**Purpose**

To provide guidelines for the development of validation protocols for new or revised processes as well as the qualification of new equipment other than computers.

**Process**

|  |  |  |  |
| --- | --- | --- | --- |
| **Step** | **Responsible Party** | **Activity** | **Related Documents** |
| **1** | * Transfusion Service Manager or Designee
 | * Develops, writes, and submits protocol.
* Assigns Validation Team
* Identifies Processes and/or Equipment that requires validation.
 | * Validation Plan Template
 |
| **2** | * TS Medical Director
* TS Compliance Analyst
 | * Reviews and approves validation protocol.
 |  |
| **3** | * Designated TSL Personnel
 | * Writes draft Procedure(s)
 | * Document Change Control Form
* Procedure and Process Validation Checklist.
* Format Standards for Document Creation and Revision
 |
| **4** | * Designated TSL Trainer
 | * Writes Training Plan
* Completes any necessary pre-validation training.
 | * Quality Process: Training
 |
| **5** | * Validation Team
 | * Performs the validation and collects the data
 |  |
| **6** | * TS Manager or Designee
 | * Prepares summary of results obtained.
 |  |
| **7** | * TS Medical Director
* TS Manager
* TS Compliance Analyst
 | * Reviews validation data
* Reviews result summary
* Approves or disapproves validation.
* Finalizes and approves Procedure(s).
 |  |
| **8** | * Designated TSL Trainer
* TSL Manager and Leads
 | * Trains remaining staff
* Implements the process
 | * Quality Process: Training
 |

**References**

Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks. AABB Press, Bethesda, MD.