Approvals

Signing below indicates agreement that the execution of the Installation and Operational Qualification Protocol for the Scales 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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I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the Scales 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 Scales at 396 Smathers Street in Waynesville, NC were executed and all acceptance criteria were met.

II. SUMMARY

Four Scales are used for product weight verification for Giles' Repackaging facility. These scales are used regularly and are calibrated on a periodic basis.

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 scale was documented

Controls/Indicators Verification – verified and documented that the power button and tare worked properly

Utility Verification – verified that the voltage to each scale 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 Scales are installed and operating as expected. The Scales are considered to be qualified for use.

IV. RECOMMENDATIONS

1. It is recommended that the Scales 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-651, Scales IQ/OQ Protocol, rev 0, 6/19/2013

Appendix I - Scales: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Scale #1:

LOCATION	
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**
Allow sufficient room around the machine for access doors and panels to be opened	YES
The scale should be level	YES

b. Scale #2:

LOCATION	
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**
Allow sufficient room around the machine for access doors and panels to be opened	YES
The scale should be level	YES

c. Scale #3:

LOCATION	
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**
Allow sufficient room around the machine for access doors and panels to be opened	YES
The scale should be level	YES

d. Scale #4:

LOCATION	
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**
Allow sufficient room around the machine for access doors and panels to be opened	YES
The scale should be level	YES

02. Equipment Identification

Equipment Identification	
Equipment	**Serial or Tag Identifier**
Scale #1	**5436063-5FF**
Scale #2	**5436062-5FF**
Scale #3	**5630793-5DL**
Scale #4	**56391685HL**

03. Utilities

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

Electrical	
Specified	**Actual**
108-132 V Scale #1	121.5V
108-132 V Scale #2	121.5V
108-132 V Scale #3	121.5V
108-132 V Scale #4	121.5V

APPENDIX II - SCALES OPERATIONAL QUALIFICATION

B. Operation Qualification

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

Controls/Indicators Verification		
Description	**Function**	**Did Item function properly (Yes/No)**
Scale #1		
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	YES
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	YES
Scale #2		
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	YES
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	YES
Scale #3		
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	YES
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	YES
Scale #4		
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	YES
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	YES

SCALES: CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date
Multimeter	100100221	At manufacture	n/a
Scale #1	5436063-5FF	6/13/13	7/13/13
Scale #2	5436062-5FF	6/13/13	7/13/13
Scale #3	5630793-5DL	6/13/13	7/13/13
Scale #4	56391685HL	6/13/13	7/13/13

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	Pat Owen	6/19/2013
~~Robert Willis~~ Lester Parton per 6/19/2013	Maintenance	Lester Parton	6-19-13
Monte Plott	Production	Monte Plott	6-19-13
Matt Haynes	Operations	Matt Haynes	6-19-13
Deborah Durbin	Quality	Deborah Durbin	6-19-13

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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I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Repackaging Scales 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 Scales located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

Giles' products are sold by weight. In order to verify that the machinery is packaging the correct amount of Epsom Salt into each package, scales are used to verify weights. The results are then used to adjust the machinery controls to dispense the correct amount of salt into the package. Giles has 4 scales in the Repackaging Area that are used for these process control purposes.

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 scale will be documented.

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

Control / Operation Verification – the controls will be verified

IV. SYSTEM DESCRIPTION:

A. The system consists of 4 scales.

B. Description of Operation

01. The scales are started by pressing the power button.

02. The scales are tared by pressing the tare button.

03. The product is weighed.

04. For weight checks, an empty package is placed on the scale before taring. The weight measured of the filled package is then assumed to be the weight of the Epsom salt dispensed.

V. SCOPE

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the scales are installed properly and function 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

Scales #1 - #4

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

Procedure

Perform each listed below for each scale

- Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Level – place a level on the scale and verify that the scale is level.
- Equipment: Document the Model and Serial or Asset Tag number of each piece of each scale
- 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 scales will be considered installed properly.

B. OPERATION QUALIFICATION

Objective

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

Equipment/Materials

Scale #1 - #4

Procedure

Start each scale with the power button.

Place a weight on the scale and press the tare button. Verify that the scale tares properly.

Acceptance Criteria

If each scale powers up and tares properly the scales will be considered operationally qualified.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Ideal Digital Multimeter Model #61-340 (SN 100100221)
- Scale #1
- Scale #2
- Scale #3
- Scale #4

Scales: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Scale #1:

LOCATION			
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened	Yes	PEO	6/20/13
The scale should be level	Yes	PEO	6/20/13

b. Scale #2:

LOCATION			
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened	YES	PEO	6/20/13
The scale should be level	Yes	PEO	6/20/13

c. Scale #3:

LOCATION			
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened	Yes	PEO	6/20/13
The scale should be level	Yes	PEO	6/20/13

d. Scale #4:

LOCATION			
Distance Criterion	**Does the Scale meet the criteria?(Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened	Yes	PEO	6/20/13
The scale should be level	Yes	PEO	6/20/13

Reviewed By: Brook Vaughn **Date:** 7-8-13

02. Equipment Identification

Equipment Identification			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Manual Line #1			
Scale #1	5436063 - 5FF	PeT	6/20/13
Scale #2	5436062 - 5FF	PST	6/20/13
Scale #3	9630793 - 5DL	PST	6/20/13
Scale #4	9639685 HL	PST	6/20/13
Comments:			

PST 6/20/13

03. Utilities

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

Electrical			
Specified	**Actual**	**Verified By**	**Date**
108-132 V Scale #1	121.5	PST	6/21/13
108-132 V Scale #2	121.5	PST	6/21/13
108-132 V Scale #3	121.5	PST	6/21/13
108-132 V Scale #4	121.5	PST	6/21/13
Comments:			

PST 6/21/13

Reviewed By: Brook Vaughn **Date:** 7-8-13

Scales per 6/20/13

Air Compressor: OPERATIONAL QUALIFICATION

B. Operation Qualification

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

Controls/Indicators Verification				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
Scale #1				
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	Yes	PSO	6/20/13
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	Yes	PSO	6/20/13
Scale #2				
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	Yes	PSO	6/20/13
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	Yes	PSO	6/20/13
Scale #3				
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	Yes	PSO	6/20/13
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	Yes	PSO	6/20/13
Scale #4				
Power Button	With line power to the machine, does pushing the Power Button cause the Scale to start?	Yes	PSO	6/20/13
Tare Button	With a weight on the scale, does pushing the Tare Button cause the scale reading to go to Zero?	Yes	PSO	6/20/13
Comments:				

PSO 6/20/13

Reviewed By: Brook Vaughn **Date:** 7-8-13

SCALES: CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Multimeter	100100221	at manufacture	n/A	PEG	6/20/13
Scale #1	5436063-SFF	6/13/13	7/13/13	PEG	6/20/13
Scale #2	5436062-SFF	6/13/13	7/13/13	PEG	6/20/13
Scale #3	5630793-SOL	6/13/13	7/13/13	PEG	6/20/13
Scale #4	5639168SHL	6/13/13	7/13/13	PEG	6/20/13

Reviewed By: Brad Vaughn Date: 7-8-13

ATTACHMENT - 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:			

per 6/20/13

ATTACHMENT: 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:

PC
6/20/13

Prepared By: _____ Date: _____

ATTACHMENT - 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 Asst.	Brook Vaughn	BV	7-8-13