POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS PFMEA)

P/N or Item: ______________________ Eng. Revision: ________ FMEA Number: ____________

Part Name: ____________ Process Responsibility ____________ Prepared by: ____________

Model Year(s)/Vehicle(s) ____________ Key Date ____________ Date (Orig.) ____________

Core Team: ______________________ Date (Rev.) ____________

Process Function Requirements	Potential Failure Mode	Potential Effect(s) of Failure	SEV	CLASS	Potential Cause(s)/ Mechanism(s) of Failure(s)	Current Process Controls Prevention	OCCUR	Current Process Controls Detection	DETECT	RPN #	Recommended Action(s) and Action Results	Responsibility & Target Completion Date	Action Results				
													Actions Taken	SEV	OCC	DET	RPN

SUGGESTED PROCESS FMEA SEVERITY RANKINGS

Severity Effect	Criteria: Severity of Effect Customer Effect	Ranking	Severity Effect	Criteria: Severity of Effect Mfg/Assy Effect
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9		May endanger operator (machine or assembly) with warning
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation)	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship
	Degradation of primary function (vehicle operable, but at reduced level of performance)	7	Significant Disruption	A portion of the production may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%)	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator.
No effect	No discernible effect.	1	No Effect	No discernible effect.

SUGGESTED PROCESS FMEA OCCURRENCE RANKINGS

Probability of Failure	Likely Failure Rates	Likely Failure Rates	Ppk	Ranking
Very High: Persistent Failures	≥ 100 per thousand pieces ≥1 in 10 pieces ≥100,000 ppm or 10%	More than one occurrence per day	<0.55	10
	50 per thousand pieces 1 in 20 pieces 50,000 ppm or 5%	One occurrence every 3 to 4 days	≥0.55	9
High: Frequent Failures	20 per thousand pieces 1 in 50 pieces 20,000 ppm or 2%	One occurrence per week	≥0.78	8
	10 per thousand pieces 1 in 100 pieces 10,000 ppm or 1%	One occurrence every month	≥0.86	7
Moderate: Occasional Failures	2 per thousand pieces 1 in 500 pieces 2,000 ppm or 0.2%	One occurrence every three months	≥0.94	6
	.5 per thousand 1 in 2,000 pieces 500 ppm or 0.05%	One occurrence every six months	≥1.00	5
	.1 per thousand 1 in 10,000 pieces 100 ppm or 0.01%	One occurrence per year	≥1.10	4
Low: Relatively Few Failures	.01 per thousand 1 in 100,000 pieces 10 ppm or 0.001%	One occurrence every 1 to 3 years	≥1.20	3
	≤.001 per thousand ≤1 in 1,000,000 pieces ≤1 ppm or 0.0001%	One occurrence every 3 to 5 years	≥1.30	2
Remote: Failure is Unlike	Failure is eliminated through preventive control	One occurrence greater than 5 years	≥1.67	1

Note: Likely failure rates are based on internal occurences only, not frequency of defect escapes to the customer

SUGGESTED PROCESS FMEA DETECTION RANKINGS

Detection	Criteria	Inspection Types A	B	C	Suggested Range of Detection Methods	Ranking
Almost Impossible	Absolute certainty of non-detection			X	No current process control; Cannot detect or is not analyzed.	10
Very Remote	Controls will probably not detect			X	Failure Mode and/or Error (Cause) is not easily detected (e.g. **random audits**).	9
Remote	Controls have poor chance of detection			X	Failure Mode detection **post-processing by operator** through visual/tactile/audible means.	8
Very Low	Controls have poor chance of detection			X	Failure Mode detection **in-station by operator** through visual/tactile/audible means or post-processing through use of **attribute gauging** (go/no-go, manual torque check/clicker wrench, etc.).	7
Low	Controls may detect		X	X	Failure Mode detection **post-processing by operator** through use of **variable gauging** or in-station by operator through use of **attribute gauging** (go/no-go, manual torque check/clicker wrench, etc.)	6
Moderate	Controls may detect		X		Failure Mode or Error (Causes) detection **in-station by operator** through use of **variable gauging** or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). **Gauging performed on setup and first-piece check** (for set-up causes only)	5
Moderately High	Controls have a good chance to detect	X	X		Failure Mode detection **post-processing by automated controls** that will detect discrepant part and lock part to prevent further processing.	4
High	Controls have a good chance to detect	X	X		**controls** that will detect discrepant part and automatically lock part in station to prevent further processing.	3
Very High	Controls almost certain to detect	X	X		Error (Cause) detection **in-station by automated controls** that will detect error and prevent discrepant part from being made.	2
Certain	Controls certain to detect	X			Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been **error-proofed** by process/product design.	1

A = Error-proofed B = Gauging C = Manual Inspection

	PRELIMINARY HAZARD ASSESSMENT **This document is subject to the attorney-client and attorney work product privileges.**	**HARARD ANALYSIS #: ________________** **DATE: ____________**

PROBLEM DESCRIPTION OR QUESTION:

<table>
<tr><td rowspan="6"><u>Instructions</u>: Record final conclusion of the Risk/ Hazard Assessment process by marking the initials of each individual in the square for which he or she independ-ently voted.</td><td rowspan="2">SEVERITY OF CONSEQUENCE</td><td colspan="6">P R O B A B I L I T Y OF M I S H A P</td></tr>
<tr><td>F
<u>Impossible</u>
(Physically impossible to occur)</td><td>E
<u>Improbable</u>
(Probability of occurrence cannot be distinguished from zero)</td><td>D
<u>Remote</u>
(Not likely to occur in system life cycle, but possible)</td><td>C
<u>Occasional</u>
(Likely to occur sometime in product life cycle)</td><td>B
<u>Probable</u>
(Likely to occur several times in product life cycle)</td><td>A
<u>Frequent</u>
(Likely to occur repeatedly in product life cycle)</td></tr>
<tr><td>I
<u>CATASTROPHIC</u>
(Death or permanent disabling injury)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>II
<u>CRITICAL</u>
(Severe injury or illness)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>III
<u>MARGINAL</u>
(Minor injury or illness)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>IV
<u>NEGLIGIBLE</u>
(No injury or illness)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

RISK MATRIX ACTIONS	CATEGORY 1	**Category 1: Operating risks are contained within acceptable levels. No corrective action is required.**	CATEGORY 2	**Category 2: Operating risks are not within acceptable levels. Corrective action plan must be recommended.**

Risk/Hazard Assessment By:	Initials	Risk/Hazard Assessment By:	Initials

The independent conclusions reached by those performing the Risk/Hazard Assessments were recorded by:

Name:____________________________ Title:_________________________ Date:________________

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	PRELIMINARY HAZARD ASSESSMENT **This document is subject to the attorney-client and attorney work product privileges.**	**HARARD ANALYSIS #: ________________** **DATE: ___________**
LOGIC/JUSTIFICATION FOR RISK ASSESSMENT:		
POSSIBLE CORRECTIVE ACTIONS (IF CATEGORY 2 RISK):		
DESIGN HAZARD OUT:		
GUARD AGAINST HAZARD:		
WARN AGAINST HAZARD:		
CORRECTIVE ACTION(S) TAKEN TO BRING RISK OF HAZARD DOWN TO ACCEPTABLE LEVELS:		
DATE CORRECTIVE ACTION(S) TAKEN:		
DATE HAZARD ANALYSIS CLOSED: ______________________ **APPROVED BY:_________________________________ TITLE: _________________________________**		

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Introduction/Profile

Jim Lee is the founder and president of simpleQuE. Jim was formerly President and Chief Operations Officer of Eagle Registrations, a registrar performing various ISO certifications. He was also a partial owner of ACLASS (an ISO 17025 accreditation body) prior to its sale to ANSI/ASQ National Accreditation Board (ANAB). Jim has lived eight years in Thailand and has traveled the world extensively.

Work Experience

ISO/Quality Management Systems

Jim has been an RABQSA and IRCA certified ISO 9001 lead auditor since 1996. He utilized the ISO 9001 standards for supplier quality requirements while at Huffy Bicycles, Gerry Baby Products and Emerson, and was an ISO management representative at Emerson Climate Technologies. As the President and Chief Operations Officer of Eagle Registrations, he attended all certification body industry meetings and performed hundreds of audits worldwide for a wide variety of industries.

Aerospace

As a design engineer for Systems Research Labs, Jim developed military avionics for the Air Force, Army and NASA, which included working at WPAFB/Armstrong Aerospace Medical Research Laboratories. He was an RABQSA certified AS9100 aerospace auditor and performed third-party audits from 2003 to 2012, and frequently attends AAQG meetings. In addition to AS9100, he also consults and audits for AS9120 and AS9110.

Laboratories

Jim worked at Systems Research Laboratories and the Armstrong Aerospace Medical Research Laboratories at WPAFB, which required a secret security clearance. He also ran the certified lab at Gerry Baby Products. In 2002, Jim bought into ACLASS Corporation, an ISO 17025 accreditation body for testing and calibration labs. Since the sale of ACLASS to ANAB (ANSI-ASQ National Accreditation Board) in 2007, he continues to participate on the Accreditation Council and chairs its Testing Committee. Jim also teaches certified lead auditor classes for ASQ and ANAB/ACLASS.

Automotive

In addition to working as an engineer and supervisor at General Motors, Jim was part of a team that successfully proposed and implemented an ultramodern press room for a metal-stamping plant that produced body panels. He was appointed by the U.S. Department of Transportation to a blue-ribbon panel of experts to resolve incompatibility issues between child seats and automobiles in 1995. After serving on a committee that successfully pushed legislation requiring anchors and tethers for children's automobile seats, Jim received a "Friend for Life" award from the Colorado Advocates for Child Transportation Safety. He also was an IATF ISO/TS 16949 certified lead auditor and performed third-party audits for six years, and while with Eagle attended the quarterly IAOB registrar meetings.

Education

In addition to earning a Bachelor of Science in Electrical Engineering from Ohio University, Jim has completed multiple graduate courses toward his MBA and MSEE from the University of Dayton, Wright State University and Ashland University.

Jim is a certified manager of quality/organizational excellence (#762) and certified quality auditor (#2766) with ASQ, and is also a six sigma quality black belt leader and champion.