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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:** **1706-2** |
| **Revision Effective Date:**1/15/14 | **Pages:**  |
| **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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| 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.
 | Remove the product from inventory immediately.* Label the product as Recalled.
* Package for return, as instructed by Manufacturer.
* Document on QIM Form
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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.
* 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 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 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.
* 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 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..