

University of Michigan Hospitals and Health Centers

Policy 05-02-006 Safe Medical Device Act Policy **Date of Issue: 4/00; Last Reviewed: 8/00 Last Revised: 8/00**

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 FDA regulations.

II. PURPOSE

The Medical Device Reporting 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.

This procedure applies to any personnel who discover, witness, or are notified 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 the [Incident Reporting Policy, 03-07-001](#), [Adverse Event/Sentinel Event, 03-07-004](#), and the [Product Recall / Hazard Warning Control Program, 05-02-007](#).

III. DEFINITIONS

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.

Medical Device: In the Medical Device Act, the FDA defines a medical device as any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate, or treat a disease or to affect the structure or 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. FDA Investigational Devices are not included in this policy. The principal investigator or their designee under stringent FDA guidelines handles these devices.

Implant/Explant Device: An implant/explant device is a device that is placed/removed into/out of 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. Any external component must not form a physical connection to the device.

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.

User Facilities: User facilities include hospitals, nursing homes, ambulatory surgical facilities, and out patient treatment facilities.

A Patient: A person registered and/or receiving medical services from UMHHC.

An Employee: A person employed by the UMHHC or a member of the medical staff.

FDA Reportable Event: A reportable event is an event where a device has the potential to cause or contributed to a serious injury, serious illness, or death of a patient or employee. This event may include equipment malfunctions and/or user errors. Reporting to the FDA is required within ten working days. These same reportable events may also fall within the Adverse Event/Sentinel Event Policy.

Reporting Requirements to FDA of User Facilities: The University of Michigan Hospitals and Health Care Centers, as a user facility, is required to submit reports to the FDA and manufacturers within ten days of an adverse/sentinel event.

Safe Medical Device Act Committee: The Safe Medical Device Act Committee (SMDA Committee) shall consist of representation from the following departments; Ambulatory Care Clinic, Biomedical Technology Services, Cardiology, Clinical Affairs, Home Care, Hospital Attorney's Office, Materiel Services, Nursing, Operating Room, Pathology, Quality Assurance, Risk Management, and Surgery.

Serious Illness or Injury: A serious illness or injury, as defined by the Act, is an illness or injury that:

- a) Is life threatening
- b) May result in permanent impairment of a bodily function or permanent damage to a bodily structure.
- c) May necessitate medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

Examples include but are not limited to: burns, temporary brain damage, loss of fingers or damage to organs, deafness, loss of limb, an eye, a kidney or a lung, paraplegia, blindness, or severe brain damage.

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.

Adverse Event: An event that is untoward, undesirable and usually unanticipated, which, under optimal conditions, is not a natural consequence of the patient's condition. It is any potential concern that may affect the quality of patient care or environment for patients, visitors, and non-employees.

Sentinel Event: An event that is an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. Examples of sentinel events include, but are not limited to: infant abductions, infants discharged to wrong family, rape by another patient or staff, hemolytic transfusion reaction, surgery on wrong patient or body part, or completed inpatient suicide.

Medical Center Risk Management: The Medical Center Risk Management (MCRM) department is responsible for identifying and attempting to contain, reduce, prevent, eliminate, or manage the risk of avoidable harm to patients, visitors, and employees, and the risk of financial loss to UMHC and its staff due to untoward events.

Quality Improvement Office: The Quality Improvement (QI) Office provides the link to the Continuous Quality Improvement (CQI) Program and ensures that issues impacting patient care and services are communicated to the CQI Lead Team through the usual reporting structure.

Biomedical Technology Services: The Biomedical Technology Services department is responsible for investigating and determining the nature of the device failure, coordinating and reporting all events to the necessary parties, including the FDA.

IV. PROCEDURE ACTIONS AND RESPONSIBILITIES

A. Individual Reporting of Devices (Other than Implant/Explant Devices):

Any individual who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that a medical device (equipment and/or product) has caused (or may cause) or contributed to the death, serious injury, or serious illness of a patient or employee of the facility, is responsible for immediately completing and 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. Complete Incident Report in duplicate as applicable to situation, including any comments from attending physicians.
3. If the device is an electronic piece of equipment, record any measurement settings on the equipment controls. If possible, do not turn off equipment.
4. If the device has been removed from inside the body, attach incident report and log device into frozen section suite in Pathology, Room 1F306. If the frozen section suite is closed, send to central distribution (room 2F367) in Pathology.

5. Collect all related disposables and packaging.
6. If the device is a disposable product, place product in a biohazard packaging.
7. Page Biomedical Technology Services to sequester the equipment and/or pick up suspected device. Attach pink copy of incident report to device.
8. Call MCRM within 24 hours if a significant injury has occurred (763-5456).
9. Send completed report to MCRM.
10. 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.

B. Departments Handling Implant/Explant Devices:

Implant/explant devices that are removed solely because of end of life and/or end of use are sent to Biomedical Technology Services (BTS) along with an explant form. The A Clinical Engineer in BTS will determine whether the device is trackable, send necessary notifications to the manufacturers, send the device to the manufacturer, return non-trackable devices to departments if requested, and/or dispose of the device. The exception to this rule are devices not involved in an incident event and are the following: silicon prosthesis, vascular grafts, intraocular lenses, arterial stents, and any titanium or stainless steel cables, screws, nuts, rods and hooks. The department takes responsibility of disposing of these devices.

Any individual who becomes aware of information that reasonably suggests that an implant/explant device has caused (or may cause) or contributed to the death, serious injury, or serious illness of a patient, is responsible for immediately completing an incident report according to [Policy 03-07-001](#) and including the following steps:

- a) An explant form and incident report is filled out.
- b) Log explant into frozen section suite in Pathology, Room 1F306 and send explant, explant form, and pink copy of incident report to Pathology. If the frozen section suite is closed, send to central distribution (room 2F367) in Pathology.

C. The SMDA Committee

The SMDA Committee, functioning under the Michigan Quality Assurance and Work Product Rules, reports to the CQI Committee, and has the responsibility of implementing and managing the Hospital and Health Center's medical device-reporting program. The Committee findings are confidential. Clinical or support departments may provide assistance.

This responsibility will include the following:

1. Establishing a hospitals and health centers wide process for documenting medical device incidents.
2. Coordinate the educational process for all current and new employees and medical staff.
3. Reviewing and analyzing all reportable incidents involving medical devices.
4. Reviewing and overseeing all reportable devices suspected of failure and/or defect that might cause harm.
5. Submitting an annual summary of reports to FDA each year for UMHHC. The summary shall include the following information: the identity of the facility; the device's name, serial number, and model number; the manufacturer's name and address; and a brief description of the event.
6. Report to UMHHC Safety Committee.

D. Medical Center Risk Management

The Medical Center Risk Management shall assist in coordinating reportable events and oversee compliance to the Incident Reporting and Adverse Event/Sentinel Event policies.

This department will be responsible for the following activities:

- a) Coordinate risk identification and investigation activities with appropriate departments.
- b) Ensure that all data collected from the UMHHC medical device reporting program shall be incorporated into the UMHHC incident-reporting program.
- c) Review the recommendation of the SMDA Committee for corrective actions involving any possible liability to the institution.
- d) Review the results of medical device investigation to determine if the event is reportable according to the criteria developed by the SMDA Committee.
- e) In cases where the manufacturer may be liable due to a design defect, improper installation and/or maintenance coordinate with the Biomedical Technology Services Department an investigation and decide if any and what kind of corrective action is necessary.

E. Pathology

The Pathology department is responsible for receiving all reportable explant devices. Pathology will also receive any device that has both been removed from the human body and involved in an incident event. Pathology department will process these devices. A professional decision will be made if there is tissue that needs to be examined

microscopically, or if a gross only diagnosis will be made. After processing, Pathology will forward these devices, explant forms and incident reports to BTS department.

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. The QI staff serves as consultative support to the SMDA Committee for performance improvement related activities. The QI staff responsibilities are as follows:

- a) Review data collected through the medical device reporting system.
- b) Provide feedback to staff on corrective action plans and activities.
- c) Monitor progress toward improvement as indicated.
- d) Provide initial and follow-up reports on incidents and improvement initiatives to the QCI Program Leadership.

G. Materiel Services

The Materiel Services department is responsible for the procurement of medical devices and to coordinate with Biomedical Technology Services to investigate equipment product defects that are reported as incidents.

The responsibilities of Materiel Services will include the following:

- a) Coordinate with Biomedical Technology Services product information for all reportable equipment defects and possible recalls when required.

H. Biomedical Technology Services

The Biomedical Technology Services shall be responsible for investigating and determining the nature of the equipment failure. The Clinical Engineer in the department will be the primary contact for this process.

The departments' responsibilities will include the following:

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

4. Coordinate with MCRM and Quality Assurance the investigation and contact of medical staff and equipment manufacturers.
5. Completing and submitting appropriate reports to outside agencies, including the appropriate reports to the Food and Drug Administration (FDA).
6. Submitting appropriate reports to the medical device manufacturer in accordance with federal law and regulation.
7. Directly reporting all activity to the SMDA Committee.
8. Information recorded shall include device description, other equipment used with this device, environmental conditions, results of performance and safety inspection of equipment, determination as to whether the device/equipment failure caused or contributed to a the serious illness or injury or death to a patient.
9. Determine whether the device along with the relevant supplies, accessories, and packaging should be impounded, repaired, or returned to service.
10. Obtain relevant information regarding previously reported hazards, recalls, and problems with respect to incident-related devices through contact with FDA and/or ECRI.
11. Work with the manufacturer, if necessary to determine the cause of a device malfunction.
12. Report findings and make recommendations to the SMDA Committee and any other appropriate departments.

To protect the confidentiality of information disclosed to a private agency, the FDA or manufacturers any report or annual summary shall contain the following disclaimer statements.

"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."

V. EXHIBITS

- A. [Incident Report Flowchart](#)
- B. [Explant Devices Flowchart](#)

Approved by: Hospital and Health Centers Safety Committee (formerly Hospital Safety and Security Committee)

Approved by: Executive Director, UMHHC, April 17, 2000 Revised: 8/2000

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