GUAM MEMORIAL HOSPITAL AUTHORITY
ADMINISTRATIVE MANUAL

APPROVED BY:	RESPONSIBILITY:	EFFECTIVE DATE:	POLICY NO.:	PAGE:
 PeterJohn D. Camacho, M.P.H. Hospital Administrator/CEO	Risk Management	May 28, 2018	A-EC700	1 of 6
POLICY TITLE: REPORTING ADVERSE MEDICAL DEVICE INCIDENT				
LAST REVIEWED/REVISED: 10/2017				
ENDORSED: EMC 12/2017				

PURPOSE:

It is the policy of Guam Memorial Hospital Authority (GMHA) to report deaths, serious injury, or illness sustained by the patient and are caused or suspected to be caused by a medical device, in compliance with the Safe Medical Device Act of 1990 (Public Law 101-629, USC).

SCOPE:

This policy applies to all personnel who discover, witness or are notified of a suspected medical device incident. Included within the scope of this policy are personnel who use or operate a medical device, including physicians, nurses, technicians, and therapists, or other medical personnel.

DEFINITIONS:

- **Serious Illness or injury:** a serious illness or injury as defined by the Safe Medical Device Act of 1990 (Public Law 101-629, USC) is an illness or injury that is life threatening or that either results in permanent impairment or a bodily function or permanent damage to a bodily structure or necessitates immediate medical or surgical intervention to a preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

- **Medical Device:** Food and Drug Administration (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 exception of drugs. For example, medical devices include but are not limited to ventilators, monitors, dialyzer, 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.

- **Reportable Incident:** Any incident that reasonably suggest that the device contributed to the death, serious injury or serious illness to a patient or an employee.

  If an incident occurs:

  - Attend to the patient
  - Report the incident
  - Remove the device(s) from services
  - Save all materials including any disposable and packaging, and
  - Fill out a medical device occurrence summary report.

RESPONSIBILITY:

Hospital Risk Management Program Officer

REPORTING PROCEDURE:

A. Any employee who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that a medical device has caused or contributed to the death of, serious illness to , or serious injury to a patient, is responsible for immediately reporting the incident to his/her supervisor, or department head, and the Hospital Risk Management Program Officer.

B. To ensure proper follow up and investigation of the incident, the personnel who reported the adverse medical device incident shall inform the Bio-Medical Department Supervisor, and/or the Hospital Risk Management Program Officer by telephone of the following:

1. Patient Name
2. Unit or department and room number
3. Name of attending physician
4. Product/device name
5. Location of the product/device
6. Serial number of the product/device
7. Model number
8. Name of the manufacturer, if known
9. Brief description of the incident/date and time of event
10. Control number
11. User/operator
12. Data on the safety check record affixed to the equipment.

C. Within twenty-four (24) hours of the suspected adverse medical device incident, the personnel who reported the incident shall complete a Medical Device Occurrence Summary Report Form and forward it to the Hospital Risk Management Program Officer. The Hospital Risk Management Program Officer will immediately start an investigation with the appropriate department and in conjunction with Bio-Medical Department Supervisor, or other relevant departments, shall remove the device(s) from service and save all materials including disposables and packaging involved in the
incident for use in the investigation.

SPECIFIC RESPONSIBILITIES:

A. Risk Management Section

1. The Hospital Risk Management Program Officer shall have overall responsibility for implementing and managing the hospital's medical device reporting program. This responsibility shall include establishing and maintaining a hospital-wide system for documenting medical device incidents, reviewing and analyzing all reportable incidents, and completing, and submitting reports to outside agencies.

2. The Hospital Risk Management Program Officer must make certain that all necessary information is documented.

3. The Hospital Risk Management Program Officer shall, in cooperation with the Bio-Medical Department Supervisor, clinical specialist, and other department heads if applicable, conduct an investigation of the event to determine whether a device caused or contributed to the event and why. The Hospital Risk Management Program Officer will prepare the findings and conclusions and forward them to the Environment of Care Committee and to other appropriate medical staff departments and committees, which shall adopt recommendations for corrective actions. Results of the investigation will also be communicated to the device users and physicians involved in the care of the patient.

4. The Hospital Risk Management Program Officer shall inform the Associate Administrator of Medical Services/Medical Director about any medical device related incidents and shall make necessary recommendation as it relates to clinical care and follow-up of the patient.

5. The Hospital Risk Management Program Officer shall prepare a summary report to the Hospital Administrator regarding the occurrence of all medical –device related deaths, serious injuries or illnesses.

6. The Hospital Risk Management Program Officer shall ensure that all data collected from the hospital's medical device reporting program shall be incorporated into the hospital-wide occurrence summary reporting program, the results of which are communicated to the Hospital Administrator, Environment of Care and the Board of Trustees Quality and Safety Committee.

B. Attending Physician

1. The attending physician who is informed of a medical device related incident shall examine the patient, evaluate the severity of 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 action taken based on the examination.

2. The attending physician shall complete an occurrence summary report form and forward it to the Hospital Risk Management Program Officer (Quality Management) within 48 hours of the incident.

C. Bio-Medical Division of Facilities Maintenance

1. The Supervisor of the Bio-Medical Department shall play a key role in maintaining the medical device reporting program, investigating incidents and evaluating the safety of devices.

2. The Bio-Medical Department shall obtain relevant information regarding previous hazards product recalls and problems with respect to the incident related devices through contract with FDA and/or manufacturers. All such information shall be shared with the Hospital Risk Management Program Officer.

3. The Bio-Medical Department shall assist the Hospital Risk Management Program Officer in collecting the medical device operating information, service and maintenance history information, and other information required in the Medical Device Occurrence Summary Form.

4. The Bio-Medical Department shall assist in conducting an investigation of the device-related incident, evaluate the safety of the device, and will determine whether the device along with the relevant supplies, accessories, and packaging should be impounded, repaired, returned to service, or taken out of service.

D. Hospital Administrator

1. The Hospital Administrator or designee will be the contact person for the hospital with whom the Food and Drug Administration (FDA) will conduct is correspondence relating to user facility reporting.

2. The Hospital Administrator or designee will be responsible for submitting appropriate reports to the FDA and/or the medical device manufacturer in accordance with federal law and regulation. The law requires the following;

   a. Patient deaths must be reported to FDA and the manufacturer within 10 working days of any person becoming aware that a device caused or contributed to the incident.

   b. Serious injuries or illnesses must be reported to the medical device manufacturer (or the FDA, if manufacturer is not known) within 10 working days of any person becoming aware that a device caused or contributed to the incident.

   c. Semi-annual summaries of reports must be submitted to the FDA on January 1 and July 1 of each year. The summary shall include the following information: identity of the facility; device name, serial number and model number; the manufacturer's name and address; and a brief description of the events(s).

RESCISSION:

6180-1, Reporting Adverse Medical Device Incident, of the Administrative Manual made effective June 3, 1992.

ATTACHMENTS:

I. Medical Device Occurrence Summary Report Form
II. Medical Device Reporting Flowsheet

ATTACHMENT I

GUAM MEMORIAL HOSPITAL AUTHORITY
MEDIAL DEVICE OCCURRENCE SUMMARY REPORT FORM
CONFIDENTIAL – FOR RISK MANAGEMENT PURPOSES ONLY
DO NOT PHOTOCOY OR FILE IN MEDICAL RECORD

PATIENT INFORMATION

1. Name_____/Hosp.#_____

2. DOB_____/Sex_____/Age_____

3. Attending Physician_____

Medical status before event (stable, critical, Fair)_____

Was more than one patient involved YES/NO_____
How many____ If yes, collect information for all.

4. Room Number_____

DEVICE INFORMATION

5. Product/Device Name_____

6. Location of the Product/Device_____

7. Serial # of the Product/Device_____

8. Model #_____/Lot#_____

9. Name of Manufacture (If known)_____

10. Control Number_____

11. User/Operator_____

EVENT INFORMATION

12. Brief Description of the incident:
_____
_____
_____
_____

13. Event Result (death, injury, Illness, malfunction)
_____

14, Date of Event: Mo._____/Day_____/Year_____

15. Time of Incident _____
16. Location of Event: Ward/Office_____
17. Specific Injury Incurred:_____
18. Date Medical Personnel become aware of event:
Mo_____/Day_____/Year_____

Employee Reporting: Fill up #1-18

19. Date event was reported to manufacture:
Mo._____/Date_____/Year_____
20. Was device used as intended (YES/NO)_____

21 Was other device in use at the time of the event?
YES/NO____If yes, pleas indicate:
_____

DEVICE MAINTENANCE/SERVICE INFORMATION (If applicable)

22. Serviced in accordance with service scheduled
YES/NO_____

23. Date of Last service_____

24. Service Performed by _____

25. Is Service Documentation available YES/NO_____

26. Device Expiration Date (If applicable)_____

27. Device Purchase Date:_____

28. Device Labeled for Single use? YES/NO ____ if No
Specify _____(re-usable)

29. Device Implanted YES/NO_____

30. If yes, Implant Date_____

REPORTING INFORMATION

Date of Completion of Incident Report _____

Date present to Patient Safety Committee/EOC_____

Date Presented to Medical Staff Committee_____
Report Date_____

Date Report Sent to FDA _____

Date of Follow up for implementation of corrective actions _____

ATTACHMENT II