**Policy:**

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

**Purpose:**

To provide direction for the processes and procedures:

* To create and control documents and records so that all documents are in standard formats.
* To create and control documents and records so that all authorized users only work from current documents.
* To archive documents and records in such a manner that access is only by authorized personnel.

|  |  |
| --- | --- |
| **Role** | **Responsibilities** |
| **Medical Director** | * Ensure that document control systems are established, and meet regulatory requirements.
* Approve the contents of controlled documents before use.
* Approve substantive changes to controlled documents before implementation.
 |
| **Laboratory Manager** | * Create or supervise the creation of controlled documents.
* Review and approve validation of documents before use.
* Review and approve changes to documents before implementation.
 |
| **Laboratory Personnel** | * Follow documented processes, procedures, and instructions as written, without personal deviations.
 |
| **Document Author** | * Follow documented processes, procedures, and instructions as written, without personal deviations.
* Develop and revise controlled documents.
 |

|  |  |  |
| --- | --- | --- |
| **Process Element** | **Process Control** | **Related Documents** |
| **Controlled Documents** | * Are created, reviewed, and approved by authorized personnel before release.
* A Master Document Index is maintained to identify the current valid revisions, and their distribution.
* Only currently authorized versions of appropriate documents are available for active use.
* Are uniquely identified. Such identification complies with regulatory requirements and good laboratory practice.
 | * Master Document Index
* Document Life Cycle
 |
| **Document Review** | * Documents are periodically reviewed, revised when necessary, and approved by authorized personnel before implementation.
* Review of documents is defined in the formal document control process.
 | * Document Development and Change Control Process
* Document Change Control Form
 |
| **Invalid or Obsolete Documents** | * Invalid or obsolete documents are promptly removed from all sites of use.
* Retained or archived superseded documents are appropriately identified to prevent their inadvertent use.
 | * Document Life Cycle
 |
| **Changes to Documents** | A formal means of making revisions to documents has been developed to ensure that:* Only authorized changes are made to approved documents.
* All changes are reviewed and approved before use.
* All copies of the document in use reflect the change.
 | * Document Development and Change Control Process
* Document Change Control Form
 |
| **Access to Results** | * + ***Note****: See QSE Information Management*
 |  |
| **Retention of Reports** | * + - Copies of results are maintained in accordance with regulatory requirements, either electronically or in hard copy.
 | * + - Quality Policy: Records Retention
 |
| **Corrected Reports** | * + - The UW Laboratory Medicine Department has established processes and procedures to ensure that corrected or altered reports are clearly identified and comply with regulations. They ensure the following:
* The original results is not deleted or made illegible.
* The corrected result is clearly identified.
* The time and date of the correction is captured.
* As defined, the attending physician is directly notified of the correction.
 | * + - UW Laboratory Medicine Administrative Manual
 |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition