Subject:	Original Issue Date:	Policy #
MEDICAL DEVICE REPORTING	12/01/93	**304**
	Supersedes: 10/16/08	Effective Date: 2/11/14

Departments Consulted:	Reviewed & Approved by:	Approved by:
Office of Risk Management Facilities Management Supply Chain Operations	Attending Staff Association Executive Committee Senior Executive Council	Chief Medical Officer Chief Executive Officer

PURPOSE

The purpose of the Medical Device Reporting Program is to identify medical device-related incidents, correct, prevent, or minimize undesirable outcomes, and comply with the federal Food, Drug, and Cosmetic Act, Safe Medical Devices Act (SMDA), and the Food and Drug Administration (FDA) reporting requirements.

POLICY

The LAC+USC Medical Center shall establish and maintain reporting systems which identify medical device-related incidents and correct and/or prevent incidents to minimize undesirable outcomes in compliance with the federal Food, Drug and Cosmetic Act, SMDA, and the FDA reporting requirements.

The Office of Risk Management shall have overall responsibility for implementing and managing the Medical Center's Medical Device Reporting program.

The Office of Risk Management shall report all incidents which reasonably suggest that a device has or may have caused or contributed to a reportable event to the manufacturer and/or the FDA within ten (10) working days of the facility becoming aware of the event.

All incidents in which a medical device may have caused or potentially contributed to a patient's death, illness, injury, or adverse outcome shall be reported to the Office of Risk Management within 24 hours of occurrence, or as soon as an incident becomes known.

DEFINITIONS

Medical Device: Any instrument, machine, implant, or other similar article used to prevent, diagnose, or treat disease, or intended to affect the structure or any function of the body. (Common medical products such as catheters, thermometers, and syringes are included.)

Illness and Injury: Any illness or injury that:

- Is life-threatening;
- Results in permanent impairment of a body function or structure; or
- Requires medical or surgical intervention to prevent permanent injury to a body function or structure.

Reportable Information: This information includes professional, scientific, or medical facts, observations, or opinions which would cause a reasonable person to believe that a device caused or contributed to a death, injury, illness, or other significant adverse outcome.

PROCEDURES

LAC+USC Medical Center Employees

1. Any employee who becomes aware of information that suggests a medical device may have caused or contributed to a patient's death, injury, illness, or other significant adverse outcome shall **immediately** report it to his or her supervisor or designee and remove the device from use.

2. The immediate supervisor or designee shall ensure an Event Notification Report form is completed and submitted, per the Event Notification Guidelines Policy (Medical Center Policy #300), to the designated facility/area administrator.

3. Device shall be wrapped with packaging materials, if available, and labeled. Supervisor or designee shall notify the Office of Risk Management to have the device sequestered.

   AT NO TIME SHALL THE DEVICE BE RETURNED TO THE MANUFACTURER, UNLESS THE OFFICE OF RISK MANAGEMENT APPROVES THE ACTION IN WRITING. THE DIRECTOR OF THE OFFICE OF RISK MANAGEMENT IS THE ONLY PERSON AUTHORIZED TO CONTACT THE MANUFACTURER REGARDING DEVICES INVOLVED IN ADVERSE EVENTS.

Facility/Area Administrator or Designee

The facility/area administrator or designee shall:

1. Sequester the device, equipment, supplies, accessories, etc., and transfer it to the Office of Risk Management or the designated Sedgwick CMS Account Executive as directed by the Office of Risk Management Director.

2. Review the Event Notification report. The facility/area administrator or designee shall coordinate further investigation with the facility/area Quality Improvement Manager, complete, and submit a *Medication and Device Problem Report* form to the Office of Risk Management, if indicated, within 72 hours of becoming aware of the event. The report number space on the form should be left blank.

3. Coordinate investigation of the suspected medical device with the facility/area Quality Improvement Manager; Building Crafts Manager or Biomedical Engineer; Supply Chain Operations Director; Unit Nurse Manager; and/or other staff involved in the use, repair or maintenance of the device and/or care of the patient. The facility/area administrator or designee and Quality Improvement Manager shall coordinate corrective action(s) if/as needed with appropriate staff.

4. Results of the investigation shall be documented on the *Medication and Device Problem Report* form and forwarded to the following:

   - Medical Center Office of Risk Management
   - Facility Administrator
   - Facility/Area Quality Improvement Manager
   - Medical Center Supply Chain Operations
   - Medical Center Facilities Management

Medical Center Office of Risk Management Director

The Office of Risk Management Director shall:

1. Review the *Medication and Device Problem Report* form to ensure reported incident and form complies with the SMDA reporting requirements.

2. Ensure that *Medication and Device Problem Report* forms are submitted within ten (10) working days of becoming aware of the occurrence as follows:

   - Medical device-related deaths are submitted to the FDA **and** the manufacturer; or
   - Medical device-related incidents causing serious illness, injury, or significant adverse outcomes, are submitted to the manufacturer or, if manufacturer is unknown, to the FDA; and
   - Maintain appropriate logs and files.

3. Submit written semi-annual summary reports to the FDA, i.e., January 1 and July 1, of all reportable incidents, using appropriate forms, and provide copies to staff as appropriate.

4. Submit a copy of report(s) sent to the FDA to the Department of Health Services Quality Improvement Program.

Facilities Management

The Building Crafts Manager, Biomedical Engineer shall:

1. Assist the facility/area administrator or designee with collection of information regarding reported hazards and recalls as requested. The Building Crafts Manager or Biomedical Engineer shall report unusual problems encountered with medical devices in the facilities to the appropriate facility/area administrator or designee;

2. Assist in conducting investigations of medical device-related incidents, evaluate the safety of the device along with relevant supplies, accessories, and/or packaging;

3. Assist the facility/area administrator or designee and Quality Improvement Manager in completing applicable portion(s) of the *Medication and Device Problem Report* form;

4. Notify facility/area administrator or designee of any significant negative findings in the course of evaluation of new equipment and/or repair and maintenance of existing equipment and devices; and

5. Maintain all required equipment maintenance reports/documentation.

RESPONSIBILITY

All Employees
Administrators
Department Managers
Supervisors
Office of Risk Management

REFERENCES

Safe Medical Devices Act of 1990 (PL 101-629, 104 Stat. 4511)
Federal Register 21 CFR Part 803 & 807
Federal Law 21 U.S.C. 321 (h)
Medical Device Amendments of 1992 (PL 102-300)
DHS Safe Medical Devices Act Policy 311.1
Medical Center Policy #300, Event Notification Guidelines

REVISION DATES

October 20, 1998; March 12, 2002, October 15, 2008; February 11, 2014