

Title:	Product Recall Notification	
Policy No:	1 MRM 008	Effective Date: 06/11/02

OBJECTIVE

The purpose of this policy is to establish a responsible and effective product and medical device recall system for the protection of patients and employees, to comply with government regulations, to avoid claims based on alleged negligence in response to product recalls, and to receive full credit or value from manufacturers for products recalled.

SCOPE

Logistics Management
All Departments

DEFINITIONS

1. **Recall:** as defined by the Food and Drug Administration is a "firm's removal or correction of distributed products that in the judgment of the Food and Drug Administration are subject to legal action under the laws administered by the Food and Drug Administration (Federal Register, 41:26929, June 30, 1976)."
 - a. **Classification of Recalls.**
 - i. **Class I Recalls** can be described as Urgent, Life-Threatening
 - 1) 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.
 - ii. **Class II Recalls** are as serious as Class I Recalls. Corrective action is required.
 - 1) A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible health consequences or where the probability of serious, adverse health consequences is remote.
 - iii. **Class III Recalls**, are described as Advisory.
 - 1) A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Emphasis added.)
 - 2) The FDA has classified recalls into three types, based on the extent of potential harm that could result from use of the product (Federal Register, 41:26929, June 30, 1976).
2. **Defective Product:** Examples of product problems are improper labeling, defective components, performance failure, poor packaging and erroneous information

POLICY

No product or device will be utilized which has been deemed by the FDA, manufacturer, Executive Director, Logistics Management, and/or Director of Infection Control, to be a hazard or that may endanger the safety and welfare of the patient.

PROVISIONS

1. The responsibility for coordinating the product recall process is centralized in the Logistics Management Department.
 - a. Logistics Management may receive notification of product recall either from the manufacturer directly, an FDA enforcement report, or internally from individual departments that have identified a product defect.
 - 1) In the case of internally identified defective products, LM will notify the FDA, Emergency Care Research Institute, and Risk Management.
 - 2) LM contacts manufacturer and completes US Pharmacopoeia FDA Reporting Form.
 - b. The Executive Director, Logistics Management, will subscribe to the weekly FDA Enforcement Reports and other relevant publications and distribute them for investigation and possible action to Director/designate of all departments in the DMC.

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- c. All communications involving a product recall will be forwarded to the Executive Director, Logistics Management, without delay.
 - 1) Departments who receive notification directly from vendor must request a formal recall notice (letter on vendor stationary with product identifiers and reason for recall). Department will notify Logistics Management immediately upon discovery of the recall and forward copy of formal notification letter when available.
 - 2) Immediately upon notification, involved department must remove product from service, tag it, and maintain it in a secure location (see 1 CLN 017 Safe Medical Device Act).
 - d. Logistics will send electronic notification of recalls, including a link to the recall notice, to all departments in the DMC. All departments/recipients are required to send a response back to Logistics Management indicating status of recall with department.
 - 1) See Attachment 1, Product Recall Notification Process.
 - e. The Executive Director, Logistics Management, will maintain a file of all product recall information and resulting action indefinitely.
2. The Pharmacy Department is responsible for coordinating any recall involving pharmaceutical products.

ADMINISTRATIVE RESPONSIBILITY

The Corporate Vice President, Materials Resource Management, has responsibility for overall coordination of this policy.

Should exception to this policy be required, such exception may be made by individuals in the positions designated below. Each exception is to be documented and a copy filed with the Corporate Vice President, Materials Resource Management.

Authorization for policy exceptions can be made by any of the following individuals:

- ◆ President/Chief Executive Officer
- ◆ Executive Vice President/Chief Operating Officer
- ◆ Senior Vice President/Chief Financial Officer

APPROVAL SIGNATURE(S)

Title: Executive Director, Logistics Management

Date

Title Corporate Vice-President, Materials Resource Management

Date

Title Executive Vice-President and Chief Operating Officer

Date

REVIEW DATE 06/11/05

SUPERSEDES 12/08/01, 03/01/98

Refer to attachment: Product Recall Notification Process