

**OLIVE VIEW-UCLA MEDICAL CENTER
POLICY & PROCEDURE**

**NUMBER: 64
VERSION: 3**

SUBJECT/TITLE: PRODUCT RECALL AND SAFETY ALERT NOTICES

POLICY: Olive View – UCLA Medical Center (OVMC) shall ensure the safe management of medical devices and/or products at all facilities.

PURPOSE: To ensure the safe management of medical devices and/or products at OVMC.

DEPARTMENTS: All.

DEFINITIONS: **Recall** – the removal of distributed product (s) deemed to be in some way harmful or defective.

Devices may be recalled for one or more of the following reasons:

1. Device defect (visible or functional)
2. Labeling (insufficient and/or incorrect)
3. Packaging defect (i.e. incomplete seal, holes)
4. Questionable sterility
5. Manufactured without proper authority (i.e., FDA approval)

The FDA classified recalls into three categories, based on the extent of Potential harm that could result from use of the product:

Class I: There is reasonable probability that the use of, or exposure to a product will cause serious adverse health consequences or death.

Class II: Exposure to a product may cause temporary or medically reversible health consequences or where the probability of serious, adverse health consequences is remote.

Class III: Exposure to a product is **unlikely** to cause adverse health consequences.

PROCEDURE: I. Safety Officer

- A. Upon receipt of a recall or safety alert notice, the Safety Officer shall immediately contact the appropriate division and advise its representatives of procedures to be followed.

SUBJECT/TITLE: PRODUCT RECALL AND SAFETY ALERT NOTICES

Policy Number: 64

Page Number: 2

- B. The Safety Officer shall then obtain the signature(s) of appropriate personnel to ensure that recall/alert information is disseminated to all affected areas.
- C. In the event of an unresolved recall/alert notice, the Safety Officer will notify the Risk Manager and/or Compliance Officer.
- D. The Safety Officer shall maintain files on all recall/alert notices; and provide status reports to the Environment of Care Committee.

II. Divisions

- A. Upon notification by the Safety Officer, it is the responsibility of the Division Manager, affected by the notice, to take the necessary action regarding the recall/safety alert notice.
- B. The Division Manager shall also be responsible for preparing and submitting a written follow-up response, in regards to recall/alert notice, within five working days to the Safety Officer. A written follow-up response shall be required for all alert notices regardless of the location of the product in question.

References:	
Approved by: VEC-2011Jan	Date: 08/14/2014
Review Date: 08/14/2017, 3/96, 3/99, 2/02, 3/05, 1/08, 4/11	Revision Date: 2/93, 3/96, 2/02
Distribution: Olive View Hospital-Wide Policies	
Original Date: 6/88	