

Introduction

- Failure Modes Effects Analysis is used in a number of industries to conduct an analysis of system, subsystem, and component design
- In some industries an FMEA is required by a regulatory body prior to receiving "authorization" to take a product to market



FMEA Definition and Basics

- Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) are methodologies designed to identify potential failure modes for a product or process, to assess the risk associated with those failure modes, to rank the issues in terms of importance and to identify corrective actions to address the most serious concerns.
- The purpose, terminology, and other details vary according to industry and type (e.g. Process FMEA, Design FMEA, etc.), the basic methodology is similar for all design efforts.
- Basics:
 - ➤ Identify Failure Modes
 - ➤ Assess Failure Modes
 - > Rank the Failure Modes
 - ➤ Identify Corrective Actions



Basic References

Failure Mode Effect Analysis: FMEA from Theory to Execution, 2 ed. by D.H. Stamatis, Quality Press

Procedures for Performing a Failure Mode, Effects and Criticality Analysis, MIL-STD-1629

FMEA and FMECA Webpage on Weibull.com (<u>www.weibull.com/basics/fmea.htm</u>), last accessed May 20, 2017

Potential Failure Mode and Effects Analysis (FMEA) Reference Manual (equivalent to SAE J-1739), 1995, (see www.lehigh.edu/~inrtibos/Resources/SAE FMEA.pdf, last accessed May 20, 2017)

Q9 Quality Risk Management, Guidance for Industry, Annex I: Risk Management Methods and Tools (subsection I.2 and I.3), US FDA publication, June 2006 (specifically

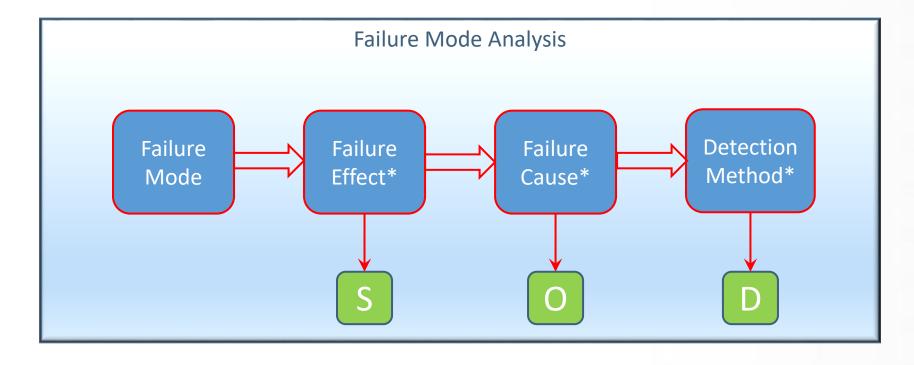
Applying Human Factors and Usability Engineering to Medical Devices, US FDA publication, Feb 3, 2016







Expanding the basic FMEA Model...



- S Severity
- O Occurrence
- D Detectability



Severity Rating

Severity (S) – a rating of the seriousness of the effect of a failure mode to the system, assembly, product, customer, or government regulation.

Severity is related to the Failure Effect.

Severity Guidance for system FMEA

Effect	Rank	Criteria
None	1	No Effect
Very Slight	2	Customer not annoyed. Very slight effect on product or system performance.
Slight	3	Customer slightly annoyed. Slight effect on product or system performance.
Minor	4	Customer experiences minor nuisance. Minor effect on product or system performance.
Moderate	5	Customer experiences some dissatisfaction. Moderate effect on product or system performance.
Significant	6	Customer experiences discomfort. Product performance degraded, but operable and safe. Partial failure, but operable.
Major	7	Customer dissatisfied. Product performance severely affected but functional and safe. System impaired.
Extreme	8	Customer very dissatisfied. Product inoperable but safe. System inoperable.
Serious	9	Potential hazardous effect. Able to stop product without mishap – time dependent failures. Compliance with government regulation is in jeopardy.
Hazardous	10	Hazardous effect. Safety related – sudden failure. Noncompliance with government regulation.

Ref: Failure Mode Effect Analysis: FMEA from Theory to Execution, by D. H. Stamatis



Occurrence Rating

Occurrence (O) – a rating corresponding to the cumulative number of failures that could occur over the design life of a system or component.

Occurrence is related to the Failure Cause

CNF – Cumulative number of failures

Occurrence Guidance for system FMEA

Effect	Rank	Criteria	CNF/1000
Almost	1	Failure unlikely, history shows no failures	< .00058
Never			
Remote	2	Rare number of failures likely	.0068
Very Slight	3	Very few failures likely	.0063
Slight	4	Few failures likely	.46
Low	5	Occasional number of failures likely	2.7
Medium	6	Medium number of failures likely	12.4
Moderately	7	Moderately high number of failures likely	46
High			
High	8	High number of failures likely	134
Very High	9	Very High number of failures likely	316
Almost	10	Failure almost certain. History of failures exists from previous	>316
Certain		or similar designs.	

Ref: Failure Mode Effect Analysis: FMEA from Theory to Execution, by D. H. Stamatis



Detectability Rating

Detectability (D) – a rating of the ability of the proposed design control to detect a potential failure mode or occurrence.

Detectability is related to the Failure Control

Detection Guidance for system FMEA

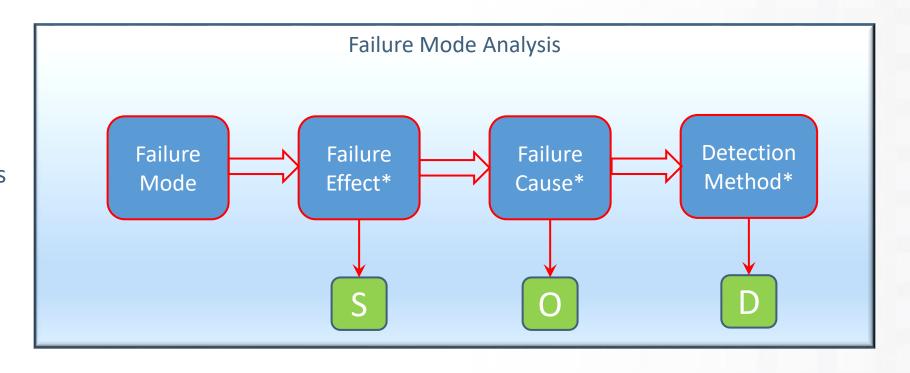
Effect	Rank	Criteria
Almost	1	Proven detection methods available while in conceptual design
certain		
Very High	2	Has very high effectiveness
High	3	Has high effectiveness
Moderately	4	Has moderately high effectiveness
High		
Medium	5	Has medium effectiveness
Low	6	Has low effectiveness
Slight	7	Has very low effectiveness
Very Slight	8	Has lowest effectiveness in each applicable category
Remote	9	Unproven, or unreliable, or effectiveness is unknown
Almost	10	No technique is available or known, and/or none is planned
Impossible		

Ref: Failure Mode Effect Analysis: FMEA from Theory to Execution, by D. H. Stamatis



Criticality of a Failure

Criticality – A relative measure of the combined influence of the consequences or a failure mode (severity or S) and its frequency (occurrence or O). The product of the severity times occurrence provides the relative criticality.



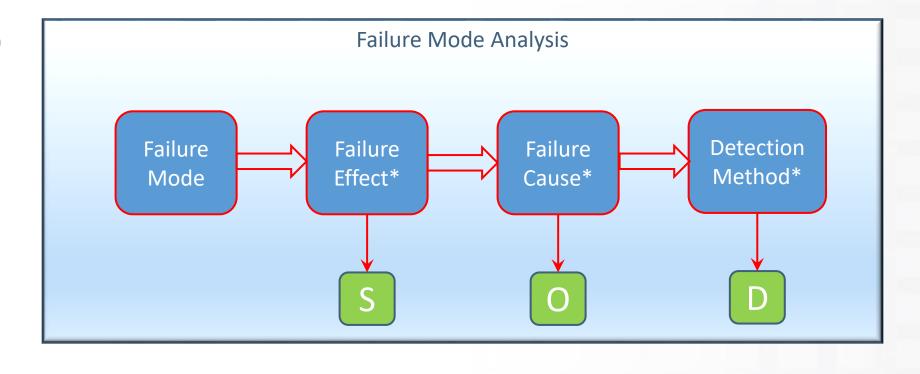




Evaluating the Failure Relative to one another

Risk Priority Number (RPN)

– A relative measure used to rank order potential system failures. The RPN defines the priority of the failure. The RPN is the product of the severity, occurrence, and detection ratings.











Recommended Actions...

No FMEA should be done without a recommended action list to improve the system design.

Recommended Actions are taken to reduce severity, occurrence, detection, or all three of them. In essence to eliminate failures and thereby eliminate system deficiencies.

Using Criticality or RPN-

- Rank Order Failures and Causes
- Determine a subset of Failure (generally > RPN value)
- Develop Follow-up, Corrective Actions







Automotive Industry Example

FAILURE MODE AND EFFECTS ANALYSIS Front Door L.H. FAILURE MODE AND EFFECTS ANALYSIS FMEA Number Page 1

1450

FMEA Type							Fron	t Door L.H.			Page	1 of	1				
Item 1.1.1	- Front Door L.I	Н.			Process	Res	ponsibility	Body Engineering	g		Prepa	red ByJ.	Ford - X6521 - As	sy O	ps		
Model Year(s)/V	/ehicle(s) 2	0XX/Lion 4dr/W	agor	1	Key Dat	te	3/10/2015				FMEA	Date (Orig.)	3/10/2015 (Rev	')	3/21	/201	15
Core Team	A. Tate Boo	dy Engrg, J. Smit	th - (OC, R.	James - Produc	tion,	J. Jones - Main	tenance					_				
Name / Function	Potential Failure	Potential	5	assification	Potential	ö	Current Process	Current Process	<u>=</u>	=	Recommended	Responsibility &	Action	Rest			
Requirements	Mode	Effect(s) of Failure	SEVi	Classifi	Cause(s) of Failure	OCCI	Controls (Prevention)	Controls (Detection)	DETI	RPNi	Action(s)	Planned Completion Date	Actions Taken & Actual Completion Date	SEVr	000	DETr	RPNr
1.1.1 - Front Door L.																	
application of wax inside door/ cover inner door, lower surfaces with wax	Insufficient wax coverage over specified surface	Allows integrity breach of inner door panel. Corroded interior lower door panels.	7		Manually inserted spray head not inserted far enough	8		Visual check each hour - 1/shift for film thickness (depth meter) and coverage.	5	280	Add positive depth stop to sprayer.		Stop added, sprayer checked on line.	7	2	5	70
to specification thickness.		Deteriorated life of door leading to: - Unsatisfactory appearance due to rust through paint									Automate spraying.	- 3/10/2003	Rejected due to complexity of different doors on same line.				
		over time - Impaired function of interior door hardware			Spray head clogged- Viscosity too high- Temperature too low- Pressure too low.	5	Test spray pattern at start-up and after idle periods, and preventive maintenance program to clean heads.	Visual check each hour - 1/shift for film thickness (depth meter) and coverage.	5	175	Use Design of Experiments (DOE) on viscosity vs. temperature vs. pressure.		Temp and press limits were determined and limit controls have been installed - control charts show process is in control Cpk = 1.85.		1	5	35
					Spray head deformed due to impact	2	Preventive maintenance program to maintain heads.	Visual check each hour - 1/shift for film thickness (depth meter) and	5	70					2	5	70

Figure 1: Process FMEA (PFMEA) in the Automotive Industry Action Group (AIAG) FMEA-4 format.

Source: www.Weibull.com/hotwire/issue46/relbasics46.htm, last accessed 5/9/2017



Integrating FMEA into an MBSE environment



Objective

- Expand the "standard" MBSE schema used in Model Based System Engineering (MBSE) to provide for traceability to the FMEA
- Provide for the ability to produce a standard FMEA table
- Provide for Traceability from the system design to the FMEA



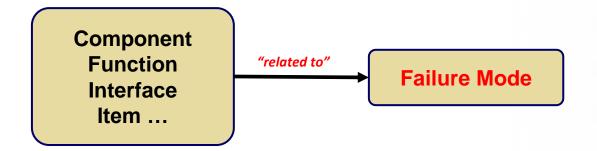
Common Elements of any FMEA ...

																	$\overline{}$
Function	Potential	Potential	S	Potential	0	Current	D		C		Responsibility	Action					
	Failure Mode	Effects(s) of Failure		Cause(s) of Failure		Process Controls		P N	R I T	Action(s)	and Target Completion Date	Action Taken	S	0	D	R P N	CR-T
Dispense amount of cash	Does not dispense cash	Customer very dissatisfied	8	Out of cash	5	Internal low- cash alert	5	200	40								
requested by customer		Incorrect entry to demand deposit system		Machine jams Power failure	2	Internal jam alert None	10	160	16								
		Discrepancy in cash balancing		during transaction										L			
	Dispenses too much cash	Bank loses money Discrepancy	6	Bills stuck together	2	Loading pro- cedure (riffle ends of stack)	7	84	12								
		in cash balancing		Denominations in wrong trays	3	Two-person visual verification	4	72	18								
	Takes too long to dispense cash	Customer somewhat annoyed	3	Heavy computer network traffic	7	None	10	210	21								
				Power interruption during transaction	2	None	10	60	6								
	Fail	ure Mode			Ca	use											
	\ Ider	ntification		\ Ide	ntif	fication											



Failure Mode Class

Need a Class to capture the Failure Mode and the relation to the system entities



This arrangement allows for capturing a failure mode for any item in the system design.



Failure Mode Entity Attributes

Failure Mode:

Name

Number

Description (Effect)

Severity

Failure Cause:

Name

Number

Description (Cause)

Occurrence

Control

Detection

RPN*

Criticality*

FMEA Analysis Features:

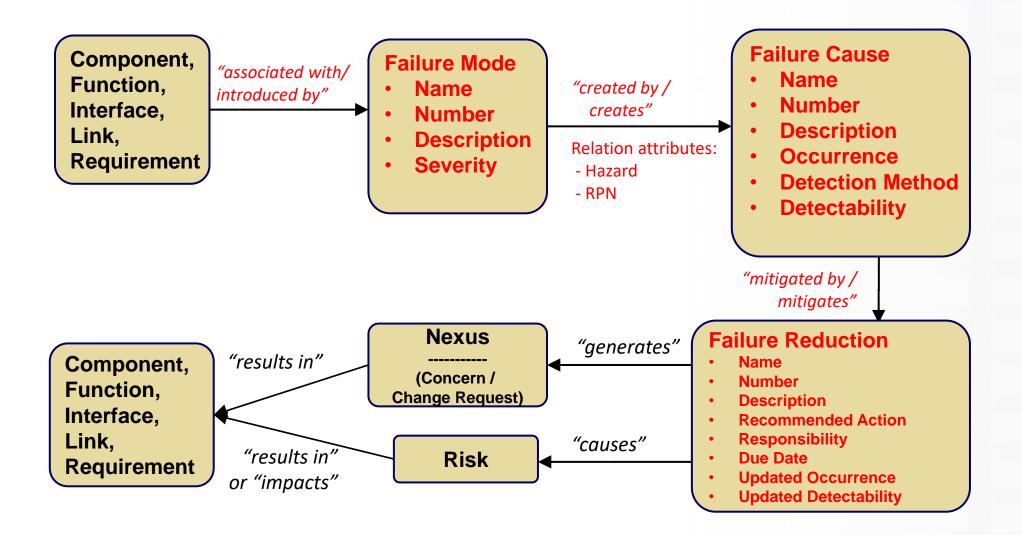
- One Failure Mode can have multiple causes
- Severity is associated with Failure Mode
- Probability of Occurrence associated with each Cause
- Detection associated with each Cause

Function	Potential	Potential	s	Potential	0	Current	D	R	C		Responsibility	Action			_		
	Failure Mode	Effects(s) of Failure		Cause(s) of Failure		Process Controls		P N	T	Action(s)	and Target Completion Date	Action Taken	S	0	D	RPN	CR-T
Dispense amount of cash requested	Does not dispense cash	Customer very dissatisfied	8	Out of cash Machine jams	5	Internal low- cash alert Internal jam	5		40								
by customer		Incorrect entry to demand deposit system Discrepancy in cash balancing		Power failure during transaction	2	alert None	10	160	16								
	Dispenses too much cash	Bank loses money Discrepancy	6	Bills stuck together	2	Loading pro- cedure (riffle ends of stack)	7	84	12								П
		in cash balancing		Denominations in wrong trays	3	Two-person visual verification	4	72	18								
	Takes too long to dispense cash	Customer somewhat annoyed	3	Heavy computer network traffic	7	None	10	210	21								
				Power interruption during transaction	2	None	10	60	6								



^{*} Calculated Values

Schema Extension









Example Generic FMEA Form

Generally, the results of an FMEA are captured in a table similar to this.

1	_ Subsyste	ent			esign responsibility by date					F	Page Page Prepared by FMEA date (Orig		_ of .			
Item/	Potential failure	Potential effect(s) of	S E	C R	Potential cause(s)	0	Current design	D E	R P	Recommended action(s)	Responsibility and target	А	ction r	esult	3	
Idilction	mode	failure	٧	T	mechanism(s) of failure	C U R	controls	T E C T	N	action(s)	completion date	Action taken	S E V	0000	D E T	R P N

Ref: Failure Mode Effect Analysis: FMEA from Theory to Execution, Appendix A, Figure E-10, D. H. Stamatis



FMEA Basic Report

System Element ▼	Failure *	Failure Description	Severity	Cause of Failure ▼	Occurrence	Detection Method ▼	Dectectabilty
Cooling Motor and Fan	Fan Vibration and	Audible Noise, vibration; increased	5	Fan Center of Gravity off axix of	5	Design calls for lightweight fan with	1
Assembly	Interference	motor wear.		rotation causing 2-plan imbalance.		minimum band mass, part thickness.	4
Cooling Motor and Fan	Misalignment of Fan and	Fan and shroud mis-aligned cause	7	Fan contacts shroud, noise or motor	2	Designed for easy assembly and alignment.	,
Assembly	Shroud	reduction or complete loss of		burnout.			3
Cooling Motor and Fan	Motor Burnout	Motor Burnout causes loss of cooling	5	Overheating of motor assembly due to	2	Vent holes in motor casing, fins in fan hub	_
Assembly		to the system.		lack of air circulation around motor.		pull air throught motor body.	3
Cooling Motor and Fan	Reduced Fan Efficiency	Fan motor is assembled 120 degrees	6	Symmetrical spacing of screw holes	7	Cuurent design requires visual verification of	
Assembly		off nominal angle causes reduction		allows for non-unique mounting of fan		assembly.	7
		of cooling effectiveness.		motor.			
				Misassebly of Fan and Motor causes	7	Visual Inspection of Fan and Motor assembly.	6
				pinched wire.			0



FMEA with Criticality and RPN Calculations

			everity		Occurrence		Dectectabilty	Criticality	NA W
		Failure Description Audible Noise, vibration; increased motor		Cause of Failure Fan Center of Gravity off axix of rotation causing 2-plan		Detection Method Design calls for lightweight fan with	4	25	100
1 - 1	Interference	wear.	,	imbalance.	,	minimum band mass, part thickness.	4	23	100
Cooling Motor and	Misalignment of Fan	Fan and shroud mis-aligned cause reduction	7	Fan contacts shroud, noise or motor burnout.	2	Designed for easy assembly and	3	14	42
Fan Assembly	and Shroud	or complete loss of cooling.				alignment.			
Cooling Motor and	Motor Burnout	Motor Burnout causes loss of cooling to the	5	Overheating of motor assembly due to lack of air	2	Vent holes in motor casing, fins in fan	5	10	50
Fan Assembly		system.		circulation around motor.		hub pull air throught motor body.			
Cooling Motor and	Reduced Fan Efficiency	Fan motor is assembled 120 degrees off	6	Symmetrical spacing of screw holes allows for non-	7	Cuurent design requires visual	7	42	294
Fan Assembly		nominal angle causes reduction of cooling		unique mounting of fan motor.		verification of assembly.			
		effectiveness.							
1				Misassebly of Fan and Motor causes pinched wire.	7	Visual Inspection of Fan and Motor	6	42	252
						assembly.			



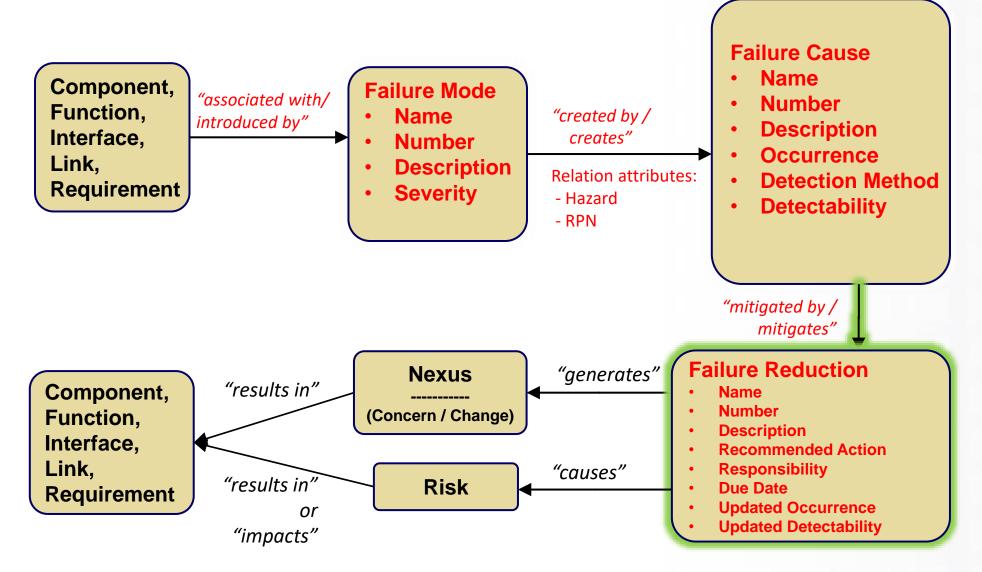
High RPN Values

System Element		Failure Description	Seve rity	Cause of Failure	Occurrence	Detection Method	Dectecta bilty	Criticality	RPN
Cooling Motor and	Fan Vibration and	Audible Noise, vibration; increased motor	5	Fan Center of Gravity off axix of rotation causing 2-plan	5	Design calls for lightweight fan with	4	25	100
Fan Assembly	Interference	wear.		imbalance.		minimum band mass, part thickness.			
Cooling Motor and	Misalignment of Fan	Fan and shroud mis-aligned cause reduction	7	Fan contacts shroud, noise or motor burnout.	2	Designed for easy assembly and	3	14	42
Fan Assembly	and Shroud	or complete loss of cooling.				alignment.			
Cooling Motor and	Motor Burnout	Motor Burnout causes loss of cooling to the	5	Overheating of motor assembly due to lack of air	2	Vent holes in motor casing, fins in fan	5	10	50
Fan Assembly		system.		circulation around motor.		hub pull air throught motor body.			
Cooling Motor and	Reduced Fan Efficiency	Fan motor is assembled 120 degrees off	6	Symmetrical spacing of screw holes allows for non-	7	Cuurent design requires visual	7	42	294
Fan Assembly		nominal angle causes reduction of cooling		unique mounting of fan motor.		verification of assembly.			
		effectiveness.							
				Misassebly of Fan and Motor causes pinched wire.	7	Visual Inspection of Fan and Motor	6	42	252
						assembly.		>	

Values above a threshold require mitigation. Threshold Value varies based on project and industry.



Failure Reduction...



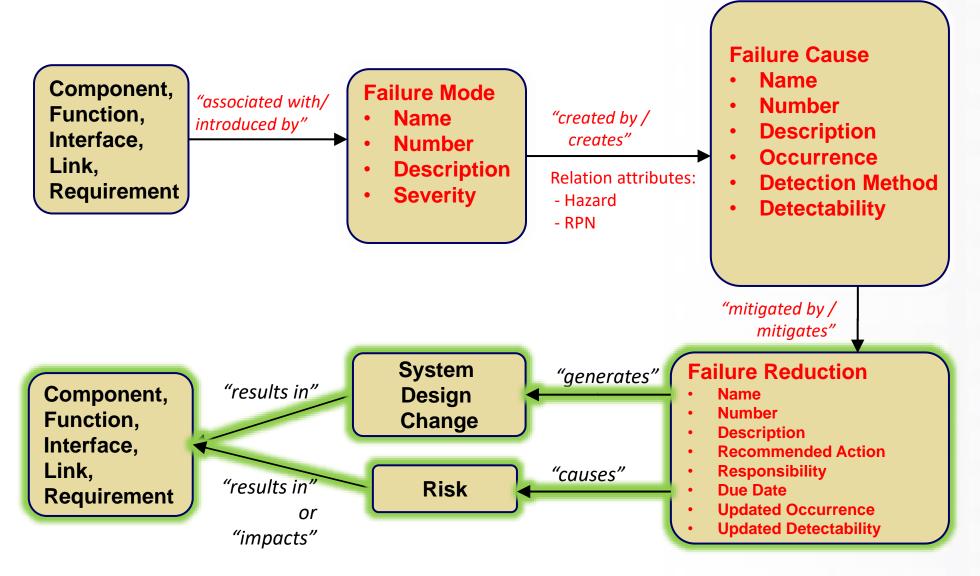


FMEA Report with Failure Reduction

System Element	Failure V	Failure Description	Soverity	Cause of Failure	Ocurence	Detection Method *	Dectectability	Ceiticality	Nag -	Recommended Action	Responsibilit. *	Due Dat€ ▼	Updated urrence	Updated ectability
Cooling Motor and Fan	Fan Vibration and	Audible Noise, vibration;	5	Fan Center of Gravity off axix	5	Design calls for lightweight	4	25	100					
Assembly	Interference	increased motor wear.		of rotation causing 2-plan		fan with minimum band mass,								
Cooling Motor and Fan	Misalignment of Fan and	Fan and shroud mis-aligned	7	Fan contacts shroud, noise or	2	Designed for easy assembly	3	14	42					
Assembly	Shroud	cause reduction or complete		motor burnout.		and alignment.								
Cooling Motor and Fan	Motor Burnout	Motor Burnout causes loss of	5	Overheating of motor	2	Vent holes in motor casing,	5	10	50					
Assembly		cooling to the system.		assembly due to lack of air		fins in fan hub pull air								
Cooling Motor and Fan	Reduced Fan Efficiency	Fan motor is assembled 120	6	Symmetrical spacing of screw	7	Cuurent design requires visual	7	42	294	Develop a unique, non-	Joe Engineer	31-Aug-17	2	2
Assembly		degrees off nominal angle		holes allows for non-unique		verification of assembly.				symmetrical bolt pattern				
		causes reduction of cooling		mounting of fan motor.						for the motor / fan				
		effectiveness.		Misassebly of Fan and Motor	7	Visual Inspection of Fan and	6	42	252	Develop a unique, non-	Joe Engineer	31-Aug-17	2	2
				causes pinched wire.		Motor assembly.				symmetrical bolt pattern				
										for the motor / fan				



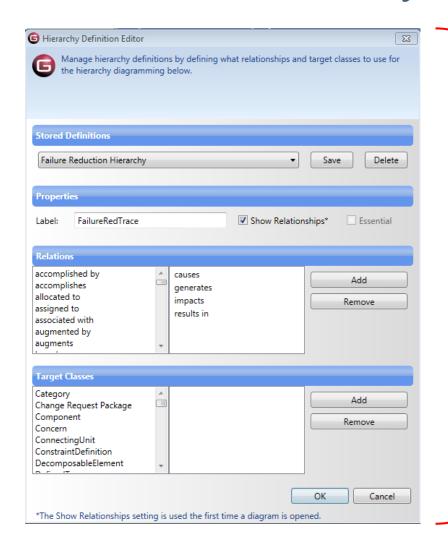
Capture Design Changes based on FMEA



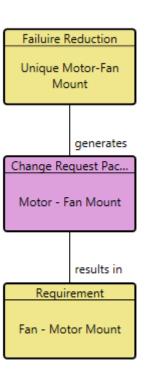


Failure Reduction Hierarchy

Using the Schema diagram, determine what relations need to be included in the custome hierarchy...



To create the diagram on the left





Organizing FMEA Analyses

Over the lifecycle you may have several different FMEA Analyses. How can we organize these?

Option 1 – Create individual folders within the Failure Mode Class

Option 2 – Create a Category for a particular analysis, then have the Category "categorize" a set of Failure Modes

Option 3 – Create a Package and have the package include the Failure Modes, Causes, and Reduction Methods



Summary / Conclusion

- Provided an examination of how to do a basic FMEA
- Looked at what we needed in an MBSE environment
- Examined a series of reports need to be produced from the MBSE environment
- Used a hierarchy to trace from the FMEA to the design model



Questions?





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