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| **University of Washington,** **Harborview Medical Center****325 9th Ave. Seattle, WA, 98104****Transfusion Services Laboratory****Policies and Procedures Manual** | **Original Effective Date:** **August 1, 2011** | **Number:** **1301-1** |
| **Revision Effective Date:** | **Pages:** **2** |
| **TITLE: QSE: Equipment Management** **Quality Policy: Computer System Management** |

**Policy:**

Harborview Medical Center Transfusion Service uses computer hardware and software systems that are appropriate for the scope and workload of the laboratory. Systems are chosen or selected in accordance with the organization’s computer selection process. Such systems ensure the security, completeness, and validity of patient information and other critical laboratory information.

**Purpose:**

To provide direction for the processes and procedures to effectively install, operate, and maintain the laboratory computer system.

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| Role | Responsibility | Supporting Documents |
| Medical Director | * Participates in the selection of the new LIS
* Approves all significant changes to the LIS or clinical decision support systems that may affect patient care.
* Oversees the use of applications within the department.
* Review and approve validations and modifications.
 | UWMC Lab Medicine IT Department Policies and Procedures. |
| Manager | * Develop LIS Processes, workflows, and procedures.
* Ensure that only authorized users operate the computers.
* Ensure that the environmental and operating conditions that are necessary to maintain the integrity of data are met.
* Ensure that computer validations are performed.
* Ensure that processes and procedures are in compliance with applicable regulations.
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| Laboratory Staff | * Use computers as necessary for work functions.
* Follow facility-wide computer policies, processes, and procedures.
* Notify applicable IT personnel with computer problems.
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| Laboratory Medicine IT Department | * Develop policies, processes, and procedures that record the choice, implementation, validation, integration, and security of laboratory information systems or clinical decision support systems.
* Provide routine maintenance and troubleshooting support of the laboratory information system or clinical decision support systems.
* Requalify computer performance after repairs or system upgrades.
* Provide appropriate backup and redundancy for laboratory records, including patient information.
 | UWMC Lab Medicine IT Department Policies and Procedures. |
| **Role** | **Responsibilities** | **Supporting Documents** |
| Vendor | * Certify that the system conforms to good manufacturing practice and regulatory requirements.
* Guarantee to support the system for the duration of the contract with the laboratory/hospital.
* Ensure that documentation is provided for the applications and upgrades used in the laboratory.
* Provide support to the IT department and the laboratory for use, development, and maintenance of the LIS.
 | Sunquest Contract with UWMC Lab Medicine Dept. |
| Physical Plant | * Assess and provide necessary physical requirements for the safe operation of laboratory information systems.
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| Computer System Validation | Computer system programs and processes are validated or revalidated to ensure the integrity and accuracy of data and calculations:* Before use in the laboratory
* After program changes, system upgrades, or system modifications.
 | HMC Blood Bank Validation Documents |
| Computer Training | The laboratory has established procedures for training personnel:* On the function and use of the LIS at orientation
* As required when the system is modified or upgraded.
 | * Quality Process: Training
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| System Maintenance | * A process and schedule are in place for preventive maintenance, monitoring, and documenting the performance of all computer equipment.
* There is a process for immediate investigation and appropriate corrective action upon activation of a system malfunction.
 | * UWMC Lab Medicine IT Department Policies and Procedures.
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| Computer Identification | Each item of computer equipment is given a unique label or other identification. | * UWMC Lab Medicine IT Department Policies and Procedures
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References

AABB Standards for Blood Banks and Transfusion Services, Current Edition.

FDA Guidance for the Industry Blood Establishment Computer System Validation in the User’s Facility,

FDA—CBER, October, 2007