

# UNIVERSITY OF TOLEDO

SUBJECT: MEDICAL DEVICE OCCURRENCES

Procedure No: ME-08-002

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## PROCEDURE STATEMENT

Serious injuries/illnesses or deaths of patients/employees if caused or contributed to by the use of a medical device(s) shall be appropriately documented, investigated and reported to the Food and Drug Administration and/or the device manufacturer as mandated by Federal Regulations in the Safe Medical Device Act (SMDA) of 1990.

## DEFINITIONS

All underlined words or phrases contained in this policy shall be defined as shown on the "definitions" attachment to this policy.

## PURPOSE OF PROCEDURE

To provide guidelines to Medical Personnel and departments in compliance with SMDA Federal Regulations

## PROCEDURE

- I. The Administrator for Risk Management shall serve as the "SMDA contact person" and is responsible for:
  - all correspondence with the FDA and Medical Device manufacturers as relates to compliance with the SMDA,
  - maintenance of all incident files as required by the SMDA,
  - coordination of all internal investigations associated with SMDA,
  - final determination of reportability as relates to compliance with the SMDA,
  - preparation and submission of all reports as required for compliance with the SMDA within 10 working days of becoming aware that a reportable event has occurred

# SEE PROCESS CHART AND DEFINITIONS GRID ON PAGE 2

- II. All department managers shall:
1. Use the following process to determine reportability.

	<b>Non-Patient</b>	<b>Patient - Insignificant</b>	<b>Patient - Significant</b>	<b>Patient - Adverse</b>
<b>Disposable</b>	DEPARTMENT	JUDGMENT	OCCURRENCE REPORT - POLICY	Safe Medical Device Act (SMDA)
<b>Non- Disposable</b>	DEPARTMENT	JUDGMENT	OCCURRENCE REPORT - POLICY	SMDA
<b>Equipment</b>	BIOMEDICAL ENGINEERING MATERIALS MANAGEMENT	BIOMEDICAL ENGINEERING MATERIALS MANAGEMENT	BIOMEDICAL ENGINEERING OCCURRENCE REPORT	SMDA

## DEFINITIONS

DEPARTMENT	The department is responsible for all necessary follow up to these situations.
BIOMEDICAL ENGINEERING- MATERIALS MANAGEMENT	Biomedical Engineering Services is to be notified and is responsible for all follow up and for involving Materials Management.
JUDGMENT	The department may handle the situation (as in DEPARTMENT), or, the department may opt to send the medical device to Biomedical Engineering who is then responsible for follow up (as in BIOMEDICAL ENGINEERING - MATERIALS MANAGEMENT).
BIOMEDICAL ENGINEERING- OCCURRENCE REPORT	The department is to contact Biomedical Engineering who will follow up (as in BIOMEDICAL ENGINEERING - MATERIALS MANAGEMENT) and will complete an Occurrence Report.
OCCURRENCE REPORT - POLICY	The department is responsible for generating an Occurrence Report and for following procedures established in this policy.

SMDA

The department is to immediately invoke investigational protocols (see Section II-2) and is to contact Biomedical Engineering and Risk Management immediately advising them that a medical device related adverse patient outcome event has occurred. The department will also initiate an Occurrence Report and hold for Biomedical Engineering.

2. Ensure proper investigation by completing the following:

- immediately advise Biomedical Engineering, departmental administrative and clinical authorities, and the attending physician.
- immediately impound all medical devices including but not limited to, disposable containers, packaging, tubing, etc., associated directly with the Incident or collecting appropriate information in the event certain devices cannot be impounded.
- assure all impounded medical devices and/or products are secured in an "as is" condition and made available for inspection or testing only to staff from Biomedical Engineering.
- document the identity and activities of all individuals in the room or area at the time of the incident whether or not they were involved in the care of the patient/employee or use of the medical device(s).
- document all control settings of devices directly or indirectly associated with the incident.
- initiate an Occurrence Report and attach a descriptive narrative of the events as they occurred.

III. Biomedical Engineering Services

1. The Department of Biomedical Engineering Services following written policies and procedures shall respond to reports from the departments that a potentially reportable event has occurred. Such written policies and procedures shall include but not be limited to:

- assigning responsibility for coordination of activities.
  - assuring immediate response to the scene of the incident.
  - collection of information from medical personnel as relates to the use of the device(s)/product(s) involved.
  - the investigation and evaluation of device(s)/product(s) that may have caused or contributed to any possible patient illness or injury.
  - documentation of all actions taken.
  - collection of data necessary to complete appropriate section of the FDA Reporting form for each device involved.
  - compilation of all data in written form and submission to the Administrator for Risk Management within three (3) days following the report of the incident.
- collect the occurrence report and medical device/product failure form from the department.

IV. Medical Staff

1. The Attending Physician shall:

- determine if a patient's illness or injury as the result of an incident is to be considered serious.
- determine to what extent a medical device may have caused or contributed to a patient's serious injury/illness or death in consideration of the patient's condition prior to the incident and the nature of the procedure(s) involved at the time of the incident.
- determine what the diagnosis (using ICD9-CM codes) and medical status of the patient was prior to and after the incident,
- develop an opinion on if a medical device caused or contributed to any death, serious injury or serious illness, and provide that information to the Administrator for Risk Management as soon as such determinations can be made.

- V. Employee education on the requirements of the Safe Medical Device Act shall be included in departmental orientation and safety training procedures and in the annual safety training as provided by the UTMC Safety & Health Committee.

Source: Risk Management Department

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