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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:** **1701-3** |
| **Revision Effective Date:**1/1/14 | **Pages:** **2** |
| **TITLE: QSE: Nonconforming Events** **Quality Policy: Occurrence Management** |

**Policy**

The Harborview Medical Center Transfusion Service identifies, investigates, and implements corrective action for all events with potential adverse outcomes and has established processes and procedures to document or provide for the following:

* Incidents, errors, near-misses, sentinel events, or unexpected occurrences
* Customer complaints
* Anonymous staff reporting of quality or safety concerns that have not been addressed by management.

**Purpose**

To provide direction for the processes and procedures to:

* Reduce risk to patients and personnel by the effective investigation of incidents and occurrences.
* Improve processes and prevent re-occurrences by using the information obtained from these investigations.

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| **Role** | **Responsibility** | **Related Documents** |
| Medical Director and Transfusion Service Manager | * Establish categories of incidents and occurrences.
* Establish the level of investigation appropriate for different categories.
* Review reports, assessing data for trends.
* Initiate corrective action
 | * Quality Improvement Monitor Form
* Specimen Rejection Form
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| Clinical department personnel involved in occurrences | * Participate in the investigation of occurrences and the development of corrective actions.
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| TS Manager and Quality Coordinator | * Establish systems to allow the efficient and effective tracking, reporting, and investigation of occurrences.
* Prepare reports for executive management
 | * Quality Policy: Process Improvement
* Using the QIM Form
* PSN
* Annual Quality Report
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| Laboratory Personnel | * Identify incidents and occurrences.
* Notify Manager immediately of any sentinel event
* Take remedial action as appropriate.
* Report incidents and occurrences.
* Identify opportunities for improvement.
* Report quality or safety concerns per SOP.
* Use anonymous reporting process if safety or quality concerns have been reported to management but are not being addressed
 | * Using the QIM Form
* QIM
* PSN
* Anonymous Communication of Concerns
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| **Quality Element** | **Action** | **Related Documents** |
| Investigation and documentation | * All occurrences are:
* Documented
* Investigate as appropriate.
* Categorized.
* Results of investigations are reported, including any corrective action taken.
* Records or occurrences are retained according to facility policy.
* All serious, or potentially serious events are investigated in a systematic process, such as a root cause analysis.
 | * Quality Policy: Process Improvement
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| Reporting occurrences | * Occurrences are reported, including any corrective action taken.
* Any patient safety issue is reported via the Patient Safety Network reporting system.
* All Biologic Product Deviations are reported to FDA as required.
 | * FDA Biological Deviation Reporting
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| Review | Reports of occurrences are:* Reviewed at regular intervals by management.
* Used to identify opportunities for education and improvement.
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**Reference**

AABB Standards for Blood Banks and Transfusion Services, Current Edition