHTS Clinical Engineering - Carbon Tank Chlorine Breakthrough"

EP8 - Equipment listed for use in oxygen enriched atmospheres is clearly and permanently labeled (withstands cleaning/ disinfecting) as follows:

- *Oxygen metering equipment, pressure reducing regulators, humidifiers, and nebulizers are labeled with name of manufacturer or supplier*
- *Oxygen metering equipment and pressure reducing regulators are labeled "OXYGEN-USE NO OIL"*

- *Labels on flowmeters, pressure-reducing regulators, and oxygen-dispensing apparatuses designate the gases for which they are intended*
- *Cylinders and containers are labeled in accordance with Compressed Gas Association (CGA) C-7*

Duke Respiratory Care Services along with Supply Chain will work to ensure that all flowmeters, pressure-reducing regulators, humidifiers, nebulizers, and oxygen metering equipment contain all the information as outlined in this standard prior to purchase and any items found without this information will be removed from service and be replaced.

EP10 - All occupancies containing hyperbaric facilities comply with construction, equipment, administration, and maintenance requirements of NFPA 99-2012: Chapter 14.

Duke coordinates activities to comply with NFPA 99-2012: Chapter 14 among various departments within Duke including, but not limited to: Hyperbaric staff, Engineering and Operations, Clinical Engineering, and Infection Control.

EP16 - 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.

EP18 - The hospital maintains the quality of the computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced.

The Medical Imaging Physics group and medical imaging physicists are responsible for the oversight and management of the quality of the CT, PET, MR and NM images produced within the Duke Health System. Performance evaluations are conducted annually at a minimum.

EP26 - The hospital performs equipment maintenance on anesthesia apparatus. The apparatus are tested at the final path to patient after any adjustment, modification, or repair. Before the apparatus is returned to service, each connection is checked to verify proper gas flow and an oxygen analyzer is used to verify oxygen concentration. Areas designated for servicing oxygen equipment are clean and free of oil, grease, or other flammables.

The Duke Clinical Engineering department maintains the oversight of all repairs to the anesthesia apparatus. Clinical Engineering will ensure that each connection is tested to verify proper gas flow and that an oxygen analyzer is used to verify oxygen concentration. Clinical Engineering will work with departments to identify and designate a space for servicing oxygen equipment and that the area designated is free of oil, grease or other flammables.

Refer to the following policies for more information:

- "DHTS Clinical Engineering - Periodic Maintenance"

EP27 - The hospital meets NFPA 99-2012: Health Care Facilities Code requirements related to electrical equipment in the patient care vicinity.

Duke hospital has processes in place to meet the requirements related to electrical equipment in the patient care vicinity. Clinical Engineering and Engineering and Operations both utilize initial incoming inspections processes along with rounds within in the patient care vicinity to ensure compliance.

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 Clinical Engineering Senior Director and management team 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.