
TITLE: EQUIPMENT/PRODUCT RECALLS AND HAZARD NOTICES

PURPOSE:
To communicate, record, and appropriately respond to all manufacturer/vendor and government agency issued medical device and product recall and/or safety notices.

POLICY:
The Procurement & Strategic Sourcing Department (PSS) will oversee the processing and resulting response to all Recalls and Safety Alerts for all NYPH departments, with the exception of Pharmacy, Food and Nutrition, Blood Bank, and Biomedical Engineering, which have their own locally managed procedures for the management of medication, food and blood product recalls.

The PSS department will be responsible for the communication of all manufacturer/vendor and government agency issued medical device and product recall and/or safety notices to the appropriate user departments in a timely manner. Procurement & Strategic Sourcing will assign at least two "Recall Process Administrators" (RPA) who will communicate with end user departments, coordinate response(s) to vendors, maintain a copy of all communications and responses, respond to regulatory agency inquiries (FDA, etc.), and periodically oversee the removal of affected product or the remediation of any affected equipment, as appropriate, or if the user department is not capable of doing so in a prescribed time frame.

APPLICABILITY:
All Hospital and Medical personnel (Personnel)

PROCEDURE:
1. Any Personnel receiving a manufacturer/vendor or regulatory agency issued Recall, Hazard, or Safety Alert notice must contact PSS immediately for instructions. Employees should not take it upon themselves to respond or remove allegedly affected items from use without direction from PSS unless, in their professional estimation, continued use of that product can or will cause harm to a patient, caregiver, other employee, or the facility.

2. Notices for General Supplies and Medical Equipment
   A. Any and all recall notices are to be dated upon receipt and communicated to PSS electronically, via e-mail to recalls@nyp.org.

B. Recall Administrator(s) will review and determine whether or not such product has been purchased and/or is being used in the Hospital by reviewing hospital generated purchase history reports and vendor provided reports, as appropriate.

C. Recall Administrator(s) will notify all departments that may currently use or have historically used or stored any affected product with a copy of the Recall, Hazard, or Safety Alert notice and instructions for response, if different from what is communicated in the notice itself. Recall Administrators will file a copy of the notice and record who the notice was distributed to in a permanent file.

D. Users or suspected user departments will inspect all procedure and storage areas for the recalled product(s) and sequester them or follow any provided instructions, if found. Users are responsible to disseminate the information as per the provided instructions. This may include the hospital and medical staffs. Users will be responsible for promptly notifying Recall Administrator(s) of action taken by either an email outlining the actions taken, or the completion of the "Product/Equipment Recall and Advisory Response Form" and returning it via e-mail to: recalls@nyp.org.

E. The end user is responsible to contact the representative of the company to determine the disposition of the affected goods and obtain credit or acceptable replacements as soon as possible. PSS is available to assist in this process if necessary.

F. An acknowledgement by the end users of the recall notice from the Recall Coordinator must be sent to recalls@nyp.org within 72 hours of receipt of the recall notice. Failure to acknowledge the recall will result in an email reminder of the notice. Without an acknowledgement of the reminder, the recall notice will be forwarded to the Department's Vice President for follow up.

G. A record of action taken is kept in the permanent files of the PSS.

3. Notices for Implantable Devices

A. Notices received by PSS are reviewed by the Recall Administrator (s) to determine if the affected product(s) have been purchased and by what procedure area.

B. Recall Administrator (s) will distribute copies of the notice to the appropriate procedure areas with any instructions for response.

C. Procedure area management will be responsible for working with clinicians to determine the disposition of the affected product(s) if they are no longer in stock.

D. Clinicians are responsible for communicating with affected patients and coordinating any recommended remediation.

E. Clinicians must communicate all remediation to the vendor/manufacturer, regulatory agency, as appropriate, and to the Recall Administrator in an expedient manner.

4. Notices for NYP Direct Source Products

A. Users are to notify the Director of Global Sourcing of any product failure or defect in a NYP direct source product immediately.

B. Director of Global Sourcing will, in conjunction with the Recall Administrator(s), Director of Supply Chain, and clinical leadership for the affected areas, craft a recall communication tool and coordinate the prompt removal of all affected product matching the product and lot codes of the item found to be defective.

C. Director of Global Sourcing (or designee) will be responsible for coordinating the replacement of any product deemed or assumed to be defective with either the same product of a different lot number or have the product replaced with an alternative until the stored inventory can be inspected and verified acceptable for use.

D. Director of Global Sourcing will notify the appropriate trading partner and/or manufacturer of the affected product(s) and negotiate replacement, reimbursement, and/or remediation, as appropriate.

5. Inquiries by Government Agencies

A. Any Hospital or Medical personnel receiving an inquiry from a government agency is to contact the Recall Administrator(s) in Procurement & Strategic Sourcing immediately, using recalls@nyp.org, or through the PSS main number of 297.4500. If the Recall Administrator(s) can not be reached, personnel may direct the agency representative to speak with NYP Legal Affairs. Hospital Staff and Medical personnel are not authorized to respond to inquiries on the hospital's behalf.

B. Recall Administrator will receive the agency representative and take the appropriate information from the representative and commit to a response within two business days or less, as may be indicated by the situation .

6. ECRI Alerts Tracker Recall System
    A. Use of the system is restricted to departmental specific recall coordinators.
    B. Access to the system is granted by the PSS recall coordinators.

RESPONSIBILITY:
VP – Procurement and Strategic Sourcing

REFERENCES:
E-138A Product/Equipment Recall Safety Advisory Response Form

POLICY DATES:
Issued: October 1999
Reviewed: May 2002 (Previously Policy #E115.3)
September 2009; September 2011; September 2013, **Sept 2015**
Revised: September 2005; September 2011; September 2013, September 2015