CENTRAL STATE HOSPITAL
POLICY

SUBJECT: **SAFE MEDICAL DEVICES AND LABORATORY PRODUCT REPORTING**

ANNUAL REVIEW MONTH: September

RESPONSIBLE FOR REVIEW: Chief Medical Officer

LAST REVISION DATE: September 2009

I. PURPOSE

The purpose of this policy is to establish guidelines to assure that the hospital is in compliance with the Safe Medical Devices Act 1990 (SMDA) which establishes a nationwide Medical Device and Laboratory Product Problem Reporting Program (PRP) for health professionals to report their observations about the quality and safety of medical products used in their practice. Additionally, a report must be submitted whenever information is known, from any source, that reasonably suggests that a device has or may have caused or contributed to a death or serious injury, to include certain events occurring as a result of user error.

II. DEFINITION/EXAMPLES

A. Medical devices include but are not limited to intravenous pumps, catheters, surgical/examination gloves, cardiac and respiratory monitors, implants, dialysis products, reagent kits, x-ray equipment, ventilators, sutures, and restraints. In a very broad sense any medical or surgical product that may have an adverse affect on a client is subject to be included in the definition.

B. Examples of Product Problems to report:

(1) Performance failures
(2) Erroneous information
(3) Poor packaging
(4) Questionable sterility
(5) Improper labeling
(6) Defective components
(7) Incomplete or confusing instructions

III. RESPONSIBILITY FOR REPORTING MEDICAL DEVICE OR PRODUCT

PROBLEMS

The Director of Staff Development & Training Department, in coordination with the Chief Medical Officer (CMO), is responsible for assuring that health professionals are provided training in the SMDA. All health professionals are to report medical devices or product deficiencies promptly to the service area Environment Of Care (EOC) chairperson, safety officer, bio medical engineering and to the service area clinical director who will, in turn, report to the CMO and EOC team. In the event a medical device(s) or product(s) results in serious illness or a life threatening event which 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 or death of a client, the Chief Medical Officer shall present the matter to the appropriate investigative committee. The committee will consist of the safety officer, risk manager, bio-medical engineer, a nursing staff member and any other CSH employee(s) deemed appropriate by the CMO. Devise related deaths must be reported directly to the Federal Drug Administration, (FDA) and the manufacturer on a FDA form 3500A "MEDWATCH", within ten (10) working days of becoming aware of the information. Serious injuries must be reported to the manufacturer within ten (10) days of becoming aware of the information or to the FDA if the manufacturer is unknown.

The CMO will also submit, on a semi-annual basis, a summary FDA form 3419 to both the FDA and product manufacturer. The semi-annual reports must include information relating to device manufactures, product(s) and a brief description of event(s). This report will reflect any incidents which occurred in the previous six months.

Approved:

This policy has been approved by the CEO and CMO on 12/09.