**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 |
| **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 |
| 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 |  |
| 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 |
| 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 |
| 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 |

**References**

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