Create a Simple Framework To Validate FMEA Performance

USE WHAT GOES ON AFTER A PRODUCT OR PROCESS GOES LIVE.

By Steve Pollock

Most quality experts agree failure mode effects analysis (FMEA) is a worthwhile prevention activity for identifying and removing failure modes during product or process design activities.[1]

Six Sigma practitioners also find FMEA to be a useful tool for pinpointing risks to the project and their solutions. There is common agreement among quality experts and Six Sigma practitioners that FMEA is applicable to both manufacturing and transactional settings. (See sidebar "FMEA Background and Basics," p. 29.)

Organizations leverage the value of effectively applying FMEAs by creating a framework for giving feedback about FMEA performance. The effectiveness of FMEA performance can be measured by what happens after the product or process goes live (see Figure 1, p. 28).

Typical metrics include warranty data, customer satisfaction or process rework. Less typical is the implementation of a shared learning process. This feedback loop connects the customer experience to the project team.

This shared learning is built on two ideas:

- When starting an FMEA, it is important to understand how its performance will be measured from the customer viewpoint.
- It is helpful to know how other FMEAs performed so any mistakes can be avoided in the future.

Initial Development

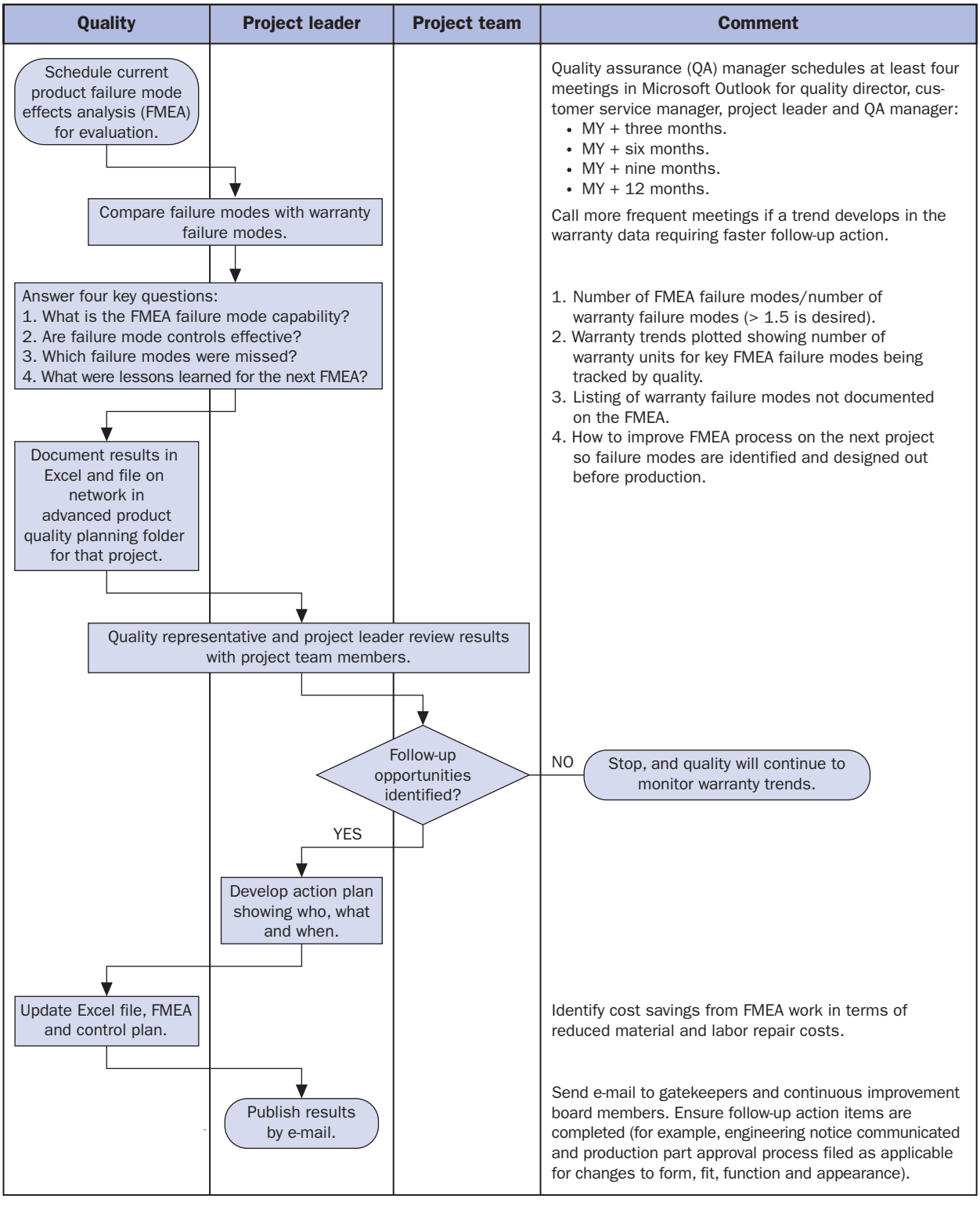
A small Midwestern design and manufacturing firm provided consumer electronics.[2] Management wanted a process to validate how well cross functional design project teams were applying advanced product quality planning (APQP) tools required by the QS-9000 standard for the automotive industry; FMEA was seen as the primary tool to promote quality.

A major customer believed disciplined use of APQP would result in faster time to market, lower total cost and better quality. This ISO 9001 certified customer wanted to go beyond auditing how well the teams conformed to procedures and was interested in expanding the sense of accountability among teams by having them evaluate their own FMEA performance at scheduled times after the product or process release.

Prior to this strategic decision, teams often finished their work and moved on to the next work assignment, leaving evaluation of their FMEA performance to other functions in the company, such as quality. This was damaging to their sense of pride in work because accountability for results was delegated to another function.

A cross functional team with Green Belt skills taught by me developed a flowchart of the validation process. The process needed to be formalized to

Figure 1. **FMEA Effectiveness Process**



MY = model year. Quarterly intervals made sense in this company; other companies will need to identify their own timing.
Outlook is an e-mail application.

better ensure it could be used as a consistent training aid. The documented process also provided protection to the organization in the event of personnel changes, allowing new users of the process to better understand their roles.

From their cumulative experiences with quality management gained over three years, this team's members had a good perspective on the challenge ahead. They had participated on design and process improvement project teams, had served as ISO 9001 auditors and, in particular, had audited the same process for a time.

Team members were also committed to the value of learning and sharing ideas with one another and had practical knowledge of variability based on using run and control charts to track processes. Thus, there was little or no resistance to the novel idea of applying the ISO 9001 concept of scheduled surveillance audits to the FMEA's performance. In other words, they set up a review schedule to assess how well the FMEA was performing.

Figure 2. **Validation Matrix**

Control	X						X
Improve						X	
Analyze			X	X	X		
Measure		X					
Define							

Note: The project plan was created and validated to ensure its anticipated work breakdown met the DMAIC phases. The validation indicated most of the team's efforts would be in the analyze phase.

Metrics

The team used Six Sigma's define, measure, analyze, improve, control (DMAIC) phases to organize activities within a matrix (see Figure 2) and as a training aid.[3]

Three new measurements for validating FMEAs were identified by the development team to test the FMEA performance for a recent model year of a primary product:

1. FMEA failure mode capability is the ratio of the number of FMEA failure modes divided by the number of warranty failure modes. The goal is to score at least 2.00. This measurement uses the statistical process control capability concept of comparing performance to a target. The goal is to identify the failure modes during design

FMEA Background and Basics

Initially used by the U.S. military after World War II as a process tool, failure mode effects analysis (FMEA) gradually spread into industry. It became widely known within the quality community as a total quality management tool in the 1980s and as a Six Sigma tool in the 1990s.

A team should apply FMEA to perform risk assessment to see what the customer will experience if a key process input (X) were to fail. The team should then take action to minimize risk and document processes and improvement activities. FMEA is a living document that should be reviewed and updated whenever the process is changed.[1]

It can be used in the define phase of the define, measure, analyze improve and control strategy as a voice of the customer input, but is more commonly created in the measure phase, updated in the analyze and improve phases and is a vital element of the control phase.

Reference

1. Six Sigma Academy, *The Black Belt Memory Jogger*, first edition, GOAL/QPC, 2002, pp. 211-220.

Figure 3. **FMEA Effectiveness Worksheet**

FMEA effectiveness worksheet

Date: Project:

			Number of warranties	Number shipped	Percentage warrantied
Evaluation stage:	MY + three months				0.000%
	MY + six months				0.000%
	MY + nine months				0.000%
	MY + 12 months	X	322	35,233	0.914%
	Other				0.000%
	Describe:				0.000%
		Totals	322	35,233	0.914%

Evaluators:

Fill out worksheet below and use the information to answer the next four blocks (1 through 4):

1. FMEA failure mode capability:
Number of DFMEA failure modes: 12 *Number of warranty failure modes:* 47 *Capability:* 0.26

2. FMEA failure mode controls effective:
Number of warranties with DFMEA controls: 1 *Number of same warranties < five field failures:* 0

3. Identify missed design FMEA (DFMEA) failure (Use this color for each DFMEA failure mode cell.)
Number of missed failure modes: 40 *Number of all DFMEA failure modes:* 46 *Percentage missed:* 87%

4. Lessons learned:

List all failure modes needing follow-up improvement work in the action list.

Summarize how the DFMEA can be done more effectively the next time it is used by a project team:

The large number of actual failure modes indicates inadequate time and thought was given to the MY XX DFMEA.
The document does not appear to have been used as a design tool before, during and after prototype build and testing.

List all failure modes even if there were no corrective actions. List all warranty failure modes using the same DFMEA row when applicable. Mark all warranty cells that need follow-up.

				(Enter SAME if equal)		*Needs follow-up*
Number	**DFMEA failure modes**	**Risk priority number**	**Corrective action**	**New risk priority number**	**Warranty failure mode**	**Number of warranties**
1.	CD won't play	56	Confirm CD mechanism specs	28	CD won't play	34
2.	CD ejection failure	24	None		CD won't eject	54
3.	CD smokes	16	None		CD skipping	25
4.	Radio no reception	27	None		FM no reception	12
5.	CB radio no reception	28	None		CB radio no reception	3
6.	CB radio no transmission	28	None		CB radio no transmission	1
7.	Chassis noise	12	None		CD won't load	21
8.	Chassis leaking light	24	None		CD door broken	7
9.	Chassis knobs inoperable	28	None		CD audio inoperable	11
10.	Chassis operation inoperable	11	None		CD audio intermittent	17
11.	Display errors	29	None		Display inoperable	12
12.	Display invisible	18	None		CD audio popping	1

Figure 3. **FMEA Effectiveness Worksheet (cont.)**

				(Enter SAME if equal)		*Needs follow-up*
Number	**DFMEA failure modes**	**Risk priority number**	**Corrective action**	**New risk priority number**	**Warranty failure mode**	**Number of warranties**
13.					Radio inoperable	53
14.					Display segments out	9
15.					Display scrambles	8
16.					Display moisture	6
17.					Display intermittent	2
18.					Rear speakers inoperable	8
19.					Automatic volume control inoperable	2
20.					Won't change bands	3
21.					Mode control inoperable	3
22.					Lens scratched	2
23					Intercom inoperable	2
24.					CB radio inoperable	1
25.					Distorted audio	2
26.					Feedback on transmit	1
27.					Bass stuck at full	1
28.					Hand microphone won't transmit	1
29.					Headset inoperable	1
30.					Clock won't update	2
31.					Intermittent static	1
32.					Clock loses time	1
33					Low volume	1
34.					Clock gains time	1
35.					Headset noise	1
36.					Speakers pop when system turns off	1
37.					Push-to-talk turns volume to full	1
38.					Radio bands by itself	1
39.					Radio blows amp	1
40.					Radio intermittent	1
41.					Radio loses memory	1
42.					Radio stuck on full volume	1
43.					Radio switches modes	1
44.					Radio won't turn off	1
45.					Rear volume control inoperable	2
46.					Auxiliary jack skewed	1
47.					**Total**	**322**

FMEA action list								
Number	**Failure mode**	**Assignee**	**Due date**	**Status**	**Closed date**	**Number of warranties before closure**	**Number of warranties after closure**	**Improvement (?) and comment**

MY = model year

Figure 4. **Scoring Worksheet**

FMEA effectiveness worksheet

Model year (MY) XX warranty rate is 0.914% (322 items warrantied/35,233 items

Date: Project:

Evaluation stage:			Number of warranties	Number shipped	Percentage warrantied
	MY + three months				0.000%
	MY + six months				0.000%
	MY + nine months				0.000%
	MY + 12 months	X	322	35,233	0.914%
	Other				0.000%
	Describe:				0.000%
		Totals	322	35,233	0.914%

Evaluators:

Twelve design failure mode effects analysis (DFMEA) failure modes were identified, but 46 unique field failure modes occurred, which results in a capability index of 0.26 (12/46); the DFMEA performance is not capable.

Fill out worksheet below and use the information to answer the next four blocks (1 through 4):

1. FMEA failure mode capability:
Number of DFMEA failure modes: 12 *Number of warranty failure modes:* 46 *Capability:* 0.26

2. FMEA failure mode controls effective:
Number of warranties with DFMEA controls: 1 *Number of same warranties < five field failures:* 0

3. Identify missed DFMEA failure modes: (Use this color for each DFMEA failure mode cell.)
Number of missed failure modes: 40 *Number of all DFMEA failure modes:* 46 *Percentage missed:* 87%

The DFMEA identified only 13% of the failure modes seen in the field; the design team did not identify 87% of the remaining failure modes (40/46 = 87%).

4. Lessons learned:

List all failure modes needing follow-up improvement work in the action list.

Summarize how the DFMEA can be done more effectively the next time it is used by a project team:

The large number of actual failure modes indicates inadequate time and thought was given to the MY XX DFMEA.
The document does not appear to have been used as a design tool before, during and after prototype build and testing.

Comments are noted here. It is important to capture failures and successes when the FMEA performed well. Shared learning about successful FMEA use is vital to identify and promote.

rather than later at the customer's expense.

2. Evaluation of failure mode control effectiveness as measured by warranty statistics and dollars saved.
3. Identification of which warranty failure modes were missed during the FMEA process. The team applied the metrics to one model year experience as a pilot to demonstrate its efficacy as a prevention tool.

Results of Pilot

The project results are shown in the Excel worksheet illustrated in Figure 3 (p. 30). This worksheet would need to be customized to a company's products and metric needs.[4]

The actual worksheet contains a section to document and summarize the data before it is entered into the form shown as Figure 4. The callout boxes in the figure indicate the results of the pilot study.

The pilot study projected the payback period would be seven months based on the anticipated corrective actions in the first year of the validation. It was projected the savings over four years would be approximately $250,000 through elimination of at least 25% of the required design and process changes to support the information gained through the validation.

The conclusion was the large number of warranty failure modes showed the design team did not give enough time and thought to the design FMEA (DFMEA). Management decided to standardize the validation process across all projects and formalized the documentation as part of the ISO 9001 quality system.

Worksheet Comparisons

The section of the worksheet comparing DFMEA failure modes with warranty failure modes is shown under DFMEA failure modes and warranty failure modes in Figure 3 (pp. 30 and 31). A color coding system as used in Figures 3 and 4 should be used to make follow-up easier:

- Gray means the failure mode needs follow-up corrective action as the trend is too high.
- Blue means the failure modes are unique and were not identified in the DFMEA. This is particularly important to help train teams to understand the importance of using the DFMEA through design activity to evaluate schematics, drawings, prototypes and block diagrams.

Transactional Settings

This process can also be implemented in transactional settings to more effectively control projects after implementation. A major challenge in these settings is how to effectively monitor performance over time when the concept of trend analysis is less mature than in more traditional manufacturing applications.

Process management control systems based on key indicators displayed in run chart format are an effective approach to linking risk management through the FMEA to actual results over time.

The next steps, shown in Table 1, are the general plan in DMAIC format for consideration by any transactional organization in creating or further developing its use of FMEAs to project work.

Table 1. **Next Steps in a DMAIC Format**

Define	· Identify a project or product for a pilot study. This should involve a prior project so you have history to use. · Obtain a sponsor who will support the pilot. · Form a small team (no more than five people) to do the pilot. · Read this validation article carefully and study the forms. · Adapt the forms and flowchart to your organization. · Estimate the cost of poor quality from a poor failure mode and effects analysis (FMEA) application.
Measure	· Outline a data collection plan so the forms can be populated. · Perform a measurement systems analysis as necessary. · Complete the forms.
Analyze	· Assess the results from Figure 4 to identify the gaps in the FMEA. · Do cause and effect analysis to identify root causes of poor risk assessment.
Improve	· Identify solutions to close the gaps. · Develop a timeframe and implementation plan.
Control	· Monitor improvement using Figure 4. · Share results to facilitate expansion of the FMEA validation process.

Utility of Validation

The time and effort involved in validating FMEA performance is a value added activity for the following reasons:

- There is the obvious evidence of its use as a key tool, including ongoing control of a project, in any serious Six Sigma effort. ISO 9001 certified organizations with design activities are required to perform risk assessment and practice ongoing evaluation. Other quality initiatives, such as that of the National Committee for Quality Assurance, accept data supported by implementation of FMEAs.
- Design engineers and improvement teams value the insight gained by seeing how well their risk assessment worked.

- Employees in transactional or administrative settings find it valuable to link identified potential failures (risks) to their control plan.
- Project management professionals who promote the lessons learned discussion at the end of a project also support FMEA validation as part of that discussion.
- Customers in major industries, such as automotive and electronics, require use of APQP and measurement of product performance over time, and the FMEA and design activity become part of that discussion.
- FMEA performance validation is cost effective, requires no capital outlay and can encourage more awareness about total cost through its use. At the company where the process was developed, reports about FMEA performance were considered an agenda item at management review meetings chaired by the president.

Any Green or Black Belt should be able to use the information in this article to explain to management why an FMEA validation process is a valuable tool that will produce both quality improvement and real profit enhancing results.

REFERENCES AND NOTES

1. The most complete reference I've seen is provided by D.H. Stamatis, *Failure Mode and Effect Analysis: FMEA From Theory to Execution*, second edition, ASQ Quality Press, 2003. Another helpful reading about process considerations of performing an FMEA is by D.L. Smith, *FMEA: Preventing a Failure Before Any Harm Is Done*, which can be found in the Library area of www.isixsigma.com. Actual instructions for completing the FMEA form may be obtained from the Automotive Industry Action Group website at www.aiag.org.

2. I am respecting the anonymity of the firm because I no longer work there.

3. The quality function played a key role in the initial flowchart because it had more expertise about facilitating organizational change. The small company size also led to people's involvement in specialized roles. It is likely larger organizations will have more opportunities to engage various levels of management in the validation process.

4. For a copy of the complete worksheet or any of the forms, contact the author at s.pollock@insightbb.com. The forms were created using Visio and Excel.

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