



MEDICAL EQUIPMENT FAILURE



Escambia County, Florida - ALS/BLS Medical Protocol

This protocol defines the process for reporting and handling medical device, equipment, or product failure/problem.

Escambia County Public Safety has a legal and ethical responsibility to report all medical device, equipment, or product failures / problems to either the product manufacturer or the Food and Drug Administration (FDA) based upon the seriousness of the failure and the impact upon the patient.

All medical device, equipment, or product failures / malfunctions shall be immediately brought to the attention of the on-duty supervisor.

Employee's Responsibility

- A. Immediately notify the on-duty supervisor of all medical device, equipment, or product failures/malfunctions by providing the following information:
 - 1 Which piece of device, equipment, or product failed?
 - 2 Events and circumstances related to the failure.
 - 3 Impact of the failure on the patient care.
 - 4 Any negative effects on the patient, crew, or bystanders.
- B. The employee(s) shall thoroughly document the event on a "Medical Device Equipment Failure Reporting Form" and submit it to the on-duty supervisor for review, prior to the end of their assigned shift.

Supervisor's Responsibility

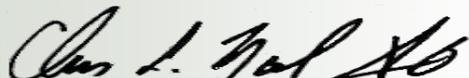
- A. Determine the severity of the failure. Any failure, which results in an injury or a negative patient outcome, shall be immediately brought to the attention of the Director of Public Safety, Operation Chief, and the Quality Assurance Coordinator.
- B. Respond to the crew's location or final destination, when appropriate, to make a



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- determination as to the extent of any injuries or patient detriment.
- C. Remove the device, equipment, or product that failed and replace it.
 - D. Properly tag the device, equipment, or product that failed as being “out of service” and store it in a secure location.
 - E. Review report(s) submitted by the employee(s).
 - F. Document on the “Medical Device/Equipment Failure Reporting Form” initial conclusions, any corrective actions, and the status of employee(s) and patient(s), if injured.
 - G. Attach a copy of the completed “Medical Device/Equipment Failure Reporting Form” to the device, equipment, or product.
 - H. Immediately forward original documents to the Training Coordinator and copies to the Operations Chief.
 - I. Contact the appropriate personnel to inspect and repair/replace the device, equipment, or product prior to placing the equipment back in service.

Training Coordinator

- A. Thoroughly review the incident.
- B. Provide remedial training to avoid a similar incident, if needed.
- C. Complete the appropriate reporting forms (Med Watch or letter to the Manufacturer), if needed.
- D. Advise the Medical Directors and Director of Public Safety of the outcome, if needed.
- E. Prepare an information packet for Risk Management, if requested by the Director of Public Safety.



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Consequences

The FDA requires that ambulance providers report any serious device related incident within 10 days.

Incidents, resulting in death, must be reported directly to the FDA and the product manufacturer.

Incidents resulting from operator error are required to be reported within 10 days of the employer "gaining knowledge of the failure".



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