	SOUTHERN FOX VALLEY EMERGENCY MEDICAL SERVICES SYSTEM POLICY & PROCEDURES
TITLE: MEDICAL DEVICES REPORTS	
SECTION: GENERAL POLICIES	POLICY NUMBER: D-25.0
APPROVED BY: DR. ARTHUR PROUST EMS MEDICAL DIRECTOR	
EFFECTIVE DATE: 04/03/1996	PAGE NUMBER: 1 OF 1

PURPOSE:

To assure compliance with the Safe Medical Devices Act of 1990. This policy also ensures that incidents involving malfunctioning medical devices are reported in a timely manner.

POLICY:

1. This applies to all EMS vehicles and pre-hospital personnel in the SFVEMS System.
2. Pre-hospital provider agencies must submit a medical device report (MDR) to the device manufacturer and/or the FDA within ten days of the date of the incident, defined as a reportable death or serious illness or injury involving a medical device. A copy of this report will also be forwarded to the EMS System CQI Coordinator.
3. If the event involves a device-related death, or if the identity of the manufacturer is not known, the report must be submitted directly to the FDA.
4. A provider agency's reporting obligation begins when any of their personnel becomes aware of a reportable event. These events include, but are not limited to:
   a. Adverse device events caused by user error.
   b. Adverse device events that result in employee injury and/or medical care arising from a device related event.
5. Provider agencies must only report information that is reasonably known and are not required to investigate adverse events.
6. Documentation and record keeping must include:
   a. Written departmental policies and procedures to assure compliance with the regulations. Copies of these policies should be submitted to the Resource Hospital.
   b. Semi-annual reports must be submitted to the FDA in the event any MDR are made during the previous six months.
   c. MDR event files must be maintained and reports kept for two years after the event.
   d. If the provider agency determines that an event is not reportable, the information leading to this conclusion must be kept in the MDR event file.
   e. MDR event files and other records kept by the provider agency must be made available to the FDA for inspection and audit.

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