Medical Device Act Training

A medical device is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition and is NOT a drug or biologic. In home care some common examples include infusion pump, telemonitoring, catheter.

Adverse medical device events involve incidents where a patient or employee experiences a serious injury/illness or death that involved a medical device. You need to know about the key points of the Safe Medical Device Act; the definition and types of medical devices; reporting requirements; and, when and what to report.

Adverse medical device events must be appropriately documented, investigated and reported to the Food and Drug Administration (FDA) and/or the device manufacturer.

The FDA requires reporting of patient deaths or serious injuries/illnesses whenever you believe an adverse medical device event has occurred.

In an adverse medical device event any of the following incidents may cause or contribute to a death or a serious injury/illness:

a) Device failure;

b) Device malfunction;

c) Improper or inadequate device design;

d) Device manufacture;

e) Device labeling; or

f) Device user error.

If a patient or employee incident occurs because of equipment or product (medical device) malfunction or defect, immediately report the incident to your supervisor as soon as you have been made aware of the event.

a) Immediately discontinue use. Isolate the equipment to ensure it will not be used again until it can be properly repaired by a designated and qualified service representative ore replaced. Do not change any control settings, test or attempt repair of the equipment. Make a note of the device settings when the event occurred.

b) Be sure to include with the equipment any attachments and accessories (e.g., leads, electrical sources).

c) Contaminated devices should be properly secured in a biohazard container.

d) If possible, always retrieve the outer packaging of a product which may provide lot numbers or other identifying information.

Your administrator/manager is required to report a serious injury or death within 10 days to the appropriate authorities (i.e., FDA, Manufacturer).

Employees must immediately report any events that involve incidents where a patient or employee experiences a serious injury/illness or death because of equipment or product (medical device) malfunction or defect. Failure to do so may result in disciplinary action or termination.