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.

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.10 The laboratory develops a process for test method validation.

LB.10.1 The laboratory implements policies and procedures on test method validation including:

LB.10.1.1 Verification of accuracy/precision.

LB.10.1.2 Verification of sensitivity (lower detection limit).

LB.10.1.3 Verification of carryover acceptability.

LB.10.1.4 Verification of the Analytic Measurement Range (AMR).

LB.10.1.5 Approval of the method for clinical use.

Standard Intent:

When the laboratory wishes to implement a test system, validation/verification studies must be performed to confirm the performance specifications, which were established by the manufacturer before approving the method for clinical use.

Validation defined as provision of objective evidence through a defined process that a test performs as intended. While verification defined as an abbreviated validation process to demonstrate that a test performs in substantial compliance to previously established claims.

At a minimum, the laboratory must demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy, precision, reportable range, and reference intervals (normal values). Although no single format for a validation plan is required, most plans include the following common elements:

1. System description.
2. Purpose or objectives.
3. Risk assessment.
4. Responsibilities.
5. Validation procedures.
6. Acceptance criteria.
7. Approval signatures.
8. Supporting documentation.

When a validation process does not produce the expected outcome, its data and corrective actions must be documented.