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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:** **1700-2** |
| **Revision Effective Date:**1/15/14 | **Pages:** **3** |
| **TITLE: QSE: Nonconforming Events** **Quality Policy: Management of Nonconforming events** |

**Policy:**

The Harborview Medical Center Transfusion Service Laboratory maintains processes and procedures that ensure the capture, assessment, investigation, and monitoring of deviations from or failures to meet specified requirements, nonconforming events, and adverse reactions to transfusion. The TSL tracks these events and deviations internally, and reports deviations to outside agencies as required.

* Deviation: Nonconforming event. A planned or unplanned occurrence that does not follow regulatory requirements, and/or the defined policies, processes, or procedures of the HMC TSL.

**Purpose:**

To provide guidelines and directions for the processes and procedures to document, investigate, track, analyze, and take corrective action on events, blood, components, tissue, critical materials or services that fail to meet specified requirements.

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| **Role** | **Responsibilities** | **Related Documents** |
| Medical Director | * Approve deviations from policy beforehand when possible.
* Verbal approvals for deviations will be documented at the first opportunity. May be retrospective.
* Approve any release, disposition, or use of nonconforming products, critical supplies, materials, or services.
* Evaluates the effect on the recipient of recalled products that have been transfused prior to recall, based on recall information provided by the Supplier.
* Evaluates, Consult and advises on medical management of Immediate Transfusion-related adverse events.
* Review and write pathology consultations on all Adverse Reactions to Transfusion both immediate and delayed.
* Advises and notifies recipient’s physician and/or recipient as specified by the FDA for Look-Back process.
* Notifies collecting facility when possible disease transmission is reported or suspected.
 | * Deviation Approval Form
* Look-Back Process
* Suspected Transfusion Reaction Process
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| Manager | * Maintains processes and procedures for capturing, assessing, investigating and monitoring deviations..
* Monitors occurrences, categorizing and reporting as required.
* Reviews Laboratory results for Transfusion-related adverse events.
* Maintains corrective action processes.
 | * Quality Policy: Occurrence Management
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| Staff | * Identifies and reports any deviation.
* Documents and takes remedial action on deviations.
 | * Quality Improvement Monitor Form
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| **Step** | **Action** | **Related Documents** |
| **Deviations** |
| **1.** | * Planned Deviation
* Approved by Medical Director prior to event.
* Documented on Deviation Approval Form
	+ Unplanned Deviation
* Reported through Occurrence Management Process
* Assessed for patient safety by Manager and Medical

 Director.* Reported to FDA if required.
 | * Deviation Approval Form
* FDA-CBER Incident Reporting
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| **2.** | * FDA Reportable Deviations
* Fatalities reported within 24 hours.
* Biological Deviations reported within 45 days.
	+ Safety or Environment of Care deviations reported to appropriate agency.
 | * + FDA-CBER Incident Reporting
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| **Nonconformances—nonconforming products** |
| **1.** | TSL maintains processes and procedure for the review, evaluation, and disposition of nonconforming products including:* Blood
* Components
* Tissue
* Critical materials
* Services
 | * Evaluation of Nonconforming Products and Services
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| **2.** | TSL maintains processes and procedures for:* Identification of nonconforming blood products.
* Quarantine of nonconforming blood products.
* Retrieval of nonconforming blood products.
* Recall of nonconforming blood products.
* Evaluation of products determined to be nonconforming after release, to determine effect of nonconformance on the product.
* Identification and management of nonconforming services.

Notification of users, providers, and outside agencies as required. | * Supplier Recall of Nonconforming Products
* Look-Back Process
* FDA-CBER Incident Reporting
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| **Adverse Transfusion-Related Events** |
| **1.** | * Immediate Transfusion-Related Event:
* TSL maintains processes and procedures for:
* Immediate notification of the transfusion service and the responsible physician.
* Prompt evaluation of all suspected transfusion-related adverse events in a manner that does not delay the proper clinical management of the patient.
* Indicating under which circumstances additional testing is performed, and what the testing will be.
* Immediate and subsequent notification of the collecting facility when a transfusion-related adverse event occurs.
* Documentation in the patient’s medical record of event.
 | * Transfusion Reaction Investigation Process
* Transfusion Reaction Investigation
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| **Step** | **Action** | **Related Documents** |
| **2.** | Delayed Transfusion-Related Event:TSL maintains processes and procedures for:* Performance of testing.
* Evaluation of testing.
* Reporting to the patient’s physician when a delayed reaction is detected or suspected.
 | * Transfusion Reaction Investigation
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| **Reporting of Transfusion-Transmitted Disease** |
| **1.** | Notification of suspected transfusion-transmitted disease may be received from Physician or Recipient. * This notification will be investigated and reported to applicable regulatory agencies and the supplier by the TSL Medical Director.
* Information about any implicated donor units will be provided to the supplier if available.
* Notification. Investigation, and findings will be documented via the Quality Improvement Process.

. | * Quality Process: Quality Improvement
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**References**

AABB Standards for Blood Banks and Transfusion Services, Current Edition

Practical Guide to Transfusion Medicine, Current Edition

Transfusion Reactions, Edited by Mark A. Popovsky, Current Edition.