Baystate Health
Supply Chain Department
Medical Supplies/Products Recall Procedure

1. DEFINITION

This procedure establishes a mechanism to promptly and effectively respond to Recall, Warning or Alert notifications pertaining to Medical Supplies/Products received by Baystate Health, Inc. (BH). BH considers all such notices to be urgent in nature.

2. PURPOSE

This procedure identifies the required steps and responsible parties involved in identifying, responding to, and documenting Recall, Warning or Alert notifications pertaining to Medical Supplies/Products received by BH.

3. SCOPE

This procedure pertains to all BH employees and its entities.

4. PROCEDURE

BH receives Medical Supply/Product (here after referred to as "product") Recall, Warning and Alert notifications from multiple external sources (External Recall). BH also generates potential internal recalls (Internal Recall) through BH staff observation of product malfunction or failure. Department Managers are responsible for ensuring identified actions for Recall, Warning and Alert notifications are complied with immediately upon receipt of the recall communication.

4.1 External Recall

Upon receipt of a product recall notification from a distributor or manufacturer the following will occur:

1. All notifications related to a Recall must be promptly reported to Inventory Control (IC) within BH Supply Chain's (BHSC) Purchasing Department.
    a. All recall documentations should first be emailed to inventorycontrol@baystatehealh.org with "Recall" in the subject line or faxed to the Purchasing Department at fax extension 24042. The recall documentation should then be sent to IC via inter-office mail.

       The following recall information must be received by Inventory Control (IC) from the person notified of the recall:

       - The original document(s), including the original mailing envelope, if applicable
       - Any enclosed supporting materials (lot number listings, mailing labels, etc.)
       - Contact information of the BH employee reporting the Recall (employee name, telephone extension, and dept.)

    b. In the event of a recall situation after normal business hours, on weekends and/or on holidays, the person reporting the Recall should contact the Hospital Administrator on Call (AOC) through the BH internal web paging system or direct page at beeper 42242.
2. Follow ***Recall Notification Process*** outlined in section 4.3.

4.2 Internal Recall

Clinical Value Analysis (CVA)/Risk Management/Clinical Leadership determine the need to initiate an Internal Recall. The steps to follow include:

1. Assess the known facts, such as reports of product malfunction.
2. Notify the manufacturer of the product malfunction or failure and that an internal recall has been initiated.
3. CVA contacts IC and the Purchasing Agent (PA) with the product information.
4. Follow ***Recall Notification Process*** outlined in section 4.3.

4.3 Recall Notification Process

1. IC documents receipt of the Recall notification in the Inventory Control Recall Database and assigns it a sequential numeric code.
2. IC researches the ordering history within Materials Management Information System (MMIS) for BH companies.
3. IC sends a Recall notification email to the Recall Distribution List (see Appendix B), detailing affected product information, order history, and areas impacted by the Recall. The Recall Action Return Form (see Appendix A) and any Recall documents are included as attachments.
4. IC pages CVA to provide immediate notification of the Recall.
5. If applicable, BH Warehouse Manager/Supervisor sends a "Reply All" response to the e-mailed Recall notification and provides information on how much of affected and unaffected product is available in the BH Warehouse.
6. CVA reviews the notification and affiliated documents. Based on the information provided, CVA determines whether additional information, such as the need to identify a substitute or alternative product, before further distribution of the notification. If so, CVA coordinates this effort with various BHSC staff, who will respond with their findings as directed by CVA.
7. CVA forwards the Recall notification to the appropriate "Designee" (the person responsible for materials management functions for that area) along with action steps and related information. This information may include but is not limited to official recall notice, order history, and Recall Action Return Form.
8. In Step 7, CVA includes clinical experts and other resources as appropriate, which may include but is not limited to: Risk Management, Infection Control, Clinical Directors, Nursing Practice and Professional Development, Clinical Engineering, and the Safety Office.
9. The Designee searches the department(s) for affected product, sequesters affected product if identified, and sends a "Reply All" response to the e-mailed Recall notification with findings.
10. Based on the availability of unaffected product or lack thereof, CVA works with appropriate clinical contacts to determine whether sequestered affected product needs to remain in use, to be discarded or to be returned. CVA communicates final decision via a "Reply All" response to the e-mailed Recall notification.
11. The Designee completes the Recall Action Return Form indicating if the department has affected product, and if so, what the method of return will be. These factors will determine the next appropriate step, as indicated in Table 4-1 below.

12. The Designee confirms completion of all identified actions by a "Reply All" response to the e-mailed Recall notification.
13. Department Managers is responsible to ensure all affected product is removed from the department.
14. CVA notifies IC to officially close the recall and file associated documents and responses in the Inventory Control Recall Database
15. IC coordinates/assists in the disposal of affected product and/or the return of product to the vendor, manufacturer, or Manufacturer Sales Representative (as referenced in Table 4-1).
16. IC completes the corresponding MMIS transactions and/or documentation to arrange the replacement and/or credit through the MMIS.
17. IC maintains in the Inventory Control Recall Database records of all notifications and actions related to Recalls covered under this procedure.

PRODUCT STATUS	ACTION
AFFECTED	**IF THE PRODUCT IS…** **a. To Be Returned to the Warehouse:** The Designee attaches a copy/print-out of the completed Recall Action Return Form to the product and returns it to the BH Warehouse, Attn: Warehouse Supervisor, 30 Bobala Road, Holyoke. **b. Contaminated:** The Designee places the product in an appropriate biohazard container, attaches a copy of the completed Recall Action Return Form, and returns it to the site-specific designated area. **c. To Be Returned via Sales Representative:** The Designee notifies IC that the Sales Representative will be collecting the product ***prior to any action being taken.*** IC will work with the department and the representative to orchestrate the removal and return of the affected product.
NOT AFFECTED	The Designee confirms that this was communicated on the Recall Action Return Form and/or provides this information by "Reply All" response to the e-mailed Recall notification.

5. RELATED POLICIES

BMC Drug Recalls Policy CO 13.190
BMC Medical Device and Biological Product Adverse Event Reporting Program CO 9.113
FMC Medical Device Reporting Program Policy 72
BMLH Medical Device Reporting Program Policy MLH-PI-10 BMC
Patient Safety Management and Reporting Policy CO 9.941 BMC
Adverse Reporting Policy CO 10.960
Materials Management BH Product Substitution Policy 3.2099

		Date
Approved:	Donald Keene, Director Supply Chain	07/05/2012
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Appendix A: Recall Action Return Form

Baystate Health

RECALL ACfiON RETURN FORM

** IMMEDIATE RESPONSE REQUIRED **

Department returning product is required to:
1. Email form by hitting submit at bottom of form o
2. Attach a copy of this completed form to the retu

Return to the attention of: Warehouse Inventory Specialist, Materials Center, 30 Bobala Roac, Holyoke

Affected product must be immediately returned to the BH Warehouse.
The recalled product must be affixed with a copy of this completed form.

Vendor:
Product: Mfr#:
BHSstock#:
Lot#/Exp.
Date:

Date:
Name:
Cost Center:
Department:
Extension:

0 NOT AFFECTED (do *not have producf)*
0AFFECTED (have*producf)*

ACTION

0 Product removed from department and sent to warehouse 8100 0 Product removed and replaced by sales representative O No affected product

Stock/MFG #	Quantity	UOM	Lot#	Item Description

If product js rontamjnated
ched appropriate box and return to:

D BMC: Central Processing Department, Wesson Ground
0 BFMC: Sterile Processing Oepartmen Ground Level
D BMLH: SUrgical Services, Decontamination Room, Second Floor

RECALL#

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Appendix B: Recall Distribution List

- Clinical Value Analysis (CVA)
- Inventory Control Analysts (IC)
- Lead Purchasing Agent (PA)
- Perpetual Inventory Purchasing Agent, in the event that any stock product is involved
- BH Materials & Procurement Assistant Director
- Supply Chain Director
- BH Warehouse Manager/Supervisor
- Ancillary Warehouse Supervisor, in the event that Ancillary Warehouse stock is involved
- Inventory Control shared mailbox

Appendix C: Recall Definitions

Recall: A Recall is defined by the FDA as "actions taken by a firm to remove a product from the market... [and] may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority."

The FDA categorizes recalls into three classes:

> **Class I –** 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.
>
> **Class II –** A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
>
> **Class III –** A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

External Recall: BH receives notification from an external source (FDA, manufacturer, distributor or other source) that a product must be removed from service.

Internal Recall: BH management receives information from an internal BH source that a product may have malfunctioned or failed. BH management investigates the report and if appropriate, contacts CVA.

Product Alert: A communication issued by the FDA, manufacturer, distributor, or other external source to inform health professionals of a risk of possible harm from a product.

Product Substitution: Product Substitution occurs when the original product is either recalled, backordered, discontinued or otherwise unavailable from the manufacturer. The substitution process provides a product or combination of products that clinically and operationally meet the intended purpose of the original product.