

D5433

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§493.1254 Standard: Maintenance and function checks

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and

test result reporting.

(b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

Interpretive Guidelines §493.1254(b)(1)

A laboratory's maintenance program is usually divided into two parts:

- Unscheduled repairs when needed; and
- Scheduled preventive maintenance (PM) which is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

Probes §493.1254(b)(1)

How does the laboratory's maintenance program ensure that instruments and equipment maintain optimum operating characteristics and minimize breakdowns?

Has the laboratory evaluated whether any modifications it has made to a manufacturer's instrument or piece of equipment has resulted in the need for additional maintenance or function checks, and, if so, have the additional procedures been established and implemented?