**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 List 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 List * 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 Revision 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 * Retained or archived superseded documents are appropriately identified to prevent their inadvertent use.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 Revision Process * Document Change Control Form |
| **Access to Results** | * + ***Note****: See QSE Information Management* |  |
| **Retention of Documents and Records** | * + - Documents and Records are maintained in accordance with regulatory requirements, either electronically or in hard copy.     - Documents and Records are archived and stored for potential retrieval. | * + - Quality Policy: Records Retention     - Quality Policy: Archive and Retrieval of Documents and Records |
| **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     - Canceling and Correcting Results in Sunquest |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition