3. EQUIPMENT

3.0 Equipment
The facility shall establish and maintain policies, processes, and procedures to identify, control, operate, maintain, and monitor critical equipment.

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

3.1 Equipment Specifications and Selection
Equipment specifications shall be defined before selection and purchase.

Guidance
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.

F 3.2 Qualification of Equipment
All critical 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, equipment maintenance or repair reports, and manufacturer’s written instructions.

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 facility shall demonstrate that equipment performs as expected for its intended use per facility-developed predetermined criteria. Facility-developed predetermined criteria shall meet or exceed the specifications established by the manufacturer.
3.3 Use of Equipment

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

Guidance

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). 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 Equipment Monitoring and Maintenance

The facility shall have a process for scheduled monitoring and maintenance of equipment that is in accordance with manufacturer’s written instructions and in accordance with the FDA or relevant Competent Authority.

F3.4.1 Calibration and Accuracy of Equipment

The facility shall:
1) Identify equipment that is to be maintained in a calibrated state.
2) Determine the measurements to be made and the accuracy and precision required.
3) Define the process for the calibration of equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and limitations.
4) Calibrate equipment used for inspection, measuring, and testing before initial use, after repair, and at prescribed intervals, using equipment certified to meet nationally recognized measurement standards. Where no such measurement standards exist, the basis for calibration shall be described and recorded.
5) Safeguard equipment from adjustments that would invalidate the calibration setting.

Guidance

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.

F3.4.2 There shall be a defined process when equipment is found to be out of calibration or specification. When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of provided cellular therapy products and services to the required specifications shall be assessed. Chapter 7, Deviations, Nonconforming Products or Services and Adverse Events, applies.

F3.4.3 Monitoring, Maintenance, and Repair
The facility shall:
1) Define cleaning and sanitization methods and intervals for each piece of equipment.
2) Ensure that environmental conditions are suitable for the calibrations, inspections, measurements, and tests carried out.
3) Define a process to inform personnel when equipment is malfunctioning/out of service.
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 critical equipment maintenance and repairs are performed by qualified individuals and in accordance with manufacturer’s written instructions. Standard 3.2 applies.

Guidance
When equipment or systems undergo preventive maintenance, calibration, or repairs, the facility should verify that the person performing the maintenance work is trained and qualified to perform the task. The facility should verify that there is a record or report about the type of work performed. The maintenance work performed should match the expectations of the facility, the agreement with the service provider, and the specifications of the manufacturer’s/operator’s manual.

F3.5 Equipment Traceability
The facility shall maintain records of equipment use in a manner that permits:
1) Equipment to be uniquely identified and traceable.
2) Tracing of any given cellular therapy product to all equipment associated with the procurement, processing, storage, distribution, and administration of the cellular therapy product.
3) Identification and recall of all cellular therapy products associated with a specific piece of equipment.

F3.6 Information Systems
Implementation and modification of information system software, hardware, and databases shall be planned and controlled. Elements of planning and ongoing control shall include:
1) Designation of system versions with inclusive dates of use.
2) Validation/verification of system software, hardware, databases, and user-defined tables prior to implementation.
3) Fulfillment of life-cycle requirements for internally developed software.
4) Defined processes for system operation and maintenance.
5) Defined process for authorizing and documenting modifications to the system.