Teleflex INCORPORATED

Quality Management

Failure Modes & Effects and Hazard Analysis Procedures Book

Quality Management

Failure Modes & Effects and Hazard Analysis Procedures Book

Reliability Engineering

Teleflex Incorporated

January 1986

Table of Contents

POTENTIAL FAILURE MODES AND EFFECTS ANALYSIS (DESIGN)

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

FOR

DESIGN AND ENGINEERING

(Design FMEA)

FAILURE MODES AND EFFECT ANALYSIS

INTRODUCTION

A failure modes and effect analysis (FMEA) or failure modes, effect, and criticality analysis (FMECA) is an analytical technique which provides a systematic assessment of a design, process or system to determine the potential nonconformances and their effects on product performance. The FMEA provides a means of communicating information to the various departments involved in producing a safe, reliable product in a cost-effective manner. The objective of an FMEA, then, is to:

a) Identify potential failure modes and their causes.

b) Prioritize the nonconformances according to their frequency of occurrence, severity of effects, and probability of being detected prior to the "effect."

c) Document corrective actions such as design changes, test plans, manufacturing process controls, quality inspection plans, and statistical process controls which relate to the identified failure modes.

FAILURE MODES AND EFFECT ANALYSIS

PROCEDURES

The effectiveness of an FMEA is dependent on several key steps:

a) **Product definition** - essential to an analysis is the complete knowledge of the product, process or system. Product specifications, performance requirements, intended use and possible misuse should all be understood prior to starting the analysis.

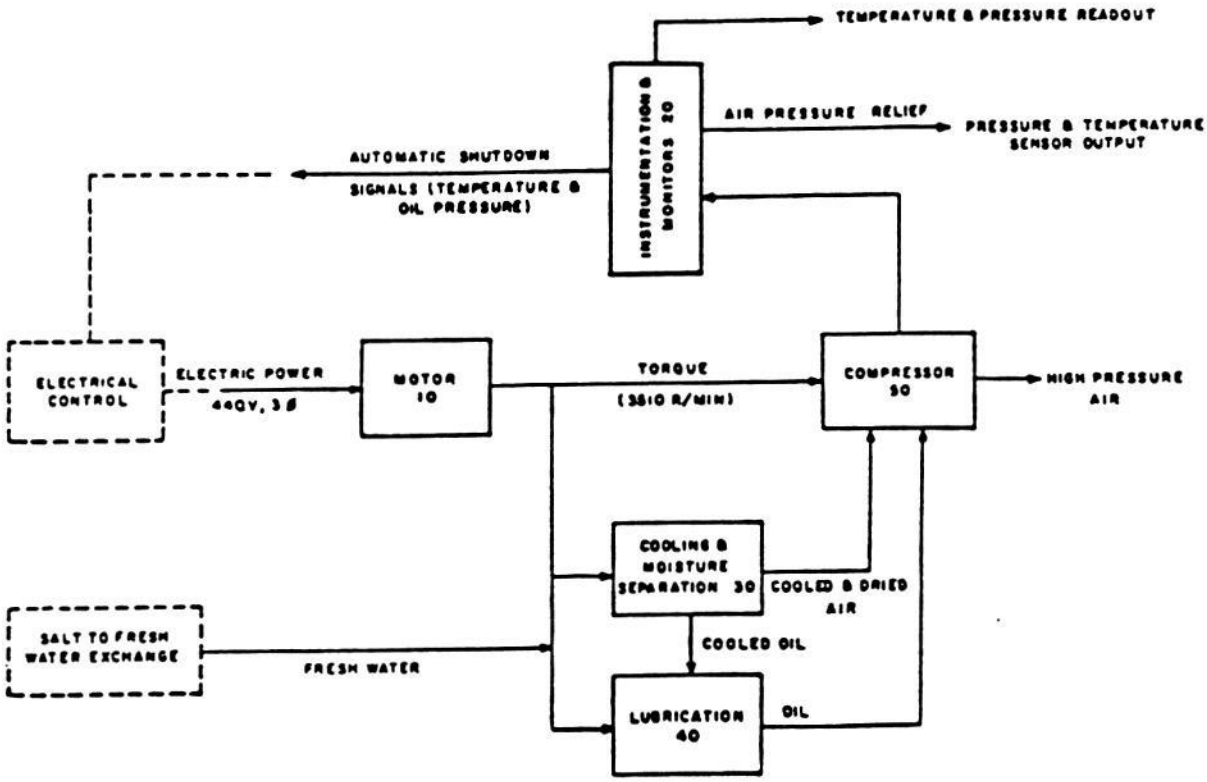
b) **Block Diagrams** - both functional and reliability block diagrams, shown as examples on the next page, are often helpful in describing the operation and system dependency on lower level functions and interfacing elements.

c) **Nonconformance definition** - definition of what constitutes a nonconformance for the assembly level of the FMEA being prepared. The FMEA item can be nonconforming depending upon the number of parts it contains and on the stresses (electrical, mechanical, and/or environmental) experienced by the parts while operating in the expected environment. Each part within the component constitutes a potential nonconformance and the manner in which the part becomes nonconforming under the given stresses may represent a possible failure mode of the component. A failure mode may be catastrophic or a performance degradation.

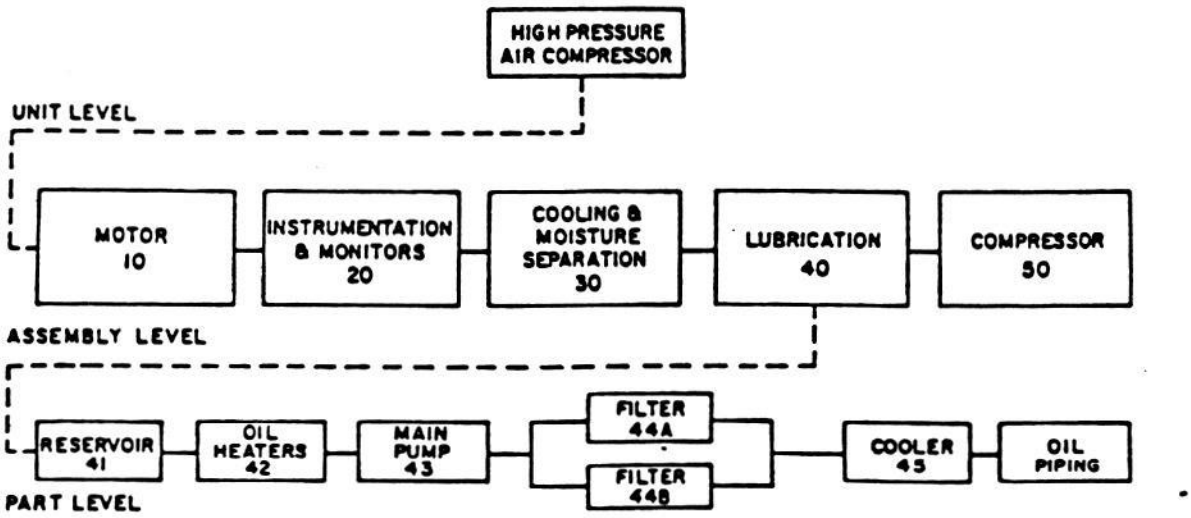
d) **Component** - identify the item by the generic name--diode, switch assembly, brake solenoid, drive shaft, seal, pump, etc.--that is the same as on the drawing. Include the drawing number, if known.

e) **Function** - describe in sufficient detail the task that the component must perform. Provide enough clarity and detail to communicate this information to all users of the FMECA/FMEA.

FAILURE MODES AND EFFECTS ANALYSIS



Example of a Functional Block Diagram



Example of a Reliability Block Diagram

FAILURE MODES AND EFFECTS ANALYSIS

f) **Ground rules** - generally in an FMEA, only single-point nonconformances will be considered. In some cases, however, chain reaction nonconformances might be considered. This is illustrated below.

Single-Point Failure:

Failure of "A" produces failure effect "B"

$$A \longrightarrow B$$

Chain Reaction Failure:

Failure of "A" produces failure effect "B" only if "C" fails.

$$A + C \longrightarrow B$$

g) **Ranking parameters** - the three specific factors which will be used to evaluate the failure modes and effects are listed below:

- **Occurrence** - Probability or frequency of the failure mode occurring
- **Severity** - Consequence of the failure mode, i.e., the severity of the effect
- **Detection** - Probability that the nonconformance will be detected before the user/owner receives the product, or before the nonconformance effect occurs in the case where warning devices are used.

h) **Parameter scales** - an objective of the analysis is to relate the various failure modes and effects to each other within the ranking parameters of Occurrence, Severity and Detection. This is accomplished by assigning a rank number between 1 and 10 in the example set shown on the following page. The level description and rank number assignments should be tailored to the particular FMEA item set and retained without change throughout the analysis to provide a uniform method of assessment toward design improvement.

The parameter scales used for Occurrence, Severity and Detection should be provided with each FMEA to show the basis for the assigned rank values.

FAILURE MODES AND EFFECTS ANALYSIS

Occurrence Ranking Guide

Probability of Occurrence	1	2	3	4	5	6	7	8	9	10
A) Unlikely, with low probability or no supporting failure data is known.	◇									
B) Unlikely, but technically possible. No known development or design data		◇								
C) Unlikely,but development data suggests a possibility			◇							
D) Unlikely at nominal environments, but likely at the extremes				◇						
E) Unlikely at minimum life, more likely beyond					◇					
F) Likely, but difficult to determine presently						◇				
G) Likely, supporting data exists for this failure for a similar design							◇	◇		
H) Very likely, specific data exists for failure of a like or duplicate design									◇	◇

Severity Ranking Guide

Severity Attribute	1	2	3	4	5	6	7	8	9	10
A) An annoyance or cosmetic failure - no functional loss	◇									
B) Minor failure causing user annoyance - possible minor degradation of performance		◇								
C) Minor failure with visual or audible indication. Minor degradation of performance.			◇							
D) Minor damage				◇						
E) Minor injury					◇					
F) Extensive damage						◇	◇			
G) Major injury								◇		
H) Major injury or death									◇	◇

Detection Ranking Guide

Probability of Detection	1	2	3	4	5	6	7	8	9	10
A) Very high, by easy methods to prevent defect from reaching the next assembly level, or in-use detection.	◇									
B) High likelihood by defined methods to find the defect during manufacture, test or installation.		◇								
C) Moderate likelihood that the defect will reach the user, or will occur.			◇							
D) Automatic detection by the owner/user - action assumed.				◇						
E) Automatic detection provided but not for user corrective action.					◇		◇	◇		
F) Special diagnostic aids required for detection.						◇				
G) Special diagnostic equipment required to isolate the defect, or by a redundant detection method.							◇		◇	
H) Skilled personnel using special diagnostic equipment required to isolate the defect.								◇	◇	◇
I) Dynamic, destructive testing required to confirm the defect.										

FAILURE MODES AND EFFECTS ANALYSIS

i) **Criticality Index** - the product obtained by multiplying the individual parameter ranks of 1 to 10 for Occurrence, Severity and Detection for each failure mode. The larger the result, the more troublesome the failure mode is predicted to be.

j) **Corrective Action/Comments** - design changes or follow-up activities should be concise and provide a statement of actions that could be taken to eliminate or reduce the failure mode and effects being analyzed.

This entry defines inherent design or maintenance compensating provisions which would eliminate or reduce the probability of occurrence of the described failure mode.

The corrective action should be to eliminate the nonconformance as the first priority, or control the risk by identifying nonconformance detection methods, or other compensating rationale.

Documentation of the changes made as a result of the FMEA, or a revision of the FMEA itself after significant design or process change, is essential to the successful use of the technique.

FAILURE MODES AND EFFECTS ANALYSIS

A summary of the information required for each column of the FMECA form is shown on the next page.

k) **Criticality Index Ranking** - is a summary listing of the failure modes with the highest CI's to direct attention to the major issues identified by the FMECA. An Index ranking listing is shown in the FMEA example section.

This ranking summary will provide an ongoing evaluation toward the elimination or reduction of the failure modes.

The CI ranking and FMEA revisions should be updated to coincide with the status of the improvements as they are implemented.

A well thought out FMECA can not only reduce the number of product problems that occur in the field, it can also serve as evidence of responsibility in product engineering which is so crucial to the outcome of product liability cases.

Failure Modes, Effect, and Criticality Analysis

EATON

Project Description

Date | Page | of

Revision Date

Engineer

(1) Component	(2) Component Function	(3) Failure Mode	(4) Effect of Failure	(5) Cause of Failure	(6) Occur	(7) Severity	(8) Detection	(9) Criticality Index	(10) Corrective Action / Remarks

(1) Part name, correct nomenclature, description or identifying number of the item being analyzed.

(2) Describe the function of the item. Describe multiple functions, if appropriate.

(3) List the various probable or known ways that the item could fail.

(4) Specify the effects of the presumed failure on the performance of the System

(5) List all causes that can generate the failure mode.

(6) Estimate the likelihood of the failure occurring using the Occurrence scale.

(7) Estimate severity of failure effect using the Severity scale.

(8) Estimate the probability of detecting (Detection) the cause of failure before failure mode occurrence.

(9) Compute the Criticality Index - the product of the values in (6), (7) & (8).

(10) Describe the action(s) that could reduce the Criticality Index value that depends upon a reduction in the (6), (7) and/or ((8) values. The concise and direct statement of the actions could include: design improvements, maintenance compensating provisions, manufacturing process controls, statistical process controls and test plans to eliminate or reduce the probability of occurrence of the failure mode.

Form 819-00(Rev.10/84)

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FAILURE MODES AND EFFECTS ANALYSIS

SUMMARY OF USE AND ADVANTAGES

The preparation of the FMEA should begin at the early development and design stages and be used and updated throughout the program to provide the following information to the program functions and activities:

a) The design engineer with a method of selecting a design with a high probability of operational success, or minimization of degradation.

b) Design engineering with a documented analysis in a uniform method for assessing failure modes and their effect on product performance.

The FMEA will show points of concern to which compensations should be made.

The compensations could be redesign, redundancy, derating, etc., for an improved design reflecting into successful product performance.

c) Early visibility of system interface problems.

d) Identification of single failure points critical to successful product performance.

e) Early criteria for test planning.

f) Help in the generation of maintenance/operation manuals and to determine spare parts requirements provided by the end item FMEA.

g) Use during the production, fabrication and assembly, and test phases. When a nonconformance occurs during a test, the FMEA serves as a source of isolating the nonconformance through most-probable-cause correlation.

If severity ≥ 9 occurrence should be ≤ 2

EXAMPLES - DESIGN FMEA

NOTE: The examples shown are not provided in their entirety. Instead, segments of two design FMEA reports are given to show the contents, procedures and flexibility of an FMEA.

FREEZE-PROTECTION VALVE
DESIGN FMECA
(Background)

The freeze-protection valve was designed for use on a residential sized solar hot water heating system. The total system is based on the thermosyphoning principle, i.e., hot water rises and therefore does not include a pump to keep the water moving. Thus, a freeze-protection valve is necessary to prevent the water in the system from freezing on cold nights. Its function is to open at low temperatures and allow water to drain through the solar panels.

INTRODUCTION TO FREEZE-PROTECTION VALVE FMEA REPORT

The purpose of this FMEA was to provide a systematic assessment of the effects of individual valve component failure modes on the total thermosyphoning system. The criticality of each freeze valve failure mode was evaluated by considering its probability of occurrence, severity, and likelihood of detection. These three criteria were rated according to the scales shown on the following page.

The occurrence, severity, and detection rankings were multiplied to obtain a "criticality index." The higher the criticality index, the more troublesome the failure mode is predicted to be.

DESIGN FAILURE MODES AND EFFECTS ANALYSIS

Occurrence Ranking Guide

Probability of Occurrence	1	2	3	4	5	6	7	8	9	10
A. Unlikely, no supporting nonconformance data is known.	◇									
B. Unlikely, no development or released design data known.		◇								
C. Unlikely, but development data suggests possibility.			◇							
D. Unlikely at mean conditions, but more likely at limits.				◇						
E. Unlikely through minimum life; more likely beyond.					◇					
F. Possible, but difficult to determine presently.						◇				
G. Supporting data for this nonconformance.							◇	◇		
H. Data points on this type of nonconformance available.									◇	◇

Severity Ranking Guide

Severity Attribute	1	2	3	4	5	6	7	8	9	10
A. Annoyance, no functional loss.	◇									
B. Minor degradation of performance.		◇	◇							
C. Major degradation of performance.				◇	◇					
D. Minor injury.						◇				
E. Major injury.							◇	◇		
F. Terminal injury or death.									◇	◇

Detection Ranking Guide

Probability of Detection	1	2	3	4	5	6	7	8	9	10
A. Detection provided by 100% inspection and will not reach assembly level.	◇									
B. Detection will be provided at subassembly level and will not reach customer.		◇								
C. Detection during final assembly.			◇							
D. Detection during final assembly through sampling of lot and destructive testing.				◇	◇					
E. Detection upon customer receipt.						◇	◇			
F. Detection possible by customer, but probably will not be detected.								◇		
G. Detection not provided at any level of manufacturing, assembly, inspection or customer acceptance.									◇	◇

EATON

Failure Modes, Effect, and Criticality Analysis

Project Description: FREEZE PROTECTION VALVE

Date:

Page: 1 of 3

Revision Date:

Engineer:

Component	Component Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
Inlet Body	Provides attachment to thermosyphoning system. Houses valve mechanism	Cracked	Water leakage	Improper material, damaged, worn	3	4	3	36	
		Threads stripped	Leak at attachment	Overtorque, cross-threading	7	4	7	196	A bevel on the end of the threaded portion is recommended to assist installation
		Thermal expansion & contraction	Possible loss of torque at attachment.	Inherent characteristics of polypropelene	2	3	2	12	Audit of material properties will detect
		ID undersize	Overtravel spring binds or impairs valve function	Out of specification, warpage after molding	2	3	2	12	
Screen	Filters particulates in water	Missing	Foreign material will collect around valve outlet. May prevent opening	Assembly error	7	3	7	147	Note: screen is not called out on assembly print D50648
		Undersize O.D.	Filter falls out when valve is inverted	Screen bent out of shape; out of specification	3	3	3	27	
		Plugged	Foreign material accumulated at entrance blocking or reducing ability to flow	High chemical/mineral content of local water	8	4	8	256	Maintenance required

EATON

Failure Modes, Effect, and Criticality Analysis

Project Description: FREEZE PROTECTION VALVE

Date:

Page 2 of 3

Revision Date:

Engineer:

Component	Component Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
Spring Seat Washer	Holds filter screen in place; helps to evenly distribute overtravel spring load	Missing	Filter falls down into inlet body and is ineffective	Assembly error	7	3	7	147	Note: washer is not called out on assembly print D50648
		OD oversize	Will not seat, causing assembly problems, or a cracked housing	Out of specification	2	3	2	12	
		ID not removed	Valve will not open	Missed operation	2	5	2	20	
Overtravel Spring	Provides spring force to hold valve shut	Broken	Valve will not close; loss of water in system	Corrosion, embrittlement	4	5	5	100	Environmental testing recommended
		Low rate/ short	Valve will not close or leaks thru	Worn; out of specification, assembly error	3	5	4	60	
		High rate/ overlength	Added stress to valve body	Spring out of specification	3	1	4	12	
		Oversize diameter	Will not fit into spring guide causing higher spring rate. Possible binding on inlet body	Spring out of specification	2	3	3	18	
		Missing	Valve will not close	Assembly error	2	2	2	8	100% inspection of open/close function

EATON

Failure Modes, Effect, and Criticality Analysis

Project Description: FREEZE PROTECTION VALVE

Date:

Page 3 of 3

Revision Date:

Engineer:

Component	Component Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
Valve Spring	Maintains constant valve outlet seal pressure when valve is closed. Maintains orientation of valve seat.	Missing	Valve will not close	Assembly error	4	2	2	16	100% inspection of open/close function
		Over-rate/ Oversize	Excessive seal force	Spring out of specification	2	3	4	24	
		Under rate/ undersize	Leak thru from inadequate seal force	Wear; spring out of specification	2	3	4	24	
		Broken frozen	"	Corrosion	4	3	4	48	
Valve Seat	Seals against outlet when valve is closed.	Worn	Leak thru; affect calibration	Aging; taking a permanent set	6	3	6	108	Hard water and/or high temperature may affect aging.
		Brass Washer missing	Improper seat for valve spring; leak with age	Defective part or missed subassembly	3	3	4	36	
		Assembled upside down	Valve seat may not allow flow when valve is in open position	Improper assembly	8	6	8	384	It is very easy to install the valve seat upside down. It is recommended that a change be made to prevent this failure mode.
Wax Thermal Element	Expands and contracts to produce a temperature versus length relationship	Off-Calibration	Opens at higher or lower temperature than spec.	Defective; wax leak due to imperfect seal	5	3	4	60	
		Water intrusion	Change calibration to cause delayed (colder) opening temperature	Water entering down pin shaft and diffusing into wax	5	4	7	140	Lab testing recommended. If water intrusion occurs, lubricant around the pin is recommended. This would also reduce the potential for corrosion of the pin.

FREEZE VALVE
FMEA

CRITICALITY RANKING

	Description	Ranking
1.	Valve seat assembled upside down, preventing valve from opening.	384
2.	Foreign material plugging inlet filter screen and preventing flow.	256
3.	Leak at inlet thread due to stripping during attachment.	196
4.	Inlet filter screen or spring seat washer missing, allowing foreign material to bypass filter and possibly clog valve.	147
5.	Water intrusion into wax element, causing a change in calibration.	140
6.	Worn or deformed valve seat caused by age, temperature, or water chemicals; affecting calibration.	108
7.	Overtravel spring broken, allowing continual draining of water.	100

FREEZE VALVE
FMEA

CONCLUSIONS

An analysis of the major component failure modes shows three basic system nonconformance effects:

1. Valve did not open before freezing, causing damage to system.

2. Valve did not close, resulting in continual use of water (which the owner may be unaware of until he gets his water bill).

3. Reduced efficiency from being out-of-calibration and allowing the system to pass water at too high a temperature.

Specific recommendations based on the FMEA include:

1. Beveling the ends of the threaded sections to prevent cross-threading and provide ease of installation.

2. Specifying filter screen and spring seal washer on assembly print.

3. Investigating a design change which would allow fool-proof assembly orientation of the valve seat.

4. Conducting lab testing to evaluate water intrusion into wax element at expected temperature range ($32^{\circ}F$-$260^{\circ}F$). Investigate possibility of adding a water-resistant lubricant to the element pin. Also investigate maintenance required to prevent plugging.

SOLID GAS GENERATOR
SYSTEM FMECA
(Background)

The solid gas generator was a system designed for automotive use which would inflate a steering wheel air bag. It consisted of a housing, ignitor, gas generating material, and filter pack. The system provided the generation of nitrogen-based gases from a solid propellant in order to inflate the air bag in 30-45 milliseconds.

INTRODUCTION TO GAS GENERATOR FMEA REPORT

The failure modes and effects analysis has been conducted on a functional basis for the steering wheel inflator. This analysis is based upon a single nonconformance; that is, multiple nonconformances were not considered.

Ranking scales for probability of occurrence, severity and probability of detection were developed. In each case, the worst ranking is ten and the best is one. The scales are listed on the following pages.

A criticality ranking was established by multiplying the probability of occurrence, severity, and detectability. Thus, the maximum ranking could be 1000 and the minimum 1.

The purpose of this analysis was to investigate each failure mode and take appropriate action to reduce its criticality ranking, thus improving the product quality.

INTRODUCTION TO GAS GENERATOR
FMEA REPORT

Likelihood of Occurrence Ranking

1 Very low or remote possibility of occurring. Less than one occurrence for each 10,000,000 units manufactured.

2-3 Low failure rate. One to 10 occurrences for each 10,000,000 units manufactured.

4-6 Moderate failure rate. One to 10 occurrences for each 1,000,000 units manufactured.

7-9 Frequent failure rate. One to 100 occurrences for each 100,000 units manufactured.

10 High probability of occurrence. Greater than one occurrence for each 100 units manufactured.

Severity Ranking

1 Noncompliance to the customer specifications, but still provides adequate protection for occupant.

2 Nonconformance of a minor nature, which causes vehicle owner dissatisfaction.

3-4 Degradation of system's performance which decreases occupant protection. Causes minor injury with low probability.

5-6 Degradation of system's performance which decreases occupant protection. Causes minor injury with high probability.

7 Malfunction of system which may cause injury and extreme vehicle owner dissatisfaction.

8 Degradation of system's performance which offers no occupant protection. Causes injury with high probability.

9 Failure to deploy upon command (with or without warning). No occupant protection.

10 Malfunction of system causes severe occupant injury or death.

INTRODUCTION TO GAS GENERATOR
FMEA REPORT

Likelihood of Detection

1-2	Detection provided during incoming 100% inspection and probably will not reach the assembly level.
3	Nonconformances will be discovered during inspection at assembly or subassembly level and probably will not reach the customer.
4-5	Nonconformances will be discovered during final assembly and probably will not reach the customer.
6-7	Nonconformances will be discovered after final assembly through lot inspection and destructive testing.
8	Nonconformances not found by lot inspection, but will be found by the customer.
9	Nonconformances will be present in a vehicle and will probably not be detected by the customer.
10	No detection is provided at any level of manufacturing, assembly, lot control, or customer acceptance testing.

EATON

Failure Modes, Effect, and Criticality Analysis

Project Description: SOLID GAS GENERATOR

Date:

Page: 1 of 2

Revision Date:

Engineer:

Component	Component Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
Steering Wheel	Activate on command and generate gas to inflate cushion without specified pressure time profiles	Gas generating rate increases	Possible injury to out-of-position driver	Gas generating material out of specification (larger diameter, greater quantity)	2	6	2	24	Lot control at receiving and distr. at audit
			Noise level increases	Wrong gas generating material composition	1	6	6	36	Require vendor certification and receiving inspection
			High particulates generated	(greater amount of nitrates)					
			Highly stressed cushion	Incorrect ratio of booster to main charge gas generating material	3	6	2	36	
			Damage to deployment cover	Ambient temperature greater than 220°F	N/A	6	N/A	N/A	
			High soak temperature of hardware	Insufficient filter (or lack of)	5	6	3	90	
				Squib out of specification (higher output)	3	6	2	36	Lot control at receiving and vendor certification
		Gas generating rate decreases	Marginal or inadequate protection in high-speed crashes	Gas generating material out of specification (lesser quantity)	2	6	2	24	
				Wrong gas generating material composition (insufficient nitrate)	1	6	6	36	
				Lesser quantity of booster than specified	3	6	2	36	
				Ambient temperature less than -20°F	N/A	N/A	N/A	N/A	
				Additional filter or blockage	5	6	3	90	
				Excessive moisture (failure of seals)	5	6	10	300	Humidity test must be conducted
				Gas generating material changes shape to powder granules	5	6	10	300	Must conduct vibration test

EATON

Failure Modes, Effect, and Criticality Analysis

Project Description: SOLID GAS GENERATOR

Date:

Page 2 of 2

Revision Date:

Engineer:

Component	Component Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
		Nonfunction with warning	Loss of passive protection to driver	Deflective squib (electrically) open or short	3	9	8	216	
		Nonfunction without warning	Loss of passive protection to driver	Incorrect installation causing wiring to abrade and short	2	9	8	144	
				Cut wires	2	9	8	144	
				Open connector or faulty	5	9	8	360	
				Squib - w/o charge	3	9	10	270	
				Missing gas generating material	2	9	2	36	
				Wrong materials	1	9	6	54	
				Extreme moisture inside	5	9	10	450	

GAS GENERATOR
FMEA

CRITICALITY RANKING

Ranking	Cause of Failure	Comments
450	Extreme moisture inside inflator due to seal failure	No detection of moisture provided (Recommendation #2)
360	Open or faulty connector	
300	Gas generating material changes shape to powder granules due to vibration	No detection provided (Recommendation #2)
300	Gas generating material changes shape - caked or large chunks (moisture and vibration)	
270	Ignitor without charge	Lot inspection may not be effective enough (Recommendation #3)
216	Defective ignitor (electrical open or short)	

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

FOR

MANUFACTURING AND ASSEMBLY PROCESSES

(Process FMEA)

PROCESS FAILURE MODES AND EFFECT ANALYSIS

INTRODUCTION

The development and execution of a potential failure mode and effects analysis for manufacturing and assembly processes (process FMEA) is conducted before production and involves the listing of **potential** failure modes and causes.

FMEA's identify actions required to **prevent** defects and thus keep products which may fail or are not fit to reach the customer.

A process FMEA is an analytical technique which:

a) Identifies potential product-related process failure modes.

b) Assesses the potential effects of the nonconformance.

c) Identifies the potential manufacturing or assembly process causes.

d) Identifies the process controls to prevent or detect the nonconforming conditions.

PURPOSE

a) Eliminate potential process failure modes.

b) Continuously minimize the effects of failure modes that cannot be eliminated.

c) Document the rationale for a specific manufacturing or assembly process.

OBJECTIVES

a) Summarize the process and manufacturing engineer's thoughts in developing process requirements.

b) Organize the analysis to prevent process nonconformances based on experience and part problems.

c) Prioritize the nonconformances according to frequency of occurrence and severity of effects to develop a Criticality Index.

d) Provide an objective technique to prioritize corrective action considerations.

e) Coordinate design improvements or revisions with engineering for maximum process capability.

PROCESS IMPROVEMENT INCENTIVES

There are current incentives that make it necessary to use the disciplined technique to identify and prevent potential problems more than ever before.

a) Changing customer's expectations.

b) Regulatory requirements.

c) Attitudes of the courts.

To these, another incentive is most important--the **Personal (Intangible) Incentive.**

Manufacturing and process FMEA's provide the disciplined approach to address product improvement and to offset the above three consequences.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

PROCESS AND DESIGN FMEA INTERACTION

The approach for a Process FMEA is the same as the approach for a Design FMEA.

The Design FMEA precedes the Process FMEA as it can be done effectively early in the product development cycle.

The Process FMEA involves manufacturing engineering knowledge. Its objective is to identify and assess failure modes introduced by the production **process** equipment, or **assembly** method.

Just as a functional block diagram is used to identify interrelationships between components, a process flow chart should be used to show the process functions.

PROCESS FAILURE MODES AND EFFECT ANALYSIS

PROCEDURES

The effectiveness of a Process FMEA is dependent on several key steps:

a) **Process Definition** - essential to an analysis is the complete knowledge of the manufacturing or assembly process. The product specifications and performance requirements should all be understood before starting the analysis.

b) **Process Flow Chart** - a process flow chart should be prepared to show the process functions and interrelationships.

c) **Nonconformance Definition** - define what constitutes a nonconformance or out-of-process control condition.

The failure mode list that follows shows representative nonconformances but is not meant to be all-inclusive. The first two columns for the Process FMEA form would be titled "Process Name" and "Process Function," instead of "Component" and "Component Function."

d) **Process** - identify the process or operation being analyzed in terms that readily identify it to others as well. Show the design level by suffixes and revision letters or numbers.

e) **Process Function** - describe, concisely, the function of the process or operation that is being analyzed.

PROCESS FAILURE MODES & EFFECTS ANALYSIS

f) Potential Failure Mode

Describe each possible failure mode. The assumption is made that the nonconformance **could** occur, but **will not necessarily** occur. The process engineer should be able to answer the following questions:

- What could possibly go wrong with the process or operation?
- How can the produced part fail to meet the engineering specifications?

Recommended starting points would be the review of:

- The design FMEA's
- Quality and Reliability problems
- Warranty and Durability problems

on comparable components.

Typical failure modes could be:

Bent	Melted
Bound	Misaligned
Broken	Misassembled
Corroded	Omitted
Cracked	Open circuited
Damaged	Out-of-balance
Deformed	Oversized
Discolored	Porous
Distorted	Rough
Eccentric	Short
Grounded	Shorted
Leaking	Undersized
Loose	

There may be others that are prompted by experience or disciplined thinking.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

g) Potential Effect(s) of Failure

Assuming that the nonconformance has occurred, describe what the customer or user might notice or experience as the effect of the nonconformance.

The description of the effect should be as specific as possible.

Typical descriptions of nonconformance effects are:

- Air leaks
- Brake chatter
- Engine will not start
- Erratic shifting
- Fuel fumes
- High oil consumption
- High operating efforts
- Insufficient A/C cooling
- Loss of power assist
- Loss of steering
- Loss of steering
- Noise (NVH)
- Odor
- Oil leakage
- Power window inoperative
- Radio inoperative
- Reduced vehicle performance
- Seat mispositioned
- Surging
- Warning light oil/temp/alt
- Water leaks

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

h) **Potential Cause(s) of Nonconformances**

List all potential causes assignable to each failure mode.

Determine the process or operation that could be an assignable cause and result in the potential failure mode.

The list of causes should be complete so that the remedial actions will be directed to all causes.

Typical causes of nonconformance are:

- Assembly error
- Damaged part
- Handling damage
- Heat treat shrinkage
- Improper surface preparation
- Improper tool setup
- Improper torque
- Inaccurate gaging
- Inadequate control system
- Inadequate gating
- Inadequate holding, clamping
- Inadequate or no lubrication
- Inadequate venting
- Incorrect speeds, feeds
- Incorrect tooling
- Material failure
- Misalignment
- Missing operation
- Out-of-tolerance
- Overheating
- Overloaded capacity
- Packaging damage
- Tool damaged
- Worn tooling

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

i) Ranking Parameters

Three specific factors are used to evaluate the failure modes and effects, as listed below:

. **Occurrence** — The estimate of the probability that the potential cause of nonconformance will occur and thus result in the indicated potential failure mode.

Assume that the cause of failure and failure mode will not be detected before the item reaches the customer.

. **Severity** — The estimate of the "effects of failure" and the seriousness of the failure to the customer after it has occurred.

. **Detection** — The estimate of the probability of detecting a defect, caused by the identified failure, before the part or component leaves the manufacturing or assembly location.

Assume the cause of failure has happened and then assess the capabilities of all current controls to **prevent shipment** of the defect. Random quality control checks would be unlikely to detect an isolated defect and therefore would not result in a noticeable detection ranking change. However, sampling done on a statistical basis is a valid detection control.

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PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Occurrence

Estimate the probability of occurrence on a 1 to 10 scale. Only consider **controls that prevent** the cause of nonconformance.

The assigned number of nonconformances is at the discretion of the engineer but must be maintained consistently through FMEA development toward closure.

The process engineer should consult with Quality to determine the appropriate occurrence rate. The statistical rates are shown as examples only and should be developed to provide a meaningful ranking system that coincides with the particular product specifications.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Occurrence Ranking Guide Example

May have to do process capability study first.

Probability of Occurrence	(Note) Ranking	Within Spec'n.?	Stat. Proportion Outside Spec'n. Limits	1	2	3	4	5	6	7	8	9	10
A. Remote	At least ± 4	Yes	1/10,000	1									
B. Low	At least ± 3	Yes	1/5000 1/2000 1/1000 1/500		2	3	4	5					
C. Moderate (occasional process nonconformances)	More than ± 2.5*	Yes	1/200						6				
D. High (previous similar process often nonconforming)	± 2.5 or less*	Yes	1/100 1/50							7	8		
E. Very High (nonconformance almost certain)	N.A.	No	1/20 1/10									9	10

Note: * - Process still within statistical process control.
- Sigma symbol - a standard deviation.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Severity

Estimate the severity of the "effects of failure" to the customer on a 1 to 10 scale.

Severity is the factor that represents the seriousness of the nonconformance to the customer after it has occurred.

Process engineering should consult with product engineering for severity ranking assignments. An estimate for the values may be required when design information is unavailable.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Severity Ranking Guide Example

Severity Attribute	1	2	3	4	5	6	7	8	9	10
A. No noticeable effect on item or system performance. Customer/user may not detect.	◇1									
B. Minor nature of nonconformance may cause slight customer/user annoyance.		◇2								
C. Customer/user will probably notice very minor system or item performance degradation.			◇3							
D. Moderate nonconformance may cause customer/user dissatisfaction, annoyance or discomfort.				◇4	◇5					
E. Moderate nonconformance may cause customer/user to notice a subsystem or system performance degradation.						◇6				
F. Nonconformance will cause high degree of customer/user dissatisfaction: system or item inoperable.							◇7			
G. Nonconformance will cause system or item to degrade in areas governed by federal, state, community regulations. Safety and noncompliance are not breached.								◇8		
H. Very high severity situation that involves potential safety problems and/or conformance to regulations.									◇9	◇10

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Detection

Estimate the probability of detecting a nonconformance before the item leaves the manufacturing or assembly location. Use a 1 to 10 scale.

It must be assumed that the cause of the nonconformance has occurred.

The next step is to assess the capabilities of all current controls to **prevent shipment** of the nonconforming item.

Valid detection control is sampling done on a statistical basis, not by random quality checks.

Selection of the detection ranking should be coordinated with the plant or division Quality function.

The following examples may be detected by operator and automatic detection methods.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

Detection Ranking Guide Example

Probability of Detection	1	2	3	4	5	6	7	8	9	10

A. **Remote** likelihood of shipment of a nonconforming product. Nonconformance would be functionally obvious.

B. **Low** likelihood that the item would be shipped. The nonconformance would be visually obvious.
- Before performing the next operation
- Before leaving a work station

C. **Moderate** likelihood that the item would be shipped with the nonconformance.
- 100% functional check performed
- 100% automatic inspection

D. **High** likelihood that the nonconforming item would be shipped. Subtle characteristic that is easily unnoticed. 100% visual or manual inspection.

E. **Very high** likelihood that the nonconforming product would be shipped. Item not checked or not checkable. Nonconformance is latent and affects durability.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

j) **Criticality Index (CI)**

The CI is the product obtained by multiplying the individual parameter rankings of 1 to 10 for Occurrence, Severity and Detection for each potential failure mode.

The CI provides a relative indicator of all causes of nonconformance.

The highest CI's and Occurrence Rankings should be given first consideration for corrective actions.

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

k) **Corrective Actions/Remarks**

The entries should be concise and provide a statement of the positive and effective corrective actions that, if taken, could eliminate or reduce the failure modes and related effects that were analyzed.

All recommendations to the affected activities should be addressed for review and follow-up to assure closure by implementation or assigning risks.

Corrective actions may require process or design revisions, or both.

Ranking Parameter Corrective Actions:

- Occurrence Reduction
  - Process or design revisions
  - Process study by statistical methods
  - Ongoing feedback of information to appropriate operations
  - Implement never-ending improvement philosophy
  - Nonconformance prevention goal
- Severity Reduction
  - Part redesign
  - Analyze the serial process operations
- Detection Increase
  - Process revisions
  - Part design or revision
  - Emphasize nonconformance prevention rather than detection
  - Use statistical process control techniques

PROCESS FAILURE MODES AND EFFECTS ANALYSIS

k) Corrective Actions/Remarks (continued)

Categories for Corrective Action that relate to SPC:

1. Improve the design by derating, failsafe feature, part selection, material selection, special testing programs, etc.

2. Redesign to foolproof the process if there is large operator content in the process.

3. Foolproof the human operator process.

4. Use SPC control throughout.

5. Use SPC controls when the design would be considered absolute.

6. Conduct training to prevent specific errors.

7. Provide instructions that are easily understood.

8. Foolproof the human inspection process.

9. Use automated inspection when economically reasonable.

10. Statistically analyze inspection data, preferably obtained by automated inspection.

The following page is a copy of an example format with a brief description of the entries for each column of the Process FMEA form.

Failure Modes, Effect, and Criticality Analysis

EATON

Project Description

Date | Page | of

Revision Date

Engineer

(1) Component	(2) Component Function	(3) Failure Mode	(4) Effect of Failure	(5) Cause of Failure	Occur (6)	Severity (7)	Detection (8)	(9) Criticality Index	(10) Corrective Action / Remarks

(1) Part name, correct nomenclature, description or identifying number of the item being analyzed.

(2) Describe the function of the item. Describe multiple functions, if appropriate.

(3) List the various probable or known ways that the item could fail.

(4) Specify the effects of the presumed failure on the performance of the process

(5) List all causes that can generate the failure mode.

(6) Estimate the likelihood of the failure occurring using the Occurrence scale.

(7) Estimate severity of failure effect using the Severity scale.

(8) Estimate the probability of detecting (Detection) the cause of failure before failure mode occurrence.

(9) Compute the Criticality Index - the product of the values in (6), (7) & (8).

(10) Describe the action(s) that could reduce the Criticality Index value that depends upon a reduction in the (6), (7) and/or ((8) values. The concise and direct statement of the actions could include: design improvements, maintenance compensating provisions, manufacturing process controls, statistical process controls and test plans to eliminate or reduce the probability of occurrence of the failure mode.

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PROCESS FAILURE MODES AND EFFECTS ANALYSIS

l) Follow-on Actions

There are two follow-on actions that are essential to realize the benefits of the FMEA efforts:

- Criticality Index Ranking

  This ranking provides a summary listing of the failure modes with the highest criticality indices to direct attention to the major issues identified in the FMEA. This rank listing would be from the highest CI to the lowest. The top 10, or 5, or any listing is arbitrarily chosen for corrective action.

  This ranking summary provides an ongoing evaluation toward the elimination or reduction of the failure modes.

- FMECA Revisions

  It is essential to document the progress toward design, manufacturing process, and operational improvements which should result in the reduction in the rank values for Occurrence, Severity and Detection, and finally in the CI calculated value.

  It should be emphasized that the FMEA may represent the first assessment of the design and processes and may, in some cases, also represent the worst-case situation. For this reason, the CI ranking and FMEA revisions should be updated to coincide with the status of the improvements as they are implemented.

GAS GENERATOR

EXAMPLE - PROCESS FMEA

NOTE: The example shown is not provided in its entirety. Instead, a segment of a process FMEA report is given to show the contents, procedures and flexibility of an FMEA.

GAS GENERATOR PROCESS FMEA

RECOMMENDATIONS

1. A process FMEA should be conducted on the steering wheel inflator to determine critical inspection areas and identify where statistical process controls techniques are applicable. In addition, a mathematical model can be generated to establish lot inspection levels and project overall risk.

2. Development testing must be conducted for environmental conditions since there is no method of inspecting the inflator after assembly. Of particular concern are vibration, humidity, and temperature and their effect on performance. A limited amount of rigorous testing should be conducted to gain confidence and to ensure the remote possibility of the failure mode occurring.

3. A nondestructive testing technique should be developed to ensure that a squib has a pyrotechnic charge. Once the testing technique has been developed, specific statistical process control measures should be implemented in production. These should include:

   A. $\bar{X}$ and R control charting on charge level.
   B. Capability study to determine minimum charge level.
   C. Normal probability plot ot assess if charge is normally distributed.

INTRODUCTION TO GAS GENERATOR PROCESS FMEA

This FMEA was generated to disclose possible problems which might arise during the assembly of a steering wheel-solid gas generator unit. Primarily, it is intended to aid the design engineers in refining the current state of the design to eliminate or reduce the probability of incorrect assembly which would result in the sale of a nonconforming component. The secondary task of this FMEA is to alert the cognizant process and quality control engineers of areas which should be addressed in order to ensure a quality product.

For reasons of clarity, the following ground rules were followed in preparing this FMEA:

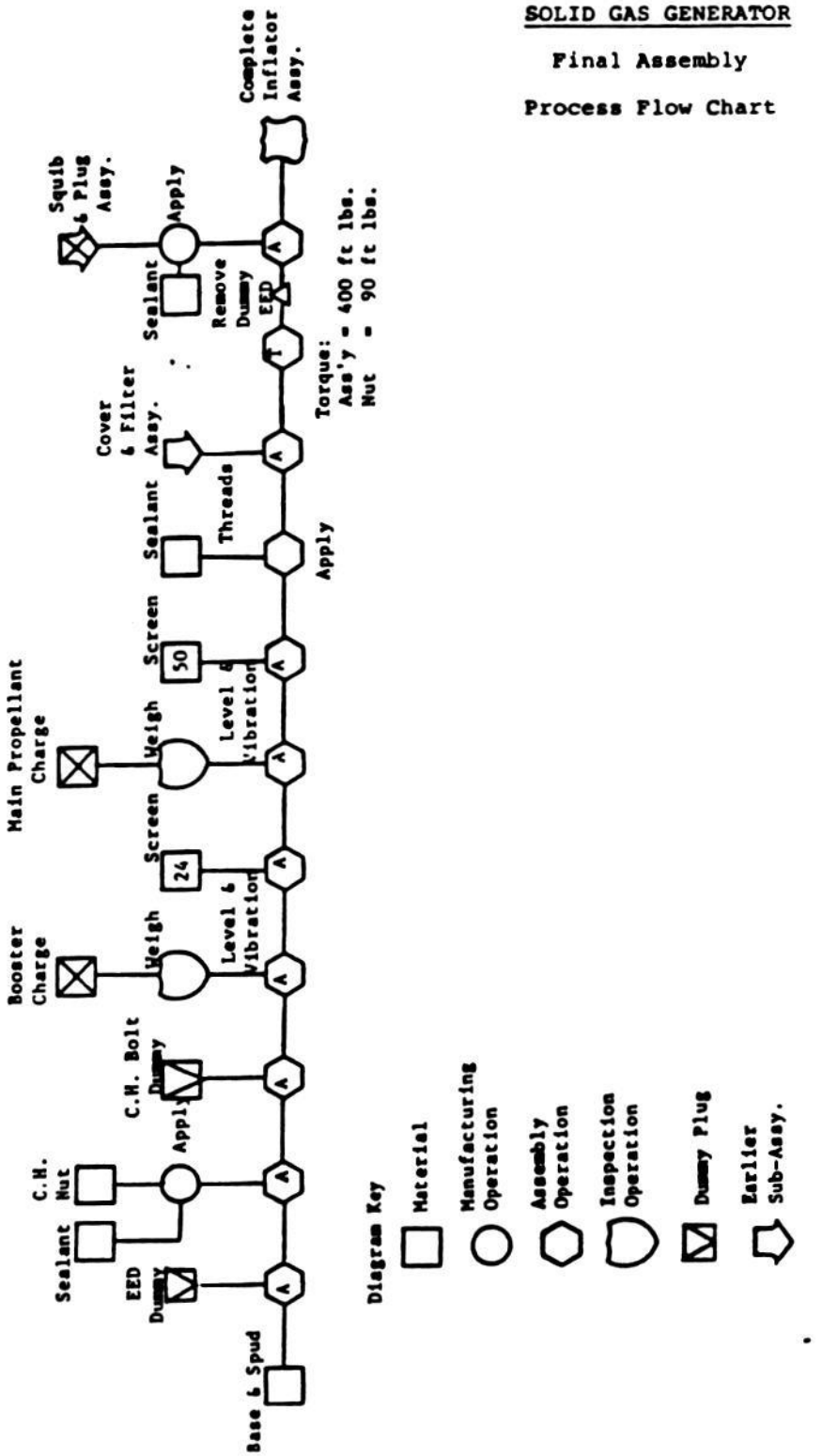
1. All components leaving the bonded receiving inspection area conform to established product prints and specifications.

2. Only processing or assembly operations are being considered to be nonconforming to normal, acceptable procedures.

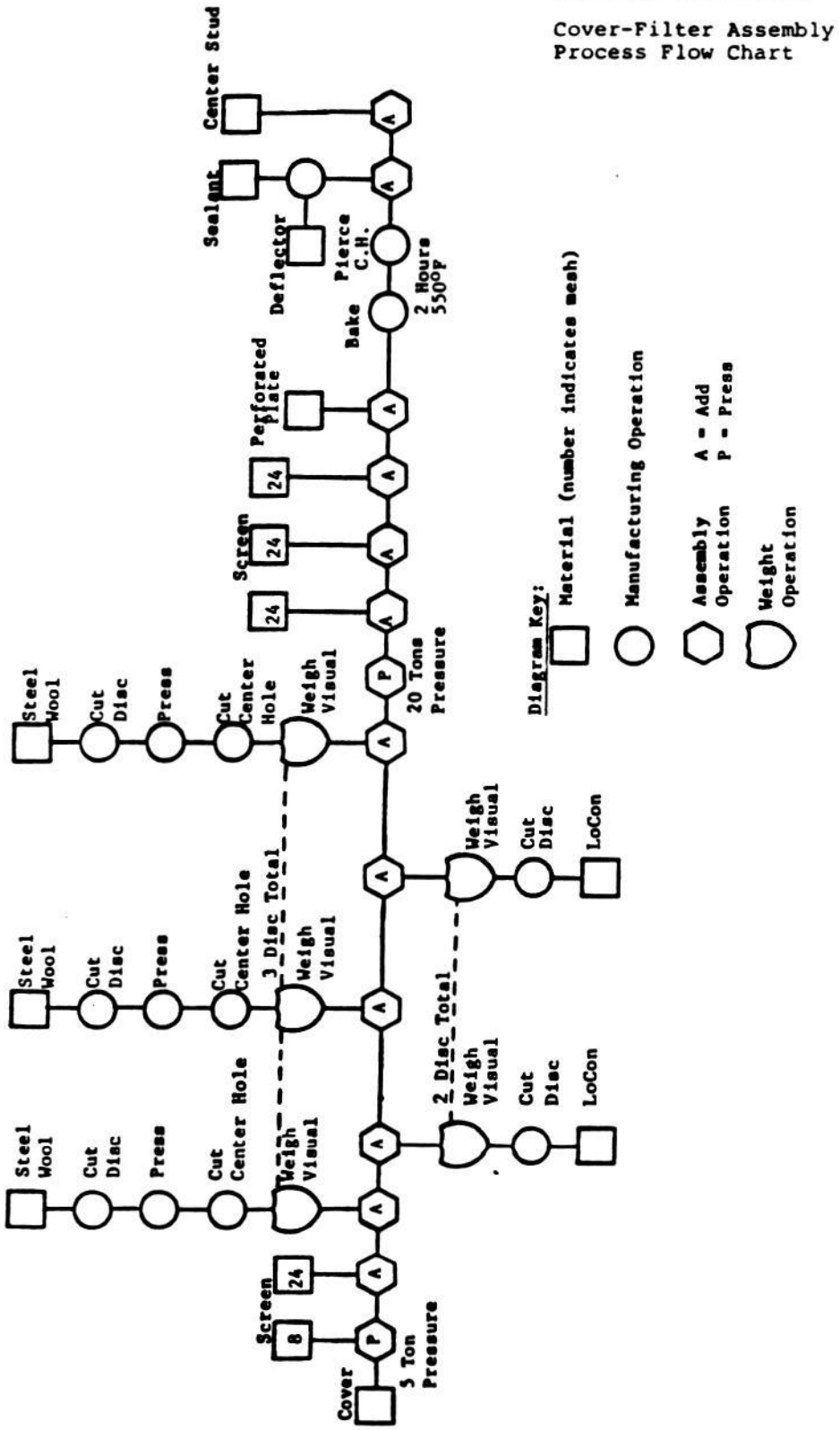
3. Only "single-point," **not** multiple failure modes were considered. In other words, only nonconformance was considered to have occurred at a time.

4. This FMEA was developed assuming volume production utilizing the automated production and assembly equipment indicated in the following process flow diagrams.

GAS GENERATOR PROCESS FMEA



GAS GENERATOR PROCESS FMEA



GAS GENERATOR PROCESS FMEA

Process Failure Modes, Effect, and Criticality Analysis

E:T·N

Project Description: STEERING WHEEL GAS GENERATOR

Date: Revision Date:

Page: 1 of

Engineer:

Process Name	Process Function	Failure Mode	Effect of Failure	Cause of Failure	Class	Severity	Detection	Rank	Corrective Action
S Mesh Screen into cover	Insert screen & press (5 tons)	Omitted screen	Channeling - increase in particulates	Assembly machine inoperative	2	3	7	147	Force & displacement of press operation must be monitored
				Assembly machine out of stock					
				Improper cover alignment					
	Flatten screen for improved filter support	Not pressed to 5 tons	(Under) - Channeling (Over) - High internal pressure	Malfunction of press equipment	3	3	5	45	Investigate light scanning inspection techniques to detect presence of screen and mesh type and auto-depth micrometer
					3	4	5	60	
		Cover off location at press	Nonassembly; part destroyed	Improper cover alignment	1	N/A	1	-	Requires location control on assembly "pallet"
		Multiple insertion of screen	Channeling & assembly height	Malfunction of ass'y machine	6	3	5	90	Measure height of screen after assembly to ensure insertion of one screen (auto-depth micrometer)
				Adhesion between screens					
		Incorrect mesh screen	High internal pressure	Incorrect part in feed bin of finer mesh screen	8	1	3	24	Monitor with auto-depth micrometer (All above items are applicable for inspection)
Add 24 Mesh Screen	Insert	Multiple	Assembly problem	Malfunction of ass'y machine	2	N/A	1	-	Investigate light scanning inspection techniques to determine presence and mesh of screen (Applicable for all items)
				Adhesion between screens					
		Incorrect part omitted screen	No problem if 50 mesh increase in particulates	Incorrect part in feed bin	7	1	3	21	
				Improper cover alignment					
				Ass'y machine out of stock	5	3	3	45	
				Ass'y machine inoperative					

GAS GENERATOR PROCESS FMEA

Process Failure Modes, Effect, and Criticality Analysis

EATON

Project Description: STEERING WHEEL GAS GENERATOR

Date:

Page: 2 of

Revision Date:

Engineer:

Process Name	Process Function	Failure Mode	Effect of Failure	Cause of Failure	Occur	Severity	Detection	Rank	Corrective Action
Add 1st Layer Steel Wool	Insert	Multiple layers	Possible lesser quantity of gas generated	Ass'y machine/conveyor malfunction	1	5	4	60	Test for verification of effects
				Adhesion between parts					
		Omitted	Higher internal pressure increase in particulates	Ass'y machine malfunction					
				Ass'y machine out of stock	1	1	4	16	Investigate manual ass'y alternative
		Incorrect part such as LoCon or screen	Higher internal pressure and increase in particulates	Incorrect part in system	7	1	1	63	Investigate light scanning
Add 1st Layer of LoCon Filter (Disc)	Insert disc	Omitted	Higher gas output/increase in particulates	Ass'y machine malfunction	5	1	1	45	Investigate layar cutting of filter components for increased quality and cost reduction
		Incorrect part (screen or steel wool)	Higher gas output/increase in particulates	Incorrect part in machine feed bin	5	1	1	45	Use magnetic field to check for metallic components
		Multiple LoCon	High internal pressure lower and slower gas generation	Malfunction of ass'y machine					Monitor LoCon height
				Conveyor not advanced	6	5	4	120	
				LoCon stuck together					
Press Filter components in cover ass'y to 20 tons (15 to 25 tons desired)	Compact filter ass'y to increase its density and reduce its height	Not pressed to 15 tons	Increase in particulates and excessive assembly height	Equipment (press) malfunction					
				Misalignment (not pressed	1	1	5	45	Monitor press forces Monitor pallet location
		Pressed over 25 tons	High generator internal pressures	Equipment malfunction					
				Excessive filter components	1	1	5	15	Monitor ram displacement Monitor press forces Consider layer cutting
		Nonuniform press	Channeling	Broken press die					
				Cover misalignment	1	1	6	54	Routine inspection of ram

HAZARD ANALYSIS

HAZARD ANALYSIS

HAZARD ANALYSIS

INTRODUCTION

A hazard analysis is a systematic evaluation of the hazards or sources of danger associated with a product. It identifies causes or conditions which present a hazard and the effects of a hazardous condition relative to human safety.

The objective of a hazard analysis is to rank potential sources of danger and thus allow for design actions which would eliminate or minimize hazards. In cases where hazards cannot be eliminated by design, the hazard analysis should identify areas where safety controls or hazard warning notices could be applied.

A hazard analysis, when used as intended, would close the loop to provide these features:

A. Advise program management and design personnel of the identified hazards.

B. Provide a quantified ranking of the hazards according to their probability of occurrence and severity of effects.

C. Identify and describe the corrective actions that would eliminate the hazard, reduce the hazard to a controllable level, or accept the potential risk with appropriate consideration to other means to minimize or warn of the hazard.

HAZARD ANALYSIS

PROCEDURES

The hazard analysis is dependent upon the key steps outlined below:

A. **Product Usage Definition** - understanding the product life cycle helps in finding hazards which might exist in the following areas:
   1. Manufacturing, assembly or shipping
   2. Normal use and misuse
   3. Environmental extremes
   4. Inadvertent use
   5. Discarding or disposal

B. **Hazard Definition** - there exists a wide range of hazards. These are the potential sources of danger associated with the product. These hazards and others that may be identified shall be shown in the analysis when they apply to the system, or lower level assemblies or components. The following page shows the wide range of hazards that could exist.

C. **Cause** - list the conditions which could cause the hazard. In hazard analysis multiple events leading to exposure to the hazard are considered.

D. **Effects** - the result in terms of performance, injury, or damage to surroundings, the system, test equipment, etc.

HAZARD ANALYSIS

HAZARDS

.Acceleration and Motion
- X-direction
- Y-direction
- Z-direction
- Unwanted

.Chemical Reactions
- Dissociation
- Oxidation
- Replacement

.Contamination

.Corrosion

.Damage

.Electrical System Failure
- Inadvertent activation
- Shock
- Thermal effects

.Explosion

.Falling Objects

.Fire

.Flying Objects

.Forces
- X-direction
- Y-direction
- Z-direction

.Heat and Temperature
- High temperature
- Low temperature
- Temperature changes

.Impact and Shock

.Leakage - slipping on hydraulic fluid spilled, etc.

.Moisture
- High humidity
- Low humidity

.Moments (torque)
- About X-axis
- About Y-axis
- About Z-axis

.Power Source Failure
- Overpower
- Underpower

.Pressure
- High pressure
- Low pressure
- Pressure changes

.Radiation
- Thermal
- Electromagnetic
- Ionizing
- Ultraviolet

.Structural Damage/Failure
- Stress concentrations
- Stress reversals

.Toxicity
- Biohazard

.Vibration and Noise

HAZARD ANALYSIS

E. **Ranking Parameters** - two factors are used to evaluate and assign priorities to the hazards:

Occurrence - estimate of the probability that the conditions required to produce the hazard will occur.

Severity - estimate of the relative degree of injury or damage.

F. **Parameter Scales** - an object of the analysis is to relate the various hazards to each other within the ranking parameters of occurrence and severity. This is done by the quantitative assignment of attributes that enable a uniform assessment of hazards to determine the criticality index. Scales of 1 to 10 are used, with 10 being the most probable or severe. The next page provides an example of the parameter scales.

The attributes and scales should be tailored for each hazard analysis item and retained throughout each analysis to provide a uniform method of assessment toward hazard elimination.

G. **Criticality Index** - the product of the occurrence and severity assigned values. This index enables the hazards to be ranked for attention to design revision, training, warning notices, and other recommendations that will eliminate or diminish the hazards. The larger the result, the more troublesome the hazard is predicted to be.

HAZARD ANALYSIS

EXAMPLE PARAMETER SCALES

Occurrence Ranking Guide

	Probability of Occurrence	1	2	3	4	5	6	7	8	9	10
A)	Low, regardless of misuse or abuse	1									
B)	Low, but technically possible		2								
C)	Low, during normal system operation			3							
D)	Unlikely with a normal maintenance schedule				4						
E)	Unlikely at a normal environment, but likely at the extremes					5	6				
F)	Likely, data of a similar design exists							7	8		
G)	High, specific data of a like design exists.									9	10

Severity Ranking Guide

	Severity Attribute	1	2	3	4	5	6	7	8	9	10
A)	Inconvenience or annoyance - no loss of function, no injury	1									
B)	Reduction of system throughput		2	3							
C)	Minor vehicle/system damage				4						
D)	Minor operator/maintenance personnel injury					5					
E)	Major interruption in production schedule						6				
F)	Extensive vehicle/system damage							7			
G)	Major personnel injury								8		
H)	System loss									9	
I)	Death										10

HAZARD ANALYSIS

H. **Remarks** - provide comments or describe the follow-up actions that could be taken to eliminate or control the hazard:

1. Other design practices that would provide inherent safety.

2. The use of safety devices that are appropriate for the known hazards which cannot be controlled or eliminated by design revisions.

3. The use of warning devices to provide the timely detection of a hazard condition and the corresponding signal or display.

4. Special procedures that would counter the hazardous condition, including the use of hazard warning notices and labels.

Documentation of the changes made as a result of the hazard analysis, or a revision of the hazard analysis itself after significant design changes, is essential to the successful use of this technique.

A summary of the information required for each column of the Hazard Analysis is shown on the next page.

I. **Criticality Ranking** - summary of the hazards with a high criticality index should be made to direct attention to the major issues identified by the hazard analysis. An Index ranking listing is shown in the Hazard Analysis example section.

This ranking summary should be updated periodically to provide current and priority attention toward hazard elimination.

EATON

Hazard Analysis

Project Description

Date | Page of

Revision Date

Engineer

Hazard (1)	Cause (2)	Effects (3)	Severity (4)	Occurrence (5)	Crit Index (6)	Remarks (7)

(1) List type of hazard i.e., source of danger

(2) Specify the conditions which must exist or occur which lead to exposure to the hazard.

(3) Describe the resulting "effect" on performance, user, or surroundings.

(4) Estimate the severity of human injury or damage.

(5) Estimate the probability that the conditions which product the hazard will occur.

(6) Determine the relative rank (the product of severity and occurrence).

(7) List corrective action which will reduce the rank value.

HAZARD ANALYSIS

J. **Hazard Corrective Action and Closure** - would be considered at confirmtion of the recommended following items:

1. The design has eliminated the hazard.

2. There has been hazard reduction to a controllable level. This reduction should be verified by successful completion of test programs, analytical studies, or other acceptable methods.

3. The hazard has been assessed and the risk has been accepted by program management.

HAZARD ANALYSIS

SUMMARY OF USE AND ADVANTAGES

The Hazard Analysis should begin at the early stages of design and development to provide the baseline documentation for an ongoing, expanded analysis as the program progresses. Updating the analysis will provide continuity and involve the interrelated areas of design, assembly, test, maintenance and operation.

The analysis should address hazards for failures, the environments, personnel error, design characteristics, normal and emergency situations, and credible accidents.

Other uses and interfaces are directed to provide coordinated and integrated program functions and activities as follows:

- Early visibility of system interface problems.
- Early criteria for test planning.
- Hazard factors that affect the generation of maintenance and operation manuals, test procedures, and manufacturing and assembly instructions to assure that these activities do not negate the inherent safety of the design.

FREEZE PROTECTION VALVE

EXAMPLE - HAZARD ANALYSIS

INTRODUCTION TO FREEZE PROTECTION VALVE HAZARD ANALYSIS

The purpose of this hazard analysis was to identify potential sources of danger or nonconformances resulting from foreseeable misuse of the freeze protection valve or use of the valve under extreme conditions. The severity of each hazard was rated on a scale of one to twenty according to the following criteria:

Rating	Description
1-2	Minor expense
3-9	Major expense
10-15	Minor owner injury
16-20	Major owner injury

The probability of occurrence during the life of the solar heating system was subjectively estimated. The severity and occurrence were then multiplied and scaled by 100 to produce the criticality index. A criticality ranking is provided which shows the hazards with the highest criticality index. These can be considered to be the most troublesome.

EATON

Hazard Analysis

Project Description: FREEZE PROTECTION VALVE

Date:

Page 1 of 2

Revision Date:

Engineer:

Hazard	Cause	Effects	Severity	Occurrence	Crit Index	Remarks
1. Damage to solar equipment	.Freeze up due to failure of valve to open at high enough temperature .Foreign material from water impurities plugging valve	.Owner dissatisfaction; liability for damages	5	.1	50	Typical thermosyphoning system costs $300-$1,000.
2. Excessive weight on flat roof causing collapse	.Sewer backup .Sewer line freeze up	.Property damage; potential liability	5	.005	2.5	
	.Nonvertical installation of valve allowing water to drain through air break holes					Possible design alternative is to drill air break hole thru only one side of outlet body. Thus allowing a nonvertical installation of valve providing that remaining vent hole is oriented upward
3. Ice on roof	.Sewer line backup or plugging or nonvertical installation combined with cold weather and/or high wind	.Owner injury from slipping on roof when attempting to drain or repair system	10	.005	5	
4. Sewer water contamination of potable water	.Sewer backup when air break is plugged due to improper installation	.Bacteria induced illness .Note: sewer contamination not readily detectable since hot water supply not used for drinking.	10	.001	1	Unlikely if system is located on the roof. Caution tag and owner instructions against plugging air break holes is recommended.
5. Excessive use of water	.Freeze valve remains open .Off calibration resulting in higher temperature opening, and excessive flow	.High water bills because excessive use of water is not immediately detectable .Owner dissatisfaction	3	.1	30	Higher water costs in South increase the severity of this hazard.

EATON

Date	Page 2 of 2
Revision Date	
Engineer	

Project Description FREEZE PROTECTION VALVE

Hazard Analysis

Hazard	Cause	Effects	Severity	Occurrence	Crit Index	Remarks
6. Low ambient temperature freeze up	.Cold climate, "dead" spots in collector or piping at which water stagnates	.Damage to solar equipment not caused by freeze protection valve	5	.01	5	Theoretical calculations show that valve allows enough flow to protect collector and tubing to -100°F.
7. Storage tank or cold water inlet pipe to tank freeze up	.Cold weather; uninsulated tank .Water level valve in tank stays shut	.Damage to piping and solar equipment not resulting from freeze protection valve failure	5	.05	25	Owner may assume that freeze protection valve protects tank and cold water inlet piping, when in fact, it may not. Liability suit may result. Recommend caution in installation instructions detailing this limitation.
8. Water leak	High water temperatures and radiant energy absorbtion by closed valve	Creep; stress relief in polypropylene body resulting in a higher temperature opening or leak due to body fracture	2	.4	80	Collector inlet temperatures of 190°F have been recorded at ERC. Combined with radiant heat absorbtion, predicted extreme temperature of valve may be up to 200°F. Material deformation limits are placed at 212-260°F. Thus some sun shielding may be necessary.
9. Flammability	High temperatures	Melting and water leakage onto valve would occur before flame point reached	20	-	-	
10. Burned hands	Owner touching unit when system is in sunlight	.Potential liability for failure to warn	12	.005	6	Include warning that valve gets hot in operating instructions and via valve label.

SOLAR FREEZE-PROTECTION VALVE HAZARD ANALYSIS

Criticality Ranking

	Description	Rank
1.	Water leak due to high water temperature and absorbed radiant energy causing valve body temperature to rise above deformation limit.	80
2.	Damage to solar equipment from freezing caused by a valve plugged with foreign material.	50
3.	Excessive use of water because valve remains open or is off calibration.	30
4.	Storage tank or cold water inlet pipe freezing causing damage to solar equipment. These components may not be influenced by the freeze-protection valve.	25
5.	Burned hands from touching valve while system is in sunlight on a hot day.	6

FREEZE-PROTECTION VALVE HAZARD ANALYSIS

CONCLUSIONS/RECOMMENDATIONS

In general, most hazards relate to property damage caused by a malfunctioning valve. The only exceptions are burns caused by someone touching the valve on a sunny day, and contamination of the water supply if the sewer backs up on a system that has been improperly installed.

Based on ERC solar temperature data and radiant heat transfer theory, an extreme upper temperature of 288°F is predicted. This exceeds the recommended maximum operating temperature of 212-260°F and thus may result in deformation. The deformation would result in elongation and a change in calibration to allow a higher temperature opening.

The recommendations derived from the hazard analysis include:

1. Investigate a design alternative which would provide an air break hole drilled through only one side of outlet body. This could reduce the possibility of water draining onto the roof due to nonvertical installation or wind effect.

2. Provide a removable tag and owner instructions to caution against plugging the air break holes.

3. Provide a caution in the installation instructions which describes the limitations of the valve in protecting the storage tank and/or inlet cold water line.

4. Consider sun shield for valve body.
   Note: Deformation of lower (outlet) body affects calibration more significantly that deformation of upper body.

5. Provide a warning label affixed to valve body to indicate that the valve gets hot enough to cause a burn, etc.