

*Quality Management System
Core Tools Study Guide in China*

FMEA实施手册 第四版

FMEA Study Guide Fourth Edition





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***Quality Management System
Core Tools Study Guide in China***

FMEA 实施手册 第四版

***FMEA Study Guide
4TH Edition***

Chrysler, Ford, General Motors and Plexus Core Tool Training System™

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FOREWORD

4th Edition

The FMEA 4th Edition 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. The manual does not define requirements; it is intended to clarify questions concerning the technical development of FMEAs. This manual is aligned with SAE J1739.

Summary of Changes in the 4th edition FMEA Reference Manual

The DFMEA and PFMEA methods described in the 4th edition FMEA Reference Manual include those associated with design at the system, subsystem, interface, and component level and the process at manufacturing and assembly operations.

General Changes

- The formatting used in the 4th edition is intended to provide easier reading.
 - An index is included.
 - Icons are used to indicate key paragraphs and visual cues are used.
- Additional examples and verbiage have been provided to improve the utility of the manual and to provide a closer tie into the FMEA process as it develops.
- Reinforcement of the need for management support, interest, and review of the FMEA process and results.
- Define and strengthen the understanding of the linkage between DFMEA and PFMEA as well as defining the linkages to other tools.
- Improvements to the Severity, Occurrence, Detection ranking tables so that they are more meaningful to real world analysis and usage.
- Alternative methods are introduced that are currently being applied in industry.
 - Additional appendices which have example forms and special case application of FMEA.
 - The focus on the “standard form” has been replaced with several options that represent the current application of FMEA in industry.
- The suggestion that RPN not be used as the primary means for assessing risk. The need for improvement has been revised including an additional method, and the use of thresholds on RPN is clarified as a practice that is not recommended.

Chapter I provides general FMEA guidelines, the need for management support and having a defined process for developing and maintaining FMEAs, and the need for continuous improvement.

Chapter II describes the general application of the FMEA methodology, which is common between DFMEA and PFMEA processes. This includes the planning, strategy, action plans, and the need for management support and responsibility in FMEAs.

前言

第四版

FMEA 第四版是克莱斯勒、福特和通用汽车公司的供方所使用的参考手册，为协助他们在开发设计和过程 FMEA 提供了指导方向。本手册不对要求进行定义；它意在澄清有关 FMEA 开发上的技术问题。本手册与 SAE J1739 保持一致。

FMEA 第四版参考手册的变更概要

FMEA 参考手册第四版中描述的设计 FMEA 和过程 FMEA 方法包括系统、子系统、接口和零部件等级中与设计有关的，以及制造和组装操作中与过程有关的内容。

总变更：

- 第四版中使用的格式意在更容易阅读。
 - 加入了索引。
 - 使用了图标指示关键的段落，并使用了视觉提示。
- 增加了一些例子和解释以便增强手册的实用性，并根据其发展与 FMEA 的过程紧密的连结在一起。
- 增强对 FMEA 过程和结果的管理支持，关注，和评审的需求。
- 对设计 FMEA 和过程 FMEA 之间连结的认识进行定义和强化，同时定义与其它工具的连结。
- 改进严重度、发生度和探测度级别表，使它们更适合于实际的分析和应用。
- 介绍了目前在行业中运用到的可选方法。
 - 增加了带有 FMEA 表格范例和特殊案例应用的附录。
 - 不再强调“标准表格”，取而代之的是代表了当前行业内 FMEA 应用的多种选择。
- 不建议使用 PRN 作为风险评估的主要方法。改进的需求已经修改，并包括了一些另外的方法，在 RPN 上使用阈值已经被澄清是不被推荐的一种做法。

第一章 提供了 FMEA 的通用指南，管理支持的需求，开发和维护 FMEA 需要有了的过程的需求，以及持续改进的需求。

第二章 描述了 FMEA 方法的一般应用，此方法对于设计 FMEA 和过程 FMEA 过程是通用的。这包括策划，策略，行动计划和 FMEA 中对管理支持及职责的需求。

Chapter III focuses on DFMEA (Design Failure Mode Effects and Analysis), establishing the scope of the analysis, use of block diagrams, various types of DFMEAs, formation of the teams, basic procedure for analysis, action plans, and follow-up, alternatives to RPN, and connection to PFMEAs and validation plans.

Chapter IV focuses on PFMEA (Process Failure Mode Effects and Analysis), establishing the scope of the analysis, use of flow diagrams, formation of teams, basic procedure for analysis, action plans, the connection to DFMEAs and the development of control plans.

The **Appendices** have several examples of forms for DMFEA and PFMEA and addresses different applications and procedures for addressing design and process risk.

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USE OF MATERIALS

These written materials are to be used only in combination with the DaimlerChrysler, Ford, General Motors and Plexus Core Tools Training System™. Clients have agreed that each participant will be provided with a set of the associated written material(s) for each participant's sole use.

第三章 重点在设计 FMEA（设计失效模式及后果分析），确立了分析的范围，方块图的使用，设计 FMEA 的不同类型，小组的构成，分析的基本程序，追踪和 RPN 的替代项，以及与过程 FMEA 的连接和验证计划。

第四章 重点在 PFMEA（过程失效模式及后果分析），定义了分析的范围，流程图的使用，小组的构成，分析的基本程序，行动计划，与设计 FMEA 的连接以及控制计划的开发。

附录中有若干 DFMEA 和 PFMEA 表格的范例，以及对处理设计和过程风险的不同应用和程序。

手册使用者反馈意见过程

为了持续不断改善的概念，本手册正在进行正式的周期性评审/修订的过程，为了达到顾客满意，这种评审不仅考虑适用的汽车制造商每年要求的改变，而且还要考虑本手册使用者为使本手册对汽车业和社会产生增值并有效的目的而提供的反馈。为此，欢迎书面提出有关本手册理解和易读性的正反两方面的建设性意见。请在下述适当位置填写您的意见，并指出手册具体的页码。按下述地址寄送您的意见：

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Chapter I

Chapter I

General FMEA Guidelines

第一章

FMEA的通用指南

Introduction

This manual introduces the topic of Potential Failure Mode and Effects Analysis (FMEA) and gives general guidance in the application of the technique.

FMEA Process

FMEA is an analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development process (APQP – Advanced Product Quality Planning). Its most visible result is the documentation of the collective knowledge of cross-functional teams.

Part of the evaluation and analysis is the assessment of risk. The important point is that a discussion is conducted regarding the design (product or process), review of the functions and any changes in application, and the resulting risk of potential failure.

Each FMEA should ensure that attention is given to every component within the product or assembly. Critical and safety related components or processes should be given a higher priority.

One of the most important factors for the successful implementation of an FMEA program is timeliness. It is meant to be a “before-the-event” action, not an “after-the-fact” exercise. To achieve the greatest value, the FMEA must be done before the implementation of a product or process in which the failure mode potential exists. Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises. Actions resulting from an FMEA can reduce or eliminate the chance of implementing a change that would create an even larger concern.

Ideally, the Design FMEA process should be initiated in the early stages of the design and the Process FMEA before tooling or manufacturing equipment is developed and purchased. The FMEA evolves throughout each stage of the design and manufacturing development process and may also be used in problem solving.

FMEA can also be applied to non-manufacturing areas. For example, FMEA could be used to analyze risk in an administration process or the evaluation of a safety system. In general, FMEA is applied to potential failures in product design and manufacturing processes where the benefits are clear and potentially significant.