



<b>University of Washington Medical Center</b> <b>1959 NE Pacific Street. Seattle, WA 98195</b> <b>Transfusion Services Laboratory</b> <b>Policies and Procedures Manual</b>	<b>Original Effective Date:</b> <b>09-30-2019</b>	<b>Number:</b> EQ-0011.01
	<b>Revision Effective Date:</b>	
<b>TITLE: Equipment Preventative Maintenance Requirements</b>		

**PURPOSE:**

- To provide a schedule and mechanism to ensure equipment is maintained according to manufacturer and regulatory laboratory standards and readily available to equipment operators. To maintain and document timely review of equipment maintenance records.

**PRINCIPLE & CLINICAL SIGNIFICANCE:**

Equipment used in the testing of patient and donor samples and handling, storing and manufacturing of blood components must be cleaned and maintained according to a defined schedule. At a minimum, written policies and procedures for maintenance and cleaning must be in-line with manufacturer’s recommendations. Equipment used in measurement should be calibrated routinely against a known standard. In addition to manufacturer recommendation and laboratory standards, the Code of Federal Regulations specifies minimum calibration frequency for some equipment. A written schedule should include all requirements and when sources differ, the most restrictive or frequent recommendation applies.

Maintenance, function checks and calibrations must be documented and reviewed monthly to ensure and demonstrate compliance. A written and posted Equipment Maintenance Schedule provides a visual mechanism to monitor and ensure equipment is properly maintained and calibrated per requirements. Records of maintenance should be reviewed monthly and should readily available for review by inspectors or assessors and for laboratory staff to verify maintenance is up-to-date prior to use.

**POLICIES:**

**Maintenance Requirements:**

- Equipment is validated before use and after repairs, as appropriate. Initial validation includes installation, operation, and performance qualification as applies to the device. Validation after repair may not include all aspects of the initial validation and is dependent on service performed.
  - Initial validation is reviewed and approved by the TSL Medical Director, TSL Operation Manager and TSL Quality Manager
- Equipment used for testing patient and donor samples and storing, handling and manufacturing of blood components is maintained, calibrated, and function checks performed according to manufacturer’s recommendations, Code of Federal Regulation and laboratory standards.
- Written policies and procedures for performing maintenance, calibration and function checks are maintained for individual types of equipment and not included in this document.
- All Transfusion Services staff is responsible for using only equipment that is maintained and calibrated according to the Equipment Preventative Maintenance Schedule and required quality control is performed and up to date prior to use. It is the responsibility of each individual to ensure maintenance is up-to-date on any equipment used.
- **Appendix 1: Equipment Maintenance Requirements and Equipment Preventative Maintenance Schedule** provide visual guides of the frequency and tasks required for each type of equipment.

- Equipment not maintained according to the **Equipment Preventative Maintenance Schedule** will not be utilized for testing or manufacturing of blood components until requirements are met.

#### **Documentation and Record Review:**

- The **Equipment Preventative Maintenance Schedule** is posted in a location easily visible to all staff.
- Maintenance performed by Transfusion Service Laboratory staff is documented on the appropriate form.
- Maintenance performed by UWMC internal contracted entities, UWMC Scientific Instruments or UWMC Operation and Maintenance Refrigeration department, or outside service providers should be documented by the service personnel and the service record submitted to a TSL manager for review
- Maintenance performed on blood storage equipment by UWMC Operation and Maintenance Refrigeration department is recorded on the appropriate form and a copy is sent to the TSL Operation and Quality Manager.
- Maintenance performed by outside contracted entities should be documented per service provider specification and a copy left with in the TSL. There may be some instances where service provider policies require internal completion or review of the form prior to providing the TSL a copy of the record. In such instances, the due date and method of delivery should be confirmed prior to the service technician leaving the site.
- Supervisory review and assessment of maintenance, calibration and function check records is performed at least monthly.
- Completed records are retained in labeled binders and stored where accessible to all TSL staff. After 2 years retention, records may be archived and can be retrieved from the archives when needed.

#### **REFERENCES:**

- Manufacturer Operating & Service Manuals
- Technical Manual, current edition, Bethesda, Maryland, AABB
- All Common Checklist – University of Washington Medical Center, current edition, Northfield, IL, College of American Pathologists
- Code of Federal Regulation, Title 21, Food and Drugs Administration, current edition, Government Printing Office, Washington, DC

#### **RELATED DOCUMENTS:**

SCHEDULE Equipment Preventative Maintenance Schedule  
FORM Cell Washer & Scale QC  
FORM Bench Equipment  
FORM Blood Component Storage Temperature  
FORM COBE 2991 Quarterly Function Check  
FORM Irradiator Monthly Maintenance Log  
FORM Plasma Thawer Quarterly & Annual Maintenance Form  
FORM Refrigerated Centrifuge QC  
FORM Serologic Centrifuge Calibration Worksheet  
FORM Thaw Bath & Heat Block QC Form  
FORM Thermometer Calibration Worksheet  
FORM Vision Maintenance  
FORM TSL Refrigeration Quarterly Maintenance  
FORM Platelet Incubator/Agitator Maintenance

<b>TITLE: Equipment Preventative Maintenance Requirements</b>	<b>Number:</b> EQ-0011.01
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<b>UWMC SOP Approval:</b>	
<b>UWMC CLIA Medical Director</b>	_____ Date _____
	Mark H. Wener, MD
<b>Transfusion Service Manager</b>	_____ Date _____
	Nina Sen
<b>Compliance Analyst</b>	_____ Date _____
	Christine Clark
<b>Transfusion Service Medical Director</b>	_____ Date _____
	Monica Pagano, MD
<b>UWMC Biennial Review:</b>	
	_____ Date _____
	_____ Date _____

**TITLE: Equipment Preventative Maintenance Requirements**

**Number:**  
EQ-0011.01

**APPENDICES:**

Appendix 1: Equipment Maintenance Requirements

Equipment	Frequency						
	Daily	Weekly	Monthly	Quarterly	As Needed	Biannually	Annually
Liquid Thermometer							Verification with NIST
Plasma Thawer Digital Thermometer					Clean		Calibration
Fluke					Verification of accuracy each time a new wire probe is used		Calibration
Tachometer							Calibration
Stopwatch							Verification with NIST
Timers							Verification with NIST
Weights					Clean		Calibration
Genesis Rapidweld			Clean				PM by manufacturer service rep
Genesis Tube Sealer		Clean			Adjustment of tubing seal thickness, and replacement of the splash guard and the fuse is strongly recommended		
Scale	Verify calibration				Clean		
Dry Bath	Temperature Verification		Clean		Clean		
Megafuge Centrifuge			Clean rotor, buckets and accessories, clean filter mat			Tach and Timer Checks	
Serofuges		Clean, check rotor for wear and corrosion			Replace rotor	Tach and Timer Checks	Optimal Spin Time Calibration
Cell Washers	Inspect tubing, drain and saline fill volume	Flush the system, clean the fill ports	Inspect rotor, tube holders, Clean exterior		Replace tube holder inserts Replace rotor every 4 years	Tach and Timer Checks	Optimal Spin Time Calibration Replace

**TITLE: Equipment Preventative Maintenance Requirements**

**Number:**  
EQ-0011.01

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	Daily	Weekly	Monthly	Quarterly	As Needed	Biannually	Annually
							supply, drain, and pump tubing.
<b>Cobe Cell Processor</b>			Periodic Clean, Check overflow bottle	Quarterly Function Check	Cleaning – routine (after every procedure)		PM by manufacturer service rep
<b>Refrigerated Centrifuge</b>		Clean housing, chamber, rotors, accessories Check rotor seating	Check rotor and accessories for wear and corrosion, Lubricate trunnions		Replace rotor when expired	Tach and Timer Checks	
<b>Irradiator</b>			Inspection & cleaning  Download of previous month irradiation verification checks			Dosimetry Testing	PM by manufacturer service rep
<b>Ortho Workstation</b>	Temperature Check, Speed Display check,				Cleaning including under the incubator, replace fuses,	Tach and Timer Checks	
<b>Ortho Vision</b>	Probe decontamination	Liquid system decontamination Pump test	Instrument cleaning, Image area cleaning, data backup				PM by manufacturer service rep
<b>Plasma Thawer</b>	Temperature verification	Clean and replace water		PM- includes high alarm check, lubrication of moving parts and check/calibration of temperature controller			Calibration of electronic thermometer and check bearings
<b>Refrigerators</b>	Temperature Verification	Change Temperature Charts		PM – includes alarm checks, calibration of temperature monitor, and annual PM			Performed Quarterly
<b>Freezers</b>	Temperature Verification	Change Temperature Charts		PM – includes alarm checks, calibration of temperature monitor, and annual PM			Performed Quarterly
<b>Platelet Incubator</b>	Temperature Verification	Change Temperature Charts		PM – includes alarm checks,			Agitator PM: all other Maintenance performed

**TITLE: Equipment Preventative Maintenance Requirements**

**Number:**  
EQ-0011.01

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	Daily	Weekly	Monthly	Quarterly	As Needed	Biannually	Annually
				calibration of temperature monitor & temperature controller and annual PM			quarterly
<b>TempTrak</b>							Calibration QARA Verification of probe settings
<b>Microscopes</b>							Performed by Scientific Instruments
<b>Eye Wash</b>		Check water pressure flow					
<b>Pipette</b>							Calibration
<b>Data Logger</b>							Replaced when calibration expires
<b>Temptrak Pager</b>		Battery check					