

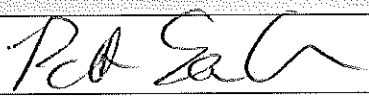

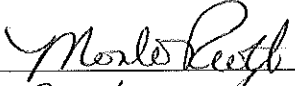
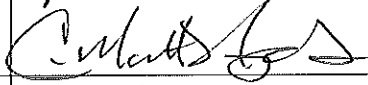



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|  | GILES CHEMICAL ~ PREMIER MAGNESIA | |  |
| | Validation Protocol | | |
| | Title: Air Compressor IQ/OQ Final Report | Number: E13-VAL-RFR-610 | |
| | Owner: Patrick Owen | Revision: 0 | |
| | Effective Date: July 11, 2013 | Page: 1 of 6 | |

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 |  | 7/11/13 |
| Robert Willis | Maintenance |  | 7/11/13 |
| Monte Plott | Production |  | 7/11/13 |
| Matt Haynes | Operations |  | 7/11/13 |
| Deborah Durbin | Quality |  | 7/11/13 |

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

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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**

Title: Air Compressor IQ/OQ Final Report

Number: E13-VAL-RFR-610

Owner: Patrick Owen

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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

1. 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 0, 6/18/2013

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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**

Title: Air Compressor IQ/OQ Final Report

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**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 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:

| 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 |

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02. Equipment Identification

| Equipment Identification | |
|--------------------------|--------------------------|
| Equipment | Serial or Tag Identifier |
| Air Compressor #1 | PX1086U03010 |
| Air Compressor #2 | PX0413U02200 |
| Air Compressor #3 | 1173 |
| Air Dryer | 11M-030551 |



03. Utilities

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

| Electrical | |
|-------------------------------|--------|
| Specified | Actual |
| 210 – 240 V Air Compressor #1 | 231V |
| 210 – 240 V Air Compressor #2 | 231V |
| 210 – 240 V Air Compressor #3 | 231V |
| 210 – 240 V Air Dryer | 231V |

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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 pushing the On Switch cause the machine to start? | YES |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | YES |
| Air Compressor #2 | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | YES |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | YES |
| Air Compressor #3 | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | YES |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | YES |
| Air Dryer | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | YES |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | YES |

AIR COMPRESSOR: CALIBRATION VERIFICATION

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

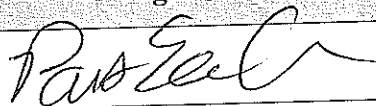
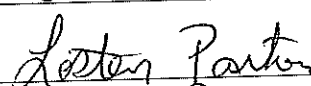
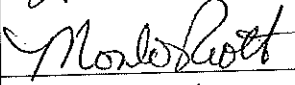
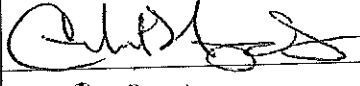

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| | Validation Protocol | | |
| | Title: Air Compressor IQ/OQ Protocol | Number: E13-VAL-RIQ-601 | |
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| | Effective Date: June 18, 2013 | Page: 1 of 12 | |

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 |  | 6/18/13 |
| Robert Willis ^{pt} 6/19/13 Lester Porter | Maintenance |  | 6-19-13 |
| Monte Plott | Production |  | 6/18/13 |
| Matt Haynes | Operations |  | 6/19/13 |
| Deborah Durbin | Quality |  | 6/18/13 |

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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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**

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I. PURPOSE:

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.

II. BACKGROUND:

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.

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 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

IV. SYSTEM DESCRIPTION:

A. The system consists of 3 air compressors and an air dryer. These are all tied into a common header system.

B. Description of Operation

01. The air compressors are started by pressing the “on” button and are stopped by pressing the “off” button.

02. The air dryer is started by pressing the “on” button and are stopped by pressing the “off” button.

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

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- ❖ 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
- Utilities

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- 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 with the start and stop buttons. 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)

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GILES CHEMICAL ~ PREMIER MAGNESIA

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PREMIER
MAGNESIA, LLC

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 | POW | 6/20/13 |
| The machine must be located in an area that is adequately ventilated | Yes | POW | 6/20/13 |

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 | POW | 6/20/13 |
| The machine must be located in an area that is adequately ventilated | Yes | POW | 6/20/13 |

c. 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 | Yes | POW | 6/20/13 |
| The machine must be located in an area that is adequately ventilated | Yes | POW | 6/20/13 |

d. Air Dryer:

| 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 | POW | 6/20/13 |
| The machine must be located in an area that is adequately ventilated | Yes | POW | 6/20/13 |

Reviewed By:

Brook Hughes

Date:

7/8/13

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GILES CHEMICAL ~ PREMIER MAGNESIA

Validation Protocol

Title: Air Compressor IQ/OQ Protocol

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Owner: Patrick Owen

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PREMIER
MAGNESIA, LLC

02. Equipment Identification

| Equipment Identification | | | |
|-----------------------------------|--------------------------|-------------|---------|
| Equipment | Serial or Tag Identifier | Verified By | Date |
| <u>Manual Line #1</u> per 6/21/13 | | | |
| Air Compressor #1 | PX1086U03010 | PSO | 6/21/13 |
| Air Compressor #2 | PX0413U02200 | PSO | 6/21/13 |
| Air Compressor #3 | 1173 | PSO | 6/21/13 |
| Air Dryer | 11M-030551 | PSO | 6/21/13 |
| Comments: | | | |

per
6/21/13

03. Utilities

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

| Electrical | | | |
|-------------------------------|--------|-------------|---------|
| Specified | Actual | Verified By | Date |
| 210 - 240 V Air Compressor #1 | 231 V | PSO | 6/21/13 |
| 210 - 240 V Air Compressor #2 | 231 V | PSO | 6/21/13 |
| 210 - 240 V Air Compressor #3 | 231 V | PSO | 6/21/13 |
| 210 - 240 V Air Dryer | 231 V | PSO | 6/21/13 |
| Comments: | | | |

per
6/21/13

Reviewed By:

Date:

7-8-13

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**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) | Verified By | Date |
| Air Compressor #1 | | | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | Yes | per | 6/20/13 |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | Yes | per | 6/20/13 |
| Air Compressor #2 | | | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | Yes | per | 6/20/13 |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | Yes | per | 6/20/13 |
| Air Compressor #3 | | | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | Yes | per | 6/20/13 |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | Yes | per | 6/20/13 |
| Air Dryer | | | | |
| On Switch | With line power to the machine, does pushing the On Switch cause the machine to start? | Yes | per | 6/20/13 |
| Off Switch | With line power to the machine, does pushing the Off Button cause the machine to stop? | Yes | per | 6/20/13 |
| Comments: | | | | |



Reviewed By:

Date:

7-8-13

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MANUAL LINES: CALIBRATION VERIFICATION

| Equipment | Serial # | Calibration Date | Calibration Due Date | Verified By | Date |
|------------|-----------|------------------|----------------------|-------------|---------|
| Multimeter | 100100221 | at manufacture | n/a | Perf | 6/20/13 |

Reviewed By:

Brook Vaughn

Date:



7-8-13

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X. 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:

*per
6/20/13*

Prepared By: _____ Date: _____

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Validation Protocol

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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 |
|------------------|------------------|-----------|---------|---------|
| Patrick Owen | Process Engineer | | PO | 6/20/13 |
| Brook Vaughn | Quality Assoc. | | BV | 7/8/13 |
| Robert D. Willis | MAINT. | | rdw | 7/8/13 |
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