

MEDICAL DEVICES: HANDLING ADVERSE EVENTS

Objectives:

Upon completion of this section, the employee will be able to:

1. Describe the basic steps for handling adverse events involving equipment
2. State the notification procedure for adverse events involving equipment
3. Identify the form used when reporting a medical device adverse event
4. Describe the procedure for impounding a suspect device

Instructions to the Employee:

Please read the following section, then answer the study questions at the end of the section.

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- I. BASIC STEPS FOR HANDLING ADVERSE EVENTS INVOLVING EQUIPMENT
 - A. **INFORM** one's supervisor, Risk Manager at ext. 2168, and Director of Environmental Safety at ext. 2835.
 - B. **IMPOUND** the device or equipment. Tag and lock it up, leave all settings and attachments in place. Notify the Director of Environmental Safety, who will direct disposition/handling.
 - C. **REPORT** the adverse event on-line through the Harbor Intranet via the Patient Safety Net (PSN). Hard copies of Event Notifications (HS-10) should only be used when the PSN is down and should be entered into the PSN as soon as the program is restored. Include type of equipment, mode, and serial number for identification purposes.
 - D. **PROTECT** oneself and the hospital by not discussing the problem with others except as directed by one's supervisor, Risk Manager, or Director of Environmental Safety.
 - E. **COOPERATE** fully with authorized personnel during the investigation.

PLEASE COMPLETE THE STUDY QUESTIONS

Study Questions

Select the best answer to each question. **DO NOT** write in the manual.

1. When witnessing a death, injury or illness caused by a medical device who must be informed immediately?
 - a. Supervisor and Hospital Administrator
 - b. Manager and Director of Environmental Safety
 - c. Supervisor, the Risk Manager, and Safety Police
 - d. Supervisor, the Risk Manager, and Director of Environmental Safety
2. To prevent a suspected device from harming others, the device is impounded by:
 - a. Tagging it and informing the supervisor
 - b. Leaving a note for the next shift to call Facilities Management
 - c. Locking it up, removing all attachments for further use
 - d. Tagging and locking it up with all attachments and control settings intact
3. Which form must be completed, on-line or in writing, when there is a medical device adverse event?
 - a. Event Notification Report
 - b. FDA MEDWATCH Form 3500
 - c. Biomedical Equipment Evaluation
 - d. Employee Report of Unsafe Condition

CHECK YOUR ANSWERS TO THE STUDY QUESTIONS

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Answers to Study Questions

1. d 2. d 3. a

If you answered all the questions correctly, go on to the next section. If you missed one or more, read the content again and repeat the study guide questions.

Bibliography

Equipment repair tags. In: *Hospital and Medical Administration Policy and Procedure Manual*. Torrance, CA: Harbor-UCLA Medical Center; 2006. Policy 473.

Guidelines for biomedical equipment. In: *Hospital and Medical Administration Policy and Procedure Manual*. Torrance, CA: Harbor-UCLA Medical Center; 2005. Policy 504.

Medical equipment management plan. In: *Hospital and Medical Administration Policy and Procedure Manual*. Torrance, CA: Harbor-UCLA Medical Center; 2007. Policy 410.