Furthermore, equipment list can be used to ensure that all appropriate actions have been performed and recorded.

The process of critical equipment selection should consider the criteria established by the laboratory and (as applicable) the criteria set by the facility. When selecting new equipment, it is important to consider not only the performance of equipment as it will be used in the facility, but also any supplier issues regarding ongoing service and support. The outcome of the selection process should be acquiring a piece of equipment that is affordable, appropriate and effective for the intended purpose. Also, there should be a mechanism to uniquely identify and track all critical equipment. The unique identifier may be the manufacturer's serial number or a unique identification applied by the laboratory or organization-wide identification system.

Upon receipt of critical equipment, the laboratory should develop a written plan for installation, operational, and performance qualifications;

1. Installation according to the manufacturer's specifications.
2. Verification of the equipment's functionality by ensuring that the criteria established by the manufacturer for its intended use are met.
3. Assurance that the equipment performs as expected in the facility's processes.

After installation, there should be documentation of any problems and the follow-up actions taken.

LB.9 The laboratory has a system for equipment validation.

LB.9.1 The laboratory implements policies and procedures describing the validation of critical laboratory equipment for its intended use, including:

LB.9.1.1 Installation Qualification.

LB.9.1.2 Operational Qualification.

LB.9.1.3 Detailed functional validation study with predefined acceptance criteria.

LB.9.1.4 Critical laboratory equipment are not used before completing the validation studies.

Standard Intent:

Upon receipt of critical equipment, the laboratory should develop a written plan for installation, operational, and performance qualifications;

1. Installation according to the manufacturer's specifications.
2. Verification of the equipment's functionality by ensuring that the criteria established by the manufacturer for its intended use are met.