**Purpose**

To describe the principles of design/change control that are utilized for the management of operational changes within the Harborview Medical Center Transfusion Service Laboratory.

**Policy Statement**

The design of new or changed Laboratory processes, services, documents, or products will be controlled by established processes and procedures to ensure that specified requirements are met.

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| **Control Element** | **Action** | **Related Documents** |
| Change Proposal  | * Any proposed change to processes, procedures, or protocols should include:
* Completed Change Control Form
* Definition of scope
* Goal of the change
* Additional resources required.
* Training resources required.
* Type of Verification and/or Validation required.
* Appropriate documentation.
* Any change may be more or less detailed, dependent on the magnitude of the change.
* Proposed changes will be reviewed by the TSL Medical Director and Manager, and forwarded for approval of Transfusion Practice Committee if deemed appropriate by the Medical Director.
* Records of Change Control are maintained in conformance with policy.
* New Product, Process, or Service—must include:
* Physical and performance criteria
* Regulatory impact and requirements
* Customer service impact and requirements
* Impact on resources.
* Impact on facility
* Equipment—must include:
* Impact on resources.
* All equipment is validated prior to being placed into use, and after major repairs.
 | * Managing Regulatory Changes
* Document Development and Revision Process
* Document Change Control Form
* Process Design, Validation, and Revision
* Process Change Control Form
* Equipment Validation Process
* Validation Template
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| **Change Elements** | **Action** | **Related Documents** |
| Implementation Plan Development  | * Use a multi-disciplinary team approach for changes affecting other stakeholders.
* Discuss and evaluate proposed changes with key staff and stakeholders prior to implementation
* Evaluate and determine whether processes and

procedures meet regulatory requirements.* Evaluate and determine resources required for the change.
* Create plans for training, validation, and implementation
* Define competency interval and scope of competency testing.
* Verify and document that the implementation plan meets the criteria listed in the Change Proposal.
* Maintain the documentation per policy.
 | * Process Design, Validation, and Revision
* Training Process
* Competency Process
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| Verification  | * A process intended to check that a product meets the set of design specifications proposed by the vendor and approved by the FDA.
* Used prior to implementation of an established, FDA approved reagent kit, for the first time in our laboratory, i.e. Elution kits.
* Used prior to implementation of an established testing method for the first time for the first time in our laboratory, i.e. Antibody Titer
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| Validation | * A process intended to ensure that a product, service, or system meets the needs and requirements for which it is being implemented.
* Used prior to implementation of a new process, or equipment.
* Used after major equipment repair, before putting back into use.
* Used prior to implementation of a test method for which the FDA has not approved.
* Used for major software updates, prior to implementation.
* Ensures that the change meets acceptance criteria prior to implementation.
 | * Process Design, Validation, and Revision
* Equipment Validation Process
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| Change Review**Change Elements** | * Review of the change should take place post-implementation.
* Corrective actions should be monitored for effectiveness using the Process Improvement Process.
* Audit
* Staff Competency performed at 6 months if indicated.

**Action** | * Quality Policy: Process Improvement
* Quality Improvement Monitor Form
* Quality Process: Competency Assessment

**Related Documents** |
| Change Control | * Any change to processes, procedures, or protocols should include:
* Definition of scope
* Goal of the change
* Additional resources required.
* Type of Verification and/or Validation required.
* Appropriate documentation.
* Any change may be more or less detailed, dependent on the magnitude of the change.
* Proposed changes will be reviewed by the TSL Medical Director and Manager, and forwarded for approval of Transfusion Practice Committee if deemed appropriate by the Medical Director.
* Records of Change Control are maintained in conformance with policy.
 | * Process/Design Change Control Form
* Document Change Control Form
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| Documentation | * All Records of Change Control are maintained in conformance with policy.
 | * Quality Policy: Document and Records Management
* Quality Policy: Records Retention
* Quality Process: Archive and Retrieval of Documents and Records
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**References**

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