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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:** **1706-3** |
| **Revision Effective Date:**8/15/14 | **Pages:** **3** |
| **TITLE: Quality Process: Recall and Retrieval 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 Reason** | **TSL Response** | **Related 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 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 Form
* Quality Improvement Monitor Form
* Using the Quality Improvement Monitor Form
* Patient Safety Network (PSN)
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| **Type of Recall** | * **Recall Reason**
 | **TSL Response** | **Related 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 Compliance section monitors the recalls, and notifies the appropriate labs.
 | Remove the product from inventory immediately.* Label the product as Recalled Not for Transfusion sticker
* Package for return, as instructed by Manufacturer.
* Document on QIM Form
* File documentation
 | * Lab Med Recall Policy, Process, and Procedure
* Recall Notification Form
* Quality Improvement

Monitor Form* Using the Quality Improvement Monitor Form
* Patient Safety Network (PSN)
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| 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 purity, potency, and safety 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 recalled product(s)* 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 and there is an indication that immediate follow up is necessary as in the case of TRALI or bacterial contamination. Otherwise leave the form for the TSL Medical Director’s review.
* 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
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| Internal Nonconforming Event | **Retrieval:**In the event that a testing error, or instrument malfunction that may affect the purity, potency, or safety of a product is discovered after that product has been issued, all un-transfused products must be retrieved. Partially Transfused products may be retrieved if specified by the Medical Director. | 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.
* Get Medical Director consult for units in process of transfusion.
* Complete QIM form
* Manager will follow BPDR (Blood Product Deviation Reporting) process
 | * Quality Improvement

Monitor Form* Using the Quality Improvement Monitor Form
* FDA-CBER Biological Deviation Reporting
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**References**

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