The University of Iowa | State Hygienic Laboratory

CLIA CORNER

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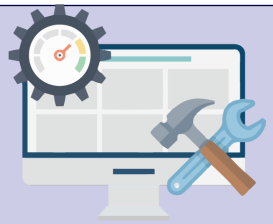

- **Requirements for maintenance and function checks**

Maintenance and functions checks are an important part of the testing process to ensure your facility is reporting accurate and reliable test results. What is the difference between maintenance and function checks? What does CLIA require when performing maintenance and function checks? What happens if the laboratory forgets to document maintenance? All these questions will be answered in this edition of the CLIA Corner.

Maintenance vs Function Checks

Maintenance is necessary to ensure the successful operation of a test system. A laboratory's maintenance program is usually divided into two parts:

Unscheduled repairs – these repairs occur as needed and usually require a service call from the manufacturer and a replacement of parts (e.g., probe, vacuum, etc.).

Scheduled preventive maintenance – this is regularly performed maintenance such as, daily, weekly, and/or monthly maintenance, which is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

Function checks refer to those activities performed to evaluate critical operating characteristics (e.g., stray light, zeroing, electrical levels, optical alignment, background counts, counting efficiency) according to the accepted method of operation for each type of device or instrument. Daily quality control activities and function checks are performed prior to patient testing to ensure that an instrument is functioning correctly and is properly calibrated (Checking electrical, mechanical, and operational functions may be independent of the procedure). The performance of daily quality control activities may serve as an additional instrument function check since analysis of external control samples checks the operating characteristics of a test system, including instrument stability and calibration.

An example of maintenance would include the daily cleaning of chemistry instrument probes. An example of a function check would be performing quarterly volume checks on a reagent dispenser.

If you would like your name added to our CLIA Corner google group, send an email to:

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CLIA requirements for performing maintenance

D5429 §493.1254 Standard: Maintenance and function checks
(a) Unmodified manufacturer's equipment, instrument, or test systems. The laboratory must perform and document the following:
(a)(1) Maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer.

Unmodified manufacturer's equipment, instruments, or test systems are those that have been classified by the Food and Drug Administration (FDA) and the laboratory follows the manufacturer instructions for system operation, including using the correct specimen type, specific reagents, etc. ***The laboratory has not modified the system in any way.***

The laboratory is required to perform all maintenance, as defined by the manufacturer. This means that the laboratory must comply with maintenance required in package inserts and/or operator's manuals for each piece of equipment and instruments in use.

When installing a new test system, it is the laboratory's responsibility to review the operator's manual for required maintenance. It should not be assumed the only maintenance required is that which is documented on the maintenance log provided by the manufacturer.

It is acceptable to establish a service contract for preventative maintenance for a specific analyzer or test system from an outside source provided that there is a description of the service to be performed and the frequency of service.

A service contract does not negate the laboratory's responsibility for performing other routine maintenance not included in the maintenance contract.

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

D5433 §493.1254 Standard: Maintenance and function checks
(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

(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.

When the manufacturer does not specify maintenance frequency or when the laboratory has modified a test system, it is the laboratory's responsibility to determine what maintenance is necessary to ensure accurate and reliable test results. The laboratory must establish a maintenance protocol and document that the necessary maintenance activities are performed per the established protocol.

CLIA requirements for performing function checks

D5431 §493.1254 Standard: Maintenance and function checks

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

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

As with maintenance checks, the laboratory is required to perform function checks as required by the manufacturer. It is the laboratory's responsibility to review operator's manual and package inserts to determine which function checks must be performed. The laboratory will need to document all function checks according to the manufacturer's instructions.

D5435 §493.1254 Standard: Maintenance and function checks

(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

The laboratory is responsible for defining the frequency of function check protocols when they are not established by the manufacturer. The laboratory must include function checks for each piece of equipment in use, including those used peripherally (e.g. centrifuge speed and timer checks, cell washer volume checks, anaerobic chamber, pipette checks, etc.). All function checks must be documented by the laboratory.

What happens if the laboratory forgets to document maintenance and function checks?

Corrective action must be documented whenever the laboratory is not in compliance with a CLIA regulation or interpretive guideline. The laboratory should:

- **Identify the problem** – why were maintenance and/or function checks not performed?
- **Determine if patients were affected by the problem** – if necessary, notify patients and/or providers of potential issues.
- **Resolution of the problem** – how will the laboratory prevent the problem from recurring? Policies for preventing problems that have been identified must be written as well as communicated to laboratory personnel and other staff as appropriate.
- **Monitor for recurrence** – the laboratory must monitor the corrective action(s) to ensure that action(s) taken have prevented recurrence of the original problem. This could include a review of maintenance as part of the laboratory's quality assessment program.