Instrument and Equipment Qualification: New Installation and After Repairs

Purpose

This document establishes the policy for qualification activities for laboratory instruments and equipment to ensure that they perform according to expectations.

Scope

Installation, operational, and performance qualification requirements for instruments and equipment are discussed.

Laboratory equipment can be classified into two major categories: general laboratory equipment and laboratory instrumentation. General laboratory equipment is that which can be used in various laboratory settings or methods, and instrumentation is that which produces measurements in an examination/analytical system or method.

Definitions

Installation Qualification (IQ): A process for confirming/verifying that the instrument's installation meets environmental requirements established by the manufacturer before implementation in the laboratory. This process is generally performed by the manufacturer's or vendor's service engineer.

Operational Qualification (OQ): A process for confirming/verifying the instrument's basic operational specifications established by the manufacturer before implementation in the laboratory. This process is generally performed by the manufacturer's or vendor's service engineer.

Performance Qualification (PQ): A process for confirming/verifying the performance of functional specifications by laboratory staff as within the acceptance criteria set forth in the validation protocol and the competence of equipment operators. This process is generally performed by the laboratory's equipment operator.

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Policy

- Equipment must be used in accordance with manufacturer instructions.
- Each instrument or piece of equipment must have a unique identification number assigned and attached.
- Each facility must maintain a list of all equipment at their facility.
- Instrument and equipment qualification must be verified upon installation and after major maintenance or service to ensure that they run according to expectations.
- Instrument qualification includes IQ, OQ and PQ.
- When equipment located in a fixed location is moved, serviced, or modified, installation and operational qualifications need reverification. This activity includes comparing data from the original IQ and OQ to the results of reverification activities to identify any significant changes. Where the manufacturer's recommendations are more stringent, the laboratory needs to follow these instead.
- Under routine operating conditions, as long as the process operates in a state of control verified by the IQ and OQ activities stated above and no changes were made to the process or output result, there should be no need to revalidate the process through PQ.
- Appropriate maintenance and function checks must be performed and records maintained for all instruments (e.g. analyzers) and equipment (e.g. centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.
- Tolerance limits for acceptable function must be defined for specific equipment wherever appropriate, with records of action when the limits are exceeded.
- Function checks must be within the defined tolerance limits prior to use within the path of workflow.
- Each facility must maintain a schedule for preventative maintenance (PM) for equipment, information on who performs the PM and approximate planned dates of those PMs.
- For equipment that has no standard frequency or requirement for maintenance and function checks, each laboratory should establish a schedule and procedure that reasonably reflects the workload and specifications of its equipment.
- Records of implementation, PMs and repairs are kept for the life of such equipment. In the case of analytic equipment, the records must be kept for the life of the equipment plus 3 years after removal from service.

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Procedure

Follow the steps below to perform qualification of instruments and equipment upon installation, after repairs or replacement of critical components.	
Step	**Action**
1.	Have the appropriate representative of manufacturer or vendor, Facility Services, or LTS perform a new or major repair check according to their protocol. • Installations of new equipment must be per manufacturer's specifications • If the manufacturer or vendor performs the installation on site, they must leave installation qualification documentation.
2.	Visibly tag the equipment so it will not be used until it has been validated.
3.	Qualification activities must be performed before actual use and must meet the manufacturer's specifications.
4.	Identify the acceptable tolerance limits per manufacturer's specified limits and regulatory/accreditation requirements.
5.	Initiate the "Equipment Qualification Checklist." Additional checklist parameters may be defined, if necessary.
6.	Complete the Checklist. • Place a checkmark to show initial acceptability of function checks or write not applicable. • Ensure that the equipment is checked for its intended use, and ensure that testing includes alarm checks if applicable etc. • For unacceptable performance, check "No." Document findings, actions, and corrections in the Detailed Information section. Attach supporting documents. • Summarize the overall performance. • Sign and date as the validator. • Have the appropriate member of the management team (as specified in the Delegation of Functions by the Laboratory Director) make the final decision by reviewing, approving, signing, and dating the checklist.
7.	Implement the equipment if acceptable and approved.

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Procedural Notes:

1. Minor maintenance or service can be made without repeating the entire checklist. Example considered to be Minor: thermometer is not calibrated

2. Major maintenance or service will require the entire process to be repeated. Example considered to be Major: replace analytic measuring device or other component critical to the proper function of the equipment.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1254]
- College of American Pathologists, All Common Checklist
- CLSI. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI document GP31-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
- CLSI. *Quality Management System: Equipment; Approved Guideline.* CLSI document QMS13-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Controlled Documents

The following controlled document supports this procedure.

- Equipment Qualification Checklist

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Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name:_____ **Operations Director, Area Laboratory**	
Name:_____ **CLIA Laboratory Director**	

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HISTORY PAGE

Type of Change: New, Major, Minor	Description of Change(s)	Quality Systems Leader Review/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
New					

Signature Manifest

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Instrument and Equipment Qualificat

Initial Approval

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