**Purpose**

To describe the process used in the HMC TSL to control changes to Sunquest-generated product labels.

**Policy Statements**

* All product labels applied by HMC TSL staff are generated by Sunquest (SQ) LIS.
* Base label stock is printed on a Hematrax label printer using Digitrax software interfaced with SQ LIS.
* All software is licensed by UWMC Laboratory Medicine IT Department.
* HMC is a paid subscriber to ISBT label software, Facility ID # W 3795.
* All ecodes and the corresponding label generated are validated as part of the LIS validation and change control procedures.

**Process**

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| **Role** | **Responsibility** | **Related Documents** |
| **Medical Director** | * Has final responsibility for department compliance with Blood Label Control policy and process.
* Approves Validation Plan for label changes.
* Approves Validation Test Scenarios for label changes.
 | * Validation Plan Template
* Process Change Control Form
* Quality Process: Validation
* Lab Med IT Change Control Policy
* Quality Improvement Monitor Form
* Quality Process: Occurrence Reporting
* FDA CBER Biological Deviation Reporting
* Validating Changes to Blood Product Labels
* Blood Product Label Validation Form
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| **Manager** | * Acts as liaison with Blood Supplier for proposed changes in product codes.
* Completes Process Change Control Form for any Label Change.
* Coordinates the Label Change Validation Process with Lab Med IT Department.
* Oversees development of Label Change Validation Plan and Test scenarios.
* Reviews Label Change Validation Plan and Test Scenario results.
* Ensures that Validation is completed prior to implementation.
* Works with Leads to develop staff training material as part of the Label Change Implementation.
* Ensures that staff training is completed prior to implementation.
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| **Quality Manager** | * Monitors Change via Quality Improvement Monitor Forms.
* Reports any issues to Manager and coordinates corrective action where appropriate.
* Reports any BPDRs per SOP.
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| **Role** | **Responsibility** | **Related Documents** |
| **Lab Med IT** | * Makes proposed changes to Sunquest Maintenance Database.
* Works with Transfusion Services to validate changes in TEST system.
* Implements changes in LIVE environment when all validation is complete and approved.
 | * Lab Med IT Policies and Procedures
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| **TSL Staff** | * Performs validation as assigned
* Submits appropriate paperwork to manager for review
 | * Validating Changes to Blood Product Labels
* Blood Product Label Validation Form
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**Reference**

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