QSE 3 – Equipment

Key Concepts

This QSE describes the selection, use, maintenance, and monitoring of equipment, including information systems. It also describes the use and testing of alternative systems when primary systems fail.

Key Terms

Backup: Digital data and/or physical storage containing copies of relevant data.

Calibrate: To set or align measurement equipment against a known standard.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials: A piece of equipment or material that can affect the quality of the organization's products.

Data Integrity: The accuracy, completeness, and consistency of information resources.

Equipment: A durable item, instrument, or device used in a process or procedure.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Processes for equipment selection, qualification, and maintenance.
- List or tool used for critical equipment identification.
- Equipment calibration and maintenance records, if applicable.
- Equipment qualification records.
- Manufacturer's written instructions.
- Records of investigation of equipment malfunction, failure, repair, and requalification, if applicable.
- Alarm system testing and records of alarm management, if appropriate.
- Evidence of information system backup and records of testing.

3. Equipment

3.0 Equipment

The organization shall define and control critical equipment.

Guidance

The program is required to define a list of equipment that is critical to its operations. Critical equipment used for collection, processing, and/or storage of blood components or used for laboratory testing (eg, point-of-care hemoglobin devices in the preoperative anemia clinic and point-of-care coagulation equipment within the operating rooms, emergency department, ICU, or elsewhere) should be suitable for the task and should be maintained appropriately. Acceptable operational limits for equipment should be defined, and processes and procedures should indicate the course of action when these limits are not achieved.

When purchasing equipment, the program should consider the following guidance:

- Identify suitable equipment.
- Approve the purchase agreement, as required in Chapter 4, Suppliers and Customers.
- Obtain the equipment.
- Inspect it upon arrival.
- Validate the equipment and maintain records of the validation.
- Ensure training and competency of staff for use of the equipment.
- Use the equipment in a suitable working environment.
- Maintain the equipment.
- Perform quality assurance and proficiency testing, if applicable.

The PBM program should have a voice in any discussion considering the selection, maintenance, and purchase of equipment—not only equipment controlled by the program but devices used by other departments that would provide patient care or have a direct impact on the PBM program (in this case the transfusion service itself).

Examples of equipment that would be covered by this standard include:

- Blood warmers.
- Storage devices for blood and blood components (including alarm systems).
- Intraoperative blood recovery equipment.
- Computer systems or information systems.
- Point-of-care testing devices.

Examples of activities that assessors may ask about:

- How is equipment qualified and installed?
- How is the equipment maintained and where is the documentation?
- Is equipment used in conformance with the manufacturer's written instructions?
- Is equipment uniquely identified and its use recorded in a manner that permits traceability?
- For analytical equipment (eg, point-of care devices), what calibration program or quality assurance is in place?
- How are equipment malfunctions or failures investigated?

Given the multidisciplinary nature of a PBM program, the devices are often not owned by the program but instead controlled by the respective department(s) that utilizes them. The program shall define the responsibility for the critical equipment and should ensure that those departments are meeting the intent of this standard. See Standard 3.2.

3.1 Equipment Specifications
Equipment specifications shall be defined before purchase.

G u i d a n c e

Standard 3.1 is a commonly cited standard for nonconformances. Examples of the reasoning behind the nonconformances include the following:

1. Equipment maintenance is not performed per manufacturer's instructions.
2. There is no evidence of validation of new equipment.
3. There is no procedure for assessing acceptability of cellular therapy products when equipment is found to be out of calibration.

3.2 Qualification of Equipment
All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.

3.2.1 Installation Qualification
Equipment shall be installed per manufacturer specifications.

3.2.2 Operational Qualification
Each piece of equipment and component of an information system shall be verified before actual use.

3.2.3 Performance Qualification
Equipment shall perform as expected for its intended use.

G u i d a n c e

When considering equipment purchase or relocation, the program should have a documented process verifying that the equipment or system is capable of performing the expected task or controlling the activity according to written and preapproved specifications. The equipment or system should be tested to ensure that it performs as described in the manufacturer's specifications, in the operator's manual, or in facility expectations. In this last phase of the equipment qualification cycle, the facility verifies that the user requirements and specifications are met.

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

G u i d a n c e

Before the actual selection of equipment for use, criteria to consider are the types of procedures to be performed, the reports to be prepared, the intended instrument operators, the type of environment in

which the equipment will be used, the expected production and turnaround time, and other facility- or practice-specific needs. These criteria can then be used to assess the various equipment options and determine which ones best meet the needs (qualification). After selection, the equipment should then be validated to ensure that it operates as expected and that an appropriate intended output can be produced before its use for patient care. If equipment cannot be used in accordance with the manufacturer's written instructions, evaluation of the impact of that deviation should be part of the validation protocol.

3.4 Unique Identification of Equipment
Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance
Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.

3.5.1 Calibration and Accuracy 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 confirmed as described below unless otherwise indicated by the manufacturer:
1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

G u i d a n c e

Appropriate calibration and maintenance of equipment includes a number of concepts. All equipment must be properly installed and calibrated before use, with appropriate records maintained of any problems encountered and corrected. The organization must develop appropriate processes and schedules for ongoing calibration, preventive maintenance, and quality control. Records of calibration, preventive maintenance, and repairs must be maintained. Defective equipment must be identified, controlled, and managed to ensure that it is not used. A system for reporting adverse events to the manufacturer must be in place.

3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.

3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

3.5.2 When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potential affected products or services (including those that have already been released or delivered) shall be verified.