I. Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for the Hayssen Bagger model SV 18-27 HP, located at 102 Commerce Street at the Main Plant production facility.

Project Member	Functional Area	Signature	Date
Patrick Owen	Engineering		10/31/16
Kenneth Basehore	Engineering		10/28/16
Sammy Henson	Maintenance		10/31/16
Jason Bumgarner	Production		10-31-16
Matt Haynes	Operations		10-31-16
Deborah Durbin	Quality		10-31-16

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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II. Purpose

The purpose of this protocol is to certify with documented evidence that the Hayssen Bagger model SV 18-27 HP (s/n U89375), functions as intended throughout its anticipated operating ranges. This protocol sets forth the objecties, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ), Operational Qualification (OQ) and Process Qualification (PQ) for the Hayssen Bagger model SV 18-27 HP, located at 102 Commerce Street at the Main Plant production facility.

III. Background

This bagger model SV 18-27 HP (s/n U89375) was manufactured by Hayssen in Duncan, SC. It was installed at Giles in July of 2016. The machine will be used to fill and seal plastic bags, typically a 50-pound size.

IV. Overview

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

The following tests will be performed during this qualification:

- Controls/Indicators verification – to document that the start/stop, emergency stop and feed controls work correctly.
- Lot code and expiration date verification – to document that the lot code is printed and legible on each bag.
- Sealed bag verification – to document that the bag is sealed correctly on the bottom, top and side.
- Fill weight verification – to document that the equipment fills the correct amount of Epsom Salt in each bag.

V. System Description

1. A roll of film is loaded on to the machine.
2. If required, the lot and expiration date is printed onto the film
3. The machine bends the film into a cylinder, and heat seals the two edges together, forming a tube of film.
4. The bottom of the tube was heat sealed during the creation of the previous bag.
5. The machine weighs salt to the setpoint defined in the recipe from a hopper mounted above the machine, and dispenses the salt into the tube.
6. The machine heat seals and cuts the tube.
7. The newly created filled bag is dispensed onto a conveyor.
8. The bag is transported to the palletizer for pallet creation and shipment.

VI. Scope

The IQ, OQ and PQ contained within this protocol is intended to certify with documented evidence that the Hayssen model SV 18-27 HP (s/n U89375) is installed, operates and functions as intended throughout its anticipated operating ranges.

The products affected by this equipment are all 50 pound bags of Epsom Salt produced at the Main Plant facility.

VII. Roles and Responsibilities

1. Engineering
   - Write and issue the protocol
   - Investigate protocol deviation reports
   - Execute the IQ, OQ and PQ portions of the validation
   - Review the data and originate the interim notification to Quality Assurance
   - Write and route the final report
2. Quality Assurance
   - Review and approve the protocol
   - Review and approve the raw data and notifications
   - Review, approve and store the final report
3. Maintenance
   - Provide equipment manuals needed to execute the validation
   - Review and approve the protocol
   - Review and approve the raw data and notifications
   - Review and approve the final report
4. Production
   - Review and approve the protocol
   - Review and approve the raw data and notifications
   - Review and approve the final report
   - Assist, as needed with the execution of the IQ, OQ and PQ

VIII. Test Program

1. Installation Qualification (IQ)

a. Objective

The objective of the installation verification is to document that the Hayssen bagger model SV 18-27 HP (s/n U89375) in installed as indicated by the manufacturer.

b. Equipment and Materials

- Hayssen model SV 18-27 HP (s/n U89375)

- Calibrated multimeter

c. Procedure

- Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Verify that the equipment is level
- Verify that the electrical and compressed air utilities fall within the manufacturers required ranges

d. Acceptance Criteria

Ensure that the installation is in accordance with the manual's specifications.

2. *Operational Qualification (OQ)*

a. Objective

The objective of the Controls/Indicators verification is to document that the Hayssen bagger model SV 18-27 HP (s/n U89375) operates as indicated by the manufacturer. The controls will be operated to test the ability of the machine to start/stop, feed and emergency stop as required.

b. Equipment and Materials

Hayssen bagger model SV 18-27 HP (s/n U89375)

c. Procedure

Test each operation of the Hayssen bagger model SV 18-27 HP (s/n U89375)

d. Acceptance Criteria

Verification that the tested operations operate as indicated by the manufacturer's instructions.

3. *Performance Qualification (PQ)*

a. Objective

The objective of the performance testing is to document that the Hayssen bagger model SV 18-27 HP (s/n U89375) performs the functions required by Giles Chemical. The final product will be tested to verify:

- The lot code and expiration date is printed clearly on each bag
- The bag is sealed along three seams
- The bag is filled to the correct weight

b. Equipment and Materials

- Hayssen bagger model SV 18-27 HP (s/n U89375)
- Bag film
- Bulk salt

- Scale model FS-60KL (s/n 4500227)

c. Procedure

Run the machine for long enough to produce two full pallets of bags (98 bags total). Examine each bag to check for:

- Seal quality
- Fill weight
- Printed lot/expiration quality

d. Acceptance Criteria

The PQ will be accepted if all 98 bags are sealed along three seams, the fill weights are within tolerance of the setpoint, and that each lot/expiration date is legible.

IX. Calibration

Verify that all instruments used are within the calibration dates.

- Calibrated multimeter
- Scale model FS-60KL (s/n 4500227)

X. References

- Primo Linear V-25 User Manual Rev. 2.0
- Primo Linear HMI Manual Rev. 1.0

XI. Installation Qualification (IQ)

1. Equipment

Device	Calibration Date	Calibration Expiration	Verified By	Date
Multimeter **Model:** 114 (FLUKE) **S/N:** 36250117WS	10/3/16	10/3/17	KLB	11/16/16

Expected	Actual	Verified By	Date
Hayssen model SV 18-27 HP s/n U89375	HAYSSEN MODEL SV 18-27 HP S/N U89375	KLB	11/16/16

2. Acceptance Testing

Expected	Actual	Verified By	Date
There is sufficient room around the machine to allow access doors and panels to be opened.	There IS sufficient room around the machine to allow access doors and panels to be opened.	KLB	11/16/16
The equipment is level	The equipment IS level	KLB	11/16/16
Power supply 240 VAC ± 20	240 V AC	KLB	11/16/16
Power supply 60 Hz	60 Hz	KLB	11/16/16
Compressed air 40 psi ± 4	41 PSI	KLB	11/16/16

3. *Acceptance of Testing and Review*

Expected	Actual	Initials	Date
All actual results match the expected values.	All actual results MATCH the expected values.	KLB	11/16/16
Results reviewed and accepted by Ashley Williams		AW	11/16/16

XII. Operational Qualification (PQ)

1. *Equipment*

Expected	Actual	Verified By	Date
Hayssen model SV 18-27 HP s/n U89375	HAYSSEN MODEL SV 18-27 HP S/N U89375	KLB	11/16/16

2. *Acceptance Testing*

Expected	Actual	Verified By	Date
The machine is stopped	The machine IS stopped	KLB	11/16/16
Press the start button	The start button IS pressed	KLB	11/16/16
The machine is running	The machine IS running	KLB	11/16/16
Press the E-Stop	The E-Stop IS pressed	KLB	11/16/16
The machine is stopped	The machine IS stopped	KLB	11/16/16
Reset the alarms	The alarms ARE reset	KLB	11/16/16
Start the machine	The machine IS running	KLB	11/16/16
Select a recipe	A recipe IS selected	KLB	11/16/16

The bags are filling	The bags ARE filling	KLB	11/16/16
The bags are ejecting to the conveyor	The bags ARE ejecting to the conveyor	KLB	11/16/16
Both lines are used to dispense salt	Both lines ARE used to dispense salt	KLB	11/16/16
Stop the machine	The machine IS stopped	KLB	11/16/16
Change the target weight	The target weight IS changed Old target weight: 49.75 New target weight: 50.00	KLB	11/16/16

3. *Acceptance of Testing and Review*

Expected	Actual	Initials	Date
All actual results match the expected values.	All actual results MATCH the expected values.	KLB	11/16/16
The IQ section is complete with no deviations	The IQ section IS complete with no deviations	KLB	11/16/16
Results reviewed and accepted by		QW	11/16/16

XIII. Performance Qualification (PQ)

1. Equipment

Device	Calibration Date	Calibration Expiration	Verified By	Date
Scale model FS-60KL s/n 4500227	10/25/16	11/16	KLB	11/16/16

Expected	Actual	Verified By	Date
Hayssen model SV 18-27 HP s/n U89375	HAYSSEN MODEL SV 18-27HP S/N U89375	KLB	11/16/16

2. Acceptance Testing

Bag #	100% Sealed? Yes/No	Lot Visible? Yes/No	Bag Weight lbs	Verified By	Date
1	Yes	Yes	49.76	KLB	11/16/16
2	Yes	Yes	49.74	KLB	11/16/16
3	Yes	Yes	49.84	KLB	11/16/16
4	Yes	Yes	49.98	KLB	11/16/16
5	Yes	Yes	49.88	KLB	11/16/16
6	Yes	Yes	49.82	KLB	11/16/16
7	Yes	Yes	49.86	KLB	11/16/16
8	Yes	Yes	50.24	KLB	11/16/16
9	Yes	Yes	49.86	KLB	11/16/16
10	Yes	Yes	49.80	KLB	11/16/16
11	Yes	Yes	49.82	KLB	11/16/16
12	Yes	Yes	49.86	KLB	11/16/16
13	Yes	Yes	49.82	KLB	11/16/16
14	Yes	Yes	49.94	KLB	11/16/16

15	Yes	Yes	49.82	KLB	11/16/16
16	Yes	Yes	49.84	KLB	11/16/16
17	Yes	Yes	49.82	KLB	11/16/16
18	Yes	Yes	49.88	KLB	11/16/16
19	Yes	Yes	49.86	KLB	11/16/16
20	Yes	Yes	49.80	KLB	11/16/16
21	Yes	Yes	49.78	KLB	11/16/16
22	Yes	Yes	49.84	KLB	11/16/16
23	Yes	Yes	49.82	KLB	11/16/16
24	Yes	Yes	49.84	KLB	11/16/16
25	Yes	Yes	49.78	KLB	11/16/16
26	Yes	Yes	49.80	KLB	11/16/16
27	Yes	Yes	49.82	KLB	11/16/16
28	Yes	Yes	49.84	KLB	11/16/16
29	Yes	Yes	49.82	KLB	11/16/16
30	Yes	Yes	49.88	KLB	11/16/16
31	Yes	Yes	49.82	KLB	11/16/16
32	Yes	Yes	49.86	KLB	11/16/16
33	Yes	Yes	49.90	KLB	11/16/16
34	Yes	Yes	49.92	KLB	11/16/16
35	Yes	Yes	49.86	KLB	11/16/16
36	Yes	Yes	49.84	KLB	11/16/16
37	Yes	Yes	49.86	KLB	11/16/16
38	Yes	Yes	49.86	KLB	11/16/16
39	Yes	Yes	49.82	KLB	11/16/16
40	Yes	Yes	49.82	KLB	11/16/16
41	Yes	Yes	49.84	KLB	11/16/16
42	Yes	Yes	49.82	KLB	11/16/16

43	YES	YES	49.84	KLB	11/16/16
44	YES	YES	49.82	KLB	11/16/16
45	YES	YES	49.82	KLB	11/16/16
46	YES	YES	49.88	KLB	11/16/16
47	YES	YES	49.86	KLB	11/16/16
48	YES	YES	49.86	KLB	11/16/16
49	YES	YES	49.80	KLB	11/16/16
50	YES	YES	49.84	KLB	11/16/16
51	YES	YES	49.80	KLB	11/16/16
52	YES	YES	49.86	KLB	11/16/16
53	YES	YES	49.80	KLB	11/16/16
54	YES	YES	49.76	KLB	11/16/16
55	YES	YES	49.80	KLB	11/16/16
56	YES	YES	49.86	KLB	11/16/16
57	YES	YES	49.86	KLB	11/16/16
58	YES	YES	49.86	KLB	11/16/16
59	YES	YES	49.82	KLB	11/16/16
60	YES	YES	49.92	KLB	11/16/16
61	YES	YES	49.92	KLB	11/16/16
62	YES	YES	49.80	KLB	11/16/16
63	YES	YES	49.84	KLB	11/16/16
64	YES	YES	50.16	KLB	11/16/16
65	YES	YES	49.78	KLB	11/16/16
66	YES	YES	49.82	KLB	11/16/16
67	YES	YES	49.80	KLB	11/16/16
68	YES	YES	49.86	KLB	11/16/16
69	YES	YES	49.82	KLB	11/16/16
70	YES	YES	49.86	KLB	11/16/16

71	YES	YES	49.82	KLB	11/16/16
72	YES	YES	49.82	KLB	11/16/16
73	YES	YES	49.86	KLB	11/16/16
74	YES	YES	49.90	KLB	11/16/16
75	YES	YES	49.90	KLB	11/16/16
76	YES	YES	49.82	KLB	11/16/16
77	YES	YES	49.82	KLB	11/16/16
78	YES	YES	49.74	KLB	11/16/16
79	YES	YES	49.78	KLB	11/16/16
80	YES	YES	49.76	KLB	11/16/16
81	YES	YES	49.80	KLB	11/16/16
82	YES	YES	49.82	KLB	11/16/16
83	YES	YES	49.82	KLB	11/16/16
84	YES	YES	49.80	KLB	11/16/16
85	YES	YES	49.80	KLB	11/16/16
86	YES	YES	49.78	KLB	11/16/16
87	YES	YES	49.78	KLB	11/16/16
88	YES	YES	49.78	KLB	11/16/16
89	YES	YES	49.80	KLB	11/16/16
90	YES	YES	49.82	KLB	11/16/16
91	YES	YES	49.82	KLB	11/16/16
92	YES	YES	49.78	KLB	11/16/16
93	YES	YES	49.74	KLB	11/16/16
94	YES	YES	49.84	KLB	11/16/16
95	YES	YES	49.86	KLB	11/16/16
96	YES	YES	49.82	KLB	11/16/16
97	YES	YES	49.78	KLB	11/16/16
98	YES	YES	49.80	KLB	11/16/16

3. Acceptance of Testing and Review

Expected	Actual	Initials	Date
All actual results match the expected values.	All actual results MATCH the expected values.	KLB	11/16/16
The IQ section is complete with no deviations	The IQ section IS complete with no deviations	KLB	11/16/16
The PQ section is complete with no deviations	The PQ section IS complete with no deviations	KLB	11/16/16
Results reviewed and accepted by		[signature]	11/16/16

XIV. Protocol Deviation Report Log

Log each protocol deviation report in the table below. Attach PDRs to this protocol.

PDR #	Description	Protocol Section	Date Initiated	Date Resolved
		N/A		
			KLB 11/16/16	

XV. Signature Identification Log

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

Name	Affiliation	Signature	Initials	Date
Kenneth Basehore	Engineering	Kenneth Basehore	KLB	11/16/16
Ashley Williams	Quality	Ashley Williams	AW	11/16/16
Jason Blumgarner	Manufacturing		JB	11-18-16