REGION 11 CHICAGO EMS SYSTEM POLICY	Title: Medical Device Malfunction Reporting
	Section: Quality Improvement
	Approved: EMS Medical Directors Consortium
	Effective: December 6, 2023

MEDICAL DEVICE MALFUNCTION REPORTING

I. PURPOSE

To define the medical device reporting requirements by EMS personnel for the Food and Drug Administration (FDA) under the Safe Medical Devices Act of 1990.

II. DEFINITIONS

A. 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, but is not limited to ventilators, cardiac monitors, electronic equipment, patient restraints, syringes, catheters, diagnostic test kits and reagents, disposables, components, parts, or accessories.

B. Malfunction: Failure of a device to meet its performance specifications or to perform as intended.

C. Medical Device Reporting (MDR) Regulation of 1995: Contains mandatory requirements for manufacturers, importers, and device user facilities (includes hospital and EMS) to report device related serious injury or death within 10 business days to the manufacturer and/or the Food and Drug Administration (FDA).

D. MDR Reportable Event: An event about which a 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.

E. MDR Authority: The Food and Drug Administration (FDA) has criminal and civil penalty to enforce MDR requirements.

III. POLICY

A. 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 EMS personnel is responsible to:

1. Report the incident to their immediate supervisor; and

2. Complete a Request for Clarification (RFC) within 24 hours.

B. Medical device malfunction is a mandatory reportable event by the EMS personnel and/or the EMS agency to the Resource Hospital EMS Coordinator and EMS Medical Director.

C. Incident investigation information will be used to complete the FDA Med Watch mandatory or voluntary reporting of adverse events form.

Reference: U.S. Food and Drug Administration, Medical Device Safety, https://www.fda.gov/medical-devices/medical-device-safety.