**Purpose**

To describe the process used to validate and implement new procedures, processes, and equipment or make changes to those that are currently in use

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**Document Validation and Implementation**

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| **Responsible Party** | **Action** | **Related Document** |
| * TSL Manager * TSL Staff | * Determines need for new or revised Document: Procedure, Policy, or Form | * Document Change Control Form |
| * Document Author * TSL Manager | * New Document: Use Appropriate Template * Writes new document or revises current version. * Determines if other documents are affected by the new or revised document and makes revisions to those if necessary. * Follows Change Management Policy * Submits all document drafts to TSL manager. | * Document Change Control Form * SOP/Policy/Process Template * Form Template * Copy of current version * Copies of other affected documents * Manufacturer’s recommendations * Package insert * Operator’s Manual * Current AABB Standards |
| TSL Manager | * Verifies completeness of information * Verifies adherence to format. * Consults with Medical Director if needed. * Consults with Leads for review. * Assigns Document Number if new. * Routes to Leads for assignment to staff for validation and suggestions. | * Master Documents List * Procedure and Process Validation Checklist * Form Validation Checklist * Draft of Document being written or revised |
| Staff assigned to validate | * Reviews the draft document. * Using the document, performs the task or process described, following each step of a new document, or the changed steps in a revised document. * Completes the Validation Checklist, adding comments as appropriate. | * Draft of Document being written or revised * Procedure and Process Validation Checklist * Form Validation Checklist |

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| **Responsible Party** | **Action** | **Related Document** |
| Author or TSL Manager | * Reviews comments from validation * Resolves any discrepancies * Makes any necessary changes | * Draft of Document being written or revised * Procedure and Process Validation Checklist |
| TSL Manager | * Routes back to staff involved to review changes. | * Final Draft of new or revised document |
| TSL Manager | * Repeats cycle above if more changes are needed. * Makes final changes. * Files electronically in “Awaiting Approval” folder on TSL Documents Drive. * Prints Master Copy on pink paper. * Completes Document Approval Form.. | * Master Copy |
| Medical Director | * Approves and signs the Master Copy of New or Revised Document. | * Pink Master Copy |
| TSL Manager | * Emails copy to Training Specialist for posting in LMS for Staff review. | * Electronic Master Copy |
| Training Specialist | * Assigns “Must Review By” date. * Posts to LMS which sends electronic notification of required review to each staff member. | * Electronic Master Copy |
| All TSL Staff | * Review new or revised document in LMS. * Answer questions assigned to the document. * Complete the document review. | * Electronic Master Copy |
| TSL Manager | * Moves Electronic Document to Appropriate folder in TSL Documents. * If a revision, archives Electronic copy of previous version, by moving it to Archived folder, by Document number. * Prints Manual Copy of new version and replaces old version in Procedure manual. * If a revision, archives pink Master Copy of previous version in Archived drawer. * Files New version of pink Master Copy in Master Document File Drawer by Document Number, along with Document Control Form, Validation Checklist, and Staff Review List from LMS. | * Electronic Master Copy * Document Approval Form * Document Change Control Form * Staff Review List * Procedure and Process Validation Checklist |

**Reference**

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