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| **University of Washington,** **Harborview Medical Center****325 9th Ave. Seattle, WA, 98104****Transfusion Services Laboratory****Policies and Procedures Manual** | **Original Effective Date:** **August 1st 2011** | **Number:** **1706-1** |
| **Revision Effective Date:** | **Pages:**  |
| **TITLE: Supplier Recall of Nonconforming Products**  |

**Purpose:**

To provide directions for the identification, quarantine, retrieval, and recall of nonconforming products, and the notification of recipients, users, and outside agencies as required.

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| **Type of Recall** | **Recall Action** | **TSL Response** | **Supporting Documents** |
| FDA notification by mail/phone | The Commissioner of the Food and Drug Administration or his designee may request initiation of a recall when the following determinations have been made:* A product has been distributed that presents a risk of illness, injury, or gross consumer deception
* A recall of such a product has not been initiated by the manufacturer
* FDA agency action is necessary to protect the public health and welfare.
 | Immediately determine the status of any recalled product.* Call the patient locations to stop transfusions of any issued products that may be have transfusions pending.
* Call the Medical Director if any product(s) have been transfused.
* Remove and quarantine any product left in inventory.
* Complete the Recall Notification Form, and QIM form.

Provide the following to the FDA:* Total amount of the product in TSL inventory.
* Total amount of the product that has been distributed, if any.
* Distribution information
* Name and phone number of the Medical Director and Manager of the TSL.
 | Recall Notification FormQim Form |
| **Type of Recall** | **Recall Action** | **TSL Response** | **Supporting Documents** |
| Manufacturer | * Manufacturers of critical supplies and products may recall a product when they have determined that the product poses a risk to the health and welfare of patients or employees.
* UWMC subscribes to a national list serve for product recalls. The Lab Med designee is Bryce Miller, who monitors the recalls, and notifies the appropriate labs.
 | Remove the product from inventory immediately.* Label the product as Recalled.
* Package for return, as instructed by Manufacturer.
* Document on QIM Form
 | Recall Notification FormQIM Form |
| Blood Supplier | Blood suppliers are required to recall blood products, tissues, or derivatives that are determined after release/distribution, not to conform to specified requirements, when that nonconformance may have affected the quality of the product.* Supplier will call and fax recall information to TSL.
* Supplier will not supply reason for recall.
 | Immediately determine the status of the product(s) involved.* Call the patient locations to stop transfusions of any issued products that may have transfusions pending.
* Call the TSL Medical Director if any product(s) have been transfused.
* Remove and quarantine any product left in inventory, for shipment back to the supplier on the first scheduled shipment.
* Complete the Recall Notification Form and leave for the TSL Medical Director and Manager.
* Complete QIM form
 | Recall Notification FormQim Form |

**References**

AABB Standards for Blood Banks and Transfusion Services, Current Edition.

AABB Technical Manual, Current Edition.