3. Equipment

3.0 Equipment

The organization shall define and control critical equipment.

G u i d a n c e

The facility is required to define a list of equipment that is critical to the facility's operations. Critical equipment used for collection, processing, and storage of samples should be suitable for the task and it 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 maintained.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

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 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).

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

1. Identify suitable equipment and exclude devices that do not meet requirements.
2. Approve the purchase agreement, as required in Chapter 4, Suppliers and Customers.
3. Obtain the equipment.

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.

G u i d a n c e

The intent of Standard 3.2 is to provide assurance that a device and the associated processes that employ the device are operating as designed and as intended. An important element of qualification is to provide assurance not only that the manufacturer's specifications are met but also that the equipment will work in the user's environment. This includes the physical environment as well as variables such as procedures and staff. Multiple factors can influence how a piece of equipment performs. These include hardware, software, individual equipment components, device design, the manufacturing process, environment, shipping, and installation, etc. Robust installation, operational, and performance qualification (IQ, OQ, and PQ) processes will give the facility confidence that the equipment functions as designed and intended in the environment in which it is installed and using the facility-developed procedures and facility-trained operators.

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

1. Inspect equipment upon arrival and install it in a suitable working environment.
2. Qualify the equipment and maintain records of the qualification.
3. Set date for implementation after training has been conducted for all users.
4. Use the equipment.
5. Maintain the equipment.

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 facility should have a documented process verifying that the equipment or system can perform 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 accordance with 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

After selection, the equipment should then be validated to ensure that it operates as expected and that an appropriate intended output can be obtained before its use for patient care. If one chooses to deviate from the manufacturer's written instructions, evaluation of the impact of that deviation should be part of the validation protocol.

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

1. Inspect equipment upon arrival and install it in a suitable working environment.
2. Qualify the equipment and maintain records of the qualification.
3. Set date for implementation after training has been conducted for all users.
4. Use the equipment.
5. Maintain the equipment.

3.4 Unique Identification of Equipment
Equipment shall have unique identification.

Guidance

This standard obligates the facility to uniquely identify the pieces of critical equipment that can affect the administration of blood products or quality of test results. The facility is required to assign a unique identification to each piece of critical equipment. To assist in calibration and maintenance, the facility should maintain a list of all critical equipment. A serial number can serve as the identification number.

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.

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.

3.5.3 The organization shall:

1) Define cleaning and sanitization methods and intervals for equipment.
2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.
4) Monitor equipment to ensure that defined parameters are maintained.
5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with the manufacturer's recommendations.