

§493.1253 Standard: Establishment and verification of performance specifications

(c) Documentation. The laboratory must document all activities specified in this section.

Interpretive Guidelines §493.1253(c)

The actual measurement(s) taken, reactions and/or observations must be recorded.

Acceptable formats for documentation may vary.

§493.1254 Standard: Maintenance and function checks

§493.1254(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following:

Interpretive Guideline §493.1254(a)

When a laboratory introduces a new test system, the laboratory may determine, depending on the outcome of the performance specifications, that additional measures are necessary in order to ensure accurate and reliable test results.