# Texas Tech University Health Sciences Center El Paso

# Medical Equipment Management Plan

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## I. Objective and Purpose

The medical equipment management plan is designed to describe proceDSSes 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, within the Clinical ambulatory departments at Texas Tech University Health Sciences Center at El Paso (TTUHSC EL PASO).

## II. Selection and Acquisition

Selection and acquisition should be in accordance with TTUHSC El Paso Operations Policy (OP) 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, equipment incident history, and availability of like equipment.

Recommendations for standardizing equipment should be directed by the Associate Dean of Clinical Affairs, with the Safety Committee to review as appropriate. Each piece of medical equipment at TTUHSC El Paso 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 915-215-4582. Additional medical device information is available through the Food and Drug Administration (FDA) (see Attachment A).

## III. Equipment Inventory

Each department is responsible to designate an individual responsible for the maintenance of medical equipment records which are current, and accurate. Records shall 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 roster.

## IV. Equipment Inspection, Preventive Maintenance & Testing

Inspection, preventative maintenance, and testing should be conducted to achieve effective, safe, and reliable operational and functional checks of all inventoried medical equipment. On yearly bases, electrical safety inspections are performed via a centralized contract through the Department of Safety Services (DDSS), or in accordance with equipment manufacturer's recommendations. Equipment repairs will be serviced through the same provider; departments will need to contact the DSS to schedule services.

## V. 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". The departments Head Nurse or his or her designee will be responsible for this task. 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 DSS 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.

Special consideration must be given to radiation, x-ray and laser producing equipment before purchasing, moving, or disposal; consult DSS Radiation Safety first, mostly for radiation control purposes.

Any equipment malfunction or failure should be reported, reviewed, tracked and trended by completing an Occurrence Report, forwarded to Director of Performance Improvement and reported to the Campus Safety 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.

## VI. Equipment Disposal

Equipment belonging to TTUHSC EL PASO Campus will be disposed of by appropriate coordination and documentation in accordance with applicable OP 61.01, 63.10, 7204, and 72.

## VII. Equipment User Training Orientation & Education

1. Departments are responsible to provide their employees with adequate equipment training. This training shall be provided in response to identified needs and core competencies which enable each employee to perform duties more effectively and efficiently as well as improving capabilities, knowledge and safety relating to the performance of his her duties. Equipment training shall include emergency clinical interventions during failures.

2. TTUHSC EL PASO 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. Annual training is required on equipment that is identified in the department inventory listing as high-risk user items.

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.

## VIII. 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 is defined as - 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 Department or Professional Liability Risk Management 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
d. The Code Manual for this form is at: http://www.fda.gov/cdrh/mdr/373.html
e. Reports will be sent within ten working days to The Food and Drug Administration (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.
f. Each department's Equipment Program data must be readily available for committee review.

4. Service Evaluation Committee Responsibilities (Safety Committee)
a) Evaluation of device related events with any identified trends referred to Professional Liability Risk Management.
b) Medical Device Reporting User Facility Report will be complete.
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)
d) Submittal of reports to the (FDA) and manufacturer is the responsibility of the Performance Improvement Department.

## IX. Loan or Rented Equipment

It is the policy of TTUHSC EL PASO 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 and the Information Technology Department if the equipment needs to interface with the Electronic Medical Record (EMR) Software.
2. All rented, loaned, or borrowed equipment must meet safety certification prior to being placed into service.

## X. Purchasing / Leasing Equipment

It is recommended for Clinical Departments that are purchasing or leasing new equipment to inform the Technology Departments (IT) prior to the ordering of the equipment. I.T. will review and assess that the equipment being ordered is compatible with our EMR software.

## XI. Request for Biomedical Equipment Services

DSS established an electronic work order request form for the departments to use when needing biomedical services; the form can be requested by calling (915)215-4823. The work order request form needs to be submitted prior to services being rendered. A Department Funds Organization Program (FOP) number needs to be identified in the request form in order to charge back the service expense to the department. Departments deviating from this process will be responsible to process their own billing invoices.

## XII. 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 or failure
b. Associated patient or staff injury
c. Trends identified

**Attachment "A"**

Medical Device Information Sources

The FDA has released its most recent version of the Manufacturer and User Facility Device Experience Database (MAUDE), which lists reports of adverse events involving medical devices.

The data consist of all voluntary reports made since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The FDA's Center for Devices and Radiological Health (CDRH) also has an online search capability that can produce information about devices that may have malfunctioned or caused a death or serious injury.

To download the MAUDE files, visit www.fda.gov/cdrh/maude.html (Internet connection required).

To search the CDRH database,
visit www.acceDSSdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (Internet connection required).

Another source of information for health care professionals can be found on the ECRI Web site. This nonprofit health services research agency provides an online database of reports based on ECRI investigations of medical device failures, and related injuries and deaths over several decades. Its goal is to provide information to help avoid "design and quality assurance problems and human factors limitations that increase the incidence of medical and user error," according to ECRI.

To access the database, visit www.ecri.org, click on the "Professional Information" link, then the Medical Device Safety Reports case studies of medical device errors (Internet connection required).

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