University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: ~~03-15-16~~ 07-19-18 Revision Effective Date: 07-19-18	Number: OM-0002.01

TITLE: Occurrence Reporting

PURPOSE:
To provide instructions for reporting occurrences or nonconforming events via a Quality Improvement Report (QI) or the UWMC Patient Safety Network (PSN)

PRINCIPLE & CLINICAL SIGNIFICANCE:
AABB Standards 9.1 states the following:
The blood bank or transfusion service shall have a process for corrective action of deviations, non-conformances, and complaints, relating to blood, blood components, tissue, derivatives, critical materials, and services, which includes the following elements:

1) Description of the event.
2) Investigation of the cause.
3) Determination of the corrective action.
4) Evaluation to ensure that corrective action is taken and that it is effective.

POLICIES:

- Both QI Reports and PSN are non-punitive, confidential and are covered by Quality Improvement regulations.
- QI Reports are also used to document pre-approved deviation by a TSL Medical Director and will be signed by the Medical Director. There will be times due to patient care when the Medical Director may verbally approve a deviation but is not available to sign until after the deviation has occurred.
- Quality Improvement Monitoring Form is completed for ***any*** deviation, non-conformance, or complaint that is related to any of the following:
  - Blood products
  - Critical materials or equipment
  - Services
  - Staff
  - Work Environment
- QI Reports are assigned unique numbers and tracked on an Excel spreadsheet
- The PSN is a maintained by the University Health System Consortium. It is an electronic system for categorizing and reporting events that relate to patient safety. Events involving sample collection, blood administration, or transfusion that might directly affect patient safety

SPECIMEN REQUIREMENTS:
NA

QUALITY CONTROL:
NA

INSTRUCTIONS:

TABLE of CONTENTS:

Initiating a QI Report

STEP	ACTION
1	Complete a QI Report by the staff member discovering the occurrence or event • Tech ID of person completing the form • Date and Time of the occurrence or incident • Any Patient Name associated with the occurrence. • HID of any patient associated with the occurrence • Unit Number of any product associated with the occurrence. • Component Type of that product. • Geographic Location in the facility associated with the occurrence • Location/Nursing Area of any patient associated with the occurrence • Lab Personnel associated with the occurrence • Record by checking the appropriate box the point in the process where the occurrence was discovered • Objective description of the occurrence
2	Take any immediate action to ensure patient safety (ie. retrieve blood components that are deemed unsafe for transfusion, notify the medical director of wrong tests reported that may be acted upon)
3	Record immediate action taken
4	If the occurrence does / Then Require immediate action by a Manager or Medical Director, or Compliance Analyst → o Notify them immediately; o Notify the lead if none of the others are available Not require immediate further action → Place the QI Report in the appropriate file

Completing Investigation

STEP	ACTION
1	QI is reviewed by the TSL Manager or Compliance Analyst and any further investigation is completed and any follow-up action determined
2	Corrective Actions will be completed. Staff members whose actions lead directly led to the event will sign the QI form acknowledging review and/or corrective action of the event
3	Occurrences identified as Biological Product Deviation will be submitted to the FDA within 45 days of discovery
4	All reports are signed by either the TSL Manager or Compliance Analyst when complete and all reportable events are signed by the TSL Medical Director

Submitting a PSN

STEP	ACTION
1	Staff member completes the PSN using the UHC website database • Go to https://www.uhc.edu/home.htm • Use AMC Username and Password • Categorize the Event type, which is automatically channeled to the appropriate workgroup
2	Completing the Patient Safety Network (PSN) cont. o Enter the Location. o Location managers receive PSN o Enter Harm score. **Note:** Notify manager for any event scoring >4. ▪ Score 1-9, with 9 being most severe. ▪ **1**: Unsafe Condition ▪ **2**: Near miss—action or safeguard prevented the event from reaching the patient. ▪ **3**: Event reached patient, but no harm was evident. ▪ **4**: Event reached patient and caused mild and transient discomfort, anxiety, or pain without requiring additional treatment. (i.e., a repeated blood sample draw) ▪ **5**: Additional Treatment—injury limited to additional intervention during encounter and/or increased length of stay. ▪ **6**: Temporary Harm—Bodily or psychological injury, but likely not permanent. ▪ **7**: Permanent Harm—Lifelong bodily or psychological injury or increased susceptibility to disease. ▪ **8**: Severe Permanent Harm—Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life. ▪ **9**: Death. o Enter description of event.
3	TSL Manager or Compliance Analyst will respond to events that occur due to Transfusion Service Actions

REFERENCES:

- Standards for Blood Banks and Transfusion Services. Bethesda, MD: AABB Press, current edition

RELATED DOCUMENTS:

FORM Quality Improvement
Patient Safety Events and Event Reporting in PSN

APPENDICES:

NA

TITLE: **Occurrence Reporting**	**Number: OM-0002.01**

UWMC SOP Approval:

UWMC CLIA Medical Director Mark H. Wener, MD — Date 7/19/18

Transfusion Service Manager D Stephens — Date 12-16-16
Deanne Stephens

Compliance Analyst Christine Clark — Date 6/27/16
Christine Clark

Transfusion Service Medical Director John R. Hess, MD — Date 6/24/2016

UWMC Biennial Review:

_____ Date _____

_____ Date _____