
2. RESOURCES

2.0 Resources

The BB/TS shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the BB/TS.

2.1 Human Resources

The BB/TS shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

2.1.1 Qualification

Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

2.1.2 Training

The BB/TS shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.


2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.*

2.1.3.1 Action shall be taken when competence has not been demonstrated.

2.1.4 Personnel Records

Personnel records for each employee shall be maintained.

 **2.1.4.1** For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

*42 CFR 493.1235 and 42 CFR 493.1451(b)(8)(9).

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 a computer 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.