<u>Medical Equipment Management Plan 2012</u>

I. Scope

The Environment of Care Committee at UTMB Health is a multidisciplinary focused group and continuous process improvement team that consists of select representatives from the service, support and patient care departments. The EOC has primary and collaborative responsibility for providing a safe, secure, and comfortable environment to facilitate patient care in the healthcare departments, hospitals and clinics that are part of the UTMB Health. The organizational responsibility and structure of the Environment of Care Program at UTMB Health has been carefully developed to create a partnership and strong communication process between the Environment of Care Committee, the UTMB Health system Quality Council and the Institutional General Safety Committee.

APPLICABLE TO: All UTMB Health personnel, students, departments and properties

II. Purpose

Medical equipment is a significant contributor to the quality of care. It is used in treatment, diagnostic activities and monitoring of the patients. It is essential the equipment be appropriate for the intended use; that staff be trained to use the equipment safely and effectively; a plan for scheduled service be developed; and equipment be maintained appropriately by qualified individuals. This plan will assist hospital staff in achieving the safe and effective use of medical equipment and meet the Environment of Care EC.02.04 recommendations.

III. Philosophy

A. UTMB Health is committed to the safety of its patients, employees, and visitors from hazardous conditions and electrical shock incidents. Special attention must be given with regard to the effective, safe and reliable operation of medical equipment used to support direct patient care.

B. The University of Texas Medical Branch (UTMB Health) Medical Equipment Management Plan shall be coordinated by the Medical Equipment Management Subcommittee which reports to the Environment of Care and General Safety Committees for the support of the clinical enterprise's medical equipment and to maintain compliance with The Joint Commission EC.02.04.01recommendations.

IV. Equipment Management

The Medical Equipment Management Subcommittee serves as a central body to review issues related to clinical equipment. Questions or concerns can be brought to this group at the regularly scheduled meetings or directly to any of its membership. The Co-chairs are Belinda Escamilla at 747-2835 and Bill Willison at 747-6143.

V. Department Responsibility for Medical Equipment Management

Each department director will assess the equipment and skills available in their area of responsibility and the competency of all staff using medical equipment. The department director will determine the necessary training, license and certification requirements of their staff; degree of risk associated with the equipment; and the frequency for retraining to ensure staff competency. This assessment will be performed with all new hires and when equipment technology changes.

VI.EC.02.04.01.01 Equipment Selection, Acquisition and Introduction

A. Before acquisition of new equipment within the clinical enterprise, department director will solicit input from individuals and departments who operate and service the equipment.

B. A process of due diligence is followed when acquiring new equipment starting with the capital planning process of projecting equipment needs over time and submitting requests in advance within the StrataCap processing program. Requested items and projects are reviewed and approvals are obtained from department management, standing equipment committees, and Purchasing.

VII. Equipment Inventory System

An inventory system of all known medical equipment owned, leased, donated or loaned within the clinical enterprise is maintained by Clinical Equipment Services (CES). A unique identification number is assigned and manufacturer's name, model, serial number and history of service performed on each device are maintained throughout the equipment's useful life and/or as required by regulatory bodies. Departments are required to report changes in the equipment inventory to CES such as trade-in transactions, new locations, surplus or retirement. The University Finance department shall also be informed of these same changes when the equipment meets the definition of an asset or controlled item. The CES group will communicate the equipment inventory of all items maintained to the department each year by the end of 2nd quarter for a sign off communication of equipment covered and the budgeting preparations

VIII. EC.02.04.01.03 Equipment Maintenance Policies and Practices.

The activities related to the CES inspecting, testing, and repair of all medical equipment on the equipment inventory system are reviewed and approved by the Medical Equipment Subcommittee and presented to the Environment of Care Committee. Other approved service departments or vendors responsible for performing these tests, inspections or repair shall provide summary procedures and schedules for review and approval by the Medical Equipment Management Subcommittee and the EOC.

iX. EC.02.04.01.04 Equipment Risk Ranking and Frequency of Inspection

The level and frequency for inspections of medical equipment are based on the equipment risk ranking and repair experience formulas reviewed and approved by the Medical Equipment Subcommittee and presented to the EOC.

X. EC.02.04.01.05 Safety Inspection Performance Standards Preventive Maintenance A. Safety hazard warnings, safety alert and recall notices are distributed to appropriate departments by the Office of Risk Management, x-24776, via the ECRI Alerts Tracker Recall and Hazard System. The recipients of the ECRI alerts shall report back their findings in a timely manner via the ECRI Tracking System. Recall information is monitored by Risk Management.

B. Safe Medical Devices Act (SMDA). UTMB Health shall maintain compliance reporting requirements under the SMDA. The Office of Risk Management, in consultation with CES or other authorized service departments shall investigate events and report as required. The Medical Equipment Management Subcommittee shall provide appropriate recommendations regarding device malfunctions and user errors as required. Hospital staffs who observe an injury or potential injury involving equipment shall report the information via the UHC Patient Safety Net (PSN) online event reporting system to Risk Management.

C. Quantitative measure of the percentage of user error related to work requests (verified as not related to an equipment malfunction or failure) completed for the specific time interval.

- 1) Such requests are related to follow-up service actions which were performed due to suspected medical device malfunctions, failure in utility supply, suspected improper operations of a device or suggestions for users about improving device operations, etc. These types of requests will require feedback to the user and/or local supervisor.
- 2) A user error feedback and reporting process shall be in place and shall include both the staff users and service providers in order to identify and follow- up problem areas related to equipment usage. Equipment safety and repair trends are to be reported to the EOC quarterly.

XI. EC.02.04.01.06 Long-Range and Emergency Planning

Emergency and contingency planning is prepared by each department via the Business Continuity Planning process. Departments shall prepare plans to provide for equipment and services in the event of disruptions due to utility failure, weather events, civil disruptions and other foreseeable circumstances such as sudden equipment failure during a procedure or test.

XII. Strategies for Achieving Effective, Safe and Reliable Operation of Equipment

A. Safety inspection and PM schedules are determined by risk and repair history.

B. A rating system is used to identify the schedule of services performed for each clinical device in the CES inventory and include a ranking based on equipment function; physical risk associated with the device; and the level of maintenance the device requires. The risk-ranking plan is reviewed and approved by the Medical Equipment Management Subcommittee annually as part of the annual plans review.

C. Preventive maintenance and repair of patient care and laboratory equipment may be provided by internal UTMB Health departments or contracted to outside agencies. All equipment management procedures shall be consistent with the Medical Equipment Management Plan and the Medical Equipment Management Subcommittee approved protocols.

D. When a device fails to pass an inspection; fails during use by the operator; or appears to be damaged; the operator or inspector shall take it out of service immediately. The equipment should be tagged with an "Out of Service" tag and followed-up for corrective action by the appropriate service provider.

E. All personnel shall be made aware that use of electricity and equipment in their assigned job introduces potential damage to equipment by possibility of burn, shock, explosion, fire, and power failure. With possibility of injury, disability or death to patients or staff. All staff shall be trained on proper use and application of medical equipment in patient care areas, and local departments shall document training. Periodic reporting of user errors and follow-up actions shall be provided to the Medical Equipment Management Subcommittee. The Sub-Committee will review the data presented and identify trends and issues where department intervention may be needed and report concerns or recommendations to the management of the area identified. Periodic reports of trends and issues are brought to the EOC for their information and action as required.

F. Electrical safety labels (green tags) will be affixed to all equipment receiving electrical safety testing and/or PM services. The labels will indicate the successful completion of such inspection(s). Such equipment shall also be included in the master equipment database. Records of electrical safety inspections, PM inspections, and repair actions shall be maintained by CES or other authorized departments, as required. Outside service vendors shall provide the department equipment owner, via CES, with appropriate documentation about repairs, PM and safety testing, etc., on their equipment.

G. Equipment contaminated with biohazard material should be cleaned prior to transportation to another location. When a piece of clinical equipment has become contaminated internally and cannot be disinfected prior to transportation, the hospital exposure control plan will be followed including

affixing a sticker with a biohazard symbol. Stickers can be obtained from the CES department at x76143.

H. Patient owned equipment should only be used upon approval by the physician or nurse manager/designate. (IHOP Policy 9.13.3) Equipment requiring connection to AC power will generally not be allowed; exceptions to this standard will be made only at the direction of the patient's physician or designate. The equipment must be inspected by a representative of CES or other authorized department and shall include an appropriate waiver of liability document on file. If an appliance does not meet equipment safety standards, it will be removed and given to the responsible party.

I. Staff owned equipment may only be used with appropriate local management approval but not allowed for use with patients.

J. Departments will strictly adhere to the vendor policy when authorizing an equipment manufacture representative to visit any buildings where healthcare is provided.

K. Contracted work is assessed by the department to ensure work is completed in a safe and competent manner. A service report of all work performed will include name and contact number of person performing the work and the organization they represent. Service reports will be recorded as part of the equipment history maintained by CES.

L. Mobile communication devices, such as cellular telephones, should be turned off upon entry into all areas when prohibited use is posted. (see IHOP Policy 9.13.17).

http://intranet.utmb.edu/Policies_And_Procedures/Search_Results/PNP_005093

M. Inspecting, Testing and Preventive Maintenance

Scheduled PM shall be performed annually, or on a schedule based on relative risks and historical data, on all patient care and laboratory related equipment by qualified personnel. Scheduled PMs shall be documented by CES and also reviewed and approved by the Medical Equipment Management Subcommittee. By adoption of the committee S.E.E.P. installations (battery back-up systems) are to be included in the CES inventory. The completion rate for safety inspection and PM shall be 96% on average.

XIii. EC.02.04.03.01 Safety Testing and Identification of Newly Acquired Equipment

Before initial use of medical equipment, within the Clinical Enterprise, electrical safety testing and tagging is performed and monitored by CES and periodically thereafter. The initial testing requirement applies to all equipment acquired through purchase, lease, donations or loan.

XiV. EC.02.04.03.02 Equipment Inspection, Testing and Repair Standards

Summary and Performance Indicator Reporting

1) Periodic summary data containing completion rates for safety testing, preventive maintenance, repair actions and user error follow-up will be submitted to the Medical Equipment Management Subcommittee by authorized service departments for review and follow-up as required. The Medical Equipment Management Subcommittee, in turn, will provide periodic performance summary feedback to the equipment user departments and the Environment of Care Committee.

2) The Environment of Care Committee, the General Safety committee and Clinical Equipment Services shall monitor the equipment management (safety, preventive maintenance and repair) program. CES shall provide the actual dayto-day service delivery function for all clinical areas. The Medical Equipment Management Subcommittee shall monitor the coordination of service providers and vendors and support of equipment safety, preventive maintenance and repair activities as required.

XV. EC.02.04.03.02. Preventive Maintenance Standard – Life Support

Preventive maintenance for life support equipment will be completed 100%. Equipment Tier Level assignments used for PM scheduling will be reviewed and approved by the committee at least annually.

XVI. EC.02.04.03.03 Preventive maintenance and Corrective Repaid Standard – Non-Life Support

Preventive Maintenance Standard–Non-Life Support equipment–Tier 1 equipment

1) Quantitative measure of the percentage of PM and electrical safety service work effort completed for specific interval, i.e., fiscal quarter.

2) An average of 96% of scheduled PM actions will be completed annually.

Corrective Repair Standard (Non PM / Safety)

1) Quantitative measures of the percentage of the service repair work completed (independent of the PM / Safety process) for specific time interval.

2) A minimum of 96% of scheduled corrective repair maintenance actions will be completed annually.

XVII. Equipment Evaluation/Consultation Standard

A. Quantitative measure of the percentage of the medical device evaluations or consultations requests (not including user error requests) completed for a specific time interval. Such requests are related to documented follow-up events associated with the performance of analysis of a medical device operation or function, providing alternatives to a specific device for purchase, answering training questions, or evaluating device interactions or compatibility, etc.

B. A minimum of 96% of requested Evaluation / Consultations will be completed annually.

XVIII. Repair Turnaround Time Standard

1) Quantitative measure of the percentage of corrective repair requests completed within a 24-hour period from the time the request was initiated.

2) A minimum of 74% of corrective repair actions will be completed within a 24-hour period.

XiX. EC.02.04.03.04 - Performance Testing of Sterilizers

Performance testing of sterilizers will be completed and records maintained by the department responsible for the equipment as outlined in the Healthcare Epidemiology Policies 01.21 Monitoring of Sterilizers. A summary of the testing results and any corrective action taken as a result of the testing will be coordinated by the Healthcare Epidemiology department and reported four times per year or more often if circumstances warrant.

XX EC.02.04.03.05 - Renal Chemical and Biological Testing

Testing of water used in renal dialysis will be completed including chemical and biological testing as outlined by the Texas Department of Health. Results will be maintained by the Renal Services department and a summary of any corrective actions required will be presented to the Medical Equipment Management Subcommittee four times per year or more often if circumstances warrant.

XXI. Laser Safety Program and Radiation Safety

1) Laser Safety programs and reporting will be coordinated by the Laser Safety Sub-Committee. The Environmental Health Safety Laser Safety Officer shall be notified when a Class IIIb (3b) or IV (4) laser or an Intense Pulsed Light (IPL) is purchased or used in any clinical area of the hospital.

2) Equipment suspected to be contaminated by radioactive material should be quarantined in place and Environmental Health and Safety shall be called for questions related to radioactive contamination

XXII. Radiology Equipment Monitoring

Radiation Safety monitors the regulatory requirements for testing and tracking the radiologic service and radiation exposure levels within UTMB HEALTH. Radiation Safety will assure that UTMB HEALTH radiologic equipment is licensed and operated according to the regulation adopted by the State of Texas and report any discrepancies in compliance to the committee.

XXiIi. Monitoring of the plan and oversight responsibility

A. Ongoing monitoring of the services performed on clinical equipment will be the responsibility of the Environment of Care and University Safety Committees via the Medical Equipment Management Subcommittee. The items monitored are preventive maintenance, corrective maintenance, consultations requested and user errors reported. The criteria monitored will be modified as needed to respond to the changing trends and issues identified by the review process. The Medical Equipment Management Plan will be reviewed annually, and at any time during the year if needed, to provide a safe environment.

B. For questions regarding the plan, or the Medical Equipment Management Subcommittee please call 772-2279.