

EC 02.04.01 MEDICAL EQUIPMENT MANAGEMENT

The hospital manages medical equipment risks

The EOC (safety) Committee has developed this document to identify and educate staff on the processes utilized to provide a safe and secure environment. The document is reviewed annually by the Committee and updated as needed.

1 The hospital solicits input from individuals who operate and service equipment when it selects and acquires medical equipment.

Medical equipment purchases are based upon the needs of the community served as identified by the staff of the requesting department. With the help of Supply Chain Management and Biomedical Engineering, the end user evaluates the options on the market and establishes a budgetary request. Health Care attempts to standardize equipment in order to reduce user errors and manage cost of repairs. A Hospital wide Standards Committee is used to review equipment based on cost, function, safety, and reliability. By standardizing equipment across the continuum, there is a greater knowledge of use by staff that may float or internal resource for repair or parts. Request for purchases are then sent to administration for review and approval. Upon arrival, Biomedical Engineering completes an incoming inspection or reviews the inspection record of contracted equipment and inventories all new medical equipment. BME uses an Equipment Checklist as the mechanism to document acquisition review.

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.

Biomedical Engineering utilizes a risk assessment to determine the frequency of preventive maintenance and inventory status of medical equipment. Equipment is delivered to Biomedical Engineering or is arranged to be inspected prior to being put into service. The risk assessment takes into account the following criteria to determine the risk classification: clinical application, equipment function, likelihood of failure, preventive maintenance, and environmental use. After determining the risk the priority, the PM interval, if any will be determined.

Biomedical Classification System

Classification	Code	Definition
Critical PM	P critical	Life Support + Mission Critical equipment where PM and up-time have most significant impact. Annual or semi-annual PM
Non-Critical PM	P	Medium priority equipment where PM has been shown to enhance safety or performance. Annual or Semi-annual PM.
No PM	B	Equipment receives an incoming surveillance and assigned a tag for tracking work order repairs

3 The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory.

Biomedical Engineering oversees the maintenance and repair of all medical equipment. Manufacturer recommendations, product history, and risk assessment are used to determine maintenance needs. The computerized Supply Chain Management system (TMS (computer system)) is utilized to schedule and document service and history of equipment. Two concepts utilized by Biomedical Engineering are functional groups and exception reporting. Functional groups are utilized when more than one piece of medical equipment are components in a system. These systems are then considered to be one unit. Biomedical Engineering utilizes exception reporting on equipment management. Only "values out of range" or "problems found" contain narrative documentation. The exception device type is Blood Warmers, where passing values are recorded. All equipment that passes PM activities will indicate that Preventive Maintenance (PM) activity has been performed.

4 **The hospital identifies, in writing, frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria such as manufacturers' recommendations, risk levels, or current hospital experience.** Frequency of testing is based upon the risk assessment, industry guidelines, manufacturer recommendations, and review of the history and performance of the equipment. Equipment is periodically reviewed to determine if risk assessment classification and the scheduled maintenance timeframe is appropriate.

5 **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.** Supply Chain Management oversees the recall process. Upon notification, the recall and the recall procedure form are sent to the affected departments for review and action. The Purchasing Department coordinates the return of recall material, notifies Biomedical Engineering, Risk Management, and maintains the historical file of recalls and action taken. Department directors are responsible for the completion of the recall notification procedure form and to notify physicians of any recalled product that may have been used by any of their patients. Recall activities are reported quarterly to the EOC (safety) Committee.

Biomedical Engineering oversees the SMDA program. When incidents occur where a medical device is suspected of causing serious injury or death to a patient, they are reported on an incident report or verbally to the Risk Management Coordinator. Biomedical Engineering and Risk Management and appropriate individuals investigate and prepare the appropriate documentation and forward it to the FDA and/or the manufacturer. The SMDA also requires mandatory tracking of certain implants. Each department that deals with traceable devices is responsible for completing a device tracking report and maintaining the record.

6 **The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.**

a) ***What to do in the event of equipment disruption or failure***

In the event a piece of medical equipment malfunction, the front line staff is responsible to remove the equipment from service, identify it as being defective, and intervene and resolve any patient care issues. An incident report will need to be generated if the failure causes injury to the patient or changes the out course of treatment.

b) ***When and how to perform emergency clinical interventions when medical equipment fails***

Departments that utilize medical equipment maintain procedures for equipment failures and, if necessary, emergency clinical intervention. Non-life support equipment is removed from service and sent for repairs.

c) ***Availability of backup equipment***

Replacements are obtained or contracted through Supply Chain Management . Supply Chain Management , Biomedical Engineering, and Surgery maintain backup equipment for essential medical and life support equipment. The hospital endeavors to standardize on medical equipment acquisition to make substitution easy, and a primary means of maintaining patient up-time. Contracted medical equipment suppliers are utilized to supply equipment on emergency basis and during high demand periods. Supply Chain Management is responsible for obtaining the equipment and notifying Biomedical Engineering of the equipment being brought in-house. Biomedical Engineering works with the contracted service to ensure the proper safety and preventative maintenance is performed on the equipment.

d) ***How to obtain repair services***

Biomedical Engineering can be contacted twenty-four hours a day to perform emergency repair of equipment. During non-operating hours, Biomedical Engineering can be contacted via an on-line work request application on the web. A record of service provided by a third party is maintained by the vendor, who has agreed to make documentation available upon request.

EC 02.04.03 MEDICAL EQUIPMENT MANAGEMENT

The Hospital inspects, tests, and maintains medical equipment.

Biomedical Engineering maintains the equipment inventory and includes all equipment that has been identified as needing to be included on the inventory regardless of ownership. Biomedical Engineering coordinates with the department users and equipment owners on the requirements of service and documentation needed.

1 Before initial use of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.

Biomedical Engineering conducts or reviews initial performance and safety testing on all medical equipment prior to use. Equipment is identified on the capital budget request form and reviewed prior to purchase by Biomedical Engineering. Supply Chain Management or the receiving department notifies Biomedical Engineering when the equipment is in-house. Biomedical Engineering tags the equipment when inspection is complete. Employees are trained to look for the equipment tag and notify Biomedical Engineering if the tag is missing. An "Environment of Care Reference Card" is used as a training aid on the nursing units.

2 The hospital inspects, tests, and maintains all life support equipment. These activities are documented.

TMS (computer system) is used to document maintenance activity on all medical equipment. Risk categories are assigned and used to group equipment in the system. Third party maintained equipment is captured and is in the process of being added to the system. Hard copy of documentation of work performed is available in the department that utilizes the equipment.

3 The hospital inspects, tests, and maintains non-life support equipment identified on the medical equipment inventory. These activities are documented.

TMS (computer system) is used to document maintenance activity on all medical equipment. Risk categories are assigned and used to group equipment in the system. Third party maintained equipment is captured and is in the process of being added to the system. Hard copy of documentation of work performed is available in the department that utilizes the equipment.

- 4 **The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.**

Infection Control monitors the testing and documentation of sterilizers. The departments that utilize the sterilizers maintain logs and monitoring strips. Infection Control checks compliance during environmental tours and independent audits. Results and compliance is reported to the Infection Control Committee. Biomedical Engineering also maintains duplicate records of the following: Sterilizer Maintenance Records. These are presented by the CSS Manager to the BME Service Manager, semiannually.

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

Chemical and biological testing of water in the Dialysis units are maintained by Dialysis and reported to Infection Control Committee. Biomedical Engineering also maintains duplicate records of the following: Dialysis Equipment Maintenance, Biological Testing, Chemical Testing. These are presented by the Dialysis Manager to the BME Service Manager at the monthly Equipment Safety Committee.