MAIMONIDES MEDICAL CENTER

CODE: AD-101 (Revised)
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SUBJECT: Medical Equipment Failures and Medical Device Reporting Program

I POLICY:

It is the policy of Maimonides Medical Center to effectively manage all medical equipment failures to minimize risk to patient.

The Safe Medical Devices Act of 1990, (SMDA) requires all deaths, serious illnesses, or serious injuries which are sustained by a patient at the Medical Center and are caused, or suspected to be cause or contributed to partially by a medical device must be reported to the Food and Drug Administration (FDA), or the manufacturer in accordance with the procedure below.

II DEFINITIONS:

A. Medical Devices
A medical device is defined as any instrument, apparatus, or other article, which 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, any other electronic equipment, implants, thermometers, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposable, components, parts, accessories, related software, defibrillators, pacemakers, suture material, infusion pumps, hospital beds, catheters, wheelchairs, tampons, etc.

B. Serious Illness and Serious Injury
A serious illness and serious injury mean an illness or injury that: (1) is life threatening; (2) results in permanent impairment of a bodily function or permanent damage to the body structure; (3) necessitates immediate medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a body structure.

C. Patient
A patient of a facility is: (1) an individual being diagnosed, treated, and/or receiving medical care under the auspices of the facility from medical personnel working in, for, or who are otherwise affiliated with a device user facility; or (2) an employee of the facility or an individual affiliated with the facility who suffers death, serious illness or serious injury from a device used at or by the facility is regarded as a patient of the facility.

III RESPONSIBILITY:

1. The Risk Department is responsible to submit device occurrence reports, and other required reports to the FDA and/or Manufacturer, and maintain appropriate files.

2. Vice Presidents, Department Managers, Clinical Chairmen, Supervisors are responsible for timely reporting of device related occurrences within their areas of responsibility.

3. It is the responsibility of the Director of Service (or designee) of departments who utilize medical devices to insure staff competency in the use of the device(s) and maintain appropriate procedures for their use.

4. It is the responsibility of all hospital personnel to report medical device or equipment problems to as soon as they are observed or suspected, and to assure the safety of patients in the event of a medical device failure.

5. It is the responsibility of the surgical / procedural team to exam and verify that all components of a medical device are accounted for whenever there is a failure or suspected failure of the device within the patient.

6. The responsibility for support of devices is as follows:

   Respiratory Care Department: ventilators, humidifiers, and other respiratory care equipment
   Medical Supply Department: feeding pumps, IV pumps, sequential compressors, hyperthermia units, portable suction
   Biomedical Engineering Department: all other

IV PROCEDURE

Immediate Reponses to Device Failures

1. In the event of any medical device failure, the use of the device should be immediately discontinued. The health care practitioner must evaluate the patient's condition and provide appropriate clinical intervention to reduce the risk of harm.

2. After the patient's well being and safety are assured, the health care practitioner must notify Director of Service (or designee) and the appropriate support department, who will provide replacement equipment, as necessary.

3. All failed medical equipment, after being repaired, must undergo

comprehensive testing by competent service personnel prior to being returned to patient use. Documentation of service history on medical equipment is maintained by Biomedical Engineering.

The Department of Risk Management shall have overall responsibility for the implementation and management of the Medical Center's medical device reporting program. This responsibility shall include establishing and maintaining a hospital-wide system for documenting medical device occurrences, reviewing and analyzing all reportable occurrences, and completing and submitting reports to outside agencies and manufacturers as appropriate.

A. General Reporting Requirements

Any individual (attending physician, house staff, nurse, therapist, technologist, etc.) who witnesses, discovers or otherwise becomes aware of information that reasonably suggests a medical device has caused or contributed to the death of, serious injury to, or serious illness of a patient of the Medical Center, will immediately report the incident to his/her supervisor or department head and to the Risk Manager Department. The occurrence is to be considered an incident and a hospital incident form must be completed and forward through incident reporting channels. [Also see AD-102 Patient Occurrence Reporting and Disclosure.]

Any individual (attending physician, house staff, nurse, therapist, technologist, etc.) who is aware of a device failure or suspected device failure without apparent injury to the patient will report the incident to his/her supervisor or department head. The occurrence is to be considered an incident and a hospital incident form must be completed and forward through incident reporting channels.

The supervisor or department head will secure the device and make every attempt to secure any packaging, identifying data, tubing, connecting devices, exterior cords, wiring etc. If the device is contaminated, it must be handled in accordance with proper infection control techniques and labeled accordingly.

To ensure proper investigation of the occurrence, the individual, supervisor or department head who reports the medical device occurrence shall provide the Risk Management Department with the following information:

a. patient name
b. room and bed number
c. name of attending physician notified
d. product name
e. present location of the product
f. serial number of the product (if appropriate)

g. model number
h. lot number (if appropriate)
I. name of manufacturer if known
j. brief description of the incident

B. Responsibility of Attending Physician

The attending physician who notes a device failure or suspects a device failure shall immediately examine the patient, and evaluate the severity of the patient's illness or injury related to the occurrence. Any broken parts of the device are to be removed when possible. The Attending physician will examine the device with the medical team to determine if the device is intact. The attending physician will document the patient's physical findings and any intervention in the medical record.

C. Investigation of the Medical Device Incident

The Risk Management Department is responsible for the investigative process. In collaboration with staff of the Safety Department, Biomedical Engineering, Legal Department, other involved departments, the Risk Manager will determine the need to impound the device and any other similar equipment and the need for evaluation of the device by the manufacturer or outside specialists.

D. Submission of Adverse Medical Device Incident Reports

1. Death

Whenever the Medical Center receives or otherwise becomes aware of information that reasonably suggests that there is a probability that the device has cause or contributed to the death of a patient, the Medical Center shall, as soon as possible, but not later than 10 working days after becoming aware of the information, report the information to the FDA, and, if the identity of the manufacturer is known, to the manufacturer of the device. The Risk Manager is responsible for reporting to the FDA and manufacturer once a determination is made of a reportable event. The completed Med Watch Mandatory Reporting Form should be mailed to MDR Reporting, Centers for Devices and Radiologic Health, Food and Drug Administration, P.O. Box 3002, Rockville, MD 20847-3002. [See Attachment A: Med Watch Mandatory Reporting Form 3500 A.]
Note: Forms and instructions are available online at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm

2. Serious Illness or Injury

Whenever the Medical Center receives or otherwise becomes aware of information that reasonably suggests that there is a

probability that a device has caused or contributed to a serious illness or serious injury, the Medical Center shall, within 10 working days after becoming aware of the information, report the information to the manufacturer of the device, or to the FDA if the manufacturer is not known. The Risk Manager is responsible for reporting to the manufacturer once a determination is made of a reportable event. [See Attachment A: Med Watch Mandatory Reporting Form 3500A.]

3. Other Adverse Events – Other adverse events may be voluntarily reported by the Risk Manager to the FDA using the Med Watch Voluntary Reporting Form 3500 (See Attachment B).
Forms may be mailed or submitted online at:
https://www.accessdata.fda.gov/scripts/medwatch/.

4. Annual Reports
On January 1st, of each year, the Medical Center is required to send the FDA an annual summary of all adverse medical device reports filed in the previous calendar year. The Risk Manager shall prepare the summaries. An annual report is not required if there were no adverse reports made to the manufacturer or to the FDA during the applicable reporting period [See Attachment B: Medical Device Reporting Annual User Facility Report Form FDA 3419] Forms and instructions available at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080796.pdf

[21 CFR Part 803]

5. The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes. [45 CFR 164.512(b)(1)(i) and (iii))]

6. Additional Requirements

1. Files
An FDA device incident file shall be established and prominently identified to facilitate access.

MDR (Medical Device Report) files:

a. May incorporate references to other information e.g. medical records, patient files, engineering reports etc. in lieu of copying and maintaining duplicates in this file.

b. Must contain information in possession of the reporting entity or references to information related to the adverse event, including all documentation of the Medical Center's deliberations and decision making process used to determine if a device death, serious illness, serious injury or malfunction was or was not reportable under SMDA.

c. Copies of all MDR form and other information related to the event which was submitted to FDA or other entities (e.g. a distributor or manufacturer) must be contained in the file.

A. The Medical Center shall permit any authorized FDA employee during all reasonable times to access, to copy and to verify the records required by SMDA.

B. The Medical Center shall retain an MDR event file for a period of 2 years from the date of the event.

V CONTROL:

A. The Vice President of Risk Management will insure compliance with the incident investigation and reporting requirements of this policy. Events meeting criteria under this policy will be included in the Risk Management Performance Improvement Report.

B. The Director of Biomedical Engineering will maintain a service history for all medical equipment, including information on device failures.

Kenneth D. Gibbs
President & CEO

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REFERENCE: Safe Medical Device Act of 1990, 21 C FR Part 803; AD-102: Patient Occurrence Reporting and Disclosure; 45 CFR 164.512(b)(1)(i) and (iii)); 21 CFR Part 803

INDEX: Medical Device Report Program
ORIGINATING DEPARTMENT: Professional Affairs
LIST OF ATTACHMENTS:

A. Med Watch Mandatory Reporting Form (FDA Form 3500A)
B. Med Watch Voluntary Reporting Form (FDA Form 3500)
C. Medical Device Reporting Annual User Facility Report (FDA Form 3419)