

Validation Protocol

Title: Air Compressor IQ/OQ Final Report Number: E13-VAL-RFR-610

Revision: 1 Owner: Patrick Owen Effective Date: July 17, 2014

Page: 1 of 6



Approvals

Signing below indicates agreement that the execution of the Installation and Operational Qualification Protocol for the Air Compressors 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	Kether 1	7/17/14
Sammy Henson	Maintenance	Daning be deisi	7/17/14
Monte Plott	Production	MontoRest	7/17/14
Matt Haynes	Operations	(Chl)	7/17/14
Deborah Durbin	Quality	Darbi	7/17/14

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



Validation Protocol

Number: E13-VAL-RFR-610 Title: Air Compressor IQ/OQ Final Report

Owner: Patrick Owen Revision: 1 Page: 2 of 6 Effective Date: July 17, 2014



		TABLE OF CONTENTS	Page#
APPROVA	AL PAGE		1
TABLE O	F CONTENTS		2
I.	PURPOSE		3
II.	SUMMARY		3
III.	CONCLUSION		3
IV.	RECOMMENDA	ATIONS	3
V.	REFERENCE		3
APPEND	IX I:	INSTALLATION QUALIFICATION	4
APPEND	IX II:	OPERATIONAL QUALIFICATION	6
ATTACH	MENT I	COMPLETED IQ/OQ PROTCOL	END



Validation Protocol

Title: Air Compressor IQ/OQ Final Report Number: E13-VAL-RFR-610

Owner: Patrick Owen Revision: 1
Effective Date: July 17, 2014 Page: 3 of 6



I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the Air Compressors function as intended and are installed properly at Repackaging. 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 Air Compressors at 396 Smathers Street in Waynesville, NC were executed and all acceptance criteria were met.

II. SUMMARY

Three air compressors supply compressed air for Giles' Repackaging facility. All 3 compressors are 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 be 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 each compressor was documented

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

Utility Verification - verified that the voltage to each 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 Air Compressors are installed and operating as expected. The Air Compressors are considered to be qualified for use.

IV. RECOMMENDATIONS

 It is recommended that the Air Compressors 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:

E13-VAL-RIQ-601, Air Compressor IQ/OQ Protocol, rev 1, 7/15/2014



Validation Protocol

Title: Air Compressor IQ/OQ Final Report Number: E13-VAL-RFR-610

Owner: Patrick Owen Revision: 1
Effective Date: July 17, 2014 Page: 4 of 6



Appendix I - Air Compressors: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Air Compressor #1:

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

b. Air Compressor #2:

Distance Criterion	Is the current area sufficient to open the access without
Distance Circiion	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

c. Air Compressor #3:

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

d. Air Dryer #1:

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

e. Air Dryer #2:

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



Validation Protocol

Title: Air Compressor IQ/OQ Final Report Number: E13-VAL-RFR-610

Owner: Patrick Owen Revision: 1
Effective Date: July 17, 2014 Page: 5 of 6



02. Equipment Identification

Equipment Identification			
Equipment Serial or Tag Identifier			
Air Compressor #1	CBV262561		
Air Compressor #2	PX1086U03010		
Air Compressor #3	PX0413U02200		
Air Dryer #1	548540		
Air Dryer #2	11M-003950		

03. Utilities

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

Electrical		
Specified	Actual	
210 – 240 V Air Compressor #1	234V	
210 – 240 V Air Compressor #2	234V	
210 – 240 V Air Compressor #3	234V	
105 - 125 V Air Dryer #1	120V	
105 – 125 V Air Dryer #2	120V	



Validation Protocol

Title: Air Compressor IQ/OQ Final Report Number: E13-VAL-RFR-610

Owner: Patrick Owen Revision: 1
Effective Date: July 17, 2014 Page: 6 of 6



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 #1		
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 #2		
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 #3		
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 Dryer #1		
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 Dryer #2		
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



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1
Effective Date: July 15, 2014 Page: 1 of 12



Approvals

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

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering	Lat roll	7/15/14
Sammy Henson	Maintenance (Janny Jokkus	7/15/14
Monte Plott	Production	Morle Lit	7/07/4
Matt Haynes	Operations	The	7/15/14
Deborah Durbin	Quality	1010 wilin	7/15/14

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.



Validation Protocol

Number: E13-VAL-RIQ-601 Title: Air Compressor IQ/OQ Protocol

Revision: 1 Owner: Patrick Owen

Page: 2 of 12 Effective Date: July 15, 2014



		TABLE OF CONTENTS	Page #
APPROVAL P	AGE		1
TABLE OF CO	ONTENTS		2
	JRPOSE		3
	ACKGROUN	VD	3
	VERVIEW		3
	STEM DES	CRIPTION	3
	COPE		3
		RESPONSIBILITIES	3
	EST PROGE		4-5
A	INSTALLA	ATION QUALIFICATION	4
В		ONAL QUALIFICATION	5
VIII, C	ALIBRATIO		5
ATTACHME!		INSTALLATION QUALIFICATION	6-7
ATTACHME		OPERATIONAL QUALIFICATION	8
ATTACHMENT IV		CALIBRATION DATA SHEET	9
ATTACHMENT V:		PROTOCOL DEVIATION REPORT LOG	10
ATTACHMENT VI:		PROTOCOL DEVIATION REPORT	11
/11110111112		SIGNATURE IDENTIFICATION LOG SHEET	12



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Revision: 1 Owner: Patrick Owen Effective Date: July 15, 2014

Page: 3 of 12



PURPOSE: I.

The purpose of this protocol is to certify with documented evidence that the Air Compressors are installed and function 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 Air Compressors located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

BACKGROUND: II.

Many of the automated packaging machines at the Repackaging facility use compressed air for operating purposes. Giles has installed 3 compressors, 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.

OVERVIEW III.

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 each compressor will be documented.

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

Control / Operation Verification - the controls will be verified

SYSTEM DESCRIPTION: IV.

- A. The system consists of 3 air compressors and 2 air dryers. These are all tied into a common header system.
- B. Description of Operation
 - 01. The air compressors are started by turning the switch to "on" and are stopped by turning the switch to "off".
 - 02. The air dryers are started by pressing the "on" button and are stopped by pressing the "off" button.

SCOPE V.

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..

ROLES AND RESPONSIBILITIES VI.

- 1. Engineering
 - Write and issue the protocol



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1
Effective Date: July 15, 2014 Page: 4 of 12



- 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 Compressors

Air Dryer

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

Procedure

Perform each listed below for Air Compressors and 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 each piece of each compressor and air dryer



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1
Effective Date: July 15, 2014 Page: 5 of 12



Utilities

o 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 Compressors will be considered installed properly.

B. OPERATION QUALIFICATION

Objective

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

Equipment/Materials

Air Compressors

Air Dryer

Procedure

Start and stop each compressor and air dryer. Verify function.

Acceptance Criteria

If the air compressors 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)



Validation Protocol

Number: E13-VAL-RIQ-601 Title: Air Compressor IQ/OQ Protocol

Revision: 1 Owner: Patrick Owen Effective Date: July 15, 2014

Page: 6 of 12



Air Compressors: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Air Compressor #1:

	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	PSV	7/16/19
The machine must be located in an area that is adequately ventilated	Ye5	Per	7/16/14

b. Air Compressor #2:

	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	Per	7/16/14
The machine must be located in an area that is adequately ventilated	Yes	Pou	7/16/41

Air Compressor #3:

	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	465	PSV	7/16/14
The machine must be located in an area that is adequately ventilated	Yes	Ph	7/16/14

d. Air Dryer #1:

	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	PSV	7/16/14
The machine must be located in an area that is adequately ventilated	Ye5	PSV	7/16/14



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1
Effective Date: July 15, 2014 Page: 7 of 12



e. Air Dryer #2:

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	Per	7/16/14
The machine must be located in an area that is adequately ventilated	Yes	per	7/16/14

Reviewed By:

Date:

7-16-14

02. Equipment Identification

Equipment Identification				
Equipment	Serial or Tag Identifier	Verified By	Date	
Air Compressor #1	CBV262561	Poe	7/16/14	
Air Compressor #2	PX1086U03010	PW	7/16/14	
Air Compressor #3	PX0413U0220	Por	7/16/14	
Air Dryer#1	548540	PSU	7/16/14	
Air Dryer #2	1M-003950	PSV	7/16/14	
Comments:				

7/16/14

03. Utilities

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

Electrical			
Specified	Actual	Verified By	Date
210 – 240 V Air Compressor #1	234V	pe	7/16/14
210 – 240 V Air Compressor #2	2347	per	7/16/14
210 – 240 V Air Compressor #3	234V	Per	7/16/14
105 - 125 V Air Dryer #1	1201	per	7/16/14
105 – 125 V Air Dryer #2	1501	ps	7/16/14

Comments

Date:

7-16-14

Reviewed By:

Controlled Document



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1

Effective Date: July 15, 2014 Page: 8 of 12



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 #1			
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	Per	7/16/14
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	Par	7/16/14
	Air Compressor #2			
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	Por	7/16/14
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	per	7/16/14
	Air Compressor #3	ing property and a second		
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	P90	7/16/14
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	P80-	7/16/14
	Air Dryer #1			
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	PSE-	7/16/14
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	PST	7/11/14
	Air Dryer #2			
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?	Yes	PSV	7/16/14
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?	Yes	PSV	7/16/14
Comments:		amari arkisisti pitara ari ara ara ara gara ay ga agay a shi ili ili ili ake anang	the of the same of	Dev-
			- /	116/14

Reviewed By:

Date:

7-16-14



Validation Protocol

Number: E13-VAL-RIQ-601 Title: Air Compressor IQ/OQ Protocol

Revision: 1 Owner: Patrick Owen

Effective Date: July 15, 2014 Page: 9 of 12



CALIBRATION VERIFICATION

Equipment Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Multimeter 100100221	At Fuctory	NJA	Par	7/16/14

Date: 7-10-14



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1

Effective Date: July 15, 2014 Page: 10 of 12



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;			

Por 7/16/14



Prepared By:

PROTOCOL DEVIATION REPORT (PDR)

IX.

GILES CHEMICAL ~ PREMIER MAGNESIA

Validation Protocol

Number: E13-VAL-RIQ-601 Title: Air Compressor IQ/OQ Protocol

Owner: Patrick Owen Revision: 1

Effective Date: July 15, 2014 Page: 11 of 12



	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.
- Reference the relevant protocol number, step and page number of the noted deviation above.
- Validation

4.	 Include the original PDR(s) with the protosol as an attachment. Summarize the impact of the deviat Report. 					
Descrip	tion of Deviation:					
Investig	ation Evaluation and Results:					
Correct	ive Action and Resolution:					
Overall	Investigation Review:					



Validation Protocol

Title: Air Compressor IQ/OQ Protocol Number: E13-VAL-RIQ-601

Owner: Patrick Owen Revision: 1

Effective Date: July 15, 2014 Page: 12 of 12



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
Patrok Lec Owen	Egy: Mumi Mor. Repark DIS Courdinator	Pow Sal	peo	7/16/14
Abroon Vousin	Repark DIS Coordinator	Bluch	BV	7-16/14
				•
