University of Arkansas for Medical Sciences

Part V – Medical Equipment Management Plan

FY20

I. MISSION

The Medical Equipment Management Plan is designed to promote safe and effective use of medical equipment used for the diagnosis, treatment, and monitoring of patient care needs. This plan also addresses administrative issues such as program structure, reporting requirements, specific responsibilities, general safety, and employee education programs.

The mission, values and philosophy of UAMS are to create and operate a comprehensive system to teach, heal, search, and serve. Consistent with the mission, values and philosophy, the medical staff, and administration has established and provide ongoing support for the Medical Equipment Management Program described in this plan.

II. SCOPE

The Medical Equipment Management Plan establishes the parameters to ensure medical equipment is maintained for safe use at UAMS Integrated Clinical Enterprise. Senior management of UAMS recognizes the need for the comprehensive clinical equipment management program managed by Clinical Engineering to ensure that all patients and employees are supported in their use of medical equipment, devices, and technology.

III. AUTHORITY /REPORTING RELATIONSHIPS

The MEMC is responsible for directing the Medical Equipment Management Program (MEMP) and an ongoing, organization-wide process to collect information about deficiencies and opportunities for improvement in the Medical Equipment Management Program.

The UAMS MEMC will evaluate trends and information gathered by the committee, develop appropriate policies and procedures, and evaluate the effectiveness of the MEMP. Reports go to the Safety Coordinating Committee through the EOC Committee.

IV. OBJECTIVES

1. Improve 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 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.

V. INTENT PROCESS

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. See policy SC.2.05 for Selecting and Acquiring Medical Equipment.

B. Criteria and Inventory

Clinical Engineering is responsible for the development of criteria used to identify risks associated with medical equipment. The criteria are used to evaluate risks related to the function of medical equipment, physical risks related to the use of equipment, and any history of patient safety issues related to the use of the equipment. Responsibilities also include assuring that all medical equipment is screened at the time of commissioning. The screening procedure is applied, as appropriate, to loaner equipment, demonstration equipment, and equipment owned by physicians or other qualified individuals that is used as part of the care or treatment of a patient at UAMS ICE. All equipment regardless of ownership will be reviewed against the inclusion criteria. Equipment will be included in the Medical Equipment Management Plan based on equipment function, physical risk, and maintenance functions. Equipment included in the Medical Equipment Management Plan will be inventoried, maintenance strategy defined and work history tracked in the CMMS. Some items may be added to the inventory for asset management purposes only. The accuracy of this inventory will be verified during scheduled maintenance inspections Department Rounds (DR) and Environmental Sweeps.

C. Maintenance Strategies

Clinical Engineering uses manufacturer recommendations, applicable codes and standards, accreditation requirements, and local or hospital experience to determine the appropriate maintenance strategy for assuring safety and maximizing equipment availability and service life. These activities and associated frequencies are in accordance with the manufactures recommendations or with strategies of alternative equipment maintenance (AEM) program.

D. Inspection, Testing, and Maintenance Intervals

Clinical Engineering is responsible for assuring that the rate of timely completion of scheduled maintenance and other service activities meets regulatory and accreditation requirements. The basis for the determination of inspection is risk, and or any “Agency Having Jurisdiction” (AHJ). All devices will receive a performance verification and safety test during the incoming inspection procedure and after completion of a major repair. All work activities, inspection schedules, and work histories are kept in the department CMMS or Vendor database. The Dialysis Department maintains their records for testing of water used for dialysis procedures and reports to Infection Control. Records of sterilizer testing are maintained by Central Sterile Department. All High risk equipment including life support such as (ventilators, heart/lung anesthesia, and defibrillators) will be checked on a regular, scheduled basis with a 100% completion rate. Non-high risk equipment known as general biomed medical equipment will be checked on a regular scheduled basis at a 100% completion rate unless classified as Incident Based maintenance or other AEM.

E. Management of Medical Equipment Hazard Notices and Recalls

The Director of Clinical Engineering (or his designee) coordinates the management of medical equipment hazard notices and recalls. The steps in the management process include:

1. Routing of all medical equipment hazard and recall notices to the responsible Clinical Engineering staff.
2. Logging of all hazard and recall notices determined to apply to equipment in use or storage in any location operated by UAMS Little Rock campus.
3. Generation and circulation of an internal hazard and recall notice tracking system to all appropriate Clinical Engineering staff with instructions addressing how to respond to the hazard or recall notice.
4. Tracking of circulated notices to assure timely completion of activities required to eliminate or manage the issues addressed by the hazard or recall notice.
5. As appropriate, routine reports of any actions taken to address published hazard and recall notices related to medical equipment.

   Risk Management, Supply Chain, and Clinical Engineering are responsible for the Safe Medical Devices Act (SMDA) Reporting process. Information about reportable events is processed through the incident reporting process. Internally, the Risk Manager applies the Root Cause Analysis (RCA) process to all SMDA events. The findings of the RCA are used to update or develop procedures and controls, make changes in the environment, or provide additional education and training to eliminate or reduce the risks that led to the reportable event.

F. Medical equipment is maintained, tested, and inspected

- **Equipment Inventory and Initial Testing**

  Clinical Engineering maintains an inventory of all equipment included in a program of planned inspection or maintenance. The inventory includes equipment owned by UAMS, leased and rented equipment, and personally owned equipment used for the diagnosis, treatment, and monitoring of patient care needs.

  All equipment in the program is tested for safety, operation and function prior to use on patients. Information from these inspections are documented and entered into the database

- **Testing of High Risk Equipment**

  Clinical Engineering assures that scheduled testing of all High Risk equipment is performed in a timely manner. Reports of the completion rate of scheduled inspection and maintenance are presented to the Environment of Care Committee each quarter. If the quarterly rate of completion falls below 100%, Clinical Engineering will also present an analysis to determine what the cause of the problem is and make recommendations for addressing it to the MEMC.

- **Testing of Non-High Risk Equipment**

  Clinical Engineering assures that scheduled testing of all non-High Risk equipment is performed in a timely manner. Reports of the completion rate of scheduled inspection and maintenance are presented to the Environment of Care Committee each quarter. If the quarterly rate of completion falls below 100%, the manager of the MEMP will also present an analysis to determine what the cause of the problem is and make recommendations for addressing it.

Testing of Sterilizers

- Sterile Processing is responsible for daily load testing and Clinical Engineering provides maintenance of all types of sterilizers used at UAMS. Records of load testing are maintained by Sterile Processing and regular maintenance records are maintained by Clinical Engineering.

- **Testing of Dialysis Water Systems**
  Clinical Engineering is responsible for maintenance of dialysis equipment used at UAMS. The program of maintenance includes regular cleaning and disinfection of all dialysis equipment and testing for compliance with biological and chemical standards for the dialysis water supply. A contracted vendor performs disinfection of dialysis units and water system. Clinical Engineering performs regular maintenance and testing of the dialysis water supply through Renal Lab. Dialysis department staff performs daily tests for purity of the water used for dialysis and out of range results are reported to Infection Control. Risk Management is notified of any event resulting in a patient injury or death will be treated as a Sentinel Event.

G. Monitoring and Reporting of Incidents (Including SMDA)

All affected employees participate in all medical equipment-related occurrence investigations as directed by coordinating individual. When indicated, a Clinical Engineer will perform or coordinate the investigation of a device involved in an event. The results of this investigation will be communicated to Risk Management. If the report findings meet the medical device reporting criteria, the information is reported to the FDA per SMDA reporting process.

H. Reporting Equipment Management Problems, Failures and User Errors

Users report equipment problems to Clinical Engineering by calling 686-5754 . The valid work order cause codes and failure codes used in the computerized maintenance management system (CMMS) allow for the identification of significant problem areas and trends. The Clinical Engineering Department will review work order summary reports monthly and include any significant findings in the report to the MEMC on a quarterly basis.

VI. ORIENTATION AND EDUCATION

A. New Employee Orientation: New employees are trained on the UAMS Medical Equipment Management Program. Training includes information on where to reference the proper information to ensure the medical equipment has been maintained, how to report medical equipment problems and the proper procedures for the Safe Medical Device Act (SMDA) of 1990.

B. Annual Continuing Education: The Annual Continuing Education Program for UAMS includes self-directed computer based learning modules. These modules contain learning materials and a test. These modules can be used by individual employees or as a guide for group presentations. Directors or Managers determine the most appropriate method of instruction for employees in their department or unit. Modules are reviewed and revised as necessary. New modules are developed when the need is identified. All employees at UAMS are required to participate in annual safety training education.

C. Department Specific Training: Department Managers and Directors are responsible for orienting new employees to the department and inform 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 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.

As part of the capital acquisition process, Clinical Engineering will request service manuals, training classes or other educational materials for the technical staff. Clinical Engineering will identify user-related problems in the work order coding and report on significant events or trends to the Medical Equipment Committee. When a significant number of user related problems occur in a specific area, Clinical Engineering will instruct or arrange for the instruction of end users in the proper operation of equipment.

D. **Contract Employees and Vendors:** Perform an assessment and educate as necessary on their specific equipment responsibilities at the time of assignment for required Medical Equipment Program training.

VII. INFORMATION COLLECTION & EVALUATION SYSTEMS (ICES) Performance Monitoring

A. UAMS conducts ongoing performance monitoring. The following performance monitors have been established

1. Numbers of user-related problems are tracked and reported. User-related or Operator Error Goal is keep the number of problems to less than 25 per month.
2. Monitor the number of medical equipment incidents that related to damage or abuse. The goal for abuse occurrences is less than 75 per month.

B. The MEMC oversees the development of performance indicators for this committee. Data from these performance monitors are reported at least quarterly to the SCC through the EOC Committee. 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 UAMS for a performance improvement activity in the environment of care. The departments are now being charged for the repair if there is a clear sign of abuse. The data will be tracked to see if this lowers our number of occurrences by increased education and staff training.

VIII. ANNUAL EVALUATION

The Safety Officer has overall responsibility for coordinating the annual evaluation process with each of the six functions associated with management of the Environment of Care. The MEMC performs the evaluation and submits to the EOC Committee. The annual review examines the objectives, scope, performance, and effectiveness of the Medical Equipment Program. The annual evaluation is presented to the SCC Committee by the end of the first quarter of each year. The Safety Coordinating Committee reviews and approves the report.

IX. CORRESPONDING POLICIES

Medical Equipment Maintenance Program