FMEA—Something Old, Something New

by **R. Dan Reid**

Managing risk is not optional for organizations. Clause 0.1 of ISO 9004 mentions risk management in the same breath with cost and benefit considerations as being important to an organization, its customers and interested parties. Clause 5.4.2 also includes risk assessment and mitigation data as necessary inputs for efficient and effective quality planning.

Some sectors, particularly aerospace and automotive, have used failure mode and effects analysis (FMEA) to manage risk for many years.

FMEA was used by NASA in the 1960s and adopted by Ford Motor Co. engineering in the 1980s and the Automotive Industry Action Group in the 1990s.[1]

To other sectors such as healthcare, it is a fairly new tool. In its accreditation standard LD.5.2, the Joint Commission for Accreditation of Healthcare Organizations now requires hospitals to select at least one high risk process for proactive risk assessment each year.[2] Clauses 7.1.3.3 and 7.3.1 of ISO 9004 list FMEA among the examples of risk assessment tools, referring to it as "fault mode and effect analysis."

Dr. Tom Reiley pointed out that given the fact that medication errors or accidents represent more than 10% of all medical errors, FMEA provides pharmacies an opportunity to apply an industry tool to prevent such errors.[3]

What Is FMEA?

The Institute for Healthcare Improvement defines FMEA as "a systematic, proactive method for evaluating a process to identify where and how it may fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change."[4]

General Motors (GM) has defined FMEA as "an analytical tool that uses a disciplined technique to identify and help eliminate product and process potential failure modes."[5]

The DaimlerChrysler, Ford and GM FMEA reference manual describes FMEA as a systematic group of activities intended to do the following:[6]

- Recognize and evaluate the potential failure of a product/process and the effects of that failure.

A manufacturing tool finds its way into the healthcare sector.

- Identify actions that could eliminate or reduce the chance of the potential failure modes occurring.
- Document the entire process.

The manual adds that studies of vehicle recalls have shown fully implemented FMEA programs could have prevented many of them.

Essentially, FMEA is a tool to list possible failure modes of a product, service or process and provide a rating so improvement efforts can focus on the most important features or characteristics.

Types of FMEAs

FMEAs now tend to go by different names, such as healthcare FMEA, machinery FMEA or system FMEA, but all FMEAs essentially pertain to either a product/service design or the subsequent realization process.

The technique is the same for completing each kind of FMEA, but the criteria involved are modified. The FMEA process is most effective when the design and process FMEAs are linked and use common evaluation criteria.

Ideally, component and subsystem FMEAs use the same evaluation criteria for better understanding of the relative risk by those completing the system or up-level FMEAs. A process FMEA, however, can and should be completed to effectively manage risk even when the applicable design FMEA is not available.

How Does FMEA Help?

Done properly, an FMEA actually quantifies design or process risk so high risk can be easily identified. This is important because in the field of quality, the right thing to do is not always intuitive—in fact, it can actually be counterintuitive. This is particularly true with characteristic management, which involves selection of the characteristics to be controlled.[7]

Once an FMEA is completed, the result is usually the identification of some high risk characteristics that would not have otherwise been identified. With this information, the organization can and should take corrective and preventive action to avoid the potential failures in the subject design or process.

These actions should be deployed across the organization to similar products, services and processes. The result should be improvements in quality, safety and cost, which should also positively impact customer satisfaction. The FMEAs also provide process documentation and organizational memory.

Like other quality tools, FMEAs are more effective when completed by a team of subject matter experts or interested stakeholders. In clause 7.3.1.1, the automotive industry international technical specification ISO TS 16949 actually requires automotive organizations to use multidisciplinary teams to prepare FMEAs.

An FMEA can be completed by a subject matter expert, but it would then be limited to that person's own knowledge, experience and bias. A process FMEA will likely involve several disciplines within an organization, so ideally each should be represented.

How Does It Work?

To start, you should list the characteristics of a product or service design or the steps of a process. The team

TABLE 1 Suggested Healthcare Detection Table

☐ Prototype ☐ Prelaunch ☐ Production Control plan number						Key contact/phone						Date (original)	Date (reverse)
Part number latest change level						Core team						Customer engineering approval/date	
Part name/description						Supplier/plant approval/date						Customer quality assurance approval/date	
Supplier/plant				Supplier code		Other approval/date (if required)						Other approval/date (if required)	
Part/ process number	Process name/ operation description	Machine, device, jig, tools for manufacturing	Characteristics			Special characteristics classification	Methods						Reaction plan
			Number	Product	Process		Specification/ tolerance	Evaluation measurement technique	Sample		Control method		
									Size	Frequency			

then identifies all the ways the design or process could fail, which is referred to as the potential failure modes. The three main types of design failure modes are materials, processes and costs.

The four main types of process failure modes are too much, too little, missing or wrong.[8] For each potential failure mode, all the potential effects are listed.

A traditional FMEA (see Table 1 for a manufacturing example) quantifies risk. This is done by calculating the risk priority number (RPN) derived from three subjective ratings—severity (S), occurrence (O) and detection (D)—best assigned by consensus of a cross functional team of subject matter experts.

Examples of suggested criteria for each rating for healthcare are shown in Tables 2, 3 and 4 (p. 92).

The severity rating is based on how serious the impact would be if the potential failure were to occur. The occurrence rating is based on the probability of the potential failure occurring. It is important each rating be determined independently of the assignment of the other ratings.

The detection rating is based on how easily the potential failure could be detected prior to occurrence. Some organizations prefer basing this rating on their ability to detect the potential failure before it is passed to the next step in the realization process, while others frame it from the view of the end user of the product or service.

Many suggest the criteria used for the assignment of the severity, detection and occurrence ratings be based on a 10-point rather than five-point scale for better discrimination of the relative risk. If this is done, the RPN calculation (RPN = S x O x D) will be a number between 0 and 1,000.

The scales should be calibrated so a lower number is better, indicating less risk. Organizations can determine their

TABLE 2 Suggested Healthcare Severity Table

Rating	Criteria	During care	After care	Example
10	Failure may seriously endanger patient.			Failure could cause patient or staff death.
9	Failure involves regulatory noncompliance.			Failure could cause long-term patient or staff disability.
8	Failure causes patient high dissatisfaction.			Patient health seriously impacted.
7	Failure causes patient dissatisfaction.			Patient health impacted.
6	Failure causes disruption of patient ADL.*			Patient has to return for major correction.
5	Inconvenience for patient and multiple providers.			Failure caught at subsequent healthcare provider organization.
4	Inconvenience at subsequent function; minor rework.			Failure caught and corrected at subsequent in-house function.
3	Slight inconvenience at next function; minor rework.			Failure caught and corrected at next in-house function.
2	Slight inconvenience at delivery; minor rework.			Failure caught and corrected at delivery.
1	Patient will probably not notice.			No effects.

*Activities of daily living.

own evaluations and rating criteria, considering any customer FMEA requirements and the customer's aversion or tolerance for risk.

The initial RPN should be recalculated after initial corrective and preventive actions are taken. This should be documented on the right side of the FMEA form.

Using the Results

Characteristics or features with high RPNs, especially after initial mitigation efforts are taken, should be identified as critical or significant and lead to proactive error proofing efforts to eliminate the risk or generate actions to lessen the effects of the potential failure were it to occur.

In manufacturing, the latter should be documented on the control plan and operator instructions to mitigate the effects of any potential failures. Appropriate training should be deployed for the operators who are potentially affected.

In this manner, risk to organizations can be systematically identified, managed and reduced. This should lead to lower warranty costs and fewer recalls in manufacturing and assembly. In healthcare, it could lead to fewer costly lawsuits and lower insurance costs.

There have been many healthcare applications for FMEAs. For example, St. Joseph's Community Hospital in Wisconsin successfully used a FMEA to improve the plans for a new facility design.[9] It reportedly led to improved measurement criteria, standardized room layout and improved adjacency. Actions taken to reduce RPN values can be many and varied across all industry and service sectors.

The FMEA must be a live document, updated with information fed back from the field, including items such as warranty, realized outcomes and customer complaints.

It is important the FMEA be worked from the left to right side of the form, which means initial RPNs are addressed to mitigate the effects of a potential failure, and the RPNs are recomputed and reprioritized on the right side of the form based on these initial actions.

Attempts should be made in the process design stage to error proof the tooling, machinery and equipment, such as that used to administer anesthesia in hospitals. This assumes the design has not been error proofed.

FMEA should be a key part of all organizations' quality planning and risk mitigation processes.

Characteristics or features identified with high RPNs or high severity after initial attempts to reduce the risk should be prioritized for additional mitigation steps, which should be documented on either the quality or

TABLE 3 Suggested Healthcare Occurrence Table

Rating	Failure probability	IPTO*	IPMO**
10	Very high	>500	>500,000
9	Very high	333	333,333
8	High	125	125,000
7	High	50	50,000
6	Moderate	12.5	12,500
5	Moderate	2.5	2,500
4	Moderate	0.5	500
3	Low	0.067	67
2	Very low	0.0067	7
1	Remote	0.00067	<1

* Incidents per thousand opportunities
** Incidents per million opportunities

TABLE 4 Suggested Healthcare Detection Table

Rating	Detection	Criteria*	Error proofed	Gauged	Manual inspection	Example
10	Almost impossible	Almost certainty of nondetection				Can not detect or is not checked
9	Very remote	Controls will probably not detect				Control achieved with indirect or random checks only
8	Remote	Control as have a poor chance of detection				Control achieved with visual inspection only
7	Very Low	Controls have a low chance of detection				Control achieved with multiple visual checks only
6	Low	Controls may detect				Control achieved with charting methods, such as statistical process control
5	Moderate	Controls may detect				Control based on variable gauging after delivery or 100% go-no go gauging after service delivery
4	Moderately high	Controls have a good chance of detection				Error detection in subsequent operations; gauging performed at service delivery
3	High	Controls have a very good chance of detection				Error detection at delivery or in subsequent operations by multiple layers of acceptance; cannot accept failure
2	Very high	Controls almost certain to detect				Error detection in delivery, such as automatic gauging with automatic stop feature; failure cannot pass
1	Almost certain	Controls will detect				Error proofed—failure cannot occur

*Process controls from failure mode effects analysis.

control plan or operator instructions.

Care should be exercised when trying to simplify the process by combining the severity, occurrence or detection ratings into one number to avoid oversimplifying the FMEA process and invalidating the result.

REFERENCES

1. "Flow Diagram, PFMEA and Process Control Plan Training," General Motors Co., 2002, 2003.
2. "Healthcare Failure Mode and Effect Analysis," Veterans Affairs National Center for Patient Safety.
3. Thomas T. Reiley, M.D., "FMEA in Preventing Medical Accidents," go to member area of www.asq.org and type "FMEA" in Search.
4. "Failure Mode and Effects Analysis, "Institute for Healthcare Improvement, 2004, p. 1.
5. "Flow Diagram, PFMEA and Process Control Plan Training," see reference 1.
6. DaimlerChrysler, Ford Motor Co. and General Motors, *Potential Failure Mode and Effects Analysis (FMEA) Reference Manual*, Automotive Industry Action Group, 1993, 1995, 2001, p. 1.
7. R. Dan Reid, "Characteristic Management," *Quality Progress*, November 2003, p. 71.
8. Flow Diagram, see reference 1.
9. R. Dan Reid, "Tips for Automotive Auditors," *Quality Progress*, May 2004, p. 72.

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