Failure Mode and Effects Analysis (FMEA)—A Primer

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1. Introduction.

The purpose of this paper is to provide an introduction to Failure Mode and Effects Analysis (FMEA), a method for reducing risk and improving the quality of products and processes. The paper is organized as follows:

1. Introduction
2. The Two Most Common FMEAs
   The design FMEA
   The process FMEA
3. Other Common *FMEAs*
   The system FMEA
   The service FMEA
4. Some Innovative Applications of the *FMEA Process*
   For assessing outsourcing risk
   For minimizing medical errors by optimizing the design of a new hospital
   For preventing medical accidents
   For aiding preventive maintenance of equipment
   As a project risk management tool
5. Summary and Conclusion

FMEA, in its essence, is a tool for reducing risk. In this case the risk can take on various meanings; for example the risk of a product or process causing

serious bodily harm (even death), the risk of losing customers when a product fails to meet their expectations, the risk of a company losing its reputation for good quality, etc.

According to Omdahl's *Reliability, Availability, and Maintainability Dictionary* (1988), FMEA is:

> A systematic method used to indentify and document potential design and process related failure modes[1)], in order to assess the overall risk of each potential failure and to identify and implement necessary corrective actions that help prevent potential failures from occurring.

According to Little (2010) FMEA was first used on Lockheed's P-80 development program. The P-80 was a jet fighter that was developed in the mid-40s and, according to Wikipedia, it was "… the first jet fighter used operationally by the United States Army Air Forces, and saw extensive combat in Korea with the United States Air Force as the F-80."

Subsequently FMEA became popular with NASA during the Apollo program and by the 1980s was adopted by the automotive "Big Three." It is now considered a valuable tool for any industry.

In general a FMEA is appropriate whenever an organization plans to develop a new product or process, or to significantly modify one. Logically it makes sense to do a FMEA as early as possible in the design phase of the new/modified product or process. This is true since the longer one waits to identify a potential failure mode in the product/process the more it will cost to remedy it should such a failure actually occur. Therefore, the FMEA would likely be conducted somewhere around the early development stage once the concept has been well established. Ideally by this time engineering drawings and even a prototype are available for the FMEA team's use in the case of a design/product FMEA. For a

1) A failure mode is simply the way in which a product component or process step could fail to perform its intended function.

process FMEA, a process flowchart should exist.

Once it is decided to carry out a FMEA, it can be broken down into three phases: assembling a team, conducting the FMEA, and follow-up actions based on the FMEA. According to McDermott et al. (2009) the "team is usually four to six people, but the minimum number of people will be dictated by the number of areas that are affected by the FMEA" (p. 11). For example a FEMA could affect engineering, manufacturing, quality, maintenance, R&D, etc. and representatives from those areas should be on the team.

There is no definite criterion for the team leader—simply the person best suited to run the FMEA. This implies that he or she should be well versed in the FMEA process. A key member of the team will be the design/product engineer for the design FMEA and the process engineer for the process FMEA. McDermott et al. caution that this person, usually having a lot invested in the product or process, may tend to inhibit efforts of the team to find fault with it. This could be especially important should this person be the leader. For this reason management may wish to appoint someone else with less personal interest in the product/process as the team leader.

An important document for clarifying the duties of the team is something McDermott et al. call a "FMEA Team Start-up Worksheet." Essentially a charter, this document states exactly what product/process the team is to conduct the FMEA on, who the team members are, what resources are available to the team (including its budget), when and to whom it reports, etc.

As for conducting the FMEA, it is a fairly standardized process that is based on completion of a form. By methodically completing the form the team will: document each potential failure mode, its effects, the estimated severity of each effect, the likely cause of the failure, any existing prevention/detection controls, and the estimated likelihood of the failure mode occurring and being detected. Figure 1 (following) is a typical design FMEA form.

As for follow-up actions, the form also provides places to: list actions recommended by the team to eliminate the failure or at least mitigate its risk, who will be responsible and a target completion date for each recommended action, the action taken, and a reassessment of the severity, prevention, and detection ratings.

2. The two most common FMEAs

A FMEA can be conducted on any organizational activity that affects the customer and this includes internal customers too. However the two most common FMEAs are the design FMEA, which analyzes the design of a product, and the process FMEA, which analyzes some process—usually a process for manufacturing something.

The design FMEA. As mentioned, to conduct a FMEA a team is assembled and a form is completed. It is important that the scope of the FMEA be well spelled out. McDermott et al. give this example for a new coffeemaker:

> [The FMEA will be] on the new RS-100 coffeemaker and the glass carafe for that coffeemaker. The FMEA will not include any parts of the coffeemaker that are common to other coffeemakers in our product line, such as the electronic clock, the electrical cord and wiring into the coffeemaker, and the gold cone coffee filter (p. 16).

To further define the scope certain questions should be asked such as who's the customer (the user), how will the product be used and possibly misused, will the FMEA include consideration of product packaging, storage, and transit, etc.

Once assembled the first step is for the team to familiarize itself with the product. Here the product/design engineer will play a key role. This will help the team decide what to place in the first column of the (Figure 1) FMEA form: "Component or Subassembly." As quoted in Little (2010, p. 13) a component is defined as "One level below the level of the part, subassembly, assembly, etc.

for which the FMEA is being performed."[2] This implies that the FMEA could be performed on something as small as a connector or as large as an automobile. For example, if the FMEA were being conducted on a connector (a part) it's components might be the connector's housing and the connector's contacts. And, if it makes more sense, the FMEA could be at the "subassembly" or higher level. At the "subassembly" level a component would likely be a "part" and at the "assembly" level, a "subassembly," etc. so strictly speaking the title for column #1 in Figure 1 should read simply "COMPONENT."

As the team decides on each component, a brief statement of its function is written in column #2 of the FMEA form. Drawing on an example in McDermott et al., if the product is a new fire extinguisher and one of the components is the hose, its function could be written as "delivers extinguishing agent." Figure 1 will be used to illustrate this example and shows these entries for columns #1 and #2.

Once all the components and their respective functions have been listed it is time for the team to put on it's collective "thinking cap" and, through brainstorming, come up with all the potential failure modes of the component—i.e., reasons it may not be able to perform its function(s).[3] These are listed in column #3 of the form. It might be helpful to give the team members time to think about potential failure modes before holding the brainstorming session and have each member bring his/her ideas to that session. Classic techniques can be used for reducing the results of the brainstorming such as combining similar ideas, nominal group technique, and multivoting.[4]

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2) This definition is from the Automotive Industry Action Group's (AIAG) *Potential Failure Mode & Effects* Analysis, 4th Edition, 2008. AIAG is a non-profit organization dedicated to improving quality in the automotive industry, primarily by publishing standards and offering training.

3) It is possible that the component could have more than one function and all should be listed.

4) With the nominal group technique ideas are ranked with those receiving the highest ↗

FAILURE MODE AND EFFECTS ANALYSIS - DESIGN **Confidential**

See last page for revision history:

PROJECT NAME			PROJECT NO.		PART NO.			ORIGINAL DFMEA DATE:			DFMEA REV.	DATE REVISED:				
RELIABILITY ENGR.			DESIGN/PROD ENGR.		APPROVED			MANUFACTURING ENGR.			TEST ENGR.					
#1 COMPONENT or SUBASSEMBLY	#2 COMPONENT FUNCTION(S)	#3 FAILURE MODE(S)	#4 EFFECTS OF FAILURE	#5 SEV S	#6 CAUSE(S) OF FAILURE	#7 PREVENTION CONTROLS	#8 OCC O	#9 DETECTION CONTROLS	#10 DET D	#11 RPN SOD	#12 RECOMMENDED ACTION(S)	#13 RESPONSIBILITY/ TARGET DATE	#14 ACTION(S) TAKEN	#15 SEV S	#16 OCC O	#17 DET D	#18 RPN SOD
Hose	Delivers extinguishing agent	Cracks	Misfire	10	Exposure to excessive heat or cold in shipping	Insulated packaging materials, temperature controlled shipping containers	5	None (however since a ranking of <10 was given for D it is assumed there were some)	6	300	Use hose that is not temperature sensitive	Kevin: 4/1	Changed hose material	10	2	6	120
					Other causes*	etc.	etc.										
			Other effects*	etc.	etc.												
		Other FMs Pinholes Blockage	etc.	etc.													
	Other Functions*	etc.	etc.														
Other components	etc.	etc.															

Revision History:

Revision	Date	Resp. Engr.	Description

*If any

Figure 1. Design FMEA example.

Continuing with the McDermott et al. example, three failure modes were listed for the fire extinguisher hose: cracks, pinholes, and blockage; our example will deal with the "cracks" failure mode only to illustrate the process.

Next the team must identify all potential effects of each failure mode; these are listed in column #4 on the form. One way to think about effects is how the failure will affect the customer. The McDermott et al. example listed "misfire" as the effect of the failure "cracks" (in the fire extinguisher hose). Again brainstorming is a good way to be sure all potential effects will be listed. McDermott et al. suggest listing even questionable effects since, as the analysis continues, a determination of that effect's likelihood of occurrence will confirm whether or not it need be included.

At this point the team is ready to begin developing what is called the Risk Priority Number (RPN), which will go in column #11 of the form. This number is simply the product of estimates of each effect's severity, likelihood of its failure mode/cause occurring, and likelihood of its failure mode/cause being detected.

The next step is for the team to judge the severity of each effect. To do this a rankin scheme should be developed such as shown in Appendix A. Appendix A, borrowed from Little (2010), is for example purposes only and, according to McDermott et. al, such a ranking system "should be customized by the organization for use with all FMEAs" (p. 31). However, regardless of the descriptors, it is common practice to use a 10 to 1 scale with 10 being assigned to effects with the most sever consequences and 1 to effects with the least sever consequences.[5)] The number arrived at by the team is placed in column #5. Note

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↘ ranking selected. With multivoting, members are asked to pick the ideas they think best (usually limited to about half of the total number of ideas) and the least preferred ideas are then dropped from the list. This continues until the number left is reasonably small.

5) Note that this ranking scheme is a bit counterintuitive since one usually associates ↗

the importance of this step in that it identifies potential failure modes that could result in death or serious injury that, in turn, could have disastrous consequences for the company. McDermott et. al's imaginary team assigned a severity value of 10 for the "misfire" effect.

Besides severity, the team must develop an estimate of the likelihood of the failure mode/cause occurring and this number will go into column #8. However to do this two other things must be done first: come up with the cause(s) of the failure (column #6) and see if there are any controls in place that might prevent the failure mode from occurring (column #7). The McDermott et. al example team determined that the cause of the "cracks" in the fire extinguisher hose—leading to the "misfire" effect—was "exposure to excessive heat or cold in shipping."

Possible prevention controls are actions already being taken to prevent or minimize the failure and are taken into account when determining the "occurrence" value. Appendix B is just one example of a ranking chart for the occurrence rating. It shows how design history and application experience can be used to help arrive at an occurrence number. It also has a column with suggested analysis techniques that might also be used. All this failing the team would simply use it best collective "engineering judgment" and a probability set as shown in the penultimate column of Appendix B.[6] The McDermott et. al example, a very simple one, listed two current prevention controls: "insulated packaging materials" and "temperature controlled shipping containers." Again the 10 to 1 ranking system is used with 10 meaning it is very likely the failure

↘ the larger numbers with some good trait so that a "high" score is better; in this case it is worse!

6) Note that in this particular example chart the penultimate column expresses "occurrence" in the "probability the design will meet objectives." Perhaps a better heading would be "probability that the failure mode will *not* occur."

mode will occur and 1 that it is very unlikely; in this case a 5 was assigned.

The next step in the FMEA process is to determine the likelihood the failure mode or cause will be detected. As with occurrence, the team must first determine what controls exist to aid in detection and thus cause the detection rating to be reduced. It could be there are no controls in place and thus the rating would be a 10 meaning the problem will not be detected before reaching the customer unless some action is taken. In our simple McDermott et. al example and for the "cracks" in the hose failure mode "None" was written in this column. Despite this a "detection" ranking of 6 (vs. 10) was assigned and will be used as we continue this example. To illustrate this step the McDermott et. al example has another failure mode for the hose, "blockage," for which two *detection controls* are cited: "incoming inspection" and "hose air passage test." In any case any existing detection controls would be listed in column #9 of the FMEA form.

After taking any detection controls into account, the team will decide on the likelihood of detection of the failure mode/cause and enter the number in column #10. Appendix C is an example from Little (2010) of a detection-ranking chart. Although a little difficult to understand, the chart attempts to show in its first column that the sooner a potential failure mode is detected in the development cycle the more likely it will receive a low ranking. The second column provides descriptors for each ranking (e.g., for a ranking of 10, "Absolute Uncertainty of Detections") and factors that might contribute to the ranking such as (for 10) "The issue can only be detected by the end user" (for some reason).

Completing the next column on the form, #11, is the easiest step in the FMEA process: determining the Risk Priority Number (RPN) for each effect. This step is only meaningful if all the prior steps have been carefully carried out. As mentioned above, the RPN is simply the product of the severity, occurrence, and detection (SOD) numbers.

Perhaps the most important thing about the RPN is that it is only to show the *relative* importance of the different failure modes. Other than that, the actual number is meaningless. And that importance is in terms of the potential risk each failure mode—based on the effects associated with it—poses to the organization. In theory each effect could generate a RPN ranging from 0 to 1000. For our simple McDermott et. al example, the RPN for the "cracks" failure mode was 300 as shown in Figure 1. In this example RPNs ranged from 810 to 80.

The next step is to rank the failure modes according to their RPNs and decide which need the most attention in terms of remedial action. Figure 2 from Little (2010) provides some general guidelines.

As indicated by the general guidance in Figure 2 the important thing is to focus on the severity of the effect when deciding which items are most important. Another important point is not to set some arbitrary cutoff for the RPNs upon which action would be taken. This could lead to the team "gaming the system" to be sure only a few items (or only those not requiring much action) are actionable by this criterion. Instead all RPNs should be arrived at as objectively as possible using sincere engineering judgment. Here the team leader can play an important role.

RPN	Action
<50	Generally no action is required. However, if severity of effect is high (>7), a review of the S, O, and D rating may be advisable to ensure their validity.
≥50, <100	Action may or may not be required. Good engineering judgment must be used to determine if action is necessary. Generally action should be taken for RPNs in this range when the severity of the effect is high (>7).
≥100	Generally action should be taken for items with RPNs in this range.

Figure 2. General guidelines for taking action based on the RPN (from Little, 2010, p. 30).

For those failure modes deemed most important in terms of risk, the team must now decide on the remedial action to eliminate or at least reduce their effect. There seems to be some difference of opinion regarding whether the severity number can be reduced. According to Little (p. 31), the "severity rating cannot be reduced" and Stamatis 2003) seems to agree saying: "The severity can be reduced only through a change in design" (p. 150). However McDermott et. al do provide some ways that severity can be reduced as shown in Figure 3. Figure 3 also suggest ways of reducing the other two RPN numbers, occurrence and detection.

The information already gained by coming up with the potential cause(s) of the failure and existing prevention and detection controls will likely suggest

Severity	*Occurrence*	*Detection*
■ Personal protective equipment (e.g., hard hats or bump caps, side shields on safety glasses, full face protection, cut-proof gloves, long gloves) ■ Safety stops/emergency shut-offs ■ Use different material, such as safety glass that will not cause as severe an injury should it fail.	■ Increasing the Cpk through design of experiments and/or equipment modifications. ■ Focus on continuous improvement/ problem-solving teams. ■ Engaging mechanism that must be activated for the product or process work (e.g., some lawn mowers have handles that must be squeezed in order for them to operate).	■ Statistical process control (to monitor the process and identify when the process is going out of control) ■ Ensure the measuring devices are accurate and regularly calibrated. ■ Institute preventive maintenance to detect problems before they occur. ■ Use coding such as colors and shapes to alert the user or worker that something is either right or wrong.

Figure 3. Possible actions to reduce rankings (from McDermott et. al, 2009, p. 39).[7)]

7) This chart also includes actions that could apply to a *process* FMEA.

appropriate action for each failure mode selected for further attention. Recommended actions are briefly written in column #12 and the person responsible/target completion date for each action in column #13. Of course each action should generate a full-fledged action plan. The actual action taken is briefly described in column #14 of the FMEA form.

The McDermott et. al team came up with the logical action of using a hose that is not temperature sensitive (see column #12 of Figure 1). Note that completion of an action may make a current control no longer necessary. In this case it would no longer be necessary to use the "insulated packaging" or "temperature controlled shipping" prevention controls.

The next step in the FMEA process is for the team to decide on new rankings for the RPN numbers based on how the actions have changed things and then recalculate the RPN. These are placed in column #15, #16, and #17. The new RPN is written in column #18.

At this point a decision has to be made as to whether the RPN now reflects an acceptable level of risk for the organization. In our simple McDermott et. al example the RPN has been reduced from 300 to 120 by the action taken to reduce the likelihood of the failure mode occurring from 5 to 2. Note that nothing could be done to reduce the severity and, apparently, the team could not come up with anything to increase the detection.

By this time the team may have enough knowledge about the product and how it will be used to make a good judgment regarding if the RPN (i.e., risk) has been reduced sufficiently and proceed accordingly (i.e., take further action to reduce the RPN or not take further action). On the other hand the team may decide to get management involved and, after presenting its findings, have management decide if the risk, as determined by the FMEA, is acceptable. If management decides the risk needs to be reduced further, the team will continue working on the FMEA.

In any event, once the FMEA is essentially complete it will be presented to management for final approval. However, it is important to realize that *a FMEA is never really complete* since work on it may be necessary should the product be significantly changed (perhaps upgraded), a customer complaint reveals a previously unforeseen weakness in the product, or for any other reason where it is found there may be a change in the effect of any potential failure mode or a new mode is discovered. As seen on the Figure 1 form, there is a place at the bottom for noting revision to the FMEA.

The process FMEA. The other most common FMEA is the process FMEA for analyzing a process, usually one for manufacturing something but it could be for any process. The FMEA form for a process FMEA is essentially the same except in this case the individual items on the form are the process steps instead of components. As quoted in Little (2010, p. 14) a step is defined as "One level below the level of the manufacturing process for which the FMEA is being performed."[8)]

As with the design FMEA, a team would be assembled of appropriate experts including of course the involved process engineer or equivalent. To help the team understand the process and each step to be analyzed a detailed flowchart of the process should be produced[9)] and studied by the team to ensure each member has a good understanding of it. Then, using essentially the same techniques as for the design FMEA, each process step is analyzed for potential failure modes; i.e., ways in which the step might fail to meet its intended purpose. Figure 4 is an example[10)] of how a step might be analyzed for potential

8) From the Automotive Industry Action Group's (AIAG) *Potential Failure Mode & Effects Analysis*, 4th Edition, 2008. See also footnote 2.

9) This would probably be something done by the process engineer before the team's first meeting. Although not for a manufacturing process, Appendix D provides an example of a flowchart.

10) Adapted from an example found at "http://www.fmeainfocentre.com" under ↗

failure modes, in this case the application of wax to the inner door of a car being produced.

Note that this example is much more involved than the simple design FMEA example from McDermott et. al shown in Figure 1. This additional complexity could also occur with a design FMEA. Of interest in this more "complete" example are the following:

- The team has found more than one potential cause for the failure and, for each cause, occurrence and detection numbers have been estimated giving each cause its own RPN number and a candidate for possible remedial action.
- There may not be any existing prevention or detection controls for a cause. In Figure 4 two of the causes show "none" under prevention controls.
- Sometimes the team will decide that it is not necessary to take any action on a cause such as is the case with the third cause in Figure 4. Recall Figure 2 provides general guidelines for when action should be taken based on the RPN. Although the severity for the third cause is 7 and borderline per Figure 2, the occurrence and detection numbers of 2 mean there is almost no chance the cause will occur and, if it does, that it will almost without a doubt be detected. Hence, the team deemed no action was necessary.
- More than one action may be recommended for a cause as shown for the first cause of Figure 4.
- When it comes to implementing a recommended action it may prove either infeasible or found to be not necessary (perhaps based on further information gained). This is illustrated by the recommended action

↘ "Examples" and then under "examplePFMEA.pdf." Accessed October 1, 2010 (may have changed).

FAILURE MODE AND EFFECTS ANALYSIS - PROCESS

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See last page for revision history:

PROJECT NAME	PROJECT NO.	PART NO.	ORIGINAL PFMEA DATE:	PFMEA REV.	DATE REVISED:
RELIABILITY ENGR.	DESIGN/PROCESS ENGR.	APPROVED	MANUFACTURING ENGR.	TEST ENGR.	

#1 PROCESS STEP	#2 PROCESS STEP FUNCTION(S)	#3 FAILURE MODE(S)	#4 EFFECTS OF FAILURE	#5 SEV S	#6 CAUSE(S) OF FAILURE	#7 PREVENTION CONTROLS	#8 OCC O	#9 DETECTION CONTROLS	#10 DET D	#11 RPN SOD	#12 RECOMMENDED ACTION(S)	#13 RESPONSIBILITY /TARGET DATE	#14 ACTION(S) TAKEN	#15 S	#16 O	#17 D	#18 RPN
Application of wax on inside of car door	To cover inner door, lower surfaces at minimum wax thinkness to retard corrosion	Insufficient wax coverage over specified surface	Deteriorated life of door leading to: – Unsatisfactory appearance due to rust through paint over time – Impaired function of interior door hardware	7	Manually inserted spray head not inserted far enough	None	8	Visual check each hour - 1/shift for film thickness (depth meter) and coverage	5	280	Add positive depth stop to sprayer	Mfg Engng (K. Jones)/ 1Nov2010	Stop added, sprayer checked online	7	2	5	70
											Automate spraying	Mfg Engng (K. Jones)/ 1Nov2010	Rejected due to complexity of different doors on same line				
					Spray head clogged – Viscosity too high – Temperature too low – Pressure too low	Test spray pattern at start-up and after idle periods, and preventive maintenance program to clean heads	5	ditto	3	105	Use Design of Experiments (DOE) on viscosity vs. temperature vs. pressure	Mfg Engng (K. Jones)/ 1Nov2010	Temp and press limits were determined and limit controls have been installed - control charts show process is in control Cpk = 1.85	7	1	5	35
					Spray head deformed due to impact	Preventive maintenace program to maintain heads	2	ditto	2	28	None	N/A	N/A	7	2	2	28
					Spray time insufficient	None	8	Operator instructions and lot sampling (10 doors/shift) to check for coverage of critical areas	7	392	Install spray timer	Mfg Engng (K. Jones)/ 1Nov2010	Automartic spray timer installed - operator starts spray, timer controls shut-off - control charts show process is in control Cpk = 2.05	7	1	7	49
Other process steps	etc.																

Revision History:

Revision	Date	Responsible Engineer	Description

Figure 4. Process FMEA example.

"Automate spraying" for the first cause in Figure 4, which was "rejected due to complexity of different doors on the same line."

- One measure that could be important for a process is that of its "capability," C_{pk}. C_{pk} is a measure of how well the process is centered with respect to the upper and lower specification limits. Generally a value of about 2.0 is considered adequate. Figure 4 illustrates the use of this measure in column #14, Action(s) Taken, for two of the four causes.
- Finally, Figure 4 shows how actions can dramatically reduce the RPN and, hence, the risk of the failure; for example, the fourth cause's RPN was reduced from 392 to 49 by installing a spray timer making the occurrence almost nil.

As with the design FMEA, an organization will have appropriate ranking criteria for each element of the RPN—S, O, and D—to assess the risk of a potential process failure. Borrowing from Little (2010) again, Appendix E shows example ranking criteria for these RPN elements for a *process* FMEA. Note again that such criteria should be appropriate to the organization and whatever serves it best for qualifying risk; Appendix E is meant only for example purposes.

2. Other common FMEAs

The system FMEA. Although not as definitive as the design and process FMEAs there is something called a system FMEA. Per Stamatis (2003):

> A system FMEA (sometimes called a concept FMEA) usually is accomplished through a series of steps to include conceptual design, detail design and development, and test and evaluation (p. 107).

Although not that clear, from this one can infer that a system FMEA would be used in the early stages of the development of new product when the product is still in the "conceptual" phase. It allows the testing, so to speak, of different

concepts for satisfying the customer's needs. These concepts would be stated in terms of functions of a system. For example, if one were thinking of making a new coffeemaker, one function expressed in conceptual terms might be "is easy to use" and another "is economical" and so forth. As the design begins to take shape it would be tested against these concepts. Therefore, the form for a system FMEA would start with a list of system functions and then each function would be brainstormed for possible ways in which it might fail to meet that conceptual requirement. Each system function would also be a criterion against which the detailed design would be evaluated. In other words, the system FMEA can be considered looking at failure modes at one level above the design FMEA level.

The service FMEA. The use of the FMEA methodology would seem a natural for assessing a service function. A service FMEA is essentially the same as a process FMEA except the process is one of providing some sort of service. Figure 5 shows a very simple example of how the first part of a service FMEA form might look for the service step of "Providing cash via ATM." Just as with any FMEA, a service-oriented team would be established and look at each significant step in some service process and brainstorm any possible failure modes for that step. (As with a process FMEA, a flowchart of the service should be used so each significant step in the service process is identified.) Then the other usual columns on the FMEA form would be completed including any recommended actions to mitigate the risk by either eliminating the failure mode or minimizing its effects.

Conducting a service FMEA would certainly make sense for any "service" that involves life-threatening consequences should it not be correctly performed such as servicing the brakes on a car or providing appropriate medication to a hospital patient (see example of the latter in the next section). However, it also would make sense any time an organization wishes to improve customer satisfaction. In this case the organization would be looking at ways a customer

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PROJECT NAME			PROJECT NO.		PART NO.		
RELIABILITY ENGR.			DESIGN/PRODUCT ENGR.		APPROVED		
#1 SERVICE STEP	#2 SERVICE STEP FUNCTION(S)	#3 FAILURE MODE(S)	#4 EFFECTS OF FAILURE	#5 S	#6 CAUSE(S) OF FAILURE	#7 CURRENT CONTROLS	#8 O
Providing cash via ATM	Dispense amount of cash requested by customer	Does not dispense cash	– Customer very dissatisfied – Incorrect entry to demand deposit system – Discrepancy in cash balancing	8	Out of cash	Internal low-cash alert	5
					Machine jams	Internal jam alert	3
					Power failure during transacton	None	2
		Dispenses too much cash	– Bank loses money – Discrepancy in cash balancing	7 6	Bills stuck together	Loading procedure (riffle ends of stacks)	2
					Denominations in wrong trays	Two-person visual verification	3
		Takes too long to dispense cash	Customer somewhat annoyed	3	Heavy computer network traffic	None	7
					Power failure during transacton	None	2
Other steps	etc.	etc.					

Revision History:			
Revision	Date	Responsible Engineer	Description

Figure 5. Service FMEA example (Adapted from an example found on the American Society for Quality [ASQ] Web site at http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html. ASQ notes that this example is "Excerpted from Nancy R. Tague's *The Quality Toolbox*, Second Edition, ASQ Quality Press, 2004, pages 236–240.")

might be annoyed by how he or she was treated in an encounter with an employee or even a machine (such as the third failure mode in the Figure 5 example).

3. Some Innovative Applications of the FMEA proces

The idea of using the FMEA approach for assessing risk has found considerable general application, as the following examples will show.

For assessing outsourcing risk. Welborn (2007) leads us through an example from RadioShack that involved outsourcing the procurement of store fixtures such as shelving. The specific situation was a decision by RadioShack to switch to metal based fixtures versus the wood based fixtures it had been buying. It was determined that significant cost savings might be realized if Asian vendors were allowed to participate in the proposal process. As a result it was "decided to award the business to an Asian manufacturer." However, "there was a concern about the risk of entering into a long-term relationship with a relatively unknown vendor not based in the United States" (p. 20). Accordingly it was decided to conduct a FMEA to assess the risk involved taking this decision and what might be done should the risk in any particular area be considered too great.

Figure 6 shows the major risk categories the FMEA team came up with: cost, lead time, and quality. Then each major category was broken down into more specific risk areas—also shown on Figure 6—such as under cost: unforeseen

Risk	Opportunity	Probability	Severity	Risk priority number
Cost				
Unforeseen vendor selection cost	2	4	2	16
Unforeseen transition cost	2	4	2	16
Unforeseen management cost	4	4	3	48
Lead Time				
Delay in production start-up	2	4	4	32
Delay in manufacturing process	5	3	2	30
Delay in transportation of goods	4	2	2	16
Quality				
Minor cosmetic/finishing defect	5	4	1	20
Major cosmetic/finishing defect	5	2	2	20
Component will not fit with mating parts—requiring rework	5	2	4	40
Structural defect—function failure	5	1	5	25

Figure 6. Risk categories and evaluation criteria for outsourcing risk assessment (from Welborn, 2007, page 18).

vendor selection cost.

As shown on Figure 6, each specific risk area was then evaluated by consensus against three criteria: opportunity, probability, and severity using a 1–5 scoring scale. Opportunity is the frequency with which the event is expected to occur from a one-time event (scored 1) to something that is a common occurrence (scored 5). Probability is the likelihood of the event actually happening, again scored on a 1–5 basis. The combination of opportunity and probability would seem to equate to the "occurrence" factor in the traditional FMEA. There is no "detection" criterion, apparently due the team's belief that all the risk events would be obvious. Finally the degree of risk to operations is covered by the severity criterion—ranging from a score of 1 for a minimal impact on operations should the risk occur, to a score of 5 should the impact be deemed very significant.

As with the traditional FMEA, these three numbers are then multiplied to provide an RPN for each specific risk area and those judged the most serious addressed. For example it became obvious the most serious risk would probably be in "unforeseen management costs" because of the team's belief that this risk area would not only occur frequently (opportunity score of 4) but would have a high likelihood of actually happening (probability score of 4). Also its impact on operations would be fairly significant (severity score of 3). The team's rational for this relatively high RPN was its concern "about the communication barrier and its ability to efficiently convey business transactions" (p. 20). To offset this concern a small team was established to work with the vendor "to manage business transactions such as communication of orders, schedules, payments, returns and repairs" (p. 21). Similar steps were taken with any of the other areas for which the risk was deemed too high.

From this case study it can be seen how one need not stick to any rigid set of criterion but rather adapt them to the situation at hand. Also the FMEA "form"

can be whatever best serves the team's purpose for the task at hand. The idea is to come up with factors to be evaluated that best help evaluate the risk to the organization and will reveal where improvement actions will give the biggest risk-reduction payoff.

For minimizing medical errors by optimizing the design of a new hospital. An article by Reiling et. al (2003) shows how FMEA can be applied to optimizing the design of a new hospital facility based on an overarching requirement to minimize the possibility of medical errors—in other words: what can we do in designing our new hospital that will to enhance patient safety?

FMEA was used during the various stages of facility design from the layout of the hospital as a whole to the layout of individual rooms. For example in using the FMEA process to evaluate different ways the hospital could be laid out as a whole it was determined patient safety would be enhanced by separating the movement of materials such as food, pharmaceuticals, linen, and waste, from where the patients were. This was achieved by making the ground level of the hospital a nonpatient area for such service traffic.

FMEA was also used to identify potential "failures" that might be overcome related to how patients were transported between different departments. For example for the transfer of certain critical patients skilled personnel might be required causing short-staffing of important services—e.g., intensive care—at that time. Another failure might be unnecessarily long distances for the movement of "vulnerable, critically ill patients." "The proposed design plan evolved to minimize the occurrence and severity of [such] failures identified using FMEA" (p. 70).

Regarding individual room layout, "numerous FMEAs were conducted on alternative designs." These were based, again, on patient safety and how to interface "a vulnerable patient with staff to minimize errors and maximize [a number of] facility design principles [such as] visibility of patients to staff;

immediate accessibility of information, close to the point of service; and patient involvement with care" (p. 70). As a result, the FMEA teams came up with several innovative room design features: e.g., "true standardization in room size and layout; in-room sink, allowing physician and staff hand washing in patient view; and charting alcove with window, increasing patient visibility for nurses, physicians and staff" (from a list on p. 70).

Finally the FMEA process was applied to the "patient room and its components…" with a typical item being the call button and what the effect would be should this button fail. Another example in this area raised by the application of FMEA was "Are all the fixed equipment outlets and switches in the right location if a vulnerable patient is in the room?" (p. 71).

It is interesting to note, as in the outsourcing case above, the FMEA form was tailored to meet the needs of this application—in this case it was greatly simplified. Figure 7 shows a sample form. In fact even the traditional numerical rating system was abandoned in favor of a "low, medium, or high" system. Apparently this was still considered sufficient to "indentify potential failures of design and their relative priority" (p. 69).

For preventing medical accidents. In another healthcare application Reiley (2002) proposes using FMEA to reduce operational medical errors. To illustrate

Potential failures/ effects mode(s) (day/night)	Severity/occurrence High-medium-low	Adjacency changes to minimize or eliminate potential failure/effect	Recommend adjacency change

Figure 7. Sample FMEA form used in the design of a new hospital facility (from Reiling et. al, 2003, page 68).

his proposal he describes a fictitious FMEA team given the task of reducing medication errors in a hospital. Having flowcharted the process of medicating patients the team develops data on all the various reasons for the medication errors such as "order overlooked/forgotten," "drug labeling error," "staff education error," etc.

Then, following the FMEA process, each of these reasons is considered as a failure mode and possible effects are assigned. In this case, Reiley's fictitious team comes up with this set of effects for the failure mode "order overlooked/forgotten"[11]:

- Non-critical (NC) illness does not improve
- Non-critical (NC) illness worsens
- Non-critical (NC) illness becomes critical
- Critical illness becomes fatal

Each effect is then assigned a "criticality score," that is, an RPN based on the fictitious team's judgment of its severity, occurrence, and chance of detection. Figure 8 casts this case in a traditional process FMEA format and shows how the criticality score (RPN) for each effect was calculated. A more complete treatment of this failure mode would take into consideration current prevention and detection controls. Of course once the criticality score for each effect is determined a judgment would be made as to what action(s), if any, should be recommended to mitigate the associated risk. Obviously the most attention would be given to the third and fourth effects: "non-critical illness becomes critical" and "critical illness becomes fatal." Accordingly, Reiley's imaginary FMEA team "recommended that orders and drug dosing for all patients with worsening or critical status at any time during an admission be reviewed on each shift by a hospital pharmacist."

11) This set of effects could apply to all the medication failure modes.

PROCESS STEP	PROCESS STEP FUNCTION(S)	FAILURE MODE(S)	EFFECTS OF FAILURE	SEV S	OCC O	DET D	CRITICALITY SCORE (RPN)
Medicate patient	Provide correct dosage at correct time	Order overlooked/ forgotten	NC illness does not improve	3	9	7	189
			NC illness worsens	6	9	5	270
			NC illness becomes critical	9	9	4	324
			Critical illness becomes fatal	10	9	10	900
Other process steps	Other process step functions	Other failure modes	Other effects	etc.	etc.	etc.	etc.

Figure 8. Example of an entry on a FMEA form for a FMEA to help prevent medical accidents (based on data from Reiley, 2002).

For aiding preventive maintenance of equipment. Cotnareanu (1999) recommends applying the FMEA process to aid the preventive maintenance of equipment. To do this the traditional process FMEA form is modified to create an "equipment" FMEA form. Figure 9, excerpted from Cotnareanu's article, shows how the form might be completed for two "equipments" that are parts of a "transfer unit machine." The first column lists each major part (equipment) and its function of the machine for which the FMEA is being performed. Then, as with the traditional FMEA, the remaining columns on the form are completed by the team coming up with potential failure modes, potential effects of the failure, the severity of the effects, etc. until an RPN is determined for each machine part/equipment. As usual, the RPN will serve as the basis on whether or not action needs to be taken—in this case to eliminate or minimize the risk due to the failure causing downtime of the machine. Note that instead of having separate columns for prevention and detection controls as shown on the traditional design or process FMEA form (Figures 1 and 4) all current controls are lumped into one column. Per Cotnareanu this is where the team would:

Line Description: Semi-Automated Assembly Line

Machine Description: Transfer Unit

FMEA Number: 63-5807

Potential Equipment Failure Mode Effects Analysis Process FMEA

Prepared by: QM (Quality Manager)

FMEA Date (Org.) 12-Nov. 1997 (Rev.) A

Page 1 of 1

Core Team: MM (Maintenance Manager), MB (Maintenance Buyer), LHM (Lead Hand Mechanic), PS (Production Supervisor), LO (Line Operator), QM

Equipment (Process Function)	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence	Current Controls (Predictive Methods)	Detection	R.P.N.	Recommended Action(s)	Person responsible/Target Completion Date	Action Results: Actions Taken	Severity	Occurrence	Detection	R.P.N.*
Transfer unit - main drive Drives the printer mechanism.	• Chain breaks. P/N X 03-31-34	• Transfer unit down. • Post-repair set-up problems.	5	• Misses limit switch. • Broken limit switch. • Stretching due to normal wear.	8	• None	10	400	• Replace limit switches with heavy duty type. • Install tension detector. • Install cycle counter. • Monitor cycles. • Evaluate changes to improve accessibility. • Spares: chain and blocks mounting to chain. • Write repair procedure: describe tasks, change sprockets with chain, periodic lube and preventive replacement.	MM MM MM PS and MM MM and MB MB MM, QM and PS					
Transfer unit-lift Lifts the fixture support.	• Chain breaks. • Chain stretches. P/N X 03-31-09 X 03-31-10 2 each	• Unit down.	2	• Wear. •Misalignment. • Lube.	1	• None	8	16	• Monitor cycles. • Write and train repair procedure.	PS and MM MM, MB and QM					

Figure 9. Example of an equipment/preventive maintenance FMEA (from Cotnareanu, 1999, page 50.) See slightly larger version at Appendix F.

> "…list actions taken to shorten the duration of a breakdown (replacement parts inventory, for example), prevent the occurrence of an equipment breakdown (reducing frequency) and acquire early warning signals (detection) (p. 52).

In this example it is obvious the first part/equipment on the form, the main drive of the transfer unit, merits a lot of action since it's RPN is quite high (400). Note that even though the severity of the item is not that high (5), its occurrence and detection ratings are, and these are the areas on which corrective action would focus.

Note also that this version of the FMEA is Revision (Rev.) A which serves to emphasize an important point Cotnareanu makes that the FMEA form is a living document and should be continuously reviewed for ways to make it better in terms of reducing risk through continuous improvements.

As a project risk management tool. Carbone & Tippett (2004) have come up with an innovative way to use the FMEA process for the management of risk associated with a project. It can be used for any project or program and in conjunction with a regular FMEA should that be part of the project. This FMEA is called a project risk FMEA abbreviated RFMEA.

Figure 10 shows how the regular FMEA format is modified for project risk management purposes. Now, instead of looking at failure modes for an individual component (the DFMEA) or process step (the PFMEA), "risk events" are identified by brainstorming by the project team. Risk events are expressed in

Typical FMEA Columns	Failure ID	Failure Mode	Occurrence	Severity		Detection	RPN
Typical RFMEA Columns	Risk ID	Risk Event	Likelihood	Impact	Risk Score	Detection	RPN

Figure 10. How the basic FMEA format is modified for a project risk FMEA (RFMEA) (from Carbone & Tippett, 2004, p. 30, Exhibit 1).

an "if such and such occurs, then this will happen or be necessary" format. Although essentially the same thing, occurrence and severity have been relabeled likelihood and impact to be more consistent with project management terminology. Using the 10 to 1 ranking scale, the likelihood of the risk event occurring can range from very likely to very unlikely. Similarly, values for the impact of the risk event can range from 10 to 1 based on schedule, cost, and technical[12] factors. As seen in Figure 10 another dimension has been added to the analysis, a "risk score." The risk score is the product of the likelihood and the impact values.

Detection is "the ability to detect the risk event with enough time to plan for a contingency and act upon the risk." Values range from 1 or 2 if the "detection method is highly effective…" to 9 or 10 if "there is no detection method available or known that will provide an alert with enough time to plan for a contingency" (p. 31, Exhibit 4).

Finally the RPN is calculated in the usual way by multiplying likelihood, impact, and detection.

Once the team of experts has come up with all the potential risk events and a risk score and RPN for each event, the next step is to display these values in Pareto diagrams and determine risk score and RPN "critical values."[13] To make this clear the authors provide case study example where the team has indentified 45 risk events. For illustrative purposes Figure 11 shows the Pareto diagrams for 14 of the 45 events. Each risk event is identified with a letter.

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12) A "technical" factor is something that causes the scope of the project to change. Such a change could range from one that is "not noticeable" (value 1) to one that "renders end item unusable" (value 10).

13) A critical value is subjectively determined by the team based on the Pareto displays that show the risk scores/RPNs in descending order (Figure 11). It is the team's best judgment as to which risk events should be dealt with first relative to all the risk events.

From examination of these two diagrams, critical values of 20 and 125 were chosen for the risk score and RPN respectively.

The next step is to display the events on a scatter plot on which the critical values have been used to divide the plot into four quadrants. This is shown in Figure 12 for the 14 sample events. As emphasized by the authors, the

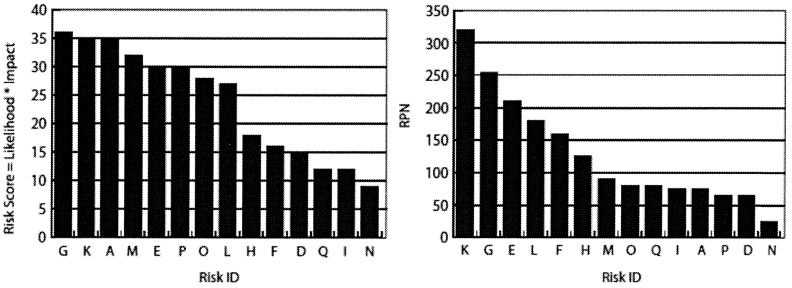

Figure 11. Examples of Pareto diagrams for risk score and RPN values. (from Carbone & Tippett, 2004, p. 33, Exhibits 8 & 9).

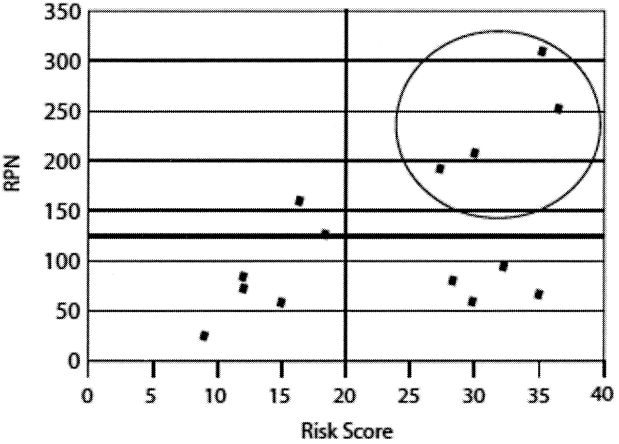

Figure 12. Example of scatter plot of RPNs vs. risk scores showing critical values of 125 for the RPNs and 20 for the risk scores. (from Carbone & Tippett, 2004, p. 34, Exhibit 10).

important thing to note is that a high *risk score* does not necessarily mean a high *RPN*. Note that of the eight events that fall above the critical value of the risk score only four are above the critical value of the RPN. Furthermore, since the factor that separates the risk score from the RPN is the detection value this sort of display makes it apparent which risks are more affected by having a better means for early detection: namely those in the upper right hand quadrant. The great benefit of this is the team can now spend its time on contingency response plans for these events (in the upper right hand quadrant) versus doing that for all eight of the events above the risk score critical value. Also it is these events that will most benefit from enhancing their "detectability."

Figure 13 will give the reader a better idea of how this RFMEA process works. G is one of the 45 risk events identified by the team in the example case study. Figure 13 shows the initially assigned likelihood, impact, and detection values and the resultant risk score and RPN. Since this event fell in the upper right hand quadrant of the scatter plot it became a prime candidate for development of a contingency response plan. By using generic test hardware the

Risk ID	Risk Event	Initial					Contingency Response Plan	Revised				
		L	I	RS	D	RPN		L	I	RS	D	RPN
G	If hardware is not valid then need to redesign and reorder with delay of 12 weeks and cost of over $100k.	4	9	36	7	252	Build generic test hardware that could be more easily modified than custom hardware.	2	3	6	3	18
etc.	etc.											
etc.	etc.											

Legend: L=Likelihood, I=Impact, RS=Risk Score, D=Detection

Figure 13. Example of how a risk event might be evaluated both before and after a contingency response plan was made. (adapted from Carbone & Tippett, 2004, from p. 33, Exhibit 7 and from information in the text of the article).

"…impact was reduced to less than a week of re-work." Furthermore by coming up with "…a novel way of using generic boards to be able to prove out the hardware earlier the detection value was reduced to three" (p. 34). As can be seen from Figure 13 these contingency actions reduced the risk of this event to acceptable values of 6 for the risk score and 18 for the RPN.

The advantage of using a technique like RFMEA for quantifying project risk is it helps to isolate those events which are most serious due to the inability to detect them early enough to take timely action. That action might be to efficiently mitigate the risk or even take advantage of any opportunities early detection might reveal. This separation of the wheat from the chaff so to speak also helps concentrate the teams scarce resources on those risk most likely to cause problems.

4. Summary and Conclusion

The purpose of the paper has been to provide a primer on FMEA by: describing the two most common versions—the design FMEA and the process FMEA, briefly discussing two other common FMEAs—the system FMEA and the service FMEA, and providing five examples of the innovative use of the FMEA process for other purposes. The latter shows that with a little imagination the FMEA concept can find very wide application as a risk management/reduction tool.

In conclusion, it is recommended that anyone involved in risk management consider the use of the FMEA as a possible way to systematically approach the problem. Here are some suggested additional sources for information on FMEA:

- The FMEA Info Centre ("Everything you want to know about Failure Mode and Effect Analysis") at http://www.fmeainfocentre.com.
- FMEA and FMECA Information ("If you want to find out more about Failure Mode and Effects Analysis (FMEA) or Failure Mode, Effects,

and Criticality Analysis (FMECA), then you have come to the right place.") at http://www.fmea-fmeca.com.

- The American Society of Quality (ASQ) at asq.org (search site using "FMEA").
- The SAE[14] standard *Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly processes (Process FMEA)* at http://standards.sae.org/j1739_200901.
- The Automotive Industry Action Group (AIAG)[15] publication *Potential Failure Mode & Effects Analysis,* 4th Edition, 2008. Per AIAG this "is a reference manual to be used by suppliers to Chrysler LLC, Ford Motor Company, and General Motors Corporation as a guide to assist them in the development of both Design and Process FMEAs." Go to www.aiag.org and "Bookstore" under the "Products" dropdown menu. Then do a Product Search using "FMEA" and scroll down that page to this document.

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Cotnareanu, T. (1999, December). Old Tools—New Uses: Equipment FMEA, *Quality Progress*, pp. 48–52.

Little, D. M. (2010). F*ailure Modes and Effects Analysis*. Three-ring binder text for his pre-conference tutorial at the 22nd Annual Quality Management Conference, New

14) SAE International (SAE), formerly the Society of Automotive Engineers, is a professional organization for mobility engineering professionals in the aerospace, automotive, and commercial vehicle industries.

15) AIAG is a non-profit organization dedicated to improving quality in the automotive industry, primarily by publishing standards and offering training. See also footnotes 2 and 8.

Orleans, LA, March 4–6, 2010. (The tutorial was March 1 & 2.)

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Note: I found the Samatis book—although apparently thought of as a comprehensive FMEA reference—ill organized, full of redundancies, and very difficult to follow. Accordingly I cannot in good conscience recommend it as a good reference.

Appendix A

Example of a Ranking Scheme for Severity for a Design FMEA

(from Little, 2010, Figure 1)

Note: This example is only to show how such a scheme might look; an actual scheme should be tailored to the needs of the organization and the FMEA being conducted.

Primary Failure Effect	Degree of Effect	Ranking
Hazardous to people or equipment	Hazardous without warning: • Failure mode affects safe system/item operation. • No indication of problem prior to failure; "occurs without warning". • Involves noncompliance with government regulation. • Causes damage to customer's product or manufacturing equipment.	10
	Hazardous with warning: • Failure mode affects safe system/item operation. • Indications of problem are evident prior to failure; "occurs with warning". • Involves noncompliance with government regulation. • Causes damage to customer's product or manufacturing equipment.	9
Complete loss of primary function	Very High: • Product inoperable; immediate loss of primary function. • Customer cannot install product.	8
	High: • Product becomes inoperable; loss of primary function occurs during expected product lifetime. • Major effect on system performance.	7
Reduced performance of primary function or complete loss of secondary function(s)	Moderate: • Product immediately operates at a reduced level of performance. • Customer has difficulty installing product or poor ergonomics. • Noticeable effect on system performance. • All customers are dissatisfied. • Design for manufacturability issue.	6
	Low: • Product operates at a reduced level of performance during expected product lifetime. • Noticeable effect on system performance. • All customers experience some dissatisfaction.	5
Reduced secondary function performance or non-performance related issue	Very Low: • Workmanship, fit, or visual item does not conform where customer(s) will return the product for replacement or rework.	4
	Minor: • Workmanship, fit, or visual item does not conform where customer(s) will accept the product but require corrective action to prevent the issue in the future.	3
	Very Minor: • Workmanship, fit, or visual item does not conform where customer(s) will accept the product although feeling dissatisfied.	2
	Not a Concern: • Product performance is unaffected. • Effect may not be noticeable or is not typically a concern. • Customer is satisfied.	1

Figure 1. Suggested DFMEA Severity Evaluation Criteria.

Appendix B

Example of a Ranking Scheme for Occurrence for a Design FMEA

(from Little, 2010, Figure 2)

Note: This example is only to show how such a scheme might look; an actual scheme should be tailored to the needs of the organization and the FMEA being conducted.

Likelihood of Prevention Before Product is Released for Production – Choose a column below that applies to the text written for Prevention. If the Prevention is not represented below, then use engineering judgment to determine a probability from the column to the right.			Probability the Design Will Meet Objectives	Ranking *
Design History	Application	Analysis		
New, unproven designs. No similar designs exist for comparison.	Have no previous experience producing products for this application.	Design/tolerance analysis was not completed.	Very Remote: ≤10%	10
• Most or all similar designs have required redesign or process controls to compensate for this failure cause/mode. • Designs with limited history. • Product is copied from an existing product or from a design specification, but used in an entirely different application.	• Little familiarity with this application. • Few or no products have been previously produced for this type of application. • Not familiar with the customers this product is targeted for or not working directly with any of the customers up front.	Monte Carlo analysis completed, but assumptions are too optimistic.	Remote: 10% < p <= 20%	9
		No tolerance or design analysis completed, the analysis is unusually complex, or it is known to be only an approximation.	Very Low: 20% < p <= 30%	8
		Monte Carlo analysis completed, but assumptions will be challenging to support in production.	Low: 30% < p <= 40%	7
• Some of similar designs have required redesign or process controls to compensate for this failure cause/mode. • Product is copied from an existing product or from a design specification, but with significant changes: substantially different amount of force, number of contacts, or size of product, etc.	• Somewhat familiar with this application. • Some products have been previously produced for this type of application. • Familiar with some of the customers this product is targeted.	Simplified tolerance analysis was completed. Not all factors, such as rotation, were taken into account.	Moderately Low: 40% < p <= 50%	6
		Monte Carlo analysis indicates a low amount of unacceptable product will be produced.	Moderate: 50% < p <= 60%	5
		Root mean squared or a moderately complex worst case tolerance analysis was completed.	Moderately High: 60% < p <= 70%	4
• No similar designs have required redesign or process controls to compensate for this failure cause/mode. • Product is copied from an existing product or from a design specification, but with no significant geometric of changes: substantially the same amount of force, number of contacts, or size of product, etc.	• High degree of familiarity with this application. •Many products have been previously produced for this type of application. • Very familiar with this customer or customer base.	Monte Carlo analysis indicates essentially no unacceptable product will be produced.	High: 70% < p <= 80%	3
		Worst case tolerance analysis was completed, is uncomplicated, and uses more than four dimensions.	Very High: 80% < p <= 90%	2
		Worst case tolerance analysis was completed, is uncomplicated, and uses four or fewer dimensions.	Almost Certain: ≥90%	1

Figure 2. Suggested DFMEA Occurrence Evaluation Criteria.

Appendix C

Example of a Ranking Scheme for Detection for a Design FMEA

(from Little, 2010, Figure 3)

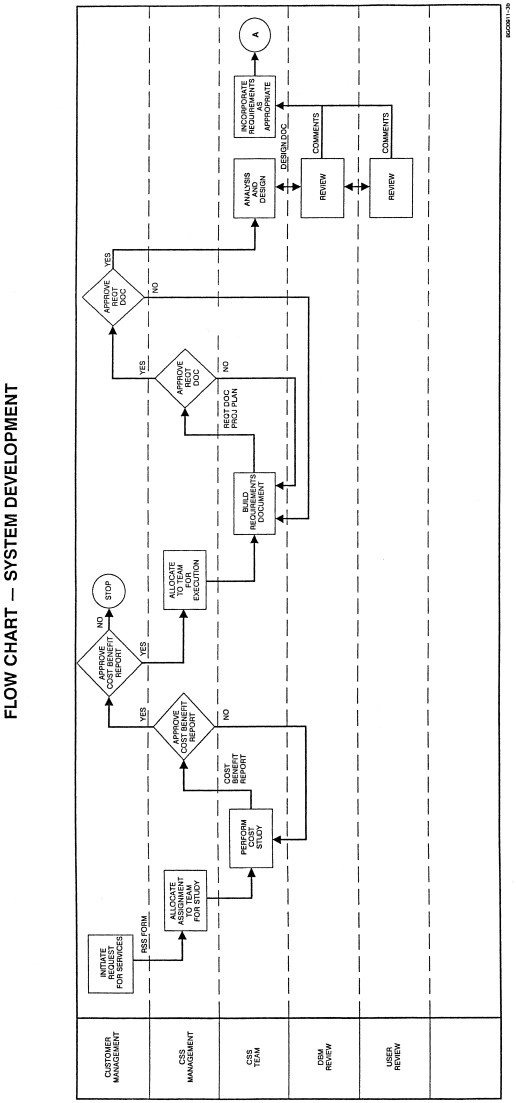
Note: This example is only to show how such a scheme might look; an actual scheme should be tailored to the needs of the organization and the FMEA being conducted.

Suggested Timing of Detection	Likelihood the control listed in the Detection column can effectively identify the issue before product is released for production	Ranking
After the start of qualification testing, production tooling, or capacity ramp-up	Absolute Uncertainty of Detection: • The potential cause or subsequent failure mode cannot be detected. • The issue can only be detected by the end user.	10
	Very Remote Chance of Detection: • Issue could occur with increased variation from new or additional tooling. • Cannot be detected internally, but could be detected by the immediate external customer.	9
During product development, pre-production manufacturing, and design verification testing	Remote Chance of Detection: • Test conditions cannot accurately replicate the actual use conditions or the customer's test requirements. • Could be detected internally by evaluating the product, but the suggested test is not planned at this time.	8
	Very Low Chance of Detection: • A test is required that demands the product is evaluated in a non-standard way or the test is not customary.	7
	Low Chance of Detection: • Customer will thoroughly evaluate either through test or actual application of the product. • An issue where various customers will react differently. • All customers' requirements may not be known. • The test might be completed although it is not specifically required by any customer or specification.	6
	Moderate Chance of Detection: • Customer will evaluate prototypes and the issue can be easily detected by one or a few customers. • Customer-specific product, but all the customer's requirements are not clear. • Evaluation of a low amount of pre-production parts is planned. • Internal evaluation of product: There is only moderate confidence that the planned test will identify the failure when it does exist.	5
	Moderately High Chance of Detection: • The issue is well-known and it is probable the engineering team will look for it or recognize it.	4
	High Chance of Detection: • Internal evaluation of product: a specific, known and customary test is planned. • Designed Experiment is planned.	3
During Concept stage or very early prototyping	Very High Chance of Detection: • Form, fit, or function item that will be detected on a few initial samples.	2
	Almost Certain Chance of Detection: • Form or fit failure that will be easily observed on first prototypes.	1

Figure 3. Suggested DFMEA Detection Evaluation Criteria.

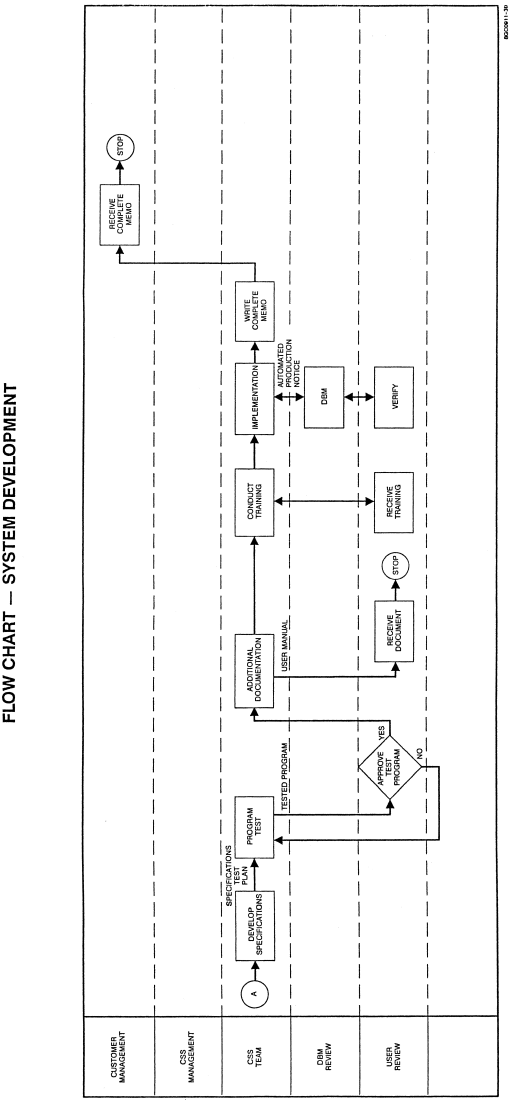
Appendix D (page 1 of 2)

Example of a Flowchart



Appendix D (page 2 of 2)

Example of a Flowchart



Appendix E (page 1 of 3)

Examples of a Ranking Schemes for a Process FMEA (PFMEA)

(from Little, 2010, Figures 4, 5 & 6)

Note: These examples are only to show how such schemes might look; actual schemes should be tailored to the needs of the organization and the FMEA being conducted.

This ranking reflects a potential failure mode that could have either a final customer or a manufacturing effect. The final customer should always be considered first. If both occur, use the more applicable of the two severities.		
Customer Effect	**Effect on Subsequent Manufacturing Operations (Internal/External)**	**Ranking**
• Unsafe system operation • Government regulation noncompliance • Damage to customer product or equipment • Hazardous failure without warning	• Endangers operator without warning • Damage to machine or tooling that requires replacement	10
• Unsafe system operation • Government regulation noncompliance • Damage to customer product or equipment • Hazardous failure with warning	• Endangers operator with warning • Damage to machine or tooling that is repairable	9
• Product inoperable; immediate loss of primary function • Customer cannot install product.	• Time consuming sort • Very expensive scrap of product • Major rework off-line	8
• Product primary function becomes inoperable during expected product lifetime • Major effect on system performance	• Time consuming sort • Costly scrap of product • Moderate rework off-line • Ability to evaluate product is compromised	7
• Product immediately operates at a reduced level of performance • Reduced performance of primary or complete loss of secondary function • Noticeable effect on system performance • All customers are dissatisfied	• Time consuming sort • Inexpensive scrap of product • Minor rework off-line	6
• Product operates at a reduced level of performance during expected product lifetime • Reduced performance of primary or complete loss of secondary function • Noticeable effect on system performance • All customers experience some dissatisfaction	• Simple sort • Very low-priced scrap of product • Major rework online, but out-of-station	5
• Workmanship, fit or visual item does not conform where customer(s) will return the product for replacement or rework	• Simple sort • No scrap • Minor rework online, but out-of-station • Process requires frequent adjustments	4
• Workmanship, fit or visual item does not conform where customer(s) will accept the product but require corrective action to prevent the issue in the future	• Simple sort • No scrap • Major rework in-station • Process runs, but only at a reduced rate	3
• Workmanship, fit or visual item does not conform where customer(s) will accept the product although feeling dissatisfied	• No sort or scrap • Minor rework in-station	2
• Performance is not affected • Effect is not noticed or is not a concern • Customer is satisfied	• No sort, rework or scrap • Minor inconvenience to operation or operator	1

Figure 4. Suggested PFMEA Severity Evaluation Criteria.

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Examples of a Ranking Schemes for a Process FMEA (PFMEA)

(from Little, 2010, Figures 4, 5 & 6)

Probability of Failure Mode and/or Effect(s)	Low Volume/Manual Production		High Volume/Automated Production		Ranking
	Possible Failure Rates	Ppk	Possible Failure Rates	Ppk	
Very High: Failure mode and/or effect(s) are almost inevitable.	≥ 1 in 2	N/A	≥ 1 in 10	≤ 0.55	10
	1 in 4		1 in 20	> 0.65	9
High: Similar processes have had a high rate of listed failure mode(s) and/or effect(s).	1 in 6		1 in 50	≥ 0.78	8
	1 in 10		1 in 100	≥ 0.86	7
Moderate: Similar processes have exhibited listed failure mode and/or effect(s), but not in major proportions.	1 in 20		1 in 200	≥ 0.94	6
	1 in 50		1 in 500	≥ 1.03	5
	1 in 100		1 in 1000	≥ 1.10	4
Low Isolated instances of listed failure mode and/or effect(s) associated with similar processes.	1 in 200		1 in 2000	≥ 1.16	3
Very Low: Isolated instances of listed failure mode and/or effect(s) associated with almost identical processes.	1 in 500		1 in 10,000	≥ 1.30	2
Remote: No incidence of listed failure mode and/or effect(s) associated with almost identical processes. Failure is unlikely.	≤ 1 in 1000		≤ 1 in 100,000	≥ 1.47	1

Figure 5. Suggested PFMEA Occurrence Evaluation Criteria.

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Examples of a Ranking Schemes for a Process FMEA (PFMEA)

(from Little, 2010, Figures 4, 5 & 6)

Criteria	Probability of Detection	Result of Detection Controls (internal or external customer)	Inspection Methods Associated with Detection Controls		Ranking
			Failure Occurs Systematically (continuously)	Failure Occurs Randomly	
Controls are absent	Almost Impossible	Multiple customer complaints	• Cannot detect or no process checks are in place		10
Controls probably will not detect	Very Remote	Detected by customer complaint	• Only indirect, random or undocumented checks	• Only indirect, random or undocumented checks • Single visual inspection of subjective or numerous criteria on a sampling basis	9
Controls have a poor chance to detect	Remote	Multiple discrepant parts may ship to customer	• Single visual inspection of subjective or numerous criteria on a sampling basis	• 100% single visual inspection of subjective or numerous criteria • Sampling checks of variable measurements in a subsequent process	8
	Very Low	Discrepant part may ship to customer	• 100% single visual inspection of subjective or numerous criteria • Sampling checks of variable measurements in a subsequent process	• 100% double visual inspection of subjective or numerous criteria • Variable measurements without SPC	7
Controls may detect	Low	Discrepant parts may be caught at final step before shipment to customer	• 100% double visual inspection of subjective or numerous criteria • Variable measurements without SPC	• Variable measurements with SPC • Sampling pass/fail evaluation of attribute characteristic in subsequent process	6
	Moderate	Discrepant parts caught out of station and before shipment, after value added	• 100% Go/No-Go gaging of variable characteristic at subsequent process • 100% pass/fail evaluation of attribute characteristic at subsequent process • Variable measurements with SPC	• 100% Go/No-Go gaging of variable characteristic at subsequent process • 100% pass/fail evaluation of attribute characteristic at subsequent process	5
Controls have a good chance to detect	Moderately High	Discrepant parts caught out of station but before shipment or value added	• 100% automatic evaluation out of station where the process step can be missed • 100% pass/fail evaluation of attribute characteristic out of station • 100% Go/No-Go gaging of variable characteristic out of station • Subsequent process cannot run with this failure		4
	High	Discrepant part caught at station	• 100% automatic evaluation that requires operator to segregate defects • 100% pass/fail evaluation of attribute characteristic in station • 100% Go/No-Go gaging of variable characteristic in station		3
Controls have a very good chance to detect	Very High	Discrepant part cannot pass out of station	• 100% automatic evaluation during the operation with automatic rejection of defects • Go/No-Go gaging or error detection built into tooling used to create parts • The station that made the defect cannot continue when the defect occurs		2
Controls almost certain to detect	Almost Certain	Cannot produce a discrepant part	• Process step is error-proofed to prevent discrepant parts from being made. If error proofing has failed or is not completely effective, it must be immediately obvious, otherwise detection must be rated assuming error proofing does not exist.		1

Figure 6. Suggested PFMEA Detection Evaluation Criteria.

Appendix F

Slightly Enlarged Version of Figure 9 (Example of an Equipment/Preventive Maintenance FMEA) (for ease of reading)

(from Cotnareanu, 1999, p. 50)

Line Description: Semi-Automated Assembly Line

Machine Description: Transfer Unit

FMEA Number: 63-5807

Potential Equipment Failure Mode Effects Analysis Process FMEA

Prepared by: QM (Quality Manager)

FMEA Date (Orig.) 12-Nov. 1997 (Rev.) A

Page 1 of 1

Core Team: MM (Maintenance Manager), MB (Maintenance Buyer), LHM (Lead Hand Mechanic), PS (Production Supervisor), LO (Line Operator), QM

Equipment (Process Function)	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) / Mechanism(s) of Failure	Occurrence	Current Controls (Predictive Methods)	Detection	R.P.N.	Recommended Action(s)	Person responsible/Target Completion Date	Action Results: Actions Taken	Severity	Occurrence	Detection	R.P.N.*
Transfer unit - main drive Drives the printer mechanism.	• Chain breaks. P/N X 03-31-34	• Transfer unit down. • Post-repair set-up problems.	5	• Misses limit switch. • Broken limit switch. • Stretching due to normal wear.	8	• None	10	400	• Replace limit switches with heavy duty type. • Install tension detector. • Install cycle counter. • Monitor cycles. • Evaluate changes to improve accessibility. • Spares: chain and blocks mounting to chain. •Write repair procedure: describe tasks, change sprockets with chain, periodic lube and preventive replacement.	MM MM PS and MM MM and MB MB MM, QM and PS					
Transfer unit-lift Lifts the fixture support.	• Chain breaks. • Chain stretches. P/N X 03-31-09 X 03-31-10 2 each	• Unit down.	2	• Wear. •Misalignment. • Lube.	1	• None	8	16	• Monitor cycles. •Write and train repair procedure.	PS and MM MM, MB and QM					