



**REGION 11
CHICAGO EMS SYSTEM
POLICY**

Title: Medical Device Reporting
Section: Quality Improvement
Approved: EMS Medical Directors Consortium
Effective: January 1, 2010

MEDICAL DEVICE REPORTING

- I. A medical device is 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, with the exception of drugs. This includes but is not limited to ventilators, monitors, electronic equipment, patient restraints, syringes, catheters, diagnostic test kits and reagents, disposables, components, parts, accessories, etc.
- II. Any individual who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that a medical device has caused or contributed to the morbidity and mortality of the patient or prehospital personnel is responsible to:
 - A. Report the incident to their immediate supervisor.
 - B. Complete an RFC as soon as possible.
- III. The Resource Hospital EMS Coordinator should be informed as soon as possible.