MATERIEL MANAGEMENT
Section: 520-3
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Issuing Office: Procurement & Contracts

RECALL OF DRUGS, MEDICAL / SURGICAL SUPPLIES, DEVICES, EQUIPMENT AND OTHER RELATED HAZARDS

I. RELATED POLICES

A. UCSD Policy and Procedure Manual (PPM)

523-1 Purchasing Division Charter
523.2.2.1 Narcotics, Dangerous Drugs and Restricted Chemicals

B. Business and Finance Bulletin (B&FB)

BUS 43 Materiel Management

II. PURPOSE

This policy establishes a program for prompt reaction to Notices of Product Recall or Product Modification issued by the Federal Food and Drug Administration (FDA), any manufacturer, vendor, or other source. This program will allow the University of California, San Diego, to respond to such notification, whether it applies to supplies, equipment or any other material.

III. POLICY

A. Precautions should be taken to prevent the use of any item that could be considered injurious to the user.

B. This policy shall apply to the San Diego campus, excluding the Hospital. The Office of Materiel Management shall be responsible for the implementation, coordination, notification, follow-up, and documentation of the program.

C. The Director, Hospital and Clinics shall publish separate internal operating policies for University Hospital, which should be used in conjunction with this PPM.

IV. PROCEDURES

A. Notification of Recalls

The FDA, the manufacturer, distributor or user via mail, telegram, telephone, or in person may notify the University or individuals of product recall, warnings, etc. If an individual receives or reads a notice of product recall or product modification directly from the manufacturer, or personally detects a product defect or problem, that individual should telephone the Recall Coordinator immediately, and forward the information to Q-026.

B. Supplies and Equipment Recall (including vehicles)

1. The Recall Coordinator will review each recall notice to determine if it is applicable to the campus.

2. If applicable, the Recall Coordinator shall in conjunction with the Purchasing Manager, Equipment Manager, and Storehouse Manager identify departments/ units which might need to be notified of the product recall.

3. The Recall Coordinator shall initiate a Product Recall Warning Notice, Exhibit A, with the pertinent information. Then disseminate the *Notice* to the campus department(s) deemed appropriate for action as well as to the Associate Director of Pharmacy, University Hospital, and Office of Environmental Health and Safety within 8 working hours after receiving notification of recall notice.

4. In the case of recalls and warnings where reasonable probability of serious injury or death may result, appropriate department/unit contacts will be telephoned with written follow-ups provided.

5. Departments shall complete the Product Recall Warning Notice\f1, take the appropriate action indicated on the form, and return the original to the Recall Coordinator.

6. The Recall Coordinator will identify collection points where applicable, supervise the disposition of all equipment and supplies affected by the recall warning, and initiate steps to obtain the appropriate credit or replacements from the manufacturer or vendor.

7. The Recall Coordinator will follow-up with all notified areas who have not complied with the recall, and act as liaison between vendor and/or manufacturer and campus units, including UCSD Medical Center.

8. The Recall Coordinator will provide a monthly status report of recall activity to the Materiel Manager.

C. Drug Recalls

1. For drug related recalls, the action taken depends upon FDA recall classifications. Definitions are listed below:

    a. Class One:

    Recalls involving a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

    Action: All products are to be immediately impounded and destroyed or returned to the manufacturer by the Recall Coordinator, according to instruction from the FDA or the manufacturer. FDA inspectors usually check to determine compliance with the regulations.

    b. Class Two:

    Recalls involving a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote.

Action: All products are to be impounded from all areas but are not to be necessarily destroyed until final instructions are received by the Recall Coordinator from the FDA or the manufacturer.

c. Class Three:

Recalls involving a situation in which the use of or exposure to a violative product is not likely to cause adverse health consequences.

Action: The department chair shall exercise administrative judgment in the removal of these products from all areas, and coordinate with the Recall Coordinator the destruction or return of products to the manufacturer.

2. Upon official notification of a drug recall, the Recall Coordinator shall immediately transmit a copy of the notice to the Associate Director, Pharmacy Services, as well as initiate the recall/warning process. (See IV.B.3)

3. In conjunction with the Purchasing Manager and drug commodity buyer, the Recall Coordinator identifies department and staff who might be affected.

V. RESPONSIBILITIES

A. Recall Coordinator

1. Implement the Recall Program.

B. Department Chairs/Unit Managers

1. Take note of recall/warning and institute action if necessary.

2. Identify departmental principal and alternate contact person to be notified of product recalls, and advise Recall Coordinator at Q-026.

3. Check all areas of responsibility for the recalled item.

4. Isolate recalled products.

5. Complete and return the Product Recall/Warning Notice along with any recalled stock to the collection point identified by the Recall Coordinator. Retain department file copy.

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EXHIBIT A

PRODUCT RECALL WARNING NOTICE

TO: _____DATE:_____

IMPORTANT! READ IMMEDIATELY! (SECTION A - TO BE COMPLETED BY RECALL CORDINATOR)

1. The Food and Drug Administration and/or the manufacturer has:

( ) recalled ( ) sent a warning notice regarding the following:
( ) drug ( ) med/surgical supply ( ) device ( ) equipment.

Description _____

Brand _____Manufacturer _____

Unit of issue/dose _____Product Number _____

Lot Number _____UCID and/or Serial Number _____

Reason for recall/warning _____

2. It is necessary that you check your area of responsibility for the item(s) and:

( ) clearly mark and quarantine the item(s) under recall to ensure that the items will not be used.
( ) immediately notify the Recall Coord, Ext. 3082, that you have located the item(s) described above
( ) return the item(s) with a copy of this form and shipping memo to _____
_____

If you have any questions, please call the Recall Coordinator on Extension 3082.

(SECTION B - TO BE COMPLETED BY DEPARTMENT) FILL OUT IMMEDIATELY!

1. ( ) this item is in our stock in the following quantities _____

2. ( ) this item has been quarantined for further disposition. Please call _____at extension _____

3. ( ) this item is not in our area.

Name of person completing form (print or type)

_____	_____	_____
Name	Department	Mail Code
_____	_____	_____
Signature	Date	Extension

Original – Return to Recall Coordinator
Copy 1 – Post for On Week
Copy 2 – Retain for File
Retention Period: 5 Years