

Summary:

The purpose of the Repack 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 where appropriate. These Critical Parameters and Critical Control points are also the basis of Validation of each processing unit.

Team:

The team met on 2/20/2013 for the purpose of performing the FMEA and included members responsible for the Quality, Production, Maintenance, and Engineering Departments.

Monte Plott – Plant Manager

Robert Willis – Maintenance Manager

Patrick Owen – Process Engineer

Ron Hall – Quality Coordinator

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 where feasible.

Criteria:

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

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

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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.

Carton Machines:

The Carton Machines receive Epsom Salt in 2000 pound super sacks and fill small pasteboard cartons for consumer use. The FMEA data are in Table I. The Critical Parameters are the Fill Weight, Seal, and Date Codes.

AutoPouch #1:

AutoPouch #1 receives Epsom Salt in 2000 pound super sacks and fills small plastic pouches for consumer use. The FMEA data are in Table II. The Critical Parameters are the Fill Weight, Seal, and Date Codes.

AutoPouch #2:

AutoPouch #2 receives Epsom Salt in 2000 pound super sacks and fills small plastic pouches for consumer use. The FMEA data are in Table III. The Critical Parameters are the Fill Weight, Seal, and Date Codes.

Manual Lines:

The Manual Lines receive Epsom Salt in 2000 pound super sacks and fill small plastic pouches for consumer use. The FMEA data are in Table IV. The Critical Parameters are the Fill Weight, Seal, and Date Codes.

Conclusions:

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

Giles Repack Critical Parameters

Area	Critical Parameter
Carton Machines	Fill Weight
Carton Machines	Seal
Carton Machines	Date Code
AutoPouch #1	Fill Weight


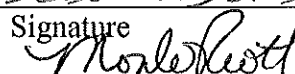
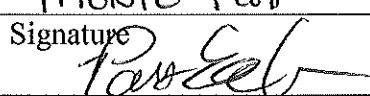
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AutoPouch #1	Seal
AutoPouch #1	Date Code
AutoPouch #2	Fill Weight
AutoPouch #2	Seal
AutoPouch #2	Date Code
Manual Lines	Fill Weight
Manual Lines	Seal
Manual Lines	Date Code

Approvals

Responsible Person(s)	Title	Date
Signature 	Director of Quality	4/30/13
Print Deborah Durbin		
Signature 	Plant Manager	4/30/13
Print MONTE PLATT		
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

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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 - Carton Machines

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Salt Unload System	Screw Stops	Machine Stops	1	1	5 Unload Operator Checks	1	5	No
Salt Delivery System	Screw Wears Out	Delivery Slow	1	1	1 Machine Rate	1	1	No
	Screw Stops	Machine Down	1	1	10 Operator Check	1	10	No
	Hopper Overfills	Housekeeping Issue	1	1	1 Unload Operator Checks	1	1	No
Auger Filler	Motor Stops	Machine Stops	1	1	10 Operator Check	1	10	No
	Salt Buildup	Low Fill Weight	5	5	5 Carton Check, Check Weigher	5	125	No
	Failure to Fill	Empty Carton	1	1	1 Carton Check, Empty Won't Transport, Packer Checks	5	5	No
	Bad Adjustment	Low or High Fill Weight	5	5	10 Carton Check, Check Weigher	5	250	Yes
	Bottom Seal	Carton Unsealed	10	10	5 Carton Check, Packer Checks, Quality Checks	5	250	Yes
Carton Machine	Chain Problem	Machine Stops	1	1	1 Operator Check	1	1	No
	Breakers	Duck Bit Cartons	10	10	1 Carton Check, Packer Checks, Quality Checks	1	10	No
	Top Seal	Carton Unsealed	10	10	5 Carton Check, Packer Checks, Quality Checks	5	250	Yes
Check Weigher	Salt Buildup	Improper Check Weight	5	5	5 Carton Check, Control Chart	1	5	No
	Drift High	Improper Feedback	5	5	1 Carton Check, Control Chart	5	25	No
	Drift Low	Improper Feedback	5	5	1 Carton Check, Control Chart	5	25	No
Date Coder	Bad Setup	Wrong Date Code	10	10	1 Operator Check, Quality Check, Startup Sheet, Packers	5	50	No
	Failure to Print	Unprinted Date Code	10	10	5 Quality Check, Packer Checks	5	250	Yes

Table II - AutoPouches #1

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Salt Unload System	Screw Stops	Machine Stops	1	1	5 Unload Operator Checks	1	5	No
Salt Delivery System	Screw Wears Out	Delivery Slow	1	1	1 Machine Rate	1	1	No
	Screw Stops	Machine Down	1	1	10 Operator Check	1	10	No
	Hopper Overfills	Housekeeping Issue	1	1	1 Unload Operator Checks	1	1	No
Scale	Motor Stops	Machine Stops	1	1	10 Operator Check	1	10	No
	Salt Buildup	Low Fill Weight	5	5	5 Weight Check	5	125	No
	Failure to Fill	Empty Pouch	1	1	1 Operator Check	5	5	No
	Bad Adjustment	Low or High Fill Weight	5	5	10 Setup Sheet, Quality Check, Weight Checks	5	250	Yes
	Dropped Pouch	Wasted Pouch	1	1	10 Operator Check, Set up and Adjustment Training	5	50	No
	Failure to Open	Missed Fill	1	1	10 Operator Check	1	10	No
	Splash Fill	Weight Incorrect, Bad Seal	5	5	1 Quality Check, Packer Checks, Weight Check	1	5	No
	Top Seal	Unsealed Pouch	10	10	5 Quality Check, Packer Checks, Weight Check	5	250	Yes
Date Coder	Bad Setup	Wrong Date Code	10	10	5 Operator Check, Quality Check, Startup Sheet, Packers	5	250	Yes
	Failure to Print	Unprinted Date Code	10	10	1 Quality Check, Packer Checks	5	50	No

Table III - AutoPouches #2

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number (P-or = 250)	Critical?
Salt Unload System	Screw Stops	Machine Stops	1	1	5 Unload Operator Checks	1	5	No
Salt Delivery System	Screw Wears Out	Delivery Slow	1	1	1 Machine Rate	1	1	No
	Screw Stops	Machine Down	1	1	10 Operator Check	1	10	No
	Hopper Overfills	Housekeeping Issue	1	1	1 Unload Operator Checks	1	1	No
Filler	Motor Stops	Machine Stops	1	1	10 Operator Check	1	10	No
	Salt Buildup	Low Fill Weight	5	5	5 Weight Check, Check Weigher	5	125	No
	Failure to Fill	Empty Pouch	1	1	1 Operator Check	5	5	No
	Bad Adjustment	Low or High Fill Weight	5	5	10 Setup Sheet, Quality Check, Weight Checks, Check Weigher	5	250	Yes
	Dropped Pouch	Wasted Pouch	1	1	10 Operator Check, Set up and Adjustment Training	5	50	No
Pouches	Failure to Open	Missed Fill	1	1	10 Operator Check	1	10	No
	Splash Fill	Weight Incorrect, Bad Seal	5	5	1 Quality Check, Packer Checks, Weight Check, Check Weigher	1	5	No
	Top Seal	Unsealed Pouch	10	10	5 Quality Check, Packer Checks, Operator Check	5	250	Yes
Date Coder	Bad Setup	Wrong Date Code	10	10	5 Operator Check, Quality Check, Startup Sheet, Packers	5	250	Yes
	Failure to Print	Unprinted Date Code	10	10	1 Quality Check, Packer Checks	5	50	No

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Table IV - Manual Lines

Parameter	Failure Mode	Failure Effects	Quality Severity Rating	Occurrence Rating	Current Controls	Detection Rating	Risk Priority Number	Critical?
Salt Unload System	Screw Stops	Machine Stops	1	1	5 Unload Operator Checks	1	5	No
Salt Delivery System	Screw Wears Out	Delivery Slow	1	1	1 Machine Rate	1	1	No
	Screw Stops	Machine Down	1	1	10 Operator Check	1	10	No
	Hopper Overfills	Housekeeping Issue	1	1	1 Unload Operator Checks	1	1	No
	Motor Stops	Machine Stops	1	1	10 Operator Check	1	10	No
Filler	Salt Buildup	Low Fill Weight	5	5	5 Weight Check	5	125	No
	Failure to Fill	Empty Pouch	1	1	1 Operator Check	1	1	No
	Bad Adjustment	Low or High Fill Weight	5	5	10 Setup Sheet, Quality Check, Weight Checks	5	5	No
Sealer	Top Seal	Unsealed Pouch	10	10	5 Quality Check, Packer Checks, Operator Check	5	250	Yes
Date Coder	Bad Setup	Wrong Date Code	10	10	5 Operator Check, Quality Check, Startup Sheet, Packers	5	250	Yes