

Safe Medical Device Act (SMDA)

Instructional Objectives:

The employee will demonstrate, by answering the review questions, complete knowledge of:

- Safe Medical Device Law
- Medical Devices
- Medical Device Report
- Incident reporting



What is the Safe Medical Device Act(SMDA)?

The SMDA Federal is legislation which was designed so that the FDA could quickly be informed of any medical product that has caused or suspected to have caused a serious illness, injury or death. The FDA will then take action to track and/or recall the product for further action. This law was passed to protect the public. Hospitals are required by law to report to manufacturers and to the FDA any device that malfunctions (mechanical or user errors) and causes serious injury/illness, or death to patients or employees. Reporting must be completed within ten working days after an event is determined to be reportable.

What are Medical Devices?

A Medical Device is defined by SMDA of 1990 as any instrument, apparatus, of other article that is used to prevent, diagnose, mitigate or treat a disease or to affect the structure or function of the body with the exception of drugs. Medical devices included but are not limited to the following:

Ventilators	Patient restraints	Monitors
Dialyzers	Gauze pads	Hospital beds
Implants	Cat scanners	Wheelchairs
Syringes	Tongue depressors	Infusion pumps
Laboratory equipment	Defibrillators	Thermometers
In vitro diagnostic kits/reagents		

What is a Medical Device Report (MDR)?

The FDA has designed a medical reporting program called MEDWATCH. This system encourages health care professionals to consider reporting adverse events and product problems as a fundamental health care responsibility. All health care professionals are expected to report adverse events, even if they are uncertain that the product caused the event and even though they do not have all the details. Hospitals are required to use the FDA Form 3500A for reporting product problems associated with medical devices. Personnel are to fill out the MCL Form #740 incident report and the FDA Form 3500A for reporting Medical Device malfunctions will be compiled by the Risk Management Department.

What to do if an incident occurs?

1. Attend immediately to the medical needs of injured patient/employee
2. Immediately report to appropriate supervisor
 - Fill out incident report MCL #740 to be sent to Risk Management
3. Remove device from area and appropriately label it
 - Save all packaging materials, instructional or operating manuals associated with device
 - Do not clean - leave device in original condition
4. Call Bio Me

REFERENCES:

1. Subject: Medical Device Reporting(MDR) and Medical Device Tracking(MDT). Available at:<http://207.299.159.241/members/F/FDA.ART.html>. Accessed May 3,2001.
2. Medical Devices Act of 1990: Current Hospital Requirements and Recommended Actions. Available at:<http://207.299.159.241/members/H/H993B.ART>. Accessed May 3,2001

Finally:

1. Initiate discussion of the topics and answer questions.
2. Have everyone complete the quiz.
3. Review the quiz and correct any errors.
4. Document attendance at the meeting, keep the quiz in your files.
5. Calculate the percentage of attendance in your area.
6. Sign-in sheets have changed. Please use new version and send original to me by July 30, 2003 also indicate **faciliator**, **time**, and **date** meeting was held.

MEDICAL CENTER OF LOUISIANA		EDUCATION/STAFF DEVELOPMENT		TRAINING EVENT SIGN-IN SHEET	
TOTAL IN ATTENDANCE: _____		PLEASE CIRCLE: D DL SI ED NO PAGE ___ OF ___			
PROGRAM: _____		DATE: _____		TIME: _____	
#	PRINT NAME <small>*Please attend for faculty and/or to receive credit</small>	SIGNATURE	DEPARTMENT	TELEPHONE	LAST 4 DIGITS OF SSN
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

FACILITATOR: _____ Legend: D-Discussion DL-Did you attend? SI-Sign-in sheet ED-Event NO-None of these CR-Clinical RN-Nursing Discussion

THE ORIGINAL SIGN-IN SHEET(S) MUST BE TURNED IN TO EDUCATION/STAFF DEVELOPMENT (C-500) ON OR BEFORE THE 10TH OF THE MONTH.

Meeting: **Electricity is Shocking - Summer 2003**

Date: _____

Meeting coordinator: _____

Area: _____

Percentage of attendance: _____

Please write any unresolved discussion questions or safety concerns on the back of this form and return both (form and sign-in sheet) to Argie Leach.