**Purpose**

To provide instructions for reporting occurrences or nonconforming events in the HMC Transfusion Service Laboratory by utilizing the Quality Improvement Monitoring Form (QIM) and Patient Safety Network (PSN).

Both QIM and PSN are non-punitive, confidential and are covered by Quality Improvement regulations.

**Background**

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 event.
3. Determination of the cause(s).
4. Implementation of the corrective action(s).
5. Evaluation to ensure that corrective action is taken and that it is effective.

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| **Step** | **Action** | **Related Documents** |
| **Completing the QIM Form** | | |
| 1 | Quality Improvement Monitoring Form is completed for ***any*** deviation, non-conformance, or complaint that is related to any of the following:   * Blood products * Tissue * Critical materials or equipment * Services * Staff * Work Environment |  |
| 2 | Top Sections Left and Right to be completed by staff person observing or discovering the QI opportunity:   * Tech ID of person completing the form * Date and Time of the occurrence or incident * Any Patient Name associated with the occurrence. * MRN 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 * Shift of those lab personnel |  |

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| **Step** | **Action** | **Related Documents** |
| **Completing the QIM Form (continued)** | | |
| 3 | The occurrence may be categorized according to the following:   * Pre-analytic - Occurred prior to testing. * Data/Order Entry Issues * Patient ID issues or Requisition issues * Sample issues * Analytic - Occurred during the Testing Process * Delay in testing * Clinical Instruments or Service delay/error * Instrument error/downtime. * Reagent or supply issue * Wrong Sample used for testing. * QC or PM not performed. * Results not verified. * Pending List not printed or reviewed. * Other * Post-Analytical * Critical Value not called or delayed call * Critical Value called but not verified. * Inappropriate sample storage post testing. * Incorrect results/comment reported * Results delayed. * Results mailed or sent to wrong provider. * Results not reported or sent to wrong Dr. * Other * Administrative * Blood Product Inventory backordered. * Billing Error * Daily Operations Reports not run * Blood supplier courier error * Customer Complaint * Environment of Care Issue * Inventory or Supply issue * Vendor supplier issue * Recalled Product * Cab/Delivery service error * Other |  |
| 4 | The bottom section of the front page is for brief description of problem:   * Summarize briefly. * Be objective, no opinions, or personalization. * Provide Who, What, Where, When. * Write legibly. * Attach documentation |  |

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| **Step** | **Action** | **Related Documents** |
| **Completing the QIM Form (continued)** | | |
| 5 | The top half of the back page is for the following categorization:   * Component, Administration, or Transfusion Issue: * Transfusion Tag info wrong or missing * MTP issue * CRYO ordered thawed but not given * FFP ordered thawed but not given * Patient testing not performed/recorded * Product not unpacked in timely manner * Product out of monitored storage >30 minutes * Product spiked, not given. * Product transport issue * BAD file not updated. * Suspected TRRX workup issue * Transfusion Record not completed by nurse. * Trauma Sample Issue. * Unit bag failure. * Unit failed inspection. * Unit hung without proper filer. * Unit issued w/o dispense in SQ * Unit not entered into LIS when returned. * Unit not released as required. * Unit testing not performed/recorded. * Wrong product ordered. * Other. * Computer Issue: * Epic Downtime/issue * Sunquest Lab issue * Hematrax issue * Instrument Interface issue * Printer issue * Copier issue * Other IT issue * Reference Lab Issue * Results delayed. * Communication delay on sample issue * Wrong Test done * Report Issue * Result incorrect or corrected * Sample Lost * Other * Product/Inventory Issue * Unit outdated on shelf * Unit outdated/received as short date |  |

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| **Step** | **Action** | **Related Documents** |
| **Completing the QIM Form (continued)** | | |
| 6 | The bottom half of the back page is for the TSL Manager and/or Compliance Analyst.   * Contributing Factor * Environmental Factor(s) * New Employee (<90 days) * Instrument malfunction/error * SOP not followed * SOP incomplete/in error * SOP not created. * Staffing low/volume high/unusual situation. * Technique Problem * Training Issue * Other * Investigation/Corrective Action Taken * Cognitive (Misinterpretation, faulty decision) * Non-Cognitive (Slip, lapse in attention) * Patient Adverse event – PSN completed. * Sentinel Event - Root Cause Analysis * Root Cause Analysis scheduled. * Revise SOP * Train Staff * Employee follow up * Transfusion FDA reportable events BPDR #\_\_\_\_\_\_\_\_\_\_ * Other * Process or Procedure Change. The manager will document what was changed as corrective action. The Compliance Analyst will decide how to monitor the change for effectiveness. * Manager Review/Date * Investigated by * Follow up by Compliance Analyst will be documented. | Process Design, Validation and Revision  Document Change Control Form  Process Change Control Form |

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| **Step** | **Action** | **Related Documents** |
| **Completing the Patient Safety Network Report (PSN)** | | |
| 1 | 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.  All TSL events that involve sample collection, blood administration, or transfusion, that might directly affect patient safety are reported as usual internally in TSL via the QIM but are also documented in the interactive PSN system as well. | HMC APOP Non-Punitive Event/Incident Occurrence Reporting 115.3  Patient Safety Net Quick Reference Guide |
| 2 | The Frontline reporter completes the PSN using the UHC website database.   * Go to HMC Intranet or link on desktop * Use AMC Username and Password. * Categorize the Event type, which is automatically channeled to the related workgroup: * Enter the Location. Location managers receive PSN * 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. * Enter description of event. * Quality Improvement/ Patient Safety Officer reviews, edits, and consults as appropriate for the event. * Harborview Event Analysis Team reviews any event with a Quality Component and reports the action plan. * Quality Improvement/Patient Safety Officer and Risk Management Team * Review all events with a harm score >6 * Conduct Root Cause if appropriate. * Report Action Plan. |

**References**

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