Part VI

Medical Equipment Management Plan

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# MEDICAL EQUIPMENT MANAGEMENT PLAN

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A. **Objective and Purpose**

The medical equipment management plan is designed to describe processes to manage the effective, safe, and reliable operation of medical equipment used for diagnosis, treatment, monitoring and care of patients as well as other fixed and portable electrically powered equipment.

B. **Selection and Acquisition**

Selection and acquisition should be in accordance with HSC Policy 72.01. The decision to acquire new medical equipment in each department is the responsibility of the Department Chair taking into consideration the following: equipment function, physical risks associated with the use, and equipment incident history. Recommendations for standardizing equipment should be directed by the Chief Medical Officer, with Environment of Care Committee review as appropriate. Each piece of medical equipment in the School of Medicine is inventoried, evaluated, tested, and maintained to perform properly and safely. The Purchasing Department is equipped to be a source, reference and information center for all equipment purchased and can be reached at 743-7841. Additional medical device information is available through the Food and Drug Administration (FDA) (see Attachment A).

C. **Equipment Inventory**

Each department should designate an individual responsible for the maintenance of medical equipment records which are current, accurate and unique and to include:

1. inventory of Medical Equipment in the department/clinic
2. maintenance schedule
3. preventive maintenance service records
4. copies of any Occurrence Reports related to equipment

Maintenance schedules and service records must be available for review and will be requested periodically to ensure proper quality controls. The Service Contractor should be notified by the Clinic Administrator or designee of new equipment for initial safety testing and to be added to routine preventive maintenance schedule.

D. **Equipment Inspection, Preventive Maintenance & Testing**

Inspection, preventative maintenance, and testing should be conducted to achieve effective, safe, and reliable operation of all inventoried medical equipment. Preventive maintenance is performed via centralized contract through the General Services Department semiannually or in accordance with equipment manufacturer's recommendations, whichever is more frequent. Any variations to the existing preventive maintenance scheduling should be communicated to the Purchasing Department.

E. **Equipment Repair**

Equipment which malfunctions, fails or exceeds the service/calibration schedule will be taken out of service and removed from patient care usage and tagged “Out of Service”. If the equipment is of a fixed nature and cannot be removed it shall be tagged and disabled in such a manner as to preclude subsequent use. The Purchasing Department or Service Contractor should be notified and the equipment not be put back into service until the fault/problem has been corrected and certified safe. This process will continue until the equipment is no longer in service or until the equipment is traded, or declared obsolete/un-repairable surplus.
Any equipment malfunction or failure should be reported, reviewed, tracked and trended by completing an Occurrence Report, forwarded to Director, Performance Improvement and reported to the Environment of Care Committee and Risk Management. An investigation for cause and effect and action plan, as appropriate, should be prompted in either of the following cases:

1. The equipment malfunction is determined to have placed patient safety at significant risk. (Safe Medical Devices Act, 1990).
2. A trend is identified.

F. Equipment Disposal

Equipment belonging to Texas Tech University Health Sciences Center will be disposed of by appropriate coordination and documentation in accordance with applicable Operating Policies 61.01, 63.10, 72.04, and 72.07.

G. Equipment (User) Training : Orientation & Education

1. Equipment training shall be provided in response to identified needs and core competencies which enable each employee to perform his/her duties more effectively and efficiently as well as improving his/her capabilities, knowledge and safety relating to the performance of his/her duties. Equipment training shall include emergency clinical interventions during failures.
2. TTUHSC treats equipment training as a risk-based function. The education requirement addresses the reality that satisfactory equipment performance depends on a trained operator.
3. Each piece of equipment on the departmental inventory listing shall be assessed for risk to determine the appropriate training frequency. Training shall be conducted before use and as needed. Indicators for “as needed” training will be user error, past failures, incidents, new procedures or procedures that have changed significantly.
4. Any equipment not on the departmental equipment inventory listing proven as high risk user items (through past failures and incidents) shall require at least annual training.
5. Training may be provided in any of the following formats: departmental, vendor training (including phone conversations, videos and written documentation), seminars and training from supervisors or other appropriate staff.

H. Safe Medical Device Act (“SMDA”)

1. To describe the criteria that is used to identify and document device-related incident(s) and/or reasonable suspicion of device-related incident(s) causing serious illness, injury, or death to patients. Medical device user facilities subject to the reporting requirement of the SMDA include: Outpatient treatment facilities that provide non-surgical therapeutic care on an outpatient basis. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and substance abuse treatment.

2. *Device: Any instrument, apparatus, or device (either electrical or non-electrical) that is used to prevent, diagnose, or treat a disease or affects the structure/function of the body. Examples would include all electrical support: equipment, implants, catheters, thermometers, syringes, pumps, etc.
3. Employee, Clinic Administrator, Resident Physician, Medical Staff Responsibility
   a. An Unusual Occurrence Report must be filed with Performance Improvement in all cases where there is reasonable suspicion of a device-related occurrence causing serious illness, injury, or death of a patient.
   b. Reporting of incidents is the responsibility of employees, departmental directors, attending and resident staff personnel.
   c. Appropriate SMDA forms and instructions for completion are available on the following websites:
      http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions
      The Code Manual for this form is at:  http://www.fda.gov/cdrh/mdr/373.html
   d. Reports will be sent within ten working days to FDA and the manufacturer if patient death occurs. Incidents that cause or contribute to serious illness or injury will be sent to the manufacturer if known, to the FDA if unknown.
   e. Each department’s Equipment Program data must be readily available for committee review.

4. Service Evaluation Committee Responsibilities (Environment of Care Committee)
   a. Evaluation of device related events with any identified trends referred to Risk Management.
   b. A Medical Device Reporting User Facility Report will be completed. (Website reference above).
   c. A semi-annual summary report will be sent to the FDA for all incidents that have been reported to the manufacturer (January and July) (Website referenced above).
   d. Submittal of reports to FDA and manufacturer is the responsibility of Performance Improvement and/or Risk Management.

I. Loan or Rented Equipment

It is the policy of TTUHSC to own its equipment when feasible. Equipment may be rented to meet an emergency condition.

1. Rental of equipment must be approved in advance by the appropriate Departmental Chair.
2. All rented, loaned, or borrowed equipment must meet safety certification prior to being placed into service.

J. Performance Indicators

The objectives, scope, performance, and effectiveness of the Medical Equipment Management Plan shall be evaluated annually. Performance measures to be evaluated on an ongoing basis include:
   a. Equipment malfunction/failure
   b. Associated patient or staff injury
   c. Trends identified