**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 DirectorTSL ManagerTSL 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
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| TSL Medical DirectorTSL ManagerTSL 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
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| TSL ManagerTSL LeadsSubject 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 ManagerTSL LeadsSubject 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.
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| TSL Medical Director(s)TSL Manager | * Review and Approve Validation Plan, timeline, training plan and implementation plan.
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| TSL ManagerDesignated ValidatorValidation 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.
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| TSL ManagerDesignated 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.
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| TSL ManagerDesignated Leads | * Oversee implementation.
* Review implementation for needed adjustments.
* Submit documents for any changes required.
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| Quality CoordinatorTSL ManagerTSL 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
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**Reference**

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