**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**

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| --- | --- | --- | --- |
| **Step** | **Responsible Party** | **Activity** | **Related Documents** |
| **1** | * Transfusion Service Manager or Designee | * Develops, writes, and submits protocol. * Assigns Validation Team | * Validation Plan Template |
| **2** | * TS Medical Director * TS QA Coordinator | * 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 | * 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, AABB, Current Edition