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Conducting FMEAs for Results

Tips and techniques for properly using the risk management tool

TODAY'S WORLD IS fraught with risk. A failure mode and effects analysis (FMEA) is a prevention-based, risk management tool that focuses the user or team on systematically:

- Identifying and anticipating potential failures.
- Identifying potential causes for the failures.
- Prioritizing failures.
- Taking action to reduce, mitigate or eliminate failures.

The real value of the FMEA is reflected in its use as a long-term, living document. It is essential that the document is owned and updated as changes are made to the design or the process.

FMEA was first developed and used by reliability engineers in the 1950s to study malfunctions of military systems. As such, it has been a worthy and valuable technique. Subsequently, it has become commonplace in just about every lean Six Sigma practitioner's tool kit. As common as the tool is, however, it is often used incorrectly. Users who invest significant time and effort in the tool often do not reap all it has to offer.

This column details FMEA and provides useful tips for gaining the most benefit from the use of this tool.

Types of FMEAs

The lean Six Sigma practitioner is likely to encounter two types of FMEAs:

1. **Design FMEA (DFMEA)**—an analysis process used to identify and evaluate the relative risk associated with a particular hardware design.
2. **Process FMEA (PFMEA)**—an analysis process used to identify and evaluate the relative risks associated with a particular process design.

Both are similar—with the exception of the first column of the FMEA document. Table 1 provides an example of an FMEA document's format.

The DFMEA's first column uses a product, assembly, subassembly or part. By contrast, the PFMEA uses a process. Therefore, the first column contains the process steps. As such, a process map, cause and effect matrix, suppliers, inputs, process, outputs and customers (SIPOC) diagram, value stream map, cause and effect diagram, or something similar, usually feed it.

The PFMEA document

Of the two primary types of FMEA documents, the lean Six Sigma practitioner likely will deal with the PFMEA the most. The PFMEA document's columns include:

1. Process step—Identify the process step and input under investigation. Each step is identified sequentially. If the PFMEA is fed from a cause and effect matrix, only high-value steps might be listed.

2. Potential failure mode—Identify all the ways a failure can occur at this process step.

3. Potential failure effects—Identify all the effects each failure mode has,

FMEA document general format / TABLE 1

May be a product, assembly, subassembly or part

Initial development of the FMEA | Improvement activities | Post-improvement activities

Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recom-mended	Resp.	Actions taken	SEV	OCC	DET	RPN
1	2	3	4	5	6	7	8	9	10	11	12	13			

DET = detection
FMEA = failure mode and effects analysis
OCC = occurence
Resp = responsible
RPN = risk priority number
SEV = severity

Many-to-many relationships between key columns / TABLE 2

Process step/input	Potential failure mode	Potential failure effects	Potential causes	Current controls
n	1	1	1	1
				2
				3
			2	4
				5
				6
		2	3	7
				8
				9
			4	10
				11
				12
	2	3	5	13
				14
				15
			6	16
				17
				18
		4	7	19
				20
				21
			8	22
				23
				24
	3	5	9	25
n + 1	4	6	10	26

Severity scale example / TABLE 3

Severity value	Descriptor	Description
1	None	No effect
3	Minimal	Greater than $1,000 and up to $100,000 in damages
7	Moderate	Greater than $100,000, but less than $1 million in damages
10	Extreme	Loss of life without warning or greater than $1 million in damages

Occurrence scale example / TABLE 4

Occurrence value	Descriptor	Description
1	Highly unlikely	1 in 10,000
3	Unlikely	1 in 1,000
7	Likely	1 in 100
10	Highly likely	1 in 10

Detection scale example / TABLE 5

Detection value	Descriptor	Description
1	Almost certain	P(detection) ≥ 0.95
3	Likely	0.50 ≤ P(detection) < 0.95
7	Possible	0 < P(detection) < 0.50
10	Not possible	P(detection) = 0

including the effects on the customer. Use a new line for each failure effect. Table 2 demonstrates the many-to-many relationships that exist across the document columns for any given step.

4. Severity—Quantify the severity of the impact of the failure effect. The scale for severity ranges from "no effect" on the low end to "safety hazard"—up to and including "loss of life without warning" on the high end. Also, the effect can be expressed in monetary damages, as well as destruction and delays. All scales must be described in the context of the FMEA situation. See Table 3.

5. Potential causes—Identify all root causes leading to the failure. If root causes are unknown at the time the FMEA is conducted, it may be necessary to divert from the FMEA temporarily and conduct a root cause analysis using the variety of quality tools available.

6. Occurrence—Quantify the frequency of occurrence of the failure mode. The scale for occurrence ranges from "highly unlikely" on the low end to "highly likely" on the high end. Some users, teams and organizations will go to great lengths to provide absolute definitions for the frequency of occurrence. For example, the Automotive Industry Action Group[1] stated that an occurrence entry value of one designates a possible failure rate ≤ 0.01 per thousand vehicles/items, and an entry value of 10 designates a possible failure rate ≥ 100 per thousand vehicles/items. The occurrence scale generally will translate to a rate or even a probability. See Table 4.

7. Current controls—Identify all the existing controls and procedures, including inspections and tests, which prevent the cause of the failure mode. Include a standard operating procedure number, if available.

8. Detection—Quantify the ability to detect the failure at a specific process step (that is, not at a previous or subsequent step, but at the step under consideration). The scale for detection ranges from

"almost certain" on the low end to "not possible" on the high end. See Table 5.

9. Risk priority number (RPN)—Determine the multiplicative effect (that is, RPN = severity value x occurrence value x detection value) of values assigned to columns four, six and eight, respectively. Although teams generally work the highest RPN values first, they may set additional prioritization criteria, such as working any line item on the FMEA where the severity value is at the highest level, the detection value is at its highest or any value is at its highest.

10. Actions recommended—Recommend actions for reducing the severity of the impact, frequency of occurrence or the ability to improve detection.

11. Responsible—Identify who is responsible for the actions recommended. If more than one individual is identified, a lead should be specified as responsible.

12. Actions taken—List the actions taken and completed, and include the completion date.

13. Severity, occurrence, detection and RPN—Identify new severity, occurrence and detection values, and compute the new RPN value. These have the same meaning as items four, six, eight and nine, respectively. However, these values reflect the actions taken in item 12. Ideally, one or more of these values will be reduced by the actions taken, resulting in a lower RPN value. If the value is not reduced, the actions taken were ineffective.

Developing the scales

For FMEAs to be successful, a team must seriously consider the scales it will use to assign values to each component of the RPN.

Some authors advocate using a 10-point scale. One issue with it is it tends to promote debate as to whether to assign an item a two versus a three, or a five versus a six. In such instances, the overall influence on the RPN value may be minimal, yet the team wastes significant time and energy debating values that are close together.

In contrast, other authors advocate using scales skewed and sparse in terms of assignable values. For example, instead of selecting a one-to-10 scale, some teams will choose one, three, seven and 10 scales, or something similar. The benefit of this type of scale is that it minimizes meaningless debate on close values and forces the team to discuss how to assign values.

Further, it bounds the RPN values between one and 1,000 (inclusive), which is convenient and easy to understand. Regardless of the scales used, they should be well defined, consistent and clearly understood by each team member.

Table 6 provides an example of a PFMEA for two failure modes for the first step of a process. Notice the severity and detection values are high in the first row. The detection control is ineffective, and the recommended actions attempt to address both of these issues. The recommended actions were taken, but only affected the detection value.

After applying revised values, the new RPN value is 10. This represents a significant drop from the previous RPN value of 300.

Although the severity value remains at a value of 10, the occurrence value dropped from a three to a one. Therefore, the team felt that because the failure is "highly unlikely" to occur, it will "almost certainly" be detected when it does. Consequently, the team decided not to pursue any additional improvements. Of course, this might be debatable.

In the second row, no current detection control mechanism exists. Therefore, the team must default to the highest value on the scale, which is a 10 in this case. This results in an RPN value of 490.

Thus, a simple action recommended is to separate the parts. This makes the revised

PFMEA example / TABLE 6

Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recommended	Resp.	Actions taken	SEV	OCC	DET	RPN
1	Part not installed	Device does not work	10	Process step skipped	3	SOP 123: process routing sheet	10	300	Modify program to halt production	T. Kubiak 06-17-14	Program modified to detect missing parts	10	1	1	10
1	Wrong part installed	Device overheats	7	Parts co-mingled in bin	7	None	10	490	Place different parts in different bins	T. Kubiak 06-17-14	Parts sorted and new bins added	7	1	3	21

DET = detection
OCC = occurence
PFMEA = process failure mode and effects analysis
Resp = responsible
RPN = risk priority number
SEV = severity
SOP = standard operating procedure

detection value a three and the resulting RPN value a 21.

Useful tips

More often than not, conducting an FMEA work session can be time consuming, tiresome for all and, in many cases, less than productive. Here are tips to make the sessions more meaningful:

1. Establish team norms.
2. Keep sessions to a reasonable length of time.
3. Establish an FMEA owner.
4. Use subject matter experts.
5. Use a professional facilitator.
6. Create meaningful scales.
7. Set up a trigger to start an FMEA update.
8. Limit the ability of participants to review past decisions for current steps.
9. Remember all decisions reflect the current step.
10. Write modes, effects, controls and causes in clear and meaningful ways.
11. Complete each step in a given work session to the extent possible.
12. Minimize the duration between sessions.
13. Identify root causes.
14. Score appropriately.
15. Support FMEAs with additional quality tools.[2]

These tips are explained further in the online version of this column at 3.4 per Million's webpage at www.qualityprogess.com.

Up-front work

FMEAs should be owned, considered living documents and updated appropriately. They require intensive work up front on the part of the team, but their value is almost immeasurable in terms of providing a positive impact on quality. The tips provided are borne from experience and, if applied, will ensure the effectiveness of your FMEA. QP

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