POLICY ■ PROCEDURE

SOUTHWEST WASHINGTON MEDICAL CENTER

Title: Quality Assurance and Risk Management Program

Number: 8437.0115

Originating Department: Biomedical Instrumentation

Effective: 10/01/92
Revised: 10/25/07
Reviewed: 10/25/07

Approved by:

GENERAL POLICY STATEMENT: The Biomedical Instrumentation Department has a defined Quality Assurance and Risk Management Program.

PURPOSE: To ensure the effectiveness of the Patient Care Equipment Management Plan and establish the criteria for reporting to the Environmental Health and Safety Committee.

PROCEDURE:

A. Equipment Evaluation and Selection

1. Biomedical Instrumentation shall participate in the process used by the Medical Center to select new equipment.

B. Equipment Recalls

1. Any equipment known to be defective will be handled in the manner recommended by the manufacturer in order to minimize the potential for patient injury. To ensure that known problems are addressed appropriately, the Biomedical Instrumentation Department will work closely with the departments that are affected by the product safety recall notification. All recalls shall be kept as part of the equipment historical record with the corrective action taken. Recalls shall be responded to as recommended by the Food and Drug Administration or manufacturer. Equipment that cannot be addressed within 7 days of notice shall be removed from service pending resolution. Equipment identified as hazardous, which could be dangerous to the patient or operator, shall be removed from service within 24 hours of notification. The urgency of each recall shall be evaluated for clinical implications before acting.
    a. Target: 100% of recalls shall be responded to in less than 7 days.

C. Equipment Acceptance Testing and Initial Inspections

1. All medical equipment as defined by the Patient Care Equipment Management policy shall be inspected prior to being placed in use for the first time. Equipment shall meet all manufacturer's specifications and pass physical and electrical safety tests. Equipment failing inspection shall be rejected and returned to the vendor.

D. Equipment Preventive Maintenance

1. Equipment preventive maintenance shall be completed within the scheduled time frame. PM completion shall be tracked by percent completed on time, percent with minor problems and percent that fail PM inspection. Refer to the Patient Care Equipment Management policy for definitions.
    a. Target: Life Support Equipment 100% on time, 30 days post due date.
    b. Target: High Risk Biomedical Equipment 95% on time, 30 days post due date.
    c. Target: Low Risk Biomedical Equipment 95% on time, 60 days post due date.

E. Equipment Repairs

1. Life support equipment shall be given the highest priority for repair. Non-life support equipment repairs shall be based on the need of the departments. The overall repair turnaround time shall me monitored and repair priorities shall be modified to meet performance goals. IV pump repairs shall be prioritized to limit turnaround time and maximize availability.

a. Goal: Repair turnaround time shall not exceed 7 days.

b. Goal: IV pump repairs shall be completed within 2 days.

2. The repair rate shall be monitored monthly for trends that demonstrate the effectiveness of the management plan.

a. Repairs per 100 devices in the inventory.

b. User-related repairs per 100 devices in the inventory.

F. Customer Satisfaction

1. Monthly customer experience results shall be monitored monthly to identify opportunities for improving service.

G. Continuing Education

1. Appropriate training shall be provided to all employees of Biomedical Instrumentation and other departments to enhance skills and work habits. Mandatory safety training is to be completed via the WebInservice on-line training module. User Education needs shall be identified when there are on-going equipment problems that show up as operator error, or other user-related problems. User education may be conducted by the equipment manufacturer, the Education department, or Biomedical Instrumentation department and may be video or other appropriate training method as indicated by department needs and/or modified accordingly.

H. Contract Review

1. Service contracts for medical equipment shall be reviewed to ensure that appropriate standards and regulations are met. Service Contracts should cover, as a minimum: repair of any malfunction which degrades performance or specifications; documentation to meet local, state, federal, and other regulatory requirements applicable to the end user; and services needed to satisfy the requirements of the Joint Commission on Accreditation of Hospitals (JCAHO). The service contract should specify the number of preventive maintenance inspections that will be provided per year and should include statements concerning on-site response time average repair time, and availability of backup equipment.

I. Staff Communications

1. Staff communication is vital to effective department operations. Staff meetings shall be held monthly or more often as needed. A communication book is also available on the department web page.

J. Incident Investigations

1. When a medical device is suspected causing or contributing to a death, or serious injury/illness, an investigation of the incident shall be conducted in accordance with the Medical Device Reporting Program. (Policy: 8610.S125)

K. Reports

1. Summary reports of medical equipment repairs, user errors, preventive maintenance regulatory compliance, and product safety recalls shall be provided to the Environmental Health and Safety Committee.

L. Policy and Procedure Review

1. Maintenance procedures will be reviewed annually for any necessary adjustments to the procedure or the frequency of inspection. All procedure adjustments that increase the inspection interval to longer than annual shall also be approved by the Biomedical Instrumentation department manager and the Director of Safety Services. There shall be an annual review of departmental policies and procedures by all Biomedical Instrumentation staff, including a review of maintenance procedures.

Related Policies: Medical Device Reporting Program 8610.S125

Patient Care Equipment Management 8437.0111