

Summary:

The purpose of the Quality Risk Assessment is to detect weaknesses in the current quality controls and find the Quality Critical Parameters in order to develop Statistical Process Controls at each Critical Control Point. It is also important for supporting the Validation efforts at Giles. Each step, or processing unit in the plant was evaluated by Failure Modes and Effects Analysis (FMEA). Each Failure Mode was assigned a Quality Severity Rating and Occurrence Rating by the team. Current Controls were evaluated and a Detection rating was assigned. The Risk Priority Number was the result of multiplying the 3 ratings together. The criticality of each Failure Mode was determined numerically. Based on experience the critical Priority Number was set a greater than or equal to 250. The parameters associated with these Risk Priority Numbers are then considered Process Critical Parameter and the controls used to adjust these parameters are then considered Critical Control Points. As a result Statistical Process Control (SPC) charts will then be established for each Critical Control Point for Process Control. These Critical Parameters and Critical Control points are also the basis of Validation of each processing unit.

Team:

The team met on 12/14/2012 for the purpose of performing the FMEA and included members responsible for the Quality, Production, Maintenance, and Engineering Departments.

Deborah Durbin – Director of Quality

Jason Bumgarner – Production Manager

Robert Willis – Maintenance Manager

Patrick Owen – Process Engineer

Paul Jones – Project Engineer

Purpose:

The purpose of the FMEA meeting was to detect weaknesses in the current quality controls and find the Quality Critical Parameters in order to develop Statistical Process Controls at each Critical Control Point.

Criteria:

Each Failure mode was evaluated by 3 criteria and ranked numerically. The numerical rankings are explained as follows.

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Quality Severity Rating – potential impact on ability of product to meet specifications

Quality Severity Rating

Ranking	Guideline
1	Little or no impact
5	Potential Impact if problem continues for extended periods
10	Potential negative impact on quality if not resolved immediately

Occurrence Rating – The frequency of which the failure mode has been a potential issue based on past problems, whether or not actual quality was affected

Occurrence Rating

Ranking	Guideline
1	Rarely if ever
5	Has been an issue
10	Is an issue on a regular basis

Detection Rating – A ranking of the confidence that the failure mode is detected using current controls within the time necessary to prevent potential quality issues

Detection Rating

Ranking	Guideline
1	Issues always detected in a timely manner
5	Issues detected in a timely manner most of the time
10	Issues have not been detected with current controls

Results:

Each area of the plant was evaluated separately. The Risk Priority Number was calculated by multiplying the Quality Severity Rating by the Occurrence Rating and the Detection Rating. A Risk Priority Number of 250 or greater is considered critical by our criteria. This is because a numerical answer of 250 is the result of at least 1 rating being a 10 with the other 2 being a 5 or greater. Experience has also shown these modes to be critical.

Digesters:

The Digesters are where the actual reaction of the Magnesium Oxide and the Sulfuric acid take place. The FMEA data are in Table I. The Critical Parameters were determined to be the Circulation Flow, pH, and Specific Gravity.

Filter Press:

The Filter Press is where the undissolved contaminants such as sand, unreacted MgO, calcium sulfate, and iron compounds are physically separated from the brine formed in the Digesters. The FMEA data are in Table II. The Critical Parameter was determined to be the Brine Color.

Crystallizers and Centrifuge:

The Crystallizers and Centrifuge are where the actual Epsom Salt crystals are formed and then separated from the de-saturated brine. The de-saturated brine is referred to as Mother Liquor. The FMEA data are in Table III. The Critical Parameters were determined to be Crystallizer Circulation, Crystallizer Absolute Pressure, Crystallizer Temperature, and Centrifuge Speed.

Dryer, Cooler, Transport

The salt is received from the centrifuges and then dried and cooled before being transported to the packaging equipment. The FMEA data are in Table IV. The Critical Parameters were determined to be Dryer Salt Temperature and Cooler Salt Temperature. These are indirect control parameters for salt surface moisture.

Packaging

Giles has two packages at the Main Plant – a Super Sack bagger and a 50 pound bagger. The FMEA data are in Table V. The Critical Parameters were determined to be Super Sack Weights, 50 lb Bag Weights, Super Sack Contamination, and 50 lb Bag Contamination.

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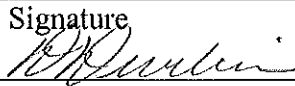
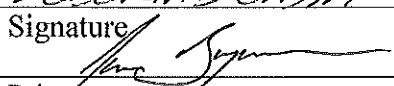

Conclusions:

Both the Validation and SPC programs will use the Critical Parameters determined by this risk assessment. A list of the parameters follows.

Giles Main Plant Critical Parameters

Area	Critical Parameter
Digesters	Circulation Flow
Digesters	pH
Digesters	Specific Gravity
Filter Press	Color
Crystallizers	Circulation
Crystallizers	Absolute Pressure
Crystallizers	Temperature
Crystallizers	Centrifuge Speed
Dryer	Dryer Salt Temperature
Dryer	Cooler Salt Temperature
Packaging	Super Sack Weight
Packaging	50lb Bag Weight
Packaging	Super Sack Contamination
Packaging	50lb Bag Contamination

Approvals

Responsible Person(s)	Title	Date
Signature 	Director of Quality	4/30/13
Print Deborah Durbin		
Signature 	Production Manager	04-30-13
Print Jason Bumgarner		
Signature 	Process Engineer	4/30/2013
Print Patrick Lee Owen		

Definitions

Critical Control Point: stages in the process where parameters must be controlled in order to assure the final product meets specifications

Critical Parameter: a parameter relevant to the system or process that can affect whether the product meets specification.

Current Controls: What controls are currently in place to prevent deviations in the parameters in each failure mode

Detection Rating: The confidence that the maintainer, operator, or detection system will identify a deviation in time to prevent quality issues with the product

Failure Mode: possible parameter deviation from standard, whether or not it has an effect on product quality

FMEA: Failure Mode and Effect Analysis

Occurrence Rating: The frequency with which the failure mode has been an issue in the process, whether or not the worst effects are seen (likelihood)

Quality Severity Rating: Considering the worst effects of a failure, a ranking of the severity of the impact on quality

Risk Priority Number: The multiplied factors of Detection Rating x Occurrence Rating x Severity Rating. For Giles' purpose a RPN of equal to or greater than 250 indicates a failure mode of a critical parameter.

Statistical Process Control: a method of quality control that uses statistical methods to monitor and control a process

Validation: a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria

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Table I - Digesters

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Agitation	Agitation Stops	Digester Salts Up	1	1	1 Alarm from Magnetic Pick Up, Operator Check every 2 hours	5	5	No
Circulation Flow	pH probe Low	pH probe dry	10	10	10 Alarm on Flow Meter, Operator Check every 2 hours	5	500	Yes
	Pump flow High	None	1	1	1 Operator Check	10	10	No
	Pump Stops	pH probe dry	10	10	1 Alarm on Flow Meter, Operator Check every 2 hours	5	50	No
Mix Pot Agitation	Agitation Stops	pH Low or High	10	5	1 Operator Check every 2 hours	1	5	No
pH	Low pH	Iron dissolves	10	5	5 Digester Probe, Weekly Calibration Checks	5	250	Yes
	High pH	SG issues, Press Issues	5	5	1 Digester Probe, Weekly Calibration Checks	5	25	No
Specific Gravity	Low SG	Production Slow	5	5	10 Hydrometer Checks	5	250	Yes
	High SG	Low Press Runs	1	1	1 Hydrometer Checks	5	5	No
Temperature	Temp Low	Low Press Runs	1	1	1 Operator Check, Weekly Probe Check	5	5	No
	Temp High	Boilover - salt lost	1	1	1 Operator Check, Weekly Probe Check	5	5	No
MgO Flow	Low	Slow Production	1	1	1 Operator Mix Pot Check 2 hours	1	1	No
	High	High Temp	1	1	1 Operator Mix Pot Check 2 hours	1	1	No
Acid Flow	Low	High pH	5	5	1 Operator Visual, pH Meter	5	25	No
	High	Low pH	10	10	1 Operator Visual, pH Meter	5	50	No
Water Flow	Low	High SG	1	1	1 Operator Visual, Density Control	1	1	No
	High	Low SG	5	5	1 Operator Visual, Density Control	1	5	No
Mother Liquor Flow	Low	None	1	1	5 Operator Check, Flow Meter	1	5	No
	High	None	1	1	5 Operator Check, Flow Meter	1	5	No

Table II - Filter Press

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Cloth Sealing	Low Flow	Low Production	1	1	10 Check at every drop	1	10	No
Cloth Fit	Exposed Plate	Brine Color	10	10	1 Check on replacement	1	10	No
Cloth Folded	Exposed Plate	Brine Color	10	10	5 Check at every drop	1	50	No
Lines Salted	Low Flow	Low Production	1	1	1 Obvious	1	1	No
Plate Busted	Salt in Squeeze	Low Flow	1	1	1 Check at every drop	1	1	No
Filtration Temperature	High Temp	None	1	1	1 Check on startup	5	5	No
	Low Temp	Low Flow	1	1	5 Check on startup	5	25	No
Brine Color	High Color	Contamination	10	10	5 Check on startup	10	500	Yes

Table III - Crystallizers and Centrifuge

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Brine Feed	Low	Level Drops	1	1	10 1 hour check	1	10	No
	High	Level Goes Up	1	1	1 1 hour check	1	1	No
Circulation	Low	Crystallizer Crashes	5	5	10 1 hour check	10	500	Yes
	High	Smaller CSD	1	1	1 1 hour check	10	10	No
Mother Liquor Feed	Low	Solids Higher	1	1	1 1 hour check	1	1	No
	High	Solids Lower	1	1	1 1 hour check	1	1	No
Absolute Pressure	Low	Temperature Cool	5	5	5 1 hour check	5	125	No
	High	Temperature Hot	10	10	10 1 hour check	5	500	Yes
Temperature	Low	Crystallizer Crashes	10	10	1 1 hour check	5	50	No
	High	Production Low / Dryer Issue	10	10	10 1 hour check	5	500	Yes
Discharge	Low	Production Slow / Dryer Issue	5	5	1 1 hour check	1	5	No
	High	Dryer Issues	5	5	1 1 hour check	5	5	No
Level	Low	Circulation Fails	5	5	5 1 hour check	5	125	No
	High	Absolute P goes up	5	5	5 1 hour check	5	125	No
Centrifuge Speed	Low	Dewatering Surfers / Dryer Is	10	10	1 Shift Check on Wash	5	125	No
	High	Hole in Basket	1	1	1 Shift Check on wash	1	1	No
Centrifuge Basket	Hole	Production Drops Dramatical	1	1	5 Shift Check with sieve	1	5	No

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Table IV - Dryer and Cooler

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number	Critical?
Feed Moisture	Low	Chalky Salt	1	10	10 Shift Check on Wash	1	10	No
	High	Moist Salt	10	1	10 Shift Check on Wash	1	100	No
Dryer Temperature	Low	DZ #1 Goes up	1	1	10 1 hour check	5	5	No
	High	DZ #1 Goes down	1	1	1 1 hour check	5	5	No
Salt Temperature	Low	Moist Salt	10	10	10 Every Sack Check	5	500	Yes
	High	Chalky Salt	10	10	10 Every Sack Check	5	500	Yes
Cooler Temperature	Low	Moist Salt	10	10	10 Every Sack Check	5	500	Yes
	High	Sticky Salt	10	10	10 Every Sack Check	5	500	Yes
Scrubber Flow	Low	EPA Compliance	1	1	1 Alarm	1	1	No
	High	OK	1	1	1 Alarm	1	1	No
Scrubber Air Flow	Low	EPA Compliance	1	1	1 Alarm	1	1	No
	High	EPA Compliance	1	1	1 Alarm	1	1	No
Dryer Zone #1 Air Flow	Low	Drying Issues	5	5	11 hour check	5	25	No
	High	OK	1	1	11 hour check	5	5	No
Dryer Zone #2 Air Flow	Low	Drying Issues	5	5	11 hour check	5	25	No
	High	OK	1	1	11 hour check	5	5	No
Cooler Air Flow	Low	Cooling Issues	5	5	11 hour check	5	25	No
	High	OK	1	1	11 hour check	5	5	No
Screw	Off	Stop Up Dryers	1	1	1 Immediate Shut Down, Alarm	1	1	No
Bucket Elevator	Off	Stop Up Screw	1	1	1 Immediate Shut Down, Alarm	1	1	No

Table V - Packaging

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number	Critical?
Super Sack Weights	Low	Out of Spec Weight	10	5	5 SPC Chart	5	250	Yes
	High	Yield	1	1	5 SPC Chart	5	25	No
Bag Weights	Low	Out of Spec Weight	10	5	5 SPC Chart	5	250	Yes
	High	Yield	1	1	5 SPC Chart	5	25	No
Super Sack Contamination	Present	Contamination	10	5	5 Visual Checks, magnets, screens	10	500	Yes
Bag Contamination	Present	Contamination	10	5	5 Visual Checks, magnets, screens	10	500	Yes