UNIVERSITY OF TOLEDO HEALTH SCIENCE CAMPUS

SUBJECT: EQUIPMENT MANAGEMENT PLAN Procedure No. ME-08-000

PROCEDURE

The University of Toledo Health Science Campus (UT HSC) shall have an Equipment Management Plan.

PURPOSE

To meet the mandates of the Joint Commission standards; to support the provision of superior patient care and medical education by enhancing the availability and reliability of advanced technology through a constantly improving, cost effective equipment management program, which provides safety and minimizes risk.

SCOPE

The Equipment Management Plan describes how the organization will provide medical equipment free of hazards and manage staff activities to reduce the risk of injuries. The plan has been developed to address all of the surveyable facilities of the University of Toledo clinical operations. These facilities have inherent safety risks associated with providing services for patients, the performance of daily activities by staff, and the physical environment in which services occur. The Equipment Management Plan has been designed to work in concert with the other Environment of Care Management Plans (i.e. Utility Systems, Hazardous Materials, Safety, Security and Fire Safety Plan). The Equipment Management Plan serves to provide safe and reliable medical equipment to provide compliance with TJC standards. The plans are reviewed and accessed annually to determine their effectiveness and ensure that they function as unit to allow for continued improvement and functioning within the Environment of Care.

RESPONSIBILITY

The Equipment Management Plan has been assigned a leader with the appropriate background and skill set to allow for continuous satisfaction of the assigned elements of performance. This individual is required to sign after reviewing the plan on an annual basis. Staff from the Bio-medical Engineering Department is assigned responsibilities to complete elements of the plan and ensure its continued implementation. Reports on the plan's implementation are reported to the Safety and Health Committee on a regular basis. A representative from hospital administration sits on the Safety and Health Committee. On an annual basis the assessment of the effectiveness of each individual management plan is presented to the Board of Trustees of the University of Toledo.

PROCESSES AND PROCEDURES

The hospital manages medical equipment risks.

- The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life support equipment) and equipment incident history. The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory. This plan is covered in procedures ME-08-008, ME-08-007, 32-03 and 32-43. Biomedical Engineering shall be responsible for administration of the program, which sets guidelines for identifying, evaluating and inventorying medical

equipment to ensure patients, staff, and visitors are safe from electrical hazards and equipment malfunction. Risk based criteria is used to determine high risk versus routine (non-high risk)equipment

This plan also ensures that all patient care equipment (i.e. purchased, leased, rental, consigned, privately owned) is included in the Biomedical Engineering equipment inventory. Equipment is categorized by risk, and then incoming inspections are performed (procedure 32-03). Scheduled maintenance and testing will be based on manufacturers' recommendations unless otherwise identified for inclusion into the alternative equipment maintenance (AEM) program.

- The hospital identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.
  Note: High-risk medical equipment includes life-support equipment.
  All high-risk equipment that is in the inventory is identified as such and is supported by procedure 32-43. Life Support equipment is labeled as High-Risk in the inventory.

- The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.
  Note 1: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice.
  Note 2: Medical Equipment with activities and associated frequencies in accordance with manufacturers' recommendations must have a 100% completion rate.
  Note 3: Scheduled maintenance activities for high-risk medical equipment in an alternative equipment maintenance(AEM) program inventory must have a 100% completion rate. Scheduled maintenance activities for non-high risk medical equipment in an alternative equipment maintenance(AEM) program inventory may be deferred as defined by organization policy, provided the completion rate is not less than 100%
  This plan ensures that all equipment is included in the equipment inventory, procedure ME 08-008. Equipment that is included in the equipment management plan will receive scheduled maintenance based on manufacture's recommendations unless otherwise identified for inclusion into the alternative equipment maintenance (AEM) program. Incoming inspections are performed (procedure 32-03). Risk based criteria is used to determine high-risk versus non-high risk equipment (procedure 32-43). Procedure 32-56 describes the alternative equipment maintenance program.

- The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations. Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing and maintaining be in accordance with the manufacturers' recommendations or otherwise establishes more stringent maintenance requirements, Medical Lasers, Imaging and radiologic equipment and new medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies.
  This plan is covered in procedures 32-03, 32-04, and 32-43. Incoming equipment shall be evaluated and categorized by risk. Scheduled inspections on equipment categorized as high risk will follow manufacturer's recommendation.

- A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternative manner that includes the following: How equipment is used, likely consequences of equipment failure or malfunction, availability of alternative or back-up equipment, incident history and maintenance requirements. Procedure 32-56 supports which

devices are on an AEM program and how the program is evaluated. Procedure 32-43 evaluates the risk criteria.

- The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program. Equipment included in an alternative maintenance program will be labeled as such in the equipment database and designated with the label (AEM). This information is stated in procedure 32-56.

- The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment. This plan requires, per procedure ME-08-008, the service of all medical equipment be provided through Biomedical Engineering. User departments can contact Biomed at ext. 4899 during normal working hours (8 a.m. – 4:30 p.m.).On-call technicians will provide emergency service after hours as stated in procedure 32-17. Emergency Clinical Intervention Documents are provided to departments per procedure ME-08-009. All updates are distributed as needed.

- The hospital identifies quality control and maintenance activities to maintain the quality of the diagnostic computed tomography (CT), position emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. The hospital identifies how often these activities should be conducted. This plan is covered in procedures 32-03, 32-04, and 32-43. Incoming equipment shall be evaluated and categorized by risk. Scheduled inspections on equipment categorized as high risk will follow manufacturer's recommendation.

The hospital inspects, tests, and maintains medical equipment.

Before initial use of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks. This plan states that Biomedical Engineering will perform an incoming inspection on medical equipment that is under their responsibility. This is covered by procedure 32-03. All devices receiving an incoming inspection will be evaluated to determine if they are to be categorized as high-risk or non-high-risk. Scheduled maintenance and testing will be based on manufacturers' recommendations unless otherwise identified for inclusion into the alternative equipment maintenance (AEM) program.

- The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.
  Note 1: High risk equipment includes medical equipment for which there is a risk of serious injury or even death to a patient or staff member should it fail, which includes life-support equipment.
  Note 2: Required activities and associated frequencies for maintaining, inspecting and testing of medical equipment completed in accordance with manufacturers' recommendations must have a 100% completion rate.
  Note 3: Scheduled maintenance activities for high-risk medical equipment in an alternative equipment maintenance(AEM) program inventory must have a 100% completion rate.
  This plan is covered by procedures 32-04, and 32-43. Biomedical Engineering documents all work performed on all high –risk equipment included in the medical equipment management plan in accordance with all applicable procedures.

- The hospital inspects, tests, and maintains non–high risk equipment identified on the medical equipment inventory. These activities are documented.
  Note: Scheduled maintenance activities for non-high-risk medical equipment in an alternative equipment maintenance(AEM) program inventory are to be completed at 100%.

AEM frequency is determined by hospital's AEM program.
Procedures 32-04 and 32-43 address this requirement. Biomedical Engineering documents all work performed on all non-high–risk equipment included in the medical equipment management plan in accordance with all applicable procedures.

- The hospital conducts performance testing of and maintains all sterilizers. These activities are documented. Biomedical Engineering performs scheduled inspections on all sterilizers following procedures 32-08, 32-43. Performance testing is recorded and performed by sterile processing staff per their departmental procedures.

- The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented. Biomedical Engineering is responsible to perform daily checks of the RO System and to note the operating parameters. These parameters are documented in a logbook as per Biomedical Engineering procedure # 1125. The weekly and bi-annual analysis is recorded and performed by Hemodialysis staff per their department procedures. RO Water Quality Testing is covered under procedure 32-58.

- Equipment listed for use in oxygen-enriched atmospheres is clearly and permanently labeled as follows: Oxygen-metering equipment, pressure reducing regulators, humidifiers, and nebulizers are labeled with the name of manufacturer or supplier. Oxygen-metering equipment and pressure- reducing regulators are labeled," Oxygen-Use No Oil". Labels on flowmeters, pressure-reducing regulators and oxygen-dispensing apparatuses designate the gases for which they are intended. Cylinders and containers are labeled in accordance with Compressed Gas Association. Equipment is reviewed during inspections to ensure the correct labeling from the manufacturer exists. This is stated in procedures 32-03 and 32-04.

- All occupancies containing hyperbaric facilities comply with construction, equipment, administration, and maintenance requirements of NFPA 99-2012 Chapter 14
  This plan is covered in procedures 32-03, 32-04, and 32-43. Incoming equipment shall be evaluated and categorized by risk. Scheduled inspections on equipment categorized as high or low risk and will follow manufacturer's recommendation or an alternative equipment maintenance (AEM) program.

- Qualified hospital staff inspect, test, and calibrate nuclear medicine equipment annually. The dates of these activities are documented. This plan states that Biomedical Engineering will evaluate nuclear medicine equipment and add them to the Equipment Management inventory.
  Once added the equipment will be evaluated and categorized by physical risk associated with use.
  Procedures 32-04, 32-22 and 32-43 address this requirement.

- The hospital maintains the quality of the diagnostic computed tomography, positron emission tomography, magnetic resonance imaging and nuclear medicine images produced.
  Equipment will be categorized by risk. Scheduled maintenance will follow either manufacturers recommendations or an alternate equipment maintenance program. This is covered by procedures 32-03, 32-04 and 32-43.

- The hospital performs equipment maintenance on anesthesia apparatus. The apparatus is tested at the final path to patient after any adjustment, modification, or repair. Before the apparatus is returned to service, each connection is checked to verify proper gas flow and an oxygen analyzer is used to verify oxygen concentration. Areas designated for servicing of oxygen equipment are clean and free of oil, grease, or other flammables. Incoming inspections are covered by procedure 32-03, risk categories are covered by 32-43 and scheduled maintenance is covered by procedure 32-04

- The hospital meets NFPA99-2012: Health Care Facilities Code requirements related to electrical equipment in the patient care vicinity.
  ME-08-007, 32-03, 32-43 and 32-04 explains how we test patient care equipment, perform an incoming inspection, assign a risk category and perform a scheduled inspection.

The hospital manages safety and security risk

- The hospital responds to product notices and recalls
  This Plan provides a means of tracking product recalls, alerts and hazards per procedures ME-08-003 and 32-14, regarding medical equipment and supplies within our facility.

The hospital plans activities to minimize risks in the environment of care.

- The hospital has a library of information regarding inspection, testing, and maintenance of its equipment and systems. NOTE: This library includes manuals, procedures provided by manufacturers, technical bulletins, and other information.
  The library for all medical equipment manuals, manufacturers procedures, technical bulletins, etc. is located in the Biomedical Engineering Department. Electronic copies are also located on the departments common drive.

- The hospital has a written plan for managing the following: Medical equipment
  Medical equipment is managed by ME-08-000 which is the Medical Equipment Management Plan.

LVAD EQUIPMENT

The testing and support of LVAD equipment is handled through procedure 32-52. It states that the equipment will be added to the inventory, scheduled maintenance will be performed per manufacturer recommendations and how equipment repairs will be handled. Device recalls and alerts are covered under procedures 32-14 and ME 08-003.

ANNUAL REPORT

The objectives, scope, performance and effectiveness of the Equipment management program/plan will be evaluated in an annual report to Administration. Evaluation will include all areas of equipment management.

SUPPORTING DOCUMENTATION AND PERFORMANCE MEASURES

Other written procedures that support this management plan can be found at http://www.utoledo.edu/depts/safety/UT%20Procedures%20and%20Plans.html. Performance measures for the equipment management program include the following:

- Equipment PM completion data
- Malfunctions due to operator error
- Performance testing of sterilizers
- RO water testing

SOURCE: Biomedical Engineering
Date:

Steve Hanenkrath
Name of Responsible Person

Director of Bio-medical Services
Title

Steve Hanenkrath
Signature

January 17,2019
Date

Review/Revision

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