



CLINICAL POLICY

Medical Equipment Management Plan

A. EFFECTIVE DATE :

July 20, 2021

B. PURPOSE :

To ensure the Medical Equipment Management Plan processes are in place to manage all medical equipment (as defined below) used at John Dempsey Hospital (JDH) and associated clinics in compliance with current Joint Commission standards

C. POLICY :

The Clinical Engineering Department will manage and document the inventory changes, service requests, repairs, performance testing, preventive maintenance and recalls on the medical equipment at JDH, UMG and associated clinics.

D. SCOPE :

The scope of this Medical Equipment Management Program applies to all medical equipment intended for use at JDH and associated clinics. In some cases, certain maintenance responsibilities under the Medical Equipment Management Plan are shared with or delegated to local managers and/or outside parties.

E. RESPONSIBILITY :

Except as otherwise noted, the Clinical Engineering Manager at JDH is responsible for development, implementation, monitoring, reporting and assuring the quality of the Medical Equipment Management Plan (MEMP).

F. DEFINITIONS :

Medical Equipment – The Joint Commission defines medical equipment as equipment used for the diagnosis, treatment, monitoring, and direct care of patients.

High-Risk Medical Equipment – Medical equipment for which there is a risk of serious injury or death to patient or staff member should the equipment fail. High-risk medical equipment includes life-support equipment.

G. MATERIAL(S) NEEDED :

NONE

H. PROCEDURES :

1) Medical Equipment Inventory

1. Clinical Engineering maintains a computer-based inventory of all medical equipment at JDH and associated clinics.
2. Medical devices requiring scheduled maintenance are included on the inventory as individual line items.
3. Medical devices not requiring scheduled maintenance are included on the inventory as individual line items for the purpose of recording item-specific service data.
4. Missing equipment (not able to be located) will be removed from the active inventory. (see Procedure 11-021A, Medical Equipment Inventory Management)
5. The inventory for all medical equipment is recorded in the appropriate computerized maintenance management system, CMMS, database managed by Clinical Engineering.
6. Each device is identified by a permanent unique device identification number, either the Property Administration HC# tag or by the device's serial number when appropriate. (e.g. when the bar code tag won't fit, the device is here temporarily, or the device is exchanged often).
7. All service events of any kind are documented in the CMMS

2) High-Risk Medical Equipment and Performance Monitoring

1. Clinical Engineering identifies high-risk medical equipment as medical equipment on the inventory for which there is a risk of serious injury or death to patient or staff member should the equipment fail.
2. The performance goal for high-risk medical equipment is 100% on-schedule completion of scheduled maintenance.
3. The performance goal for non-high risk medical equipment is 100% on-schedule completion of scheduled maintenance.
4. Scheduled maintenance is considered to have been completed on schedule if it was performed in the month scheduled, the month before or the month after (three month window). (see HAM Policy # 11-050 & Medical Equipment Scheduled Service Procedure 11-021B)
5. Medical equipment that is scheduled for maintenance but is in long-term use, cannot be located, is out of service, is out for service, or is otherwise unavailable for maintenance, is not included in the calculation of on-schedule completion of scheduled maintenance.
6. Multiple efforts are made to access high-risk medical equipment that is initially unavailable for scheduled maintenance. These efforts are documented in the Clinical Engineering CMMS system.
7. Failure to access high-risk medical equipment is communicated to clinical departments and reported to the EOC Committee. When equipment that is in use on a patient becomes available, the clinical department takes the equipment out of service and notifies Clinical Engineering of its availability.
8. Clinical Engineering, JDH and UMG departments may use outside vendors to perform some of the required maintenance work. Clinical Engineering periodically evaluates vendor performance (see Vendor Management policy HAM policy # 11-049).
9. High-risk medical equipment is identified in the Clinical Engineering computerized maintenance monitoring system, CMMS.
10. The percentage of scheduled maintenance completed on schedule is calculated monthly and reported to the EOC Committee. In addition to reporting for JDH as a whole, separate reports are generated for (a) medical equipment managed by Clinical Engineering and (b) medical equipment managed by other departments (e.g. Clinical Laboratory, Central Supply, and Pharmacy).
11. Outside vendors will be evaluated for timeliness, qualifications and service requested vs. service provided vs. service billed.

3) Equipment Maintenance Program

1. The hospital identifies the activities and frequencies for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and frequencies are in accordance with manufacturer recommendations or with the AEM policy (See Medical Equipment Alternate Equipment Maintenance (AEM) Assessment, HAM policy # 11-050).
2. CE performs safety, operational, and functional checks before initial use of medical equipment and after major repairs or upgrades (see Medical Equipment Electrical Safety HAP policy 11-060& Medical Equipment Unscheduled Service Procedure 11-021C).
3. CE Inspects all non-owned equipment entering the hospital if it will be used for patient care (see Rental, Demo, Loaner and Other Non-hospital Owned Patient Care Equipment Used by John Dempsey Hospital Staff, policy HAM # 11-002 and Patient Owned Equipment and Non-standard Medical Devices policy HAM policy # 11-034).
4. Medical equipment maintenance is documented in the Clinical Engineering CMMS, including safety, operational, and functional checks before initial use and after major repairs or upgrades.
5. Following completion of any scheduled work, Clinical Engineering places an inspection sticker on the medical device with the next inspection due date.
6. Clinical Engineering documents decision-making regarding inclusion of medical equipment in the AEM program and monitors the safety of medical equipment in the AEM program. These activities are annually reported to the EOC Committee.
7. The Clinical Engineering CMMS identifies which equipment has been included in an AEM program.
8. For all medical equipment which is not managed by clinical engineering, but managed by other departments (e.g. Laboratory, Dialysis, Central Sterile Supply, Pharmacy) is documented and tracked by their departmental procedures

4) Incident Monitoring and Reporting

1. Clinical Risk Management and Regulatory Compliance is responsible for monitoring and reporting medical equipment-related incidents. (See Incident Reporting-Clinical Hospital Acquired Adverse Event, Serious Adverse Event (Never-Event) and Sentinel Event, HAM # 11-017, Equipment Involved in Patient Injury policy HAM # 11-020 and Reporting Adverse Medical Device Incidents policy HAM # 11-032).
2. Upon request by Clinical Risk Management and Regulatory Compliance, Clinical Engineering assists with investigations of medical-equipment related incidents.
3. Medical equipment-related incidents are documented by the Clinical Risk Management and Regulatory Compliance Department.
4. The Manager of Clinical Engineering and files the FDA medwatch reports for JDH (see Reporting Adverse Medical Device Incidents policy 11-032).

5) Response to Medical Equipment Failure

1. Clinical Engineering is staffed from 7:30am to 4:00 pm, Monday through Friday. Outside of these hours, Clinical Engineering staff are on call. (see Medical Equipment Unscheduled Service Procedure 11-021C)
2. Departments using medical equipment are responsible for educating users regarding procedures to follow when medical equipment fails. (see Medical Equipment Quality Management Procedure 11-021D)
3. If replacement equipment is needed for patient care clinical engineering is contacted for assistance (see Equipment: Safety of Patient in Case of Malfunction HAM policy # 11-048).
4. Written procedures when equipment fails are maintained by their respective departments utilizing the equipment. The hospital provides guidelines for which departments to call when equipment fails. (See Equipment Involved in Patient Injury HAM policy #11-020 and Equipment: Safety of Patient in Case of Malfunction HAM policy # 11-048).

5. Documentation of education about this policy is maintained by the departments using medical equipment or in Nursing Education.

6) Response to Product Notices and Recalls

1. The Clinical Engineering Manager is the coordinator and tracks this program. Reporting of device related incidents to the manufacturer and/or the FDA is managed by the Clinical engineering Department's Clinical Engineers. (see Reporting Adverse Medical Device Incidents HAM policy # 11-032 and Tracking of Medical Devices for Recalls HAM policy # 11-036).
2. Any information that comes into the organization regarding manufacturer recalls or warnings about medical equipment is immediately forwarded to the Clinical Engineering Manager. Immediate action is taken and documented to ensure that suspect equipment is identified, located, taken out of service, inspected, and repaired as appropriate.
3. On a regular basis, the ECRI Alerts Tracker electronically distributes applicable hazard alert/product recalls to each user assigned to the particular area of responsibility. The following health center departments will address any alert/recalls that are assigned under their areas of responsibility. Each of these departments shall review the notifications in a timely manner to determine relevance to their areas of responsibility; and act accordingly to their respective policies/procedures for addressing recall notifications.
4. Any hospital department receiving a product recall, field correction, or hazard alert directly from a manufacturer or other outside source, will respond to the notification, if applicable, and forward the notification to the Clinical Engineering Manager (Hazard Alert/Product Recall Coordinator) as needed.
5. **URGENT, LIFE-THREATENING RECALLS OR HAZARD ALERT, NOTIFICATIONS** will be telephoned and emailed to relevant areas. The Hazard Alert/Product Recall Coordinator shall also be notified by the department first receiving the notification.

7) Computed Tomography (CT), Positron Emission Tomography (PET), Magnetic Resonance Imaging (MRI), and Nuclear Medicine (NM) Equipment

1. Radiology is responsible for quality control and equipment maintenance to maintain the quality of diagnostic CT, PET, MRI, NM images.
2. Imaging equipment preventative and corrective maintenance is managed by Clinical Engineering and equipment is maintained according to each manufacturer's recommendations for procedure and frequency.
3. Documentation of Imaging quality control is maintained in Radiology.
4. Radiographic equipment inventory and maintenance records are kept in clinical engineering's CMMS.

I. **ATTACHMENTS :**

NONE

J. **REFERENCES :**

HAP EC.02.01.01 EP 11: *The organization responds to product notices and recalls*

HAP EC.02.04.01 EP 2: *The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life-support equipment) and equipment incident history. The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory.*

HAP EC.02.04.01 EP 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.*

Note: High-risk medical equipment includes life-support equipment.

HAP EC.02.04.03 EP 2: *The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.*

HAP EC.02.04.03 EP 3: *The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.*

HAP EC.02.04.01 EP 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.*

HAP EC.02.04.01 EP 5: *The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:*

Equipment subject to federal or state law or Medical 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.

HAP EC.02.04.01 EP 6: *A qualified individual uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternative 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 the equipment fails or malfunctions.

Incident history of identical or similar equipment.

Maintenance requirements of the equipment.

HAP EC.02.04.01 EP7: *The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.*

HAP EC.02.04.03 EP 1: *Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the organization performs safety, operational, and functional checks.*

HAP EC.02.04.01 EP 8: *The hospital monitors and reports all incidents in which medical equipment is suspected of contributing to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act.*

HAP EC.02.04.01 EP 9: *The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.*

HAP EC.02.04.01 EP 10: *The hospital identifies quality control and maintenance activities to maintain the quality of diagnostic CT, PET, MRI, NM images produced.*

HAP EC.02.04.03 EP 14: *Qualified hospital staff inspect, test, and calibrate nuclear medicine equipment annually. The dates of these activities are documented.*

HAP EC.02.04.03 EP 15: *The hospital maintains the quality of the diagnostic CT, PET, MRI, and NM images produced.*

HAP EC.02.04.03 EP 17: *At least annually, a diagnostic medical physicist [measures the radiation dose of each diagnostic CT imaging system].*

HAP EC.02.04.02 EP 19: *At least annually, a diagnostic medical physicist conducts a performance evaluation of all diagnostic CT imaging equipment.*

HAP EC.02.04.02 EP 20: *At least annually, a diagnostic medical physicist or an MRI scientist conducts a performance evaluation of all MRI imaging equipment.*

HAP EC.02.04.02 EP 21: *At least annually, a diagnostic medical physicist or NM physicist conducts a performance evaluation of all NM imaging equipment.*

HAP EC.02.04.02 EP 22: *At least annually, a diagnostic medical physicist conducts a performance evaluation of all PET imaging equipment.*

Hospital Administrative Manual (HAM):

11-002	Rental, Demo, Loaner Patient Care Equipment
11-017	Incident Reporting
11-020	Equipment Involved in Patient Injury
11-032	Reporting Adverse Medical Device Incidents
11-034	Patient Owned equipment and Non-standard Medical Devices
11-036	Tracking of Medical Devices for Recalls
11-048	Safety of Patient in Case of Equipment Malfunction
11-049	Vendor Management
11-050	Medical Equipment AEM Assessment
11-060	Medical Equipment Electrical Safety
ADM-050	Enterprise PACS and Imaging Data Quality

K. SEARCH WORDS :

NONE

L. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

M. STAKEHOLDER APPROVALS :

On File

N. COMMITTEE APPROVALS :

NONE

O. FINAL APPROVAL :

- | | |
|---|---------------------------|
| 1. <u>Andrew Agwunobi, MD (Signed)</u>
Andrew Agwunobi, MD, MBA
UConn Health Chief Executive Officer | <u>07/28/2021</u>
Date |
| 2. <u>Anne D. Horbatuck, (Signed)</u>
Anne D. Horbatuck, RN, BSN, MBA
Clinical Policy Committee Co-Chair | <u>07/28/2021</u>
Date |
| 3. <u>Scott Allen, MD (Signed)</u>
Scott Allen, MD
Clinical Policy Committee Co-Chair | <u>07/22/2021</u>
Date |
| 4. <u>Caryl Ryan (Signed)</u>
Caryl Ryan, MS, BSN, RN
Interim Chief Operating Officer, JDH
VP Quality and Patient Services & Chief Nursing Officer | <u>07/21/2021</u>
Date |

P. REVISION HISTORY :

Date Issued: 6/87, 2018 MEM Plan

Date Revised: 12/88, 1/92, 12/94, 8/09, 5/10, 9/12, 1/13, 4/14, 8/15, 3/18

Date Reviewed: 5/97, 1/00, 10/03, 5/06, 11/08, 7/21