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§493.1254 Standard: Maintenance and function checks

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

Interpretive Guidelines §493.1254(a)(1)

"As defined by the manufacturer" means that the laboratory must comply with the maintenance required in package inserts and/or instrument operator manuals for each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves and microscopes). We encourage laboratories to also comply with the manufacturer's maintenance recommendations.

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.

A service contract for PM from an outside source is acceptable provided that for each instrument or piece of equipment, there is a description of the service to be performed and frequency of service.

A service contract does not negate the laboratory's responsibility for performing other routine maintenance not included in the maintenance contract. Acceptable performance parameters (if applicable) must be documented.

The laboratory must perform and document maintenance as specified by the manufacturer for the LIS computer and devices such as monitors, printers and modems. All devices must be maintained to ensure accurate, clear, and interference-free transmission.

Probes §493.1254(a)(1)

Are LIS system components (e.g., server, hard drives, disk packs) maintained according to the manufacturer's instructions?

When downtime is required to perform maintenance on LIS equipment, how are LIS users notified?

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