[](http://depts.washington.edu/labweb/index.htm)

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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) |
| 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 |
| **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) |
| 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 |
| 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 |

**References**

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