LABCONCO CORPORATION
8811 Prospect Avenue
Kansas City, MO 64132
(800) 821-5525, (816) 333-8811
(816) 363-0130 fax
labconco@labconco.com

IQ/OQ Protocol
Installation Qualification/ Operation Qualification

FreeZone® Triad™ Freeze Dryers

(To be used with FreeZone Triad Freeze Dryers manufactured after August 2018 – 79400** Series)**

Labconco No. – 1065802 Rev. C, ECO 15446
Available at **labconco.com**

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FreeZone Triad Freeze Dryers, which are new or relocated. Design changes occurred in 2018 which impact which IQ/OQ protocol is to be used with your Triad Freeze Dryer. Check the model number on the equipment that needs to be validated to ensure the correct protocol is used. This document is to be used to validate the following models:

79400**** Series (* last four digits represent the various gas and electrical configurations)

Protocol 1059502 is to be used to validate FreeZone Triad Freeze Dryer models 7400030, 7400040, 7400060 & 7400070 manufactured between 2005 & 2018.

This document 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.

The use of this document does not replace the need for the User's Manual (# 7343300). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or downloaded from their website, www.labconco.com

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the freeze dryer 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 careful 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 applying the Triad Freeze Dryer. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each Triad Freeze Dryer prior to shipment. The manufacturer must retain these records. Labconco's staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

Performance Qualification

Once the Triad Freeze Dryer has been checked for proper installation and operation, its performance can 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, making several runs and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**Site Planning**			
1a	Work surface / stand weight requirements	The Triad Freeze Dryer weighs 400 pounds. The vacuum pump weighs at least an additional 45 pounds. Is the location where the Triad Freeze Dryer will be located stable and capable of safely supporting the required weight?	Y	N
1b	Space Requirements	Refer to the Appendix in the Triad Freeze Dryer User's Manual for dimensions of the model you have chosen. Has overhead and working space been provided for the equipment? (A minimum of 3-inches is required between the back and sides of a Triad Freeze Dryer and the wall for proper airflow through the refrigeration system. Additional space is required on the left side if freeze drying will be performed in flasks)	Y	N
1c	Electrical Service	Refer to the User's Manual for electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?	Y	N
		All models are shipped with a region specific power cord. Does the power cord match the available receptacle at the installation site?	Y N/A	N
1d	Optional Features	Serum bottles, ampules, flasks and related accessories are not included with the Triad Freeze Dryer. Have these been considered / available for this application?	Y	N

		Is a suitable vacuum pump available or has it been ordered? Refer to the User's Manual It must have a displacement of at least 98 Liters/min (144 liters per minute recommended) and be capable of achieving an ultimate vacuum (total pressure) of .020 mbar. The power cord should have a reverse IEC 320 plug to plug into the rear of the Triad	Y	N
2	**Prior to Operation**			
2a	Damage Claims	Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete. **WARNING: Do not attempt to pull a vacuum on a Triad Freeze Dryer with any damage to the clear door. Implosion and potential for injury can occur.** If damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Triad Freeze Dryer Installation	Place the Triad Freeze Dryer on top of the work surface or stand. **Caution: Triad Freeze Dryers are extremely heavy. Follow safe lifting guidelines.** Has the vacuum pump been connected using the rubber hose and clamps provided?	Y	N
2c	Electrical Connection	Plug the Triad Freeze Dryer into a dedicated electrical outlet. Has the electrical service been verified to be adequate in size, voltage, amperage and frequency? (The ID plate on the rear of the freeze dryer has the electrical requirements.)	Y	N
	Electrical Grounding	Has the ground on the electrical service been verified?	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**Freeze Dryer**			
1a	Start Up	With the: Triad Freeze Dryer's Power switch ON, Stoppering control in the "raise" position, Vac Release control in the "close" position, Empty serum vials with loose stoppers on the four corners of the shelf, Temperature probe taped to the top-center of the shelf with aluminum tape, Door on the Tray Dryer latched & closed, Vacuum pump plugged into the back of the Triad Freeze Dryer and its power switch turned on (if so equipped), Room ambient temperature 72°F or cooler, Vacuum set point set at 0 (zero) mbar, Go to the "Home" screen, press the "MANUAL" button, enter -55°C for Shelf Temp Set Point, and press the "Start" button. Then press Vacuum button, then the "Start" button. Does the Triad Freeze Dryer's refrigeration system start? Does the vacuum pump start? (Allow refrigeration and vacuum pump to continue to operate.) Record the time it started. _____	Y Y	N N
1b	Cooling of the Shelf and collector	Did the Triad Freeze Dryer shelf temperature reach -55ºC, (+/-1 ºC), within 5 hours of starting?	Y	N

<table>
<tr><td></td><td></td><td>Did the Triad Freeze Dryer collector temperature reach -80°C within 1 hours of starting?</td><td>Y</td><td>N</td></tr>
<tr><td>1c</td><td>Vacuum Leaks</td><td>Does the system reach a displayed vacuum level less than or equal to 0.040 mbar in 2 hours?</td><td>Y</td><td>N</td></tr>
<tr><td>1d</td><td>Heating of the Shelf</td><td>Go to the “Home” screen, press the “MANUAL” button, enter +50°C for Shelf Temp Set Point, and press the “Start” button.

Monitor the displayed temperature for the shelf. Does the temperature of the shelf reach 50°C, (+/-1°C) within 1 hour?</td><td>Y</td><td>N</td></tr>
<tr><td>1e</td><td>Program Operation</td><td>To test the program function enter any parameters for a new program, for example:

<table>
<tr><th colspan="5">Triad Freeze Dryer Program Table</th></tr>
<tr><th>Step</th><th>Ramp Rate (°C/min)</th><th>Shelf Temp. (°C)</th><th>Time (hh:mm)</th><th>Vacuum (mbar)</th></tr>
<tr><td>1</td><td>---</td><td>MC</td><td>00:10</td><td>---</td></tr>
<tr><td>2</td><td>1.5</td><td>-55</td><td>00:20</td><td>0.000</td></tr>
<tr><td>3</td><td>1.5</td><td>50</td><td>00:10</td><td>0.000</td></tr>
<tr><td>4</td><td>0.5</td><td>24</td><td>00:10</td><td>0.000</td></tr>
</table>

(Large temperature swings and long hold times will prolong the test.)

Start the new program.</td><td></td><td></td></tr>
<tr><td>1f</td><td>Program Operation</td><td>Does the shelf temperature rise and fall as programmed?</td><td>Y

N/A</td><td>N</td></tr>
</table>

1g	Verify Displayed Temperature	The shelf temperature indicated on the display during Manual Mode operation or Program Mode operation is measured where the heat transfer fluid enters the shelf (**except during Max Cold (MC) mode, do not use MC mode during this verification step)**. The collector temperature is measured where the refrigerant leaves the collector. These sensors each have a reference thermocouple (T-Type, red/blue) that can be accessed only by removing the back cover of the Triad Freeze Dryer. A thermocouple meter can be used to read each thermocouple and compare to the respective display readings. **CAUTION: Electrical Shock Hazard – Disconnect power to the unit prior to removal of any covers.** Does the Collector display correlate to the reference gauge/meter +/- 2ºC? Does the Shelf display correlate to the reference gauge/ meter +/- 2°C Ref. Instrument? _____ If the temperature does not correlate, see Triad Freeze Dryer Manual for calibration procedure.	Y N/A Y N/A	N N
1h	Stoppering Operation	Rotate the Stoppering knob to the “lower” position. Did the top platen slowly lower from the top and did each serum vial seal with the stoppers?	Y N/A	N
		Rotate the Stoppering knob to the “raise” position. Did the platen return to its highest position?	Y N/A	N

1i	Temperature Probes	The Sample temperature probe can be verified by placing it into an ice bath. Agitate a crushed ice and water bath and place the temperature probes into it. Does the displayed temperature read between 1°C and -1°C? If the temperature does not correlate, see Triad Freeze Dryer Manual for calibration procedure.	Y N/A	N

1j	Verify Displayed Vacuum	The vacuum level indicated on the LCD display is measured at the rear of the chamber. The value was calibrated at the factory by correlating its reading with that of a reference gauge. The calibration was performed at a very low level, approximately 0.010 mbar. NOTICE: Factory calibration was performed using a precision Active Pirani Gauge calibrated to a Capacitance Manometer standard. Despite the system's calibration and repeatability, the readings taken at such a low level of vacuum should only be considered as a verification of a leak-free system. Vacuum swings can be attributed to contamination of surfaces, which could take days to outgas. Adjustments are discouraged. Before any adjustments are made to the factory calibration of the vacuum measurement, answer positively to each of these questions: 1) Is the vacuum standard being used to verify the freeze dryer accepted by the organization to be precise and has it been calibrated recently? 2) Is the level of accuracy we are attempting to reach pertinent to the freeze drying applications? Does the vacuum display correlate to the reference gauge? Ref. Instrument? _____ If the vacuum reading does not correlate, see Triad Freeze Dryer Manual for calibration procedure.	Y N/A	N

2	**Routine Maintenance**	Below are helpful hints to be included in the organization's preventive maintenance plan.		
2a	Vacuum Grease	Vacuum grease should be applied to rubber components as required. In general, vacuum grease should be the first step in troubleshooting vacuum leaks. Thin layers of grease are adequate for all seals. Only use grease specially formulated for low vacuum service. Use grease only on the inner and outer sealing surfaces of the rubber manifold valve body. Is vacuum grease readily available and documented? Type of grease used? _____	Y	N
2b	Inspect for Wear & Damage	Has there been a procedure to periodically inspect the interior metal surfaces for corrosion due to acids?	Y	N
		Is there a maintenance procedure to check the clear acrylic door for chips, cracks, deep scratches or chemical attack? WARNING: This is a safety issue. Implosion can occur with damaged or corroded components!	Y	N
		Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration?	Y	N
2c	Refrigeration System Cleaning	At least annually, will the refrigeration condenser be cleaned of dust that would restrict free airflow? (Include in the preventive maintenance schedule)	Y	N
2d	Heat Transfer Fluid	Annually check the fluid level of the Lexsol™ heat transfer fluid with the label applied to the side of the reservoir. Has this been included in the preventive maintenance plan?	Y N/A	N

3	**Personnel Training**			
3a	User Training Related to Equipment	Have personnel that will use the Triad Freeze Dryers been adequately trained? Are personnel familiar with: All the buttons, knobs and displays on the control panel; The use of vacuum grease; Opening, closing and venting samples; Cleaning of the freeze dryer and neutralization of acids?	Y	N
3b	User's Manual	Are the personnel who are to use or maintain the Triad Freeze Dryer able to locate the User's Manual for the machine?	Y	N

C. Summary

Labconco FreeZone Triad Freeze Dryers IQ/OQ Document 1065802 Rev C

Equipment Location _____

FreeZone Ser. 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