**Purpose**

To describe the process for design and validation of new processes or revision of those currently in operation.

**Policy Statement**

The design, validation, and revision of processes in the Harborview Medical Center Transfusion Service will be controlled by established processes and procedures to ensure that specified requirements are met.

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| **Responsible Party** | **Action** | **Related Documents** |
| TSL Medical Director  TSL Manager  TSL Staff | * Determines need for new or revised process * May be a minor or major change * May be more or less detailed, depending on magnitude. * May result from any of the following: * Upgrade in Computer System * Creation of new product or service * Change in current product or service * New Equipment or new use for current equipment. * Regulatory requirement * Submits completed Process Change Form and relevant documentation. | * Quality Policy: Change Management * Process Change Control Form |
| TSL Medical Director  TSL Manager  TSL Leads | * Review of Proposed Change may include the following: * Multi-disciplinary consultations * Seeking approval from appropriate entity. * Research about the change. * Review of submitted Process Change Form * Evaluation of resources required for training and implementation. * Review Process must be documented, and documents retained per policy. | * Quality Policy: Change Management * Process Change Control Form * Quality Policy: Documents and Records Management * Quality Policy: Documents and Records Retention |
| TSL Manager  TSL Leads  Subject Matter Experts | * Design of process or change includes: * Work Flow maps * Research and Study * Work group input * Planning Outcome should include * A Validation and/or implementation plan | * Validation Plan Template |

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| **Responsible Party** | **Action** | **Related Documents** |
| TSL Manager  TSL Leads  Subject Matter Experts | * Planning Outcome should include, cont. * Evaluation of Impacts to Stakeholders, resources, and facility. * Creation of Time Line. * Assignment of tasks and responsibilities for validation, training, document preparation, and implementation. |  |
| TSL Medical Director(s)  TSL Manager | * Review and Approve Validation Plan, timeline, training plan and implementation plan. |  |
| TSL Manager  Designated Validator  Validation Team | * Perform Validation per approved Validation Plan. * Submit any anomalies to TSL Manager for review and approval by Medical Director(s). * Anomalies or unexpected findings during validation must be approved by Medical Director(s) and Manager. * Anomalies or unexpected findings may require changes to Validation Plan, and Re-validation. * Ensure any changes to validation are included in training and implementation plans as well as documents. |  |
| TSL Manager  Designated Trainer | * Make Training Assignments with deadlines. * Review all Training Checklists for acceptable performance. * Make any required re-training assignments and review outcomes. * All training checklists must be approved prior to implementation. |  |
| TSL Manager  Designated Leads | * Oversee implementation. * Review implementation for needed adjustments. * Submit documents for any changes required. |  |
| Quality Coordinator  TSL Manager  TSL Medical Director(s) | * Post-Implementation: * Monitor new process via Quality Improvement Process. * Discuss any occurrences with Management. * Track and trend any occurrences for assessment of potential revision. * Design Audit Schedule for monitoring the change. | * Quality Policy: Process Improvement |

**Reference**

Standards for Blood Banks and Transfusion Services, AABB, Bethesda, MD, Current Edition.