

HACKETTSTOWN REGIONAL MEDICAL CENTER
Administrative Policy and Procedure

SECTION: ADMINISTRATION

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TITLE: MEDICAL DEVICE REPORTING

PURPOSE:

To maintain and report within 10 days of awareness, all medical devices that may have contributed to an injury or illness to a patient who was admitted to Hackettstown Regional Medical Center or any of its outpatient diagnostic facilities.

DEFINITIONS:

1. Serious Injury/Serious Illness means injury on illness that:
 - a. Is life-threatening
 - b. Results in permanent impairment of a body function or permanent damage to a body structure, or
 - c. Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
2. “Becomes aware” of a reportable event at the time medical personnel who are employed or otherwise affiliated with the facility learns of the information.
3. The FDA defines Medical Device as any item that is used for the diagnosis, treatment or prevention of a disease, injury, illness or other condition and that is not a drug.

POLICY:

1. Hackettstown Regional Medical Center will report any death, serious injury or serious illness to a patient which the hospital believes is the direct result of a medical device.
2. The report must be filed no later than ten (10) working days after the hospital becomes aware of the device's role in the death, illness or injury of the patient.
3. The hospital will report:
 - a. Death to the FDA with a copy to the manufacturer if known, or
 - b. Serious injury/illness to the manufacturer or the FDA if the manufacturer is unknown.

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4. Semiannual reports will be submitted January 1 (for reports made July – December) and July 1 (reports made from January – June) on all the reports previously submitted to FDA during the time frames as indicated above.
5. If no reports are submitted, no semiannual report is required.

PROCEDURE:

1. Staff will remove the device or equipment, if possible, and send it to Materials Management or to the Administrative Coordinator on off shifts to be secured.
2. Staff and/or Materials Management will notify Risk Management by incident report of any such injury or illness.
3. Risk Management will complete the proper Med Watch form for either a mandatory or voluntary report.