LAC+USC MEDICAL CENTER POLICY

Subject:	Original Issue Date:	Policy #
	1/15/84	**620**
PRODUCT RECALL	Supersedes: 6/29/18	Effective Date: 10/21/22

Departments Consulted:	Reviewed & Approved by:	Approved by:
Facilities Management Supply Chain Operations	Attending Staff Association Executive Committee Senior Executive Council	(Signature on File) Chief Medical Officer
		(Signature on File) Chief Executive Officer

PURPOSE

To delineate responsibility for the management of product recalls, medical alerts, and product warnings received by the LAC+USC Medical Center.

POLICY

The LAC+USC Medical Center shall establish and maintain a process to manage product recalls, medical alerts, and product warnings received by the organization.

PROCEDURE

1. Notification: Upon notification of medical product recall, medical alert, or product warning, Supply Chain Operations shall coordinate appropriate corrective action to protect the safety of all patients, staff, and visitors.

   Recall and Alert notices are managed through an electronic recall and alert notification and tracking system. Notices are sent to appropriate staff and marked as applicable or not applicable after being reviewed. Notes and actions are recorded and stored on data servers for quality control and risk management purposes.

2. Initial Action: Initial response to recall notifications will be coordinated by the Supply Chain group that ordered the supplies, in partnership with Nursing, Clinical Engineering for mechanical devices, and relevant medical staff departments, and supported by Risk Management
   a. Supply Chain Operations is responsible for recalls related to warehouse stock items
   b. For items ordered through the OLR process, the ordering department or service is responsible

3. All recalled products will be requisitioned back to Supply Chain Operations, and all purchased products must be accounted for during this process. If all products are returned without patient exposure, Supply Chain Operations shall serve as the LAC+USC Medical Center Product Recall Coordinator and shall ensure:
   - Minimal disruption to patient care and services as medical products or supplies are removed from inventory.
   - Facilitation of product substitution arrangements with recalling suppliers pending approval.

4. Action Taken if Patients Exposed: In the event that during the accounting of recalled products it is determined that patients were exposed to the product, Risk Management will be notified. Risk Management will work with the Chief Medical Officer or his/her designee, the appropriate clinical services, other appropriate departments (e.g., infection control if a sterilization concern is present), and Nursing to assess the risk to the patients, and when deemed appropriate, to determine the most expeditious, safe manner to retrieve the product from the patients, and develop a response plan.

RESPONSIBILITY

Administrators
Supply Chain Operations
Facilities Management

PROCEDURE DOCUMENTATION

Supply Chain Operations Policy and Procedure Manual

REFERENCE

DHS Policy #331, Medical Supplies Evaluation
Joint Commission Standard – Environment of Care

REVISION DATES

September 1, 1994; February 22, 1999; April 9, 2002; January 27, 2004; September 5, 2008; March 13, 2012; December 9, 2014; July 14, 2015, June 29, 2018, October 21, 2022