ENVIRONMENT OF CARE

MEDICAL EQUIPMENT MANAGEMENT PLAN

JANUARY 2013

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1. Goal. This management plan describes the framework to manage medical equipment risks and continuously improve program performance. The scope and objectives of this plan are consistent with the Command’s values, vision, and mission to provide quality healthcare to Soldiers, retirees, and their families.

2. Objectives. The following objectives will ensure the physical safety of patients, visitors, and staff and prevent the loss of property:

a. Effectively manage medical equipment risks by using best industry practices

b. Optimize resources by using efficient medical equipment processes and lifecycle management of equipment

c. Improve staff performance through effective education and training

d. Improve staff and patient satisfaction by providing a safe physical environment

3. Scope. This management plan applies to all government owned and contracted medical equipment, including general, radiographic, electronic, and digital medical equipment used in this Military Treatment Facility (MTF) and all subordinate MTFs to include (LIST ALL CLINICS AND SATELLITE LOCATIONS SERVED BY THE MTF AND COVERED UNDER THIS PLAN).

4. Responsibilities.

a. The Chief, Medical Equipment Maintenance is responsible for developing, implementing, and monitoring this plan and the MTF’s Medical Equipment Maintenance Regulation.

b. The Organization Chart in Appendix A shows the primary officers, departments, and services that provide input into the development, implementation, and maintenance of this plan.

c. Service and department chiefs develop and implement department-specific standing operating procedures (SOPs) for the safe operation of medical equipment, and they implement MTF-wide medical equipment policies and regulations.

d. All medical equipment users are trained and competent in the capabilities, limitations, safe operation, and emergency procedures for the medical equipment that they use.

5. Medical Equipment Elements of Performance. The Reference Crosswalk in Appendix B lists the corresponding policies, regulations, SOPs, systems, and databases pertaining to each of these requirements.

a. Medical Equipment Management Plan. This management plan is based on a plan, teach, implement, respond, monitor, and improve framework, and it addresses the essential process for making sure that all medical equipment used at the MTF is safe and functional and supports patient care.

b. Risk Assessments.

(1) The medical equipment risk assessment process focuses on the impact of a particular type of equipment based on four criteria: function, physical risks associated with use, maintenance requirements, and incident history.

(2) Both proactive risk assessments (e.g., internal performance improvement data; staff, patient, and family feedback; environmental monitoring; results of failure mode and effects analyses; governmental regulation reviews; association, society, and professional literature reviews; emergency exercise after action reports; preventive maintenance; and design reviews; etc.) and reactive risk assessments (incident investigations, medical equipment failure investigations, root cause analyses, etc.) are used to identify trends for which corrective action is needed.

(3) The risk assessment process is also used to manage “gray areas” that do not have a clear resolution. An example of a “gray area” is deciding the best way to secure sharps in the Emergency Room. “Gray area” issues are brought to the Safety/EC Committee for discussion and resolution.

c. Risk Management Process.

(1) Medical equipment maintenance personnel work with supervisors and staff to exchange information and educate each other on any risks associated with medical equipment. First-line supervisors are responsible for making sure users understand the application, safe operation, and emergency procedures for the medical equipment that they use.

(2) All medical equipment risks are evaluated, tracked, and abated on a worst-first basis. Interim measures are implemented when hazards cannot be immediately abated to manage risk and minimize potential harm to patients, staff, and visitors.

d. Selection and Acquisition. The selection process begins in the department that will use the equipment. After a request is made, but before acquisition, the Chief, medical equipment maintenance participates in the formal review process to assess any risks associated with the equipment; make sure that the equipment is appropriate to meet the user’s needs and that it is compatible with existing equipment; evaluate maintenance requirements; and determine space and utility needs and education and training requirements.

e. Medical Equipment Inventory. The Chief, Medical Equipment Maintenance uses the following risk criteria to create and evaluate the medical equipment inventory:

(1) Equipment function (life support, monitoring, treatment, diagnostic, and patient support)

(2) Physical risks associated with its use

(3) Maintenance requirements

(4) Equipment incident history

The inventory is documented in the Defense Medical Logistics Standard Support (DMLSS) System database.

f. Preventive Maintenance Strategies.

(1) The DMLSS database serves as a tracking tool to document completion of required inspections, tests, and maintenance. Each month, the DMLSS database automatically generates scheduled services requirements based on the maintenance types and intervals described in Paragraph 5.g. below. Additional preventive maintenance work orders may be generated for those devices that have missed their previous preventive maintenance inspections because the device could not be located or it was in use.

(2) Each month, Medical Equipment Maintenance QA personnel randomly select a percentage of the equipment having undergone maintenance, inspects the chosen equipment, and compares the findings with the equipment repairer’s (who originally inspected the equipment) findings. Appropriate action is taken whenever discrepancies occur.

g. Preventive Maintenance Intervals

(1) Inspecting, testing, and maintenance intervals are based on function, physical risks, maintenance requirements, incident history, and the manufacturer’s recommendations.

(a) Technical inspections are conducted prior to use.

(b) Safety inspections are conducted annually for equipment where there is no patient contact and semiannually where there is patient contact and after repairs or modifications have been made to the equipment’s electrical or electronic circuitry.

(c) Preventive maintenance checks and services (PMCS) are performed according to the equipment manufacturer’s recommendation or the risk assessment published in TB MED 750-1, whichever is more stringent.

(d) Calibration/Verification/Certification checks are performed according to the equipment manufacturer’s recommendation or the risk assessment published in TB MED 750-1, whichever is more stringent.

(2) The Chief, Medical Equipment Maintenance may adjust maintenance schedules for equipment when technical manuals, manufacturer’s literature, or past maintenance experience indicate the need for more or less frequent intervals.

h. Safe Medical Devices Act of 1990

(1) Users immediately notify the Patient Safety Manger, Risk Manager, Medical Equipment Maintenance, and Safety Manager of all incidents where medical equipment fails during use and results in death, serious injury, or serious illness.

(2) Users secure the involved equipment until it can be investigated.

(3) The Risk Manager assembles a team to investigate such incidents. The team may consist of the Patient Safety Manager, Risk Manager, Safety Manager, a member of the clinical staff who is familiar with the operation and use of the equipment, and a medical equipment repairer (not the individual who last serviced the equipment).

(4) If the team determines that the equipment contributed to or caused the incident, an SF 380, Reporting and Processing Medical Material Complaints/Quality Improvement Report, is prepared and sent to the Defense Supply Center Philadelphia (DCSP). The DCSP prepares semi-annual summaries and forwards them to the Food and Drug Administration (FDA).

(5) In addition, the MTF receives hazard notices and device recalls from several sources: the FDA, U.S. Army Medical Material Agency (USAMMA), equipment manufacturers, and from miscellaneous publications, periodicals, and advertisements. Medical Equipment Maintenance personnel review each notice/recall and take corrective actions as needed. A semi-annual report is submitted to the Safety/Environment of Care (EC) Committee stating the findings and actions taken.

i. Emergency Procedures. Medical equipment maintenance personnel and Department of Nursing develop emergency procedures for medical equipment management which address the following:

(1) Emergency clinical intervention when medical equipment fails

(2) Identifying the locations of spare equipment for use when equipment fails

(3) Procedures for obtaining repair services

(4) Reporting medical equipment failures, user errors

j. Initial Inspections. Medical equipment maintenance personnel complete a technical inspection (TI) on all new medical equipment, regardless of ownership, before acceptance and issue to the user. The purpose of the TI is to make sure that the equipment meets contract specifications, that it is safe for use, whether to include the equipment on the inventory, and to decide the preventive maintenance strategies and intervals.

k. Life Support Equipment.

(1) Medical equipment used for life support receives the highest priority to ensure that

100 percent of this type of equipment is located and appropriate inspections and maintenance is performed on schedule.

(2) All repairs are prioritized and performed in a timely manner. To assure the continuation of patient care in the event of equipment failure, backup devices are available for most critical devices (e.g., anesthesia units, physiologic monitors, defibrillators, ventilators, infusion pumps, etc.). Backup devices may be located either within the using department or in the Medical Equipment Maintenance Department. These backup devices are also available for use in expanding the MTF’s capacity to provide patient care in the event of an internal/external disaster.

l. Non Life Support Equipment. The expected on-time maintenance completion rate for non life support equipment is at or better than 90 percent.

m. Sterilizers. Medical equipment maintenance personnel service all steam sterilizers and document all preventive maintenance and repairs. The user departments conduct biological testing and quality assurance testing and maintain documentation within the work areas.

n. Hemodialysis. Medical equipment maintenance personnel service all hemodialysis equipment maintenance and document all preventive maintenance and repairs. Each user department ensures that chemical and biological testing of water used in renal dialysis is done on a scheduled basis to meet regulatory compliance. Each department maintains testing results for product water quality to meet AAMI standards for total viable microbial count and endotoxin levels and Association for the Advancement of Medical Instrumentation’s maximum allowable levels of contaminants in water.

o. Nuclear Medicine Equipment. Medical equipment maintenance personnel manage the inspections, tests, and maintenance of nuclear medicine equipment by qualified technicians through annual maintenance contracts. Where computed tomography (CT) services are provided, a qualified medical physicist measures the actual radiation dose for each system annually, and verifies the radiation dose displayed on the system is within 20% of the actual amount of radiation dose delivered, and documents the test results.

p. Orientation and Annual Refresher Education and Training Program

(1) The orientation and education component pertaining to Medical Equipment addresses the following criteria:

(a) Equipment users

(1) The capabilities, limitations, and special applications of medical equipment that they operate

(2) Operating and safety procedures

(3) Emergency procedures in the event of equipment failure

(4) Reporting procedures for equipment failures

(b) Equipment maintainers

1. Shop safety

(2) Procedures for responding to equipment failures

(3) Technical training as required

(2) The Chief, Plans, Training, Mobilization, and Security (PTMS) manages the MTF-wide New Employee Orientation Program. Generally, new employees are scheduled to attend orientation within 30 days of hire.

(3) The Chief, PTMS also manages the Annual Refresher Training Program. Generally, all staff and personnel attend annual refresher training during their birth month.

(4) Supervisors provide worksite-specific orientation and annual refresher training.

(5) All training is documented in the staff competency folders.

q. Information Collection and Evaluation System.

(1) Reporting and Investigating Medical Equipment Incidents, Problems, Failures, and Use Errors.

(a) In the event that a device fails the user shall immediately replace and tag the defective equipment and notify the Medical Equipment Management Department via telephone or by submitting a DA Form 4106, Quality Assurance/Risk Management Document along with a work order request.

(b) Medical Equipment Maintenance, the Risk Manager, or other MTF representatives as deemed appropriate by the Commander promptly review incident reports to identify trends, determine root cause(s), and suggest corrective actions to prevent recurrence. Summary reports are submitted to the appropriate committee for further review and resolution as needed.

(2) Annual Evaluation.

(a) The Chief, Medical Equipment Maintenance keeps the management plan current by reviewing the plan at lease annually (i.e., one year from the date of the last review, plus or minus 30 days) and making modifications based on changes to policies, regulations, and standards. In performing the annual review, the Chief uses a variety of sources such as inspection and audit results, accident/incident reports, employee reports of unsafe or unhealthy working conditions, customer satisfaction surveys, suggestion boxes, performance improvement committees, and other statistical information and tracking reports. The Chief may also use other forms of review and input from relevant sources such as leadership, other EC/PE disciplines, management, staff, personnel, and volunteers.

(b) The annual evaluation includes an assessment of the plan’s:

(1) Scope. Based on the current locations and services offered, the scope of the plan is expanded, reduced or maintained at its present scope (buildings, equipment, people, operations, services).

(2) Objectives. An annual assessment is made to determine if the objectives, as outlined in paragraphs 2.a through 2.d are relevant and current.

(3) Performance. An acceptable level of performance is determined by the achievements related to the medical equipment processes necessary for maintaining a successful Medical Equipment Management Program.

(4) Effectiveness. An acceptable level of effectiveness is determined by attaining success in meeting objectives and producing a satisfactory level of performance.

(c) Once the Safety/EC Committee approves the annual review, the results are submitted to the Executive Committee for review and approval.

(d) The annual review is used as an opportunity to develop or modify programs, plans, and policies; identify and implement additional or more effective controls; and enhance the Employee Orientation and Annual Refresher Training Programs.

(3) Safety/EC Committee. The Chief, Medical Equipment Maintenance is a standing member of the Safety/EC Committee and is responsible for coordinating, documenting, and presenting information related to Medical Equipment to the committee. In addition, the Chief is responsible for providing recurring reports on the status of the Medical Equipment Management Plan to include:

(a) Annual evaluation of the Medical Equipment Management Plan

(b) Performance improvement standards/initiatives

(c) Risk assessments

(d) Deficiencies, problems, failures, user errors

(e) Status of the Testing/Inspecting, and Maintenance Program

(f) Equipment hazard notices/recalls

(4) Monitoring of Performance.

(a) Performance monitoring is used to –

(1) Identify areas of concern and strengths in the MTF’s Medical Equipment Program

(2) Identify or determine actions necessary to address areas of concern

(3) Assess actual compliance with relevant security standards

(b) The Chief, Medical Equipment Maintenance –

(1) Identifies at least one measurable performance improvement standard regarding actual or potential risk related to one or more of the following:

(a) Staff knowledge and skills

(b) Level of staff participation

(c) Monitoring and inspection activities

(d) Emergency and incident reporting

(e) Inspection, preventive maintenance, and testing of equipment

(2) Considers high-risk, high-volume or chronic problems when developing performance standards to better focus limited resources.

(3) Sets desired goals or benchmarks and develops and implements data collection and reporting procedures.

(4) Appendix C lists the Medical Equipment Performance Measure(s) for this year.

(c) The Safety/EC Committee tracks performance and documents the results in the committee minutes.

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| **Regulation, Policy, or SOP Number** | **Regulation, Policy, or SOP Name** | **Date Published** | **Point of Contact** | **Relevant EC Standard and Element of Performance** |
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| **Performance Objective** | | **Performance Indicator(s)** | **SMART Performance Measure/**  **Action Plan** |
| --- | --- | --- | --- |
| Effectively manage medical equipment risks by using best industry practices. Specifically, managing risk through prompt preventive maintenance checks and calibration. (BSC: Internal Processes) | | % Preventive maintenance, checks, calibration completed on time | * What is your goal? * Is it measurable? * SMART performance measure * What constraints do you have (time, money, other resources)? * What are the steps you will take to meet your goal? * How will you prioritize these steps? * What data do you need to collect? * How will you collect and report the data? |
| Optimize resources by using efficient medical equipment processes and lifecycle management of facilities. Specifically, making sure the department is sufficiently staffed to maintain the medical equipment included in the inventory. (BSC: Resources) | | % man-hours applied to scheduled work  *The percentage of scheduled available man-hours to total available man-hours over the specified time period. A world*  *class target of >80% of man-hours should be applied to scheduled work.* | * What is your goal? * Is it measurable? * SMART performance measure * What constraints do you have (time, money, other resources)? * What are the steps you will take to meet your goal? * How will you prioritize these steps? * What data do you need to collect? * How will you collect and report the data? |
| Improve staff performance through effective medical equipment education and training. Specifically, identifying gaps in user’s knowledge of medical equipment use. (BSC: Learning and Growth) | # of corrective maintenance activities resulting from user error or abuse | * What is your goal? * Is it measurable? * SMART performance measure * What constraints do you have (time, money, other resources)? * What are the steps you will take to meet your goal? * How will you prioritize these steps? * What data do you need to collect? * How will you collect and report the data? |
| Improve staff and patient satisfaction by providing a safe physical environment. Specifically, reduce the number complaints resulting from the time needed to repair equipment. (BSC: Customer Satisfaction | # Customer complaints received each quarter | * What is your goal? * Is it measurable? * SMART performance measure * What constraints do you have (time, money, other resources)? * What are the steps you will take to meet your goal? * How will you prioritize these steps? * What data do you need to collect? * How will you collect and report the data? |