U-M Hospitals and Health Centers
Policies and Procedures

UMHHC Policy 05-02-006 Safe Medical Device Act Policy
Issued: 4/00; Last Reviewed: 10/04; Last Revised: 10/04

- **Return to UMHHC Policies Table of Contents**

I. POLICY STATEMENT

It shall be the policy of the University of Michigan Hospital and Health Centers (UMHHC) that all incidents involving patient care devices, related equipment hazards, and explant devices suspected of a possible failure be reported to the UMHHC Safe Medical Device Act (SMDA) Committee. This policy is required in order to conform to the Safe Medical Device Act of 1990 and Food and Drug Administration (FDA) regulations.

II. PURPOSE

The Safe Medical Device Act Policy is intended to integrate with existing UMHHC policies and procedures involving medical device related incidents and to comply with the education, documentation, and reporting requirements of the Safe Medical Device Act of 1990. The Safe Medical Device Act of 1990 was passed by the United States Congress to better protect the public health by increasing reports of device related adverse events by both manufacturers and user facilities.

This procedure applies to any medical personnel who discover, witness, are notified or otherwise become aware of a suspected medical device malfunction or incident. Included within the scope of this policy are personnel who use or operate a medical device, including physicians, nurses, technicians, therapists, or other medical personnel. Other relevant policies are Incident Reporting, 03-07-001, Sentinel Event Review, 03-07-004, Product Recall / Hazard Warning Control Program, 05-02-007, and Explanted Devices Handling Policy, I-310-00.

III. DEFINITIONS

Becomes Aware: A user facility "becomes aware" of a reportable event when medical personnel, who are employed by or formally affiliated with the facility, acquire information that reasonably suggests that a reportable event has occurred. At UMHHC, this is noted by the date that an incident report form is filed.

Device Failure: A device failure is the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

Explant: An implant that has been surgically removed from the human body.

Implant: An implant is a device that is placed into a surgically or naturally formed cavity in the human body. The purpose of this device is to continually assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. These devices are totally encased by the human body.

Incident: An incident is any event that is not consistent with the routine operation of the hospital

or the routine care of a particular individual. It may be an accident or a situation that might result in an accident. It may cause injury or have potential for injury.

Medical Device: The FDA defines a medical device as any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or

- intended to affect the structure or any function of the body, with the exception of drugs.

For example, a medical device includes but is not limited to ventilators, monitors, dialyzers, and any other electronic equipment, implants, thermometers, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposables, components, parts, accessories, and related software. Generally, if it is used in medical practice and it is not a drug or biologic, it is a device. Note, FDA Investigational Devices are not included in this policy. The principal investigator or their designee under stringent FDA guidelines handles these devices.

Medical Personnel: According to the FDA, medical personnel means an individual who either is licensed, registered, or certified by a State, territory, or other governing body to administer health care; has received a diploma or a degree in a professional or scientific discipline; is an employee responsible for receiving medical complaints or adverse event reports; or is a supervisor of such persons. At UMHHC, the definition of medical personnel further includes any employee or individual who is formally affiliated with the UMHHC.

Reportable Event: A reportable event is an event about which a user facility becomes aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury/illness.

Serious Injury/Illness: A serious injury/illness is an injury or illness that:

- is life threatening;

- results in permanent impairment of a body function or permanent damage to a body structure; or

- necessitates medical or surgical intervention to preclude permanent damage or impairment.

Examples include but are not limited to burns which will result in scarring, damage to internal organs, loss of limb, brain damage, deafness, blindness, or paraplegia.

User Facility: A facility that uses medical devices. User facilities include hospitals, nursing homes, ambulatory surgical facilities, and outpatient diagnostic/treatment facilities.

IV. PROCEDURE ACTIONS AND RESPONSIBILITIES

A. Individual Reporting of Devices (Other than Implants/Explants):

Any individual who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that a medical device has caused or contributed to the death or serious

injury/illness of a patient or employee of the facility or their representative, is responsible for immediately completing an Incident Report according to Policy 03-07-001 and including the following steps:

1. Take appropriate corrective action to address immediate safety/operational/treatment issues, as specified in Unit policy.

2. To assist in the investigation process:

a. If possible, do not to turn off the device or unplug it unless further injury would result.

b. Note all settings on the device. Produce a printout of any recording strips that illustrate failure, default settings, alarm settings, etc.

c. Label the device as defective and sequester the device.

d. Obtain all disposables and accessories that were being used with the device, along with their packaging. If contaminated/biohazardous, place in biohazard packaging as appropriate.

e. List any environmental conditions that may have contributed to the incident.

3. The attending physician shall examine the patient's illness or injury related to the incident, record the patient's physical findings, and document in the patient's progress notes the occurrence of the suspected adverse medical device incident and any actions taken based on the examination.

4. Complete an Incident Report in duplicate as applicable to situation, including any comments from attending physicians. If the incident resulted in a death or serious injury/illness, call Hospitals and Health Centers Risk Management (763-5456) immediately.

5. Page Biomedical Engineering (pager 5663) to sequester the equipment and/or pick up the suspected device. Attach a copy of the incident report to the device.

6. Submit the completed Incident Report to Hospitals and Health Centers Risk Management within 48 hours.

B. Individual Reporting of Devices (Implants/Explants):

Any individual who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that an implant/explant has caused or contributed to the death or serious injury/illness of a patient of the facility or their representative, is responsible for immediately completing an explant form according to Policy I-310-00.

C. The SMDA Committee

The SMDA Committee, reports to the Continuous Quality Improvement Lead Team via the Environment of Care Committee. The SMDA Committee has the responsibility of monitoring the UMHHC medical device reporting program. Committee representation includes Ambulatory Care, Anesthesiology, Biomedical Engineering, Cardiology, General Counsel, Home Care Services, Value Analysis, Nursing, Pathology, Quality Improvement, Radiology, Hospitals and Health

Centers Risk Management, Safety Management, and Surgery.

Responsibilities of the committee include:

1. In conjunction with Hospitals and Health Centers Risk Management, establish a UMHHC process for documenting medical device incidents.

2. Coordinate the educational process for all current and new employees and medical staff.

3. Review and analyze all incidents involving medical devices. Recommend corrective action as appropriate to prevent similar incidents from reoccurring.

4. Determine whether medical device incidents require mandatory or voluntary reporting in accordance with federal law and regulation. Submit appropriate reports to the medical device manufacturer and the FDA in accordance with federal law and regulation.

a. If the SMDA Committee is not scheduled to meet within ten business days of the facility becoming aware of a medical device incident, an ad hoc committee consisting of Biomedical Engineering, Hospitals and Health Centers Risk Management, and any other committee members as appropriate, will be called upon to determine whether the medical device incident requires mandatory reporting in accordance with federal law and regulation. Determination regarding voluntary reporting shall remain the responsibility of the SMDA Committee.

5. Report to the Environment of Care Committee.

Under the Michigan Quality Assurance and Work Product Rules, all committee discussions and findings are confidential. To protect the confidentiality of this information, all documents will contain one of the following disclaimer statements:

1. "All information in the submitted report has been collected in compliance with the FDA SMDA of 1990 and is part of the UMHHC's quality assurance process and is protected from disclosure. The University of Michigan Hospitals and Health Centers denies that the report or information submitted constitutes an admission that the device, the employees or affiliated staff, caused or contributed to a death, serious injury or serious illness."

2. "Confidential, Quality Assurance Document, MCLA 333.21515.20175"

D. Hospitals and Health Centers Risk Management

Hospitals and Health Centers Risk Management shall assist in coordinating reportable events and oversee compliance to the Incident Reporting and Adverse Event/Sentinel Event policies.

Responsibilities of Hospitals and Health Centers Risk Management include:

1. Coordinate risk identification and investigation activities with appropriate departments.

2. Ensure that all data collected from the UMHHC medical device reporting program shall be incorporated into the UMHHC incident reporting program.

3. Review the recommendation of the SMDA Committee for corrective actions involving any possible liability to the institution.

4. Review the results of medical device investigation to determine if the event is reportable according to the criteria developed by the SMDA Committee.

5. In cases where the manufacturer may be liable due to a design defect, improper installation and/or maintenance coordinate with Biomedical Engineering an investigation and decide if corrective action is necessary.

E. Pathology

Pathology is responsible for receiving, examining, and reporting upon explants that have been requested for pathological exam, as requested by either a physician, Biomedical Engineering, or Hospitals and Health Centers Risk Management.

F. Quality Improvement Office

The Quality Improvement Office is responsible for assisting the SMDA Committee in the analysis of reportable medical device incidents, or patterns of incidents, as needed, and serves as consultative support to the SMDA Committee for performance improvement related activities.

Responsibilities of the Quality Improvement Office include:

1. Review data collected through the medical device reporting system.

2. Provide feedback to staff on corrective action plans and activities.

3. Monitor progress toward improvement as indicated.

4. Provide initial and follow-up reports on incidents and improvement initiatives to the CQI Program leadership.

G. Supply Chain/Value Analysis

Supply Chain/Value Analsis is responsible for the procurement of disposables for UMHHC and will coordinate with Biomedical Engineering clinical departments any product information and/or stock levels of products that are affected by incidents, product problems, recalls, etc.

Value Analysis reviews all product complaints that do not cause patient injury and follows up with manufacturer for investigation and/or resolution.

H. Biomedical Engineering

Biomedical Engineering is responsible for investigating and determining the nature of a medical device failure. The Clinical Engineers within Biomedical Engineering will be the primary contacts for this process.

Responsibilities of Biomedical Engineering include:

1. Conduct an immediate and thorough investigation and evaluate the safety of the device.

2. Inspect the equipment to determine whether the device malfunctioned or if a user error

occurred. Determine whether the device along with the relevant supplies, accessories, and packaging should be impounded, repaired, or returned to service.

3. Document any and all information pertaining to the incident, investigation and corrective action.

4. Coordinate investigational findings with Hospitals and Health Centers Risk Management and contact medical staff, medical device manufacturers, and outside agencies as appropriate.

5. Submit appropriate reports to the medical device manufacturer and the FDA in accordance with federal law and regulation.

6. Report to the SMDA Committee.

7. Obtain relevant information regarding similarly reported hazards, recalls, and problems with respect to incident-related devices through contact with FDA and/or ECRI.

V. EXHIBITS

None

Approved by: SMDA Committee, October 7, 2002; October 4, 2004
Approved by: Environment of Care Committee, November 25, 2002
Approved by: Executive Director, UMHHC, December 6, 2002; October 22, 2004