


Name of Policy:	Equipment Calibration/ Validation/Preventative Maintenance	
Policy Number:	3364-108-103	
Department:	Pathology/Laboratory – Blood Bank	
Approving Officer:	Associate Professor Director, Clinical Pathology/Hematopathology	
Responsible Agent:	Core Lab Coordinator (Michelle Bartkowiak, MT(ASCP)SBB) Manager, Lab (Cynthia O’Connell)	
Scope:	Pathology/Laboratory – Blood Bank	Effective Date: 6/9/2008 Initial Effective Date: 6/1996
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Minor/technical revision of existing policy <input type="checkbox"/> Major revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy		

(A) Policy Statement

The Blood Transfusion Service has a defined program to identify, assess the function and condition and to maintain equipment used in the department.

(B) Purpose of Policy

To assure safe and expected function of equipment.


(C) Procedure

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
All centrifuges	Daily	Clean with Quat Disinfectant	NA	NA
Serological Centrifuge 36337 36338 36339	Quarterly or after repairs	Timer accuracy: optimum time of centrifugation See 500.010	2800 RPM (±50); timer corresponds with stopwatch; optimum time of centrifugation determined by calibration.	Refer to Biomed. Dept.
MTS centrifuges	Biannually	Check RPMs, timer accuracy	895±25 RPM 10:00 min ±10 sec	Factory pre-set: calibration performed by Biomed.
Impact MTS-pipettors	Annually	Check amount dispensed at 25µ and 50µ settings	See 500.085	Refer to Biomed Dept.
Automatic cell washer CW-1 2415	Monthly	Rinse interior with deionized water; check saline levels; check bowl and tubing for crack/leaks/proper positioning. Soak carrier/head in (soft) soapy water; rinse well with DI water.		Change saline as needed Repair, or refer to Biomed Dept as necessary.

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
Automatic cell washer	Quarterly, Before use and after repair	Measure dispensed saline volume. See 500.020 and Cellwasher Function Verification and Maintenance Log for scheduled procedures. Replacement of seal	CW1 (54± 2 ml.)	Adjust to correct dispensing volume; if not corrected, notify Biomed Dept.
Water baths 35309 8305	Daily	Record Temperature	30-37°C	Adjust setting
	At least weekly or as needed	Drain, disinfect with hospital-supplied detergent, refill with DI water		
Heating blocks 8604 8650 MTS Incubators 33836 33834	Daily	Record Temperature	37° C ± 1° C	Adjust and calibrate using separate procedure MTS Incubators are factory preset. Refer to Ortho.
Heating blocks MTS Incubators	Quarterly, Before use and after repair	Check temperature of all wells (500.060)	37° C ± 1° C	Cover unacceptable wells; adjust heat block temp and repeat; if not corrected, refer to Biomed. Dept.
Blood Warmers 2389 3434 5515	Each day of use	Check display temperature and alarm activation	37° C or less; alarm at 38° C or greater	Refer to Biomed dept.
Blood Warmers	Biannual	Electrical check; temperature check and alarm activation	same as above	Performed by Biomed. Dept. Repair as needed.
Sealer	Biannual	Electrical check; Decontamination/ Cleaning as needed		Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Centrifuge	Biannual	Electrical check; Decontamination/ Cleaning as needed	3600 rpm	Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Platelet Agitator	Biannual	Electrical check; Decontamination/ Cleaning as needed		Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
Storage Units Zone 1 Zone 2 Freezer Zone 3 Zone 4 Zone 6 Plc Incubator	Daily, Before use and after repair	Record temperature, assure proper chart recorder function. Ensure operating conditions are appropriate to manufacturers instructions	See policy 3364-108- 201	See policy 3364-108- 201
Storage Units	Quarterly, Before use and after repair	Alarm and temperature display check	See policy 3364-108- 201	See policy 3364-108- 201
Coolers	Before use	Monitor internal temperature maintained with cool-paks or ice. Check temperature indicators of units returned after storage in cooler.	<10 °C after 12 hrs	Do not use for storage
Hemo-Temp indicators	Before implementat ion	Comparison of indicator with RBC units wrapped around NBS thermometer	Temp indicated matches NBS thermometer within 2 °C	

Validation of expected function is performed on all new and repaired equipment. Equipment and Storage units must be monitored and meet acceptable criteria for 24 hours before placing in service. Designated staff in the Blood Transfusion Service performs validation, calibration and maintenance procedures. Procedures for maintenance and calibration are written and performed according to manufacturer's instructions and accreditation standard requirements. The BTS supervisor reviews records of validations, calibrations and maintenance. The BTS supervisor initiates corrective actions. Records of equipment maintenance, repair and equipment operation are available in the BioMed Department and the BTS supervisor office.

<p>Approved by:</p> <p style="text-align: center;"></p> <p>Robert L. Booth, Jr., M.D. _____ Date</p> <p>Associate Professor Director, Clinical Pathology/Hematopathology</p> <p>Review/Revision Completed By: Michelle Bartkowiak, MT(ASCP)SBB</p>	<p>Review/Revision Date:</p> <p>6/96 1/98 3/99 7/00 5/02 1/05 1/2008 6/9/2008</p> <hr/> <p>Next Review Date: 6/1/2011</p>
<p>Policies Superseded by This Policy:</p>	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.

References:

Reference: AABB Standards for Blood Banks and Transfusion Services, current edition.