**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 |
| **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. |
| **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. |
| **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 |
| **TSL Staff** | * Performs validation as assigned * Submits appropriate paperwork to manager for review | * Validating Changes to Blood Product Labels * Blood Product Label Validation Form |

**Reference**

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