A Policy Statement

Specific steps must be followed in the event of a medical device related incident involving patients and/or employees.

B Purpose of Policy

To provide guidelines for Heart and Vascular Center employees that comply with SMDA federal regulations and safety policy ME-08-002.

C Procedure

1. All Heart and Vascular Center employees shall take the following actions in the event of a medical device related incident involving patients or employees.

   A. Determine if the event may have resulted in a patient/employee injury or illness. If so:

      1) Immediately advise Biomedical Engineering (Ext. 4899 or the operator (0) on weekends and second and third shifts), the department head and/or supervisor, Heart and Vascular Center Medical Director (Dr. Samer J. Khouri) and the attending physician.

      2) Immediately impound all medical devices including but not limited to disposable, containers, packaging, tubing, etc. associated directly or indirectly with the incident or collecting appropriate information if certain items cannot be impounded.

      3) 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 Services.

      4) 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).

      5) Document all control settings of devices directly or indirectly associated with the incident.

      6) Initiate an Occurrence Report.

      7) Prepare a descriptive narrative of the events as they occurred.

      8) Complete a Medical Device/Product Failure form, located in the bottom drawer of the file cabinet in the typing area.

      9) Give the Occurrence Report and Medical Device Product Failure form to Biomed.

2. All employees shall take the following action in the event of the failure of a medical device or product not related to the patient/employee injury.

   A. Initiate an Occurrence Report and the Medical Device/Product Failure Form and forward to Biomedical Engineering.

   B. Call Biomedical Engineering and inform them of the failure.
3. Copy of the Medical Device/Product Failure Form is attached.


(D) Definitions

The following is the definition of "medical device" as it pertains to this policy:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related articles, including any component, part or accessory, which is:

1. recognized in the official National Formulary, or the USP, or any supplement to them

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animal, or

3. intended to affect the structure of any function of the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.