**Policy:**

The Harborview Medical Center Transfusion Service has established processes and procedures that comply with applicable standards and regulatory requirements for the retention of time-sensitive and critical laboratory documents and records.

**Purpose:**

To provide direction for the processes and procedures for the retention of time-sensitive and critical laboratory documents and records.

**Principle:**

Documents will be retained onsite for adequate time to provide access for potential investigation, as deemed necessary. Applicable documents will be sent for archival off site for a designated period of retention as necessary per regulatory standards.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document or Record** | **Active Storage- On Site** | **Short term Storage- On Site** | **Short term retention period** | **Archived Off site retention period****(total)** |
| **Inventory Management & Pending Lists** |
| Daily Blood Issued Final report | Daily Reports notebook | Filing cabinet | 2 months | 10 year |
| Daily Operations Reports: 4,12,14 | Daily Reports notebook | Filing cabinet | 2 months | N/A |
| BBR2 - Blood Bank Inventory Summary | Administrative Secured Filing cabinet | Filing cabinet | 24 months | N/A |
| Label Verification Form | Filing cabinet | Filing cabinet | 2 months | 10 years |
| PL - Pending Test Log | Pending Reports notebook |  | 2 weeks | N/A |
| Order Distribution Report/Packing Slip | Filing cabinet |  | 2 months  | 10 years |
| **Inventory reports:*** Notification of abnormal results
* Look-back investigations
* BPDR reports
 | Administration Secured Filing Cabinet |  | 10 years | N/A |
| **All supplier records*** Evaluation and performance of suppliers
* Supplier agreements
* Validation of new or changed processes
 | Administration Secured Filing Cabinet |  | 5 years | N/A |
| **Document or Record** | **Active Storage- On Site** | **Short term Storage- On Site** | **Short term retention period** | **Archived Off site retention period (total)** |
| **Patient Testing and Transfusion Records** |
| **Bone Flap Tracking Records**:* Current Inventory & Quarantine
* Issued
* Discarded
 | Tissue Tracking, Tissue Discards, and Tissue Issue notebooks |  | 2 years | 10 years post implant or discard |
| Blood Products Received with Transfused Patients Log | Transferred with Patient’s Log notebook |  | Current year | 10 years |
| HMC Transfusion Record | Electronic | Indefinite |
| Modification to Patient Blood Product Restrictions Form | Modification Forms notebook |  | 2 months | N/A |
| Historical Data Reconciliation and Linking Form  | LINK notebook |  | 2 months | N/A |
| Patient/Unit Antigen Typing Worksheet | Patient-Unit Antigen Typing notebook |  | Current year | 10 years |
| Request for Urgent Blood Product Release | Trauma Logs Current Month notebook | Trauma Logs Previous Month notebook | 2 months | 10 years |
| Trauma and Massive Transfusion Protocol Response LogCredo Cooler Log (used products) | Trauma Logs Current Month notebook | Trauma Logs Previous Month notebook | 2 months | 10 years |
| Credo Cooler Log (unused products) | Credo Cooler Log notebook |  | 2 yearsrolling calendar | N/A |
| **Transfusion Reaction Form, including:*** Immediate evaluation including clerical review of all immediate Suspected TX Reactions
* Interpretation of the evaluation of Suspected Immediate TX Reactions
* Evaluation and interpretation of Delayed TX Reactions
 | Filing cabinet |  | 10 years | Indefinite  |
| * TS Blood Products Release Form
* Portable Refrigerator Response Log
 | Filing cabinet | Filing cabinet | 2 months | 10 years |
| TS Testing & Blood Product Order Form, paper Epic orders | Filing cabinet | Filing cabinet | 2 months | 10 years |
| Antibody Identification Workups | Filing cabinet | Indefinite |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document or Record** | **Active Storage- On Site** | **Short term Storage- On Site** | **Short term retention period** | **Archived Off site retention period****(total)** |
| **Policies & Communications** |
| MLS Shift Duties Checklist  | Clipboard in technical area | Filing cabinet | Rolling calendar year | N/A |
| CLT Shift Duties Checklist | Clipboard in CLT area | Compliance Analyst | 6 months | N/A |
| Shift Hand Off Form | Shift Reports notebook | 2 weeks | N/A |
| Transfusion Service Updates | Communication log | Current year | N/A |
| TSL Staff Meeting Minutes | Electronic | Indefinite |
| TSL Lab Staff Document Review in MTS system | Electronic | Indefinite |
| Archived policies and procedures | Electronic Archival Indefinite; Master Copy 10 years. |
| **Quality Assurance & Maintenance** |
| **Manual Reagent QC Forms:*** Antigen Typing QC Record
* Daily Manual Testing QC Form
 | Manual Reagent QC Forms notebook | Filing cabinet | Current year + prior year | 10 years |
| **Manual Testing Bench QC Forms:*** Bench Daily Reagent & Equipment QC Form
* Cell Washer Daily QC Form
* Heat block Daily QC Form
 | Manual Testing QC Notebooks (labeled, one per bench) |  | Current year + prior year | 10 years |
| Quality Improvement Monitoring Form (QIM) | Secured Admin area filing cabinet | Current year | 10 years |
| BBR7 Quality Assurance Report | Secured Admin area filing cabinet | Current year + prior year | 10 years |
| Equipment Validation and Qualification | Electronic: indefiniteMaster Signed copy: Secured Administration Filing cabinet, 10 years post retirement of equipment | N/A |
| Refrigerator, Thawer, Rotator temperature logs | Daily QC Log notebook | Freezers, Portable Refrigerators, and Blood Refrigerators notebooks | Previous and Current year | 10 years |
| Refrigerator, Thawer, Rotator alarm check logs | Daily QC Log notebook |  | Previous and Current year | 10 years |
| TempTrak logs and/or audits | Temptrak binder |  | 1 year | Electronic |
| Tango Control Journal | Tango Daily QC Reports notebook | Filing cabinet | Current year | 10 years |
| Tango Maintenance Form | Tango Maintenance Notebook |  | Current year | 10 years post retirement of equipment |
| **Document or Record** | **Active Storage- On Site** | **Short term Storage- On Site** | **Short term retention period** | **Archived Off site retention period****(total)** |
| Testing Cellular Reagent Antigrams  | Antigram Master Binder | Electronic  |
| Testing Reagent Package InsertsReagent Receipt Record for Validation SuppliesTS Review of Package Insert Form | Reagents Package Insert Notebooks |  | Current year | 10 years |
| **Assessment Records:*** Internal Audits
* Corrective Actions
 | Electronic | 5 years Secured Administration Filing Cabinet | 10 years |
| **Assessment Records:*** CAP Survey results
* Blood Usage
 | CAP notebooksAdministrative Filing Cabinet | 5 years in TSLAdministrative Filing Cabinet | N/A |
| **Laboratory Information System** |
| **Sunquest:*** Patient Test Results
* Patient Information and transfusion history
* Unit Receipt, visual inspection, confirmation testing, modification and final distribution
 | Indefinite |
| All validations of Computer Systems | Master in LAB MED IT department | 2 years post retirement of system |
| **Human Resources** |
| **Personnel records:*** Job descriptions
* Qualifications to perform critical tasks
* Training records
* Competency records
 | Labmed HRTraining and Competency Filing Cabinet | 5 years | 10 years post employee exit |
| Records of names, signatures, initials, or identification codes, and inclusive dates of employment for staff that perform or review critical tasks | Quality Plan Notebook | 5 years | 10 years |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition

CAP checklist

Washington State Regulations V1.9 and V6.1