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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:** **1701-2** |
| **Revision Effective Date:**8/15/13 | **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:

* Incidents
* Errors
* Near-Misses
* Unexpected occurrences
* Customer complaints

**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
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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.
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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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References

AABB Standards for Blood Banks and Transfusion Services, Current Edition