Approvals

Signing below indicates agreement that the execution of the Installation and Operational Qualification Protocol for the 100HP Air Compressor located at 396 Smathers Street at the Repackaging facility is complete and the equipment is installed and suitable for use at that facility.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		4/18/16
Thomas Evans	Maintenance		4/18/16
Monte Plott	Production		4/18/16
Matt Haynes	Operations		4/18/16
Deborah Durbin	Quality		4/18/16

A copy of the executed protocol will be attached behind this report.

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I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the 100HP Air Compressor functions as intended and is installed properly at the Repackaging facility. This final report provides documented evidence that the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ) and Operational Qualification (OQ) for the 100HP Air Compressor at 396 Smathers Street in Waynesville, NC was executed and all acceptance criteria was met.

II. SUMMARY

One 100HP air compressor supplies compressed air for Giles' Repackaging facility. The compressor has a built-in air dryer unit and is tied to a common header system.

The products that are impacted by this study were all Epsom Salt products manufactured by Giles Chemical. No other departments or systems were affected by the installation or use of this equipment.

The following tests were performed in this qualification:

Installation Documentation – the serial number or asset tag number of the compressor was documented

Controls/Indicators Verification – verified and documented that the switches work properly.

Utility Verification – verified that the voltage to the compressor was correct

All Installation and Operational acceptance criteria were met as displayed in the tables in the Appendices.

III. CONCLUSION

The results of the completed Installation and Operational Qualification protocol show that all acceptance criteria were met. All testing results provide documented evidence that the 100HP Air Compressor is installed and operating as expected. The 100HP Air Compressor is considered to be qualified for use.

IV. RECOMMENDATIONS

1. It is recommended that the 100HP Air Compressor located at Giles Chemical Repackaging, 396 Smathers Street, Waynesville, NC 28786 be considered qualified based on meeting the acceptance criteria of the IQ/OQ protocol.

V. REFERENCE:

E16-VAL-RIQ-602, 100HP Air Compressor IQ/OQ Protocol, rev 0, 3/10/2016

Appendix I – Air Compressors: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Air Compressor #4:

Distance Criterion	Is the current area sufficient to open the access without obstructions (Yes/No)
Allow sufficient room around the machine for access doors and panels to be opened	YES
The machine must be located in an area that is adequately ventilated	YES

02. Equipment Identification

Equipment Identification	
Equipment	**Serial or Tag Identifier**
Air Compressor #4	**NK2529U15278**

03. Utilities

a. Verify that unit is receiving its specified utility requirements.

Electrical	
Specified	**Actual**
458 – 488 V Air Compressor #4	481.2V

APPENDIX II - Air Compressor: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the Air Compressor controls work properly

Controls/Indicators Verification		
Description	**Function**	**Did Item function properly (Yes/No)**
Air Compressor #4		
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	YES
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	YES

AIR COMPRESSOR: CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date
Multimeter	100100221	At manufacture	n/a

Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation and Operational Qualification for the 100HP Air Compressor located at 396 Smathers Street in Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		
Thomas Evans	Maintenance		
Monte Plott	Production		
Matt Haynes	Operations		
Deborah Durbin	Quality		

A final summary report that consists of results and conclusions based on the data collected after protocol execution will be written and approved. The executed protocol will be attached behind the report.

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I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the 100HP Air Compressor is installed and functions as intended. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ) and Operational Qualification (OQ) for the 100HP Air Compressor located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

Many of the automated packaging machines at the Repackaging facility use compressed air for operating purposes. Giles has installed one compressor with built-in air dryer unit, tied to a common header system, to provide air for all of these machines.

The products that are impacted by this study are all Epsom Salt products manufactured by Giles Chemical.

III. OVERVIEW

No other departments or systems will be affected by the installation or use of this equipment.

The following tests will be performed in this qualification:

Installation Documentation – the serial number or asset tag number of the compressor will be documented.

Utility Verification – the voltage to the compressor will be documented and verified to be correct.

Control / Operation Verification – the controls will be verified

IV. SYSTEM DESCRIPTION:

A. The system consists of one air compressor and one built-in air dryer unit. This unit is tied into a common header system.

B. Description of Operation

01. The air compressor is started by turning the switch to "on" and is stopped by turning the switch to "off".

02. The air dryer is automatically turned on when the air compressor is turned on.

V. SCOPE

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the air compressor system is installed properly and functions as desired by Giles..

VI. ROLES AND RESPONSIBILITIES

1. Engineering

- ❖ Write and issue the protocol
- ❖ Investigate protocol deviation reports

- ❖ Execute the IQ and OQ.
- ❖ Review raw data and originate interim notification to Quality Assurance
- ❖ Write and route the final report

2. Quality Assurance
   - ❖ Review and approve the protocol.
   - ❖ Review and approve raw data and notifications.
   - ❖ Review, approve, and store the final report.
3. Maintenance
   - ❖ Provide Equipment Manuals, if available, to execute operational qualification.
   - ❖ Review and approve the protocol.
   - ❖ Assist with executing the IQ and OQ if needed.
   - ❖ Review and approve raw data and notifications.
   - ❖ Review and approve the final report
4. Production
   - ❖ Review and approve the final report.

VII. TEST PROGRAM

A. INSTALLATION QUALIFICATION

Objective

The objective of the installation verification is to document each piece of Air Compressor equipment.

Equipment/Materials

Air Compressor/Air Dryer

Ideal Digital Multimeter Model #61-340 (SN 100100221)

Procedure

Perform each listed below for Air Compressor/Air Dryer

- Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Equipment: Document the Model and Serial or Asset Tag number of the air compressor/air dryer unit
- Utilities
  - Electrical Requirements: Verify that instrument is receiving its specified Voltage.

Acceptance Criteria

If the voltage is correct, each piece is uniquely identified, and sufficient access for all doors and panels is available, the Air Compressor will be considered installed properly.

B. OPERATION QUALIFICATION

Objective

The objective of Controls Verification is to document that the Air Compressor operates as needed by Giles. The controls will be operated to test the ability of the Air Compressor to be started and stopped as needed.

Equipment/Materials

Air Compressor/Air Dryer

Procedure

Start and stop air compressor. Verify function.

Acceptance Criteria

If the air compressor and air dryer start and stop then the controls are considered to be operationally qualified.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Ideal Digital Multimeter Model #61-340 (SN 100100221)

Air Compressor: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Air Compressor #4:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened	Yes	JE	3/17/16
The machine must be located in an area that is adequately ventilated	Yes	JE	3/17/16

Reviewed By: _____ **Date:** 3-17-16

02. Equipment Identification

Equipment Identification			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Air Compressor #4	NK2529U15278	JE	3/17/16
Comments:			JE 3/17/16

03. Utilities

a. Verify that unit is receiving its specified utility requirements.

Electrical			
Specified	**Actual**	**Verified By**	**Date**
458 – 488 V Air Compressor #4	481.2	JE	3/17/16
Comments:			JE 3/17/16

Reviewed By: _____ **Date:** 3-17-16

Air Compressor: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the Air System controls work properly

Controls/Indicators Verification				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
Air Compressor #4				
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	[signature]	3/17/16
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	[signature]	3/17/16
Comments:				

[signature] 3/17/16

Reviewed By: [signature] **Date:** 3-17-16

CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Multimeter	100100221	at manufacture	N/A	[signature]	3/17/16

Reviewed By: [signature] **Date:** 3-17-16

ATTACHMENT I - PROTOCOL DEVIATION REPORT LOG

Log each Protocol Deviation Report in the table below. Attach the PDRs to this Attachment.

PDR #	DESCRIPTION	DATE INITIATED	DATE RESOLVED
Comments:			

3/17/16

IX. PROTOCOL DEVIATION REPORT (PDR)

General Information

System Name: _____ Protocol Number: _____

Deviation Report Number: _____ Protocol Step & Page No.: _____

Instructions

1. The validation specialist assigns a sequential report number for each deviation with a specific protocol. For example, 001, 002, etc. can be easily referenced in a report.
2. Reference the relevant protocol number, step and page number of the noted deviation above.
3. Complete the below listed sections. If necessary, use additional pages and attach any supporting info.
4. Include the original PDR(s) with the protocol as an attachment. Summarize the impact of the deviation in the Validation Report.

Description of Deviation:

Investigation Evaluation and Results:

Corrective Action and Resolution:

Overall Investigation Review: JE 3/17/16

Prepared By: _____ Date: _____

ATTACHMENT III - SIGNATURE IDENTIFICATION LOG SHEET

Identify in the table below any personnel involved in the execution of this protocol.

Name	Affiliation	Signature	Initial	Date
Thomas Evans	Engineering / Maint.	Thomas Evans	TE	3/17/16
Brook Vaughn	Quality	BVaughn	BV	3-17-16