**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**

|  |  |  |
| --- | --- | --- |
| **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
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**Reference**

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