

Whiting Forensic Hospital
Management of the Environment of Care
2018 Medical Equipment Management Plan

MISSION STATEMENT

The mission of the Medical Equipment Management Plan is to improve the health of the people of Connecticut by providing cost effective, quality health and hospital services. Consistent with this mission, the Governing Body, medical staff and administration have established and provide ongoing support for the Medical Equipment Management Program described in this plan. Note: WFH is not a medical hospital.

SCOPE

The Medical Equipment Management program applies to all hospital owned, leased and rented devices used for the diagnosis, treatment and monitoring of patients. The program establishes and evaluates the role of contractors in the selection, acquisition and maintenance of equipment and in the training of staff.

WFH Medical Equipment management program includes all owned, rented or leased bio-medical equipment at WFH.

Purpose of the Medical Equipment Management Plan

The purpose of the Medical Equipment Management Plan is to promote a safe patient care treatment environment at WFH by managing risks associated with the use of clinical equipment technology.

The plan includes processes for the selection, maintenance and employee education/training designed to promote safe and effective use of clinical equipment.

1. Improve the employee knowledge of medical equipment requirements and support the routine operational needs of equipment users.
2. Participates with pre-purchase equipment selection and new product evaluations.
3. Manage and track all maintenance requirements, activities, and expenses required to service, repair, and keep operational all Medical Equipment included in the plan.
4. Develop and manage all aspects of a comprehensive maintenance program and related quality assurance activities that take into account equipment function, safety risks, and maintenance requirements

Objectives:

- To assure that all rented and leased equipment is tested and documented in accordance to our management plan requirements.
- Continue to improve Nursing staff notification to Central Medical when medical equipment is broken, in need of repair, retest, removed from service, or relocated.
- To improve Nursing and Clinical staff awareness of Bio-medical equipment safety and inspection compliance (i.e. Out of date Bio-Med test stickers, missing stickers, or undocumented relocation of medical equipment)
- To improve procedures to test equipment prior to issue.
- To improve procedures to assure compliance of annual electrical safety testing utilizing the computerized maintenance management system.

ORGANIZATIONAL RESPONSIBILITIES**Authority and Appointment:**

- The Chief Executive Officer at WFH appoints a:
 1. Environment of Care (MEC) Chairperson/Safety Officer (CFO, in their absence the Plant Facilities Engineer 2)
- A WFH Product Evaluation Committee, chaired by the Nurse Executive, consists of:
 - Director of Nursing
 - Director of Ambulatory Care Services (ACS)
 - Plant Facilities Engineer 2
 - CFO
 - Supervisor of Central Medical Supplies
 - Supervisor of Physical Therapy
 - Supervisor of Dental
 - Infection Prevention representative

And is established to implement and monitor the activities of the plan.

The WFH Product Evaluation Committee Chair is responsible for directing the WFH Product Evaluation Program and an ongoing, organization-wide process to collect information and evaluate trends about deficiencies and opportunities for improvement in the WFH Product Evaluation program.

The WFH Environment of Care Chairperson/Safety Officer reviews the Annual Report for effectiveness and reviews and revises the annual management plan.

PERFORMANCE

INTENT

- A. Selecting and Acquiring Equipment-** As part of the capital budgeting cycle, Directors and/or Managers are responsible for identifying and justifying new and replacement medical equipment technology for their departments or areas of responsibility. Requests are subject to administrative and/or committee approval. Funds for approved capital projects are released on an annual basis. As a rule, the WFH Nurse Executive will participate with the user departments and the capital buyer to evaluate equipment alternatives and represent the equipment support issues in vendor negotiations. Purchase requests for biomedical equipment will be reviewed and approved by the Nursing Executive Committee (NEC).
- B. Equipment Inclusion in the Medical Equipment Management Plan -** The plan includes processes for the selection, maintenance and training designed to promote safe and effective use of clinical equipment.
- C.** The Equipment Management Plan is designed to effectively and efficiently organize the ongoing maintenance requirements of the bio-medical equipment utilized in the treatment of patients at WFH. Each new item is evaluated for the inclusion on the inventory based on the results of the equipment questionnaire (Appendix A).
- D.** Any 120 volt “electrical” supply/equipment that comes into direct contact with a patient shall be Bio-med tested for electrical safety and functionality prior to use in the Hospital.

Examples of items: Suction Pumps, AED's Ophthalmoscopes, Nebulizers, Vital Sign Monitors (Walking Nurse), Electrical Exam Tables, Air Mattresses, CPAP Concentrators, Cavitron, Feeding Pump, Ultrasound, Exercise Machines

Bio-Medical Equipment “Cleaning” Procedures

A WFH Medical Equipment Inventory & Cleaning schedule” file is located on:
T:\MedicalControlEquip\Medical Equipment Cleaning

- Classification of Medical Equipment (Critical, Semi-Critical, Non-Critical)
- Frequency of Cleaning of Medical Equipment (As Used, Daily, Weekly, Monthly, Quarterly) ~ could be more than 1
- Method of Cleaning of Medical Equipment (Decontamination, Cleaning, Sanitizing, Disinfection, Steam (Sterilization)

Bio-Medical Equipment “Repair” Procedures

- A.) All repair calls for Bio-Med Medical Equipment items are to be made by the Central Medical Supply Department to the approved contract vendor.
- B.) Follow-up: Central Med Supply Unit will contact Repair requestor the next (business) day and confirm:
 - Repair was made according to contract terms and time frames
 - Note on log that the repair was made in a timely manner
 - Note what repair was done

NOTE: Any **Medical Equipment Failures** will be reported immediately to Central Medical & respective Nursing Supervisors. Failed Medical equipment will be immediately removed from the patient care area, and noted as Out of Service. Central Medical will expedite replacement and/or rental of the required medical equipment item. In the interim, emergency clinical interventions as well as backup medical equipment should be implemented while awaiting replacement equipment.

Bio-Medical Equipment “Replacement” Procedure

- A.) Central Med Supply will coordinate all medical equipment replacement & asset surplus activities with the CVH Asset/Surplus Coordinator (Fiscal Services).
- B.) If the broken item is not returned then an Asset Loss Report Form CO-853, needs to be filed by the patient unit etc. to Central Med Supply (for processing through the Business Office). An administrative review/follow-up will be initiated for nursing staff failing to return a broken medical equipment item for either repair or replacement.
- C.) If any issues develop as to the above then they shall be reported to the Central Med Supply coordinator or designee immediately.

Bio-Med Medical Equipment “New Purchases” Procedures

- A.) All new medical equipment purchase requests will be coordinated through the Nurse Executive and the Fiscal Services Director, and subsequently with the Central Med Supply Coordinator. The WFH Asset/Surplus Coordinator will be made aware of these purchases. All newly introduced medical equipment (not replacing like items) will be approved by the WFH Hospital Environmental of Care committee (MEC).
- B.) Before initial use and after major repairs or upgrades of medical equipment on the medical inventory, the hospital (through Central Medical) will perform a safety, operational & functional check. A copy of this certification will be retained in the Central Med Supply area and a copy sent to the WFH Maintenance unit – Bio-Med Testing Coordinator.
- C.) If these Bio-med supplies are Asset tagged, the Central Med Supply coordinator will coordinate with the CVH Asset/Surplus Coordinator to tag and record these assets.

Alarm Systems

An inventory of all medical equipment alarm systems shall be maintained and updated. The alarm systems shall be tested weekly. All alarm systems shall be tested as per manufacturer recommendations or determined through organizational experience and based on the risk assessment. Examples of these alarms are: bed or chair alarms (for fall risk), AED alarms, and other medical equipment alarms.

Documentation, Testing & Inventory

The Environment of Care Chair/Safety Officer oversees the results of annual testing of all hospital-owned bio-medical equipment and receives a copy of the test results. Central Supply Services oversees the results of all testing of all rented/leased bio-medical medical equipment and receives copies of the test. In the event that a piece of equipment fails to meet the established criteria, the item will be removed from service until it can be repaired or replaced.

Central Supply Services shall collect and maintain all documents and manuals of bio-medical equipment.

Records and documentation of all services and preventive maintenance from contracted vendors shall be collected and maintained.

Inventory

All bio-medical equipment utilized at this facility shall be inventoried & tested for electrical safety and proper operation at the time the new equipment is acquired, repaired, and annually.

The database for the equipment will include the item description, facility identification number, location, date of last inspection, date of next inspection. The database will be updated when the bio-medical equipment is relocated or discarded.

All bio-medical equipment shall be tested for electrical safety and proper operation annually and shall have a sticker affixed which includes the name of the tester, equipment ID# or serial #, the date tested and passed, and the next test due date.

Monitoring & Acting on Equipment Hazard & Recall Notices

In the event of a product safety alert, hazard notice, or product recall notification, all proper procedures shall be followed to assure that staff and patients are not exposed to a potentially dangerous situation. Products and equipment shall be immediately removed from service until such time that testing or manufacturer verification allows the return of said equipment.

Pursuant to SMDA, Safe Medical Devices Act, any equipment failure resulting in patient injury will be reported to the FDA by the Plant Facilities Engineer. A copy of the report will be submitted to the Nurse Executive and reporting in the Daily Safety Huddle meeting.

NRAC Operating Information

The latest method of using the National Recall Alert Center, hereafter referred to as NRAC, is as follows:

The system is set up so that all people are in a three-tiered layout. The first tier is the direct person responsible for their specific area(s) only, the *Department Contact*. For instance, the Supervisor of Central Medical is responsible for medical equipment only, and the Pharmacy Supervisor is responsible for pharmaceuticals only, etc.

The second tier is the overseer of the direct contact for the specific area(s) of responsibility, the *Secondary Department Contact*. This would be Director of ACS for Pharmacy and X-ray, Director of Fiscal and Support Services for Medical Devices, etc.

The third tier is the administrator, Maintenance Supervisor 2 and/or Director of Plant Operations identified as *Facility Primary*, *Facility Secondary*.

The way it works is that the Facility Primary assigns specific people for the related areas of responsibility for Department Contacts, and their Secondary Department Contacts.

All product recalls are filtered by the assigned responsibility tag, i.e., X-ray, Medical Devices, Infection Control, etc. and emailed to the *department contact*. The person responsible for that individual product is emailed with information about the recall including the class, Recall ID#, the exact recall, listed products and the reason for the recall. The email contains a direct link to the NRAC website whereby they can “click” on the button and thereby are brought directly to their area of responsibility. They can click on a quick response button if we don’t have it, or on the individual recall click on the response that accurately mirrors our specific situation.

The response options are shown below:

Class: 2

Status:

Message:

Sometimes a recall falls between two or more departments. When that situation occurs all department contacts must respond to the recall individually.

Any one person along the chain can respond to a recall. However it is obviously preferable to have the Department Contact respond as they are best suited to respond to the recall items whereby the Secondary and Facility Contacts may not have exact knowledge on every single piece of equipment.

The notification order is below:

Notification order:

1st Notice: Department Contact

2nd Notice: Department Contact, Secondary Department Contact

3rd and Final Notice: Dept. Contact, Secondary Dept. Contact, Facility Primary, Facility Secondary

The notification times are below:

Notification Times:

	Class 1	Class 2 & 3
1st Notice:	Day of Recall	Day of Recall
2nd Notice:	+2 Business Days	+4 Business Days
3rd and Final Notice:	+4 Business Days	+7 Business Days

Further, we have report capability from the website able to key off dates, departments, specific recalls, etc.

Monitoring and Reporting of Incidents (Including SMDA)-All affected employees participate in all medical equipment-related occurrence investigations as directed by the coordinating individual. When indicated, the Safety Director will perform or coordinate the investigation of a device involved in an event. The results of this investigation will be communicated to the Nurse Executive. If the report findings meet the medical device reporting criteria, the information is reported to the FDA per SMDA reporting process.

Reporting Equipment Management Problems, Failures and User Errors – Equipment Users report equipment problems to WFH Maintenance via work order. WFH Maintenance will review work order summary reports no less than monthly and include any significant findings in the report to the EOC Committee.

Emergency Procedures and Clinical Intervention - In the event of any emergencies, the department employee's first priority is the safety and care of patients, visitors, and employees. All employees will comply with emergency management and other policies and procedures.

Note: Anytime any staff receives a Recall notice this notice shall be expedited up the chain of command to be discussed in the daily Morning Report.

ORIENTATION AND EDUCATION

Annual Continuing Education: The Annual Education Program for WFH Staff includes self-directed computer based learning modules; Learning Management System (LMS). These modules contain learning materials and test. Modules are reviewed and/or revised as necessary. New modules are developed when the need is identified. All employees at WFH are required to participate in annual safety training education which includes Medical Equipment (Environment of Care LMS e-Training module).

Department Specific Training: Department Managers and Directors are responsible for orienting new employees to the department and informing them of specific medical equipment procedures. Managers and/or Directors will train their employees in departmental or job-related medical equipment procedures or precautions. Managers and/or Directors are provided with appropriate Medical Equipment Program guidelines and directed to maintain a current awareness of the Medical Equipment Program, and to ensure its effective implementation within his or her department.

Each employee is responsible for following the guidelines set forth in the Medical Equipment Program. Employees are required to complete annual education regarding Medical Equipment Safety in the workplace and are responsible for understanding how medical equipment management relates to his or her specific job requirements and patient care.

As part of the capital acquisition process, WFH Maintenance will request service manuals, training classes or other educational materials for the technical staff. WFH Nursing Executive Committee (NEC) will, as part of the annual performance review, identify technical training needs and assist with the creation of individual development plans. WFH Maintenance will identify user-related problems in the work order coding and report on significant events or trends to the Environment of Care Committee. When a significant number of user related problems occur in a specific area, WFH Maintenance & Nursing will instruct or arrange for the instruction of end users in the proper operation of equipment.

Contract Employees and Vendors: Perform an assessment and educate as necessary at the time of assignment for required Medical Equipment Program training.

PERFORMANCE MONITORING / INDICATORS

- A. WFH Maintenance, Nursing & Environment of Care Committees (MEC) conduct ongoing performance monitoring. The following Performance Indicators/Monitors have been established:**
1. Medical Equipment Tested for Electrical Safety
 2. Medical Equipment not Tested
 3. Medical Equipment not in Proper Location
 2. Medical Equipment Failures
 3. Missing or Out of Date Bio-Med stickers
- B. The Environment of Care Committee oversees the development of performance monitors for this committee. Data from these performance monitors are reported at least quarterly to the EOC Committee and bi-annually to the Hospital Quality Risk & Safety Committee (QRS). Performance Indicators are compiled and sent annually to the Governing Body. Annually, the data from the environment of care performance monitors are analyzed and prioritized to select at least one recommendation to be made to the leadership of QRS for a performance improvement activity in the environment of care.**
- C. Off site locations meet at least quarterly and membership includes representation for the six functions of Environment of Care. Performance monitor reports are submitted quarterly to the WFH MEC Committee.**

Contract Performance Monitoring

The Medical Equipment Management contract will be evaluated based on monitor of key indicators and feedback from end user staff:

- Vendor Performance & Timeliness
- Number of Reported Failed Medical equipment
- Number of Reported Medical Equipment Tests Expired or Not Tested
- Number of Reported Bio-Medical Equipment Missing Stickers
- Number of Reported Medical Equipment Mis-Calibration
- Verify the Inspection, Testing & Maintaining activities: Inventory Location Verification, Bio-Med Sticker to Report verification, Revised dates for Failed or Repaired Medical Equipment

EFFECTIVENESS:

ANNUAL EVALUATION PROCESS

How and When the Annual Evaluation will Occur: The Director of Plant Operations/Safety Director (CFO) will perform an annual review each January. The report will address all elements of the program. It will review performance indicators such as equipment failures, user errors, equipment record maintenance, or equipment with out of date or missing Bio-Med stickers. The report will also review the effectiveness of the plan and make recommendations for improvement of the Equipment Management Plan.

Circulation: The annual evaluation is presented to the Hospital MEC Committee by the end of the first quarter of each year. The Hospital MEC Committee reviews and approves the report. The deliberations, actions, and recommendations of the Hospital MEC Committee are documented in the minutes. The annual evaluation is distributed to the Governing Body. This finalizes the evaluation process.

Goals & Objectives for 2018

1. Improve the employee knowledge of medical equipment requirements and support the routine operational needs of equipment users
2. Develop and manage all aspects of a comprehensive maintenance program and related quality assurance activities that take into account equipment function, safety risks, and maintenance requirements
3. Manage and track all maintenance requirements, activities, and expenses required to service, repair, and keep operational all Medical Equipment included in the plan
4. Deploy anti-ligature resistant patient beds

APPEXDIX A

Bio-Medical Equipment Questionnaire

The purpose of this questionnaire is to allow the related departments, Equipment Control, Central Supply, Dental Clinic, etc. to add or deduct equipment from the Bio-Medical Equipment Inventory by answering the two simple questions below.

- 1.) Does this piece of equipment need to be plugged into a standard 110/120-Volt receptacle during normal operation?

YES or NO: If the answer is YES, proceed to question #2. If the answer is NO then this item does not go on the inventory.

- 2.) Does this piece of equipment normally come into direct contact with a patient/client during treatment or diagnosis?

YES or NO: If the answer is YES, the equipment must be added to the Bio-Medical Inventory. If the answer is NO then this item does not go on the inventory.

Equipment Information

Manufacturer: _____ Model#: _____
Description: _____
Manual(s) Location: _____