



**Administrative
Policies and Procedures**

Originating Venue: Environment of Care
Title: Medical Equipment Management Plan
Date Issued: 11/14
Date Reviewed:
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Attachment:

Policy No.: N/A
Cross Reference:

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Purpose:

The essential objective of the Medical Equipment Management Program is to establish systems, procedures, and methods, that ensure all equipment used in the care and treatment of patients within the organizations environment is safe and properly maintained.

Scope:

EC.02.04.01 (1)The organization has a systematic approach to selecting and acquiring medical equipment.

EC.02.04.01(2) The organization 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 organization evaluates new types of equipment before initial use to determine whether they should be included in the inventory.

EC.02.04.01 (3) The organization identifies the activities and frequencies for maintaining, inspecting, and testing for all medical equipment on the inventory. Various maintenance strategies may be used to ensure reliable performance (for example, predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance). Defined intervals may be based on criteria such as manufacturers' recommendations, risk levels, and current organization experience.

EC.02.04.01 (5) The organization 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.

EC.02.04.01 (6) The organization has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.

EC.02.04.03 The organization inspects, tests, and maintains medical equipment.

EC.02.04.03 (1) Before initial use of medical equipment on the medical equipment inventory, the organization performs safety, operational, and functional checks.

EC.02.04.03 (2) The organization inspects, tests, and maintains all high-risk equipment. These activities are documented.

EC.02.04.03 (3) The organization inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.

EC.02.04.03 (4) The organization conducts performance testing of and maintains all sterilizers. These activities are documented.

EC.04.01.01 (15) Every 12 months, the organization evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness.

Program Summary:

The following is a summary of the individual program components and procedures specific to medical equipment maintenance at (PMG).

Medical Equipment Management Program – (MEMP) Inclusion Criteria, Inventory, Inspections, SM Intervals:

- a. All patient care equipment regardless of ownership is evaluated for inclusion into the MEMP.

Medical Equipment is categorized as:

1. Life Support
 2. Non-Life Support
 3. High Risk
 4. Low Risk
 5. Hazard Surveillance Only
 6. Tracking Only
- b. All pertinent (PMG) equipment information is entered into a vendor tracking system and the equipment is added to the equipment inventory. A maintenance interval is established in accordance with the manufacturers and/or regulatory agency recommendations, and a maintenance schedule is established. All continuing and repair services are entered into, and tracked by the aforementioned established tracking system.
 - c. Prior to initial use, a documented incoming inspection is performed on all equipment entered into the "MEMP".

Scheduled Maintenance / Inspection and Testing:

- a. The scheduled maintenance service schedule will be established consistent with all equipment located within or assigned to a specific site location. Maintenance completion is tracked by the vendor's medical equipment tracking system by site location and the data will be made available for the EOC Committee. Incomplete maintenance due to any justifiable reason such as: "unable to locate", or "continually in use" is subject to a 30 day follow-up and completion period in accordance with policy.
- b. Scheduled maintenance is performed in accordance with an established maintenance procedure and the manufactures recommendations, intervals, specifications, and tolerances, or in accordance with regulatory or accreditation agency requirements, and safety standards. All scheduled maintenance is documented by assigned vendors, and is entered into, and tracked by the vendor's medical equipment tracking system.
- c. Sterilization Equipment, endoscopes, cystoscopies, and colonoscopies shall be maintained in accordance with the regulatory requirements for re-processing and prevention of cross-contamination.
- d. Laboratory Equipment shall be maintained in accordance with EC.02.04.03 and all applicable regulatory agency requirements.

Test Equipment Calibration:

- Test equipment utilized to ensure the accuracy and safety of clinical/medical equipment is calibrated in accordance with the manufacturer's specifications and National Institute of Standards Technology (NIST) (as applicable), at a minimum of every two years, or as required by the manufacturer. Vendors are required to maintain current test equipment calibration certificates for all test equipment used in the performance of both scheduled maintenance and repair services of medical equipment. Copies of the certificates will be made available to the organization in which the test equipment is used upon request.

Joint Commission Patient Safety Goal Compliance:

- All necessary steps to comply with any pertinent Patient Safety Goals are a requirement of the program. This will be met through evaluation of each goal that is specific to the (MEMP) and establishing policies, procedures, and education of maintainers and users of the equipment. This will be accomplished at whatever level is needed to mitigate potential safety issues noted, as well as fully complying with each goal.

Equipment Repair:

- a. Equipment repair will be conducted in accordance with the manufacturer's specifications and tolerances. A minimum of functional test and safety inspection will be conducted upon completion of the repair. Additional functions such as calibration and overhaul will be conducted as needed. All equipment repairs will be tracked by vendor's medical equipment tracking system. The FDA regulates the manufacture of medical devices in the United States. Vendors and (PMG) staff is specifically prohibited from altering or modifying any medical device in any way that might change its essential functional characteristics other than as directed by the device manufacturer.

- b. At no time should equipment that is found to be malfunctioning be left in service unless a judgment is made by an appropriate physician or clinician that the risk to the patient's well-being would be greater if the device were removed. In such case, and if an authorized decision is made to leave the equipment in service it is to be documented and signed off by the authorizing decision maker. Such document will be forwarded to the appropriate Practice Manager for his/her review.
- c. If repair is required during normal business hours staff will label the device as "repair needed", remove the device from service, and contact the appropriate vendor to acquire service for the repair/replacement. The appropriate documentation into the vendor's medical equipment tracking system will be made to track the device(s) through the process of servicing.

Hazard Alert and Recall Notices:

- a. Hazard and recall notices from nationally recognized organizations, as well as manufacturers alerts, recalls, and technical bulletins are reviewed on an ongoing basis, applicable equipment identified, and corrective actions taken as specified In the notice will be reported to the EOC Committee.

Reporting System / Data Acquisition and Aggregation:

- a. Acquisition and aggregation of appropriate data is achieved through the vendor's medical equipment tracking system. Specific data collected should include all services scheduled and performed such as; Scheduled Maintenance, Repairs and "Special Condition" service events such as; Accidental equipment damage, user errors, equipment incident, and repetitive repair data. The vendor's tracking system will have the ability to analyze, evaluate, and report service information that can be used for service management.

Process Improvement:

- a. Data collected through the vendor's medical equipment tracking system can be used to evaluate the performance of the (MEMP) against measurable performance monitors such as; Maintenance completion, repair rates, and inventory accuracy. MEMP performance, weaknesses, corrective actions, improvement measures and recommendations, are available to the EOC Committee.

Annual Assessment of the MEMP:

- a. A comprehensive Annual Assessment will be performed to evaluate the effectiveness of the (MEMP) and to establish a working baseline and effective program performance goals.
- b. Going forward the following will be reviewed and reported:
 - 1. As per contract an annual summary of Planned Maintenance completion as applicable.
 - 2. Trends in key component indicators related to equipment / user interface, including accidental damage, operator error, hazard and recall, equipment incident, and incidental in service data.
 - 3. Net changes to inventory.
 - 4. Review and evaluation of that year's program goals, and establishing goals for the coming year. Goals will be created through a cooperative effort between the Biomedical vendor(s) and the appropriate Premier management staff to ensure that their shared values are seen and understood.
 - 5. As applicable review and evaluation of the contracts between the organization and the vendor(s).
 - 6. Review of training and education program.
 - 7. Review of MEMP policy and procedure to ensure all information is current.

Medical Equipment Related Incidents (Safe Medical Device Act of 1990)

- a. The Safe Medical Devices Act of 1990 (SMDA) (Public Law 102-629) requires ambulatory surgery centers, hospitals, outpatient diagnostic centers and other user facilities to report all incidents in which a medical device or user error may have caused or contributed to the death, serious injury or serious illness of a patient.
- b. In the event that possible negative patient outcome is linked to any item of patient care equipment, immediate notification is to be made to the Clinical Director who will initiate the process per policy and pursuant to the "Safe Medical Device Act of 1990".

Education and Training / Skills and Competency

- a. Equipment User Training is limited to incidental in-service training when user-errors are identified. Medical and Clinical Application related education is the responsibility of the organization. Education related to medical devices conducted either by the vendor or by the organization is documented.
- b. Equipment Maintainer Education and training needs are identified on an ongoing basis. Vendor staff education is based on evaluation of new equipment acquisitions, the service plan for each new system evaluated, training and certification requirements for specific equipment. The appropriate staff training is identified and planned for accordingly.

Infection Control:

The organization's Biomedical vendor will conduct all medical equipment maintenance and repair activities in accordance with standard New York State regulatory Infection Control Standards. Vendors shall ensure that all medical equipment received for service or destined to patient care areas is properly cleaned (removal of dust, dirt, tape and label residue) as recommended by the manufacturer and/or recognized infection control regulatory agencies. Proper disinfection of medical equipment will be conducted by the organizations medical personnel utilizing the Infection Control guidelines, policy and procedures as set forth by the Premier Medical Group.

Date Plan to be reviewed: 11/15