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

Nexus™ Horizontal Clean Bench

Purpose and Scope

This Qualification Protocol is solely intended to be used with a Labconco Nexus Horizontal Clean Bench, which is 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:

5330 Series	5340 Series	5350 Series	5360 Series	5380 Series
5331 Series	5341 Series	5351 Series	5361 Series	5381 Series

The full catalog (model) number is 7 digits for standard product, represented by the series numbers above plus three (3) additional numbers at the end.

Custom product may contain 5 or more alphanumeric characters after the standard 7 digit catalog (model) number.

Responsibilities

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

Certifier – All Nexus Horizontal Clean Benches must be certified prior to use. A qualified certifying technician must complete this process with calibrated instruments. The cabinet must be certified upon installation, on a scheduled annual basis (at minimum) 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 Nexus Horizontal Clean Bench prior to shipment. The manufacturer must retain these records. Labconco Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for conducting the actual installation or validation processes.

Performance Qualification

Once the Nexus Horizontal Clean Bench has been checked for proper installation and operation, its performance may be validated. Any performance validation should be designed to meet the specifications and accuracy required of the product (Nexus Horizontal Clean Bench) by the 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.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Proper airflows	Is the Nexus Horizontal Clean Bench to be located in a room with windows that will remain closed?	Y	N
		Is the bench 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 Nexus on level cabinetry or a level stand of suitable strength and proper height?	Y	N
1c	Space Requirements	Refer to the Manual, Appendix B. Has adequate floor space been provided for placement of the Nexus and its base stand or cabinet?	Y	N
		If the Nexus will be installed on a Labconco Base Stand, refer to the User Manual and base stand instructions for installation instructions. Is the stand or cabinet set to the proper height for use with the Nexus?	Y	N
		For proper operation of the Nexus, there should be at least 6 inches (150 mm) of clearance from any overhead obstructions when in its final operating position. Does the installation location have the proper overhead clearance?	Y	N
1d	Gas Services	Has the facilities manager been consulted with regard to service fixture requirements?	Y N/A	N

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		<p>Does the Nexus ordered/received have field installable 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 hazardous and flammable gasses or solvents within the Nexus should be avoided. Excessive heat may alter the laminar airflow. A Safety Officer should approve the use of gasses within the Nexus.</p>	<p>Y N/A</p>	<p>N</p>
1e	Electrical Service	<p>Refer to the Electrical Requirements section of the User Manual for a list of model numbers and their corresponding electrical ratings. Are services available for the Nexus to be connected to a dedicated circuit with over-current protection of adequate size and the proper voltage?</p>	<p>Y</p>	<p>N</p>
1f	Delivery Requirements	<p>If the Nexus 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?</p>	<p>Y</p>	<p>N</p>
		<p>Is there a clear path from the loading platform to the final install destination?</p>	<p>Y</p>	<p>N</p>
		<p>When required, will there be equipment to move the cabinet onto the final mounting surface/stand?</p>	<p>Y</p>	<p>N</p>
2	Prior to Operation		<p>Y</p>	<p>N</p>
2a	Damage Claims	<p>Has the Nexus 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 Manual for information on shipping damage claims.</p>	<p>Y</p>	<p>N</p>

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2b	Set Up	Has the Nexus been mounted to a substantial supporting stand or cabinet that has been checked for level within 1/16 inch (1.5mm)?	Y	N
		Is the cabinet or stand set at a suitable height for the operator to work ergonomically?	Y	N
		The User Manual, power cord, factory test report and spare pass-thru plugs are shipped in a box, taped to work surface. Have these been unpacked and stored for future use?	Y	N
2c	Electrical Connections	Has the Nexus been connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the rear side of the Nexus.	Y	N
		Is the duplex receptacle(s) inside the Nexus operational? Does the GFI “TEST” button remove power from and “RESET” button restore power to the outlet(s) (115V models only)?	Y	N
2d	Service Fixtures	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
2e	Basic Operational Checks	Does the Blower operate when the blower icon is pressed?	Y	N
		Does the Light illuminate when the light icon is pressed? Does the LED light illuminate the interior of the Nexus?	Y N/A	N
		If equipped, does the UV light operate when the UV light icon is pressed and the UV shade is fully closed?	Y	N
		Do the audible and visual alarms indicate when prefilters are blocked?	Y	N
		Has the Nexus 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	<p>Prior to use, all Nexus clean benches should be certified by a qualified certifier. Under normal operating conditions, the Nexus Clean Bench should be recertified at least annually and when moved or serviced. The certifier should perform the following tests, as recommended in Institute of Environmental Sciences and Technology, IEST-RP-CC002.4:</p> <ul style="list-style-type: none"> • Airflow Velocity Test • HEPA Filter Leak Test • Airborne Particle Count (when appropriate) • Lighting Intensity Test (when appropriate) <p>In addition, the following tests should also be performed at the user’s discretion by a qualified electrician:</p> <ul style="list-style-type: none"> • Electrical Leakage and Ground Circuit Resistance Test • Smoke Test to determine airflow patterns 	Y	N
	Routine Certification	<p>Certification should be done at least annually. Has the next required certification been added to your quality system’s preventive maintenance or certification schedule?</p>	Y	N
2	Training			
2a	Safety Officer Evaluation	<p>Because air from the work area is dispersed directly into the operators breathing zone, the Nexus should not be used in conjunction with biohazardous material, toxins, radionuclides or any hazardous materials or gases. Have operators and qualified safety officer(s) carefully assessed the risk associated with any operation performed in the Nexus?</p>	Y	N

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2b	User Training	Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Initial start-up and decontamination of work surfaces operations. <input type="checkbox"/> Sterile Product manipulation in a sterile air flow. <input type="checkbox"/> Material transfers into and out of the Sterile Airflow. 	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior of the Nexus been cleaned of dust that accumulated throughout installation?	Y	N
3b	Interior Cleaning	Have the Nexus interior surfaces been cleaned and disinfected appropriately for the work that is about to be performed in it?	Y	N
4	Alarm Operation			
4a	Airflow Alert	Using a piece of cardboard, block 50% or more of the prefilter(s) on the top of the clean bench, being careful not to damage the prefilter(s). Does the Nexus: <ul style="list-style-type: none"> <input type="checkbox"/> Audibly increase blower speed? <input type="checkbox"/> Signal an “Alert – Airflow” message? 	Y	N
4b	Airflow Monitor (Optional)	If the Nexus has been equipped with the optional airflow sensor(s) – open/remove the prefilters atop the unit. Block the airflow sensor inlet with rigid plastic board (or equivalent). If Nexus is a 5ft, 6ft or 8ft model, repeat for the second airflow sensor. While the touchscreen display is on the ‘Sensors’ screen, when the airflow sensor(s) inlet is blocked, the value displayed next to “Airflow Sensor” reduces by 10 fpm (0.05 m/s) or greater? If Nexus is a 5ft, 6ft, or 8ft model, the respective “Airflow Sensor Right” and “Airflow Sensor Left” value displayed reduces by 10 fpm (0.05 m/s) when the airflow sensor (right/left determined when viewing from the front) is blocked?	Y	N

C. Performance Qualification

NOTE: This Performance Qualification section is only a recommendation of 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	Result	
			YES	NO
1	Periodic Certification			
1a	Cabinet Performance	<p>The Nexus should be certified by a qualified certification technician before its initial use. Certification testing of the HEPA filter and air flow velocity should be done at a minimum, annually. Labconco’s Quality Assurance Test Report is included with each unit, located in the parts box.</p> <p>An experienced user or certifier can verify the cabinet’s performance to manufacturer’s specifications. (Appendix C and D in User Manual)</p> <p><input type="checkbox"/> Has the Factory Quality Assurance Test Report been filed for reference?</p>	Y	N
		Is the current certification of the Nexus within the acceptable timeframe set by your organization?	Y	N
		Is the next required certification noted in your quality system’s preventive maintenance or certification schedule?	Y	N
		Has there been a procedure established if the Nexus is found to have exceeded its certification due date?	Y	N
2	Maintenance Schedule	Under normal operation, your Nexus Horizontal Clean Bench will require little routine maintenance. The following schedule is recommended:		

2a	Cleaning	<p>Daily</p> <ul style="list-style-type: none"> • Clean as required per your protocol. Following use of disinfectant, ensure all residue is removed by a follow-up wipe with 70% IPA or sterile water. <p>Weekly</p> <ul style="list-style-type: none"> • Wipe down the interior surfaces of the clean bench with a mild household detergent, cleaner or 70% IPA and allow to dry. Using a damp cloth, clean the exterior surfaces of the clean bench, particularly the front and top of the clean bench to remove any accumulated dust. <p>Monthly (or more often as required)</p> <ul style="list-style-type: none"> • Check all service valves, if so equipped, for proper operation. • Check the prefilters and replace if necessary. The prefilters should be replaced at least quarterly. • All weekly activities. <p>Quarterly</p> <ul style="list-style-type: none"> • Replace the prefilter. See page User Manual for ordering information. • All monthly activities. <p>Annually</p> <ul style="list-style-type: none"> • Have the clean bench recertified by a qualified certification technician. • All quarterly activities. <p>Biannually</p> <ul style="list-style-type: none"> • Replace the UV lamp (if included). • All annual activities. 		
2b	UV Lamp	If equipped, the UV Lamp should be replaced at least annually or every 6,000-hours to remain effective. The UV Maintenance Timer tracks the hours of operation and provides an alert.		
2c	LED Light	Regular maintenance should ensure that the LED Light is operating properly.		
2d	Prefilter	The Nexus prefilters should be changed every 3 months, or as needed.		

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