TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	8.18.2014
Department:	Blood Bank	**Due Date:**	9.15.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Equipment Policy for Transfusion Services

Description of change(s):

AABB standard 5.1.8.1.3 has been edited to the following:

For storage of blood or blood components, the temperature should be monitored continuously and recorded at least every 4 hours.

This was added to the SOP (when the chart is down).

Quest Diagnostics

Document No.: WAHQDHOS702[1.0B]
Title: EQUIPMENT POLICY FOR TRANSFUSION SERVICES
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 17-Sep-2014 **Next Review Date:**

Non-Technical SOP

Title	**Equipment Policy for Transfusion Services**
Prepared by	Priscilla Sundara, Manager, NQA-CP Date: 12/01/10

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval		
Owner/BPT Leader	Dianne Zorka	
BPT Medical Advisor	R. Schlesinger, M.D.	
Signature	*Approval on file*	Date: 5/5/2011
Chief Laboratory Officer/Designee	Stephen Suffin, M.D.	
Signature	*Approval on file*	Date:
Corporate Issue Date		

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1. PURPOSE

This policy provides direction for development of processes and procedures used to effectively manage transfusion service instruments and equipment.

2. POLICY

The laboratory must establish and maintain processes and procedures that ensure calibration, maintenance, and monitoring of equipment in conformance with all federal regulations and accreditation requirements.

3. SCOPE

This policy applies to all Quest Diagnostics Managed Hospital laboratories.

4. RESPONSIBILITY

Responsible Party	Task
Laboratory Director or designated **Technical Supervisor** (qualified in the specialty of Immunohematology)	• Provides initial approval of this Policy • Ensures implementation of this Policy.
Department Manager/Supervisor	• Implements and maintains this Policy as part of the laboratory's local policies. • Ensures applicable training is performed.
Blood Bank **Staff**	• Complies with this Policy.

5. KEY ELEMENTS

The laboratory maintains:

- A process to identify all equipment critical to the provision of blood, components, tissue, derivatives, and/or services.
- Policies and procedures for each piece of critical equipment, describing calibration, maintenance, and monitoring, as applicable.
- Records of calibration, preventive maintenance, equipment monitoring, repairs and troubleshooting.
- A process for defining criteria and methods for acquisition/replacement, installation, validation, calibration, maintenance, operation, inspection, troubleshooting, service and repair of all equipment.
- Criteria and mechanism for retiring outmoded or obsolete equipment.
- The use of standardized devices and materials.
- An equipment master log.

Equipment Selection

- The laboratory maintains a process for defining the selection criteria for equipment.
- Equipment is validated for its intended use.
- Devices and equipment are validated on receipt, prior to patient testing.
- Equipment (including computer hardware) is used in conformance with manufacturer's written instructions.

Equipment Identification

- Each piece of critical equipment is given a unique identifying number prior to being placed into service, i.e. serial numbers, asset numbers, or other unique identifying number assigned by the laboratory.

Monitoring

- Each department maintains a process and schedule for monitoring all critical equipment.
- Calibration of equipment and preventive maintenance are performed at a minimum, in accordance with manufacturer's instructions.

Calibration

- Critical equipment is calibrated and adjusted:
  1. Prior to use,
  2. After activities that may affect the calibration, and
  3. At prescribed intervals.
- Only equipment that has been proven to have adequate accuracy and precision will be used.
- Safeguards are implemented to prevent adjustments that would invalidate the calibration setting.

Investigation and Follow-up

- Assessment of service compliance is made when equipment malfunctions or fails, is found to be out of calibration, or is involved in an adverse event. This review must include:
    1. An assessment of affected blood, components, tissue, derivatives, and services provided.
    2. An assessment of the effect on patient safety.
    3. Steps to ensure that the equipment is removed from service.
    4. An investigation of the malfunction, failure, or adverse event.
    5. Steps for revalidation of the equipment.
    6. Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.
- When a piece of equipment does not function as expected or breaks down while in use, it will be affixed with a "Do Not Use, Not in Service" sign and taken out of service until it is repaired.
- All service and repairs must be documented.
- All function checks must be performed prior to placing equipment back into service.

Storage Devices

- The laboratory maintains storage devices that have the capacity and design to ensure that the proper temperature is maintained.
- The laboratory maintains a process to monitor and record the temperature of storage devices.
- The Transfusion Services Department maintains a process for continual monitoring as well as alarm notification when temperatures fall outside of established range.
- Each component storage unit must have an audible alarm; the alarm must be continuously monitored 24 hours per day (in laboratory or remotely).
- The response system to an alarm must be validated.
- For component storage units lacking continuous automated temperature recording (e.g. refrigerators, freezers, and platelet incubators), the temperatures are monitored continuously and recorded at least every 4 hours
- The blood in the refrigerator must be arranged to facilitate the location and separation of units such as different groups and types of blood, unprocessed blood, blood that is suitable for issue or release, quarantined, rejected or outdated units, autologous units, and crossmatched and non-crossmatched units. Such a system is important to minimize the inadvertent transfusion of the wrong unit.

Alarm Systems

- Transfusion services storage devices are equipped with alarm systems.
- Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action. All action taken must be documented.
- Specific procedures must be documented and understood by personnel handling blood and blood components if storage temperature limits cannot be maintained. The primary concern is the preservation of blood. If there is a power failure, arrangements must be made for service, and for alternative storage of blood.

- Alarms are set to be triggered before the temperature falls outside the acceptable temperature range. This provides the opportunity to take action before the temperature of blood or components falls outside of acceptable ranges. For examples: refrigerators with an acceptable range of 1 - 6 ° C, the alarm must be set to trigger at 1.5 ° C or greater and 5.5° C or lower. For freezers with an acceptable range of ≤ -18° C, the alarm must be set to trigger at -19° C or lower.
- An alarm system check (Alarm Activation) must be performed on a quarterly basis (for both low and high settings where applicable) and results recorded.
- Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

Equipment Records

The following records are kept:

- Equipment identification.
- Results of calibrations and follow-up actions.
- Results of maintenance and follow-up actions.
- Temperatures of heat-regulated equipment.
- Fulfillment of applicable life-cycle requirements.
- Numerical designation of system versions (where applicable) with inclusive dates of use.

6. RELATED DOCUMENTS

QDQC710	Laboratory Method Validation for Quantitative and Semi-Quantitative Methods
QDNQA702	Procedure for Centrifuge Maintenance and Function Checks
QDNQA703	Procedure for Thermometer Selection and Accuracy Verification
QDNQA603	Process for Pipetting Device Calibration Checks
QDNQA704	Procedure for Monitoring Temperature Dependent Equipment

7. REFERENCES

Standards for Blood Banks and Transfusion Services, 27th edition, AABB, 2011.
AABB Technical Manual, 16th edition, 2008.
Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.60]
Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.160(b)(3)(iii)]

8. REVISION HISTORY

Version	Date	Section	Revision Purpose	Reviser	Approval
1.0	7/25/11		Minor formatting changes to header, footer and margins Supersedes SOP WAH/SGAHQDHBB300 v1.0A	L. Barrett	Dr Cacciabeve
A	8.18.14	5	Added that refrigerators are monitored continuously and temps recorded every four hours as required by AABB std 5.1.8.1.3	S. Codina	Dr Cacciabeve
		Footer	New local version numbering adopted per corporate policy change	L. Barrett	

9. PROCESS DOCUMENT RETIREMENT

Version	Date	Reason for retirement/superseded by	Name