



POLICY AND PROCEDURE MANUAL
DUKE UNIVERSITY HOSPITAL
Clinical Engineering Policy CE-009
SMDA / Voluntary Reporting System



DEFINITIONS:

Medical Device: Anything that is used in treatment or diagnosis that is not a medication. The FDA defines a medical device as an 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. Example of medical devices are: x-ray machine, suture material, defibrillator, vascular graft, syringe, surgical laser, heating pad, bone screw, gauze pad, patient restraint, wheelchairs, infusion pump, etc.

Serious Illness and Serious Injury: An injury or illness that (1) is life threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

POLICY:

The Clinical Engineering Department is a receiving entity for Duke University Hospital device reports as part of the Voluntary Reporting System (VRS). When equipment related failures occur, Clinical Engineering will receive the initial VRS report, provide instruction to the reporting personnel, provide consultation to Risk Management, and when appropriate as a matter of quality assurance, investigate device incidents on behalf of Risk Management/Counsel's Office. Risk Management is the designated reporting official in the Hospital to report incidents to equipment manufacturers and to the FDA.

PURPOSE:

To comply with the DUHS VRS protocol, which Clinical Engineering will follow as it responds to the VRS report. This procedure will provide guidelines for completion of required documentation, necessary notification, and procedures to follow for equipment investigations.

PROCEDURE:

Clinical Engineering shall follow all Duke University Health System VRS procedures as outlined in the Occurrence Reports Procedure.