



Taylor-Wharton

DQ / IQ / OQ / PQ

**Design / Installation / Operating / Performance
Qualification Protocol
for
Taylor-Wharton Cryogenic Freezers**

Serial ID# _____

I. APPROVAL PAGE

The Owner/User signature indicates this document has been reviewed to assure that it effectively documents all customer requirements for Design / Installation / Operational / Performance Qualification.

System Owner:

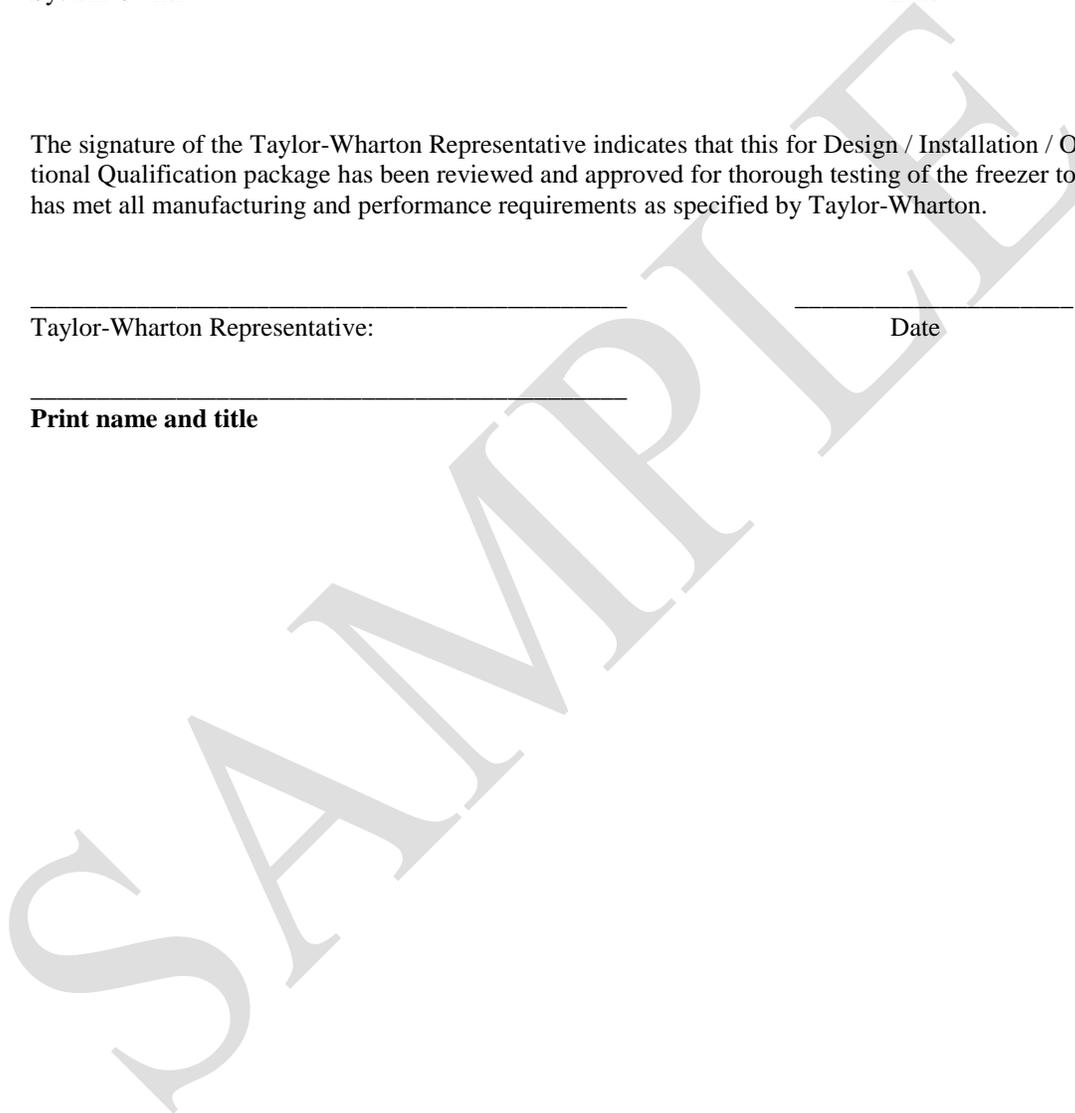
Date

The signature of the Taylor-Wharton Representative indicates that this for Design / Installation / Operational Qualification package has been reviewed and approved for thorough testing of the freezer to ensure it has met all manufacturing and performance requirements as specified by Taylor-Wharton.

Taylor-Wharton Representative:

Date

Print name and title



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SAMPLE

II. INTRODUCTION

The intent of this DQ/IQ/OQ/PQ protocol is to define and assure the implementation of the organizational practices, standards, methods, and documentation conventions to be used for the requirements, proper specification, design and acceptance of the Taylor-Wharton Stainless Steel Cryogenic Freezer Serial Number 815-003-LL10.

A. Purpose

The purpose of this qualification protocol documentation package is to identify the minimum acceptance requirements to assure the complete and proper specification, design and acceptance of the Taylor-Wharton Cryogenic Freezer specified in this document.

Successful acceptance requires that the specifications and criteria are adequately addressed, managed, tested, and documented. To this end, evidence that this Taylor-Wharton Cryogenic Freezer will perform its functions repeatedly, reliably and as expected throughout the life of the system will include the following:

- Adherence to applicable standards, codes, practices and guides
- Adherence to the specifications and design criteria listed in the DQ protocol section
- Adherence to the initial condition of the Freezer system, packaging, documentation, and proper installation criteria is listed in IQ protocol section
- Adherence to the Freezer's controller functional testing and operational criteria is listed in the OQ protocol section
- Adherence to the Freezer's mechanical functional testing and performance criteria is listed in the PQ protocol section
- Records collection, maintenance and retention
- Training

B. Scope

This qualification protocol document package pertains specifically to the Taylor-Wharton Stainless Steel Cryogenic Freezer, which serve as a product storage container and comprised of:

- Vacuum Insulated Product Storage Container
- Control System

This document package is intended to serve as a guide during the Design Qualification, Installation Qualification, Operational Qualification, Performance Qualification protocol. It outlines how the freezers are to be tested, and documented in order to conform to all of the above requirements and acceptance criteria.

III. RESPONSIBILITIES

This section describes the organization, tasks and responsibilities required for defining, developing, implementing, testing, operating and maintaining the Cryogenic Freezer Systems. The following comprise the individuals required for this qualification protocol. These individuals are assigned specific responsibilities detailed in the paragraphs below:

System Owner (SO): _____

A. System Owner (SO)

The SO shall provide all documents and related functions listed. In support of this work, the SO shall:

1. Provide information to support the creation of the qualification protocol package for the Taylor-Wharton Cryogenic Freezer and assure that any compliance issues are addressed.
2. Review an outline of the T-W standard qualification protocol package, and identify any additional customer specific requirements before protocol is begun.
3. Provide technical guidance to assure that the system is in compliance with its specified functional requirements and standards.
4. Understand the function and operation of the cryogenic freezers.
5. Oversee the installation of the systems.
6. Retain, secure, and maintain all system documentation.
7. Execute Operation and Maintenance (O & M) Procedures as required.
8. Approve the Qualification Protocol Criteria.
9. Issuing a controlled copy for use.

C. Manufacturer's Representative (MR)

The MR shall supply all facilities, supplies and resources necessary to execute all system testing. In support of this protocol, the MR is:

1. Responsible for the generation of this protocol and reporting the outcome of this protocol in a final report.
2. Responsible for the procedures outlined in this protocol.
3. Responsible to ensure that all control instruments are calibrated and functional prior to the start of the qualification

IV. SYSTEM QUALIFICATION PROCEDURE

A. System Qualification Procedure

System performance shall be initially validated and initially qualified by the successful execution of the DQ/IQ/OQ/PQ protocol procedures at the suppliers' factory.

System performance shall be formally approved and qualified by the successful review and / or execution of the DQ/IQ/OQ/PQ protocol procedures at the system owners' site.

V. DESIGN QUALIFICATION (DQ) PROTOCOL

The DQ Protocol section of this qualification package defines and validates the Freezer System design.

The DQ Protocol section also defines and validates the manufacturer processes, manufacturing equipment, and quality procedures used to manufacture the design.

And finally, the DQ Protocol section defines and verifies that the Quality Certificates of the facility, equipment, and components used to design and manufacture the Cryogenic Freezer System design are current and within standards.

The DQ Protocol documentation includes specification sheets, component and material lists, and drawings that define the basic Cryogenic Freezer and the completed Cryogenic Freezer System, which includes the controller, solenoid valve, and other pertinent components, if applicable.

The DQ Protocol documentation also includes a flow diagram of the Manufacturing Processes with Quality Check Points, a Freezer Dimensional Checklist, a Controller Checklist, and Manufacturing Traveler.

And finally, the DQ Protocol documentation includes Quality Certificates of the facility, equipment, and components used to design and manufacture the Cryogenic Freezer System design.

The results and expectations of each section of the DQ Protocol is reviewed and signed by Manufacture's Representative at the factory. Each section of the DQ Protocol also has an acceptance box for the System Owner.

The DQ protocol documentation is in Appendix A.

VI. INSTALLATION QUALIFICATION (IQ) PROTOCOL

The IQ Protocol section of this qualification package defines and validates the cleanliness, the external and internal appearances, the labeling, and the overall workmanship of the Cryogenic Freezer System.

The IQ Protocol section also defines and validates that the complete Cryogenic Freezer System is properly packaged for shipment, and has all required documentation.

The IQ Protocol documentation includes quality inspection reports, and checklists of the Cryogenic Freezer System labeling and documentation.

The IQ Protocol documentation includes confirmation reports of basic mechanical functionality tests used to verify that the Cryogenic Freezer will perform its mechanical functions repeatedly, reliably, and as expected throughout the life of the system.

The results and expectations of each section of the IQ Protocol is reviewed and signed by Manufacture's Representative at the factory. Each section of the IQ Protocol also has an acceptance box for the System Owner.

The IQ protocol documentation is in Appendix B.

VII. OPERATIONAL QUALIFICATION (OQ) PROTOCOL

The OQ Protocol section of this qualification package defines and validates that the Cryogenic Freezer System will perform its operational functions repeatedly, reliably, and as expected throughout the life of the system.

The OQ Protocol documentation includes confirmation reports of operational functionality tests used to verify that the Cryogenic Freezer will perform its operational functions repeatedly, reliably, and as expected throughout the life of the system.

The OQ Protocol documentation also includes the Operating and Maintenance Manual.

The results and expectations of each section of the OQ Protocol is reviewed and signed by Manufacture's Representative at the factory. Each section of the OQ Protocol also has an acceptance box for the System Owner.

The OQ protocol documentation is in Appendix C.

VIII. PERFORMANCE QUALIFICATION (PQ) PROTOCOL

The PQ Protocol section of this qualification package defines and validates that the Cryogenic Freezer System will perform per the specifications repeatedly, reliably, and as expected throughout the life of the system.

The PQ Protocol documentation includes a Normal Evaporation Rate (NER) test report, and confirmation reports of operational functionality tests used to verify that the Cryogenic Freezer will perform its operational functions repeatedly, reliably, and as expected throughout the life of the system.

The results and expectations of each section of the PQ Protocol is reviewed and signed by Manufacture's Representative at the factory. Each section of the PQ Protocol also has an acceptance box for the System Owner.

The PQ protocol documentation is in Appendix D.

IX. DESIGN QUALIFICATION (DQ) DOCUMENTATIONAPPENDIX A

Appendix A includes the following documentation:

- A. Freezer Specification Sheet
- B. General Arrangement Drawing
- C. Manufacturing Process with Quality Check Points
- D. Manufacturing Quality Traveler (sample)
- E. Manufacturing Equipment Calibration Checklist
- F. ISO Certificate

SAMPLE

X. INSTALLATION QUALIFICATION (IQ) DOCUMENTATION..... APPENDIX B

Appendix B includes the following documentation:

- A. Inspection of Condition of External Packaging
- B. Inspection of Condition of Freezer Internal and External Surfaces
- C. Inspection of Cleanliness of Equipment
- D. Confirmation that Unit is Properly Labeled
- E. Confirmation of Documentation Package
- F. Confirmation of Receipt of all Required Parts
- G. Confirmation that Freezer has Correct Power Supply
- H. Confirmation that Freezer is Level
- I. Confirmation of Components are Leak Tight after Connection to LN2 Supply

Note: Installer will work through this section – referring back to appendix A as needed.

Appendix B

A. Inspection of Condition of External Packaging

Purpose:

To confirm that the external packaging meets the requirements of the packaging drawings

Materials used:

T-W Freezer and packaging drawings

Procedure

1. Confirm that the external packaging drawing is for the correct T-W freezer
2. Confirm that the external packaging meets the requirements of the packaging drawings
3. Confirm that the external packaging drawings is included in the protocol binder

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The external packaging meets the requirements of the packaging drawings			
The external packaging drawing is the protocol binder			

Deviations:

Resolution:

Comments:

Appendix B

B. Inspection of Condition of Freezer Internal and External Surfaces

Purpose:

To confirm the condition of both the internal and external surfaces of the T-W Freezer meet the construction drawings; and are free of scratches, blemishes, stains, or dings

Materials used:

T-W Freezer, and construction drawings.

Procedure

1. Review internal and external surfaces conditions per manufacturing drawings
2. Confirm that the internal and external surfaces meet conditions per drawings
3. Confirm that the internal and external surfaces are free of scratches, blemishes, stains, and dings

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
Internal and external surfaces meets the conditions per manufacturing drawings			
Internal and external surfaces are free of scratches, blemishes, stains, and dings			

Deviations:

Resolution:

Comments:

Appendix B

C. Inspection of Cleanliness of Equipment

Purpose:

To confirm that the T-W Freezer meets the cleanliness requirements of the manufacturing construction drawings

Materials used:

T-W Freezer, and construction drawings

Procedure

1. Review cleanliness requirements listed on the manufacturing drawings
2. Confirm that the T-W Freezer meets the cleanliness requirements of the manufacturing drawings

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The T-W Freezer meets the cleanliness requirements of the manufacturing drawings			

Deviations:

Resolution:

Comments:

Appendix B

D. Confirmation that Unit is Properly Labeled

Purpose:

To confirm that the T-W Freezer is properly labeled

Materials used:

T-W Freezer and manufacturing construction drawings

Procedure

1. Review labeling requirements on manufacturing drawings
2. Confirm the all of the appropriate labels are on the T-W Freezer per the manufacturing drawings

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The T-W Freezer has all appropriate labels per the manufacturing drawings			

Deviations:

Resolution:

Comments:

Appendix B

E. Confirmation of Documentation Package

Purpose: To confirm that the complete and correct documentation was shipped with the T-W Freezer

Materials used: T-W Freezer, and appropriate documentation package

Procedure

1. Review list of documentation for T-W Freezer
2. Confirm that the complete and correct documentation was shipped with the T-W Freezer

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The complete and correct documentation package was shipped with the T-W Freezer			

Deviations:

Resolution:

Comments:

Appendix B

F. Confirmation of Receipt of all Required Parts

Purpose:

To confirm that all of the required loose plumbing and / or electrical components were shipped with the T-W Freezer

Materials used:

T-W Freezer, bill-of-materials, manufacturing drawing, and sales order, if applicable

Procedure

1. Review manufacturing drawing, bill-of-materials, and sales order, if applicable, to determine all loose plumbing and / or electrical components, and accessories
2. Confirm that all loose plumbing and / or electrical components were shipped with the T-W Freezer

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
All plumbing and / or electrical components were shipped			
All T-W accessories were shipped with T-W Freezer			

Deviations:

Resolution:

Comments:

Appendix B

G. Confirmation that Freezer has Correct Power Supply

Purpose:

To confirm that the correct power supply was shipped with the T-W Freezer

Materials used:

T-W Freezer, bill-of-materials, manufacturing drawing, and sales order, if applicable

Procedure

1. Review manufacturing drawing, bill-of-materials, and sales order, if applicable, to determine the correct power supply
2. Confirm that the correct power supply was shipped with the T-W Freezer

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The correct power supply was shipped with the T-W Freezer			

Deviations:

Resolution:

Comments:

H. Confirmation that Freezer is Level

Purpose: To confirm that the T-W Freezer is level

Materials used: T-W Freezer

Procedure

1. Measure levelness of T-W Freezer with level instrument
2. Adjust casters, if necessary
3. Confirm that T-W Freezer is level

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
T-W Freezer is level			

Deviations:

Resolution:

Comments:

Appendix B

I. Confirmation of Components are Leak Tight after Connection to LN2 Supply

Purpose:

To confirm that the components are leak tight after connection to LN2 Supply

Materials used:

T-W Freezer, manufacturing drawings and / or standard practice instructions, liquid nitrogen source, and Operating Manual

Procedure

1. Review safe handling of liquid nitrogen guidelines
2. Hook up liquid nitrogen supply to T-W Freezer per Operating Manual
3. Open fill valve on liquid nitrogen supply
4. Inspect component connections for leaks using leak test procedures
5. Tighten any leaks, if required
6. Re-inspect the component connections, if required

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
Components are leak tight after connection to LN2 supply			

Deviations:

Resolution:

Comments:

XI. OPERATIONAL QUALIFICATION (OQ) DOCUMENTATIONAPPENDIX C

Appendix C has the following documentation:

- A. Operating and Maintenance Manual
- B. Mowden Controller Function Checklist (factory test)
 - 1. Confirmation of Mowden Controller LN2 Level Reading
 - 2. Confirmation of High Temperature Alarm Set Point
 - 3. Confirmation of Low Temperature Alarm Set Point
 - 4. Confirmation of Audio and Visual Alarms
 - 5. Confirmation of Remote Timer Setting
 - 6. Confirmation of Lid Switch, Autodefog, and Quickchill Timer Settings
 - 7. Confirmation that Lid Switch activates the Autodefog and Quickchill
 - 8. Confirmation that Lid Switch activates the Lid Open Alarm
 - 9. Confirmation of Control Panel Temperature Reading
 - 10. Confirmation that Start and Stop Thermistor Operates the Solenoid Valve
 - 11. Confirmation that all Thermistors are Functioning from the Control Panel

XII. PERFORMANCE QUALIFICATION (PQ) DOCUMENTATION.....APPENDIX D

Appendix D includes the following documentation:

- A. Temperature Map
- B. Normal Evaporation Rate
- C. Confirmation that Lid Opens and Closes Smoothly
- D. Confirmation that Lid Seal is uniform and Level
- E. Confirmation that Turntable rotates freely, if applicable
- F. Mowden Controller Functional Checklist

SAMPLE

Appendix D

B. Normal Evaporation Rate

Purpose:

To confirm the Normal Evaporation Rate (NER) and verify that the unit is within factory specification.

Materials used:

Taylor-Wharton Cryogenic Freezer which has been factory assembled.

Procedure

1. Unit is pre-cooled for 48 hours with LN2.
2. There is no inventory system or product in the cryogenic freezer.
3. Follow the procedure on page 35 of the Operating and Maintenance Manual

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The unit lost less than or equal to factory specifications per a 24-hour period.			

Deviations:

Resolution:

Comments:

Appendix D

C. Confirmation that Lid Opens and Closes Smoothly

Purpose:

To confirm that the lid opens and closes smoothly.

Materials used:

Taylor-Wharton Cryogenic Freezer which has been factory assembled.

Procedure

1. Open Lid
2. Close Lid

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The Lid opens smoothly			
The Lid closes smoothly			

Deviations:

Resolution:

Comments:

Appendix D

D. Confirmation that Lid Seal is Uniform and Level

Purpose:

To confirm that the lid seal is uniform and level

Materials used:

Taylor-Wharton Cryogenic Freezer which has been factory assembled.

Procedure

1. Open, close, and open lid
2. Observe that the lid seal is uniform and level

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The lid seal is uniform and level			

Deviations:

Resolution:

Comments:

Appendix D

E. Confirmation that Turntable Rotates Freely, if applicable

Purpose:

To confirm that the turntable rotates freely.

Materials used:

Taylor-Wharton Cryogenic Freezer which has been factory assembled.

Procedure

1. Rotate turntable
2. Observe that the turntable rotates freely and smoothly

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
The turntable rotates freely			

Deviations:

Resolution:

Comments:

Appendix D

F. Confirmation that Mowden Controller functions normally

Purpose: To confirm that the Mowden Controller functions normally.

Materials used: Taylor-Wharton Cryogenic Freezer which has been factory assembled, LABS functional test check sheet.

Procedure Complete check sheet

Results

Expected Results	Actual Results	Did Actual Agree with Expected (YES/ NO)	Conducted By/ Verified By Date
Check sheet filled out, all tests O.K.'ed			

Deviations:

Resolution:

Comments:

“LABS” FUNCTIONAL TEST – **Mowden** CONTROLLER

PERFORMANCE QUALIFICATION PROTOCOL

Type Refrigerator _____ Refrigerator Serial No. _____

Date _____ Controller Serial No. _____

Tested by: _____

Preparation for test:

1. Connect a liquid cylinder filled with LN₂ at 1,5 bar to inlet on refrigerator.
2. Connect transformer of unit to 230 Vac +/- 10% outlet. Plug into power panel before plugging in to AC outlet.
3. Turn liquid cylinder liquid valve on.
4. Confirm that pressure is applied to closed solenoid valve, and there are no plumbing leaks and that Relief Valve is fully closed.

Ready to start test:

1. Turn power ON by pushing power button.
 Solenoid should open, liquid should begin filling the unit, observe to be sure that liquid is entering unit and that there are no restrictions. This starts validation of LN₂ level and validates high temperature, solenoid operation and audible and visual alarms. This function will also validate the Remote Alarm function, if set up with an output.

*** HIGH TEMPERATURE ***
 *** LEVEL EXTRA LOW ***
 TEMPERATURE +15°C (variable)

System owner Manuf. Rep

OK

2. When controller shuts off liquid, panel should read:

TEMPERATURE -185°C (variable)
 LEVEL HIGH

OK

LABS” FUNCTIONAL TEST – Mowden CONTROLLER

PERFORMANCE QUALIFICATION PROTOCOL

3. Open lid, defog should come on for approx. 10 sec. Close lid, unit should Quick Chill for 10 sec and shut off **OK**
-

4. Open lid. After 5 minutes the ‘Lid Open’ alarm should be displayed,

*** LID OPEN ***
TEMPERATURE -185°C (*variable*)
LEVEL NORMAL

OK

5. Disconnect 230 VAC power cord from wall outlet. Battery backup will supply power to unit, and alarms will indicate. Display will go dark after 30 seconds to conserve power. Reconnect 230 VAC power supply. Alarm / event code is inserted into the data log to identify the nature of the alarm condition or the event

OK
