3. EQUIPMENT

3.0 Equipment

The BB/TS shall identify the equipment that is critical to the provision of blood, blood components, tissue, derivatives, and/or services. The BB/TS shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these *BB/TS Standards* and other specified requirements.

3.1 Selection of Equipment

The BB/TS shall have a process to define the selection criteria for equipment.

3.2 Qualification of Equipment

All equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment requalified, as appropriate, based on the facility's policies and manufacturer recommendations.

3.2.1 Installation Qualification

Equipment shall be installed per the manufacturer's specifications.

3.2.2 Operational Qualification

The functionality of each piece of equipment and each component of an information system shall be verified before actual use and shall meet the manufacturer's operational specifications.*

3.2.3 Performance Qualification

The BB/TS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.

3.3 Use of Equipment

Equipment shall be used in accordance with the manufacturer's written instructions.

3.4 Unique Identification of Equipment

Equipment shall have unique identification. Standard 5.1.6.2 applies.

*FDA Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility (April 2013).

3.5 Equipment Monitoring and Maintenance

The BB/TS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer's written instructions. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

3.5.1 Calibration of Equipment

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed as described below unless otherwise indicated by the manufacturer:

1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting. Standard 5.1.3 applies.

3.5.1.2 Calibration procedures shall follow the manufacturer's written instructions and shall include:

1) Instructions for performing calibrations.
2) Acceptance criteria.
3) Actions to be taken when unsatisfactory results are obtained.

3.5.2 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1) Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications.
2) Assessment of the effect on donor eligibility and donor and patient safety.
3) Steps to ensure that the equipment is removed from service.
4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected.
5) Steps for requalification of the equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.*

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

*21 CFR 803.30.

3.6 Storage Devices for Blood, Blood Components, Reagents, Tissue, and Derivatives

3.6.1 Storage devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.8.1.3 applies.

3.6.2 Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored. Standard 5.1.8.1.3 applies.

3.6.3 If storage devices utilize liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored.

3.7 Alarm Systems

Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards:

3.7.1 The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, derivatives, or reagents reach unacceptable conditions.

3.7.2 The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level.

3.7.3 Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action. Standard 5.1.3 applies.

3.8 Warming Devices for Blood and Blood Components

Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components. Standard 3.5 applies.

3.9 Information Systems

The BB/TS shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these *BB/TS Standards*. Standard 5.1.1 applies. These processes shall include:

1) Risk analysis, training, validation, implementation, and evaluation of postimplementation performance.
2) System maintenance and operation.
3) Documentation written in language understandable to the user.
4) Display and verification of data before final acceptance, when data are added, or when data are amended.
5) Evaluation, authorization, and documentation of modifications to the system.