STANDARD OPERATION PROCEDURE - 1008

SAFE MEDICAL DEVICE TRACKING

PURPOSE: To outline the responsibilities and procedures to comply with the requirements of the Safe Medical Devices Act of 1990.

POLICY: It is a requirement of the Safe Medical Device Act to report deaths, serious injuries, serious illnesses, near misses or potential harm that are caused by medical devices.

DEFINITIONS:

A. Device User Facility – A hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility, excluding physician's office, that utilize medical equipment in patient treatment.

B. Patient Alert – Disclosure of any and all information that reasonably suggests that there is a possibility that a device has caused or contributed to a death, serious injury or illness.

C. Patient – anyone who is being diagnosed, treated or otherwise receives medical care in a facility.

D. Healthcare provider - An employee of the facility or person affiliated with a facility that suffers death, serious injury, or serious illness from a device used at or by the facility, and as a consequence, becomes a patient.

E. Serious illness or serious injury are defined as:

    1. Life threatening.
    2. Results in permanent impairment of body function or permanent damage to a body structure.
    3. Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure.

PROCEDURE AND RESPONSIBLITY:

1. Upon determination or notification of a problem, Supply, Processing, and Distribution personnel will retrieve all malfunctioning patient care equipment or supplies. Notify all potential users of the affected. All components, reusable and disposable, used in conjunction with the equipment will be confiscated.

2. Packaging materials, especially labels including lot number, will be saved.

3. Equipment should not be unplugged or turned off until data is saved unless doing so could result in further injury.

4. Notify Chief, Biomed Engineering, Service Chief, and appropriate Nursing personnel as soon as possible.

5. Complete detailed documentation, including Incident Involving a Beneficiary and other Quality/Risk Management forms. Chief, SPD is to review documentation completed by staff to ensure all pertinent information has been included such as lot, serial, and model numbers of involved equipment and forward to Risk Management.

Reference: Medical Device Reporting for User Facilities: Questions and answers based on the tentative final rule. U.S. Department of Health and Human Services, Rockville, Maryland
Central Service Technician Manual, Fifth Edition, page 241