1. Date received
2. Lot number and expiration date
3. Whether or not acceptance criteria were met and if any follow-up
4. Date placed in service or disposition, if not used.

Grades of water defined in the current edition of CLSI Guideline C3-A4 as:

1. Clinical Laboratory Reagent Water (CLRW) suitable for most laboratory procedures.
2. Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications.
3. Instrument Feed Water, specified by the manufacturers as suitable for use with their instruments.

The CLSI Guidelines provide testing information for microbial content, and resistivity, as well as total organic carbon. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water.
The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and documented at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be documented if water does not meet acceptability criteria.
For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water.

LB.8 The laboratory has a process describing its role in equipment management.

LB.8.1 The laboratory has a role in the selection of critical laboratory equipment (equipment that must be operated at defined specifications to ensure the quality of the product or service).

LB.8.2 The laboratory has a role in the receipt, installation and identification of critical laboratory equipment.

Standard Intent:

Critical equipment must operate within defined specifications to ensure the quality of blood components, test results and services. Critical equipment may include instruments, measuring devices, and computer systems (hardware and software). Maintaining a list of all critical equipment helps in the control function of scheduling and performing functional and safety checks, calibrations, preventive maintenance, and repair.

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.