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IQ/OQ Protocol Installation Qualification/ Operation Qualification

PuriCare[®] Open Access Animal Transfer Station

Purpose and Scope

This Qualification Protocol is intended to be used with Labconco PuriCare Open Access Animal Transfer Stations only, which are new or relocated.

Models:

3820000	115V
3820020	230V
3820010	100V

It is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning for the piece of equipment and therefore is of value prior to receipt of delivery.

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the Open Access 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 Open Access. Records should be stored in a safe, easily retrievable location. The location of the Open Access, preventive maintenance and certification schedules should be documented in the company's quality system.

Cabinet Certifier – All Animal Transfer Stations (ATS) should be certified prior to use. A qualified certifying technician must do this process with calibrated instruments. The cabinet is to 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 Open Access prior to shipment. The manufacturer must retain these records. Their staff of Product Service Representatives and Product 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 Open Access has been checked for proper installation and operation, its performance may be validated. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

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

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Proper Airflows	Is the Open Access location planned away from heavy foot traffic, doors, fans, ventilation registers and any other air-handling devices that could disrupt its airflow patterns?	Y	N
1b	Level Surface	Have accommodations been made for placement of the Open Access on reasonably level flooring?	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 side and overhead clearance for the Open Access? There must be 6-inches, (150 mm) above the intake pre-filters and 12" to adjacent walls for exhaust flows.	Y	N
1d	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 Open Access to be connected to a dedicated circuit with over-current protection of adequate size and the proper voltage?	Y	N
1e	Delivery Requirements	If the Open Access 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
		The Open Access is delivered with casters and can be rolled off the shipping pallet. Is there a clear path from the loading platform to the final destination in the lab?	Y	N
2	Prior to Operation			
2a	Damage Claims	The Open Access 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. If so, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Set Up	Is the cabinet hydraulically set at a suitable height for the operator to work ergonomically?	Y	N

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		<p>Before attempting to operate verify that;</p> <ul style="list-style-type: none"> The work surface is clean. (Do not use chlorinated cleaners without thoroughly rinsing.) <p>See Installation Instruction Sheet affixed to the sash for photos and details.</p>	Y	N
		The User's Manual is shipped within the cabinet. Have these been unpacked and stored for future use.	Y	N
2c	Electrical Connections	Is the Open Access connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the top of the cabinet.	Y	N
		Is the duplex receptacle inside the post of the cabinet operational? Does the GFI test and reset button work properly?	Y	N
2d	Basic Operational Checks	Do the Blower(s) operate with the Main Power Switch ON?	Y	N
		Do the Fluorescent Lights operate when the Main Power Switch and Light Switch are turned ON?	Y	N
2e	Hydraulic Lift System	With the Main Power Switch ON, press the UP and DOWN lift system switch. Does the Open Access raise and lower?	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 upper and lower HEPA filters for leaks?	Y	N
		The down flow and exhaust velocities have been measured as described in the User's Manual.		
		Certification should be done 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 benefits, theory of operation and limitations of the Open Access?	Y	N
		Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Cleaning & disinfection of the surfaces. <input type="checkbox"/> Not disturbing the laminar flow, <input type="checkbox"/> Shutting down the cabinet? 	Y	N
		Are users aware of ergonomic factors that can cause unnecessary fatigue or personal discomfort?	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior been cleaned of dust that accumulated throughout shipment and installation?	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	Certification should be done at a minimum annually. An experienced certifier can verify the cabinet's performance to manufacturer's specifications. Is the Open Access current certification within the acceptable timeframe set by your organization? 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	Pre-filters	The disposable pre-filters located under the worksurface should be checked for any foreign debris at least weekly. The disposable pre-filters located on the top of the Open Access should be checked at least monthly. Replace when accumulation of dust or bedding is visible.
2b	Fluorescent Lamp	Regular maintenance should ensure that the Fluorescent Lamp is operating properly.

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