**Purpose**

To describe the process for assessing regulatory changes for impact to operations.

**Background**

The Harborview Transfusion Service maintains compliance with current regulatory requirements as documented in the following:

* College of American Pathologists Accreditation Checklists.
* Standards for Blood Banks and Transfusion Services, AABB
* Code of Federal Regulations, 21 Parts 200 to 299, parts 600-799
* Circular of Information

**Process**

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| **Step** | **Action** | **Related Documents** |
|  | * When new regulations are released via CAP checklist, new AABB standards, Circular of Information, or FDA published guidance, the Quality Coordinator, Manager, or Lead will review the new regulations for changes and impacts. | * Annual Regulatory Update Schedule |
|  | * Each change will be compared side by side with any previous requirement, if applicable. |  |
|  | * Impacted TSL process, procedure, or policy will be reviewed for compliance with new regulation. |  |
|  | * Any gaps will be analyzed, and a plan for reaching compliance will be documented on the Regulatory Change Review Form. | * Regulatory Change Review Form |
|  | * Each process or document impacted will be listed on the form. |  |
|  | * All changes will be addressed by revision or additions to policies, processes, or procedures. |  |
|  | * A Training Plan will be developed and implemented in accordance with current policy. * Competency testing will be administered at six months post change implementation. | * Training Process * Training Evaluation Process * Competency Testing Process |
| **Step** | **Action** | **Related Documents** |
|  | * All changes will be made in accordance with the Change Control Policy. | * Quality Policy: Change Control |
|  | * After all changes are completed, the Quality Coordinator will write a summary report, which will be filed in the Regulatory Review Manual. |  |