

CENTRAL STATE HOSPITAL
POLICY

SUBJECT: **MANUFACTURER'S RECALL OF SUPPLIES AND/OR EQUIPMENT**

ANNUAL REVIEW MONTH: September

RESPONSIBLE FOR REVIEW: Safety Director

LAST REVISION DATE: July 2009

I. POLICY

- A. PURPOSE: The intent of this policy is to establish guidelines and procedures that ensure all products, devices or equipment recalled from appropriate sources are handled in an expeditious manner for the protection of all facility employees, clients, and visitors.
- B. APPLICABILITY: This Policy is applicable to CSH.
- C. DEFINITIONS:
1. Code U (Urgent) - A recalled item or product that will directly and negatively affect the health or safety of a person if that person uses or is exposed to that item or product.
 2. Code S (Serious) - A recalled item or product that could indirectly affect or cause some negative effect to the health and safety of a person if that person uses or is exposed to that item or product.
 3. Code A (Advisory) - A recalled item with the potential to affect the health or safety of a person if the item or product does not receive corrective action in a timely manner.
- D. POLICY STATEMENT: It is the policy of the Central State Hospital (CSH) to take appropriate action whenever information on any item that has a manufacturer or distributor recall is brought to the attention of the facility. This policy also prescribes the requirements for manufacturer's recall or special warnings.
- E. DISCUSSION: For the purpose of this policy, certain steps are required for removing recalled equipment and/or supplies.

- (1) The procedural action may be predicated by the comments or requirements of the manufacturer's announcement.
- (2) Obsolete goods will be disposed of in accordance with State Law, DOAS, and Department of Behavioral Health and Developmental Disabilities Policy and Procedures.
- (3) Many prepackaged medical supplies have disposal instructions on the label or package.
- (4) The procurement and safety director will direct the user departments when circumstances dictate special requirements.
- (5) All special warnings and recalls will be handled expediently with complete documentation.

II. PROCEDURE:

When any employee, department or service becomes aware of a recall notification or safety alert, the Safety Director and the Director of Materials Management shall be notified immediately.

RESPONSIBILITY

ACTION

Director of Materials Management

1. Will determine user departments.
2. Will immediately notify safety director and user departments via Groupwise.

Safety Director

1. Will evaluate and act upon all information concerning recalls and safety alerts.
2. Will initiate notification of any recall to the appropriate facility staff using Form # 3.02A (9/98) "Manufacturer Recall Notification".
3. Will include instructions to the appropriate service director for corrective measures to be taken.
4. Will document and maintain files on all corrective action.
5. Will report actions to the Environment of Care Team and the CSH Leadership Team.

User Department Heads &
Supervisors

6. Will forward a copy of all related documentation to the procurement office.
1. Will suspend use of recalled products.
2. Will inventory quantity on hand.
3. Will widely disseminate information of suspension.
4. Will collect product and comply with recall/safety alert instructions.
 - a. Requirement may be destruction or return shipment to vendor.
 - b. Items will be taken to the warehouse for packaging and shipping.
 - c. Items will be turned over to the property control officer if destruction is required.
 - d. All actions will be documented.
 - e. Will complete Form #3.02A (9/98) and forward to safety director.
5. If using department receives notice of a recall directly, will forward information immediately to the safety director and the Director of Materials Management for distribution.

Safety Director

1. Will record and verify that all recall alerts have been appropriately acted upon.
2. Will report all recalls and respective corrective action to the appropriate departments.
3. Will submit an annual summary report of all recalls and corrective actions to the Environment of Care Function Team.

APPROVED BY:

This policy has been approved by the CEO and CMO on August 2009.

ATTACHMENTS:

Attachment I: Form 3.02A (9/98): Manufacturer Recall Notification

MANUFACTURER RECALL NOTIFICATION



Notification of Device-Related Hazard	<input type="checkbox"/> Class U - URGENT
Distribution Date _____	<input type="checkbox"/> Class S - SERIOUS
Recall Number _____	<input type="checkbox"/> Class A - ADVISORY
DEVICE(S) INVOLVED	MANUFACTURER: DEVICE: MODEL/SERIAL NO: LOT/DISTRIBUTION:
NOTIFICATION DISTRIBUTED TO:	Name Department
DESCRIPTION OF HAZARD	
SOURCE & DATE OF HAZARD NOTIFICATION	SOURCE DATE
ACTION RECOMMENDED	
ACTION TAKEN	<input type="checkbox"/> We do not have any of the devices identified above. <input type="checkbox"/> We do have one (or more) of the above devices. ACTION REQUIRED/TAKEN: DATE
SIGNATURE/NAME	DATE
Return completed form to the Safety Director	