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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:** **1300-2** |
| **Revision Effective Date:**7/1/2020 | **Pages:** **2** |
| **TITLE:** QSE: Equipment Management Quality Policy: Equipment Management |

**Policy:**

Harborview Medical Center Transfusion Service Laboratory has established and maintains processes and procedures for the provision and use of laboratory equipment that is appropriate for the medical needs, scope, and workload of the laboratory, and is in accordance with the organization’s critical equipment selection process. HMC Transfusion Service defines critical equipment as that which is essential to providing required services to patients and customers.

**Purpose:**

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

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| **Role** | **Responsibilities** | **Related Documents** |
| **Laboratory Management** | * Ensures that mechanisms to determine criteria and methods for acquisition/replacement, installation, validation, maintenance, operation, inspection, troubleshooting, service and repair are in place.
* Ensure that a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents, and analytical systems is established.
* Ensure that only authorized users operate equipment.
* Provide a safe work environment for the operation of equipment.
 | Schedule for Routine Maintenance and QC of equipment |
| **Medical Director** | * Has ultimate responsibility for instrument performance, including validations and problem logs.
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| **Manager** | * Maintains a critical equipment list.
* Ensure that equipment validations are performed before use and after repairs as appropriate and that validations include installation, operational and performance qualification.
* Ensure that processes and procedures are in compliance with appropriate standards and regulations and are followed.
* Ensure that scheduled maintenance and routine calibrations are performed.
* Monitors equipment performance.
 | Critical Equipment ListSchedule for Routine Maintenance and QC of equipmentHelmer Cell Washer QC and MaintenanceMaintenance and Troubleshooting of Blood Storage DevicesHelmer Plasma Thawer QC and MaintenanceARK Microwave Plasma Defroster QC and Maintenance |

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| **Role** | **Responsibilities** | **Related Documents** |
| **Compliance Analyst** | * Reviews Storage Device Temperature logs and maintenance monthly
* Reviews Storage Device alarm checks quarterly
 | Refrigerator/Freezer QC/Maintenance |
| **Laboratory Staff** | * Follow manufacturer’s instructions and applicable safety procedures for the safe operation of equipment.
* Perform scheduled maintenance.
* Troubleshoot equipment performance and determines if other equipment is similarly affected.
* Perform routine calibration.
* Requalify and recalibrate equipment after repairs or system upgrades by designated personnel.
 | Schedule for Routine Maintenance and QC of EquipmentResponding to Temperature Alarms |
| **Scientific Instruments** | * Perform scheduled maintenance as required by manufacturer.
 | Schedule for Routine Maintenance and QC of Equipment |
| **Facility Engineering** | * Assigns unique identifier for all equipment when received.
* Perform installation qualification as part of equipment validation process
* Assess and provide necessary physical requirements for the safe operation of laboratory equipment.
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| **Supplier/Vendor** | * Provide proof that the equipment meets the specified needs of the laboratory, and meets the installation qualification requirements for new, or repaired, equipment.
* Provide support for the equipment for a defined period of time. This may include preventive maintenance, repairs, technical support, and recalibration.
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| **Reference and Therapeutic ranges** | * As appropriate, reference and therapeutic ranges are established before equipment is placed into use.
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| **Equipment Maintenance** | * A process and schedule are in place for preventive maintenance, monitoring, and documenting the performance of all equipment.
* There is a process for immediate investigation and appropriate corrective action, upon activation of the alarm system for storage devices equipped with alarm systems.
 | Responding to Temperature AlarmsSchedule for Routine Maintenance and QC of equipmentQuality Policy: Process Improvement |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition