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IQ/OQ/PQ Protocol Installation Qualification/ Operation Qualification/ Performance Qualification

Purifier[®] Axiom[™] Series Class II Biological Safety Cabinets

Purpose and Scope

This Qualification Protocol is solely intended to be used with Labconco Purifier Axiom Series Biological Safety Cabinets, which are new or relocated. It is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of delivery.

Models:

30441 Series	30461 Series
30448 Series	30468 Series

Responsibilities

End-User – The end user or equipment owner is responsible for ensuring that the BSC is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through cautious forethought.

End-User Employer – The employer is responsible for supporting the validation through adequate resources and training. The organization shall also ensure the validation process has been fully carried out prior to use of the BSC. Records should be stored in a safe, easily retrievable location. The location of the BSC, preventive maintenance and certification schedules should be documented in the company's quality system.

Cabinet Certifier – All BSC's must be certified prior to use. A qualified certifying technician must do this process with calibrated instruments. The cabinet must be certified upon installation, on a scheduled annual basis and whenever the cabinet is moved to a new location. Certification is the key requirement of this protocol.

Manufacturer – Labconco Corporation, certified ISO 9001, is responsible to fully test the Purifier Axiom BSC to NSF 49 requirements prior to shipment. The manufacturer must retain these records. Labconco's Product Service Representatives and Application Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for carrying out the actual installation or validation processes.

Performance Qualification

Once the Purifier Axiom has been checked for proper installation and operation, its performance may be validated. Labconco cannot recommend specific procedures to perform additional validation. Any performance validation should be designed to meet the specifications and accuracy required of the BSC's application.

In general, additional validation may involve establishing acceptance criteria, inspecting and testing the results with calibrated equipment and qualified personnel. Some basic suggestions are included after the Operational Qualification section.

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Proper airflows	Is the Purifier Axiom to be located in a room with windows that will remain closed?	Y	N
		Is the cabinet to be located away from heavy foot traffic, doors, fans, ventilation registers and any other air-handling devices that could disrupt its airflow patterns?	Y	N
1b	Mounting Surface	Have accommodations been made for placement of the Purifier Axiom on cabinetry or stand of suitable strength and proper height?	Y	N
1c	Space Requirements	Refer to Appendix B in User's Manual. Has adequate floor space been provided for placement of the cabinet?	Y	N
		Is there proper overhead clearance for the Purifier Axiom? There must be 6-inches, (150 mm) above the exhaust cover for units not connected to exhaust systems.	Y	N
1d	Exhaust Requirements	Certain applications require the BSC to be exhausted to the outside. Have the applications been reviewed with the Safety Officer?	Y	N
		For cabinets to be connected to exhaust systems, has a facilities manager or qualified HVAC person reviewed and approved the site plans for placement of exhaust duct?	Y N/A	N
		For units requiring exhausting to the outside, have the exhaust blower, ductwork, dampers, and canopy connection been ordered?	Y N/A	N
		Has the room/building been evaluated for adequate air changes with the device?	Y	N
		Has the heating and cooling load been considered in the planning? All 4' Type A2 Axiom = 990 BTU/hr All 6' Type A2 Axiom = 1672 BTU/hr	Y N/A	N
1d	Gas Services	Has the facilities manager been consulted with regard to gas/vacuum requirements?	Y N/A	N

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		<p>Does the BSC ordered/received have service valves to match expectations?</p> <p>Connections to service valves are ¼" OD metal and require a shut-off valve.</p> <p>WARNING: The use of flammable gasses or solvents within the BSC should be avoided. Excessive heat may alter the laminar airflow and could potentially damage the HEPA filter. A Safety Officer should approve the use of flammable materials within the cabinet.</p>	<p>Y N/A</p>	<p>N</p>
1e	Electrical Service	Refer to the Electrical Requirements section of the User's Manual for a list of model numbers and their corresponding electrical ratings. Are services available for the BSC to be connected to a dedicated circuit with over-current protection of adequate size and the proper voltage?	Y	N
1f	Delivery Requirements	If the BSC has not been delivered yet, have arrangements been made with the facility or delivery agent to have equipment capable of gently handling a packaged skid of this size and weight?	Y	N
		Is there a clear path from the loading platform to the final destination in the lab?	Y	N
		When required, will there be equipment to move the cabinet onto the final mounting surface/stand?	Y	N
2	Prior to Operation		Y	N
2a	Damage Claims	<p>Has the BSC has been inspected for any signs of damage that may have occurred while in transit or within the building? Keep packaging materials until inspection is complete.</p> <p>If so, refer to the User's Manual for information on shipping damage claims.</p>	Y	N
2b	Set Up	Has the cabinet been mounted to a substantial supporting stand or cabinet that has been checked for level?	Y	N

		Is the cabinet or stand set at a suitable height for the operator to work ergonomically?	Y	N
		<p>Before attempting to operate the sash, remove the side panels and verify the following:</p> <ul style="list-style-type: none"> ❑ Are the sash cables centered on the pulleys? ❑ Has the weight restraining pin under each weight been removed and discarded? <p>See Installation Instruction Sheet affixed to the sash for photos and details.</p>	Y	N
		The User's Manual and Small Parts Kit are shipped under the work surface. Have these been unpacked and stored for future use?	Y	N
2c	Drain Valve	If the optional Drain Valve provided is to be installed, has it been sealed and fastened to the underside of the work surface per the User's Manual.	Y N/A	N
2d	Electrical Connections	Is the BSC connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the front surface of the electrical box above the front panel.	Y	N
		Duplex receptacle(s) inside the cabinet are operational? Do the GFI test and reset buttons work properly (115V models only)?	Y N/A	N
2e	Gas Services	Has a qualified technician installed the gas/vacuum services? Checked for leaks?	Y N/A	N
		Have the valves been labeled appropriately?	Y N/A	N
2f	Exhaust System	If exhausted to the outside, has a qualified installer completed the connections to the BSC?	Y N/A	N
		If exhausted to the outside, is the exhaust system to the BSC is ON continuously?	Y N/A	N
2g	Basic Operational Checks	Press the Light Switch ON, does the Fluorescent Light illuminate the interior of the cabinet?	Y	N
		Does the Blower operate with the Blower Switch ON and the sash open?	Y	N

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		If equipped, does the U.V. Light, mounted in the upper-rear of the interior, operate when the U.V. Light Switch is turned ON and the sash is fully closed?	Y N/A	N
		Does the sash rise smoothly to the appropriate height for the model indicated on the ID Plate? Series 30441 & 30461 should have a 10-inch sash opening. Series 30448 & 30468 should have an 8-inch sash opening.	Y	N
		Do the audible and visual alarms indicate when the sash has been raised above the 8 or 10-inch positioning mark?	Y	N
		Does the Alarm Mute button stop the audible alarm for approximately 5 minutes when pressed?	Y	N
		Has the BSC been posted with warnings to not be used until certified?	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Certification			
1a	Initial Certification	Prior to use, has a qualified certifier tested the cabinet to the NSF 49 standard the cabinet was listed under? Has the certifier labeled the BSC with the successful certification date?	Y	N
		Certification should be done at least annually. Has the next required certification been added to your quality system's preventive maintenance or certification schedule?	Y	N
2	Training			
2a	User Training	Have all users been properly trained on the safety, theory of operation and limitations of the BSC?	Y	N
		Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Cleaning & disinfection of the cabinet's interior <input type="checkbox"/> Loading supplies and equipment <input type="checkbox"/> Avoiding cross contamination <input type="checkbox"/> Not disturbing the laminar flow <input type="checkbox"/> Spill control and clean up <input type="checkbox"/> Shutting down the cabinet <input type="checkbox"/> If equipped, use of the U.V. light? <input type="checkbox"/> Proper placement of materials and chemical containers (if applicable) <input type="checkbox"/> Use of cabinet in A-mode <input type="checkbox"/> Use of cabinet in B-mode 	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior of cabinet been cleaned of dust that accumulated throughout installation?	Y	N
3b	Interior Cleaning	Have the BSC's interior surfaces been cleaned and disinfected appropriately for the work that is about to be performed in it?	Y	N
		Inspect the towel catch screen located in the rear under the worksurface for any foreign debris, remove any foreign objects from the towel catch.	Y	N

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4	Alarm Operation			
4a	Sash Position Alarm	Raise the sash above the operational sash height of 8 or 10-inches. Does the BSC signal a “Alarm - Sash Height” message screen?	Y	N
4b	Airflow Alert	Using a notebook or cardboard block the large series of airflow slots on the air inlet grille. Does the BSC: <ul style="list-style-type: none"> ❑ The internal motor/blower audibly increase speed? ❑ Signal an “Alert – Airflow” message screen? 	Y	N
4c	Airflow Monitor (Optional)	If the BSC has been equipped with the optional airflow sensor – block the black airflow sensor inlet. Does the airflow value drop?	Y	N
4d	Exhaust Alarm (only in B-mode)	If the BSC has been installed to an exhaust system and calibrated in B-mode – Close the Exhaust Damper until the front air intake valve closes, does the BSC signal an Exhaust Alarm message screen	Y	N

C. Performance Qualification

NOTE: This Performance Qualification section is only a recommendation of some basic items to consider for your protocol. Your protocol should include tests and inspections that are pertinent to the applications performed within the equipment.

Step	Description	Suggested Criteria
1	Periodic Certification	
1a	Cabinet Performance	<p>Certification should be done at a minimum annually. A qualified certifier can verify the cabinet's performance.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Is the BSC's current certification within the acceptable timeframe set by your organization? <input type="checkbox"/> Has there been a procedure established if a cabinet is found to have exceeded its certification due date?
		Is the next required certification noted in your quality system's preventive maintenance or certification schedule?
2	Maintenance	
2a	U.V. Lamp	If equipped, the U.V. Lamp should be replaced at least annually or every 6,000-hours to remain effective. Or, the U.V. Maintenance Timer can track the hours of operation and supply an alert.
2b	Towel Catch	The towel catch screen located in the rear under the worksurface should be checked for any foreign debris when the cabinet is cleaned.
2c	Fluorescent Lamp	Regular maintenance should ensure that the Fluorescent Lamp is operating properly.
2d	BSC Sumps	Regularly clean and maintain the sumps located underneath the removable work surfaces. If installed, clean the drain valve.

D. Summary

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Equipment Location _____

Serial No. _____ Model No. _____

User Protocol _____ Revision (or Date published) _____

Contact (print name): _____

Title: _____

Review the "Response" columns for answers of "NO." Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for "Corrective Actions." Once acceptable results are obtained, the deficiency is "accepted" by initialing the Corrective Action.

Step	Deficiency followed by Corrective Action	Initial