

STANDARD OPERATING GUIDELINE - 5.1.5

TOPIC - MEDICAL DEVICE REPORTING

PURPOSE:

To provide direction leading toward compliance with 21 CFR 803, a federal regulation related to any adverse event involving a medical device.

GENERAL:

The federal Department of Health and Human Services, Food and Drug Administration has developed regulations designed to promote significant aspects of the Safe Medical Devices Act, and amendments, of 1990, and 1992. These regulations require manufacturers, distributors, and device user facilities to submit to the agency reports [Medical Device Report (MDR)] on certain types of medical device-related adverse events. As a provider of rescue services, the fire district is defined as a device user facility and is obligated to file and maintain reports meeting the regulation.

GUIDELINE:

Terms & Definitions:

1. A "medical device" is defined as any thing intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other condition. Generally, if it is a thing used in medical practice and it is not a drug or biologic agent, it is a device.

EXAMPLES: Hospital beds, heart valves, ventilators, patient restraints, x-ray machines, defibrillators, bandages, etc.

2. An "MDR reportable event" is an event about which the user facility becomes aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury (adverse event).

The concept of "may have" is applied if there is a reasonable possibility that a device caused or contributed to an adverse event without requiring absolute certainty of the fact.

3. "Serious injury" means an injury or illness that is:
 - a. life threatening;
 - b. results in permanent impairment of a body function or permanent damage to a body structure; or
 - c. necessitates medical or surgical intervention to preclude permanent damage or impairment.
4. "Caused or contributed to" means that the device is identified as a

factor in the death or injury due to device failure or malfunction, improper or inadequate design, manufacture, labeling, or user error.

Identification and Evaluation of an Adverse Event:

1. Whenever a device malfunctions or fails while in operation, or whenever there is an operator error that causes a device to perform in a manner other than what is expected, a written report shall be made describing all significant elements of the incident.
2. The written report shall be submitted to the EMS Committee for review within 48 hours of the incident.
3. If there is a death or serious injury associated with the event, the EMS Committee must arrange to contact the hospital, or other appropriate facility, to gain information regarding contributing factors to the status of the patient.
4. Based upon the information gained from the hospital or other facility, the EMS Committee must make a determination, within five (5) days of the event, of whether or not the event is reportable.
5. All deliberations and discussions regarding the incident must be documented and retained as a part of the total report.

Reporting:

1. An individual adverse event report must be submitted, within ten (10) working days of the incident, to the manufacturer whenever there is a serious injury, or to both the manufacturer and to FDA whenever there is a death.
2. Instruction for filling out the appropriate form is located in the Medical Device Reporting manual located in the EMS office.
3. Semiannual reports must be submitted by January 1, and July 1 as those dates apply.
4. If a report has been filed by another user facility regarding the same patient and same event there is no need for this agency to file a duplicate report.

Files:

1. Files must be clearly marked identifying them as Medical Device Report files, and filed to facilitate timely access.

2. All information and documentation regarding each incident must be included in its own file.
3. All files must be retained for a period of two (2) years from the date of the incident.

Public Availability of Reports:

1. Information contained in an MDR is available for public disclosure except for those portions which would constitute an unwarranted invasion of personal privacy.
2. Whenever a patient makes a request for information we will disclose all information regarding that patient.