Central DuPage Emergency Medical Services System

Medical Device Failure/Malfunction

INTRODUCTION AND APPROVAL: 8/96	EMS MEDICAL DIRECTOR: _____
REVIEW & APPROVAL: 1/98	EMSS COORDINATOR: _____
REVISION & APPROVAL: 2/09	

PURPOSE

Central DuPage EMS System prehospital care providers are to submit a report to the EMS System Coordinator whenever they work with a device or piece of equipment that reasonably suggests the device has or may have "caused or contributed" to a death or serious injury (including certain events occurring as result of user error).

In any situation involving a medical device failure or malfunction, immediate steps shall be taken to ensure the health and safety of the patient and the prehospital care providers. Immediate action shall also be taken to preserve the medical device as it was at the time of the occurrence to document the condition/status of the device and to immediately remove the device from service.

DEFINITIONS:

1. Caused or Contributed: A death or serious injury was or may have been attributed to a medical device or a user error; or a medical device was or may have been a factor in a death or serious injury.

2. Medical Device: any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate or treat a disease or to affect the structure or function of the body. This includes disposable and non-disposable products such as catheters, laryngoscope blades, patient restraints and syringes.

3. Serious Injury: Any injury or illness that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

POLICY:

1. Incident Identification

At the moment of a medical device failure or malfunction:

a. Attend to the medical needs of the patient or the injured parties, removing them from the area if necessary.
b. Immediately remove the device from service. Preserve the device precisely as it was being used at the time of the malfunction/failure, including attachments and/or disposable items. Do not change any settings or disconnect any attachments. Save all parts if an item breaks into pieces.
c. Contact your immediate supervisor as soon as patient care is completed. If a death or injury occurred, immediately notify the EMS System Coordinator and/or the EMS Medical Director.

2. Documentation Requirements

a. Document objective, pertinent information regarding the patient's condition, description of the event and medical interventions taken in the Patient Care Report.
b. DO NOT make any reference to the fact that Documenting Problems Report was completed in the Patient Care Report.
c. DO NOT make any judgments or conclusion regarding the cause of the occurrence in the Patient Care Report.
d. As soon as patient care is appropriately transferred to the receiving hospital, fill out a Documenting Problems Report. Be as specific as possible, noting the following information:

1. The name of the device.
2. The manufacturer of the device, if known.
3. The model number of the device.
4. The lot and serial number of the device.
5. The location in which the device was being used.
6. The settings or modes operative at the time of the event.
7. Patient information such as name, age, gender, estimated weight, presumptive diagnosis, status pre-event, status post-event, procedure being performed at the time of the event.
8. If a prehospital worker was injured, list the name, age, gender, status pre-event, and status post-event.
9. Narrative description of the event, including how the device contributed to the event.
10. Description of the medical intervention(s) taken as a result of the event.

e. Forward the completed Documenting Problems Report to your supervisor and simultaneously fax a copy to the Resource Hospital EMS Office at (630)260-2441.

Evaluation

1. The manufacturer's product specifications, the product's preventive maintenance records and repair records shall be available for review during the investigation.

2. If the device is maintained under a service agreement, sequester the defective device and perform your investigation. Contact the manufacturer's representative or contracted agency to perform their inspection while maintaining the device within your jurisdiction.

3. A thorough inspection of the device shall be completed in accordance with the manufacturer's specifications, documented and presented to the Resource Hospital EMS Office. If deemed necessary, photographs shall be taken of the device.

4. The Resource Hospital EMS Office will complete a thorough investigation of the occurrence, interviewing all crew members present at the time of the incident and the patient, if necessary.

5. Within 72 hours of the occurrence, preliminary inspection report must be provided to the EMS Medical Director.

6. Only upon notice from the EMS Medical Director shall the device be returned to service.

FDA Reporting

1. If it is determined by the EMS Medical Director that the medical device caused or contributed to a patient or healthcare worker's death or resulted in serious injury or illness, a report will be submitted to the FDA and/or product manufacturer by the EMS Agency, with assistance from the Resource Hospital EMS Office.

2. These reports are to be filed as soon as practical, but no later than 10 working days after the provider becomes aware of the information. A provider "becomes aware" when prehospital care providers or employees obtain such information about a reportable event.

3. Assistance in completing FDA form 3500 A will be provided to the EMS Agency by the EMS Resource Hospital EMS Staff.

4. If there is any dispute regarding the cause of the equipment failure or malfunction, a review panel (comprised of at least the crew members present at

the time of the occurrence, the Fire Chief or his designee, the EMS Medical Director and if necessary, a biomedical engineer) will meet to review the details of the occurrence and make a determination if the medical device caused or contributed to a patient's's death, serious illness or injury.

5. Semiannual reports (FDA #3419) must be submitted by the EMS Agency with assistance from the Resource Hospital EMS Staff, to the FDA by January 1 for reports made July through December and by July 1 for reports made January through June of each year. If no reports are submitted to either the FDA or a manufacturer during these six month time periods, no semiannual report is required.

Record Keeping

1. Provider Agencies must establish and maintain Medical Device Reporting (MDR) event files that contain information related to the adverse event, documentation of deliberations and decision making processes, copies of forms and other information submitted to the FDA and others.

2. These records must be retained in an MDR event file for a period of two (2) years.

3. FDA employees are permitted to access, copy and verify the records in the MDR event file.