I. LEGISLATIVE IMPERATIVE

A. On December 11, 1995, the Food and Drug Administration (FDA) issued its final rule on medical device reporting (FedRegist 1995 Dec. 11; 60[237]:63578-606) under the Safe Medical Devices Act. This rule expands the existing requirements for medical device reporting, record keeping, confidentiality, mandatory forms, coding manuals, written policies and procedures, and includes new definitions.

B. **Penalties for non-compliance**: Failure to comply with the rule may result in civil monetary penalties and increase risk of liability exposure.

II. POLICY

A. EMS personnel must submit a report whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device has or may have "caused or contributed" to a death or serious injury. This includes certain events occurring as a result of user error.

B. Deaths must be reported to the FDA and the manufacturer, if known. Serious injuries must be reported to the manufacturer or to the FDA if manufacturer is unknown.

C. 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 healthcare providers.

D. 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.

III. DEFINITIONS

A. **Caused or contributed**: A death or serious injury was or may have been attributed to a medical device, or a medical device was or may have been a factor in a death or serious injury.

B. **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.

C. **Serious injury**: An 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.

IV. PROCEDURE

A. **Incident identification & notices-** Actions at the time of a medical device malfunction:

1. Attend to the medical needs of the patient or the injured parties, removing them from the area if necessary.

2. Immediately remove the device from service. Preserve the device precisely as it was at the time of the malfunction/failure, including attachments and/or disposable items. Return to Agency's Provider EMS Coordinator for analysis by the manufacturer. Do not change any settings or disconnect any attachments. Save all parts if an item breaks into pieces.

3. Contact the EMS crew's immediate supervisor as soon as patient care is completed. If a death or injury occurred. This is a reportable incident. Contact the EMS MD as soon as possible.

B. **Documentation requirements**

1. Document objective, pertinent information regarding the patient's condition, description of the event and medical interventions taken on the patient care report.
2. **DO NOT** make any reference to the fact that an incident report was completed on the patient care report.
3. **DO NOT** make any judgments or conclusions regarding the cause of the occurrence on the patient care report.
4. As soon as patient care is appropriately transferred to the receiving hospital, fill out a Medical Device Failure report. Be as specific as possible, noting the following information:
   a. The name of the device
   b. The manufacturer of the device, if known
   c. The model number of the device
   d. The lot and serial number of the device
   e. The location in which the device was being used
   f. The settings or modes operative at the time of the event
   g. Patient information such as initials, incident number, age, gender, estimated weight, presumptive diagnosis, status pre-event, status post-event, procedure being performed at the time of the event
   h. If an EMS worker was injured, list the name, age, gender, status pre-event and status post-event
   i. Narrative description of the event, including how the device contributed to the event
   j. Description of the medical intervention(s) taken as a result of the event
5. Forward the completed report to the EMS crew's immediate supervisor and simultaneously fax a copy to the Resource Hospital EMS office at (847) 618-4489.

C. **Evaluation**

1. The EMS Agency shall complete a thorough investigation of the occurrence, interviewing all crew present at the time of the incident and the patient, if necessary.
2. Pull all manufacturers' product specifications, preventive maintenance records and repair records for review during the investigation.
3. If the device is maintained under a service agreement, contact the manufacturer's representative or contracted agency to perform the inspection. If the EMS Agency does not have a service contract or desires assistance, they should contact their assigned hospital's Biomedical Engineering Department as a resource in performing an inspection of the device involved in the occurrence.
4. A thorough inspection of the device shall be completed in accordance with the manufacturer's specifications and documented in accordance with EMS Agency policy. If necessary, photographs shall be taken of the device.
5. A preliminary inspection report shall be provided to the EMS MD within 72 hours of the occurrence.
6. The device shall only be returned to service upon approval from the EMS MD.

D. **FDA Reporting**

1. If it is determined by the EMS MD that the medical device caused or contributed to a patient or healthcare worker's death or resulted in serious illness or injury, a report must be submitted to the FDA on form 3500A and/or the product manufacturer by the EMS Agency.

2. These reports are to be made as soon as practical, but not later than 5 working days after the provider becomes aware of the information. A provider "becomes aware" when medical personnel or employees acquire such information about a reportable event.

3. For assistance in completing FDA form 3500 A, contact the EMS Administrative Director for full instructions and a list of codes.

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 Chief or his designee, the EMS MD and a Biomedical Engineering manager shall meet to review the details of the occurrence and make a determination if the medical device caused or contributed to a patient's death, serious illness or injury.

5. Semiannual reports or electronic equivalents must be submitted by the EMS Agency 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.

E. **Record keeping**

1. Providers 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 years.

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

V. **System procedure for reporting Medical Device Failure/Malfunctions that DO NOT cause or contribute to death or serious injury**

A. Providers shall file a report with the NWC EMS office whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device has or may have malfunctioned whether or not it involved patient care or an injury.

B. It is important for the System to track incidents of malfunction to perform an informed risk/benefit analysis prior to determining if a product should be recalled from System use.

C. If a product has malfunctioned, remove it immediately from service. Preserve it precisely as it was being used at the time of the malfunction/failure, including attachments and/or disposable parts and **return it to the Provider EMS Coordinator for analysis by the manufacturer**. Do not change any settings or disconnect any attachments. Save all parts if an item breaks into pieces.

D. Follow the procedure as specified in Section IV; Subsections A, B, and C.

E. The System will maintain centralized records of MDR events that do not require reporting to the FDA and correspond with manufacturers as the EMS MD determines is necessary.

VI. **Ambulance failure**

A. If at any time an ambulance is unexpectedly taken out of service and unable to complete a run, either enroute to or during a call, complete the Equipment Failure form as soon after the event as possible and forward to the NWC EMS office on the same shift as the incident occurrence. Review of these incidences is considered continuous quality improvement, and, as such is protected under the Medical Studies Act.

B. In all cases of ambulance failure, a second ambulance should be called that can arrive within 6-15 minutes of the request for assistance. If an ambulance cannot respond within 6 minutes in their primary service area, the provider agency must attempt to notify the person requesting aid and inform them of the anticipated delay.

John M. Ortinau, M.D., FACEP
EMS Medical Director

Connie J. Mattera, M.S., R.N.
EMS Administrative Director

Northwest Community EMS System

MEDICAL DEVICE FAILURE REPORT

Submission of this report does not constitute an admission that medical personnel, a user facility, distributor, manufacturer or product caused or contributed to the event. This report constitutes CQI and is protected by the Medical Studies Act.

PATIENT INFORMATION

Initials (in confidence)	Age at time of event or date of birth:	Gender [ ] Female [ ] Male	Weight lbs. or kgs.

EMS Agency: | EMS Incident #:

Adverse event or product problem: [ ] Adverse event [ ] Product problem

Status of patient pre-event: [ ] Stable [ ] Unstable [ ] Cardiac/respiratory arrest
Status of patient post-event: [ ] Stable [ ] Unstable [ ] Cardiac/respiratory arrest

Paramedic impression of patient's diagnosis at time of event:

Outcomes attributed to adverse event (check all that apply)

[ ] Death _____ [ ] Life-threatening [ ] Hospitalization [ ] Disability
month/day/year

[ ] No adverse outcome evident [ ] Other:

Date of event: | Date of this report:

SUSPECT MEDICATION(s)

Name (give labeled strength & mfr/labeler, if known)
#1.
#2.

Dose, frequency & route used
#1.
#2.

Indications for use
#1.
#2.

Lot number, if known	Expiration date, if known:
#1. #2.	#1. #2.

SUSPECT MEDICAL DEVICE

Name of the device | Brand name:

Manufacturer name, address, & phone #

Operator of device:
[ ] Health professional
[ ] Lay user/patient
[ ] Other:

Model #:
Catalog #:
Serial #:
Lot #:
Other #:

Expiration date (if known)

If implanted, give date (if known)

Location in which device was being used:

Settings and modes operative at the time of event:

Describe procedure being performed at time of the event and how the device contributed to the event or problem:

Describe the medical interventions taken as a result of the event:

List the following for any EMS workers who were injured:

Initials	Age	Gender	Status pre-event	Status post-event

Device available for evaluation?

[ ] Yes [ ] No [ ] Returned to manufacturer on:

AMBULANCE FAILURES

Time of failure: Time mutual aid arrived: Time arrived at hospital:

System hospital notified of failure:

Nature and cause of failure:

Potential or actual adverse impact to patient:

INITIAL REPORTER

Name:		Address:	
Phone:	Health professional? [ ] Yes [ ] No	Occupation:	**Initial reporter also sent report to FDA?** [ ] Yes [ ] No