



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 75.30, **Medical Equipment Policy**
JC Environment of Care 2.04.03

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is 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. This equipment is being used in the TTUHSC El Paso clinics also known as Texas Tech Physicians of El Paso.

REVIEW: The senior director of safety services will review this policy every two (2) years. Recommendations and revisions will be forwarded to the managing director of physical plant and support services and the chief operating officer.

PROCEDURE:

I. **Selection and Acquisition**

Selection and acquisition of medical equipment should be in accordance with HSCEP 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 its use, and equipment incident history. Recommendations for standardizing equipment should be directed by the dean of clinical affairs, with the Safety Committee for 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 resource, reference and information center for all equipment purchased and can be reached at 215-4554. Additional medical device information is available through the Food and Drug Administration (FDA) (See Attachment A).

II. **Equipment Inventory:**

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

- A. Inventory of medical equipment in the department/clinic
- B. Maintenance schedule
- C. Preventive maintenance service records
- D. 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 clinic administrator or designee will contact the Department of Safety Services to coordinate a service visit for initial safety testing of new equipment and equipment repair. The service company will add the equipment to the routine preventive maintenance schedule.

III. **Equipment Inspection, Preventive Maintenance and Testing**

Inspection, preventative maintenance, and testing should be conducted to achieve effective, safe, and reliable operation of all inventoried medical equipment. Preventive maintenance and repairs are performed via a centralized contract through the Department of Safety Services in accordance with equipment manufacturer's recommendations. The Department of Safety Services established an on-line bio-medical service request procedure that is to be used when requesting equipment services for maintenance, inspections and repairs. Departments will be held responsible for any services they request that deviate from this procedure.

IV. **Equipment Repair**

Equipment that malfunctions, fails or exceeds the service/calibration schedule will be taken out of service, 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 Department of Safety Service Department or service contractor should be notified, and the equipment not be put back into service until the fault/problem has been corrected and the equipment is 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, Quality 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:

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

V. **Equipment Disposal**

Equipment belonging to TTUHSC El Paso will be disposed of by appropriate coordination and documentation in accordance with applicable HSCEP OPs 61.01, 63.10, 72.04, and 72.07.

VI. **Equipment (User) Training, Orientation and Education**

- A. 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 equipment failures.
- B. 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.
- C. Each piece of equipment in 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 and procedures that have changed significantly.
- D. 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.
- E. 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. All equipment training must be

documented and kept on file; this will be the responsibility of the clinic administrator or his/her designee.

VII. **Safe Medical Device Act (SMDA)**

- A. This describes the criteria that are 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.
- B. *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 include all electrical support equipment, implants, catheters, thermometers, syringes, pumps, etc.
- C. Applies to employees, clinic administrators, resident physicians, medical staff

VIII. **Responsibility**

- A. An Unusual Occurrence Report must be filed with performance improvement or 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>
 - 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.
- F. Service Evaluation Committee Responsibilities (Safety Committee)
 - 1. Evaluation of device-related events with any identified trends is referred to risk management.
 - 2. A Medical Device Reporting User Facility Report will be completed. (Website reference above).
 - 3. 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).

4. Submittal of reports to FDA and manufacturer is the responsibility of performance improvement and/or risk management.

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 or when not feasible for TTUHSC El Paso to purchase.

- A. 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.
- B. All rented, loaned, or borrowed equipment must meet safety certification prior to being placed into service.

X. Purchasing Leasing Equipment

Departments that are purchasing or leasing new equipment need to notify the Information Technology Department (IT). IT will review and assess that the equipment you are ordering is compatible with our electronic medical record (EMR) software and/or computer system.

XI. Request for Biomedical Equipment Services

The Department of Safety Services established an electronic work order request form for the departments to use when needing biomedical equipment services; the form can be found on the Department of Safety Services webpage; by clicking on the link below the policy. The work order request form needs to be submitted prior to services being rendered. A department form of payment (FOP) number needs to be identified in the request form in order to charge back the service cost to the department. Departments will be held responsible for any services they request that deviate from this procedure.

XII. Performance Indicators

The objectives, scope, performance, and effectiveness of the medical equipment management plan shall be evaluated annually with input from all clinical departments' annual environment of care risk assessment tool. Performance measures to be evaluated on an ongoing basis include:

- A. Equipment malfunction/failure
- B. Associated patient or staff injury
- C. Trends identified

Medical Device Information Sources

The Food and Drug Administration (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 provide 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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (Internet connection required).

Another source of information for health care professionals can be found on the Emergency Care Research Institute (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).