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## 3. EQUIPMENT

### 3.0 Equipment

The perioperative program shall identify the equipment that is critical to the provision of perioperative blood components. The perioperative program shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to these *Perioperative Standards* and other specified requirements.

#### 3.1 Selection of Equipment

The perioperative program shall have a process to define the selection criteria for equipment.

#### 3.2 Equipment Qualification

Equipment shall be qualified for its intended use.

##### 3.2.1 Installation Qualification

Equipment shall be installed per 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 perioperative program shall demonstrate that equipment performs as expected for its intended use in the perioperative program's work processes. Standard 5.1.1 applies.

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**3.2.3.1** Performance specifications shall be established and met for all equipment.

**3.3 Use of Equipment**

All equipment that is qualified to collect, prepare, process, test, store, or administer perioperative blood components shall be used in accordance with the manufacturers' written instructions or facility-defined procedures. The perioperative program shall validate devices and equipment, including Food and Drug Administration (FDA)-cleared or -approved devices, for their intended use.\*

 **3.4 Unique Identification of Equipment**

Equipment shall have unique identification. Standard 5.1.6 applies.

**3.5 Equipment Monitoring and Maintenance**

The perioperative program shall have a process for scheduled monitoring and maintenance of equipment. 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 follows:

- 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 adjustments that would invalidate the calibrated setting. Standard 5.1.2 applies.

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\*21 CFR 211.68.

- 3.5.1.2** Calibration procedures shall follow 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 the following:

- 1) Assessment of the conformance of components provided when equipment is found to be out of calibration.
- 2) Assessment of the effect on the donor/patient.
- 3) Steps to ensure that the equipment is removed from service.
- 4) Investigation of malfunction, failure, or adverse event.
- 5) Steps for requalification of equipment.
- 6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer and/or regulatory agencies, when indicated.\*

Chapter 7, Deviations, Nonconforming Components or Materials, and Adverse Events, applies.

**3.6 Storage Devices and Storage Containers for Perioperative Blood Components**

The perioperative program shall have storage devices and/or storage containers (eg, portable coolers) for collected perioperative blood components, if applicable.

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\*21 CFR 803.30.