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		7/15/14
Sammy Henson	Maintenance		7/15/14
Monte Plott	Production		7/15/14
Matt Haynes	Operations		7/15/14
Deborah Durbin	Quality		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.

TABLE OF CONTENTS		Page #
APPROVAL PAGE		1
TABLE OF CONTENTS		2
I.	PURPOSE	3
II.	BACKGROUND	3
III.	OVERVIEW	3
IV.	SYSTEM DESCRIPTION	3
V.	SCOPE	3
VI.	ROLES AND RESPONSIBILITIES	3
VII.	TEST PROGRAM	4-5
A	INSTALLATION QUALIFICATION	4
B	OPERATIONAL QUALIFICATION	5
VIII.	CALIBRATION	5
ATTACHMENT I:	INSTALLATION QUALIFICATION	6-7
ATTACHMENT II:	OPERATIONAL QUALIFICATION	8
ATTACHMENT IV	CALIBRATION DATA SHEET	9
ATTACHMENT V:	PROTOCOL DEVIATION REPORT LOG	10
ATTACHMENT VI:	PROTOCOL DEVIATION REPORT	11
ATTACHMENT VII	SIGNATURE IDENTIFICATION LOG SHEET	12

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 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.

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 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
    - 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)

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			
The machine must be located in an area that is adequately ventilated			

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			
The machine must be located in an area that is adequately ventilated			

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			
The machine must be located in an area that is adequately ventilated			

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			
The machine must be located in an area that is adequately ventilated			

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			
The machine must be located in an area that is adequately ventilated			

Reviewed By: _____ **Date:** _____

02. Equipment Identification

Equipment Identification			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Air Compressor #1			
Air Compressor #2			
Air Compressor #3			
Air Dryer #1			
Air Dryer #2			
Comments:			

03. Utilities

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

Electrical			
Specified	**Actual**	**Verified By**	**Date**
210 – 240 V Air Compressor #1			
210 – 240 V Air Compressor #2			
210 – 240 V Air Compressor #3			
105 - 125 V Air Dryer #1			
105 – 125 V Air Dryer #2			
Comments:			

Reviewed By: _____ **Date:** _____

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?			
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?			
Air Compressor #2				
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?			
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?			
Air Compressor #3				
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?			
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?			
Air Dryer #1				
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?			
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?			
Air Dryer #2				
On Switch	With line power to the machine, does turning the switch to On cause the machine to start?			
Off Switch	With line power to the machine, does turning the switch to Off cause the machine to stop?			
Comments:				

Reviewed By: _____ **Date:** _____

CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Multimeter					

Reviewed By: _____ **Date:** _____

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:			

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:

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