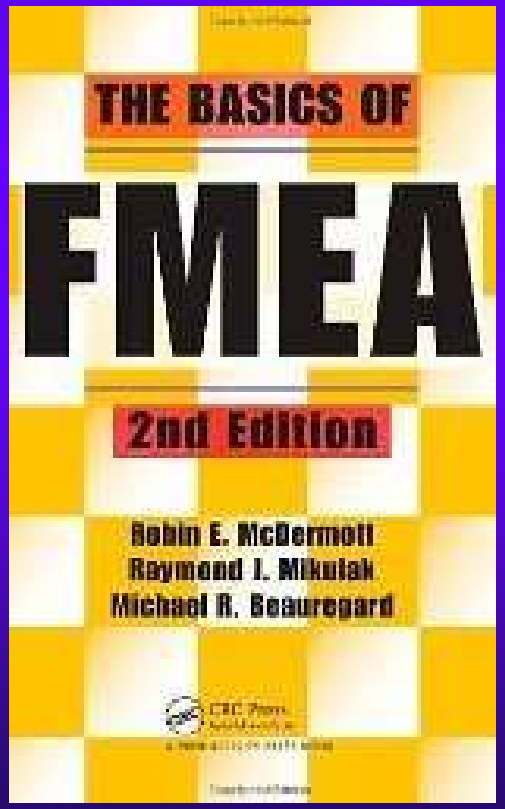
REFERENCE:

THE BASICS OF FMEA

Robin E. McDermott
Raymond J. Mikulak
Michael R. Beauregard



Presented By:

Joseph E. Kenol

ASQ North Jersey, October 20, 2010

DEFINITION

- FMEA is a systematic analysis of potential failure modes aimed at preventing failures. It is intended to be a preventive action process carried out before implementing new or changes in products or processes

- Ideally, FMEAs are conducted in the product design or process development stages, although conducting it on existing products and processes may also yield benefits

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

PURPOSE

- An effective FMEA identifies corrective actions required to prevent failures from reaching the customer; and to assure the highest possible yield, quality, and reliability

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

THE HISTORY

- The first formal FMEAs were conducted in the aerospace industry in the mid-1960s, specifically looking at safety issues
- Before long, FMEAs became a key tool for improving safety, especially in the chemical process industries
- While Engineers have always analyzed processes and products for potential failures, the FMEA method standardizes the approach and establishes a common language that can be used both, within and between companies

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

HISTORY (CONT…)

- FMEA techniques have been around for 40 + years
- More widespread use thanks in large part to U.S. automotive industry and its QS-9000 supplier requirements
- QS-9000 standard requires suppliers to conduct product/design and process FMEAs in an effort to eliminate potential failures

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

TYPES OF FMEA

- **System** – focuses on global system function
- **Design** – focuses on components and subsystems
- **Process** – focuses on manufacturing and assembly processes
- **Service** – focuses on service functions
- **Software** – focuses on software functions

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

PRODUCT/DESIGN VS PROCESS FMEAs

Product/Design

- The objective for a product or design FMEA is to uncover problems with products that will result in safety hazards, product malfunctions, or a shortened product life

- Product FMEAs can be conducted at different phases of a product life cycle (preliminary or final design, prototype) or on product that are already in production

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

PRODUCT/DESIGN VS PROCESS FMEAs

Process FMEA

Uncovers problems related to the delivery of services or the manufacture of products

Examples: http://www.youtube.com/watch?v=uzXZd0b_lW4

- A piece of automated assembly equipment may mis-feed parts resulting in products not being assembled correctly
- In a chemical manufacturing process, temperature and mixing time could be sources of potential failures resulting in unusable product

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

BENEFITS

- **Substantially reduce costs by identifying design and process improvements early in the development process when relatively easy and inexpensive changes can be made**
- **Improves product/process quality and reliability**
- **More robust process, and reduces or eliminates the trend for after-the-fact corrective action and late changes crises**
- **Significantly reduce potential costly liability when product or process do not perform as promised**
- **Provide new ideas for improvements in similar designs or processes**

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

PART OF COMPREHENSIVE QUALITY SYSTEM

- While FMEAs can be effective used alone, maximum benefits cannot be achieved if systems are not in place to support it

- Examples of comprehensive quality systems include: ISO 9001, QS-9000 guidelines, Six Sigma management system

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

TWELVE KEY QMS ELEMENTS SUPPORTING FMEA PROCESS

Quality System Element	Role in the FMEA Process
Leadership	Supports FMEA process, assuring the team has the necessary tools, resources, and time to work on the FMEA
Strategic Quality Planning	Uses the results of FMEAs to assist in directing future improvement activities
Process and business measures	Measures and monitors the results of FMEAs both, in terms of product quality and bottom line results
Effective use of data and information	Provides facts and dates to confirm FMEA analysis and to measure the results of the FMEA process
Process control (Both, company and suppliers)	Assures a stable process and product at the start of an FMEA and statistically monitors improvements made through the FMEA process
Human resources	Supports the FMEA team with appropriate training in quality improvement tools and techniques
Training	Provides the basic skills necessary to work on an FMEA team, identify potential problems, and determine solutions
A documented quality plan	Identifies FMEA as part of the overall quality strategy of the company. Defines when and where FMEAs should be used and documents the FMEA process the teams should use
Documented procedures	Assures the consistent operating methods are being used thus reducing unnecessary variation in the product or process
Design control	Assures consistency in the design process
Customer focus	Provides the team with information about what's important to the customer, and information that can be incorporated in the FMEA process
A customer feedback system	Provides the FMEA team with additional data to consider during the FMEA process

OBJECTIVE

- **To look for ALL of the ways a process or product can fail**
  - Failures are not limited to problems with the product
  - Because failures also can occur when the user makes a mistake, those types of failures should be included in the FMEA
  - Anything that can be done to assure the product works correctly, regardless of how the user operates it, will move the product closer to 100% customer satisfaction

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

EVALUATING THE RISK OF FAILURES AND EFFECTS

- The relative risk of a failure and its effects is determined by three factors:
  - ***Severity***- the consequence of the failure should it occur
  - ***Occurrence***- the probability or frequency of the failure occurring
  - ***Detection***- the probability of the failure being detected before the impact of the effect is realized

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

ASSESSING THE RISK PRIORITY NUMBER [RPN]

- Using data and knowledge of the process or product, each potential failure mode and effect is rated in each of the three factors identified in the previous slide
- Rating the three factors is based on a predetermined scale, low to high
- The RPN is used to rank the need for corrective actions to eliminate or reduce the potential failure modes

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

RISK PRIORITY NUMBER

- The failure modes with the highest RPNs should be attended first
- Once corrective action has been taken, a new RPN is determined by re-evaluating the severity, occurrence, and detection ratings

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

CALCULATE THE RISK PRIORITY NUMBER

The risk priority number (RPN) is simply calculated by multiplying across the 3 factors

Risk Priority Number =

Severity X Occurrence X Detection

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

EXAMPLE OF A SEVERITY RATING SCALE

Rating	Description	Definition
10	Dangerously High	Failure could injure the customer or an employee
9	Extremely High	Failure would create noncompliance with the federal government
8	Very High	Failure would render the unit inoperable or unfit for use
7	High	Failure causes a high degree of customer dissatisfaction
6	Moderate	Failure result in a subsystem or partial malfunction of the product
5	Low	Failure creates enough of a performance loss to cause the customer to complain
4	Very Low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss
3	Minor	Failure would create a minor nuisance to the customer, but the customer can overcome it in the process or product without performance loss
2	Very Minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product
1	None	Failure would not be noticeable to the customer and would not affect the customer's process or product

EXAMPLE OF AN OCCURRENCE RATING SCALE

	Description	Definition
10	Very High-Failure is almost inevitable	More than one occurrence per day or a probability of more than three occurrences in 10 events (Cpk < 0.33)
9		One occurrence every three days to four days or a probability of three occurrences in 10 events (Cpk apprx. 0.33)
8	High-Repeated Failure	One occurrence per week or a probability of 5 occurrences in 100 events (Cpk apprx. 0.67)
7		One occurrence every month or one occurrence in 100 events (Cpk apprx. 0.83)
6	Moderate-Occasional Failure	One occurrence every three months or three occurrences in 1000 events (Cpk apprx. 1.00)
5		One occurrence every six months to one year or one occurrence in 10,000 events (Cpk apprx. 1.17)
4		One occurrence per year or six occurrences in 10,000 events (Cpk apprx. 1.33)
3	Low-Relatively few Failures	One occurrence every one to three years or six occurrences in 10 million events (Cpk apprx. 1.67)
2		One occurrence every three to five years or 2 occurrences in 1 billion events (Cpk apprx. 2.00)
1	Remote-Failure is unlikely	One occurrence in greater than five years or less than two occurrences in 1 billion events (Cpk apprx. 2.00)

EXAMPLE OF A DETECTION RATING SCALE

Detection Rating Scale*

***Should be modified to fit the specific product or process**

Rating	Description	Definition
10	Absolute Uncertainty	The product is not inspected or the defect caused by failure is not detectable
9	Very Remote	Product is sampled, inspected, and released based on Acceptable Quality Level (AQL) sampling plans
8	Remote	Product is accepted based on no defectives in a sample
7	Very Low	Product is 100% manually inspected in the process
6	Low	Product is 100% manually inspected using go-no-go or other mistake-proofing gauges
5	Moderate	Some Statistical Process Control (SPC) is used in process, and product is final inspected off-line
4	Moderately High	SPC is used and there is immediate reaction to out-of-control conditions
3	High	An effective SPC program is in place with process capability (CPk) greater than 1.33
2	Very High	All product is 100% automatically inspected
1	Almost Certain	The defect is obvious or there is 100% automatic inspection with regular calibration and preventive maintenance of the inspection equipment

FMEA WORKSHEET

FAILURE MODE AND EFFECTS ANALYSIS (FMEA) Page 1 of 3

Subsystem/Name: DC motor
Model Year/Vehicle(s): 2000/DC motor

P = Probabilities (chance) of Occurrences
S = Seriousness of Failure to the Vehicle
D = Likelihood that the Defect will Reach the customer
R = Risk Priority Measure (P x S x D)

Final Design: 31/5/2000
Prepared by:
Reviewed by: Chris
FMEA Date (Org.): 27/4/2000 (Rev.) 31/5/2000)

1 = very low or none 2 = low or minor 3 = moderate or significant 4 = high 5 = very high or catastrophic

No.	Part Name Part No.	Function	Failure Mode	Mechanism(s) & Causes(s) of Failure	Effect(s) Of Failure	Current Control	P.R.A.				Recommended Corrective Action(s)	Action(s) Taken
							P	S	D	R		
1	Position Controller	Receive a demand position	Loose cable connection Incorrect demand signal	Wear and tear Operator error	Motor fails to move Position controller breakdown in a long-run		2 4	4 4	1 3	8 48	Replace faulty wire. Q.C checked. Intensive training for operators.	

FMEA WORKSHEET

FAILURE MODE AND EFFECTS ANALYSIS (FMEA) Page 2 of 3

Subsystem/Name: DC motor
Model Year/Vehicle(s): 2000/DC motor

P = Probabilities (chance) of Occurrences
S = Seriousness of Failure to the Vehicle
D = Likelihood that the Defect will Reach the customer
R = Risk Priority Measure (P x S x D)

Final Design: 31/5/2000
Prepared by:
Reviewed by: Chris
FMEA Date (Org.): 27/4/2000 (Rev.) 31/5/2000)

1 = very low or none 2 = low or minor 3 = moderate or significant 4 = high 5 = very high or catastrophic

No.	Part Name Part No.	Function	Failure Mode	Mechanism(s) & Causes(s) of Failure	Effect(s) Of Failure	Current Control	P.R.A.				Recommended Corrective Action(s)	Action(s) Taken
							P	S	D	R		
2	Drive	Receive speed demand	Incorrect speed demand being received	Fault in position controller's output	Extensive damage to the machine		2	4	4	32	Indicator and Audile warning	
		Measures actual speed	Incorrect speed reading	Wear and tear	Extensive damage		4	4	5	80	Voltmeter Improve check procedures	

FMEA WORKSHEET

FAILURE MODE AND EFFECTS ANALYSIS (FMEA) Page 3 of 3

Subsystem/Name: DC motor
Model Year/Vehicle(s): 2000/DC motor

P = Probabilities (chance) of Occurrences
S = Seriousness of Failure to the Vehicle
D = Likelihood that the Defect will Reach the customer
R = Risk Priority Measure (P x S x D)

Final Design: 31/5/2000
Prepared by:
Reviewed by: Chris
FMEA Date (Org.): 27/4/2000 (Rev.) 31/5/2000)

1 = very low or none 2 = low or minor 3 = moderate or significant 4 = high 5 = very high or catastrophic

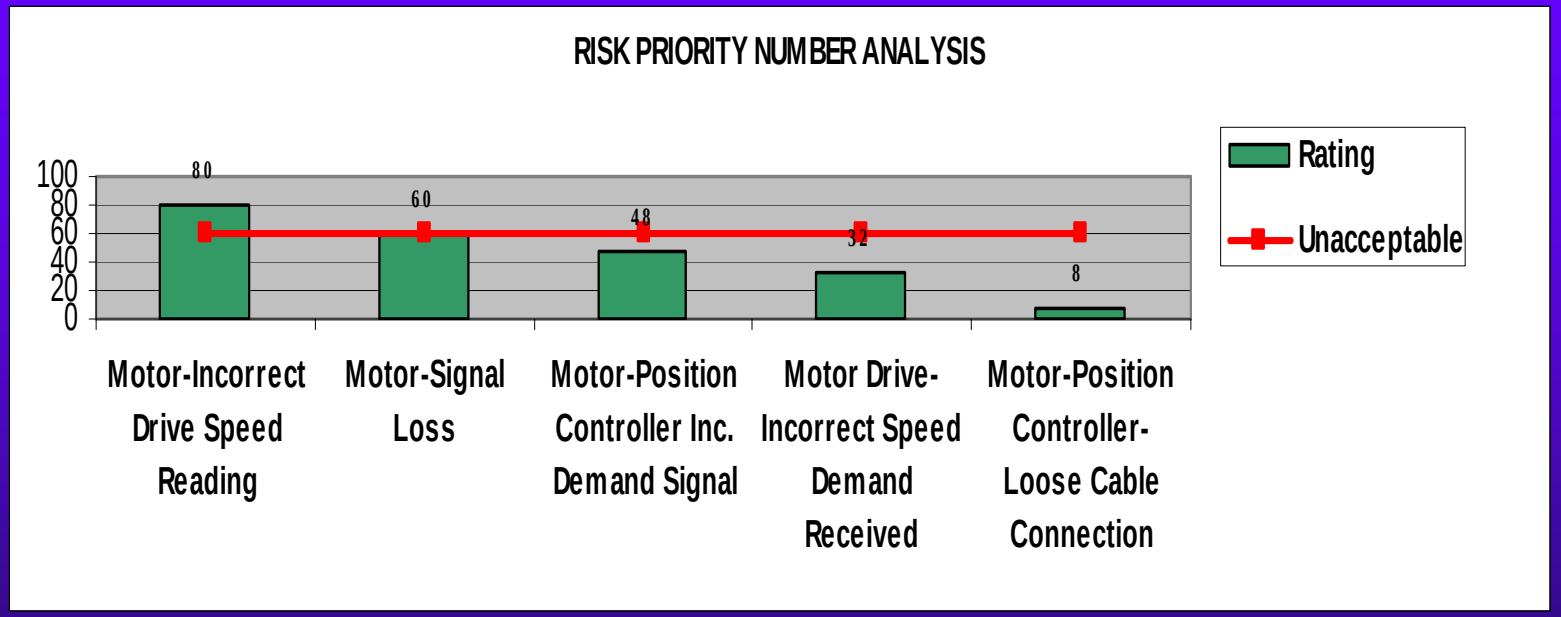
No.	Part Name Part No.	Function	Failure Mode	Mechanism(s) & Causes(s) of Failure	Effect(s) Of Failure	Current Control	P.R.A.				Recommended Corrective Action(s)	Action(s) Taken
							P	S	D	R		
3	Motor	Provides voltage signal	Signal loss	Faulty leads	Unstable control loop Endanger operators Serious damage		3	5	4	60	Durability test on leads	

PRIORITIZING FAILURE MODES FOR ACTION

- The FMs can now be prioritized by ranking them in order from the highest risk priority number to the smallest
- A Pareto diagram is helpful to visualize the differences between the various ratings
- Usually, it helps to set a cut-off RPN, where any FMs with an RPN above that establish point of unacceptable risk are attended to

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

PRIORITIZING THE FMs FOR ACTION



RESULTING RPN

- The new RPN is called the Resulting RPN
- Improvement and corrective action must continue until the resulting RPN is at an acceptable level for all potential failure modes

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

RISK ASSESSMENT COMPLETED WORKSHEET

System	LTN2001 GPS SSU			**Potential Failure Mode and Effects Analysis (Design FMEA)**							**Revision**	B					
Subsystem	Receiver Card										**Prepared By**	Robert Crow					
Part Number	466230-100										**FMEA Date**	8/18/1992					
Design Lead	J. Davies										**Revision Date**						
													Action Results				
Item / Function	**Potential Failure Mode(s)**	**Potential Effect(s) of Failure**	**Sev**	**Potential Cause(s)/ Mechanism(s) of Failure**	**Prob**	**Current Design Controls**	**Det**	**RPN**	**Recommended Action(s)**	**Responsibility & Target Completion Date**	**Actions Taken**	**New Sev**	**New Occ**	**New Det**	**New RPN**
Circuit Block 4.1.1	Output loss from pre-amp	Receiver & output data loss; track loss; GPS shut-down	5	C1 short	1	PR-20 & HW-5	2	10	QA Proc 20-6	R. Jones, 11/30/92	Added to control plan	2	1	1	2
			5	C88 short	2		2	20	QA Proc 20-6	R. Jones, 11/30/92	Added to control plan	2	1	1	2
			5	L1 open/short	3		2	30	QA Proc 20-3	R. Jones, 11/30/92	Added to control plan	2	2	1	4
			5	U21 function	4		2	40	Test 147	R. Jones, 11/30/92	Added to control plan	2	3	1	6
								0							0
Circuit Block 4.1.2	Undetected & insignificant component failure mode	No noticeable system effect	1	C1open/chg val	2	None	8	16	None						0
			1	C88open/chg val	2		8	16	None						0
								0							0
Circuit Block 4.2.1	Loss of signal from 2nd RF amplifier & 1st down converter	Loss of position, velocity & time output data; track loss; GPS shut-down	4	C2 short	1	PR-20 & HW-5	2	8	QA Proc 20-6	D. Howell 10/15/92	Added to control plan				0
			4	C3 short	1	PR-20 & HW-5	2	8	QA Proc 20-6	D. Howell 10/15/92	Added to control plan	2	1	1	2
			4	C4 open/short	2	PR-20 & HW-5	2	16	QA Proc 20-6	B. Howell 10/15/92	Added to control plan	2	1	1	2
			4	C5 short	2	PR-20 & HW-5	2	16	QA Proc 20-6	B. Howell 10/15/92	Added to control plan	2	1	1	2
			4	C66 open/short	2	PR-20 & HW-5	2	16	QA Proc 20-6	D. Howell 10/15/92	Added to control plan	2	1	1	2
			4	C99 short	3	PR-20 & HW-5	2	24	QA Proc 20-6	B. Howell 10/15/92	Added to control plan	2	2	1	4
			4	FL1 short/open	5	None	2	40	100% Insp.	B. Howell 10/15/92	Added to control plan	2	2	2	8
			4	FL2 short/open	5	None	2	40	100% Insp.	D. Howell 10/15/92	Added to control plan	2	2	2	8
			4	R2open/chg val	2		2	16	None						0
			4	R18 open/chg val	2		2	16	None						0

TRAINING THE FMEA TEAM

- While it is helpful for the FMEA team members to have some understanding of the FMEA process, extensive training is not necessary if team members have previous problem solving team experience
- A team leader who is well versed in the FMEA process can easily guide the team through the process as they are actually performing the FMEA
- This means that there is no need for extensive classroom training and the team can immediately be productive, while at the same time, benefit from the most powerful form of training- Experience

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

WHAT DOES IT TAKE?

- Although one person is responsible for coordinating the FMEA process, all FMEAs are team-based
- The purpose of an FMEA team is to bring a variety of perspectives and experiences to the project
- Because each FMEA is unique in dealing with different aspects of the product or process, FMEA teams are formed when needed and disbanded once the FMEA is complete

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

FMEA TEAM

- The best size for the team is usually four to six people. The minimum number of people however, will be dictated by the number of areas affected by the FMEA
- The customer of the process or product, whether internal or external to the organization, can add another perspective as well and should be considered for team membership

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard

10 STEPS FOR AN FMEA

1. Review the process/product requirements
2. Brainstorm potential failure modes
3. List potential effects of each failure mode
4. Assign a severity rating for each effect
5. Assign an occurrence rating for each FM
6. Assign detection rating for each FM and/or effects
7. Calculate the risk priority #(RPN) for each effect
8. Prioritize the FMs for action
9. Take action to eliminate or reduce the high-risk FMs
10. Calculate the Resulting RPN as the FMs are reduced or eliminated

"The Basics of FMEA" 2nd Edition, Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard