OREGON STATE HOSPITAL

PORTLAND – SALEM

POLICIES AND PROCEDURES

SECTION 8: Safety, Security, Emergency Management **POLICY: 8.030**

SUBJECT: **Safe Medical Device Reporting**

POINT PERSON: **RON BRINLEE**
MDC WAREHOUSE MANAGER

APPROVED: **GREGORY P. ROBERTS**
SUPERINTENDENT

DATE: APRIL 27, 2012

I. POLICY

To establish procedures to ensure compliance with the Safe Medical Device Act (SMDA) of 1990.

II. DEFINITIONS

A. "Medical Equipment/Device" means the Food and Drug Administration (FDA) defines a medical device as any piece of equipment, device, instrument, or other article that is used to monitor, prevent, diagnose, mitigate, or treat a disease or to affect the structure or function of the body, with the exception of drugs. This includes, but is not limited to: monitors, thermometers, patient restraints, syringes, catheters, diagnostic test kits and reagents, and disposables.

B. "Serious Injury/Illness" means:

1. Life threatening - the person's life is in jeopardy.

2. Results in permanent damage to a bodily structure or permanent impairment of a bodily function.

3. Necessitates medical or surgical intervention to preclude permanent damage to a bodily structure or permanent impairment of a bodily function.

III. PROCEDURES

A. Whenever there is reasonable basis to believe that a piece of medical equipment or a medical device has caused or contributed to a

patient/employee death, serious injury, or serious illness, the user of the equipment or device is responsible for notifying his/her supervisor immediately.

B. All medical equipment or devices related to such an event shall be taken out of service, labeled "out of order" or "faulty" and secured until an investigation can be conducted.

C. The user of the equipment or device shall fill out the hospital's Incident Report Form according to hospital policy. A copy of the report shall also be sent to the Safety Officer.

D. The Chief Medical Officer (CMO) shall review reports related to equipment/device failures. If it is determined that the equipment/device resulted in or contributed to the death or serious injury/illness of a patient or another person, a report shall be completed and submitted to the Superintendent for review and approval. The Superintendent or designee shall file the report within ten (10) working days with either the manufacturer or the Food and Drug Administration (FDA) according to the following:

1. In the event of a serious injury/illness, the report is filed with the manufacturer. If the identity of the manufacturer is not known, the report shall be submitted to the FDA.

2. In the event of a death, the report is filed with the FDA and the manufacturer, if known.

3. Additionally, semi-annual reports shall be submitted to the FDA for each reportable event that occurred during the reporting period. Reports shall be submitted January 1 (for events reported July through December) and July 1 (for events reported January through June).

E. The Biomedical Equipment Program consists of the following:

1. A database of all biomedical equipment inventory maintained in the Material Distribution Center Warehouse.

2. As new equipment is purchased, it shall be reviewed based on the biomedical requirement criteria and the hospital’s needs. If the equipment meets the criteria, it shall be enrolled in the inventory and given a biomedical property number.

3. Employees that use biomedical equipment receive orientation to its use. Rosters of employees that receive training are maintained and kept on the units in each staff person’s supervisory file.

4. Employees who use the biomedical equipment are to receive annual refresher training. Attendance records shall be maintained as documentation that training is ongoing.

5. All biomedical equipment in the hospital shall be maintained on a yearly maintenance schedule that takes place in April/May of each year.

6. Monitoring of effectiveness shall be done on each piece of equipment with a review of all incidents by the biomedical person.

7. If a piece of biomedical equipment requires repair, the unit/department staff shall notify the MDC Warehouse by phone, or shall complete a work request form. The biomedical person will then call the biomedical vendor to schedule a repair. If a piece of equipment is deemed not repairable, then the equipment shall be removed from the biomedical database.

IV. REFERENCES

Safe Medical Device Act of 1990
21 CFR 803
21 USCS 360
OSH Safety Manual, Procedure 1.82, General Safety & Health Procedures
The Joint Commission Comprehensive Accreditation Manual for Hospitals, Standard EC.6.10, pages EC20 to EC21.

Replaces Oregon State Hospital Policy and Procedure 8.030, *Safe Medical Device Reporting,* dated 10/17/2006.