

FMEA is an analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development cycle. Its most visible result is the documentation of the collective knowledge of cross-functional teams and the action items that mitigate the potential risk.

This is accomplished by first identifying and scoping the area of the product or process design through some form of boundary, block diagram or flowchart. This establishes the depth and level

- Alternative methods for evaluating and limiting risk
- Read: Reduced emphasis on RPN

Formatting and Organization

One of the FMEA committee's objectives was to make the FMEA Fourth Edition more readable. This was accomplished by improving the organization of the manual and improving the format of the material. Additional examples and graphics were added to aid in understanding the specific subjects.

The Revised FMEA Reference Manual

Auditors, suppliers and OEMs will benefit from the new *Potential Failure Mode and Effects Analysis (FMEA) Fourth Edition*, which includes the introduction of alternative methods and supporting analysis to help reduce risk in product and process design.

of the analysis. The design change or scope, based on its complexity, may require a simple component or multiple FMEAs (system level and components). Through the APQP process, OEMs and suppliers identify areas of concern or risk in the design that would require an FMEA analysis. During that discussion, the FMEA Fourth Edition is used as a reference to identify key areas and recommend methods needed to evaluate the product or process design.

New Improvements

Significant improvements were made in the new FMEA Fourth Edition. Updates include:

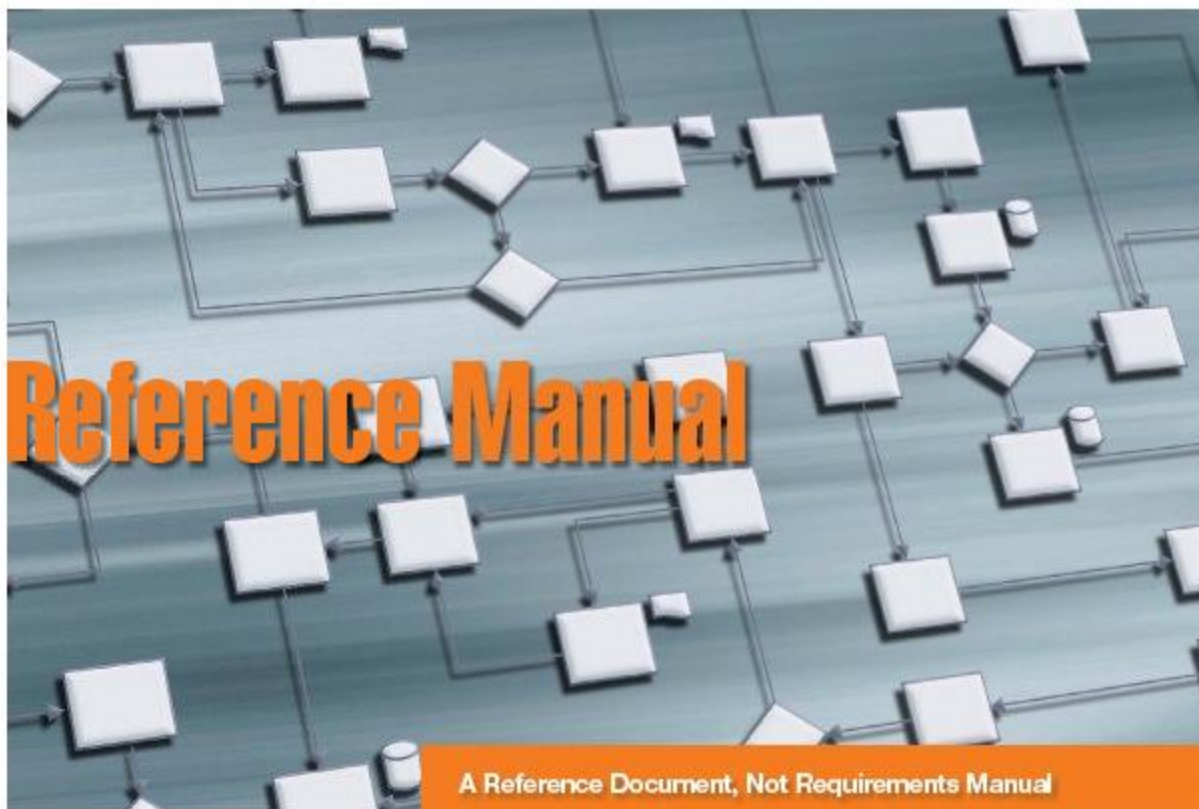
- Formatting and organization
- Process driven rather than form driven
- Additional examples and explanation
- Management support
- Importance of teams
- Scope and content definition
- Changes in the ranking tables
- Linkages between DFMEA and the PFMEA

Process Driven Rather than Form Driven

In the FMEA Third Edition, there was too much emphasis on filling out the form. To illustrate the point, the title in the appendix for the example FMEA form was "Standard Form." This caused a focus on the AIAG FMEA form being interpreted as a requirement and reduced the FMEA methodology to filling out the form.

In the new Fourth Edition, the focus was placed on the process of doing an FMEA analysis and not just filling out the form. It was recognized that it is more important that the analysis team have a good discussion on the physics of the design and risk issues, and that mitigation was accomplished on the areas of risk and concern in the product or process design. Now the context for completing the FMEA form is to provide evidence that the analysis was completed. The FMEA Fourth Edition explains how to complete the form fields, but the emphasis is on a robust FMEA process.

Several different varieties of forms



A Reference Document, Not Requirements Manual

It's important to understand that the FMEA Fourth Edition is a reference document and not a requirements manual. Through evaluation and discussion with the OEM or customer, techniques and applications are selected from the reference manual. The FMEA Fourth Edition does recommend, but does not mandate, any particular method.

Where alternative methods are used, the OEM expectation is that the application meets the intent in the FMEA Fourth Edition. It should also be emphasized that ISO/TS 16949 and OEM customer specifics have compliance requirements related to FMEA implementation.

of generic steps to both a DFMEA and PFMEA, and then goes into detail for both Design and Process FMEAs.

Management Support

The success and quality of FMEAs is directly related to the level of management support and involvement in the process. Evidence supports the importance of management showing inter-

est and providing active support. This includes providing resources, monitoring and reviewing FMEA progress, and reports. Management activity delivered at the right time with the right people for the right reasons will achieve a higher quality and complete FMEA analysis.

The FMEA Fourth Edition reinforces management support by focusing on the levels of support management can

give: training, manpower and regular reviews of the FMEA process. Without these key elements, any FMEA activity, design or process will not function successfully.

Importance of Teams

Another element critical to the FMEA process is the need to assemble the proper team of subject matter experts to have a knowledgeable and thorough discussion about the product or process design. A single person can fill out the form if the only objective is to get a "check" in the box. A team, however, is required for robust FMEA analysis.

If only the design or process engineer (or a delegate) provides input to the FMEA, only one view is covered in the analysis and little support may be given to mitigating action items. The FMEA analysis team membership requirement varies depending on the scope of the analysis and the complexity of the design or process. There will be a more thorough analysis and better results if there is a high quality and knowledgeable team. Also, with appropriate management sanction granted to the team, commitment can be gained on completing identified action items.

The FMEA Fourth Edition gives clear definition of how to determine who should be on the team, with examples based on the level of the design being evaluated.

Scope and Content Definition

The beginning of an FMEA requires the need to evaluate the scope and content of the analysis. The FMEA Fourth Edition reinforces this by showing a greater variety of methods for capturing the scope than was provided in the third edition.

The basic block, boundary and the parameter diagrams are reviewed. The purpose of the diagram is to show what will be included in the analysis; it is a visual accounting method to ensure no elements are missed during the evaluation and discussion.

In addition, to help define the scope of the DFMEA, the different applications of DFMEA are reviewed, which would impact the way a design is scoped. Applications of a DFMEA include: the

component level; the subsystem level; the interface level; and the system level. Also, the analysis of software or an algorithm FMEA may be required. (A non-traditional FMEA format and style could result based on the type of analysis performed.)

Linkages between DFMEA and the PFMEA

Another item emphasized in the FMEA Fourth Edition is the connection between the DFMEA and the PFMEA. While it is acknowledged that there is consistent use of DFMEAs and PFMEAs at all lev-

replace FMEA; however, each of these methods has a unique purpose that can supplement an organization's overall risk mitigation effort.

For example, DRBFM is used when a DFMEA has been completed and a design change is made at some point in time. Instead of repeating a complete FMEA, the analysis and discussion is focused on the point of change. This is done by the design engineer. Next, it is reviewed by management, peers, and technical experts to ensure that risks have been identified and any action plans don't result in creating additional issues.

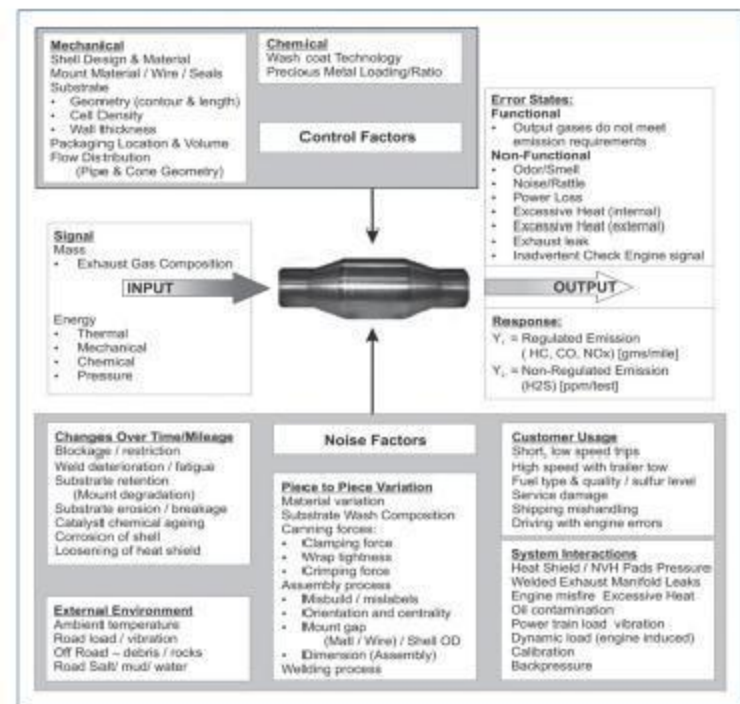


Figure 1. Example of a Parameter (P) Diagram for a Generic Catalytic Converter

Changes in the Ranking Tables

Another big change in the FMEA Fourth Edition is improved ranking tables. The purpose was to improve the usefulness of the tables, both in language and better definition of level. Most noticeable are changes to the Severity and the Detection tables.

The FMEA Fourth Edition includes new ranking tables. While the 10-point scales for Severity, Occurrence and Detection remain, the criteria for each have been improved. The tables will be more useful because of improvements in explanation and clearer definition of the criteria.

els of the supply chain, there is a gap in communication between the design and process analyses. This gap includes missing or erroneous information leading to a possible lack of prevention and detection controls in the process control plan.

Alternative Methods for Evaluating and Limiting Risk

The FMEA Fourth Edition briefly summarizes Fault Tree Analysis (FTA), Failure Mode Effects Criticality Analysis (FMECA), and Design Review Based on Failure Modes (DRBFM) as alternative methods for risk assessment. This is not to imply that any of these methods can

"While... there is consistent use of DFMEAs and PFMEAs at all levels of the supply chain, there is a gap in communication between the design and process analyses."

Reduce the Emphasis on RPN

Finally, there is a major effort to reduce the emphasis on the Risk Priority number (RPN) as a trigger point for the development of recommended actions or continuous improvement. While RPN = Severity (S) x Occurrence (O) x Detection (D) within the scope of the individual FMEA, this value can range between one and 1,000.

The use of an RPN threshold is not a recommended practice for determining the need for actions. Applying thresholds assumes that RPNs are a measure of relative risk (which they often are not) and that continuous improvement is not required (which it is). A threshold can be predetermined or implied. For example, if the supplier took action on an RPN = 30, an appropriate organization or auditor question may be why RPN = 36 or 45 had no action.

Alternative methods are suggested in the FMEA Fourth Edition. One method

is to sort for S x O (severity x occurrence); this tends to put focus on the impact of the failure mode to the customer. Many companies have used this approach and have reported good success.

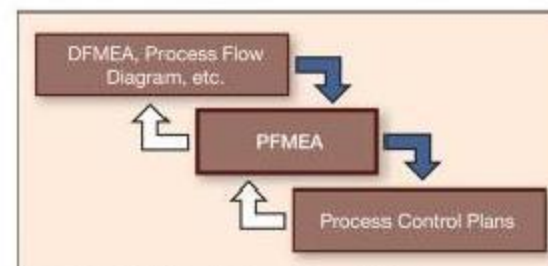


Figure 2. PFMEA Information Interrelationship Flow

Conclusions

The FMEA Fourth Edition is a significant improvement over the FMEA Third Edition, offering greater clarity and more implementation examples. Current automotive practices, as well as concepts from outside the automotive industry, were used to develop

"The FMEA Fourth Edition has added more clarity to the DMFEA and PFMEA process, with more how-to explanations and examples."

FMEA Fourth Edition. The development process included input from OEMs, the automotive supply chain, and those experienced in doing audits to provide practical application and guidance to all FMEA practitioners, both new and experienced.

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Additional references

- Potential Failure Mode and Effects Reference Manual, Third Edition, GM, Ford, DaimlerChrysler, AIAG, July 2001
- Potential Failure Mode and Effects Reference Manual, Fourth Edition, GM, Ford, Chrysler LLC, AIAG, June 2008
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