SOUTHWEST WASHINGTON MEDICAL CENTER

POLICY ■ PROCEDURE

Title: Medical Equipment Hazards, Alerts, Recalls and Internal and External Notices

Number: 8437.0121

Effective: 10/27/98
Revised: 10/23/07
Reviewed: 10/23/07

Originating Department: Biomedical Instrumentation

Approved by:

GERNERAL POLICY STATEMENT: Medical Equipment Hazards, Alerts, Recalls, and Internal and External Notices will be reviewed to determine if any of the affected equipment or product exists at SWMC.

PURPOSE: To institute comprehensive safety practices that minimize hazards to Southwest Washington Medical Center patients, Staff and Visitors.

DEFINITIONS: The Federal Drug Administration (FDA) has established the following definitions of "recall classes." A FDA "Recall" may involve removal of a product from the market or return to the manufacturer for repair. However, FDA also uses the word "Recall" to describe field corrections, field repairs, labeling changes, Hazard warnings and other situations. The FDA assigns each recall to one of the three classes, defined as follows:

Class 1 Recall: A situation in which there is a reasonable probability that the use of exposure to, a violative product will cause serious adverse consequences or death.

Class 2 Recall: A situation in which the use of, or exposure to, a violative product may cause temporary of medically reversible health consequences or the probability of serious adverse health consequences is remote.

Class 3 Recall: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Manufacturer Notices: Often a manufacturer discovering a problem with one of their devices will distribute letters to all known customers. Usually, an immediate course of action is outlined.

PROCEDURE: Upon receipt of all medical equipment hazards, alerts, recalls and internal/external notices, the Biomedical Instrumentation department shall search the computerized maintenance management system database to determine if any of the affected devices exist at SWMC.

If none of the affected devices exist at SWMC, the document shall be marked as "None Present", dated and filed by year and date.

Should any affected devices exist at SWMC, Biomedical Instrumentation shall notify the affected department. Any device 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 department(s), that are affected by the recall notification. All recalls will kept as part of the device

historical record with the corrective action. (policy 8437.0115)

1. Defective or Deficient devices may require any of four types of action:
    a. Permanent removal from service
    b. Modification
    c. Changes in instructions
    d. Warning to User

If a device must be removed from service, all affected units must be located and replacements obtained to meet clinical needs.

If the affected device causes a serious injury or death, it shall be reported to the Risk Management Department (per - policy 8610.S125) and reported to the manufacturer and the FDA.

Periodically, as learned from internal and external sources, Biomedical Instrumentation will disperse Safety Alert Notices to appropriate departments. Biomedical Instrumentation shall report all actions taken on hazard / recall notices to the Environment Health and Safety Committee. (policy 8610.S103)

Ref policies: 8610.S103, 8610.S125 & 8437.0115