AIAG | Automotive Industry Action Group & VDA | Verband der Automobilindustrie

Failure Mode and Effects Analysis
失效模式及影响分析

FMEA Handbook
FMEA手册

Design FMEA
Process FMEA
Supplemental FMEA for Monitoring & System Response
设计FMEA
过程FMEA
监视及系统响应的补充FMEA

1st Edition 2019
2019年第一版

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Published by:
Automotive Industry Action Group
4400 Town Center
Southfield, Michigan 48075
Phone: (248) 358-3570 • Fax: (248) 358-3253

APPROVAL STATUS
The AIAG Quality Steering Committee and designated stakeholders approved this document for publication on April 2, 2019.

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ISBN#: 978 1 60534 367 9

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Due to country and organization specific guidelines for publications, the Chinese edition of the AIAG & VDA FMEA manual appears in different format and layout.

Chinese Version translation:

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FOREWORD

The AIAG & VDA FMEA Handbook is a reference manual to be used by the automotive industry suppliers as a guide to assist them in the development of Design FMEA, Process FMEA, and Supplemental FMEA for Monitoring and System Response.

The Handbook does not define requirements; it is intended to clarify the steps, activities, and tools related to the technical development of FMEAs. Efforts were taken to align the AIAG & VDA FMEA Handbook with the SAE J1739 standard.

Highlights of the Change Points from the AIAG 4th Edition FMEA Manual and from the VDA Volume 4 Manual are provided in Appendix F.

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前言

AIAG & VDA FMEA手册是供汽车行业供应商使用的参考手册，用以指导其制作设计 FMEA、过程 FMEA 以及监视及系统响应的补充 FMEA。

本手册未对要求进行定义，其目的是阐明与 FMEA 的专业制作相关的步骤、活动和工具。编者已尽力使 AIAG & VDA FMEA 手册与 SAE J1739 标准保持一致。

相对于 AIAG 第 4 版 FMEA 手册和 VDA 第 4 卷手册的修订内容，请参见附录 F。

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1 INTRODUCTION

This joint publication is the culmination of more than three years of collaboration between OEM and Tier 1 supplier members of the Automotive Industry Action Group (AIAG), and the Verband der Automobilindustrie (VDA). The text has been completely rewritten, and the FMEA method has been revised in a few key areas. The intent is to provide a common foundation for FMEA across the sectors of the automotive industry which are represented by these organizations. While every effort was made to achieve consensus, it may be necessary to refer to individual corporate publications or Customer-Specific Requirements (CSR).

A new method: Supplemental FMEA for Monitoring and System Response (FMEA-MSR) has been added. It provides a means for the analysis of diagnostic detection and fault mitigation during customer operation for the purpose of maintaining a safe state or state of regulatory compliance.

This handbook supersedes AIAG 4th Edition FMEA and "Product and Process FMEA" of VDA Volume 4.

1.1 Purpose and Description

The industry is challenged by increasing quality demands of the customer, the necessary cost optimization of the products and processes, and higher complexity, as well as the product liability of the designer and manufacturer required by legislation. Therefore, the FMEA method is used to address the technical aspects of risk reduction.

Failure Mode and Effects Analysis (FMEA) is a team-oriented, systematic, qualitative, analytical method intended to:

- evaluate the potential technical risks of failure of a product or process
- analyze the causes and effects of those failures
- document preventive and detection actions
- recommend actions to reduce risk

Manufacturers consider different types of risk including technical risks, financial risks, time risks, and strategy risks. The FMEA is used for analyzing the technical risks to reduce failures and improve safety in the products and processes. Figure 1.1-1 shows the scope of FMEA and this handbook.

1 引言

本联合出版物是美国汽车工业行动集团（AIAG）与德国汽车工业联合会（VDA）的整车厂（OEM）和一级供应商成员合作逾三年的成果。本手册已进行改写，并在几个关键领域对 FMEA 方法进行了修订。其目的是为这些组织所代表的汽车行业提供 FMEA 通用基础知识。尽管我们尽了最大努力以达成共识，但可能仍有必要参考特定公司的出版物或顾客特定要求（CSR）。

一种新方法：本手册增加了一个新的 FMEA 类别，即"监视及系统响应 FMEA"（FMEA-MSR）。在顾客进行有关操作时，FMEA-MSR 提供了一种诊断探测和失效缓解的分析方法，以使车辆保持安全状态或合规状态。

本手册替代美国汽车工业行动集团编制的 FMEA 第四版和 VDA4 "产品和过程 FMEA"。

1.1 目的和说明

随着顾客对质量要求不断提高，产品和过程不得不进行成本优化，更高的复杂程度，以及法律要求设计提供商和制造商需承担更多的产品责任，汽车行业正面临各种挑战。因此，我们采用 FMEA 方法来解决技术问题，以降低风险。

FMEA 是一套面向团队的系统的、定性分析方法，其目的是：

- 评估产品/过程中失效的潜在技术风险
- 分析失效的起因和影响
- 记录预防和探测措施
- 针对降低风险的措施提出建议

制造商考虑的风险类型很多，包括技术风险、财务风险、时间风险和战略风险。FMEA 仅用于分析技术风险，从而减少失效、提高产品和过程的安全性。图 1.1-1 显示了 FMEA 和本手册的范围。



Figure 1.1-1 Aspects of Risks

1.2 Objectives and limits of FMEA

The objective of FMEA is to identify the functions of a product or steps of a process and the associated potential failure modes, effects, and causes. Furthermore, it is used to evaluate whether prevention and detection controls already planned are enough, and to recommend additional actions. The FMEA documents and tracks actions that are taken to reduce risk. The FMEA methodology helps engineers prioritize and focus on preventing product and/or process problems from occurring.

Business objectives exist that are supported by the FMEA and other activities, such as:

- Increase the quality, reliability, manufacturability, serviceability, and safety of automotive products
- Ensure the hierarchy, linkage, interface, and cascading and alignment of requirements between components, systems and vehicles are captured
- Reduce warranty and goodwill costs
- Increased customer satisfaction in a highly competitive market
- Prove product and process risk analysis in the case of product liability
- Reduce late changes in development
- Maintain defect-free product launches
- Target communication in internal and external customer and supplier relationships
- Build up a knowledge base in the company, i.e. document lessons-learned



图 1.1-1 风险类型

1.2 FMEA 的目标和限制

FMEA 的目标是识别产品的功能或过程步骤、以及相关的潜在失效模式、影响和起因。此外，它还用于评估计划中的预防和探测措施是否是充分的，以推荐额外的措施。对于采取的措施，FMEA 将形成文件并跟踪这些措施的实施情况，以降低风险。FMEA 方法可帮助工程师将各种事项按重要性排序，并将重点放在产品和/或过程中发生问题的预防上。

FMEA 及其它活动的商业目标，如下：

- 提高汽车产品的质量、可靠性、可制造性、可服务性和安全性
- 确保获取各组件、系统和车辆之间的层次结构、连接、接口、级联和要求符合性信息
- 降低保修和商誉成本
- 在市场的激烈竞争中提高顾客满意度
- 证明产品和过程风险分析，从而为承担法律责任做好准备
- 减少开发过程中的后期变更
- 保持无缺陷产品的发布
- 在内外部顾客和供应商之间进行有针对性的沟通
- 在公司内部建立知识库，即将获得的经验教训形成文件

- Comply with regulations in the registration approval of the components, systems, and vehicles

Limitations of the FMEA include the following:

- It is qualitative (subjective), not quantitative (measurable)
- It is a single-point failure analysis, not a multi-point failure analysis
- It relies on the team's level of knowledge which may, or may not predict future performance
- It is a summary of the team's discussions and decisions therefore, the quality of the FMEA report is subject to the recording skills of the team which may reflect the discussion points in whole, or in part (it is not a transcript of a meeting)

For quantitative analysis and multi-point failure analysis, other methods such as FTA (Fault Tree Analysis) and FMEDA (Failure Modes, Effects, and Diagnostic Analysis) are used. These are the methods which can calculate and analyze the relevant metrics (single-point failure analysis, multi-point faults, latent faults) to reach a quantified analysis result.

1.3 Integration of FMEA in the Company

FMEA is a multi-disciplined activity affecting the entire product realization process. The implementation of FMEA needs to be well planned to be fully effective. The FMEA method is an integral element of Product Development and Process Development activities. The FMEA can reduce product redevelopment timing and cost. It supports the development of comprehensive specifications, test plans, and Control Plans.

1.3.1 Potential Considerations of the FMEA

The competent performance of the FMEA and the implementation of its results are among the responsibilities of companies that design, manufacture, and/or assemble products for the automotive industry. It is critical that the analysis take into consideration the product's operating conditions during its useful life, particularly with regard to safety risks and foreseeable (but unintentional) misuse.

When the FMEA is performed, the following norms are observed:

- **Clear**, i.e. potential failure modes are described in technically precise, specific terms, enabling a specialist to assess failure causes and possible effects. Descriptions are free from possible misunderstanding. Emotion-laden terms (dangerous, intolerable, irresponsible, etc.) are not appropriate.
- **True**, i.e. the consequences of potential failures are described accurately (potential for odor, smoke, fire, etc.).
- **Realistic**, i.e. failure causes are reasonable. Extreme events are not considered (falling rock on road, no power to manufacturing plant, etc.). Failures resulting from misuse relative to perception, judgement, or action are considered foreseeable when documented by systematic methods (including brainstorming, expert judgement, field reports, use case analysis, etc.). Failures resulting from intentional misuse are not considered (e.g. deliberate manipulation and sabotage).

- 使组件、系统和车辆符合注册获批所需的法规

FMEA 具有以下局限性：

- 定性（主观的），非定量（可测量的）
- 单点失效分析，非多点失效分析
- 依赖团队的知识水平，可能预测、也可能无法预测未来的性能
- 团队成员对他们讨论的内容和决定自行总结，因此，FMEA 报告的质量取决于团队的文字记录能力，所做的记录可能全面，也可能不全面（该记录不是会议记录）

FTA（故障树分析）和 FMEDA（失效模式、影响和诊断分析）等其他方法可用于定量分析和多点失效分析。这些方法可以计算和分析相关指标（单点失效分析、多点故障、潜在故障），从而得出量化分析结果。

1.3 企业 FMEA 整合

FMEA 活动涉及多个学科，可影响整个产品实现过程。FMEA 的实施需要经过周密的计划才能完全有效。FMEA 方法是产品开发和过程开发活动中的必要组成部分。FMEA 可以减少产品再开发的时间和成本。它对综合规范、测试计划和控制计划的制定给予支持。

1.3.1 FMEA 实施潜在注意事项

FMEA 的有效实施及其结果执行是汽车行业产品设计者、制造商和/或组装企业的职责之一。在进行分析时，必须考虑产品在使用寿命期间的运行条件，特别是安全风险和可预见的（但非故意）不当使用，这一点至关重要。

实施 FMEA 时，应遵循以下规范：

- **明确**，即用严格准确的技术术语描述潜在失效模式，使专家能够评估失效起因和可能产生的影响。描述应避免产生误解、避免使用带有情绪的词语（如危险、不可容忍、不负责任等）。
- **真实**，应准确描述潜在失效的影响（例如产生异味，烟雾，火灾等）。
- **合理**，失效起因应合理，不考虑极端事件（如道路上的落石、制造厂断电等）。当通过系统方法（包括头脑风暴、专家判断、现场报告、使用案例分析等）进行记录时，因感知、判断或各种行为相关的不当使用导致的失效应被视作可预见。蓄意不当使用（例如故意操作和破坏）导致的失效不予考虑。

- **Complete**, i.e. foreseeable potential failures are not concealed. Concern about revealing too much know-how by creating a correct and competent FMEA is not a valid reason for an incomplete FMEA. Completeness refers to the entirety of the product/process under analysis (system elements and functions). However, the depth of detail depends on the risks involved.

Technical risks of failure identified in the FMEA are either assessed as acceptable, or actions are assigned to further reduce risk. The closure status of actions to reduce the risk is documented.

1.3.2 Senior Management commitment

The FMEA process can take considerable time to complete. A commitment of the required resources is vital. Active participation of the product and process owners and commitment from senior management are important to successful FMEA development.

Senior Management carries the responsibility for the application of FMEA. Ultimately, senior management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.

1.3.3 Know-How Protection of the Design FMEA/Process FMEA

The sharing of intellectual property found in the Design FMEA and/or Process FMEA between suppliers and customers is governed by contractual agreements between suppliers and customers and is beyond the scope of this handbook.

1.3.4 Agreements between Customers and Suppliers

The customer specific requirements regarding FMEA should be coordinated with the parties involved and/or the suppliers. An agreement made about the execution of FMEAs may include but is not limited to items such as; system boundaries, necessary work documents, analysis methods, and evaluation tables.

- **完整**，不应对可预见的潜在失效进行隐瞒。担心创建一个准确有效的FMEA 文件会透漏太多的知识经验，不能作为 FMEA 文件不完整的正当理由。完整性是指被分析产品/过程的整体性（系统要素和功能）。然而，应根据所涉及风险的具体情况来决定描述的详细程度。

FMEA 中确认的失效技术风险要么被评估为可接受，要么需指定措施进一步降低风险。措施的实施结果应形成文件。

1.3.2 高层管理者的承诺

FMEA 过程可能需要相当长的时间才能完成，所需资源的参与和承担至关重要。产品和过程所有者的积极参与和高层管理者的承诺对成功实施 FMEA 很重要。

高层管理者负责 FMEA 的应用，并最终负责接受 FMEA 中确定的风险和风险最小化措施。

1.3.3 设计 FMEA/过程 FMEA 中的知识经验保护

设计 FMEA 和/或过程 FMEA 中供应商和顾客之间的知识产权共享受供应商和顾客之间的合同协议管辖，不在本手册的范围之内。

1.3.4 顾客和供应商之间的协议

有关 FMEA 的顾客特定要求应与相关方和/或供应商协调。关于执行 FMEA 的协议可能包括但不限于以下项目：系统边界、必要的工作文件、分析方法和评估表。

1.3.5 Transition Strategy

Existing FMEAs developed using the previous AIAG 4th Edition FMEA or "Product and Process FMEA" of VDA Edition, may remain in their original form for subsequent revisions.

The organization should thoughtfully plan the transition from their current FMEA process(es) and methods to the new AIAG VDA FMEA process and tools. When practical, existing FMEAs used as a starting point for new programs should be converted to reflect the new rating scales, analytical methods, and format. However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave the FMEA in the existing format.

New projects should follow the FMEA method presented in this Handbook unless company leadership and Customer Specific Requirements (CSRs) mandate a different approach. The transition date and project milestone after which new projects follow this method should be defined by the company taking into consideration customer specific requirements.

1.3.6 Foundation and Family FMEAs

Foundation and family FMEAs are recommended to be created and used as a basis for new analyses. These optional practices provide the greatest opportunity to leverage past experience and knowledge and ensure that knowledge is accumulated over product lifecycles and that prior performance issues are not repeated (lessons learned). Furthermore, such reuse also reduces effort and expenditures.

Foundation FMEAs (also known as generic, baseline, template, core, master, or best practice FMEAs, etc.) are FMEAs that contain knowledge of the organization from prior developments which make them useful as a starting point for new FMEAs. The foundation FMEA is not program specific, therefore the generalization of requirements, functions, and measures is allowed.

Family FMEAs are specialized foundation FMEAs. It is common to develop products that generally contain common or consistent product boundaries and related functions (a Product Family) or processes which contain a series of operations that produce multiple products or part numbers. In these cases, it is appropriate to develop Family FMEAs which cover the commonalities for these Families.

When using the family or foundation FMEA approach, for the new product or process under development the team should identify and focus the analysis on the differences between the existing and the new product, process or application. The information and ratings carried over from the family or foundation are to be critically examined with regard to the respective use case and experiences from the known application.

1.3.5 过渡策略

使用 AIAG FMEA 第四版和 VDA 版本“产品和过程 FMEA”制作的现有 FMEA 可以保持原有格式并用于后续版本修订。

组织应仔细规划从当前的FMEA过程和方法过渡到新的AIAG VDA FMEA过程和工具。如若可行，在新项目中，需要从现有的 FMEA 开始，进行转变，以反映新的评级量表、分析方法和格式。但是，如果团队确定该新计划只是现有产品的微小变更，他们可以保留 FMEA 现有格式。

除非公司领导层和顾客特定要求（CSR）要求采用不同的方法，新项目应遵循本手册中介绍的 FMEA 方法。新项目遵循此方法的过渡日期和项目里程碑应由公司根据顾客的具体要求确定。

1.3.6 基础 FMEA 和家族 FMEA

建议创建和使用基础 FMEA 和家族 FMEA，为新的分析提供基础信息。这些可选实践提供了利用过去经验和知识的最大机会，以确保在产品生命周期内积累知识，并且不会重复先前的性能问题（吸取经验教训）。此外，这种重复使用还可以减少工作量和费用支出。

基础 FMEA（也称作一般、基准、模板、核心、母版或最佳实践 FMEA 等）包含了组织先前开发过程中积累的知识，可为创建新的 FMEA 提供基础。基础 FMEA 不针对某个具体项目，因此允许对需求、功能和措施进行笼统的概述。

家族 FMEA 是基础 FMEA 的具体化。通常，企业会开发包含共同或一致产品边界和相关功能（一个产品系列）的产品，或开发包含一系列操作的过程来生产多个产品或零件。在这种情况下，合适的做法是，创建一个涵盖同一产品系列下所有产品的家族 FMEA。

对于正在开发的新产品或过程，使用家族 FMEA 或基础 FMEA 方法时，团队应识别和专注分析现有的和新的产品、过程或应用之间的差异。从家族 FMEA 或基础 FMEA 获得的信息和评级，应根据具体的使用案例和已知应用经验进行严格检查。

1.4 FMEA for Products and Processes

There are three basic cases for which the FMEA is to be applied, each with a different scope or focus.

Case 1: New designs, new technology, or new process.

The scope of the FMEA is the complete design, technology, or process.

Case 2: New application of existing design or process

The scope of the FMEA is an existing design or process in a new environment, location, application, or usage profile (including duty cycle, regulatory requirements, etc.). The scope of the FMEA should focus on the impact of the new environment, location, or application usage on the existing design or process.

Case 3: Engineering changes to an existing design or process.

New technical developments, new requirements, product recalls, and reports of failures in the field may drive the need for design and/or process changes. In these cases, a review or revision of the FMEA may be necessary.

The FMEA contains a collection of knowledge about a design or process and may be revised after start of production if at least one of the following points applies:

- Changes to designs or processes
- Changes to the operating conditions
- Changed requirements (law, norms, customer, state of the art)
- Quality Issues, i.e. Plant experience, zero mileage, or field issues, internal / external complaints
- Changes to the Hazard Analysis and Risk Assessment (HARA)
- Changes to the Threat Analysis and Risk Assessment (TARA)
- Findings due to product monitoring
- Lessons learned

There are two main approaches to FMEA: the analysis according to product functions (Design FMEA) or according to process steps (Process FMEA).

1.4产品和过程 FMEA

FMEA 在三种基本情形下使用，每种情形都有不同的范围或重点。

情形 1：新设计、新技术或新过程

FMEA 的范围包括完整的设计、技术或过程。

情形 2：现有设计或过程的新应用

FMEA 的范围包含新环境、新场地、新应用或使用概况（包括工作周期、法规要求等）下的现有设计或过程。FMEA 的范围应关注于新环境、新场地或新应用对现有设计或过程的影响。

情形 3：对现有设计或过程的工程变更

新技术开发、新要求、产品召回和使用现场失效可能会需要变更设计和/或过程。在这种情况下，可能需要对 FMEA 进行审查或修订。

FMEA 包含一系列关于设计或过程的知识，如果至少有以下一点适用，则可在生产开始后进行修订：

- 设计或过程变更
- 运行条件变更
- 要求变更（法律、规范、顾客、或最新技术变更）
- 质量问题，即工厂经验、零公里、使用现场问题、内部/外部投诉
- 危害分析和风险评估变更
- 威胁分析和风险评估变更
- 产品监视过程中发现问题
- 经验教训

FMEA 主要有两种实施方法：根据产品功能（设计 FMEA）或根据过程步骤（过程 FMEA）进行分析。

1.4.1 Design FMEA

A Design FMEA (DFMEA) is an analytical technique utilized primarily by a design responsible engineer/team as a means to assure that, to the extent possible, potential Failure Modes and their associated Causes or mechanisms of failure have been considered and addressed prior to releasing the part to production.

The Design FMEA analyzes the functions of a system, subsystem, or component of interest as defined by the boundary shown on the Block/Boundary Diagram, the relationship between its underlying elements, and to external elements outside the system boundary. This enables the identification of possible design weaknesses to minimize potential risks of failure.

A System DFMEA is comprised of various subsystems and components which are represented as system elements (items).

System and subsystem analyses are dependent on the viewpoint or responsibility. Systems provide functions at the vehicle level. These functions cascade through subsystems and components. For purpose of analysis, a sub-system is considered the same way as a system.

Interfaces and interactions among systems, subsystems, the environment and the customers (i.e. Tier N, OEM, and end user) may be analyzed in System FMEAs.

Within a system there may be software, electronic, and mechanical elements. Examples of systems include: Vehicle, Transmission System, Steering System, Brake System or Electronic Stability Control System, etc.

A component DFMEA is a subset of a system or subsystem DFMEA. For example, an Electrical Motor is a component of the Window Lifter, which is a subsystem of Window Lifter System. A Housing for the Electrical Motor may also be a component or part. For this reason, the terms "system element" or "item" are used regardless of the level of analysis.

Design FMEA may also be used to assess the risks of failure of non-automotive products such as machines, and tooling. The actions resulting from the analysis may be used to recommend design changes, additional testing, and other actions which reduce the risk of failure or increase the ability of a test to detect failures prior to delivery of the design for production.

1.4.2 Process FMEA

In contrast to the Design FMEA (DFMEA), which analyzes the failure possibilities that may be created during the design phase of the product, the Process FMEA (PFMEA) analyzes the potential failures of manufacturing, assembly and logistical processes to produce products which conform to design intent. Process-related failures are different than the failures analyzed in the Design FMEA.

1.4.1 设计 FMEA

设计 FMEA（DFMEA）是一种主要由设计责任工程师/团队使用的分析技术，用于确保在将零件交付生产之前，尽可能考虑并解决潜在失效模式及其相关失效起因或机理。

设计 FMEA 用于分析如块/边界图所示边界中所定义的系统、子系统或相关组件的功能，其内部要素之间的关系以及与系统边界外要素之间的关系。从而识别出可能存在的设计缺陷，将潜在的失效风险降到最低。

系统设计 FMEA 由表示为系统要素（项目）的各种子系统和组件组成。

系统和子系统分析取决于视角或责任。系统提供整车层面的功能。这些功能通过子系统和组件级联。为了便于分析，子系统的考虑方式与系统相同。

系统 FMEA 中可能会分析系统、子系统、环境和顾客（例如：N 级供应商、OEM 和最终用户）之间的接口和交互作用。

一个系统可能包含软件、电子和机械要素。系统实例包括：整车、传动系统、转向系统、制动系统或电子稳定控制系统等。

组件设计 FMEA 是系统或子系统设计 FMEA 的一个子集。例如，电机是车窗升降器的一个组件，而车窗升降器是车窗升降系统的一个子系统。电机的外壳也可以是一个组件或零件。因此，无论分析级别如何，都会使用术语"系统要素"或"项目"。

设计 FMEA 也可用于评估非汽车产品（如设备和模具）的失效风险。分析后得出的措施可用于建议设计变更、附加测试和其他措施等，以降低失效风险或提高在生产设计交付之前检测失效的检验能力。

1.4.2 过程 FMEA

设计 FMEA（DFMEA）用于分析产品设计阶段可能产生的失效，过程 FMEA（PFMEA）则与之不同，它分析的是制造、装配和物流过程中的潜在失效，以确保生产的产品符合设计目的。过程中的相关失效与在设计 FMEA 中分析的失效不同。

The Process FMEA analyzes processes by considering the potential failure modes which may result from process variation, to establish priority of actions for prevention, and as needed; improve controls. The overall purpose is to analyze processes and take action prior to production start, to avoid unwanted defects related to manufacturing and assembly and the consequences of those defects.

1.4.3 Collaboration between FMEAs

There are opportunities for collaboration between both Design and Process FMEAs in the same company and outside of the company. To help communicate effects and severities, a joined and agreed to severity evaluation can be reviewed between Tiers (different companies in the supply chain starting with Tier 1, Tier two, Tier 3, etc.) as shown in Figure 1.4-1 FMEA Collaboration.

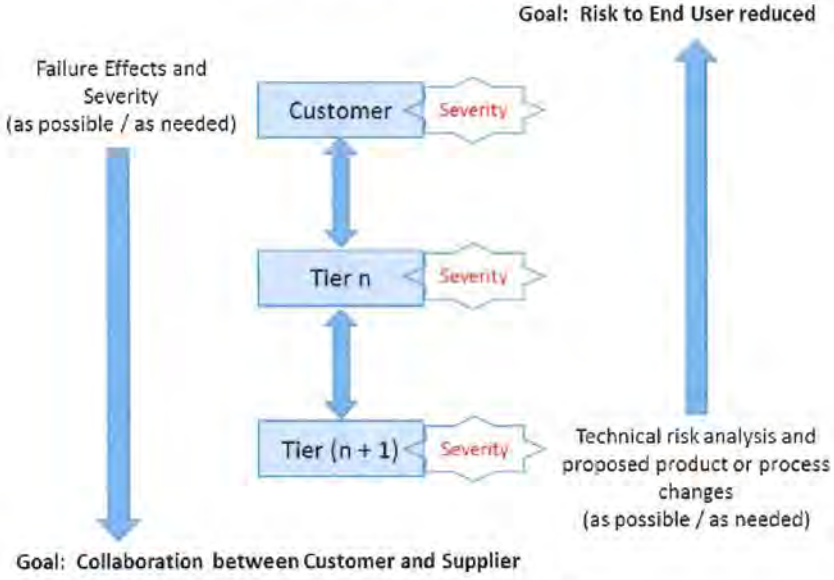


Figure 1.4-1 FMEA Collaboration

过程 FMEA 通过考虑过程变差可能导致的潜在失效模式来分析过程，以确定预防措施的优先顺序，并根据需要改进控制。其总体目标是在生产开始之前分析过程并采取措施，以避免与制造和装配有关的不必要缺陷以及这些缺陷产生的后果。

1.4.3 不同 FMEA 之间的协作

在同一公司内部和公司外部，设计 FMEA 和过程 FMEA 都有协作的机会。为了有助于沟通影响和严重度，可以在各层级供应商（供应链中不同的公司，包括 1 级、2 级、3 级供应商等）之间对一个共同参与且达成一致的严重度评估进行评审，如图 1.4-1 FMEA 合作所示。

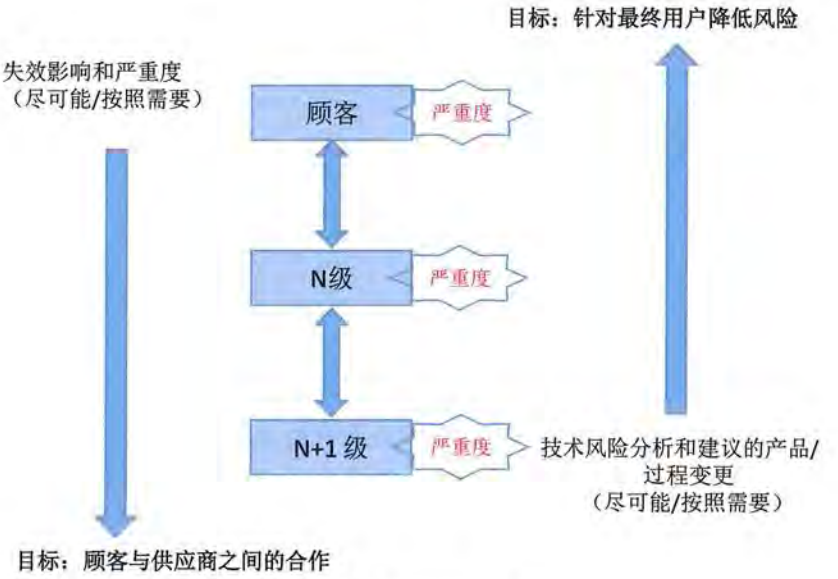


图 1.4-1 FMEA 协作

A good starting point for a manufacturer is to make sure the severity in the DFMEA and PFMEA are the same when the failure effects are the same. If the "product" failure effects to the end user (vehicle-level) are not included in the PFMEA then the correlation between the DFMEA and PFMEA is not possible. A correlation needs to be made so that a failure of a feature in design that leads to a certain failure effect is also captured in the PFMEA for the same feature (product characteristic). Please see the note in Section 3.4.8 for non-traditional development flows.

1.5 Project Planning

The Five T's are five topics that should be discussed at the beginning of a DFMEA or PFMEA in order to achieve the best results on time and avoid FMEA rework. These topics can be used as part of a project kick-off.

FMEA In Tent – Why are we doing FMEA?

FMEA Timing – When is this due?

FMEA Team – Who needs to be on the team?

FMEA Task – What work needs to be done?

FMEA Tool – How do we conduct the analysis?

1.5.1 FMEA In Tent

It is recommended that members of the FMEA team are competent in the method, based on their role on the team. When team members understand the purpose and intent of FMEA, they will be more prepared to contribute to the goals and objectives of the project.

1.5.2 FMEA Timing

FMEA is meant to be a "before-the-event" action, not an "after-the- fact" exercise. To achieve the greatest value, the FMEA is conducted before the implementation of a product or process in which the failure mode potential exists.

One of the most important factors for the successful implementation of an FMEA program is timeliness. Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises. The FMEA as a method for system analysis and failure prevention is best initiated at an early stage of the product development process. It is used to evaluate the risks, valid at that time, in order to initiate actions to minimize them. In addition, the FMEA can support the compilation of requirements.

对于制造商而言，一个好的开始是确保当失效影响相同时，设计 FMEA 和过程 FMEA 中的严重度也相同。如果~~产品~~"失效对最终用户（整车层面）的影响不包括在过程 FMEA 中，那么设计 FMEA 和过程 FMEA 之间的相关性便不可能。需要建立一种相关性，以便使特定失效影响的设计中的失效特征也能在过程 FMEA 中捕获到相同特征（产品特性）的失效。非传统开发流程见第 3.4.8 节注释。

1.5 项目规划

"5T"是在设计 FMEA 和过程 FMEA 开始时应该讨论的五个主题，以便及时取得最佳效果、避免 FMEA 返工。这些主题可以作为项目启动的一部分。

FMEA 目的 – 我们为什么要做 FMEA?

FMEA 时间安排– 什么时候完成?

FMEA 团队– 需要包括哪些人?

FMEA 任务 – 需要做哪些工作?

FMEA 工具 – 如何进行分析?

1.5.1 FMEA 目的

建议 FMEA 团队中扮演不同角色的成员能各自胜任该方法。当团队成员了解了 FMEA 的目的和意图时，他们会更好地为完成项目具体目标和总体目标作出贡献。

1.5.2 FMEA 时间安排

FMEA 是一种"事发前"的行为，而不是"事发后"的行动。为了达到最大价值，FMEA 应在产品或过程实施之前进行，（因为）产品或过程中存在潜在的失效模式。

成功实施 FMEA 方案的最重要因素之一是及时性。为了产品/过程变更可以非常容易和低成本执行，提前正确完成 FMEA，这将最小化后期变更的风险。作为系统分析和失效预防的方法，FMEA 最好在产品开发过程的早期阶段启动。它用于评估风险，在早期阶段有效，以便采取措施将风险最小化。此外，FMEA 还可以支持要求的汇编。

The FMEA should be carried out according to the project plan and evaluated at the project milestones according to the state of the analysis.

It is recommended that a company define desired maturity levels for their FMEAs according to overall company-specific development project milestones.

<table>
<tr><th>Advanced Product Quality Planning (APQP) Phases</th><th>Plan and Define Program</th><th>Product Design and Development Verification</th><th>Process Design and Development Verification</th><th>Product and Production Validation</th><th>Feedback Assessment and Corrective Action</th></tr>
<tr><td>DFMEA</td><td rowspan="2">Start FMEA planning in concept phase before product development begins
Information flow from DFMEA to PFMEA
The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs</td><td>Start DFMEA when the design concept is well understood</td><td>Complete DFMEA analysis prior to release of design specifications for quotation</td><td>Complete DFMEA actions prior to start of production tooling</td><td rowspan="2">Start again with DFMEA and PFMEA planning if there are changes to an existing design or process</td></tr>
<tr><td>PFMEA</td><td>Start PFMEA when production concept is well understood</td><td>Complete PFMEA analysis prior to final process decisions</td><td>Complete PFMEA actions prior to PPAP/PPA</td></tr>
</table>

Figure 1.5-1 FMEA Timing Aligned with APQP Phases

应根据项目计划实施 FMEA，并根据分析状态在项目不同里程碑节点进行评估。

建议公司根据其特定的整体项目开发里程碑节点，为他们的 FMEA 定义所需的成熟度水平。

<table>
<tr><th>先期产品质量策划(APQP)阶段</th><th>策划和定义方案</th><th>产品设计与开发的验证</th><th>过程设计与开发的验证</th><th>产品与生产确认</th><th>反馈评估和纠正措施</th></tr>
<tr><td>设计FMEA</td><td rowspan="2">在产品开发启动之前的概念阶段开始FMEA计划
从设计FMEA到过程FMEA的信息流动
应在同一时间段内执行设计FMEA和过程FMEA，以便优化产品和过程设计。</td><td>充分理解设计概念后，启动设计FMEA</td><td>在用于报价的设计规范发布之前完成设计FMEA分析</td><td>在生产工装开始之前完成设计FMEA行动</td><td rowspan="2">如果现有设计和过程发生改变，则重新开始策划设计FMEA和过程FMEA</td></tr>
<tr><td>过程FMEA</td><td>充分理解生产概念后，启动过程FMEA</td><td>在最终过程决策之前完成过程FMEA分析</td><td>在PPAP/PPA之前完成过程FMEA</td></tr>
</table>

图 1.5-1 先期产品质量策划（APQP）阶段的 FMEA 时间安排

VDA Maturity Level Assurance for New Parts	ML0	ML1	ML2	ML3	ML4	ML5	ML6	ML7
	Innovation Approval for serial Development	Requirement Management for Procurement Extensive	Definition of the Supply Chain and Placing of Extensive	Approval of Technical Specification	Production Planning Done	Serial tools, Spare Parts and Serial Machines Available	Product and Process Approval	Project End, Responsibility Transfer to Serial Production, Start, Requalifikation
DFMEA		Start FMEA planning in concept phase before product development begins **Information flow from DFMEA to PFMEA** The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs	Start DFMEA when the design concept is well understood	Complete DFMEA analysis prior to release of design specifications for quotation		Complete DFMEA actions prior to start of production tooling		**Start again with DFMEA and PFMEA planning if there are changes to an existing design or process**
PFMEA			Start PFMEA when production concept is well understood		Complete PFMEA analysis prior to final process decisions		Complete PFMEA actions prior to PPAP/ PPA	

Figure 1.5-2 FMEA Timing Aligned to MLA Phases

NOTE: Exceptions to this FMEA timing include non-traditional development flows such as where development of a "standard" process precedes the development of products that will be manufactured using the process.

VDA 新零件成熟度保障	ML0	ML1	ML2	ML3	ML4	ML5	ML6	ML7
	量产开发创新批准	**采购范围的需求管理**	**确定供应链并下订单**	**技术规范批准**	**生产规划完成**	**量产工装，备件和量产设备完成**	**产品和过程批准**	**项目结束，责任移交至批量生产，开始再确认**
设计FMEA		在产品开发启动之前的概念阶段开始FMEA计划 **从设计FMEA到过程FMEA的信息流动**应在同一时间段内执行设计FMEA和过程FMEA，以便优化产品和过程设计。	充分理解当设计概念后，启动设计FMEA	在用于报价的设计规范发布之前完成设计FMEA分析		在生产工装开始之前完成设计FMEA行动		如果现有设计和过程发生改变，则重新开始策划设计FMEA和过程FMEA
过程FMEA			充分理解生产概念后，启动过程FMEA		在最终过程决策之前完成过程FMEA分析		在PPAP/PPA之前完成过程FMEA	

图 1.5-2 成熟度保障（MLA）阶段的 FMEA 时间安排

> 注意：此 FMEA 时间安排的例外情况包括非传统的开发流程，例如，在开发出使用本过程生产的产品之前，先开发出一个"标准"过程。

1.5.3 FMEA Team

The FMEA team consists of multi-disciplinary (cross-functional) members who encompass the necessary subject matter knowledge. This should include facilitation expertise and knowledge of the FMEA process. The success of the FMEA depends on active participation of the cross-functional team as necessary to focus on the topics of discussion.

1.5.3.1 The Design FMEA Team

The Core Team may consist of the following people:

- facilitator
- design engineer
- system engineer
- component engineers
- test engineer
- quality/reliability engineer
- others responsible for the development of the product

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator or meeting organizer).

The Extended Team may consist of the following people:

- technical experts
- process/manufacturing engineer
- service engineer
- project manager
- functional safety engineer
- purchasing
- supplier
- customer representative
- others that may have specialized knowledge which will help the core team analyze specific aspects of the product

1.5.3.2 The Process FMEA Team

The Core Team may consist of the following people:

- facilitator
- process/manufacturing engineer
- ergonomic engineer
- process validation engineer

1.5.3 FMEA 团队

FMEA 团队由多方论证（跨职能）成员组成，他们具备必要的专业知识，这应包括能促进 FMEA 过程的专业技术和知识。FMEA 的成功实施取决于跨职能团队的积极参与，因为它需要专注于讨论的主题。

1.5.3.1 设计 FMEA 团队

核心团队可由以下人员组成:

- 推进者
- 设计工程师
- 系统工程师
- 零件工程师
- 测试工程师
- 质量/可靠性工程师
- 负责产品开发的其他人员

核心团队成员准备 FMEA 系统分析（步骤 1-3）并参加 FMEA 会议。扩展团队成员根据需要参与（由 FMEA 推进者或会议组织人协调）。

扩展团队可由以下人员组成：

- 技术专家
- 过程/制造工程师
- 维修工程师
- 项目经理
- 功能安全工程师
- 采购
- 供应商
- 顾客代表
- 其他具有专业知识的人员，他们能帮助核心团队分析产品的特定问题

1.5.3.2 过程 FMEA 团队

核心团队可由以下人员组成：

- 推进者
- 过程/制造工程师
- 人机工程学工程师
- 过程验证工程师

- quality/reliability engineer
- others responsible for the development of the process

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator or meeting organizer).

The Extended Team may consist of the following people:

- design engineer
- technical experts
- service engineer
- project manager
- maintenance staff
- line worker
- purchasing
- supplier
- others (as necessary)

1.5.3.3 FMEA Team Roles and Responsibilities

Within the organization's product development process, the following roles and responsibilities for FMEA participation should be assigned. Responsibilities of a given role can be shared amongst different persons and/or multiple roles may be assigned to the same person.

1.5.3.3.1 Management, i.e. project manager

- Authority to make decisions about the acceptability of identified risks and the execution of actions
- Defines the persons responsible for pre-work activities, FMEA facilitation, and the design/process engineer responsible for implementation of actions resulting from the analysis
- Responsible for selecting and applying resources and ensuring an effective risk management process is implemented within scheduled project timing
- Responsibility and ownership for development and maintenance of the FMEAs.
- Management responsibility also includes providing direct support to the team(s) through on-going reviews and eliminating roadblocks.
- Responsible for budget.

1.5.3.3.2 Lead Design/Process Engineer (Technical Lead)

- Technical responsibility for the FMEA contents

- 质量/可靠性工程师
- 其他负责过程开发的人员

核心团队成员准备 FMEA 系统分析（步骤 1-3）并参加 FMEA 会议。扩展团队成员根据需要参与（由 FMEA 推进者或会议组织人协调）。

扩展团队可由以下人员组成：

- 设计工程师
- 技术专家
- 维护工程师
- 项目经理
- 维修人员
- 现场工作人员
- 采购
- 供应商
- 其他（视需要）

1.5.3.3 FMEA 团队角色和责任

在组织的产品开发过程中，FMEA 参与的以下角色和责任应该进行分配。某个角色的责任可以由不同的人员分担，或者可以将多个角色分配给同一个人。

1.5.3.3.1 管理者，例如项目经理

- 对识别风险和执行措施是否可接受有决定权
- 指定前期工作负责人，FMEA 推进，并指定设计/过程工程师负责执行来自分析结果的措施
- 负责选择和分配资源，并确保在计划的项目时间内实施有效的风险管理
- FMEA 开发和维护的责任人和所有者
- 管理者责任还包括，通过不断的评审和消除障碍，为团队提供直接支持
- 负责预算

1.5.3.3.2 设计主管/工艺工程师（技术主管）

- 对 FMEA 内容负技术责任

- Preparation of the Business Case for technical and/or financial decisions
- Definition of elements, functions, requirements, and interfaces
- Focusing on the topics
- Procurement of the necessary documents and information
- Incorporating lessons learned

1.5.3.3.3 FMEA Facilitator

- Coordination and organization of the workflows in the FMEA
- Mitigation of conflicts
- Participation in the team formation
- Participation in the Preparation of the rough schedule
- Participation in the invitation to the 1st team meeting for the analysis phase
- Participation in the Preparation of the decision guidelines/criteria
- Development of Corporate or Product Line Examples for Rating Tables (Optional) with support from Design/Process Engineer
- Method competence (FMEA) and familiarization of participants in the FMEA method
- FMEA Software documentation competence (as necessary)
- Social skills, able to work in a team
- Competent moderator, ability to convince, organization and presentation skills
- Managing execution of the 7 steps of FMEA method
- If necessary, Preparation or wrap-up of FMEA meetings
- Moderation of the FMEA workgroup

NOTE: Any team member with the relevant competence and training may fulfill the role of facilitator.

1.5.3.3.4 Core Team Members

- Contribute knowledge from relevant product and process experience
- Contribute necessary information about the product or process that is the focus of the FMEA
- Contribution of existing experiences from previous FMEAs already known
- Participation in the execution of the 7 steps of FMEA
- Involvement in the Preparation of the Business Case
- Incorporating lessons learned

- 为技术/财务决策准备商业案例
- 定义要素、功能、要求和接口
- 关注项目
- 采购必要的文件和信息
- 吸取经验教训

1.5.3.3.3 FMEA 推进者

- FMEA 工作流程的协调和组织
- 缓解冲突
- 参与组建团队
- 参与编制粗略的时间表
- 参加分析阶段第一次团队会议的邀请
- 参与拟定决策准则/标准
- 在设计/工艺工程师的支持下，开发公司或生产线的评估表示例（可选）
- 方法能力（FMEA）以及使参与者熟悉 FMEA 方法
- FMEA 软件文件化能力（必要时）
- 社交能力，能够在团队中工作
- 具备调解、说服、组织和表达能力的主持人
- 管理 FMEA 7 步法的执行
- 如有必要，准备或总结 FMEA 会议
- 协调 FMEA 工作组的工作

注： 任何具有相关能力和培训经验的团队成员都可以担任推进者。

1.5.3.3.4 核心团队成员

- 提供相关产品和过程的相关经验知识
- 提供关于 FMEA 关注产品或过程的必要信息
- 提供现有 FMEA 已知经验
- 参与执行 FMEA 的 7 个步骤
- 参与编写商业案例
- 吸取经验教训

1.5.3.3.5 Extended Team Members / Experts

- Contribution of additional information about special topics
- Contribution of necessary information about the product or process that is the focus of the FMEA
- Involvement in the Preparation of the Business Case

1.5.4 FMEA Tasks

The 7-Step Overview provides the framework for the tasks and deliverables of the FMEA. In addition, the FMEA team should be prepared to review the results of their analysis with management and the customer, upon request.

The FMEA may also be audited by an internal auditor, customer auditor, or third-party registrar to ensure each task has been fulfilled.

1.5.5 FMEA Tools

There are numerous FMEA software packages that can be used to develop a DFMEA and PFMEA as well as follow up on actions. This software ranges from dedicated FMEA software to standard spreadsheets customized to develop the FMEA. Companies may develop their own in-house database solution or purchase commercial software. In any case, the FMEA team needs to have knowledge of how to use the FMEA software selected for their project as required by the company.

There are two views of FMEA examples shown in this manual. The software view depicts what the user sees when developing a FMEA using specialized software that utilized i.e. system element structure, function net, failure net, etc. The Form view depicts what the user sees when developing a FMEA in a spreadsheet.

Figures in this handbook include an example of how to develop an FMEA using either a Structure Tree or Form. In the case of using Structure Trees to develop elements, functions, and failures; a software view is also presented to show how the information may look when placed in documentation. In either case the 7-Step process is the same.

1.6 FMEA METHODOLOGY

The analyses for the Design FMEA, Process FMEA and Supplemental FMEA for Monitoring and System Response (FMEA-MSR) are each described completely in the following sections. Consequently, redundancies are unavoidable. For the user this has the advantage that they can refer directly to the Design FMEA and/or Process FMEA and/or FMEA-MSR chapter without referring to the content of the other chapters.

1.5.3.3.5 扩展团队成员 /专家

- 提供有关特殊项目的补充资料
- 提供关于 FMEA 关注产品和过程的必要信息
- 参与编写商业案例

1.5.4 FMEA 任务

"七步法"提供了 FMEA 的任务框架和交付成果。另外，FMEA 团队应按照要求准备好与管理层和顾客评审其分析结果。

FMEA 可由内审员、顾客审核员或第三方注册机构进行审核，以确保每个任务都按要求完成。

1.5.5 FMEA 工具

目前有许多 FMEA 软件包可用于开发设计 FMEA 和过程 FMEA 以及用于追踪措施。这些软件包括专用 FMEA 软件和为开发 FMEA 而定制的标准电子表格。公司可以开发自己的内部数据库解决方案或购买商业软件。无论是哪种情况，FMEA 团队成员都需要了解如何使用公司按照项目要求选择使用的 FMEA 软件。

本手册给出了两个 FMEA 视图的例子。软件视图描述了使用者在使用专业软件开发 FMEA 时会看到什么，即系统要素结构、功能网和失效网等。表格视图描述了使用者在电子表格中开发 FMEA 时会看到什么。

本手册中的图例包括如何使用结构树或电子表格开发 FMEA 的示例。在使用结构树来开发要素、功能和失效时，还会显示该信息在报告中的视图。无论哪种情况，七步法的过程都是一样的。

1.6 FMEA 方法

设计 FMEA、过程 FMEA 和监视及系统响应的补充 FMEA（FMEA-MSR）在下面章节中都各自有完整描述。因此，不可避免地会有些冗余。对于使用者而言，这也有一个好处，即他们可以直接参考设计 FMEA 和/或过程 FMEA 和/或监视及系统响应 FMEA，而无需参考其它章节的内容。

The FMEA process is carried out in seven steps.
These seven steps provide a systematic approach to perform a Failure Mode and Effects Analysis and serve as a record of the technical risk analysis.

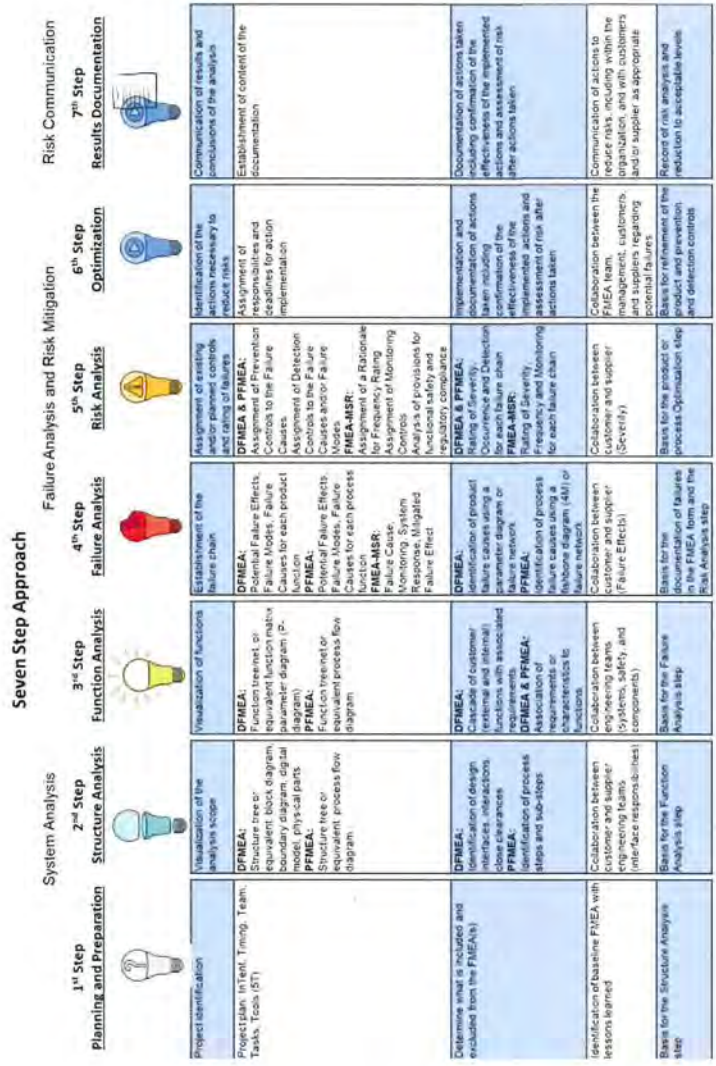


Figure 1.6-1 FMEA 7 Step Approach

FMEA 分七个步骤执行.

这七个步骤提供了执行失效模式及影响分析的系统方法，并作为技术风险分析的一个记录。

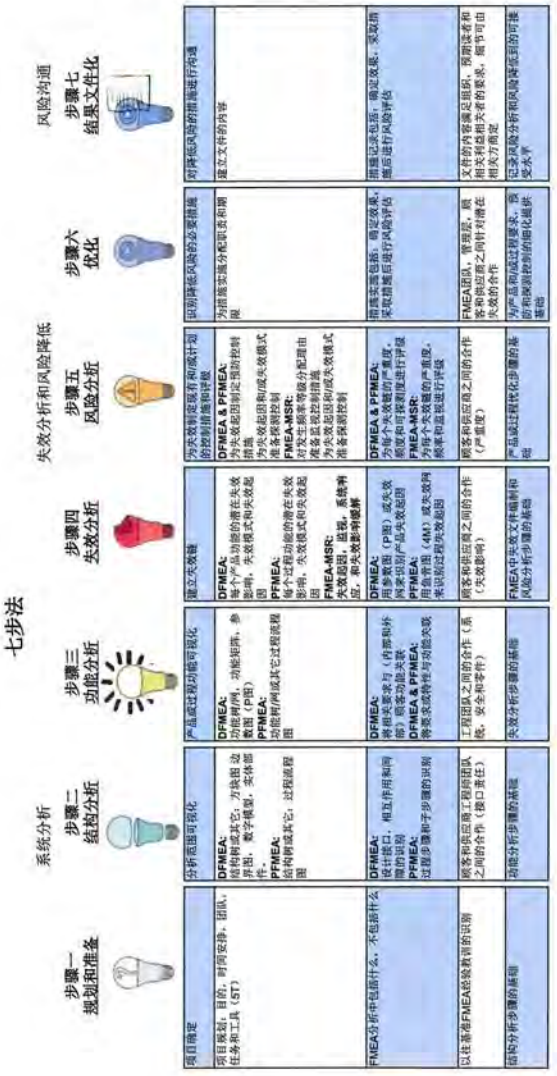


图 1.6-1 FMEA 七步法

2 EXECUTION OF THE DESIGN FMEA

2.1 Design FMEA 1st Step: Planning and Preparation

2.1.1 Purpose



The purpose of the Design FMEA Planning and Preparation Step is to define which FMEAs will be done for a project, and to define what is included and excluded in each FMEA based on the type of analysis being developed, i.e. system, subsystem or component.

The main objectives of Design FMEA Planning and Preparation are:

- Project identification
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: Determine what is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step

2.1.2 DFMEA Project Identification and Boundaries

DFMEA Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the DFMEAs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

Below are some basic questions that help identify DFMEA

projects.

- What is the customer buying from us?
- Are there new requirements?
- Does the customer or company require a DFMEA?
- Do we make the product and have design control?
- Do we buy the product and still have design control?
- Do we buy the product and do not have design control?
- Who is responsible for the interface design?
- Do we need a system, subsystem, component, or other level of analysis?

Answers to these questions and others defined by the company help create the list of DFMEA projects needed. The DFMEA project list assures consistent direction, commitment and focus.

The following may assist the team in defining DFMEA boundaries, as applicable:

- Legal Requirements

2 设计 FMEA 的执行

2.1 设计 FMEA 步骤一：规划和准备

2.1.1 目的

设计 FMEA"规划和准备"步骤的目的是确定项目将要执行的 FMEA 类型，并根据正在进行的分析类型（即系统、子系统或组件）定义每个 FMEA 类型中包含和不包含的内容。



设计 FMEA（DFMEA）"规划和准备"步骤的主要目标是:

- 项目确定
- 项目计划：目的、时间安排、团队、任务和工具（5T）
- 分析边界：分析中包括什么、不包括什么
- 利用以往的经验确认基准 FMEA
- 结构分析步骤的基础

2.1.2 DFMEA 项目确定和边界

DFMEA 项目确定包括明确了解需要评估的内容。这涉及到一个决策过程来确定顾客项目所需的 DFMEA。在分析中需要不包括和包括的内容同样重要。

以下基本问题可帮助确认 DFMEA 项目：

- 顾客要向我们购买什么？
- 是否有新要求？
- 顾客或公司是否需要 DFMEA？
- 我们是否制造产品、并拥有设计控制权？
- 我们是否购买产品、并拥有设计控制权？
- 我们是否购买产品、但不拥有设计控制权？
- 谁负责接口设计？
- 我们是否需要系统、子系统、组件或其他层面的分析？

对这些问题和公司定义的其他问题的回答有助于创建所需的设计 FMEA 项目清单，从而确保了方向、承诺和工作重点的一致性。

以下可有助于团队定义边界，适用于：

- 法律要求

- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary) from similar project
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products
- Error proofing requirements, Design for Manufacturability and Assembly (DFM/A)
- QFD Quality Function Deployment

The following may be considered in defining the scope of the DFMEA, as appropriate:

- Novelty of technology/ Degree of innovation
- Quality / Reliability History (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- Complexity of Design
- Safety of people and systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog & standard parts

2.1.3 DFMEA Project Plan

A plan for the execution of the DFMEA should be developed once the DFMEA project is known.

It is recommended that the 5T method (In Tent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The plan for the DFMEA helps the company be proactive in starting the DFMEA early. The DFMEA activities (7-step process) should be incorporated into the overall project plan.

2.1.4 Identification of the Baseline DFMEA

Part of the preparation for conducting the DFMEA is knowing what information is already available that can help the cross-functional team. This includes use of a foundation DFMEA (described in Section 1.3), similar product DFMEA, or product family DFMEA. The family DFMEA is a specialized foundation design FMEA for products that generally contain common or consistent product boundaries and related functions. For a new product in the family, the new project specific components and functions to completethe new product's DFMEA would be added to the family FMEA. The additions for the new product may be in the family DFMEA itself, or in a new document with reference to the original family or foundation DFMEA. If no baseline is available, then the team will develop a new DFMEA.

- 技术要求
- 顾客需要/需求/期望（外部和内部顾客）
- 要求规范
- 类似项目图表（方块图/边界图）
- 示意图、图纸和/或 3D 模型
- 物料清单、风险评估
- 类似产品曾用的 FMEA
- 防错要求、可制造性和可装配性设计（DFM/A）
- 质量功能展开

在界定 DFMEA 范围时，可酌情考虑以下方面：

- 技术新颖性/创新程度
- 质量/可靠性历史（内部、零公里、现场失效、类似产品的保修和保险索赔）
- 设计复杂性
- 人员和系统安全
- 网络物理系统（包括网络安全）
- 法律合规性
- 目录和标准零件

2.1.3 DFMEA 项目计划

确定设计 FMEA 项目后，应立即制定 DFMEA 的执行计划。

建议使用本手册第 1.5 节所述的 5T 方法（目的、时间安排、团队、任务、工具）。DFMEA 的计划有助于公司提前启动 DFMEA。DFMEA 活动（"七步法过程）应纳入总体项目计划。

2.1.4 确定基准 DFMEA

DFMEA 的部分准备工作包括了解哪些可用信息可以帮助跨职能团队，如基础 DFMEA（第 1.3 节中所述）、类似产品的 DFMEA 或同一产品系列的 DFMEA。系列 DFMEA 是一个 基础设计 FMEA 的具体化，用于那些包含共同或一致产品边界和相关功能的产品。对于同一个产品系列中的新产品，为完成该新产品 DFMEA 所需的新项目特定组件和功能将添加到家族 FMEA 中。新产品的添加要素可能来源于系列 DFMEA，也可能来源于参考系列 DFMEA 或 基础 DFMEA 的新文件。如果没有可用的基准，那么团队将开发一个新的 DFMEA。

2.1.5 DFMEA Header

During the Planning and Preparation Step, the header of the DFMEA document should be filled out. The header may be modified to meet the needs of the organization. The header includes some of the basic DFMEA scope information as follows:

Company Name: Name of Company Responsible for DFMEA

Engineering Location: Geographical Location

Customer Name: Name of Customer(s) or Product

Model Year / Program(s): Customer Application or Company Model /Style

Subject: Name of DFMEA Project (System, Subsystem and/or Component)

DFMEA Start Date: Start Date

DFMEA Revision Date: Latest Revision Date

Cross-Functional Team: Team Roster needed

DFMEA ID Number: Determined by Company

Design Responsibility: Name of DFMEA owner

Confidentiality Level: Business Use, Proprietary, Confidential

Example: Design Failure Mode and Effects Analysis (Design FMEA)

Planning and Preparation (Step 1)

Company Name:	Acme Automotive	Subject:	PX123 Upper Jacket		
Engineering Location:	Munich, Germany	DFMEA Start Date:	19-Mar-2018	DFMEA ID Number:	123456
Customer Name:	Jackson Industry	DFMEA Revision Date:	2S-Sep-2018	Design Responsibility:	S. Gray
Model Year(s) / Program(s):	2020 PX123	Cross-Functional Team:	See Team List	Confidentiality Level:	Confidential

Figure 2.1-1 Example of Completed DFMEA Header Planning and Preparation Step 1

2.1.6 Basis for Structure Analysis

The information gathered during Step 1 Planning and Preparation will be used to develop Step 2 Structure Analysis.

2.1.5 DFMEA 表头

在规划和准备阶段，DFMEA 文件的表头应该填写。表头可根据组织的需要修改。表头包含了一些基本的 DFMEA 范围的信息，如下：

公司名称：负责设计 FMEA 的公司的名称

工程地点：地理位置

顾客名称：顾客名称或产品名称

年型/项目：顾客应用或公司型号/风格

项目：设计 FMEA 项目的名称（系统、子系统和/或组件）

DFMEA 开始日期：开始的日期

DFMEA 修订日期：最新修订日期

跨职能团队：所需的团队成员名单

DFMEA ID 编号：由公司确定

设计责任人：DFMEA 所有者的姓名

保密级别：商业使用、专有、保密

示例：设计失效模式及影响分析（设计FMEA）					
规划与准备（步骤一）					
公司名称：	Acme Automotive	项目：	PX123 上部导管架		
工程地点：	德国慕尼黑	DFMEA开始日期：	2018年3月19日	DFMEA ID 编号：	123456
顾客名称：	Jackson Industry	DFMEA修订日期：	2018年9月25日	设计职责：	S. Gray
年型/项目	2020 PX123	跨职能团队：	见团队清单	保密级别：	保密

图 2.1-1 填好的 DFEMA 表头示例 （“规划和准备”步骤一）

2.1.6 结构分析的基础

在步骤一“规划和准备”中收集的信息将为步骤二“结构分析”做准备。

2.2 Design FMEA 2nd Step: Structure Analysis

2.2.1 Purpose



The purpose of Design Structure Analysis is to identify and breakdown the design into system, subsystem, and component, parts for technical risk analysis.

The main objectives of a Design Structure Analysis are:

- Visualization of the analysis scope
- Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts
- Identification of design interfaces, interactions, close clearances
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

2.2.2 System Structure

A system structure is comprised of System Elements. Depending on the scope of analysis, the system elements of a design structure can consist of a system, subsystems, assemblies, and components. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity. A system has a boundary separating it from other systems and the environment. Its relationship with the environment is defined by inputs and outputs. A system element is a distinct component of a functional item, not a function, a requirement or a feature.

2.2.3 Define the Customer

There are two major customers to be considered in the FMEA analysis:

- END USER The individual who uses a product after it has been fully developed and marketed.
- ASSEMBLY and MANUFACTURING: the locations where manufacturing operations (i.e., powertrain, stamping and fabricating) and vehicle/ product assembly and production material processing takes place. Addressing the interfaces between the product and its assembly process is critical to an effective FMEA analysis. This may be any subsequent or downstream operation or a next Tier manufacturing process.

2.2 DFMEA 步骤二：结构分析

2.2.1 目的



设计结构分析的目的是将设计识别和分解为系统、子系统、组件和零件，以便进行技术风险分析。

设计结构分析的主要目标是：

- 分析范围的可视化
- 结构树或其它：方块图、边界图、数字模型、实体零件
- 设计接口、相互作用和间隙的识别
- 顾客和供应商工程团队之间的协作（接口职责）
- 功能分析步骤的基础

2.2.2 系统结构

系统结构由系统要素组成。根据分析的范围，设计结构的系统要素可以由系统、子系统、装配件和组件构成。复杂的结构可以分为若干子结构（工作包）或不同层次的方块图，并根据组织起因分别进行分析，或确保足够清楚。系统有一个边界，将自身与其他系统和环境分开。其与环境的关系由输入和输出决定。系统要素是功能项目的独特组件，而不是功能、要求或特性。

2.2.3 定义顾客

在 FMEA 分析中有两种主要顾客需要考虑：

- 最终用户：在产品充分开发和销售后使用该产品的个人。
- 装配和制造作：制造作业（如动力总成、冲压和制造）以及整车/产品总装和生产材料加工的地点。处理好产品与其装配过程之间的接口对于有效的 FMEA 分析至关重要。这可能是任何后续或下游作业，或是下一级的制造过程。

Knowledge of these customers can help to define the functions, requirements and specifications more robustly as well as aid in determining the effects of related failure modes.

NOTE: Reference the NOTE in section 2.4.4 for cases when the end user is not known.

2.2.4 Visualize System Structure

A visualization of the system structure helps the DFMEA team develop the structural analysis. There are various tools which may be used by the team to accomplish this. Two methods commonly used are described in the sections below:

- Block/Boundary Diagrams
- Structure Tree

2.2.4.1 Block/Boundary Diagram

Block/Boundary Diagrams are useful tools that depict the system under consideration; and its interfaces with adjacent systems, the environment and the customer. The diagram is a graphic representation that provides guidelines for structured brainstorming and facilitates the analysis of system interfaces as a foundation for a Design FMEA. The diagram below shows the physical and logical relationships between the components of the product. It indicates the interaction of components and subsystems within the scope of the design as well as those interfaces to the product Customer, Manufacturing, Service, Shipping, etc. The diagram identifies persons and things that the design interacts with during its useful life. The Boundary Diagram can be used to identify the Focus Elements to be assessed in the Structure Analysis and Function Analysis.

The diagram may be in the form of boxes connected by lines, with each box corresponding to a major component of the product. The lines correspond with how the product components are related to, or interface with each other; with arrows at the end point(s) to indicate the direction of flow. Interfaces between elements in the Boundary Diagram can be included as Focus Elements in the Structure and Function Analysis Structure Tree.

There are different approaches and formats to the construction of a Block/Boundary Diagram, which are determined by the organization. In this handbook, the terms "block diagram" and "boundary diagram" are used interchangeably. However, the Boundary Diagram tends to be more comprehensive due to the inclusion of external influences and system interactions.

In the context of the DFMEA, Block/Boundary Diagrams define the analysis scope and responsibility and provides guidelines for structured brainstorming. The scope of analysis is defined by the boundaries of the system; however, interfaces with external factors/systems are to be addressed.

了解这些顾客有助于更好地定义功能、要求和规范，并有助于确定相关失效模式的影响。

> 注：在不知道最终用户的情况下，参考第 2.4.4 节中的说明。

2.2.4 系统结构可视化

系统结构的可视化有助于 DFMEA 团队进行结构分析。团队可以使用各种工具来实现这一点。以下章节中介绍了常用的两种方法：

- 方块图/边界图
- 结构树

2.2.4.1 方块图/边界图

方块图/边界图是一种有用的工具，用于描述考虑中的系统及其与相邻系统、环境和顾客的接口。它是一种图表展示法，为结构化的头脑风暴提供指导，并有助于分析系统接口，从而为设计 FMEA 打下基础。下图显示了产品组件之间的物理和逻辑关系，表示了设计范围内组件和子系统的交互作用、以及与产品顾客、制造、服务、运输等的接口。该图还标识了设计在其使用寿命期间与之交互的人员和事物。边界图可以用来识别结构分析和功能分析中需要评估的关注要素。

图表可能以直线连接的方框形式出现，每个方框对应产品的一个主要组件。直线对应产品组件之间的关系或相互接口，直线的箭头表示流动方向。边界图中要素之间的接口可以作为关注要素被纳入结构和功能分析结构树中。

构建方块图/边界图的方法和格式有很多，可由组织自己决定。在本手册中，术语"方块图"和"边界图"交替使用。然而，由于边界图包含了外部影响和系统交互作用，因此更为全面。

在 DFMEA 语境下，方块图/边界图定义了分析范围和责任，并为结构化的头脑风暴提供了指导。分析范围由系统的边界来确定；但是，需要解决与外部因素/系统的接口问题。

- Defines scope of analysis (helps to identify potential team members)
- Identifies internal and external interfaces
- Enables application of system, sub-system, and component hierarchy

When correctly constructed, Block/Boundary Diagrams provide detailed information to the P-Diagram, and the FMEA. Although Block/Boundary diagrams can be constructed to any level of detail, it is important to identify the major elements, understand how they interact with each other, and how they may interact with outside systems.

Block/Boundary Diagrams are steadily refined as the design matures.

The steps involved in completing a Block/Boundary Diagram may be described as follows:

a. Describe components and features
   - Naming the parts and features helps alignment within the team, particularly when features have "nicknames'.
   - All system components & interfacing components shown.

b. Reorganize blocks to show linkages
   - Solid line for direct contact
   - Dashed line for indirect interfaces, i.e. clearances or relative motion
   - Arrows indicate direction
   - All energy flows/ signal or force transfers identified.

c. Describe connections

   Consider all types of interfaces, both desired and undesired:

   P----Physically touching (welded, bolted, clamped, etc.)

   E----Energy transfer (Torque (Nm), heat, etc.)

   I -----Information transfer (ECU, sensors, signals, etc.)

   M ---Material exchange (Cooling fluid, exhaust gases, etc.)

d. Add interfacing systems and inputs (persons and things)

   The following should be included:
   - Adjacent systems – including systems that are not physically touching your system but may interact with it, require clearance, involve motion, or thermal exposure.

- 定义分析范围（有助于确定潜在的团队成员）
- 确定内部和外部接口
- 使系统、子系统和组件层次得以应用

正确构建的方块图/边界图可为参数图（P 图）和 FMEA 提供详细信息。尽管方块图/边界图的详细程度可以不同，但要标识出主要要素，并了解它们如何相互作用，以及它们如何与外部系统相互作用，这一点很重要。

方块图/边界图随着设计的成熟而不断完善。

方块图/边界图的制作可包括以下步骤：

a. 描述组件和特性
   - 给零件和特性命名有助于团队内部保持一致，特别是当一些特性有“别名”时。
   - 显示所有的系统组件和接口组件。

b. 调整方块以显示相互间的联系
   - 用实线表示直接接触
   - 用虚线表示间接接口，即间隙或相对运动
   - 用箭头表示方向
   - 标识出所有的能量流/信号或力传递

c. 描述连接

   考虑各种类型的接口，包括期望的和不期望的：

   P----物理连接（焊接、螺栓紧固、夹紧等）

   E----能量传递（扭矩（Nm）、热量等）

   I ----信息传递（ECU、传感器、信号等）

   M ----物料交换（冷却液、废气等）

d. 增加接口系统和输入（人员和物件）

   应包括以下方面：
   - 相邻系统—这些系统包括物理上与您的系统不接触，但可能会与您的系统有交互作用，且需要间隙、涉及运动或热辐射的系统

- The customer/end user
- Arrows indicate direction

e. Define the boundary (What parts are within the span of control of the team? What is new or modified?)

   Only parts designed or controlled by the team are inside the boundary. The blocks within the boundary diagram are one level lower than the level being analyzed. Blocks within the boundary may be marked to indicate items that are not part of the analysis.

f. Add relevant details to identify the diagram.

   - System, program, and team identification
   - Key to any colors or line styles used to identify different types of interactions
   - Date and revision level

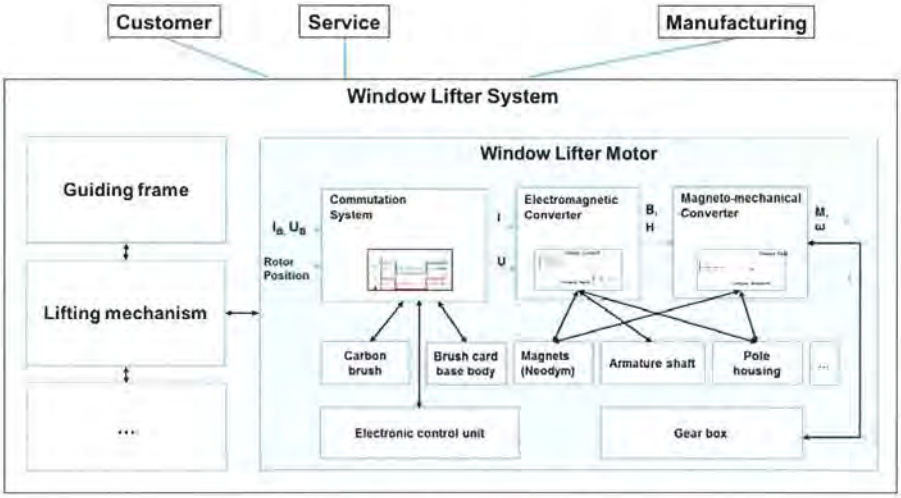


Figure 2.2-1 Example of Block/Boundary Diagram

- 顾客/最终用户
- 箭头表示方向

e. 确定边界（团队控制范围内有哪些零件？哪些是新的或修改过的？）

只有团队设计或控制的零件才放在边界内。边界图中的方块比正在分析的层次低一级。可以对边界图中的方块做标记，以显示分析范围之外的零件。

f. 增加相关细节以便确定图表

- 系统、项目和团队确定
- 使用不同颜色或线来识别不同类型的交互作用
- 日期和修改等级

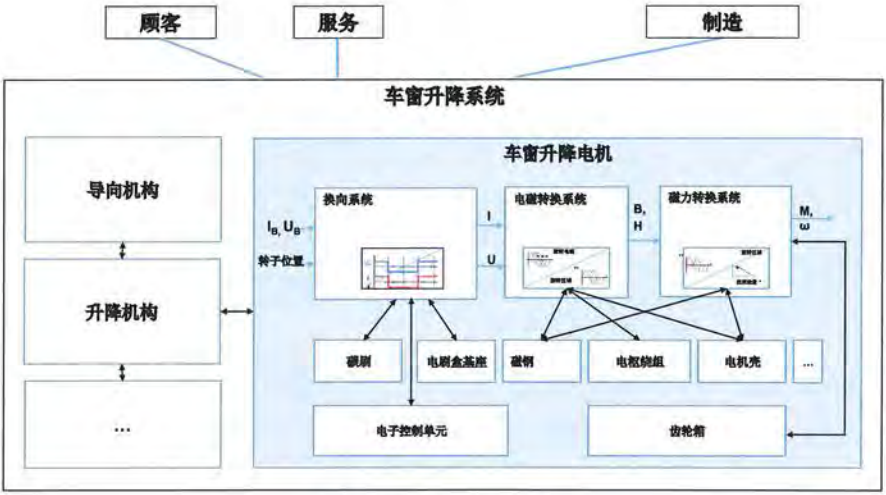


图 2.2-1 方块图/边界图示例

2.2.4.2 Interface Analysis

An interface analysis describes the interactions between elements of a system.

There are five primary types of interfaces:

- Physical connection (i.e. brackets, bolts, clamps and various types of connectors)
- Material exchange (i.e. compressed air, hydraulic fluids or any other fluid or material exchange)
- Energy transfer (i.e. heat transfer, friction or motion transfer such as chain links or gears)
- Data exchange (i.e. computer inputs or outputs, wiring harnesses, electrical signals or any other types of information exchange, cyber security items)
- Human-Machine (i.e. controls, switches, mirrors, displays, warnings, seating, entry/exit)

Another type of interface may be described as a physical clearance between parts, where there is no physical connection. Clearances may be static and/ or dynamic.

Consider the interfaces between subsystems and components in addition to the content of the sub-systems and components themselves.

An interface analysis documents the nature (strong/weak/none, beneficial/harmful) and type of relationships (Physical, Energy, Information, or Material Exchange) that occur at all internal and external interfaces graphically displayed in the Block/Boundary Diagram.

Information from an interface analysis provides valuable input to a Design FMEA, such as the primary functions or interface functions to be analyzed with potential causes/mechanisms of failure due to effects from neighboring systems and environments. Interface analysis also provides input to the P-Diagram on ideal functions and noise factors.

2.2.4.3 Structure Trees

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

The clearly structured illustration of the complete system is thereby guaranteed by the fact that each system element exists only once to prevent redundancy.

The structures arranged under each System Element are independent sub-structures (see figure 2.2-2).

2.2.4.2 接口分析

接口分析描述系统要素之间的交互作用。

接口有五种主要类型:

- 物理连接（例如：支架、螺栓紧固、夹紧和其各种连接）
- 材料交换（例如：气压、液压油或任何其它液体或物料的交换）
- 能量传递（例如：热量传递、摩擦或运动传递，如链条或齿轮）
- 数据交换（例如：计算机输入或输出、线束、电信号或任何其他类型的信息交换、网络安全项目）
- 人-机（例如控制、开关、镜子、显示器、警告、座位、出入口）

另一种类型的接口可以描述为没有物理连接的零件之间的物理间隙，间隙可以是静态和/或动态的。

除了子系统和组件本身的内容外，还应考虑子系统和组件之间的接口。

接口分析将方块图/边界图中显示的所有内、外部接口发生的关系性质（强/弱/无、有益/有害）和类型（物理、能量、信息或材料交换）形成文件。

接口分析中的信息可为设计 FMEA 提供有价值的输入，例如主要功能或接口功能，这些功能将与相邻系统和环境影响导致的潜在失效起因/机理一起进行分析。接口分析还为参数图（P 图）提供理想功能和噪音因素的输入。

2.2.4.3 结构树

结构树按层次排列系统要素，并通过结构化连接展示依赖关系。

为了防止冗余，每个系统要素只存在一次，这就保证了整个系统结构清晰明了。

每个系统要素下排列的结构都是独立的子结构（见图 2.2-2）。

The interactions between System Elements may be described later as functions and represented by function nets (see Step 3 Function Analysis).

There is always a system element present, even if it is only derived from the function and cannot yet be specified more clearly.

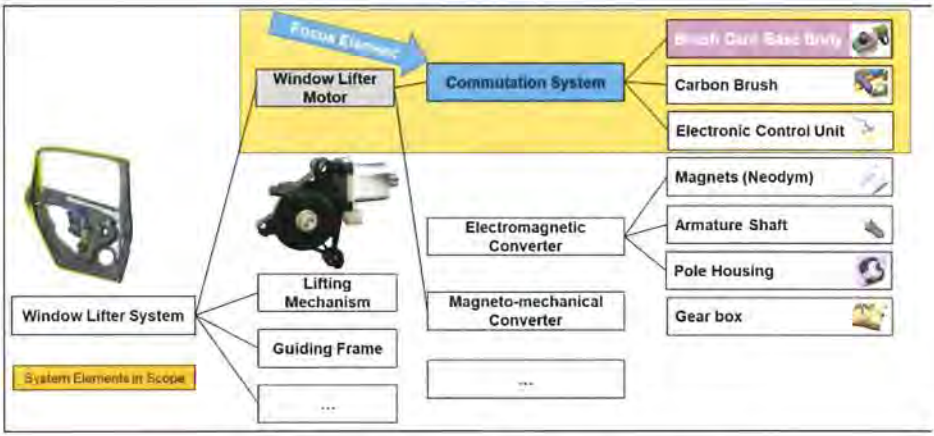


Figure 2.2-2 Example of Structure Analysis Structure Tree

The system structure can be created in the Structure Analysis section:

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter Motor	Commutation System	Brush Card Base Body

Figure 2.2-3 Example of Structure Analysis Form

1. Next Higher Level:

   The highest level of integration within the scope of analysis.

2. Focus Element:

   The element in focus. This is the item that is topic of consideration of the failure chain.

系统要素之间的交互作用稍后可以描述为功能并由功能网表示（见步骤三“功能分析”）。

结构树中总是会存在一个系统要素，即使它只是从功能派生出来，而且还不能清楚地定义它到底是什么。

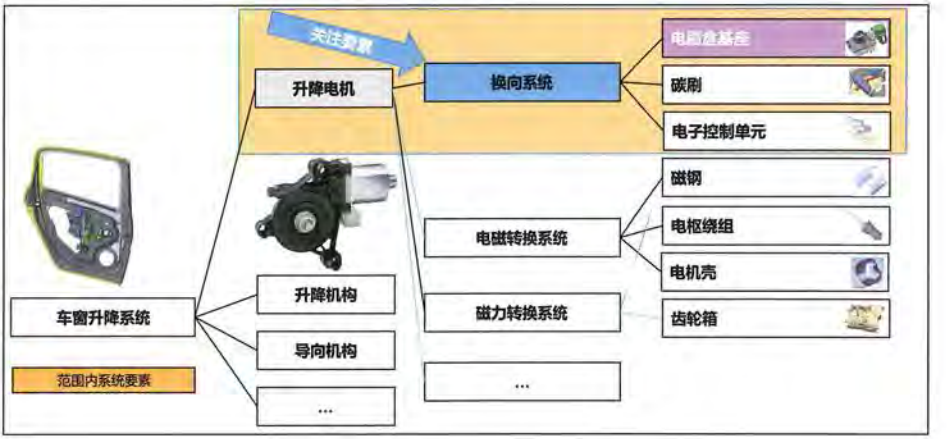


图 2.2-2 结构分析结构树示例

可以在结构分析部分创建系统结构：

结构分析 (步骤二)		
1. 上一较高级别	2. 关注要素	3. 下一较低级别或特性类型
车窗升降电机	换向系统	电刷盒基座

图 2.2-3 结构分析表格示例

1. 上一较高级别：
   分析范围内最高集成层级。
2. 关注要素：
   受关注的要素，也是考虑失效链的主题项目。

3. Next Lower Level or Characteristic Type:

   The element that is the next level down the structure from the focus element.

2.2.5 Collaboration between Customer and Supplier

The output of the Structure Analysis (visualization of the design and its interfaces) provides a tool for collaboration between customers and suppliers during technical reviews of the design and/or DFMEA project.

2.2.6 Basis for Function Analysis

The information defined during Step 2 Structure Analysis will be used to develop Step 3 Function Analysis. If design elements (items) are missing from the Structure Analysis they will also be missing from the Function Analysis.

2.3 Design FMEA 3rd Step: Function Analysis

2.3.1 Purpose



The purpose of the Design Function Analysis is to ensure that the functions specified by requirements/ specifications are appropriately allocated to the system elements. Regardless of the tool used to generate the DFMEA, it is critical that the analysis is written in functional terms.

The main objectives of a Design Function Analysis are:

- Visualization of product or process functions
- Development of function tree/net or function analysis form and parameter diagram (P-diagram)
- Cascade of customer (external and internal) functions with associated requirements
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

The structure provides the basis so that each System Element may be individually analyzed with regard to its functions and requirements.

For this, comprehensive knowledge of the system and the operating conditions and environmental conditions of the system are necessary, for example heat, cold, dust, splash water, salt, icing, vibrations, electrical failures, etc.

3. 下一较低级别或特性类型：
   结构中处于关注要素下一低级别的要素

2.2.5 顾客和供应商之间的协作

结构分析的输出（设计及其接口的可视化）为顾客和供应商在设计和/或DFMEA项目技术评审期间的协作提供了工具。

2.2.6 功能分析的基础

步骤二"结构分析"中定义的信息将被用于步骤三"功能分析"。结构分析中缺少的设计要素（项目），在功能分析中也会缺少。

2.3 设计 FMEA 步骤三：功能分析

2.3.1 目的



设计功能分析的目的是确保要求/规范中规定的功能被适当地分配给系统要素。无论DFMEA使用什么工具创建，其分析都要用功能术语编写，这一点至关重要。

设计功能分析的主要目标是：

- 产品或过程功能可视化
- 制作功能树/网或者功能分析表格和参数图（P图）
- 将相关要求与顾客（内部和外部）功能关联
- 将要求或特性与功能关联
- 工程团队（系统、安全和组件）之间的协作
- 失效分析步骤的基础

该结构提供了基础，以便能够就每个系统要素的功能和要求对其进行单独分析。

为此，有必要全面了解系统及其运行条件和环境，如热、冷、灰尘、溅水、盐、冰、振动、电气故障等。

2.3.2 Function

A function describes what the item/ system element is intended to do.

A function is to be assigned to a system element. Also a structure element can contain multiple functions.

The description of a function needs to be clear.

The recommended phrase format is to use an "action verb" followed by a "noun" to describe a measurable function.

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: deliver power, contain fluid, control speed, transfer heat, color black.

Functions describe the relationship between the input and output of an item/ system element with the aim of fulfilling a task.

Note: A component (i.e. a part or item in a part list) may have a purpose/function where there is no input/output. Examples such as a seal, grease, clip, bracket, housing, connector, flux, etc. have functions and requirements including material, shape, thickness, etc.

In addition to the primary functions of an item, other functions that may be evaluated include secondary functions such as interface functions, diagnostic functions, and serviceability functions. (See figure 2.3-1)

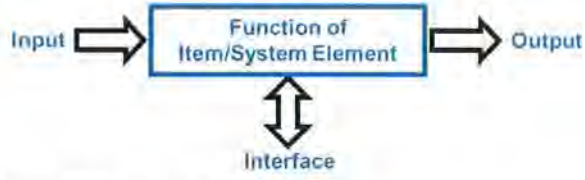


Figure 2.3-1 Input/Interface/Output Flow

2.3.3 Requirements

ISO 9000 defines a requirement as a need or expectation that a particular design, product or process aims to satisfy.

Requirements are divided into two groups: functional requirements and non-functional requirements.

A functional requirement is a criterion by which the intended performance of the function is judged or measured (i.e. material stiffness).

2.3.2 功能

功能描述了项目/系统要素的预期用途。

一个功能被分配给一个系统要素，一个结构要素也可以包含多个功能。

功能的描述需清晰准确。

推荐的短语格式为：一个"行为动词"后加一个"名词"，表示可测量的功能。

功能应该是"现在时态"，并使用动词的基本形式（交付、包含、控制、组装、传输）。

例如：传输动力、包含液体、控制速度、传递热量、标记黑色。

功能描述了一个项目/系统要素的输入和输出之间的关系，目的是完成一个任务。

注： 一个组件（即零件清单中的零件或项目）在没有输入/输出的情况下，也可能有一个目的/功能。例如密封件、润滑脂、夹具、支架、外壳、连接件、焊剂等都有功能和要求，如材料、形状和厚度。

一个项目除了其主要功能外，可以评估的其它功能包括接口功能、诊断功能和可服务性功能等辅助功能（见图 2.3-1）。

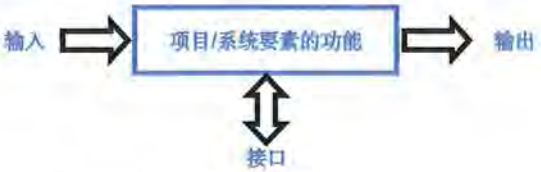


图 2.3-1 输入/接口/输出流程

2.3.3 要求

ISO 9000 将要求定义为一个特定设计、产品或过程需要满足的需求或期望。

要求可分为两类：功能性要求和非功能性要求。

功能性要求是判断或测量功能预期性能的标准（如材料硬度）。

A non-functional requirement is a limitation on the freedom for design decision (i.e. temperature range).

Requirements may be derived from various sources, external and internal, these could be:

Legal requirements:

- Environmentally friendly product design, suitable for recycling, safe in the event of potential misuse by the operator, non- flammable, etc.

Industry Norms and Standards:

- ISO 9001, VDA Volume 6 Part 3, Process audit, SAE J, etc. (i.e. ISO 26262 Functional Safety, SAE J3061 Cyber security)

Customer Requirements:

- Explicit (i.e. in customer specification) and implicit (i.e. freedom from prohibited materials) – under all specified conditions

Internal Requirements:

- Product Specific (i.e. Requirements Specifications, manufacturability, suitability for testing, compatibility with other existing products, reusability, cleanliness, generation, entry and spreading of particles)

Product Characteristics:

- A distinguishing feature (or quantifiable attribute) of a product such as a journal diameter or surface finish.

2.3.4 Parameter Diagram (P-Diagram)

Parameters are considered to be attributes of the behavior of a function. A Parameter (P) Diagram is a graphical representation of the environment in which an item exists. A P-Diagram includes factors which influence the transfer function between inputs and outputs, focusing on design decisions necessary to optimize output.

A P-Diagram is used to characterize the behavior of a system or component in the context of a single function. P-Diagrams are not required for all functions. Teams should focus on a few key functions affected by new conditions and those with history of robustness issues in previous applications. More than one P- Diagram may be needed in order to illustrate the function(s) of the system or component that are of concern to the FMEA Team.

The complete functional description forms the basis for subsequent failure analysis and risk mitigation.

A P-Diagram focuses on achievement of function. It clearly identifies all influences on that function including what can be controlled (Control Factors), and what cannot reasonably be controlled (Noise Factors).

非功能性要求是对设计决策自由度的限制（如温度范围）。

要求可以来自内部和外部的各种来源，它们可能是：

法律要求：

- 环境友好型产品设计、适合回收利用、操作者不当使用时仍能保持安全、不易燃等。

行业规范和标准：

- ISO 9001、VDA6.3 过程审核、SAE J 等（如 ISO 26262 功能安全、SAE J3061 网络安全）

顾客要求：

- 明确要求 （如顾客规范）和隐含要求（如无违禁材料） – 在所有规定的条件下

内部要求：

- 特定产品的要求（如：要求规范、可制造性、测试应用性、与其它现有产品的兼容性、可重复使用性、清洁性、清洁度、颗粒物的进入和扩散性）

产品特性：

- 产品特性指产品的显著特征（或可量化的属性），如轴的直径、表面光洁度

2.3.4 参数图（P-图）

参数是功能行为的属性。参数图（P-图）是一个项目所在环境的图表展示。参数图（P 图）包括影响输入和输出之间传递功能的因素，专注于优化输出所需的设计决策。

参数图（P 图）用于描述单个功能语境下系统或组件的行为特点。并非所有功能都需要参数图（P 图）。团队应关注于受新条件影响的几个关键功能、以及那些在以前的应用中具有稳健性历史问题的功能。可能需要一个以上的参数图（P 图），以便说明 FMEA 团队关注的系统或组件的功能。

完整的功能描述能够为后续失效分析和风险缓解提供基础。

参数图（P 图）专注于功能的实现。它可以清楚地识别该功能的所有影响因素，包括可以控制的因素（控制因素）和不能适当控制的因素（噪音因素）。

The P-Diagram, completed for specific Ideal Functions, assists in the identification of:

- Factors, levels, responses and signals necessary for system optimization
- Functions which are inputs to the DFMEA
- Control and Noise factors which could affect functional performance
- Unintended system outputs (Diverted Outputs)

Information gained through developing a P-Diagram provides input to the test plan.

Referring to Figure 2.3-2 below, the output (grey area) of the Item/ System Element often deviates/varies from the desired behavior (straight line). The control factors act on the design to achieve as close as practical to the desired behavior.

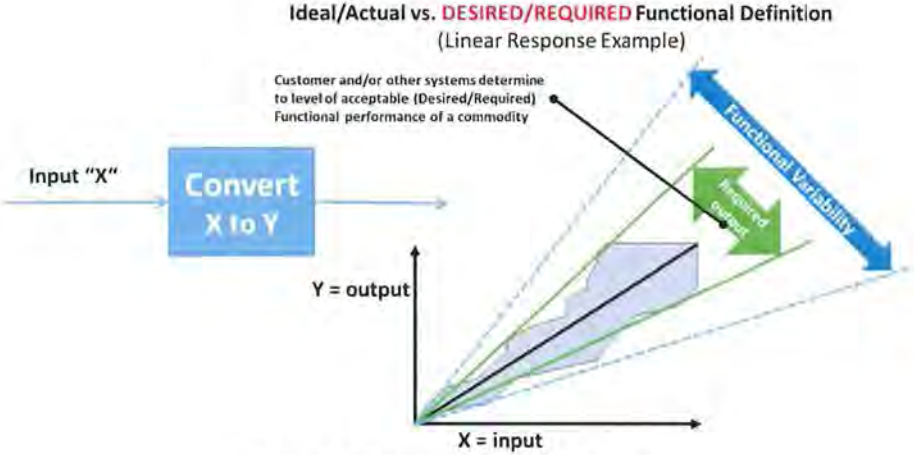


Figure 2.3-2 Example of system behavior

A Parameter Diagram consists of dynamic inputs (including signals), factors that could affect system performance (control and noise), sources of variation, and outputs (intended outputs and unintended/diverted outputs).

The following is an example of a Parameter Diagram which is used to assess the influences on a function of a product includes:

针对特定理想功能完成的参数图（P 图）有助于确认以下各项：

- 系统优化所需的因素、级别、响应和信号
- 作为设计 FMEA 输入的功能
- 可能影响功能性能的控制和噪音因素
- 非预期系统输出（转向输出）

通过创建参数图（P 图）获得的信息为测试计划提供了输入。

参考下文中的图 2.3-2，项目/系统要素的输出（灰域）经常偏离/相对于期望行为的变差（直线）。控制因素作用于设计，以尽可能接近期望的行为。

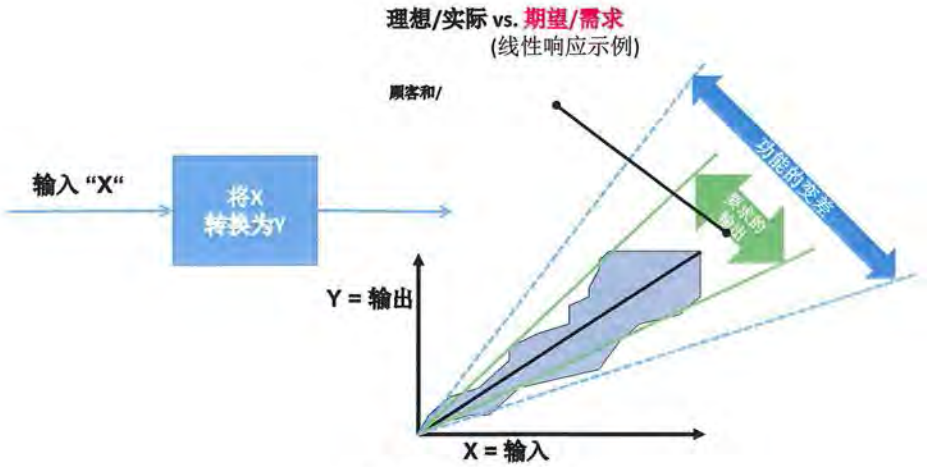


图 2.3-2 系统行为示例

参数图由动态输入（包括信号）、可能影响系统性能的因素（控制和噪音）、变差源和输出（预期输出和非预期/偏离输出）组成。

以下是参数图的示例，用以评估对产品功能的影响：

Input (What you want to put in to get the desired result) is a description of the sources required for fulfilling the system functionality.

Function (What you want to happen) is described in a Parameter Diagram with an active verb followed by a measurable noun in the present tense and associated with requirements.

Functional Requirements (What you need to make the function happen) are related to the performance of a function

Control Factors (What you can do to make it happen) which can be adjusted to make the design more insensitive to noise (more robust) is identified. One type of Control Factor is a Signal Factor. Signal Factors are adjustment factors, set directly or indirectly by a user of a system, that proportionally change the system response (i.e., brake pedal movement changes stopping distance). Only dynamic systems utilize signal factors. Systems without signal factors are called static systems.

Non-Functional Requirements (What you need beside the functional requirements) which limit the design option.

Intended Output (What you want from the system) are ideal, intended functional outputs whose magnitude may (dynamic system) or may not (static system) be linearly proportional to a signal factor (i.e., low beam activation for a headlamp, stopping distance as a function of brake pedal movement).

Unintended Output (What you don't want from the system) are malfunctioning behaviors or unintended system outputs that divert system performance from the ideal intended function. For example, energy associated with a brake system is ideally transformed into friction. Heat, noise and vibration are examples of brake energy diverted outputs. Diverted Outputs may be losses to thermal radiation, vibration, electrical resistance, flow restriction, etc.

Noise Factors (What interferes with achieving the desired output) are parameters which represent potentially significant sources of variation for the system response and cannot be controlled or are not practical to control from the perspective of the engineer. Noises are described in physical units.

Noise factors are categorized as follows:

- Piece to Piece Variation
  (in a component and interference between components)
- Change Over Time
  (aging over life time, i.e. mileage, aging, wear)
- Customer Usage
  (use out of desired spec.)
- External Environment
  (conditions during customer usage, i.e. road type, weather)

输入（您为取得期望结果而输入的内容）是对实现系统功能所需的信息源的描述。

功能（您想要发生的情形）在参数图中描述，使用现在时态，主动动词后加上一个可测量的名词，并与需求相关。

功能要求（实现功能所需的要求）与功能的性能相关。

控制因素（您为达到期望效果可以做什么）被识别出来。控制因素可以调整，以使设计对噪音更不敏感（更稳健）。信号因素是控制因素的一种，它是由系统用户直接或间接设置的调整因素，可适当地改变系统响应（即，制动踏板的移动改变刹车距离）。只有动态系统才利用信号因素。没有信号因素的系统称为静态系统。

非功能性要求（您需要的除功能性要求以外的要求）可以限制设计选择。

预期输出（您希望从系统获得的输出）是理想的、预期的功能输出，其量级可能会（动态系统）或可能不会（静态系统）与信号因素成线性比例（如，前照灯的近光启动、制动踏板移动导致的刹车距离）。

非预期输出（您不希望从系统中获得的输出）指故障行为或意外的系统输出，它们使得系统性能从理想的预期功能偏离。例如，与制动系统相关的能量理想地转化为摩擦。热量、噪音和振动是制动能量的非预期输出。转向输出可能会对热辐射、振动、电阻、流量限制造成损失。

噪音因素（妨碍获得期望输出的因素）是指代表系统响应潜在的显著变化源的参数，从工程师的角度来看，这些参数无法控制或要控制它们不切实际。噪音以物理单位描述。

噪音因素分为以下几类：

- 组件间的变化
  （在一个组件中，以及组件之间的相互干扰）
- 随着时间变化
  （随着使用寿命增加不断老化，如里程、老化和磨损）
- 顾客使用
  （超出预期规范的使用）
- 外部环境
  （顾客使用时的环境，例如道路状况、天气等）

- System Interactions

  (interference between other systems)

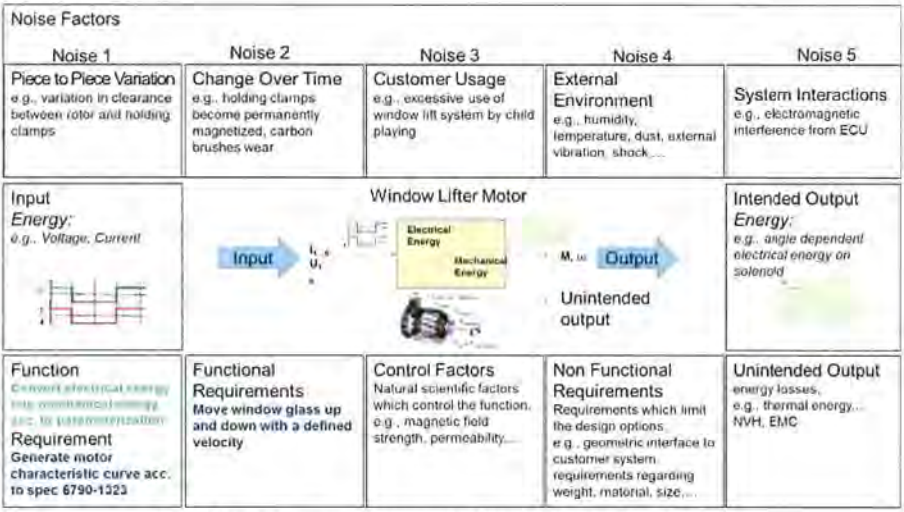


Figure 2.3-3 Example of Parameter Diagram with Electrical Motor

2.3.5 Function Analysis

The interactions of the functions of several System Elements are to be demonstrated, for example as a function tree/network, or using the DFMEA form. The focus of the analysis cascades from OEM to Tier 1 supplier to Tier N supplier.

The purpose of creating a function tree/network or functional matrix is to incorporate the technical dependency between the functions. Therefore, it subsequently supports the visualization of the failure dependencies. When there is a functional relationship between hierarchically linked functions, then there is a potential relationship between the associated failures. Otherwise, if there is no functional relationship between hierarchically linked functions, there will also be no potential relationship between the associated failures.

For the Preparation of the function tree/ network, the functions that are involved need to be examined. Sub-functions enable the performance of an overall function. All sub-functions are linked logically with each other in the function structure (Boolean AND- relationships).

- 系统交互作用

  （与其它系统之间的相互干扰）

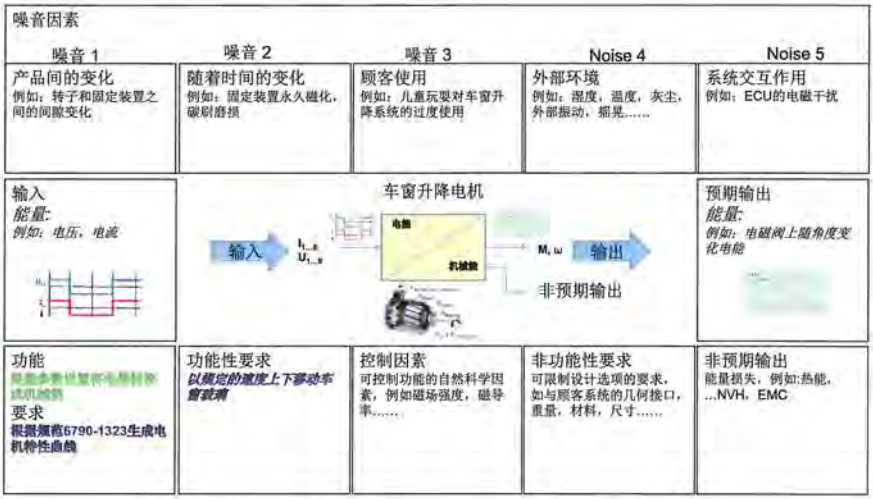


图 2.3-3 电机参数图示例

2.3.5 功能分析

应利用功能树/网或DFMEA表格展示若干系统要素功能之间的交互作用。分析的重点从 OEM 到一级供应商再到 N 级供应商。

创建功能树/网或功能矩阵的目的是将功能之间的技术依赖关系进行整合。因此，它在后期将支持失效依赖关系的可视化。当按层次连接的功能之间存在功能关系时，相关失效之间就会存在潜在关系。否则，如果按层次连接的功能之间不存在功能关系，那么相关失效之间也将不存在潜在关系。

为了创建功能树/网，必须检查所涉及的功能。子功能使整体功能得以执行。所有子功能在功能结构（布林逻辑 AND 关系）中按照逻辑相互连接。

A function structure becomes more detailed from top down. The lower level function describes how the higher level function is to be fulfilled. For the logical linking of a function structure, it is helpful to ask:

- "How is the higher level function enabled by lower level functions?" (Top-Down) and
- "Why is the lower level function needed?" (Bottom-Up).

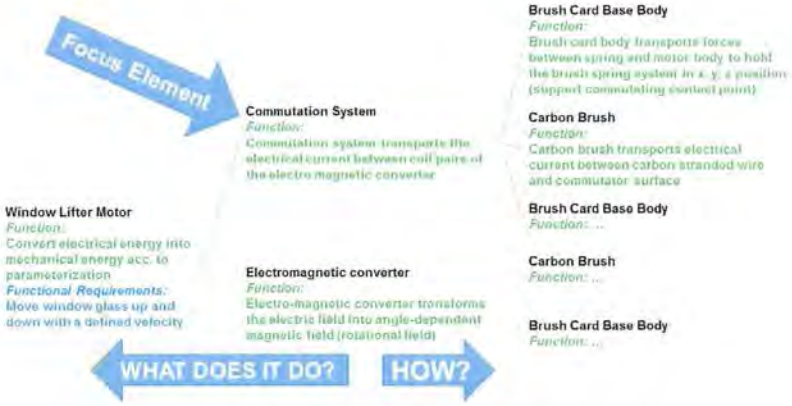


Figure 2.3-4 Example of Function Analysis Structure Tree

功能结构自上至下逐渐详细，较低级别功能描述了较高级别功能是如何被满足的。以下几个问题有助于功能结构符合逻辑地连接：

- “较低级别功能如何使得较高级别功能生效?”（自上而下）以及
- “为什么需要较低级别功能?”（自下而上）

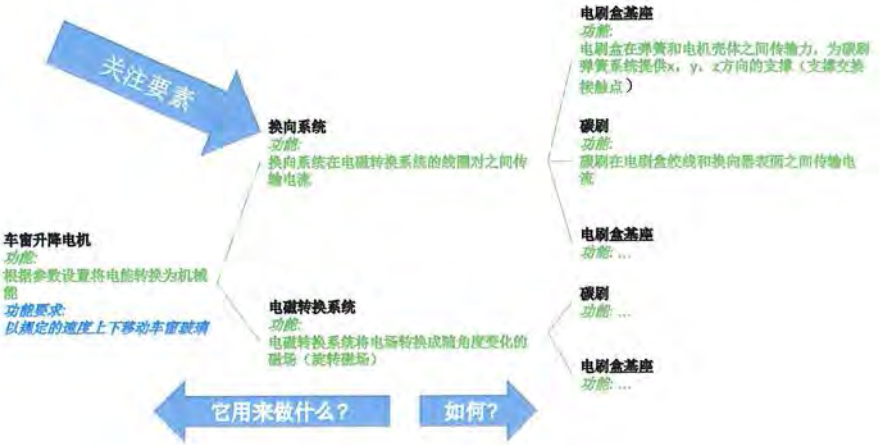


图 2.3-4 功能分析结构树示例

The function structure can be created in the Functional Analysis section:

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Convert electrical energy into mechanical energy according to parameterization	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)

Figure 2.3-5 Example of Function Analysis Form

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis (see figure 2.3-5). In this section you work from left to right answering the question: "How is the higher level function enabled by lower level functions?"

1. Next Higher Level Function and Requirement: The function in scope of the Analysis.
2. Focus Element Function and Requirement:

   The function of the associated System Element (item in focus) identified in the Structure Analysis.
3. Next Lower Level Function and Requirement or Characteristic: The function of the associated Component Element identified in the Structure Analysis.

2.3.6 Collaboration between Engineering Teams (Systems, Safety, and Components)

Engineering teams within the company need to collaborate to make sure information is consistent for a project or customer program especially when multiple DFMEA teams are simultaneously conducting the technical risk analysis. For example, a systems group might be developing the design architecture (structure) and this information would be helpful to the DFMEA to avoid duplication of work. A safety team may be working with the customer to understand the safety goals and hazards. This information would be helpful to the DFMEA to ensure consistent severity ratings for failure effects.

功能结构可以在功能分析部分创建：

功能分析 （步骤三）		
1. 上一较高级别功能及要求	2. 关注要素功能及要求	3. 下一较低级别功能及要求或特性
根据参数设置将电能转换为机械能	换向系统在电磁转换系统的线圈对之间传输电流	电刷盒在弹簧和电机壳体之间传输力，为碳刷弹簧系统提供 x、y、z 方向的支撑（支撑交换接触点）

图 2.3-5 功能分析表格示例

表头栏的编号（1，2，3）和颜色有助于显示结构分析和功能分析相关内容的一致性（见图 2.3-5）。在这一节中，从左到右回答这个问题："较低级别的功能如何使得较高级别的功能生效？"

1. 上一较高级别功能及要求：在分析范围内的功能
2. 关注要素功能及要求：

   在结构分析中识别的相关系统要素的功能（关注项目）
3. 下一较低级别功能及要求或特性：在结构分析中识别的相关组件的功能

2.3.6 工程团队之间的协作（系统、安全和组件）

公司内部的工程团队需要彼此协作，以确保项目或顾客项目的信息一致，特别是当多个 DFMEA 团队同时进行技术风险分析时。例如，系统团队可能正在创建一个设计架构（结构），这些信息将有助于 DFMEA 避免重复工作。安全团队可能正与顾客协作了解安全目标和危险。此信息将有助于 DFMEA 确保失效影响的严重度评级一致。

2.3.7 Basis for Failure Analysis

Complete definition of functions (in positive words) will lead to a comprehensive Step 4 Failure Analysis because the potential failures are ways the functions could fail (in negative words).

2.4 Design FMEA 4th Step: Failure Analysis

2.4.1 Purpose



The purpose of the Design Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The main objectives of a Design Failure Analysis are:

- Potential Failure Effects, Failure Modes, Failure Causes for each product function (Failure Chain)
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

2.4.2 Failures

Failures of a function are deduced from the functions. There are several types of potential failure modes including, but not limited to:

- Loss of function (i.e. inoperable, fails suddenly)
- Degradation of function (i.e. performance loss over time)
- Intermittent function (i.e. operation randomly starts/stops/starts)
- Partial function (i.e. performance loss)
- Unintended function (i.e. operation at the wrong time, unintended direction, unequal performance)
- Exceeding function (i.e. operation above acceptable threshold)
- Delayed function (i.e. operation after unintended time interval)

2.3.7 失效分析的基础

功能的完整定义（用肯定的词语）将使步骤四失效分析更全面，因为潜在失效的方式和功能失效的方式相同（用否定的词语）。

2.4 设计 FMEA 步骤四：失效分析

2.4.1 目的

设计失效分析的目的是识别失效起因、模式和影响，并显示它们之间的关系，以便能进行风险评估。



设计失效分析的主要目标是：

- 确认每个产品功能的潜在失效影响、失效模式和失效起因（失效链）
- 顾客和供应商之间的协作（失效影响）
- 为在 FMEA 表格中记录失效和"风险分析"步骤提供基础

2.4.2 失效

功能的失效由功能推导而来。潜在失效模式包括但不限于以下几种：

- 功能丧失（即无法操作、突然失效）
- 功能退化（即性能随时间损失）
- 功能间歇（即操作随机开始/停止/开始）
- 部分功能丧失（即性能损失）
- 非预期功能（即在错误的时间操作、意外的方向、不相等的性能）
- 功能超范围（即超出可接受极限的操作）
- 功能延迟（即非预期时间间隔后的操作）

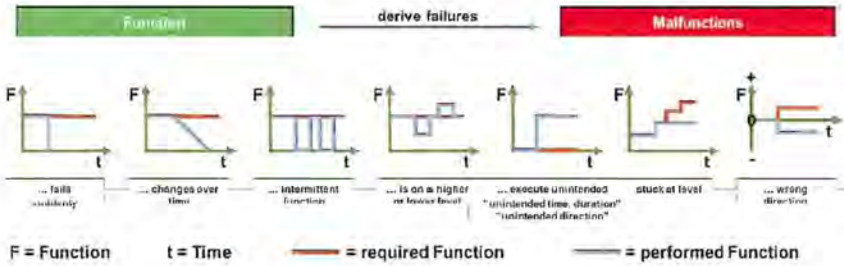


Figure 2.4-1 Types of Failure Modes

The description of a system and subsystem failure mode is described in terms of functional loss or degradation i.e. steering turns right when the hand wheel is moved left, as an example of an unintended function. When necessary the operating condition of the vehicle should be included i.e. loss of steering assist during start up or shut down.

A component/part failure mode is comprised of a noun and a failure description i.e. seal twisted.

It is critical that the description of the failure is clear and understandable for the person who is intended to read it. A statement "not fulfilled", "not OK", "defective", "broken" and so on is not sufficient.

More than one failure may be associated with a function. Therefore, the team should not stop as soon as one failure is identified. They should ask "how else can this fail?"

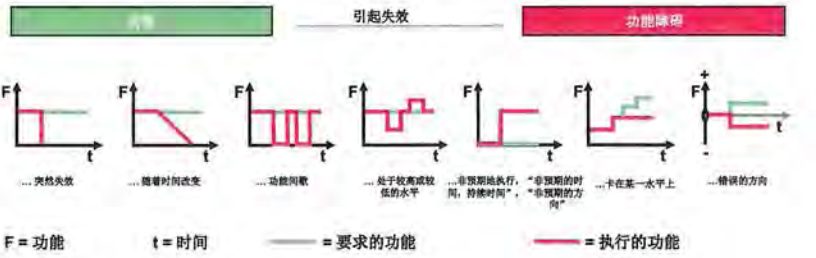


图 2.4-1 失效模式的类型

系统和子系统的失效模式描述的是功能损失或退化，例如，当向左打方向盘时，车辆向右转，这就是一个非预期功能。必要时，应包括整车的运行状况，例如：在车辆启动或熄火时失去转向助力。

组件/零件的失效模式由名词和失效描述组成，例如，密封件扭曲。

对失效的描述一定要清楚，以便阅读人员能看懂，这一点很重要。例如“未满足”、“不好”、“有缺陷”和“坏了”这样的陈述都是不充分的。

一个功能可能会有多个失效，因此团队不能识别出一个失效后就停止。他们应该问“还有没有其它的失效？”

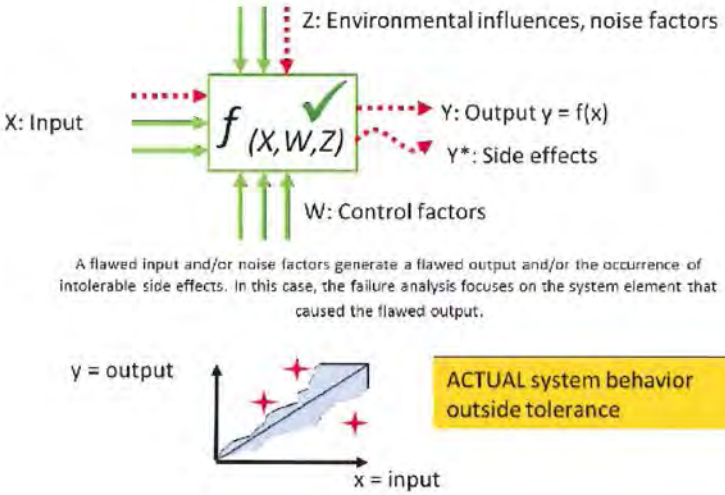


Figure 2.4-2 Definition of a Failure

2.4.3 The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

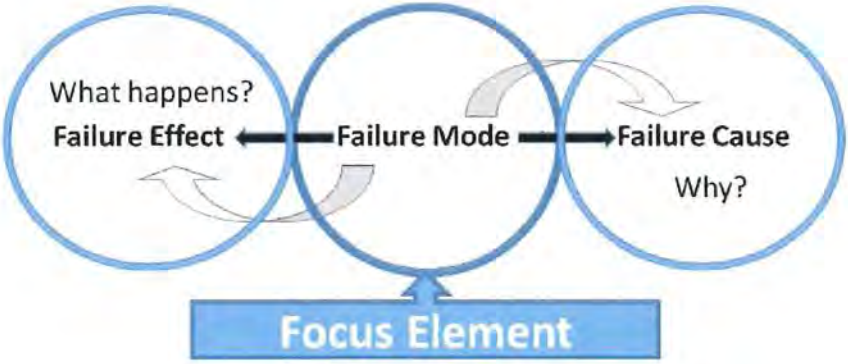
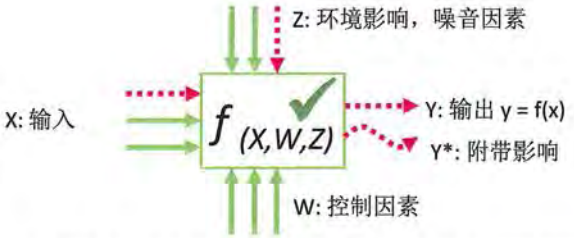


Figure 2.4-3 Theoretical failure chain model



错误的输入和/或噪音因素将产生错误的输出和/或产生无法容忍的附带影响。在这种情况下，失效分析应专注于导致错误输出的系统要素。

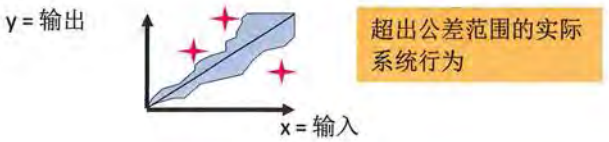


图 2.4-2 失效定义

2.4.3 失效链

FMEA 中对失效的分析包括三个不同方面：

- 失效影响 (FE)
- 失效模式 (FM)
- 失效起因 (FC)

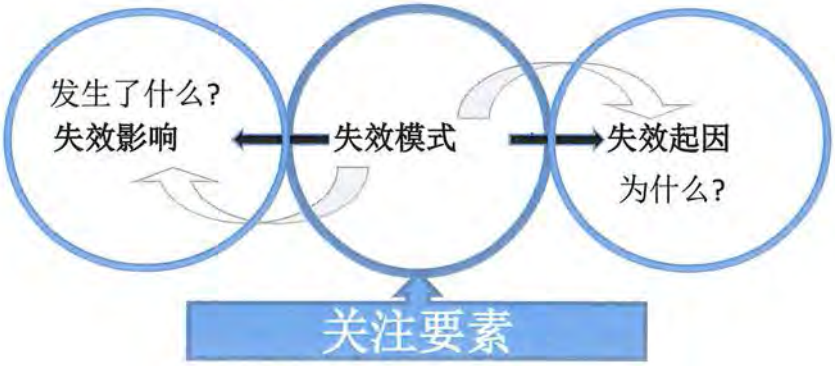


图 2.4-3 理论失效链模型

2.4.4 Failure Effects

A Failure Effect is defined as the consequences of a failure mode.

Describe effects on the next level of product integration (internal or external), the end user who is the vehicle operator (external), and government regulations (regulatory) as applicable

Customer effects should state what the user might notice or experience including those effects that could impact safety. The intent is to forecast the failure effects consistent with the team's level of knowledge. A failure mode can have multiple effects relating to internal and external customers.

Effects may be shared by OEMs with suppliers and suppliers with sub-suppliers as part of design collaboration.

The severity of failure effects is evaluated on a ten-point scale according to Table D1.

Examples of failure effects on the End User:

- No discernible effect
- Poor appearance i.e. unsightly close-out, color fade, cosmetic corrosion
- Noise i.e. misalignment/rub, fluid-borne noise, squeak/rattle, chirp, and squawk
- Unpleasant odor, rough feel, increased efforts
- Operation impaired, intermittent, unable to operate, electro-magnetic in-compatibility (EMC)
- External leak resulting in performance loss, erratic operation, unstable
- Unable to drive vehicle (walk home)
- Noncompliance with government regulations
- Loss of steering or braking

NOTE: In some cases, the team conducting the analysis may not know the end user effect, i.e. catalogue parts, off- the-shelf products, Tier 3 components. When this information is not known, the effects should be defined in terms of the part function and specification. In these cases the system integrator is responsible for ensuring the correct part for the application is selected, i.e. auto, truck, marine, agriculture.

An additional column is shown on the Rating Tables for "Corporate or Product Line Examples".

2.4.5 Failure Mode

A Failure Mode is defined as the manner in which an item could fail to meet or deliver the intended function.

2.4.4 失效影响

失效影响定义为失效模式产生的后果。

失效影响描述的是对下一级产品集成的影响（内部或外部），对操作整车的最终用户的影响（外部），以及对适用的政府规章的影响（法规）。

顾客影响应该说明用户可能注意到或体验到的情况，包括那些可能影响安全性的影响。目的是预测与团队知识水平一致的失效影响。一个失效模式可能导致多个与内外部顾客相关的影响。

作为设计协作的一部分，OEM 可以和供应商和次级供应商分享这些影响。

失效影响的严重度按照表格 D1 中的 10 分制进行评级：

对最终用户的失效影响示例：

- 无可察觉的影响
- 外观不良，如近观难看、褪色、表面腐蚀
- 噪音，例如：未对准/摩擦、流体噪音、吱吱声、啁啾声、嘎嘎声
- 异味、手感粗糙、操作更费劲。
- 操作受损、间歇、无法操作、电磁不兼容
- 外部泄漏造成性能损失、运行不稳定
- 无法驾驶整车（步行回家）
- 不符合政府规定
- 转向或刹车功能损失

注：在某种情况下，进行分析的团队可能不知道最终用户影响，例如：目录零件、现货成品、第 3 级组件。当不了解这些信息时，应按照零件功能和规格来定义影响。在这种情况下，系统集成人员负责确保选择正确的应用零件，如汽车、卡车、船舶、农用车。

另一列显示在"公司或产品线示例"的评级表上。

2.4.5 失效模式

失效模式定义为一个项目可能无法满足或交付预期功能的方式。

The Failure Modes are derived from the Functions. Failure Modes should be described in technical terms, and not necessarily as symptom noticeable by the customer.

In preparing the DFMEA, assume that the design will be manufactured and assembled to the design intent. Exceptions can be made at the team's discretion where historical data indicates deficiencies exist in the manufacturing process.

Examples of component-level failure modes could be, but are not limited to:

NOT RECOMMENDED		RECOMMENDED
Cracked	→	Component cracked
Deformed	→	Component deformed
Fractured	→	Component fractured
Loose	→	Part loose
Oxidized	→	Part oxidized
Sticking	→	Component sticking

Examples of system-level failure modes include but are not limited to:

- Complete fluid loss
- Disengages too fast
- Does not disengage
- Does not transmit torque
- Does not hold full torque
- Inadequate structural support
- Loss of structural support
- No signal / Intermittent signal
- Provides too much pressure/signal/voltage
- Provides insufficient pressure/signal/voltage
- Unable to withstand load/temperature/vibration

2.4.6 Failure Cause

A Failure Cause is an indication of why the failure mode could occur. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential cause for each failure mode. The consequences of not being robust to noise factors (found on a P-Diagram) may also be Failure Causes. The cause should be listed as concisely and completely as possible so that remedial efforts (controls and actions) can be aimed at appropriate causes.

失效模式来源于功能。失效模式应该用技术术语来描述，而不一定是顾客注意到的症状。

在编制 DFMEA 时，假设设计将按照设计目的进行制造和组装。如果历史数据显示制造过程中存在缺陷，团队可以自行决定是否进行例外处理。

组件级失效模式的示例可以包括，但不限于以下：

不推荐	→	推荐
破裂	→	组件破裂
变形	→	组件变形
断裂	→	组件断裂
松脱	→	零件松脱
氧化	→	零件氧化
黏贴	→	组件黏贴

系统级失效模式的示例包括但不限于以下：

- 机液完全滤失
- 脱离得太快
- 不脱离
- 不传递扭矩
- 不保持充分扭矩
- 结构支撑不足
- 结构支撑损失
- 无信号/间歇信号
- 提供太多的压力/信号/电压
- 提供的压力/信号/电压不足
- 不能承受负载/温度/震动

2.4.6 失效起因

失效起因是指失效模式发生的原因。起因造成的后果是失效模式。应尽可能识别每种失效模式的所有潜在起因。无法稳健应对噪音因素（参数图中）也可能是引起失效的起因。起因应尽可能简明、完整地列出，以便针对具体起因采取适当的补救措施（控制和措施）。

The Failure Causes can be derived from the Failure modes of the next lower level function and requirement and the potential noise factors (e.g. from a Parameter Diagram).

Types of potential failure causes could be, but are not limited to:

- Inadequate design for functional performance (incorrect material specified, incorrect geometry, incorrect part selected for application, incorrect surface finish specified, inadequate travel specification, improper friction material specified, insufficient lubrication capability, inadequate design life assumption, incorrect algorithm, improper maintenance instructions, etc.)
- System interactions (mechanical interfaces, fluid flow, heat sources, controller feedback, etc.)
- Changes over time (yield, fatigue, material instability, creep, wear, corrosion, chemical oxidation, electro migration, over- stressing, etc.)
- Design inadequate for external environment (heat, cold, moisture, vibration, road debris, road salt, etc.)
- End user error or behavior (wrong gear used, wrong pedal used, excessive speeds, towing, wrong fuel type, service damage, etc.)
- Lack of robust design for manufacturing (part geometry allows part installation backwards or upside down, part lacks distinguishing design features, shipping container design causes parts to scratch or stick together, part handling causes damage, etc.)
- Software Issues (Undefined state, corrupted code/data)

2.4.7 Failure Analysis

Depending on whether the analysis is being done at the system, sub-system or component level, a failure can be viewed as a failure effect, failure mode, or failure cause. Failure Modes, Failure Causes and Failure Effects should correspond with the respective column in the FMEA Form.

Figure 2.4-4 shows a cascade of design-related failure modes, causes, and effects from the vehicle level to the characteristic level. The focus element (Failure Mode), Causes, and Effects are different depending on the level of design integration. Consequently, a Failure Cause at the OEM becomes a Failure Mode at a next (Tier1) level. However, Failure Effects at the vehicle level (as perceived by the end user) should be documented when known, but not assumed. Therefore, the communication according to Figure 1.5-1 should be considered. Failure Networks may be created by the organization that owns multiple levels of the design. When multiple organizations are responsible for different levels of the design they are responsible to communicate failure effects to the next higher or next lower level as appropriate.

失效起因可能源自于下一较低级别的功能失效模式、要求和潜在噪音因素（例如：参数图）。

潜在失效起因的类型可能包括，但不限于：

- 功能性能设计不充分（指定的材料不正确、几何形状不正确、选择的零件不正确、规定的表面处理不正确、行程规范不充分、定义的摩擦材料不当、润滑能力不足、设计寿命假设不当、计算程序不正确、维护指南不当等）
- 系统交互作用（机械接口、流体流动、热源、控制器反馈等）
- 随时间变化（良率、疲劳、材料不稳定、蠕变、磨损、腐蚀、化学氧化、电迁移、过度压力等）
- 对于应对外部环境设计不足（热、冷、潮湿、振动、路面碎片、路面盐等）
- 最终用户的错误操作或行为（错误使用档位、错误使用踏板、超速、拖曳、错误燃料型号、服务损坏等）
- 制造设计不可靠（零件几何形状使得零件安装向后或倒过来，零件缺乏明显的设计特性，运输容器设计使得零件摩擦或黏在一起，零件处理造成损坏等）
- 软件问题（未定义的状态、损坏的代码/数据）

2.4.7 失效分析

根据分析是在系统、子系统还是组件级别进行的，失效可以视为失效影响、失效模式、或失效起因。失效模式、失效起因和失效影响应该与 FMEA 表格中的相应列对应。

图 2.4-4 显示了从整车层面到特性层面的设计相关失效模式、起因和影响之间的级联。关注要素（失效模式）、起因和影响因设计集成的级别而异。因此，OEM 级别的失效起因在下一个（一级供应商）级别上可能成为失效模式。然而，在整车层面上的失效影响（如最终用户所感知的）应在已知时予以记录，但不应假定。因此，应考虑图 1.5-1 所示的沟通。失效网可由拥有多个设计级别的组织创建。当多个组织负责不同级别的设计时，他们应负责酌情将失效影响传达给上一较高或下一较低级别。

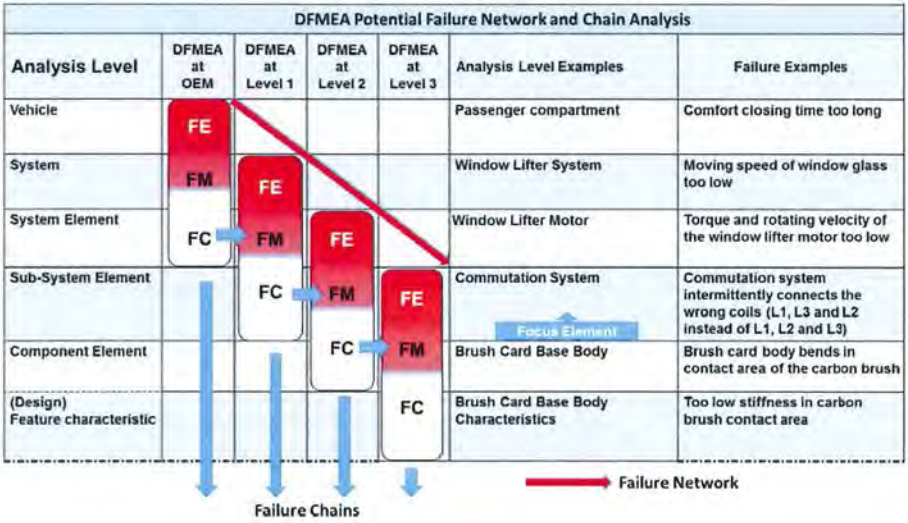


Figure 2.4-4 Failure Structure at different levels

To link Failure Cause(s) to a Failure Mode, the question should be "Why is the Failure Mode happening?"

To link Failure Effects to a Failure Mode, the question should be "What happens in the event of a Failure Mode?"

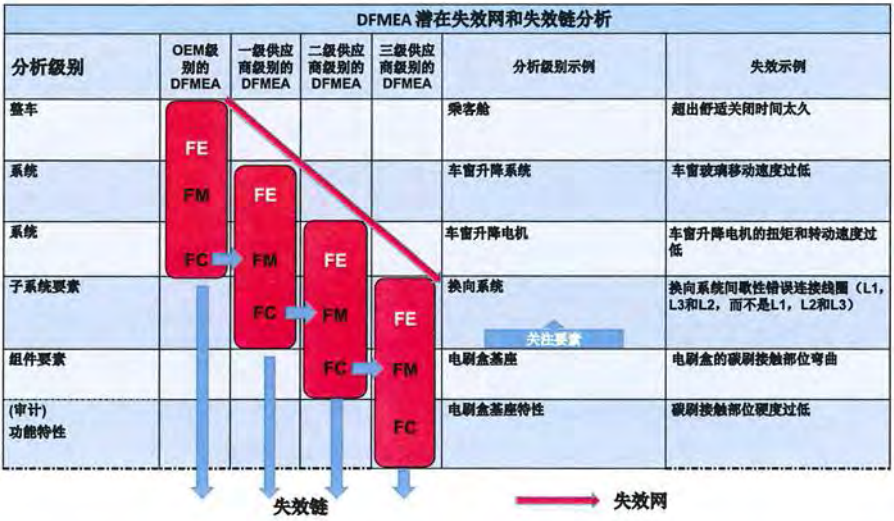


图 2.4-4 不同级别的失效结构

将失效起因与失效模式联系起来，应该问"为什么失效模式会发生？"

将失效影响与失效模式联系起来，应该问"失效模式出现时，会发生什么？"

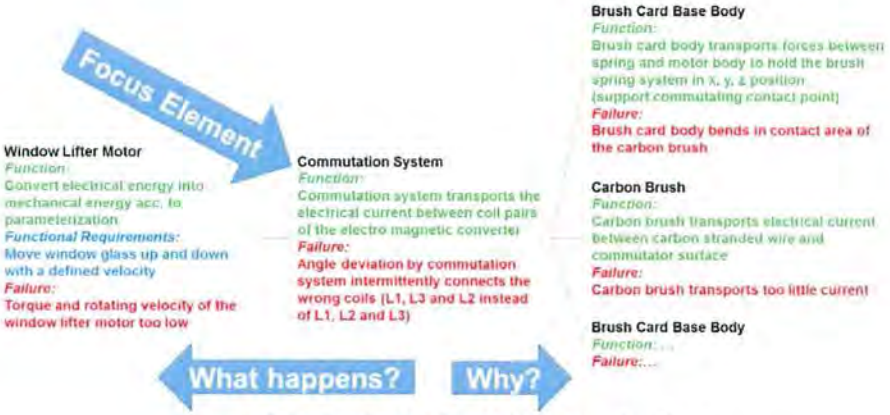


Figure 2.4-5 Example of Failure Analysis Structure Tree

The failure structure can be created in the Failure Analysis section.

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Next Lower Element or Characteristic**
Torque and rotating velocity of the window lifter motor too low	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush

Figure 2.4-6 Example of Failure Analysis Form

Following once again the header numbering (1, 2, 3) and color coding, by inspecting the items in the Function Analysis, begin building the Failure Chain.

1. Failure Effects (FE):

   The effect of failure associated with the "Next Higher Level Element and/or End User" in the Function Analysis.

2. Failure Mode (FM):

   The mode (or type) of failure associated with the "Focus Element" in the Function Analysis.

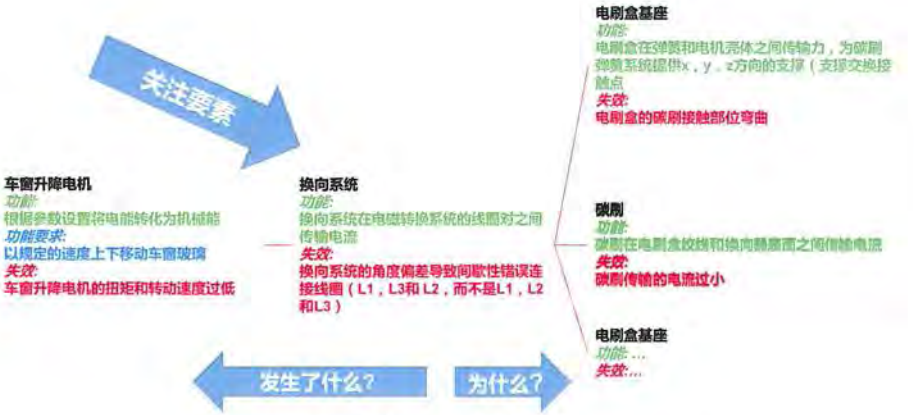


图 2.4-5 失效分析结构树示例

失效结构可在失效分析部分创建。

失效分析 （步骤四）		
1. 对于上一较高级别要素和/或最终用户的失效影响（FE）	2. 关注要素的失效模式（FM）	3. 下一较低级别要素或特性的失效起因（FC）
车窗升降电机的扭矩和转动速度过低	换向系统的角度偏差导致间歇性错误连接线圈（L1、L3 和 L2，而不是 L1、L2 和 L3）	电刷盒的碳刷接触部位弯曲

图 2.4-6 失效分析表格示例

再次遵循表头编号（1，2，3）和颜色标注，通过检查功能分析中的各个项目，开始构建失效链。

1. 失效影响(FE)：
   功能分析中与~~上~~一较高级要素和/或最终用户"相关的失效影响

2. 失效模式(FM)：
   功能分析中与~~关~~注要素"相关的失效模式（或类型）

3. Failure Cause (FC):

   The cause of failure associated with the "Next Lower Element or Characteristic" in the Function Analysis.

The Structure Analysis, Function Analysis and Failure Analysis may be documented as in the form below.

2.4.8 Failure Analysis Documentation

The DFMEA Form can have multiple views once the Structure Analysis, Function Analysis and Failure Analysis are complete.

1. Next Higher Level	1. Next Higher Level Function and Requirement	1. Failure Effects (FE) to the Next Higher Level Element and/or End User
Window Lifter Motor	Convert electrical energy into mechanical energy acc. to parameterization	Torque and rotating velocity of the window lifter motor too low

Figure 2.4-7 View of Product End Item-Function-Failure Form

2. Focus Element	2. Focus Element Function and Requirement	2. Failure Mode (FM) of the Focus Element
Commutation System	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)

Figure 2.4-8 View of Focus Item/Element-Function-Failure Form2

3. Next Lower Level or Characteristic Type	3. Next Lower Level Function and Requirement or Characteristic	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Brush Card Base Body	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)	Brush card body bends in contact area of the carbon brush

Figure 2.4-9 View of Lower Level Item-Function-Failure Form

3. 失效起因（FC）：

结构树中与"下一较低级别要素或特性"相关的失效起因

结构分析、功能分析和失效分析可按照下表记录。

2.4.8 失效分析记录

结构分析、功能分析和失效分析完成后，DFMEA 表格可以有多个视图。

1. 上一较高级别	1. 上一较高级别的功能和要求	1. 对于上一较高级别要素和/或最终用户的失效影响（FE）
车窗升降电机	根据参数设置将电能转换为机械能	车窗升降电机的扭矩和转动速度过低

图 2.4-7 产品最终项目-功能-失效表格视图

2. 关注要素	2. 关注要素的功能和要求	2. 关注要素的失效模式（FM）
换向系统	换向系统在电磁转换系统的线圈对之间传输电流	换向系统的角度偏差导致间歇性错误连接线圈（L1、L3 和 L2，而不是 L1、L2 和 L3）

图 2.4-8 关注项目/要素-功能-失效表格视图

3. 下一较低级别或特性类型	3. 下一较低级别的功能和要求或特性	3. 下一较低级别要素或特性的失效起因（FC）
电刷盒基座	电刷盒在弹簧和电机壳体之间传输力，为碳刷弹簧系统提供 x、y、z 方向的支撑（支撑交换接触点）	电刷盒的碳刷接触部位弯曲

图 2.4-9 较低级别项目-功能-失效表格视图

2.4.9 Collaboration between Customer and Supplier (Failure Effects)

The output of the Failure Analysis may be reviewed by customers and suppliers prior to the Risk Analysis step or after to the Risk Analysis step based on agreements with the customer and need for sharing with the supplier.

2.4.10 Basis for Risk Analysis

Complete definition of potential failures will lead to a complete Step 5 Risk Analysis because the rating of Severity, Occurrence, and Detection are based on the failure descriptions. The Risk Analysis may be incomplete if potential failures are too vague or missing.

2.5 Design FMEA 5th Step: Risk Analysis

2.5.1 Purpose



The purpose of Design Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, and prioritize the need for actions.

The main objectives of the Design Risk Analysis are:

- Assignment of existing and/or planned controls and rating of failures
- Assignment of Prevention Controls to the Failure Causes
- Assignment of Detection Controls to the Failure Causes and/or Failure Modes
- Rating of Severity, Occurrence and Detection for each failure chain
- Collaboration between customer and supplier (Severity)
- Basis for the product or process Optimization step

2.5.2 Design Controls

Current design controls are proven considerations that have been established for similar, previous designs. Design control documents are a basis for the robustness of the design. Prevention-type controls and detection-type controls are part of the current library of verification and validation methods. Prevention controls provide information or guidance that is used as an input to the design. Detection controls describe established verification and validation procedures that have been previously demonstrated to detect the failure, should it occur. Specific references to design features that act to prevent a failure or line items in published test procedures will establish a credible link between the failure and the design control. Those prevention and/or detection methods that are necessary, but not part of a current library of defined procedures should be written as actions in the DFMEA.

2.4.9 顾客和供应商之间的协作（失效影响）

根据与顾客的协议和与供应商共享的需要，失效分析的输出可在风险分析步骤之前或之后由顾客和供应商进行评审。

2.4.10 风险分析的基础

对潜在失效的完整定义将为步骤五"风险分析"的完整实施提供基础，因为严重度、频度和探测度的评级都基于失效描述。如果潜在失效过于模糊或缺失，可能导致风险分析不完整。

2.5 设计 FMEA 步骤五：风险分析

2.5.1 目的



设计风险分析的目的是通过评估严重度、频度和探测度来估计风险，并对需要采取的措施进行优先排序。
设计风险分析的主要目标是：

- 对现有和/或计划的控制进行分配、并对失效进行评级
- 针对失效起因，分配预防控制
- 针对失效起因和/或失效模式，分配探测控制
- 针对每个失效链进行严重度、频度和探测度评级
- 顾客和供应商之间的协作（严重度）
- 产品或过程优化步骤的基础

2.5.2 设计控制

现有的设计控制是针对以前类似的设计建立的，其效果已得到证实。设计控制文件为设计的稳健性提供基础。预防型控制和探测型控制是现有的验证和确认方法库的一部分。预防控制提供信息或指导，作为设计的输入使用。探测控制则描述了已建立的验证和确认程序，这些程序已被证明在出现失效时，能探测到失效。用于防止已发布的测试程序中的失效或行项的设计特征的特定参考将在失效和设计控制之间建立可靠的联系。对于那些必要的但不属于当前已确定的程序库的预防和/或探测方法，应作为措施写入设计 FMEA。

2.5.3 Current Prevention Controls (PC)

Current Prevention Controls describe how a potential cause which results in the Failure Mode is mitigated using existing and planned activities. They describe the basis for determining the occurrence rating. Prevention Controls relate back to the performance requirement.

For items which have been designed out-of-context and are purchased as stock or catalog items from a supplier, the prevention control should document a specific reference to how the item fulfills the requirement. This may be a reference to a specification sheet in a catalog.

Current Prevention controls need to be clearly and comprehensively described, with references cited. If necessary, this can be done by reference to an additional document. Listing a control such as "proven material" or "lessons learned" is not a clear enough indication.

The DFMEA team should also consider margin of safety in design as a prevention control.

Examples of Current Prevention Controls:

- EMC directives adhered to, directive 89/336/EEC
- System design according to simulation, tolerance calculation and Procedure - analysis of concepts to establish design requirements
- Published design standard for a thread class
- Heat treat specification on drawing
- Sensor performance specifications.
- Mechanical redundancy (fail-safe)
- Design for testability
- Design and Material standards (internal and external)
- Documentation - records of best practices, lessons learned, etc. from similar designs
- Error-proofing (Poka-Yoke design i.e. part geometry prevents wrong orientation)
- Substantially identical to a design which was validated for a previous application, with documented performance history. (However, if there is a change to the duty cycle or operating conditions, then the carry-over item requires re-validation in order for the detection control to be relevant.)

2.5.3 当前预防控制（PC）

当前预防控制描述了如何使用现有的和计划中的行为来减轻导致失效模式的潜在起因，为确定频度评级提供基础。预防控制与性能要求相关。

对于不是在该背景下设计的项目或从供应商购买的作为库存或目录项的项目，预防控制应具体说明该项目如何满足要求。可以引用目录中的规范表。

当前探测控制必须清楚全面地说明。诸如"测试"或"实验室测试"之类的陈述，不能算是对探测控制的明确说明。如适用，应当引用具体测试、测试计划或程序，以表明 FMEA 团队已确定该测试将在失效模式或起因发生时切实探测出它们（例如：测试号 1234 爆裂压力测试，第 6.1 段）。

DFMEA 团队还应该在设计中把安全边际作为预防控制来考虑。

当前预防控制的示例：

- EMC 指令遵守、指令 89/336/EEC
- 根据模拟、公差计算和程序的系统设计 - 分析概念，以建立设计要求
- 公布的线程类设计标准
- 图纸热处理规范
- 传感器性能规范
- 机械冗余（安全失效）
- 可测试性设计
- 设计和材料标准（内部和外部）
- 文件 - 类似设计的最佳实践、经验等记录
- 防错法（例如，零件的几何结构防止错误方向）
- 与以前应用中经过验证的并具有性能历史记录的设计完全相同。（然而，如果工作周期或运行条件发生变化，则借用的项目需要重新验证，以便探测控制与此相关。）

- Shielding or guards which mitigate potential mechanical wear, thermal exposure, or EMC
- Conformance to best practices

After completion of the preventive actions the occurrence is verified by the Detection Control(s).

2.5.4 Current Detection Controls (DC)

Current Detection Controls detect the existence of a failure cause or the failure mode before the item is released for production. Current Detection Controls that are listed in the FMEA represent planned activities (or activities already completed), not potential activities which may never actually be conducted.

Current Detection controls need to be clearly and comprehensively described. Listing a control such as "Test" or "Lab Test" is not a clear enough indication of a detection control. References to specific tests, test plans or procedures should be cited as applicable, to indicate that the FMEA team has determined that the test will actually detect the failure mode or cause, if it occurs (i.e. Test No. 1234 Burst Pressure Test, Paragraph 6.1).

Examples of Current Detection controls:

- Function check
- Burst test
- Environmental test
- Driving test
- Endurance test
- Range of motion studies
- Hardware in-the-loop
- Software in-the-loop
- Design of experiments
- Voltage output lab measurements

All controls that lead to a detection of the failure cause, or the failure mode are entered into the "Current Detection Controls" column.

- 屏蔽或防护，可减轻潜在的机械磨损、热暴露或 EMC
- 与最佳实践相一致

预防措施完成后，频度通过探测控制来确认。

2.5.4 当前探测控制（DC）

当前探测控制在项目交付生产前探测失效起因或失效模式是否存在。FMEA 中列出的当前探测控制表示计划的活动（或已完成的活动），而不是可能永远不会实施的潜在活动。

当前探测控制必须清楚全面地说明。诸如"测试"或"实验室测试"之类的陈述，不能算是对探测控制的明确说明。如适用，应当引用具体测试、测试计划或程序，以表明 FMEA 团队已确定该测试将在失效模式或起因发生时切实探测出它们（例如：测试号 1234 爆裂压力测试，第 6.1 段）。

当前探测控制的示例：

- 功能检查
- 爆裂测试
- 环境测试
- 驾驶测试
- 耐久性测试
- 运动范围研究
- 硬件在环
- 软件在环
- 实验设计
- 电压输出实验室测量

所有对于失效起因或失效模式的探测控制都应输入到"当前探测控制"一栏中。

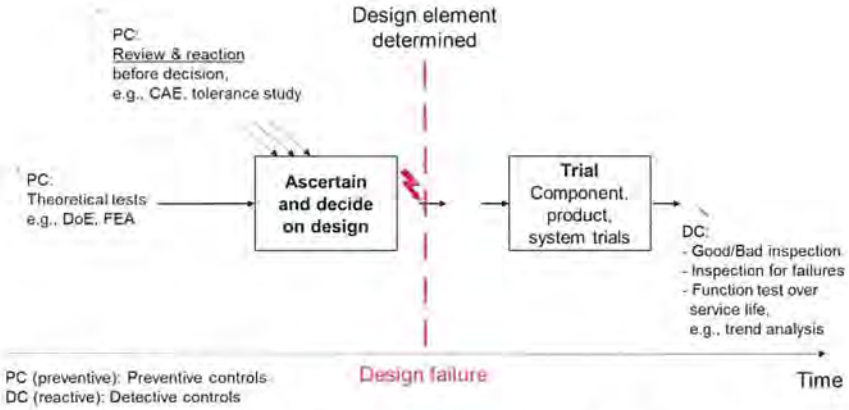


Figure 2.5-1 Prevention and Detection in the Design FMEA

2.5.5 Confirmation of Current Prevention and Detection Controls

The effectiveness of the current prevention and detection controls should be confirmed. This can be done during validation teardown reviews. Such confirmation can be documented within the DFMEA, or within other project documents, as appropriate, according to the team's normal product development procedure. Additional action may be needed if the controls are proven not to be effective.

The occurrence and detection evaluations should be reviewed when using FMEA entries from previous products, due to the possibility of different conditions for the new product.

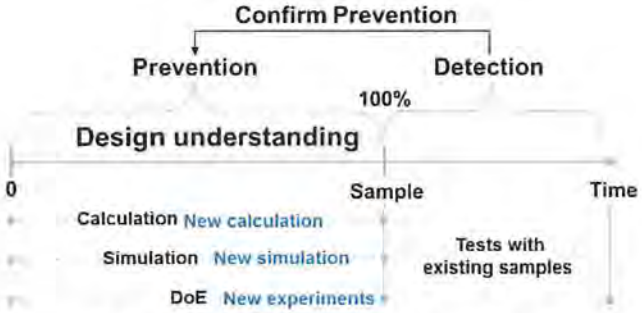


Figure 2.5-2 Roadmap of design understanding

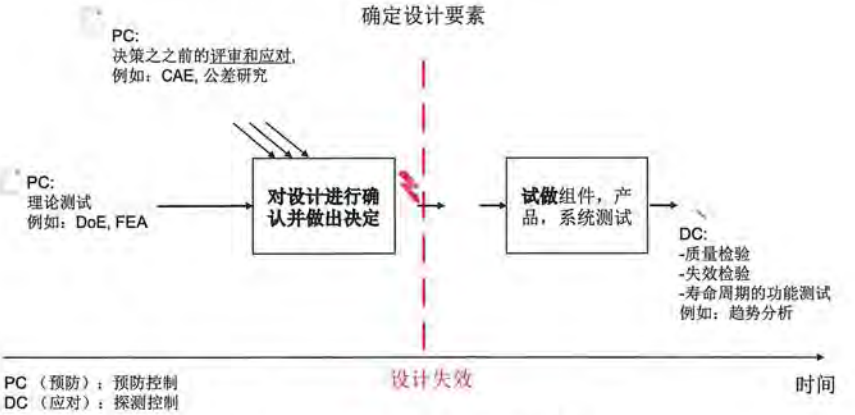


图 2.5-1 设计 FMEA 中的预防和探测

2.5.5 当前预防和探测控制的确认

应确认当前预防和探测控制的有效性。这可以在验证分解评审过程中完成。该确认可以根据团队的正常产品开发程序，适当地在 DFMEA 或其它项目文件中记录。如果这些控制被证明无效，则需要额外的措施。

若使用之前产品的 FMEA 条目，应对频度和探测度评估进行评审，因为新产品可能有不同的条件。

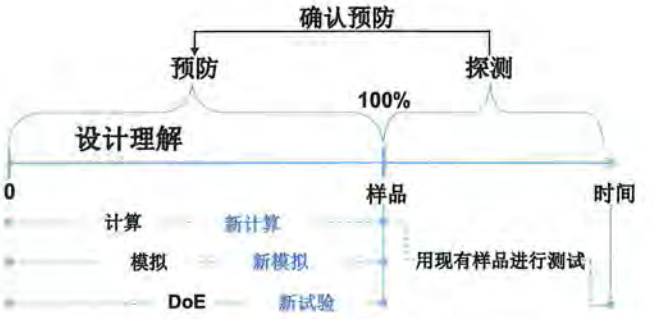


图 2.5-2 设计理解路线图

2.5.6 Evaluations

Each failure mode, cause and effect relationship is assessed to estimate risk. There are rating criteria for the evaluation of risk:

Severity (S):	stands for the severity of the failure effect
Occurrence (O):	stands for the occurrence of the failure cause
Detection (D):	stands for the detection of the occurred failure cause and/or failure mode.

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, where 10 stands for the highest risk contribution.

NOTE: It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/ process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e. the ratings are subjective).

2.5.7 Severity (S)

The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated. The rating is used to identify priorities relative to the scope of an individual FMEA and is determined without regard for occurrence or detection.

Severity should be estimated using the criteria in the Severity Table D1. The table may be augmented to include product- specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent even if modified for individual design analysis.

The Severity evaluations of the failure effects should be transferred by the customer to the supplier, as needed.

2.5.6 评估

应评估每一个失效模式、起因和影响，以便对风险进行估计。评估风险的级别标准如下：

严重度(S):	代表失效影响的严重程度
频度(O):	代表失效起因的发生频率
探测度(D):	代表已发生的失效起因和/或失效模式的可探测程度

S、O 和 D 的评估分别采用 1-10 分制，10 代表最高风险。

> 注： 即使产品/过程看起来相同，将一个团队的 FMEA 和另一个团队的 FMEA 评级进行比较是不合适的。因为每个团队的环境都不同，因此他们各自的评级都是独一无二的（也就是说，评级是主观的）。

2.5.7 严重度（S）

严重度评级是一种度量，它关系到被评估功能的既定失效模式的最严重失效影响程度。严重度评级用于确定某个 FMEA 范围的优先级，并在不考虑频度和探测度的情况下确定。

严重度应使用严重度表 D1 中的标准进行估计。该表可以扩充，以包括特定产品的示例。FMEA 项目团队应就评估标准和评级体系达成一致，即使根据单个设计分析做了修改，该标准和体系也是一致的。

如果需要，失效影响的严重度评估应该由顾客转移给供应商。

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect.	

Table D1 - DFMEA SEVERITY (S)

2.5.8 Occurrence (O)

The Occurrence rating (O) is a measure of the effectiveness of the prevention control, taking into account the rating criteria.

Occurrence ratings should be estimated using the criteria in the Occurrence Table D2. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual de-sign analysis (i.e. passenger car, truck, motorcycle, etc.).

The Occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The Occurrence rating describes the potential of the failure cause to occur in customer operation, according to the rating table, considering results of already completed detection controls.

产品一般评估标准严重度(S)			
根据以下标准对潜在失效影响进行评级。			空白，由使用人员填写
S	影响	严重度标准	公司或产品系列示例
10	非常高	影响到车辆和/或其他车辆的操作安全，驾驶员、乘客、道路使用者或行人的健康状况。	
9		不符合法规。	
8	高	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	
6	中	**失去**车辆次要功能	
5		**降低**车辆次要功能	
4		外观、声音、振动、粗糙度或触感令人感觉非常不舒服。	
3	低	外观、声音、振动、粗糙度或触感令人感觉中度的不舒服。	
2		外观、声音、振动、粗糙度或触感令人略微感觉不舒服。	
1	非常低	没有可觉察到的影响。	

表 D1 - DFMEA 严重度 （S）

2.5.8 频度（O）

频度评级是根据评级标准对预防控制有效性的衡量。

频度评级应使用频度表 D2 中的标准进行估计。该表可以扩充，以包括特定产品的示例。FMEA 项目团队应就评估标准和评级体系达成一致，即使根据单个设计分析（例如客车、卡车、摩托车等）做了修改，该标准和体系也是一致的。

频度评级值是 FMEA 范围内的一个相对级别，可能不能反映实际发生的情况。

根据评级表，并考虑已经完成的探测控制的结果，频度评级描述了顾客操作中可能发生的潜在失效起因。

Expertise, data handbooks, warranty databases or other experiences in the field of comparable products, for example, can be consulted for the analysis of the evaluation numbers.

When failure causes are rated for occurrence, it is done taking into account an estimation of the effectiveness of the current prevention control. The accuracy of this rating depends on how well the prevention control has been described.

Questions such as the following may be helpful for a team when trying to determine the appropriate Occurrence rating:

- What is the service history and field experience with similar components, subsystems, or systems?
- Is the item a carryover product or similar to a previous level item?
- How significant are changes from a previous level item?
- Is the item completely new?
- What is the application or what are the environmental changes?
- Has an engineering analysis (i.e. reliability) been used to estimate the expected comparable occurrence rate for the application?
- Have prevention controls been put in place?
- Has the robustness of the product been proven during the product development process?

在分析评价值时，可以查阅类似产品领域的专家意见、数据手册、保修数据库和其它经验。

当针对频度评定失效起因时，考虑了对当前预防控制有效性的估计。评级的准确性取决于对预防控制的描述。

以下问题可帮助团队确定适当的频度等级：

- 类似组件、子系统或系统的过往使用情况和使用现场经验是怎样的？
- 该项目是否是一个借用件或类似于先前水平的项目？
- 与先前水平的项目相比，变化有多大？
- 该项目是完全新的吗？
- 应用是什么或有哪些环境改变？
- 是否使用了工程分析（例如：可靠性）来对应用的预期可比较频度等级进行估计？
- 预防控制是否到位？
- 在产品开发过程中，其稳健性是否得到验证？

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	Extremely high	First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	Very high	First use of design with technical innovations or materials within the company. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8		First use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	**对失效起因发生的预测**	**频度标准 - DFMEA**	**公司或产品系列示例**
10	**极高**	在无操作经验和/或在运行条件不可控制的情况下的任何地方对新技术的**首次**应用。没有对产品进行验证和/或确认的经验。 不存在标准，且尚未确定最佳实践。预防控制不能预测使用现场绩效或不存在预防控制。	
9	**非常高**	在公司内**首次**应用具有技术创新或材料的设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 预防控制不是针对确定特定要求的性能。	
8		在新应用内**首次**使用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 极少存在现有标准和最佳实践，不能直接用于该设计产品。预防控制不能可靠地反映使用现场绩效。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
7	High	New design based on similar technology and materials. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance	
6		Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	
5	Moderate	Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4		Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate likely design conformance.	

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	对失效起因发生的预测	频度标准 - DFMEA	公司或产品系列示例
7	高	根据相似技术和材料的**新型**设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 标准、最佳实践和设计规则符合基础设计要求，但不适用于创新产品。预防控制提供了有限的性能指标。	
6		应用现有技术和材料，与之前设计**相似**。类似应用，工作周期或运行条件有改变。之前的测试或使用现场经验。 存在标准和设计规则，但不足以确保不会出现失效起因。预防控制提供了预防失效起因的部分能力。	
5	中	应用成熟技术和材料，与之前设计相比有**细节**上的变化。类似的应用、工作周期或运行条件。之前的测试或使用现场经验，或为具有与失效相关测试经验的新设计。 在之前设计中所学到的与解决设计问题相关的教训。在本设计中对最佳实践进行再评估，但尚未经过验证。预防控制能够发现与失效起因相关的产品缺陷，并提供部分性能指标。	
4		与短期现场使用暴露几乎相同的设计。类似应用，工作周期或运行条件有细微变化。之前测试或使用现场经验。之前设计和为新设计而进行的改变符合最佳实践、标准和规范要求。 预防控制能够发现与失效起因相关的产品缺陷，很可能地反映设计符合性。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
3	Low	Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause and predict conformance of production design.	
2	Very low	Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate confidence in design conformance.	
1	Extremely low	Failure eliminated through preventive control and failure cause is not possible by design	
Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.			
Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins			
Note: O 10, 9, 8, 7 can drop based on product validation activities.			

Table D2 - DFMEA Occurrence (O)

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	O	O	公司或产品系列示例
3	低	对已知设计（相同应用，在工作周期或操作条件方面）和测试或类似运行条件下的现场经验的细微变化或成功完成测试程序的新设计。 考虑到之前设计的经验教训，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并预测了与生产设计的一致性。	
2	非常低	与长期现场暴露几乎相同的设计。相同应用，具备类似的工作周期或运行条件。在类似运行条件下的测试或使用现场经验。 考虑到之前设计的经验教训并对其具备充足的信心，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并显示出对设计符合性的信心。	
1	极低	失效通过预防控制消除，通过设计失效起因不可能发生。	
产品经验：在公司内使用产品的历史（新品设计、应用或使用案例）。已经完成的探测控制结果提供了设计经验。			
预防控制：在产品设计中使用最佳实践、设计规则、公司标准、经验教训、行业标准、材料规范、政府规定，以及以预防为导向的分析工具的有效性（分析工具包括计算机辅助工程、数学建模、模拟研究、公差叠加和设计安全边际）。			
注：频度 10、9、8、7 可根据产品验证活动降低。			

表 D2 - DFMEA 频度 （O）

2.5.9 Detection (D)

The Detection rating (D) is an estimated measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production. The detection rating is the rating associated with the most effective detection control.

Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for severity or occurrence. Detection should be estimated using the criteria in Table D3. This table may be augmented with examples of common detection methods used by the company. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual product analysis.

The detection rating is initially a prediction of the effectiveness of any yet unproven control. The effectiveness can be verified and re-evaluated after the detection control is completed. However, the completion or cancellation of a detection control (such as a test) may also affect the estimation of occurrence.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size is required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	**Very low**	Test procedure yet to be developed.	Test method not defined	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	

2.5.9 探测度（D）

探测度评级（D）是对探测控制有效性的估计，用于在项目交付生产前，可靠地证明失效起因或失效模式。探测评级与最有效的探测控制相关。

探测度是一个相对的评级，且在单个 FMEA 范围内进行评级，它的确定不考虑严重度或频度。应使用表 D3 中的标准对探测度进行评估。这个表格可以用公司常用的探测方法进行补充。FMEA 项目团队应该就评估标准和评级体系达成一致，即使针对个别产品分析作了修改，该标准和体系也是一致的。

探测度评级最初是对任何尚未被证实的控制的有效性进行的预测。在探测控制完成后，可以对其有效性进行验证和重新评估。然而，探测控制（例如：测试）的完成或取消也会影响对频度的估计。

在确定该估计时，应考虑以下问题：

- 探测失效起因或失效模式的最有效测试是什么？
- 探测失效所需要的使用记录/工作周期是什么？
- 探测失效需要多少样品？
- 探测该起因/失效模式的测试程序是否已得到证明？

用于产品设计验证的潜在探测度 (D)				
根据探测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
10	**非常低**	尚未制定测试过程。	尚未确定测试方法	
9		没有为探测失效模式或失效起因而特别地设计测试方法。	通过/不通过测试、失效测试、老化测试	

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
8	**Low**	New test method; not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or re-tooling.	Pass-Fail Testing	
6	**Moderate**		Test-to-Failure	
5			Degradation Testing	
4	**High**	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	**Very high**	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause.		

Table D3 - DFMEA DETECTION (D)

2.5.10 Action Priority (AP)

Once the team has completed the initial identification of Failure Modes, Failure Effects, Failure Causes and controls, including ratings for severity, occurrence, and detection, they must decide if further efforts are needed to reduce the risk. Due to the inherent limitations on resources, time, technology, and other factors, they must choose how to best prioritize these efforts.

The Action Priority (AP) method is introduced in this handbook. It accounts for all 1000 possible combinations of S, O, and D. It was created to give more emphasis on severity first, then occurrence, then detection. This logic follows the failure-prevention intent of FMEA. The AP table offers a suggested high-medium-low priority for action. Companies can use a single system to evaluate action priorities instead of multiple systems required from multiple customers.

用于产品设计验证的潜在探测度 (D)				
根据探测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
8	低	新测试方法，尚未经过验证。	通过/不通过测试、失效测试、老化测试	
7		已经验证的测试方法，该方法用于功能性验证或性能、质量、可靠性以及耐久性确认；测试计划时间在产品开发周期内较迟，如果测试失败将导致重新设计、重新开模具导致生产延迟。	通过/不通过测试	
6	中		失效测试	
5			老化测试	
4	高	已经验证的测试方法，该方法用于功能性验证或性能、质量、可靠性以及耐久性确认；计划时间充分，可以在开始生产之前修改生产工装。	通过/不通过测试	
3			失效测试	
2			老化测试	
1	非常高	之前测试证明不会出现失效模式或失效起因，或者探测方法经过实践验证**总是**能够探测到失效模式或失效起因。		

表 D3 - DFMEA 探测度（D）

2.5.10 措施优先级（AP）

团队完成失效模式、失效影响、失效起因和控制的初始确认（包括严重度、频度和探测度的评级）后，他们必须决定是否需要进一步努力来降低风险。由于资源、时间、技术和其它因素的固有限制，他们必须选择如何最好地将这些工作进行优先排序。

本手册介绍了措施优先级（AP）方法，提供了所有 1000 种 S、O、D 的可能组合。该方法首先着重于严重度，其次为频度，然后为探测度。其逻辑遵循了 FMEA 的失效预防目的。AP 表建议将措施分为高-中-低优先级别。公司可使用一个体系来评估措施优先级，而不是使用多个顾客要求的多个体系。

Risk Priority Numbers are the product of S x O x D and range from 1 to 1000. The RPN distribution can provide some information about the range of ratings, but RPN alone is not an adequate method to determine the need for more actions since RPN gives equal weight to S, O, and D. For this reason, RPN could result in similar risk numbers for very different combinations of S, O, and D leaving the team uncertain about how to prioritize. When using RPN it is recommended to use an additional method to prioritize like RPN results such as S x O. The use of a Risk Priority Number (RPN) threshold is not a recommended practice for determining the need for actions. The RPN and S x O methods are not included in this publication.

Risk matrices can represent combinations of S and O, S and D, and O and D. These matrices provide a visual representation of the results of the analysis and can be used as an input to prioritization of actions based on company-established criteria not included in this publication.

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S, O, D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

Note: Action Priority rating tables are the same for DFMEA and PFMEA, but different for FMEA-MSR.

Priority High (H): Highest priority for review and action.

The team needs to either identify an appropriate action to improve Prevention and / or Detection Controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action.

The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action.

The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 Failure Effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

风险顺序数是 S x O x D 的乘积，范围为 1-1000。RPN 分布可以提供有关评级范围的一些信息，但仅 RPN 并不能确定是否需要采取更多措施，因为 RPN 对 S、O 和 D 的权重相等。因此，RPN 可能会对 S、O 和 D 的不同组合产生类似的风险数，使团队无法确定如何进行优先级排序。使用 RPN 时，建议使用其他方法对类似 RPN 结果进行优先级排序，例如 S x O。不推荐使用风险顺序数（RPN）阈值来确定所需要的措施。本出版物不包括 RPN 和 S X O 方法。

风险矩阵可以表示 S 和 O、S 和 D、O 和 D 的组合。这些矩阵形象地展示了分析结果，并可作为输入来对措施进行优先级排序。这样做时要根据公司设立的标准进行，而本出版物中不包括此标准。

由于 AP 表的设计是为了和本手册中提供的严重度、频度和探测度表一起使用，如果组织针对特定产品、过程或项目选择修改 S、O、D 表，则 AP 表也应该仔细检查。

注：设计 FMEA 和过程 FMEA 的措施优先级评级表是相同的，但是监视及系统响应 FMEA 则不同。

优先级高（H）： 评审和措施的最高优先级。

团队需要确定适当的措施来改进预防和/或探测控制，或证明并记录为何当前的控制足够有效。

优先级中（M）： 评审和措施的中等优先级。

团队应该确定适当的措施来改进预防和/或探测控制，或由公司自行决定，证明并记录当前的控制足够有效。

优先级低（L）： 评审和措施的低优先级。

团队可以确定措施来改进预防或探测控制。

对于潜在的严重度为 9-10 且措施优先级为高和中的失效影响，建议至少应由管理层评审，包括所采取的任何建议措施。

This is not the prioritization of High, Medium, or Low risk, it is the prioritization of the actions to reduce risk.

Note: It may be helpful to include a statement such as "No further action is needed" in the Remarks field as appropriate.

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

这不是对高、中、低风险的优先排序，而是对降低风险的措施的优先排序。

注：　酌情在备注部分写上诸如"无需进一步措施"之类的陈述，这可能会有帮助。

DFMEA 和 PFMEA 的措施优先级 (AP)							
措施优先级是以严重度、频度以及探测度评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	**S**	**对失效起因发生的预测**	**O**	**探测能力**	**D**	**措施优先级 (AP)**	**备注**
对产品或工厂的影响度非常高	9-10	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

DFMEA 和 PFMEA 的措施优先级 (AP)							
措施优先级是以严重度、频度以及探测度评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	**S**	**对失效起因发生的预测**	**O**	**探测能力**	**D**	**措施优先级 (AP)**	**备注**
对产品或工厂的影响度高	7-8	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	M	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度中等	4-6	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	M	
				非常高	1	M	
		高	6-7	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	M	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	M	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
				Low - Very low	7-10	L	
		Low	2-3	Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
				Very high - Very low	1-10	L	
		Very low	1	Very high - Very low	1-10	L	
No discernible Effect	1	Very low - Very high	1-10				

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

DFMEA 和 PFMEA 的措施优先级 (AP)							
措施优先级是以严重度、频度以及探测度评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	**S**	**对失效起因发生的预测**	**O**	**探测能力**	**D**	**措施优先级 (AP)**	**备注**
对产品或工厂的影响度低	2-3	非常高	8-10	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		高	6-7	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
没有可觉察到的影响。	1	非常低 - 非常高	1-10				

AP 表 – DFMEA 和 PFMEA（过程 FMEA）的措施优先级

FAILURE ANALYSIS (STEP 4)				DFMEA RISK ANALYSIS (STEP 5)					
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
Torque and rotating velocity of the window lifter motor too low	6	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L	

Figure 2.5-3 Example of DFMEA Risk Analysis Form

2.5.11 Collaboration between Customer and Supplier (Severity)

The output of the Risk Analysis creates the mutual understanding of technical risk between customers and suppliers. Methods of collaboration range from verbal to formal reports. The amount of information shared is based on the needs of a project, company policy, contractual agreements, and so on. The information shared depends on the placement of the company in the supply chain. Some examples are listed below.

1. The OEM may compare design functions, failure effects, and severity from a vehicle-level DFMEA with the Tier 1 supplier DFMEA.
2. The Tier 1 supplier may compare design functions, failure effects, and severity from a subsystem DFMEA with the Tier 2 supplier who has design responsibility.
3. The Tier 1 supplier communicates necessary information about product characteristics on product drawings and/or specifications, or other means, including designation of standard or special characteristics and severity. This information is used as an input to the Tier 2 supplier PFMEA as well as the Tier 1's internal PFMEA. When the design team communicates the associated risk of making product characteristics out of specification the process team can build in the appropriate level of prevention and detection controls in manufacturing. Reference: PFMEA Section 3.4 for more information.

失效分析 （步骤四）				设计 FMEA 风险分析 （步骤五）					
1. 对于上一较高级别要素和/或最终用户的失效影响（FE）	FE 的严重度	2. 关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）	对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	设计 FMEA 措施优先级	筛选器代码（可选）
车窗升降电机的扭矩和转动速度过低	6	换向系统的角度偏差导致间歇性错误连接线圈（L1、L3 和 L2，而不是 L1、L2 和 L3）	电刷盒的碳刷接触部位弯曲	根据 FEM 6370 进行的电刷盒动态受力模拟	2	抽样测试：依据测试规范 MRJ82/60 测量电刷盒的弹性和塑性变形影响。	2	L	

图 2.5-3 DFMEA 风险分析表格示例

2.5.11 顾客和供应商之间的协作（严重度）

风险分析的结果是顾客和供应商对技术风险达成的一致理解。协作的方法从口头报告到正式报告不一。共享的信息量取决于项目的需要、公司政策、合同协议等。共享的信息内容取决于公司在供应链中的位置。下面列出了一些示例：

1. OEM 可将整车级 DFMEA 的设计功能、失效影响和严重度与一级供应商的 DFMEA 进行比较。
2. 一级供应商可将子系统设计 FMEA 的设计功能、失效影响和严重度与负有设计责任的二级供应商进行比较。
3. 一级供应商以产品图纸和/或规范或其他方式传达有关产品特性的必要信息，包括对标准或特殊特性和严重性的指定。此信息用作二级供应商 PFMEA 以及一级供应商内部 PFMEA 的输入。当设计团队传达"产品特性超出规范"的相关风险时，过程团队可以在制造过程中建立适当水平的预防和探测控制。参考 PFMEA 第 3.4 节了解更多信息。

2.5.12 Basis for Optimization

The output of Steps 1, 2, 3, 4, and 5 of the 7-step FMEA process is used to determine if additional design or testing action is needed. The design reviews, customer reviews, management reviews, and cross-functional team meetings lead to Step 6 Optimization.

2.6 Design FMEA 6th Step: Optimization

2.6.1 Purpose



The purpose of the Design Optimization is to determine actions to mitigate risk and assess the effectiveness of those actions.

The main objectives of a Design Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures
- Basis for refinement of the product requirements and prevention and detection controls

The primary objective of Design Optimization is to develop actions that reduce risk and increase customer satisfaction by improving the design. In this step, the team reviews the results of the risk analysis and assigns actions to lower the likelihood of occurrence of the Failure Cause or increase the robustness of the Detection Control to detect the Failure Cause or Failure Mode. Actions may also be assigned which improve the design but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls and are already considered in the initial risk analysis.

2.5.12 优化的基础

FMEA"七步法"中前五个步骤的输出结果用于确定是否需要额外的设计或测试措施。设计评审、顾客评审、管理层评审和跨功能团队会议为步骤六"优化"提供基础。

2.6 设计 FMEA 步骤六：优化

2.6.1 目的



设计优化的目的是确定减轻风险的措施以及评估这些措施的有效性。

设计优化的主要目标是：

- 确认降低风险的必要措施
- 为措施实施分配职责和任务期限
- 实施措施并将其形成文件，包括对所实施措施的有效性的确认以及采取措施后的风险评估
- FMEA 团队、管理层、顾客和供应商在潜在失效方面的协作
- 为改进产品要求和预防、探测控制提供基础

设计优化的主要目的是通过改进设计来制定降低风险和增加顾客满意度的措施。在这一步骤中，团队要评审风险分析的结果、并分配措施，以降低失效起因发生的可能性，或者增强探测控制的有效性，以便探测出失效起因或失效模式。对于那些能改进设计但不一定降低风险评估等级的措施，也可以分配。这些措施指的是具体、可衡量、可实现的措施，而不是可能永远不会实施的潜在措施。这些措施不用于已经计划的活动，因为它们已经在预防或探测控制中记录下来并且已经在初始风险分析中考虑过了。

If the team decides that no further actions are necessary, "No further action is needed" is written in the Remarks field to show the risk analysis was completed.

The DFMEA should be used to assess technical risks related to continuous improvement of the design.

The optimization is most effective in the following order:

- Design modifications to eliminate or mitigate a Failure Effect (FE).
- Design modifications to reduce the Occurrence (O) of the Failure Cause (FC)
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).
- In the case of design modifications, all impacted design elements are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different design concept.

2.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

2.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

如果团队决定不需要进一步采取措施，则在备注部分写上"无需进一步的措施"，以表示风险分析已完成。

应使用 DFMEA 来评估与持续改进设计有关的技术风险。

优化的最有效顺序如下：

- 修改设计以消除或减少失效影响（FE）
- 修改设计以降低失效起因（FC）的频度（O）
- 提高探测（D）失效起因（FC）或失效模式（FM）的能力
- 在发生设计修改的情况下，所有受影响的设计要素都要重新评估。

在概念变更的情况下，FMEA 的所有步骤都要针对受影响的部分进行评审。这是必要的，因为初始分析是基于不同的设计概念，已不再有效。

2.6.2 责任分配

每个措施都应该有负责人和与之相关的目标完成日期。

负责人应确保措施的状态保持更新。如果措施被确认，那么该负责人也要对措施的实施情况负责。

应记录预防和探测措施的实际完成日期，包括措施实施的日期。

目标完成日期应切合实际（例如，按照产品开发计划、在过程验证之前、在生产开始之前）。

2.6.3 措施的状态

措施的状态，建议分为以下几类：

尚未确定

没有确定的措施。

尚未决策（可选）

措施已经确定，但还没有决定。正在创建决策文件。

尚未执行（可选）

已对措施作出决定，但尚未执行。

Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions.

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product design. Actions are open loops that need to be closed in writing.

2.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Design FMEA Occurrence and Detection rating tables.

2.6.5 Continual Improvement

The DFMEA serves as an historical record for the design. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or at a minimum available and accessible as part of version history. The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, O, D ratings may be modified for foundation, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

已完成

已完成状态是指措施已经被执行，其有效性已经被证明和记录，并已经进行了最终评估。

不执行

当决定不执行某项措施时，就会分配"不执行"的状态。如果实践和技术限制超出当前能力，就会发生这种情况。

只有当 FMEA 团队评估了每个项目的措施优先级，并接受风险水平或记录措施结束时，FMEA 工作才算完成。

如果"不采取措施"，那么"措施优先级"就不会降低，失效风险就会继续进入产品设计。对于具有开放性目标的措施，需以书面形式将其关闭。

2.6.4 措施有效性评估

当措施完成时，频度和探测度值将重新评估，一个新的措施优先级可能要被确定。

新的措施将获得初步措施优先级评估，作为对有效性的预测。

然而，该措施将一直保持"尚未执行"的状态，直到其有效性得到测试为止。测试完成后，初步评估必须得到确认或在必要时调整。然后，措施的状态从"尚未执行"改为"已完成"。

重新评估应基于采取的预防和探测措施的有效性，并且新的值应基于设计 FMEA 频度和探测度评级表中的定义。

2.6.5 持续改进

DFMEA 是设计的历史记录。因此，初始严重度、频度和探测度（S、O、D）编号需显示可见，或至少可作为历史记录一部分使用和访问。分析完成后将形成一个存储库，能够记录过程决策和设计改进的进展。然而，对于基础、系列或一般 DFMEA，初始的严重度、频度和探测度（S、O、D）评级可能被修改，因为这些信息在特定应用中被用作特定应用分析的起点。

DFMEA RISK ANALYSIS (STEP 5)						DFMEA OPTIMIZATION (STEP 6)									
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP
Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L		None	Final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	Test Engineer Mr. Max Mueller	dd.mm .yyyy	planned			6	2	1	L

Figure 2.6-1 Example of DFMEA Optimization with new Risk Evaluation Form

2.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures

Communication between the FMEA team, management, customers and suppliers during the development of the technical risk analysis and/or when the DFMEA is initially complete brings people together to improve their understanding of product functions and failures. In this way, there is a transfer of knowledge that promotes risk reduction.

2.7 Design FMEA 7th Step: Results Documentation

2.7.1 Purpose



The purpose of the Results Documentation step is to summarize and communicate the results of the FMEA activity.
The main objectives of Design Results Documentation are:

- Communication of results and conclusions of the analysis
- Establishment of the content of the documentation
- Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Communication of actions taken to reduce risks, including within the organization, and with customers and/or suppliers as appropriate
- Record of risk analysis and risk reduction to acceptable levels

DFMEA 风险分析（步骤五）						DFMEA 优化（步骤六）									
对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	DFMEA AP	筛选器代码（可选）	DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	DFMEA AP
根据 FEM 6370 进行的电刷盒动态受力模拟	2	抽样测试：依据测试规范 MRJ82/60 测量电刷盒的弹塑性和形变影响	2	L		无	MRJ1140 最终产品测试：根据测试规范 MRJ1140 在最苛刻条件下测量电流	测试工程师 Max Mueller 先生	年月日	已计划			6	2	1	L

图 2.6-1 进行最新风险评估的 DFMEA 优化表格示例

2.6.6 FMEA 团队、管理层、顾客和供应商之间针对潜在失效的协作

在技术风险分析进行期间和/或当 DFMEA 初步完成时，FMEA 团队、管理层、顾客和供应商之间的沟通会将相关人员聚在一起，以提高他们对产品功能和失效的理解。通过这种方式可以使得如何降低风险的知识得以传播。

2.7 设计 FMEA 步骤七：结果文件化

2.7.1 目的



“结果文件化”步骤的目的是，针对 FMEA 活动的结果进行总结和交流。“将结果文件化”的主要目标是：

- 对结果和分析结论进行沟通
- 建立文件内容
- 记录采取的措施，包括对实施措施的效果进行确认、采取措施后进行风险评估
- 在组织内部，以及与客户和/或供应商之间（如需）针对降低风险的措施进行沟通
- 记录风险分析和风险降低到的可接受水平

2.7.2 FMEA Report

The report may be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the DFMEA details when requested by management, customers, or suppliers. It is meant to be a summary for the DFMEA team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfills the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan

   a. FMEA Intent – Purpose of this FMEA?

   b. FMEA Timing – FMEA due date?

   c. FMEA Team – List of participants?

   d. FMEA Task - Scope of this FMEA?

   e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (e.g. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

F. A plan and commitment of timing for ongoing FMEA improvement actions.

   a. Commitment and timing to close open actions.

   b. Commitment to review and revise the DFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)

   c. Commitment to capture "things gone wrong" in foundation DFMEAs for the benefit of future analysis reuse, when applicable. Refer to section 1.3.6 Foundation and Family FMEAs)

2.7.2 FMEA 报告

该报告可用作公司内部或公司之间的沟通使用。当管理层、顾客或供应商要求时，该报告不应取代对 DFMEA 细节的评审。它是 DFMEA 团队和其他人员的总结，以确认每个任务都已完成、并评审分析结果。

文件的内容应满足组织、预期读者和利益相关方的要求，这一点很重要。具体细节可由各方商定。这样，还可以确保分析的所有细节和知识产权都由编制 FMEA 的公司保留。

文件的格式可根据具体公司而定。但是，报告应指出失效的技术风险，并将其视为为开发计划和项目里程碑的一部分。报告可包括以下内容：

A. 相较于第 1.5 节"项目计划"中的初始目标，说明一下最终状态。

   a. FMEA 目的 – FMEA 的目的是什么?

   b. FMEA 时间安排 – FMEA 的截止日期?

   c. FMEA 团队 – 参与人员清单?

   d. FMEA 任务 - FMEA 的范围?

   e. FMEA 工具 – 如何使用所采取的分析方法?

B. 总结分析范围并确认新的内容。

C. 对功能是如何开发的进行总结。

D. 至少对团队确定的高风险失效进行总结，并提供一份具体的 S/O/D 评级表和措施优先级的方法（如措施优先级表）。

E. 对采取的和/或计划中的措施进行总结（包括这些措施的状态），以解决高风险的失效。

F. 为进行中的 FMEA 改进措施制定计划和时间安排，并承诺完成。

   a. 对尚未确定的措施进行关闭做出承诺和时间安排

   b. 承诺在批量生产期间对 DFMEA 进行评审和修订，以确保相对于生产设计来说，分析是准确和完整的（例如，根据公司程序，由设计变更、纠正措施等引起的修订）。(参考第 1.4 节案例 3 FMEA 修订）

   c. 承诺在"基础 DFMEA"中找到"出差错的地方"，以便在将来适用时可以再次用于分析。参见第 1.3.6 节基础和家族 FMEA。

3 EXECUTION OF THE PROCESS FMEA (PFMEA)

3.1 Process FMEA 1st Step: Planning and Preparation

3.1.1 Purpose

The purpose of the Process Planning and Preparation Step is to describe what product/processes are to be included or excluded for review in the PFMEA project.

The process takes into account that all processes within the facility can be analyzed or reanalyzed using PFMEA. This process allows an organization to review all processes at a high level and to make a final determination for which processes will be analyzed. The overall advantage of Preparation is to focus resources on processes with the highest priority.



The main objectives of the Process Planning and Preparation Step are:

- Project identification
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step

3.1.2 PFMEA Project Identification and Boundaries

PFMEA Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the PFMEAs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

Below are some basic questions that help identify PFMEA projects.

- What is the customer buying from us?
- Are there new requirements?
- What specific process/elements cause a risk in imparting the requirement/characteristic?
- Does the customer or company require a PFMEA?
- Do we make the product and have design control?
- Do we buy the product and still have design control?
- Do we buy the product and do not have design control?
- Who is responsible for the interface design?
- Do we need a system, subsystem, component, or other level of analysis?

3 过程 FMEA（PFMEA）的执行

3.1 过程 FMEA 步骤一：规划与准备

3.1.1 目的

过程规划与准备步骤旨在描述 PFMEA 项目评审中包含或不包含的产品/过程。

该过程考虑工厂内所有过程均可通过 PFMEA 进行分析或重新分析。它使得组织能够在较高水平上评审所有过程，并最终决定需要分析哪些过程。准备阶段的总体优势是将资源集中在优先级最高的过程上。



过程规划与准备步骤的主要目标是：

- 项目确定
- 项目计划：目的、时间安排、团队、任务、工具（5T）
- 分析边界：分析中包括什么、不包括什么
- 根据经验教训确定基准 FMEA
- 结构分析步骤的基础

3.1.2 PFMEA 项目确定和边界

PFMEA 项目确定包括明确了解评估内容。这涉及到一个决策过程来确定顾客项目所需的 PFMEA。在分析中，不包含和包含的内容同等重要。

以下基本问题可帮助确认 PFMEA 项目：

- 顾客从我们这里购买什么？
- 是否有新的要求？
- 在传达要求/特性时，哪些特定过程/要素会导致风险？
- 顾客或公司是否要求 PFMEA？
- 我们是否制造产品并拥有设计控制权？
- 我们是否购买产品且仍然拥有设计控制权？
- 我们是否购买产品且没有设计控制权？
- 谁负责接口设计？
- 我们是否需要系统、子系统、组件或其他层面的分析？

Answers to these questions and others defined by the company help create the list of DFMEA projects needed. The PFMEA project list assures consistent direction, commitment and focus.

The following may assist the team in defining PFMEA boundaries, as available:

- Legal Requirements
- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary/System)
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products
- Error proofing requirements, Design for Manufacturability and Assembly (DFM/A)
- QFD Quality Function Deployment

Preparation needs to be established at the start of the process to assure consistent direction and focus, i.e. an entire process line, process item / process element.

Processes within the plant that can impact the product quality and can be considered for PFMEA analysis: receiving processes, part and material storage, product and material delivery, manufacturing, assembly, packaging, labeling, completed product transportation, storage, maintenance processes, detection processes and rework and repair processes, etc.

对这些问题以及公司定义的其它问题的回答，将帮助创建所需的 PFMEA 项目清单，从而确保了方向、承诺和工作重点的一致性。

以下内容可帮助团队确定 PFMEA 的边界，如下所示：

- 法律要求
- 技术要求
- 顾客需要/需求/期望（外部和内部顾客）
- 要求规范
- 图表（方块图/边界图/系统图）
- 示意图、图纸和/或 3D 模型
- 物料清单（BOM）、风险评估
- 类似产品以往的 FMEA
- 防错要求、可制造及可装配性设计（DFM/A）
- 质量功能展开（QFD）

准备阶段需要在过程开始时就绪，以确保工作方向和关注点一致，即完整的生产线、过程名称/过程要素。

工厂内会影响产品质量且可考虑进行 PFMEA 分析的过程包括：接收过程、零件和材料储存、产品和材料交付、制造、装配、包装、标签、成品运输、储存、维护过程、检测过程以及返工和返修过程等。

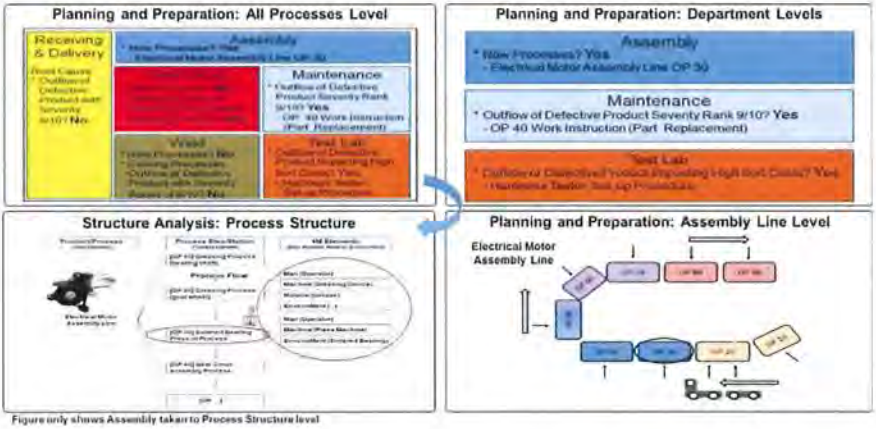


Figure only shows Assembly taken to Process Structure level

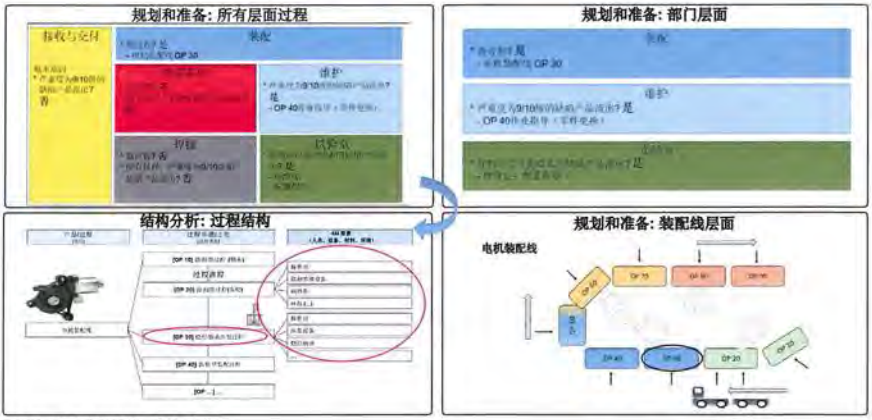
Figure 3. 1-1 Demonstration of the process for narrowing the Preparation

The following may be considered in defining the scope of the PFMEA, as appropriate:

- Novelty of technology/ Degree of innovation
- Quality/Reliability History (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- Complexity of Design
- Safety of people and systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog & standard parts

Items that may assist in determining whether an existing PFMEA should be included in the final scope:

- New development of products & processes.
- Changes to products or processes
- Changes to the operating conditions
- Changed requirements (laws/regulations, standards/norms, customers, state of the art)
- Manufacturing experience, 0 km issues, or field issues / Warranty
- Process failures that may result in hazards
- Findings due to internal product monitoring
- Ergonomic issues
- Continuous Improvement



图表仅显示过程结构层别中的装配

图 3.1-1 缩小准备范围的过程演示

在确定 PFMEA 的范围时，可酌情考虑以下方面：

- 技术新颖性/创新程度
- 质量/可靠性历史（内部、零公里、使用现场失效、类似产品的保修和保险索赔）
- 设计的复杂性
- 人员和系统安全
- 网络物理系统（包括网络安全）
- 法律合规性
- 目录和标准零件

可帮助决定是否将现有 PFMEA 纳入最终范围的项目：

- 新开发的产品和过程
- 产品或过程变更
- 运行条件变更
- 要求变更（法律/法规、标准/规范、顾客、最新技术变更）
- 制造经验、零公里问题或现场问题/保修
- 可能产生危险的过程失效
- 内部产品监视的结果
- 人体工程学问题
- 持续改进

3.1.3 PFMEA Project Plan

A plan for the execution of the PFMEA should be developed once the DFMEA project is known.

It is recommended that the 5T method (Intent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The organization also needs to factor in development of the applicable Customer Specific Requirement(s) (CSRs) methods and/or deliverables into the project plan. The plan for the PFMEA helps the company be proactive in starting the PFMEA early. The DFMEA activities (7-step process) should be incorporated into the overall project plan.

3.1.4 Identification of the Baseline PFMEA

Part of the preparation for conducting the PFMEA is knowing what information is already available that can help the cross-functional team. This includes use of a foundation PFMEA (described in Section 1.3), similar product PFMEA, or product foundation PFMEA. The foundation PFMEA is a specialized foundation process FMEA for products that generally contain common or consistent product boundaries and related functions. For a new product in the foundation, added to this foundation PFMEA would be the new project specific components and functions to complete the new product's PFMEA. The additions for the new product may be in the foundation PFMEA itself, or in a new document with reference to the original family or foundation PFMEA. If no baseline is available, then the team will develop a new PFMEA.

3.1.5 Process FMEA Header

During Preparation, the header of the PFMEA document should be filled out. The header may be modified to meet the needs of the organization and includes some of the basic PFMEA Preparation information as follows:

3.1.3 PFMEA 项目计划

DFMEA 项目明确后，应当立即制定 PFMEA 的执行计划。

建议使用本手册第 1.5 节所述的 5T 方法（目的、时间安排、团队、任务、工具）。在制定项目计划时，组织还需要考虑适用的顾客特定需求（CSR）方法和/或可交付成果的进展情况。PFMEA 计划有助于公司提前启动 PFMEA。DFMEA 活动（七步法过程）应纳入总体项目计划中。

3.1.4 确定基准 PFMEA

PFMEA 的部分准备工作包括了解哪些可用信息对跨职能团队有帮助作用。其中包括使用基础 PFMEA（如第 1.3 节中所述）、类似产品 PFMEA 或产品基础 PFMEA。基础 PFMEA 是专门适用于具有共同或一致产品边界或相关功能的产品的基础过程 FMEA。在新产品的基础上，基础 PFMEA 将添加新项目特定组件和功能，以完成新产品的 PFMEA。新产品的添加要素可能来源于 PFMEA 本身，也可能来源于参考初始系列或基础 PFMEA 的新文件中。若没有可用的基准，团队则会开发一个新 PFMEA。

3.1.5 过程 FMEA 表头

在准备阶段中，PFMEA 文件的表头应填写。表头可根据组织的需要修改，且包括以下一些基本的 PFMEA 准备信息：

Company Name: Name of Company Responsible of PFMEA
Manufacturing Location: Geographical Location
Customer Name: Name of Customer(s) or Product Family
Model Year / Program(s): Customer Application or Company Model /Style
Subject: Name of PFMEA project
PFMEA Start Date: Start Date
PFMEA Revision Date: Latest Revision Date
Cross-Functional Team: Team: Team Roster needed
PFMEA ID Number: Determined by Company
Process Responsibility: Name of PFMEA owner
Confidentiality Level: Business Use, Proprietary, Confidential

Example: Process Failure Mode and Effects Analysis (Process FMEA)

Planning and Preparation(Step 1)

Company Name:	Acme Autornotive	**Subject:**	PX123 Manual Column Assembly		
Manufacturing Location:	Plant 6, Saginaw, Michigan	**PFMEA Start Date:**	19-Mar-2018	**PFMEA ID Number:**	654321
Customer Name:	Jackson Industry	**PFMEA Revision Date:**	25-Sep-2018	**Process Responsibility:**	B. Black
Model Year(s) **/ Program (s):**	2020 PX123	**Cross Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure 3.1-2 Example of Completed PFMEA Header Preparation (Step 1)

3.2 Process FMEA 2nd Step: Structure Analysis

3.2.1 Purpose



The purpose of Process Structure Analysis is to identify and breakdown the manufacturing system into Process items, Process steps, and Process Work Elements.

The main objectives of a Process Structure Analysis are:

- Visualization of the analysis scope
- Structure tree or equivalent: process flow diagram
- Identification of process steps and sub-steps
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

A Process Flow Diagram or a Structure Tree helps define the process and provide the basis for Structure Analysis. Formats may vary by company including the use of symbols, symbol type and their meaning. A Process FMEA is intended to represent the process flow as it physically exists when "walking the process", describing the flow of the product through the process. Function Analysis (Step 3) should not begin until Structure Analysis (Step 2) is complete.

公司名称：负责 PFMEA 的公司名称
制造地址：地理位置
顾客名称：顾客名称或产品系列
年型/项目：顾客应用或公司模式/类型
项目：PFMEA 项目名称
PFMEA 开始日期：开始日期
PFMEA 修订日期：最后修订日期
跨职能团队：团队：所需的团队成员名单
PFMEA ID 编号:由公司确定
过程职责：PFMEA 所有人姓名
保密级别：商业应用、专有、保密

示例：过程失效模式与影响分析（过程FMEA）					
规划与准备（步骤一）					
公司名称：	Acme Autornotive	**项目：**	PX123手动管柱总成		
制造地址：	密歇根萨吉诺6厂	**PFMEA开始日期：**	2018 年 3 月 19 日	**PFMEA ID编号**	654321
顾客名称：	Jackson Industry	**PFMEA修订日期：**	2018 年 9 月 25 日	**过程职责：**	B. Black
年型/项目：	2020 PX123	**跨职能团队：**	参见团队成员列表	**保密级别：**	保密

图 3.1-2 填好的 PFMEA 准备表头示例（步骤一）

3.2 过程 FMEA 步骤二：结构分析

3.2.1 目的



过程结构分析旨在确定制造系统并将其分解为过程项、过程步骤和过程工作要素。

过程结构分析的主要目标是：

- 分析范围的可视化
- 结构树或其他：过程流程图
- 确定过程步骤和子步骤
- 顾客和供应商工程团队之间的协作（接口职责）
- 功能分析步骤的基础

过程流程图或结构树可帮助定义流程，并为结构分析提供基础。具体形式可因公司而异，包括使用符号、符号类型及其含义。过程 FMEA 旨在展示"走流程"时实际存在的过程流程，其描述了整个产品过程的流程。在结构分析（步骤二）结束前不得开始进行功能分析（步骤三）。

3.2.2 Process Flow Diagram

A Process Flow Diagram is a tool that can be used as an input to the Structure Analysis.

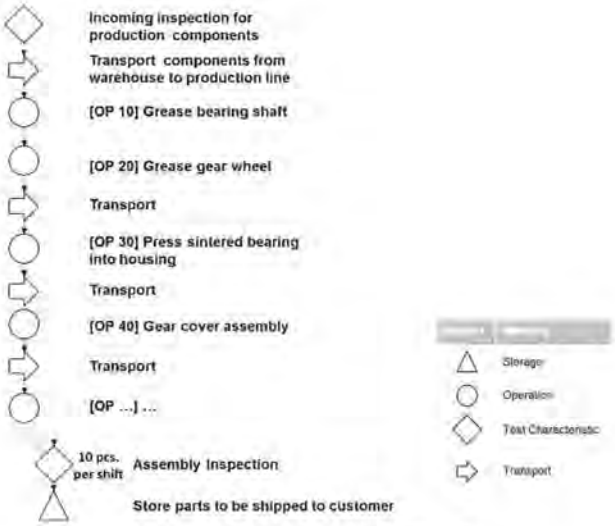


Figure 3.2-1 Process Flow Diagram

3.2.3 Structure Tree

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections. This pictorial structure allows for an understanding of the relationships between Process Items, Process Steps and Process Work Elements. Each of these is a building block that will later have functions and failures added.

3.2.2 过程流程图

过程流程图是一种工具，可被用作结构分析的输入。

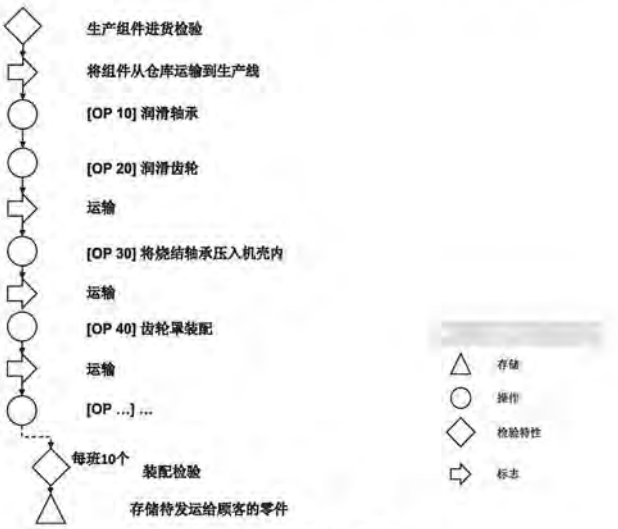


图 3.2-1 过程流程图

3.2.3 结构树

结构树按层次排列系统要素，并通过结构连接展示依赖关系。这种图形结构可帮助理解不同过程项过程步骤和过程工作要素之间的关系。每个元素都是一个构建块，随后会增添相应的功能和失效。

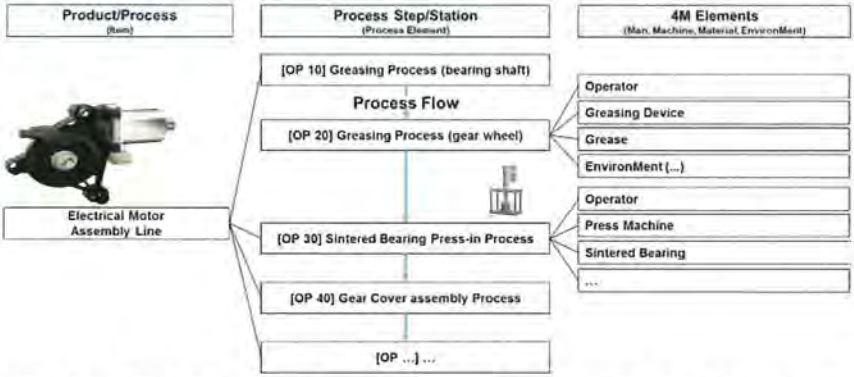


Figure 3.2-2 Example of Structure Analysis Structure Tree (Electrical Motor Assembly Line)

The Process Item of the PFMEA is the highest level of the structure tree or process flow diagram and PFMEA. This can also be considered the end result of all of the successfully completed Process Steps.



Electrical Motor Assembly Line

Figure 3.2-3 Process Item

The Process Step is the focus of the analysis. Process Step is a manufacturing operation or station.

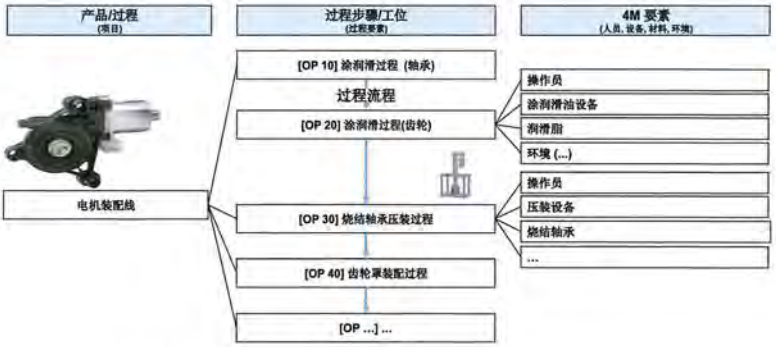


图 3.2-2 结构分析结构树示例（电机装配线）

PFMEA 过程项是结构树或过程流程图和 PFMEA 的最高级别。它也可以被视为成功完成所有过程步骤后的最终成果。



图 3.2-3 过程项

过程步骤是分析的焦点。过程步骤指制造工站或工位。

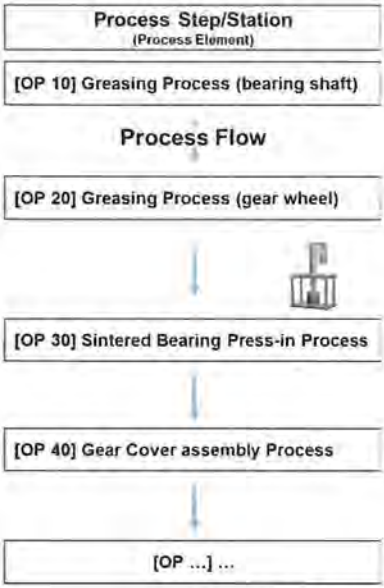


Figure 3.2-4 Process Steps

The Process Work Element is the lowest level of the process flow or structure tree. Each work element is the name of a main category of potential causes that could impact the process step. The number of categories may vary by company, i.e. 4M, 5M, 6M, etc. and is commonly called the Ishikawa Approach. A process step may have one or more categories with each analyzed separately. Refer to Section 3.4-7 Failure Cause for more information about how the 4M approach is used to identify Failure Causes.

4M Categories: Machine

Man

Material (Indirect)

Milieu (EnvironMent)

Additional categories could be, but are not limited to:

Method

Measurement



图 3.2-4 过程步骤

过程工作要素是过程流程或结构树的最低级别。每个工作要素都是一个可能影响过程步骤的主要潜在原因类别的名称。类别数量可能因公司而异，即 4M、5M、6M 等，这通常被称为石川法。过程步骤可能包括一个或多个类别，每个类别都会单独进行分析。关于如何使用 4M 类型确定失效起因，请参见第 3.4-7 节"失效起因"。

4M 类型：设备
人员
材料（间接）
环境

其他类别包括但不限于：
方法
测量

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Press Machine

Figure 3.2-5 Example of Structure Analysis Form

1. **Process Item:**

   The highest level of integration within the scope of analysis.

2. **Process Step:**

   The element in focus. This is the item that is topic of consideration of the failure chain.

3. **Process Work Element:**

   The element that is the next level down the structure from the focus element.

3.2.4 Collaboration between Customer and Supplier engineering teams (interface responsibilities)

The output of the Structure Analysis (visualization of the process flow) provides a tool for collaboration between customers and suppliers (including machine suppliers) during technical reviews of the process design and/or PFMEA project.

3.2.5 Basis for Function Analysis

The information defined during Step 2 Structure Analysis will be used to develop Step 3 Function Analysis. If process elements (operations) are missing from the Structure Analysis they will also be missing from the Function Analysis.

结构分析（步骤二）		
1. 过程项 系统、子系统、组件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素 4M 类型
电机装配线	[OP 30]烧结轴承压装过程	操作人员
电机装配线	[OP 30]烧结轴承压装过程	压装机

图 3.2-5 结构分析表示例

1. **过程项：**
   分析范围内最高整合级别。

2. **过程步骤：**
   受关注的要素。也是考虑失效链的重要项。

3. **过程工作要素：**
   结构中处于关注要素下一低级别的要素。

3.2.4 顾客和供应商工程团队之间的协作（接口职责）

结构分析的输出（过程流程可视化）为顾客和供应商（包括设备供应商）在过程设计和/或 PFMEA 项目技术评审期间的协作提供了工具。

3.2.5 功能分析的基础

步骤二结构分析中定义的信息将被用于步骤三功能分析。若结构分析中缺少过程要素（操作），那么功能分析中也会相应缺少这些要素。

3.3 Process FMEA 3rd Step: Function Analysis

3.3.1 Purpose



The purpose of the Process Function Analysis is to ensure that the intended functions / requirements of the product / process are appropriately allocated.

The main objectives of a Process Function Analysis are:

- Visualization of product or process functions
- Function tree/net or equivalent process flow diagram
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

3.3.2 Function

A function describes what the process item or process step is intended to do. There may be more than one function for each process item or process step.

Prior to beginning the Function Analysis, information to be gathered could include but is not limited to; product and process functions, product/process requirements, manufacturing environment conditions, cycle time, occupational or operator safety requirements, environmental impact, etc. This information is important in defining the "positive" functions and requirements needed for the Functional Analysis.

The description of a Function needs to be clear.

The recommended phrase format is to use an "action verb" followed by a "noun" to describe the measurable process function ("DO THIS" "TO THIS").

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: Drill hole, apply glue, insert pin, weld bracket

The Function of the Process Item begins at a high level, and references the Process Item in the Structure Analysis. As a high- level description, it can take into account functions such as: Internal function, external function, customer related function and/or end user function.

Note: The negative of these will be the Failure Effects.

Example: Assemble components

The Function of the Process Step describes the resulting product features produced at the station.

3.3过程 FMEA 步骤三：功能分析

3.3.1 目的

过程功能分析旨在确保产品/过程的预期功能/要求得到妥善分配。



过程功能分析的主要目标是：

- 产品或过程功能可视化
- 结构树/网或等效过程流程图
- 将要求或特性与功能关联
- 工程团队（系统、安全和组件）之间的协作
- 失效分析步骤的基础

3.3.2 功能

功能描述了过程项或过程步骤的预期用途。每个过程项或过程步骤可能具备多个功能。

在功能分析开始前，需收集的信息可能包括但不限于：产品和过程功能、产品/过程要求、制造环境条件、周期、职业或操作人员安全要求、环境影响等。在定义功能分析所需的"正面"功能和要求时，此类信息至关重要。

功能的描述需清晰准确。

推荐的短语格式为：一个"行为动词"后加一个"名词"，表示可测量的过程功能（"做这个""到这个"）。

功能应该是"现在时态"，并使用动词的基本形式（交付、包含、控制、组装、传输）。

示例： 钻孔、涂胶、插销、焊接支架

过程项的功能从较高级别开始描述，并在结构分析中引用过程项。作为一项高级别描述，过程项可考虑以下功能：内部功能、外部功能、顾客相关功能和/或最终用户功能。

注释： 上述功能的"反面"即为失效影响。

示例： 装配组件

该过程步骤的功能描述了在工位上产生的最终产品特征。

Note: The negative of these will be the Failure Modes.

Example: Press in sintered bearing to pole housing

The Function of the Process Work Element reflects the contribution to the Process Step to create the process / product features.

Note: The negative of these will the Failure Causes.

Example: Get sintered bearing from chute manually

Example: Press force to press sintered bearing into pole housing

For the logical linking of a function and structure, questions are asked as:

"What does it do?"

How to achieve the product / process requirements - from right to left

(Process Item → Process Step → Process Work Element)

"How?"

Why implement the product / process requirements - from left to right

(Process Work Element → Process Step → Process Item)

3.3.3 Requirement(s) (Characteristics)

A Characteristic is a distinguishing feature (or quantifiable attribute) of a product. For example, a diameter or surface finishes. For PFMEA, Requirements are described in terms of Product Characteristics and Process Characteristics.

Note: The negative of these will be the Failure Mode and the Failure Cause.

A Product Characteristic (Requirement) is related to the performance of a process function and can be judged or measured. A product characteristic is shown on a product drawing or specification document i.e. Geometry, Material, Surface Finish, Coatings, etc. Process functions create product characteristics. The design documents comprehend legal requirements (i.e. lead- free material), industry requirements (i.e. thread class), customer requirements (i.e. quantity), and internal requirements (i.e. part cleanliness). Product characteristics can be measured after the product has been made (i.e. gap). Product Characteristics can come from performance requirements, i.e., legal (performance of windshield wipers). In these cases, the measurable Product Characteristic should be listed, followed by the Performance Requirement, i.e., Spline Over-pin Diameter (Government Windshield Wiper Regulation XYZ). The specific quantitative value is optional for the PFMEA form.

注： 上述功能的"反面"即为失效模式。

示例： 将烧结轴承压入电机壳

该过程工作要素的功能反映了过程工作要素对创建过程/产品特性的过程步骤的贡献。

注： 上述功能的"反面"即为失效起因。

示例： 从滑槽手动获取烧结轴承

示例： 用力将烧结轴承压入电机壳

关于功能和结构的逻辑连接关系，需要问以下问题：

"它用来做什么？"

如何实现产品/过程要求—从右到左

（过程项→过程步骤→过程工作要素）

"如何？"

为什么执行产品/过程要求—从左到右

（过程工作要素→过程步骤→过程项）

3.3.3 要求（特性）

特性是产品的区别特征（或量化属性）。例如，轴的直径或表面处理状态。PFMEA 的要求被描述为产品特性和过程特性。

注：上述的"反面"为失效模式和失效起因。

产品特性（要求）与执行过程功能的绩效有关，是可判断或测量的。产品特性展示在产品图纸或规范文件中，例如：几何结构、材料、表面处理状态、涂装等。过程功能产生产品特性。设计文件包括法律要求（例如：无铅材料）、行业要求（例如：螺纹等级）、顾客要求（例如：数量）和内部要求（例如：零件清洁度）。产品特性可在产品制造后测量（例如：间隙）。产品特性可能源于性能要求，例如：法律要求（雨刮器性能）。在上述情况下，应首先列出可测量的产品特性，然后是性能要求，例如：花键过针直径（政府雨刮器条例 XYZ）。在 PFMEA 表格中，具体量值为可选项。

Product Characteristics:

- I.e. may be derived from various sources, external and internal

Legal requirements:

- I.e. compliance with designated health & safety and environmental protection regulations

Industry Norms and Standards:

- I.e. ISO 9001, VDA Volume 6 Part 3, Process Audit, SAE J

Customer Requirements:

- According to customer specifications, i.e. adherence to required quality, manufacture and provision of product(s) in time x and quantity y (output z/hour)

Internal Requirements:

- I.e. manufacture of the product, in process cycle, compliance with expected production costs (i.e. facilities availability, limited rejects, no corrective work), production system principles, process quality and cleanliness instructions

Process Characteristics:

- A Process Characteristic is the process control that ensures the Product Characteristic is achieved by the process. It may be shown on manufacturing drawings or specifications (including operator work instructions, set-up instructions, error-proofing verification procedures, etc.). Process characteristics can be measured while the product is being made (i.e. press force). The specific quantitative value is optional for the PFMEA form.

产品特性：

- 例如：可以从各种外部和内部来源获得

法律要求：

- 例如：遵循指定的健康安全和环境保护条例

行业规范和标准：

- 例如：ISO 9001、VDA6.3过程审核、SAE J 标准

顾客要求：

- 符合顾客规范，例如：满足要求的质量，根据时间 x 和数量 y（输出 z/小时）制造和提供产品

内部要求：

- 产品制造在工艺周期内、符合预期的生产成本（例如：设施可用性、不良品数量有限、无纠正工作）、生产系统原则、过程质量和清洁度说明

过程特性：

- 过程特性指确保通过过程实现产品特性的过程控制。过程特性可展示在制造图纸或规范（包括操作手册、调试手册、防错验证程序等）中。过程特性可以在产品制造过程中测量（例如：压力）。在 PFMEA 表格中，具体量值为可选项。

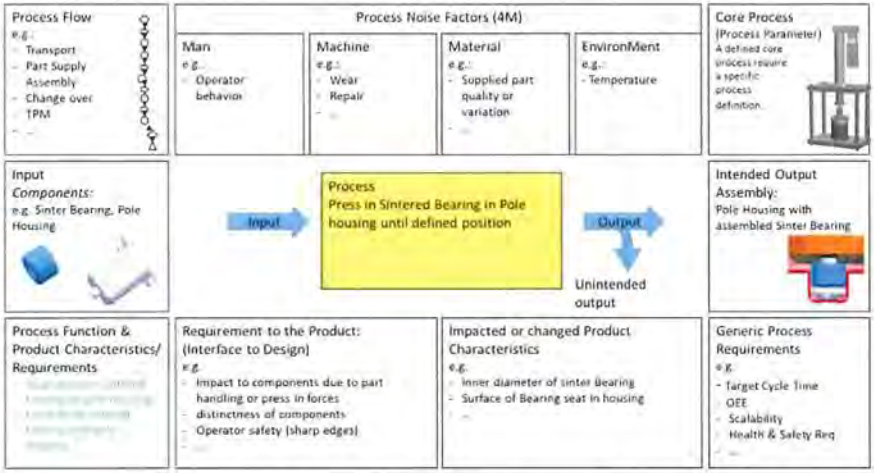


Figure 3.3-1Example of Parameter Diagram of Press in Sintered Bearing

3.3.4 Visualization of functional relationships

The interaction of process item functions, process step functions and process work element functions may be visualized as: function network, function structure, function tree, function matrix, and/or function analysis depending on the software tool used to perform the PFMEA. For example, Function Analysis is contained in the Form to perform the PFMEA.

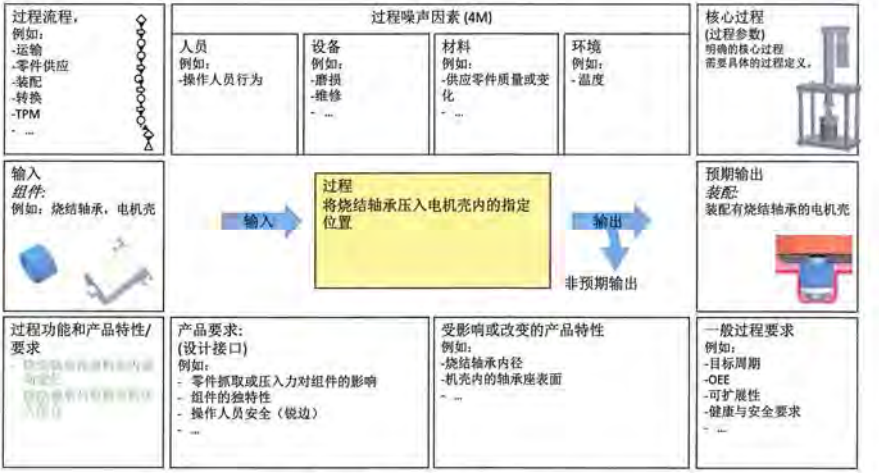


图 3.3-1 压入烧结轴承参数图示例

3.3.4 功能关系可视化

过程项的功能，过程步骤的功能和过程工作要素的功能之间的交互能够可视化为：功能网、功能结构、功能树、功能矩阵和/或功能分析，具体取决于执行 PFMEA 所使用的软件工具。例如，表格中包含了执行 PFMEA 的功能分析。



Figure 3.3-2 Example of Function Analysis Structure Tree

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine presses sintered bearing into the pole housing seat until the defined axial position

Figure 3.3-3 Example of Function Analysis Form

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis. In this section you work from left to right answering the question: "How is the higher level function enabled by lower level functions?"



图 3.3-2 功能分析结构树示例

1. 过程项的功能 系统、子系统、零件要素或过程的功能	2. 过程步骤的功能 和产品特性（量值为可选项）	3. 过程工作要素的功能 和过程特性
您的工厂： 将轴安装至电机壳总成内 发运至工厂： 将电机安装至车门上 最终用户： 升起和降下车窗	压装烧结轴承，在每次压装时实现电机壳内的轴向定位保留最大间隙	机器将烧结轴承压入电机壳，实现轴向定位

图 3.3-3 功能分析表示例

表格内采用了表头栏编号（1、2、3）和颜色编码，以显示结构分析和功能分析相关内容之间的对应关系。在本节中，您需要从左到右回答以下问题："高级别功能是如何通过低级别功能实现的？"

3.3.5 Collaboration between Engineering Teams (Systems, Safety, and Components)

Engineering teams within the company need to collaborate to make sure information is consistent for a project or customer program especially when multiple PFMEA teams are simultaneously conducting the technical risk analysis. For example, design information from systems, safety, and/or component groups helps the PFMEA team understand the functions of the product they manufacture. This collaboration may be verbal (program meetings) or written as a summary.

3.3.6 Basis for Failure Analysis

Complete definition of process functions (in positive words) will lead to a comprehensive Step 4 Failure Analysis because the potential failures are ways the functions could fail (in negative words).

3.4 Process FMEA 4th Step: Failure Analysis

3.4.1 Purpose

The purpose of the Process Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The main objectives of a Process Failure Analysis are:



- Establishment of the failure chain
- Potential Failure Effects, Failure Modes, Failure Causes for each process function
- Identification of process failure causes using a fishbone diagram (4M) or failure network
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

A failure analysis is performed for each element/step in the process description (Structure Analysis/Step 2 and Function Analysis/Step 3).

3.4.2 Failures

Failures of a process step are deduced from product and process characteristics. Examples include:

- non-conformities,
- inconsistently or partially executed tasks,
- unintentional activity
- unnecessary activity

3.3.5 工程团队（系统、安全和组件）之间的协作

公司内部的工程团队需要相互协作，以确保项目或顾客项目的信息保持一致，尤其是多个 PFMEA 团队同时执行技术风险分析时。例如，系统、安全和/或组件团队提供的设计信息可帮助 PFMEA 团队了解团队制造产品的功能。这种协作可通过口头（项目会议）或书面总结的形式实现。

3.3.6 失效分析的基础

对过程功能进行完整定义（正面词汇）后，将能够执行全面的步骤四"失效分析"，因为潜在失效通常是功能无法被满足（反面词汇）。

3.4过程 FMEA 步骤四：失效分析

3.4.1 目的

过程失效分析旨在确定失效起因、模式和影响，并展示它们之间的关系，以便进行风险评估。



过程失效分析的主要目标是：

- 建立失效链
- 每个过程功能的潜在失效影响、失效模式和失效起因
- 使用鱼骨图（4M 类型）或失效网识别过程失效起因
- 顾客和供应商之间的协作（失效影响）
- FMEA 中失效的文件编制和风险分析步骤的基础

每个过程要素/步骤（结构分析/步骤二和功能分析/步骤三）都会执行失效分析。

3.4.2 失效

过程步骤失效源于产品和过程特性。示例包括：

- 不符合要求
- 不一致或部分被执行的任务
- 没有目标的活动
- 不必要的活动

3.4.3 The Failure Chain

For a specific failure, there are three aspects to be considered:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

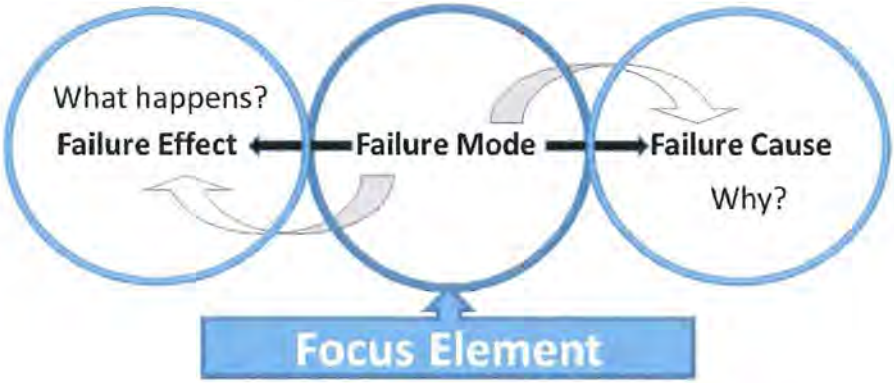


Figure 3.4-1 Theoretical failure chain model

3.4.4 Failure Effects

Failure Effects are related to functions of the process item (System, Subsystem, Part Element or Name of Process). Failure Effects are described in terms of what the customer might notice or experience. Failures that could impact safety or cause noncompliance to regulations should be clearly identified in the PFMEA.

Customers could be:

- Internal customer (next operation/subsequent operation/operation tar-gets)
- External customer (Next Tier Level/OEM/dealer)
- Legislative bodies
- Product or Product end user/operator

Failure Effects that are given a Severity rating:

1. Your Plant: the effect of the failure mode assuming the defect is detected in the plant (what action will the plant take i.e. scrap)

3.4.3 失效链

针对特定失效，需考虑以下三个方面：

- 失效影响（FE）
- 失效模式（FM）
- 失效起因（FC）

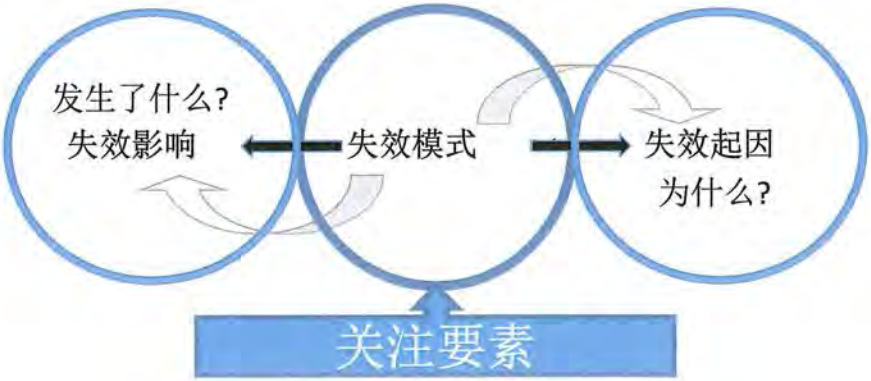


图 3.4-1 理论失效链模型

3.4.4 失效影响

失效影响与过程项的功能（系统、子系统、组件要素或过程名称）相关。失效影响被描述为顾客注意或体验的结果。PFMEA 中应明确指出可能影响安全或导致不符合法规的失效。

顾客可能是：

- 内部顾客（下一步操作/后续操作/操作目标）
- 外部顾客（下一层级/OEM/经销商）
- 立法机构
- 产品或产品最终用户/操作人员

以下失效影响会进行严重度评级：

1. 您的工厂：假设在工厂内检测到失效，则该失效模式的影响（工厂会采取什么措施，例如：报废）

2. Ship-to plant: the effect of the failure mode assuming the defect is not detected before shipping to the next plant (what action will the next plant take i.e. sort)
3. End user: the effect of the process item effect (what will the end user notice, feel, hear, smell, etc. i.e. window raises too slow)

The following questions should be asked to help determine which group of failure effects apply:

1. Does the failure mode physically impact downstream processing or cause potential harm to equipment or operators?

   This includes an inability to assemble or join to a mating component at any subsequent customer's facility.

   If so, then identify the manufacturing impact "Your Plant" and/or "ship-to plant" in the PFMEA. If not, then go to question 2.

   Examples could include:

   - Unable to assemble at operation x
   - Unable to attach at customer facility
   - Unable to connect at customer facility
   - Cannot bore at operation x
   - Causes excessive tool wear at operation x
   - Damages equipment at operation x

- Endangers operator at customer facility

Note: When parts cannot be assembled there is no impact to the End User and question 2 does not apply.

2. What is the potential impact on the End User?

Independent of any controls planned or implemented including error or mistake-proofing, consider happens to the process item that leads to what the End User would notice or experience. This information may be available within the DFMEA. If an effect is carried from the DFMEA, the description of the product effects in the PFMEA should be consistent with those in the corresponding DFMEA.

2. 发运至工厂：假设在发运至下一个工厂前未检测到失效，该失效模式的影响（下一个工厂会采取什么措施，例如：分拣）

3. 最终用户：过程项影响的后果（最终用户关注、感觉、听到、闻到什么等，例如：车窗升得太慢）

在决定哪一组失效影响适用时，提出以下问题会有帮助：

1. 失效模式是否会对下游加工过程造成物理影响，或对设备或操作人员造成潜在伤害？
   在后续任何顾客工厂内无法进行组装或与对手件对配。

   若答案为是，则应确定 PFMEA 中"您的工厂"和/或"发运至工厂"的制造影响。若答案为否，请回答第 2 个问题。

   示例可包括：
   - 无法在工位 x 处组装
   - 无法在顾客端进行卡嵌
   - 无法在顾客端进行对接
   - 不能在工位 x 处钻孔
   - 导致工位 x 处刀具过度磨损
   - 工位 x 处设备损坏

- 对顾客端操作人员带来安全风险

注：　若零件无法组装，则对最终用户不产生影响，第 2 个问题也不适用。

2. 对最终用户有什么潜在影响？

独立于计划或实施的任何控制，包括错误或防错，请考虑导致最终用户注意或体验的过程项会发生什么。此类信息可能通过 DFMEA 获得。若某一影响来自 DFMEA，则 PFMEA 中的产品影响描述应与相应的 DFMEA 保持一致。

NOTE: In some cases, the team conducting the analysis may not know the end user effect (i.e. catalogue parts, off- the-shelf products, Tier 3 components). When this information is not known, the effects should be defined in terms of the part function and/or process specification.

Examples could include:

- Noise
- High effort
- Unpleasant odor
- Intermittent operation
- Water leak
- Rough idle
- Unable to adjust
- Difficult to control
- Poor appearance
- Regulatory System Function reduced or failed
- End user lack of vehicle control
- Safety effect on End user

3. What would happen if a failure effect was detected prior to reaching the End User?

   The failure effect at the current or receiving locations also needs to be considered.

   Identify the manufacturing impact "Your Plant" and/or "ship-to plant" in the PFMEA.

   Examples could include:

   - Line shutdown
   - Stop shipment
   - Yard hold
   - 100% of product scrapped
   - Decreased line speed
   - Added manpower to maintain required line rate
   - Rework and repair

注：　在某些情况下，分析团队可能并不了解最终用户影响（例如：目录零件、现货产品、第 3 级组件）。若不了解此类信息，应根据产品功能和/或过程规范定义影响。

示例可包括：

- 噪声
- 很费劲
- 气味难闻
- 间歇运行
- 漏水
- 怠速不稳
- 无法调整
- 难以控制
- 外观不良
- 监管系统功能下降或失效
- 最终用户无法控制车辆
- 对最终用户的安全影响

3. 若在到达最终用户前检测到失效影响，会发生什么？

当前或接收位置的失效影响也需要考虑在内。

确定 PFMEA 中"您的工厂"和/或"发运至工厂"的制造影响。

示例可包括：

- 停线
- 停止发运
- 整车候检
- 产品 100%报废
- 生产线生产速度降低
- 增加人力以维持所需的生产线节拍
- 返工和返修

3.4.5 Failure Mode

A (Process) Failure Mode is defined as the manner in which the process could cause the product not to deliver or provide the intended function.

The team should assume that the basic design of the product is correct; however, if there are design issues which result in process concerns, those issues should be communicated to the design team for resolution.

Assume that the failure mode could occur but may not necessarily occur. Failure modes should be described in technical terms, not as a symptom noticeable by the customer.

Verification of completeness of the failure modes can be made through a review of past things-gone-wrong, reject or scrap reports, and group brainstorming. Sources for this should also include a comparison of similar processes and a review of customer (End User and subsequent operation) claims relating to similar components.

There are several categories of potential failure modes including:

- loss of process function/operation not performed
- Partial function-- Incomplete operation
- Degradation of process function
- Overachieving process function - Too much too high.
- Intermittent process function-operation not consistent
- unstable operation
- Unintended process function-wrong operation
- wrong part installed
- Delayed process function-operation too late

Typical failure modes could be, but are not limited to:

- Hole too shallow, too deep, missing or off location.
- Dirty surface
- Surface finish too smooth
- Misaligned connector pins
- Connector not fully seated
- Pass a bad part, or reject a good part, bypass inspection operation
- Label missing
- Barcode not readable
- ECU flashed with wrong software.

3.4.5 失效模式

（过程）失效模式指过程导致产品无法交付或提供预期功能的方式。

团队应假设产品的基本设计是正确的；但如果存在设计问题，且此类设计问题会导致过程问题，则应将问题和设计团队沟通以获得解决。

假设失效模式可能但不一定会出现。失效模式应使用技术术语描述，而非顾客容易察觉的现象。

失效模式的完整性可通过评审以往错误案例、不合格品或废品报告以及集体讨论的方式进行验证。其来源还应包括：对比类似过程，以及评审有关类似组件的顾客（最终用户和后续操作）索赔案例。

潜在失效模式的类别包括：

- 过程功能丧失/操作未执行
- 部分功能丧失—操作不完整
- 过程功能降低
- 过程功能超出预期—高出太多
- 间歇过程功能—操作不一致
- 运行不稳定
- 非预期过程功能—操作错误
- 安装错误零件
- 过程功能延迟—操作太迟

典型的失效模式可能是但不限于：

- 孔太浅、太深、缺失或偏离位置
- 表面脏污
- 表面处理过度
- 连接器插脚错位
- 连接器未完全到位
- 接收不合格零件，拒收合格零件，跳过检测工位
- 标签丢失
- 条形码不可读
- ECU 刷新时用错软件

3.4.6 Failure Cause:

A failure cause is an indication of why a failure mode could occur. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential manufacturing or assembly cause for each failure mode. The cause should be listed as concisely and completely as possible so that efforts (controls and actions) can be aimed at appropriate causes.

Typical failure causes may include the classic Ishikawa's 4M, but are not limited to:

- **Man**: set-up worker, machine operator/ associate, material associate, maintenance technician etc.
- **Machine/Equipment:** robot, hopper reservoir tank, injection molding machine, spiral conveyor, inspection devices, fixtures, etc.
- **Material (Indirect):** machining oil, installation grease, washer concentration, (aid for operation), etc.
- **Milieu/Environment:** ambient conditions such as heat, dust, contamination, lighting, noise, etc.

Note: In preparing the FMEA, assume that the incoming part(s)/material(s) are correct. Exceptions can be made by the FMEA team where historical data indicate deficiencies in incoming part quality.

One method to help reveal / uncover failure causes is to have a facilitator that leads the team through "Thought Provoking Stimulation Questions". These questions can be broad category questions, enough to stimulate the process experts thought process, while keeping the number of questions to a manageable level. Questions can be process specific and broken down into the 4M categories. Initial list of questions can be formed by reviewing the Failure Causes in previous PFMEA's.

Example - Assembly Process:

3.4.6.1 Man

1. From parts available within the process, can wrong part be applied?
2. Can no part be applied?
3. Can the parts be loaded incorrectly?
4. Can parts be damaged - From pickup to application?
5. Can wrong material be used?

3.4.6.2 Machine

1. Can automated process be interrupted?

3.4.6 失效起因：

失效起因指失效模式出现的原因。失效模式是失效起因的结果。在可能的范围内，应确定每个失效模式在制造或装配方面的潜在原因。尽可能简明扼要地列出原因，以便针对性地采取相应的行动（控制和措施）。

典型的失效起因可能包括经典的石川 4M 类型，但不仅限于：

- **人员**：安装工人、机器操作人员/助理、材料助理、维护技术员等。
- **机器/设备**：机器人、漏斗型储料罐、注塑机、螺旋输送机、检验设备、夹具等。
- **材料（间接）**：机油、安装润滑脂、浓缩洗涤剂、（操作辅助工具）等。
- **环境**：热度、灰尘、污染、照明、噪音等环境条件。

> 注：　在编制 FMEA 时，应假设来料零件/材料正确。若历史数据显示来料零件存在质量缺陷，则 FMEA 团队可例外处理。

安排推进者引导团队思考"值得深思的激励问题" 能够帮助揭示/发现失效起因的一种方法。这些问题可以是广义问题，它们应该能够激励过程专家思考整个过程，且问题数量应维持在可管理的水平。它们可以仅与过程相关，且能够按照 4M 类型细分。通过分析以往 PFMEA 中的失效起因，可制定问题初始列表。

示例—装配过程：

3.4.6.1 人员

1. 是否可能使用过程中的可用错误零件？
2. 是否可能没有零件使用？
3. 是否可能错误加载零件？
4. 零件从拿取到应用期间是否会损坏？
5. 是否可能使用错误材料？

3.4.6.2 设备

1. 自动化过程是否可能中断？

2. Can inputted data be entered incorrectly?
3. Can machine be run in manual mode, bypassing automated controls?
4. Is there a schedule to confirm prevention and detection controls?

3.4.6.3 Material (indirect)

1. Can too much / too little / no material be used?
2. Can material be applied to a wrong location?

3.4.6.4 EnvironMent

1. Is lighting adequate for task?
2. Can parts used within the process, be considered foreign material?

The description of the failure cause needs to be clear. Terms such as defective, broken, operator failure, non-fulfillment or not OK and so on are insufficient to comprehensively assign the failure cause and mode and to determine actions.

3.4.7 Failure Analysis

Based on the process steps, the failures are derived and failure chains (i.e. Failure structure/failure trees/failure network) are created from the function analysis (see figure 3.3-1).

The focus element of the failure structure is the Failure Mode, with its associated Failure Effects and their Failure Causes. Depending on the focus, a failure can be viewed as a Failure Effect, Failure Mode, or Failure Cause.

To link failure cause(s) to a failure mode, the question should be "Why is the failure mode occurring?"

To link failure effects to a failure mode, the question should be "What happens in the event of a failure mode?"

2. 数据是否可能错误输入？
3. 机器是否可能绕过自动控制，在手动模式下运行？
4. 确定预防和探测控制措施是否需要遵循相关计划？

3.4.6.3 材料（间接）

1. 是否可能过多/过少/没有材料使用？
2. 是否可能在错误位置使用材料？

3.4.6.4 环境

1. 任务所需的照明是否足够？
2. 过程中使用的零件是否被视为异物？

失效起因的描述需清晰准确。“缺陷”、“破损”、“操作失败”、“不遵守要求”或“不正常”等术语无法全面描述失效起因和模式并确定应对措施。

3.4.7 失效分析

根据过程步骤，导出故障并从功能分析中创建故障链（即失效结构/失效树/失效网）（见图 3.3-1）。

失效结构的关注要素被称为失效模式，失效模式存在相应的失效影响和失效起因。根据关注对象的不同，失效可被理解为失效影响、失效模式或失效起因。

可通过解答“为什么会出现失效模式”这一问题找到失效起因和失效模式之间的关联。

可通过解答“失效模式会导致什么后果”这一问题找到失效影响与失效模式之间的关联。



Figure 3.4-2 Example of Failure Analysis Structure Tree

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure 3.4-3 Example of Failure Analysis Form

Begin building the failure chain by using the information in the Function Analysis. When using a customer specific form or software, follow the methodology as defined by your customer. This handbook recommends the Function Analysis section of the spreadsheet is filled-out following the header numbering (1, 2, 3) and color coding.

1. Failure Effects (FE):

   The effect of failure associated with "1. Function of Process Item" in the Function Analysis.

Note for spreadsheet users: A potential failure mode may have more than one failure effect. Failure effects are grouped in the spreadsheet in order to avoid excessive duplication of the same failure modes and causes.



图 3.4-2 失效分析结构树示例

失效分析（步骤四）		
1.对于上一较高级别要素和/或最终用户的失效影响（FE）	2.关注要素的失效模式（FM）	3.工作要素的失效模式（FM）
您的工厂： 间隙太小无法安装轴，没有潜在损害 发运至工厂： 将电机安装至车门上需要额外插入力，存在潜在损害 最终用户： 舒适模式关闭时间过长	不能实现烧结轴承的轴向定位	设备在达到最终位置前停止

图 3.4-3 失效分析表示例

利用功能分析中的信息开始构建失效链。在使用顾客特定表格或软件时，请遵循顾客定义的方法。本手册建议根据下列表头编号（1、2、3）和颜色编码填写电子表格的功能分析部分。

1. 失效影响（FE）：

   与功能分析中"1.过程项的功能"相关的失效影响。

> 电子表格用户注意：潜在失效模式可导致多个失效影响。电子表格中对失效影响进行了分类，以避免相同的失效模式和起因过多重复。

2. Failure Mode (FM):

   The mode (or type) of failure associated with "2. Function of Process Step" in the Function Analysis.

Note for spreadsheet users: It is recommended that users start with the failure mode and then identify related failure effects using the information in the #1 Function of the Process Item column of the Function Analysis section because some or all categories may apply.

3. Failure Cause (FC):

   The cause of failure associated with the "3. Function of Process Work Element" in the Function Analysis.

3.4.8 Relationship between PFMEA and DFMEA

A design failure of a feature (product characteristic) can cause a failure for one or more product functions. The corresponding process failure is the inability of the process to manufacture the same feature as designed. The failure to conform to a product characteristic alone leads to the Failure Effect. Only in this case is the Failure Effect in the Design FMEA the same as in the Process FMEA. All Failure Effects which are caused by a failure of the processes and which are not identified in Design FMEA have to be newly defined and assessed in the Process FMEA.

The Failure Effects related to the product, system, and/or end user and their associated severities should be documented when known, but not assumed. The key to the identification of Failure Effects and associated severities is the communication of the involved parties and the understanding of differences and similarities of the analyzed failures in DFMEA and PFMEA see also figure 1.4-1).

Figure 3.4-4 shows a potential interrelation of product-related Failure Effects, Failure Modes and Failure Causes from the "End User" level to the level of production (PFMEA level).

Note: The expectation of the relative time of and the flow of information from the DFMEA to the PFMEA is different in non-standard development flows, such as where development of a "standard" process precedes development of the products that will be manufactured using it. In such cases, the appropriate timing and flow of information between these FMEAs should be defined by the organization.

2. 失效模式（FM）：

与功能分析中"2.过程步骤的功能"相关的失效模式（类型）。

电子表格用户注意：建议用户从失效模式开始填写，然后利用功能分析部分"1.过程项的功能"分栏中所示的信息确定相应的失效影响，这是因为其中部分或全部类别可能是有适用的。

3. 失效起因（FC）：

与功能分析中"3.过程工作要素的功能"相关的失效起因。

3.4.8 PFMEA 与 DFMEA 的关系

一项特征（产品特性）的设计失效可能导致一项或多项产品功能失效。相应的过程失效指过程无法实现设计特征。不符合产品特性这一项就会导致失效影响。只有在这种情况下，设计 FMEA 和过程 FMEA 中的失效影响才会一致。所有因过程失效导致的失效影响以及设计 FMEA 中未识别的失效影响都必须在过程 FMEA 中进行重新定义和评估。

应在了解事实后对与产品、系统和/或最终用户相关的失效影响及其严重度进行记录，而非对其作出假设。确定失效影响及其严重度的关键在于参与方之间互相沟通以及了解 DFMEA 和 PFMEA 中所分析的失效的异同点（另见图 1.4-1）。

图 3.4-4 显示了与产品相关的失效影响、失效模式和失效起因之间从"最终用户"级别到生产级别（PFMEA 级别）的潜在相互关系。

注：　在非标准开发流程中，DFMEA 到 PFMEA 的相对时间和信息流动预期是不一样的，例如，"标准"过程的开发优先于通过该过程制造的产品的开发。在这种情况下，组织应确定 FMEA 之间合适的时间安排和信息流动。



Figure 3.4-4 Relationship between PFMEA and DFMEA

3.4.9 Failure Analysis Documentation

After the Structure Analysis, Function Analysis and Failure Analysis are complete a structure tree or spreadsheet can have multiple views.

1. Process Item System, Subsystem, Part Element or Name of Process	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	1.Failure Effects (FE) to the Next Higher Level Element and/or End User
Electrical Motor Assy Line	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.

Figure 3.4-5 View of Process Item-Function-Failure Form

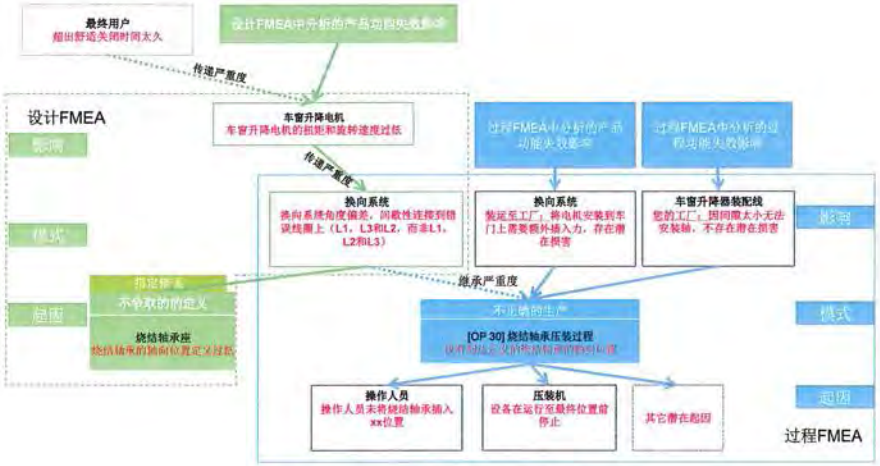


图 3.4-4 PFMEA 与 DFMEA 的关系

3.4.9 失效分析文件化

结构分析、功能分析和失效分析完成后，结构树或电子表格可制成多种视图。

1.过程项 系统、子系统、零件要素或过程名称	1. 过程项的功能 系统、子系统、零件要素或过程的功能	1.对于上一较高级别要素和/或最终用户的失效影响（FE）
电机装配线	您的工厂： 将轴安装至电机壳总成内 发运至工厂： 将电机安装至车门上 最终用户： 升起和降下车窗	您的工厂： 间隙太小无法安装轴，没有潜在损害 发运至工厂： 将电机安装至车门上需要额外插入力，存在潜在损害 最终用户： 舒适模式关闭时间过长

图 3.4-5 过程项-功能-失效表格视图

2. Process Step Station No. and Name of Focus Element	2.Function of the Process Step and Product Characteristic (Quantitative value is optional)	2. Failure Mode (FM) of the Process Step
[OP 30] Sintered Bearing Press-In Process	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached

Figure 3.4-6 View of Process Step-Function-Failure Form

3. Process Work Element 4M Type	3. Function of the Process Work Element and Process Characteristic	3. Failure Cause (FC) of the Work Element
Press Machine	Machine presses sintered bearing into the pole housing seat until the defined axial position	Machine stops before reaching final position

Figure 3.4-7 View of Process Work Element-Function-Failure Form

3.4.10 Collaboration between Customer and Supplier (Failure Effects)

The output of the Failure Analysis may be reviewed by customers and suppliers prior to the Risk Analysis step or after to the Risk Analysis step based on agreements with the customer and need for sharing with the supplier.

3.4.11 Basis for Risk Analysis

Complete definition of potential failures will lead to a complete Step 5 Risk Analysis because the rating of Severity, Occurrence, and Detection are based on the failure descriptions. The Risk Analysis may be incomplete if potential failures are too vague or missing.

3.5 Process FMEA 5th Step: Risk Analysis

3.5.1 Purpose



The purpose of Process Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, in order to prioritize the need for actions.

The main objectives of the Process Risk Analysis are:

- Assignment of existing and/or planned controls and rating of failures
- Assignment of Prevention Controls to the Failure Causes

2.过程步骤工位编号和关注要素名称	2.过程步骤的功能和产品特性（量值为可选项）	2.过程步骤的失效模式（FM）
[OP 30]烧结轴承压装过程	压装烧结轴承，在每次压装时实现电机壳内的轴向定位按照图纸保留最大间隙	不能实现烧结轴承的轴向定位

图 3.4-6 过程步骤-功能-失效表格视图

3.过程工作要素 4M 类型	3.过程工作要素的功能和过程特性	3.工作要素的失效模式（FM）
压装机	机器将烧结轴承压入电机壳，实现轴向定位	设备在达到最终位置前停止

图 3.4-7 过程工作要素-功能-失效表格视图

3.4.10 顾客和供应商之间的协作（失效影响）

根据与顾客达成的协议以及与供应商共享信息的需求，失效分析的输出可在风险分析步骤之前或之后由顾客和供应商进行评审。

3.4.11 风险分析的基础

潜在失效的完整定义将为步骤五"风险分析"的完整实施提供基础，因为严重度、频度和探测度评级都是建立在失效描述的基础上。如果潜在失效过于模糊或缺失，则可能导致风险分析不完整。

3.5过程 FMEA 步骤五：风险分析

3.5.1 目的



过程风险分析的目的是通过严重度、频度和探测度评级进行风险评估，并对需要采取的措施进行优先排序。

过程风险分析的主要目标是：

- 对现有和/或计划的控制进行分配、并对失效进行评级
- 针对失效起因，分配预防控制

- Assignment of Detection Controls to the Failure Causes and/or Failure Modes
- Rating of Severity, Occurrence and Detection for each failure chain
- Collaboration between customer and supplier (Severity)
- Basis for the product or process Optimization step

There are two different Control Groups: Current Prevention Controls, and Current Detection Controls.

3.5.2 Current Prevention Controls (PC)

3.5.2.1 Process planning

Definition: Current Prevention Controls facilitate optimal process planning to minimize the possibility of failure occurrence.

Prevention of possible layout deficiencies of the production facility:

- Test runs according to start-up regulation AV 17/3b

3.5.2.2 Production process

Definition: Eliminate (prevent) the failure cause or reduce its rate of occurrence.

Prevention of defectively produced parts in the production facility:

- Two-handed operation of machines
- Subsequent part cannot be attached (Poka-Yoke)
- Form-dependent position
- Equipment maintenance
- Operator maintenance
- Work instructions / Visual aids
- Machine controls
- First part release

Failure Causes are rated for occurrence, taking into account the effectiveness of the current prevention control (Chapter Risk Evaluation).

Current Prevention Controls describe measures which should be implemented in the design process and verified during prototype, machine qualifications (run-off), and process verification prior to start of regular production. Prevention Controls may also include standard work instructions, set-up procedures, preventive maintenance, calibration procedures, error-proofing verification procedures, etc.

- 针对失效起因和/或失效模式，分配探测控制
- 针对每个失效链进行严重度、频度和探测度评级
- 顾客和供应商之间的协作（严重度）
- 产品或过程优化步骤的基础

有两种不同的控制类型：当前预防控制和当前探测控制。

3.5.2 当前预防控制（PC）

3.5.2.1 过程规划

定义：当前预防控制有助于优化过程规划，从而最大程度降低将失效发生的可能性。

防止生产工厂中可能存在的布局缺陷：

- 根据启动条例 AV 17/3b 开展试运行

3.5.2.2 生产过程

定义：消除（防止）失效起因或降低失效频度。

防止生产工厂内生产不合格零件：

- 双手操作机器
- 后续零件无法连接（防错技术）
- 与形状相关的位置
- 设备维护
- 操作人员维护
- 作业指导书/视觉辅助
- 机器控制
- 首件放行

考虑当前预防措施的有效性（风险评估章节），评估失效起因的发生频度。

当前预防控制描述了设计过程中应实施的措施，此类措施应在原型件、设备验收（运转）和正式生产开始前的过程验证期间进行验证。预防控制措施还包括标准作业指导、安装程序、预防性维护、校验程序、防错验证程序等。

3.5.3 Current Detection Controls (DC)

Definition: Current Detection controls detect the existence of a failure cause or the failure mode, either by automated or manual methods, before the item leaves the process or is shipped to the customer.

Examples of Current Detection controls:

- Visual inspection
- Visual inspection with sample checklist
- Optical inspection with camera system
- Optical test with limit sample
- Attributive test with mandrel
- Dimensional check with a caliper gauge
- Random inspection
- Torque monitoring
- Press load monitoring
- End of line function check

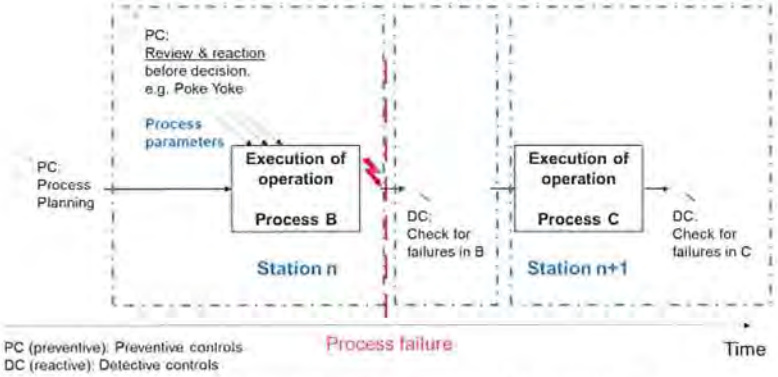


Figure 3.5-1 Prevention and Detection in the Process FMEA

3.5.3 当前探测控制（DC）

定义：当前探测控制指在产品离开过程或发运给顾客前，通过自动或手动方法探测是否存在失效起因或失效模式。

当前探测控制示例包括：

- 目视检验
- 使用样本检查表进行目视检验
- 使用摄像系统进行光学检验
- 使用极限样本进行光学测试
- 使用通止规进行定性检验
- 用卡尺检验尺寸
- 随机检验
- 扭矩监测
- 压力负荷监测
- 下线前功能检验

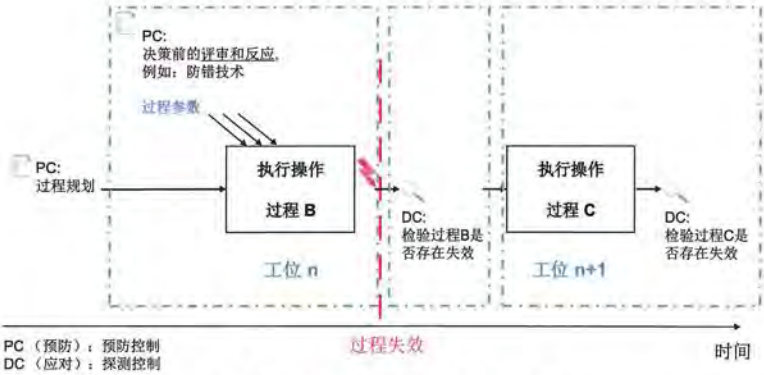


图 3.5-1 过程 FMEA 中的预防和探测

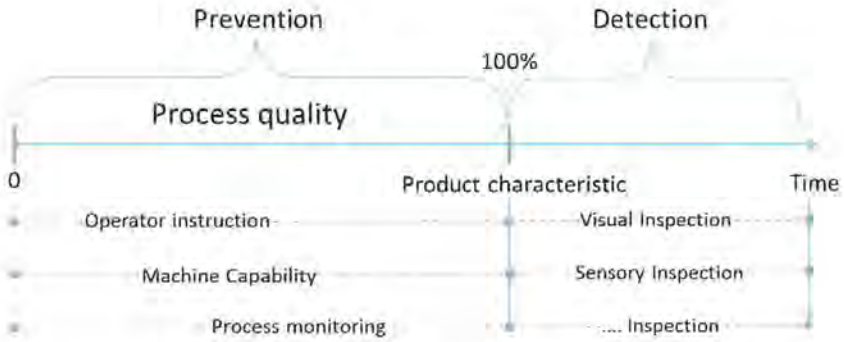


Figure 3.5-2 Roadmap of process understanding

3.5.4 Current Prevention and Detection Controls

Current Prevention and Detection Controls should be confirmed to be implemented and effective. This can be done during an in- station review (i.e. Line Side Review, Line walks and Regular audits). If the control is not effective, additional action may be needed.

The Occurrence and Detection ratings should be reviewed when using data from previous processes, due to the possibility of different conditions for the new process.

3.5.5 Evaluations

Each Failure Mode, Cause and Effect relationship (failure chain or net) is assessed for its independent risk. There are three rating criteria for the evaluation of risk:

Severity (S):	stands for the Severity of the Failure Effect
Occurrence (O):	stands for the Occurrence of the Failure Cause
Detection (D):	stands for the Detection of the occurred Failure Cause and/or Failure Mode

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, in which 10 stands for the highest risk contribution.

NOTE: It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e., the ratings are subjective).

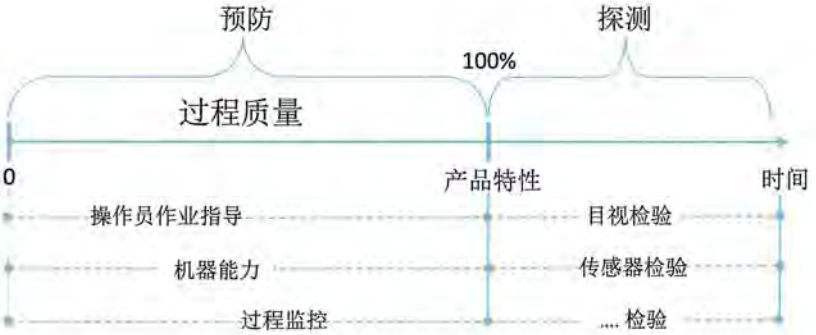


图 3.5-2 过程理解路线图

3.5.4 当前预防和探测控制

应确认当前的预防和检测控制措施的实施和有效性。这一步可以通过工位内评审（例如：线边评审、生产线巡查和定期审核）实现。若控制无效，则可能需要采取其他措施。

由于新过程中可能存在不同条件，在使用前期过程的数据时应对频度和探测度评级进行评审。

3.5.5 评估

每种失效模式、起因和影响之间的关系（失效链或失效网）的独立风险均需进行评估。风险评估需遵循三个评级标准：

严重度（S）：失效影响的严重度。

频度（O）：失效起因的发生频率。

探测度（D）：失效起因和/或失效模式的探测度。

S、O 和 D 评级结果分别使用从 1 到 10 表示，其中 10 代表最高风险。

> 注：　将某一团队的 FMEA 评级与其他团队的 FMEA 评级进行比较并不合适，即便二者的产品/过程相似，但由于每个团队的环境是独一无二的，因此其各自的评级也应该是独一无二的（即：评级是主观的）。

3.5.6 Severity (S)

Severity is a rating number associated with the most serious effect for a given failure mode for the process step being evaluated. It is a relative rating within the scope of the individual FMEA and is determined without regard for Occurrence or Detection.

For process-specific effects, the Severity rating should be determined using the criteria in evaluation Table P1. The table may be augmented to include corporate or product line specific examples.

The evaluations of the Failure Effects should be mutually agreed to by the customer and the organization.

NOTE: If the customer impacted by a Failure Mode is the next manufacturing or assembly plant or the product user, assessing the severity may lie outside the immediate process engineer's/team's field of experience or knowledge. In these cases, the Design FMEA, design engineer, and/or subsequent manufacturing or assembly plant process engineer, should be consulted in order to comprehend the propagation of effects.

3.5.6 严重度（S）

严重度是指与评估的过程步骤中针对给定失效的模式最严重影响相关的评级得分。它是在一个 FMEA 范围内的相对评级，评定时无需考虑频度或探测度。

对于过程的特定影响，应使用评估表 P1 中的标准确定严重度评级。该表格可以扩展增添有关公司或产品线的示例。

失效影响的评估结果应经过顾客和组织的一致同意。

注：　若受失效模式影响的顾客是下一个制造或装配厂或产品用户，则严重度评估可能不在直接过程工程师/团队的经验或知识领域内。在这种情况下，应咨询设计 FMEA、设计工程师和/或下一个制造或装配厂的过程工程师，以了解影响的扩散情况。

Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in- plant regulatory noncompliance	Failure may result in in- plant regulatory noncompliance	Noncompliance with regulations.	
8	**Moderately high**	100% of production run affected may have to be scrapped. Failure may result in in- plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in- plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	

过程一般评估标准严重度 (S)					
根据以下标准对潜在失效影响进行评级。					空白，由使用人员填写
S	**影响**	**对您的工厂的影响**	**对发运至工厂的影响（在已知情况下）**	**对最终用户的影响（在已知情况下）**	**公司或产品系列示例**
10	**高**	失效可能会导致从事生产或组装作业的工人面临严重的健康和/或安全风险	失效可能会导致从事生产或组装作业的工人面临严重的健康和/或安全风险	影响到车辆和/或其他车辆的操作安全性，驾驶员、乘客、交通参与者或行人的健康状况。	
9		失效可能会导致厂内不符合法规	失效可能会导致厂内不符合法规	不符合法规。	
8	**较高**	生产运行 100%会受到影响，产品不得不报废。失效可能会导致厂内不符合法规，或导致从事生产或组装作业的工人面临慢性健康和/或安全风险	生产线停工超过一个完整的班次；可能停止发货；需要使用现场返修或更换（装配线到终端用户），并且不符合相关法规。失效可能会导致厂内不符合法规，或导致从事生产或组装作业的工人面临慢性健康和/或安全风险。	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		产品可能需要进行分拣，其中一部分（少于 100%）会报废；主要过程有偏差；生产过程速度降低或增加劳动力	生产线停工从 1 小时起到一个完整的班次；可能停止发货；需要使用现场返修或更换（装配线到终端用户），并且不符合法规。	在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	

Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
6	**Moderately low**	100% of production run may have to be reworked off line and accepted	Line shutdown up to one hour	**Loss** of secondary vehicle function.	
5		A portion of the production run may have to be reworked off line and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect	No discernible effect or no effect	No discernible effect.	

Table P1 - PFMEA SEVERITY (S)

3.5.7 Occurrence (O)

The Occurrence rating (O) describes the occurrence of Failure Cause in the process, taking into account the associated current prevention controls.

The occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

过程一般评估标准严重度 (S)					
根据以下标准对潜在失效影响进行评级。					空白，由使用人员填写
S	影响	对您的工厂的影响	对发运至工厂的影响（在已知情况下）	对最终用户的影响（在已知情况下）	公司或产品系列示例
6	较低	100%的产品可能需要线下返工后才能被接受	生产线停工超过一个小时	失去车辆次要功能	
5		部分产品可能需要线下返工后才能被接受	少于100%的受到影响；极有可能出现额外的缺陷产品；需要分拣；生产线没有停工	降低车辆次要功能	
4		100%的产品可能需要在工位上返工后才能继续加工	缺陷产品缺陷产品会触发重大应对计划的启动；可能不会出现额外的瑕疵产品；不需要分拣	外观、声音、振动、粗糙度或触感令人感觉非常不舒服。	
3	低	部分产品可能需要在工位上返工后才能继续加工	缺陷产品会触发次要应对计划的启动；可能不会出现额外的缺陷产品；不需要分拣	外观、声音、振动、粗糙度或触感令人感觉一般性的不舒服。	
2		会导致过程、操作或操作人员的不方便	缺陷产品不会触发应对计划的启动；可能不会出现额外的缺陷产品；不需要分拣；需要向供应商提供反馈	外观、声音、振动、粗糙度或触感令人略微感觉不舒服。	
1	非常低	没有可觉察到的影响。	没有可觉察到的影响或没有影响。	没有可觉察到的影响。	

表 P1—PFMEA 严重度（S）

3.5.7 频度（O）

频度（O）描述了失效起因在过程中的发生频率，同时考虑了相关的当前预防控制。

频度评级得分是 FMEA 范围内的相对评级数值，可能并不反映实际频度。

The Occurrence rating describes the potential of the failure cause to occur, according to the rating table, without regard to the detection controls.

Expertise or other experiences with comparable processes, for example, can be considered in the assessment of the rating numbers.

In determining this rating, questions such as the following should be considered:

- What is the equipment history with similar processes and process steps?
- What is the field experience with similar process?
- Is the process a carryover or similar to a previous process?
- How significant are changes from a current production process?
- Is the process completely new?
- What are the environmental changes?
- Are Best Practices already implemented?
- Do standard instructions exist? (i.e. work instructions, set-up and calibration procedures, preventive maintenance, error- proofing verification procedures, and process monitoring verification checklists)
- Are technical error-proofing solutions implemented? (i.e. product or process design, fixture and tool design, established process sequence, production control tracking/traceability, machine capability, and SPC charting)

<table>
<tr><th colspan="5">Occurrence Potential (O) for the Process</th></tr>
<tr><td colspan="4">Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.</td><td>Blank until filled in by user</td></tr>
<tr><th>O</th><th>Prediction of Failure Cause Occurring</th><th>Type of Control</th><th>Prevention Controls</th><th>Corporate or Product Line Examples</th></tr>
<tr><td>10</td><td>Extremely high</td><td>None</td><td>No prevention controls.</td><td></td></tr>
<tr><td>9</td><td rowspan="2">Very high</td><td rowspan="2">Behavioral</td><td rowspan="2">Prevention controls will have little effect in preventing failure cause.</td><td></td></tr>
<tr><td>8</td><td></td></tr>
<tr><td>7</td><td rowspan="2">High</td><td rowspan="4">Behavioral or Technical</td><td rowspan="2">Prevention controls somewhat effective in preventing failure cause.</td><td></td></tr>
<tr><td>6</td><td></td></tr>
<tr><td>5</td><td rowspan="2">Moderate</td><td rowspan="2">Prevention controls are effective in preventing failure cause.</td><td></td></tr>
<tr><td>4</td><td></td></tr>
</table>

频度评级根据评级表描述了失效起因发生的可能性，不需要考虑探测控制。

例如，在确定评级得分时可考虑使用类似过程的专业知识或其他经验。

确定评级得分时应考虑以下问题：

- 设备经历过的哪些类似过程或过程步骤？
- 类似过程有哪些使用现场经验？
- 该过程是否与以往过程相同或相似？
- 与当前生产过程相比，变化有多显著？
- 该过程是否为全新的过程？
- 发生了哪些环境变化？
- 是否已经实施了最佳实践？
- 是否存在标准指导书？（例如：作业指导、安装和校验程序、预防性维护、防错验证程序和过程监视验证检查表）
- 是否实施了技术防错解决方案？（例如：产品或过程设计、夹具和工具设计、既定的过程顺序、生产控制跟踪/追溯、机器能力和 SPC 图表）

<table>
<tr><th colspan="5">过程的潜在频度 (O)</th></tr>
<tr><td colspan="4">根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑预防控制。频度是在评估时进行的预估定性评级，可能不能反映真实的频度。频度评级得分是在 FMEA（正在评估的过程）范围内进行的相对评级数值。针对多个频度评级中的预防控制而言，可以使用最能反映控制有效性的评级。</td><td>空白，由使用人员填写</td></tr>
<tr><th>O</th><th>对失效起因发生的预测</th><th>控制类型</th><th>预防控制</th><th>公司或产品系列示例</th></tr>
<tr><td>10</td><td>极高</td><td>无</td><td>没有预防控制。</td><td></td></tr>
<tr><td>9</td><td rowspan="2">非常高</td><td rowspan="2">行为控制</td><td rowspan="2">预防控制在防止失效起因出现的方面起到的作用很小。</td><td></td></tr>
<tr><td>8</td><td></td></tr>
<tr><td>7</td><td rowspan="2">高</td><td rowspan="4">行为或技术控制</td><td rowspan="2">预防控制在防止失效起因出现的方面可以起到一定的作用。</td><td></td></tr>
<tr><td>6</td><td></td></tr>
<tr><td>5</td><td rowspan="2">中</td><td rowspan="2">预防控制在防止失效起因出现的方面可以起到有效的作用。</td><td></td></tr>
<tr><td>4</td><td></td></tr>
</table>

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very low**			
1	**Extremely low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (i.e. part geometry) or process (i.e. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error- proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table P2 - PFMEA OCCURRENCE (O)

3.5.8 Detection (D)

Detection is the rating associated with a prediction of the most effective process control from the listed detection-type process controls. Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for Severity or Occurrence. Detection should be estimated using the criteria in Table P3. This table may be augmented with examples of common detection methods used by the company.

The intent of the term "control discrepant product" used in Table P3 Ranks 3 and 4 is to have controls / systems / procedures in place that controls the discrepant product in such a manner, that the probability of the product escaping the facility is very low.

The controls start from when the product is identified as discrepant to the point of final disposition. These controls usually exceed controls that are used for discrepant products with higher Detection Ranks.

过程的潜在频度 (O)				
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑预防控制。频度是在评估时进行的预估定性评级，可能不能反映真实的频度。频度评级得分是在FMEA（正在评估的过程）范围内进行的相对评级数值。针对多个频度评级中的预防控制而言，可以使用最能反映控制有效性的评级。				空白，由使用人员填写
O	对失效起因发生的预测	控制类型	预防控制	公司或产品系列示例
3	低	最佳实践：行为或技术控制	预防控制在防止失效起因出现的方面可以起到高度有效的作用。	
2	非常低			
1	极低	技术控制	预防控制在预防失效起因设计（例如：零件形状）或过程（如夹具或模具设计）而发生的失效起因方面极其有效。预防控制的目的 - 失效模式不会因失效起因而实际发生。	

预防控制的有效性：在确定预防控制的有效性时，应考虑预防控制是否为技术措施（依靠机械设备、工具寿命、工具材料等），或应用最佳实践（夹具、工装设计、校准程序、防错验证、预防性维护、作业指导书、统计流程控制表、过程监视、产品设计等），或行为措施（依靠持有证书或未持有证书的操作人员、技术工人、团队领导等）。

表 P2—PFMEA 频度（O）

3.5.8 探测度（D）

探测度指在列出的探测类型过程控制中，预测最有效的过程控制相关的评级。探测度是在一个 FMEA 范围内的相对评级，评定时无需考虑严重度或频度。探测度评级应遵循表 P3 中所述的标准。该表格可扩展增添公司常用的探测方法的示例。

表 P3 第 3 和 4 行中使用的术语"控制差异产品"的目的是制定能够控制差异产品的适当控制/系统/程序，以确保产品流出工厂的可能性很低。

若确定产品与最后处理状态存在差异，则会开始执行控制。此类控制通常超过对探测度等级较高的差异产品应用的控制。

After implementation of any unproven control, the effectiveness can be verified and re-evaluated.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size is required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	Corporate or Product Line Examples
10	Very low	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	Low	Test or inspection method **has not been** proven to be effective and reliable (i.e. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	
6	Moderate	Test or inspection method **has been** proven to be effective and reliable (i.e. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

在实施任何未经验证的控制后，可验证和重新评估其有效性。

确定评级时，应考虑以下问题：

- 探测失效起因或失效模式的最有效测试是什么？
- 探测失效所要求的使用场景/工作周期是什么？
- 探测失效需要的样本量是多少？
- 探测该起因/失效模式的测试程序是否已得到证明？

用于过程设计验证的潜在探测度(D)				
根据检测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
10	非常低	尚未建立或有已知的测试或检验方法。	不能或无法探测到失效模式。	
9		测试或检验方法不可能探测到失效模式。	通过任意或不定时的审核很难探测到失效模式。	
8	低	测试或检验方法**尚未**经过实践证明为有效和可靠（例如：工厂在测试或检验方法方面没有或很少有经验，有关类似过程或本程序的测量可重复性和再现性分析结果接近边际值等）。	可以探测失效模式或失效起因的人工检验（视觉、触觉，听觉）方法，或使用人工检验（计数型或计量型）方式。	
7			以设备为基础的检验方式（采用光学、蜂鸣器等装置的自动化或半自动化方式），或使用可以探测失效模式或失效起因的检验设备，例如坐标测量机。	
6	中	测试或检验方法**已经**经过实践证明为有效和可靠（例如：工厂在测试或检验方法方面具备经验，有关类似过程或本程序的测量可重复性和再现性结果可以接受等）。	可以检验失效模式或失效起因（包括产品样本检验）的人工检验（视觉、触觉、听觉）方法，或使用人工测量（计数型或计量型）方式。	
5			以设备为基础的检验方式（采用光学、蜂鸣器等装置的半自动化方式），或使用可以探测失效模式或失效起因（包括产品样本检验）的检验设备，例如坐标测量机。	

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	Corporate or Product Line Examples
4	High	System has been proven to be effective and reliable (i.e. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode **downstream**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect the failure mode **in- station**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
2		Detection method has been proven to be effective and reliable (i.e. plant has experience with method, error-proofing verifications, etc.).	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	Very high	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

Table P3 - PFMEA DETECTION (D)

3.5.9 Action Priority (AP)

Once the team has completed the initial identification of failure modes and effects, causes and controls, including ratings for severity, occurrence, and detection, they must decide if further efforts are needed to reduce the risk. Due to the inherent limitations on resources, time, technology, and other factors, they must choose how to best prioritize these efforts.

The Action Priority (AP) method is introduced in this handbook. It accounts for all 1000 possible combinations of S, O, and D. It was created to give more emphasis on severity first, then occurrence, then detection. This logic follows the failure-prevention intent of FMEA. The AP table offers a suggested high-medium-low priority for action. Companies can use a single system to evaluate action priorities instead of multiple systems required from multiple customers.

用于过程设计验证的潜在探测度 (D)				
根据检测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
4	高	已经过实践证明为有效或可靠的系统（例如：工厂在关于相同过程或本程序的测试或探测方法方面具备经验），测量可重复性和再现性结果可以接受等。	以设备为基础的自动化探测方法，其可以在**下游**探测到失效模式，进而避免进一步加工、或系统可以识别差异产品，并允许其在过程中自动前进，直至到达指定的不合格品卸载区。差异产品将在一个有效的系统内受到监视，避免这些产品从工厂内流出。	
3			以设备为基础的自动化探测方法，其可以**在工位上**探测到失效模式，进而避免进一步加工、或系统可以识别差异产品并允许其在过程中自动前进，直至到达指定的不合格品卸载区。差异产品将在一个有效的系统内受到监视，避免这些产品从工厂内流出。	
2		探测方法已经经过实践证明为有效或可靠（例如：工厂在探测方法、防错确认措施方面具备经验等）。	以设备为基础的探测方法，其可以探测失效起因并避免出现失效模式（差异零件）。	
1	非常高	根据设计或加工过程而不会实际出现失效模式，或者探测方法经过实践验证**总是**能够探测到失效模式或失效起因。		

表 P3—PFMEA 探测度（D）

3.5.9 措施优先级（AP）

团队完成失效模式、失效影响、失效起因和控制的初始确认（包括严重度、频度和探测度的评级）后，他们必须决定是否需要进一步努力来降低风险。由于资源、时间、技术和其它因素的固有限制，他们必须选择如何最好地将这些工作进行优先排序。

本手册介绍了措施优先级（AP）方法，提供了所有 1000 种 S、O、D 的可能组合。该方法首先着重于严重度，其次为频度，然后为探测度。其逻辑遵循了 FMEA 的失效预防目的。AP 表建议将措施分为高-中-低优先级别。公司可使用一个体系来评估措施优先级，而不是使用多个顾客要求的多个体系。

Risk Priority Numbers are the product of S x O x D and range from 1 to 1000. The RPN distribution can provide some information about the range of ratings, but RPN alone is not an adequate method to determine the need for more actions since RPN gives equal weight to S, O, and D. For this reason, RPN could result in similar risk numbers for very different combinations of S, O, and D leaving the team uncertain about how to prioritize. When using RPN it is recommended to use an additional method to prioritize like RPN results such as S x O. The use of a Risk Priority Number (RPN) threshold is not a recommended practice for determining the need for actions. The RPN and S x O methods are not included in this publication.

Risk matrices can represent combinations of S and O, S and D, and O and D. These matrices provide a visual representation of the results of the analysis and can be used as an input to prioritization of actions based on company-established criteria not included in this publication.

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S, O, D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

Note: Action Priority rating tables are the same for DFMEA and PFMEA, but different for FMEA-MSR.

Priority High (H): Highest priority for review and action.

The team needs to either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action.

The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action.

The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

风险顺序数是 S x O x D 的乘积，范围为 1-1000。RPN 分布可以提供有关评级范围的一些信息，但仅 RPN 并不能确定是否需要采取更多措施，因为 RPN 对 S、O 和 D 的权重相等。因此，RPN 可能会对 S、O 和 D 的不同组合产生类似的风险数，使团队无法确定如何进行优先级排序。使用 RPN 时，建议使用其他方法对类似 RPN 结果进行优先级排序，例如 S x O。不推荐使用风险顺序数（RPN）阈值来确定所需要的措施。本出版物不包括 RPN 和 S X O 方法。

风险矩阵可以表示 S 和 O、S 和 D、O 和 D 的组合。这些矩阵形象地展示了分析结果，并可作为输入来对措施进行优先级排序。这样做时要根据公司设立的标准进行，而本出版物中不包括此标准。

由于 AP 表的设计是为了和本手册中提供的严重度、频度和探测度表一起使用，如果组织针对特定产品、过程或项目选择修改 S、O、D 表，则 AP 表也应该仔细评审。

注：　设计 FMEA 和过程 FMEA 的措施优先级评级表是相同的，但是监视及系统响应 FMEA 则不同。

优先级高（H）：　评审和措施的最高优先级。

团队需要确定适当的措施来改进预防和/或探测控制，或证明并记录为何当前的控制足够有效。

优先级中（M）：　评审和措施的中等优先级。

团队应该确定适当的措施来改进预防和/或探测控制，或由公司自行决定，证明并记录当前的控制足够有效。

优先级低（L）：　评审和措施的低优先级。

团队可以确定措施来改进预防或探测控制。

对于潜在的严重度为 9-10 且措施优先级为高和中的失效影响，建议至少应由管理层评审，包括所采取的任何建议措施。

This is not the prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.

Note: It may be helpful to include a statement such as "No further action is needed" in the Remarks field as appropriate.

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							**Blank until filled in by user**
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

这不是对高、中、低风险的优先排序，而是对降低风险的措施的优先级排序

注：　酌情在备注部分写上诸如“无需进一步措施”之类的陈述，这可能会有帮助。

DFMEA 和 PFMEA 的措施优先级 (AP)							
措施优先级是以严重度、频度以及检测评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	S	对失效起因发生的预测	O	探测能力	D	措施优先级 (AP)	备注
对产品或工厂的影响度非常高	9-10	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度高	7-8	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	M	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	

Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate High	5-6 2-4	H M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

对产品或工厂的影响度中等	4-6	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	M	
				非常高	1	M	
		高	6-7	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	M	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	M	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度低	2-3	非常高	8-10	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		高	6-7	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
没有可觉察到的影响。	1	非常低 - 非常高	1-10	非常高 - 非常低	1-10	L	

AP 表–DFMEA 和 PFMEA 的措施优先级

FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5)						
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element	Current Preventi on Control (PC) o FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)
Your Plant: Assembly of shaft is not possible because clearance too small Ship to Plant: None End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position	Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038	2	M		

Figure 3.5-3 Example of PFMEA with Risk Analysis Form

3.5.10 Collaboration between Customer and Supplier (Severity)

The output of the Risk Analysis creates the mutual understanding of technical risk between customers and suppliers. Methods of collaboration range from verbal to formal reports. The amount of information shared is based on the needs of a project, company policy, contractual agreements, and so on. The information shared depends on the placement of the company in the supply chain. Some examples are listed below.

1. The OEM may compare design functions, failure effects, and severity from a vehicle-level DFMEA with the Tier 1 supplier PFMEA.
2. The Tier 1 supplier communicates necessary information about product characteristics on product drawings and/or specifications, or other means, including designation of standard or special characteristics and severity. This information is used as an input to the Tier 2 supplier PFMEA as well as the Tier 1's internal PFMEA. When the design team communicates the associated risk of making product characteristics out of specification the process team can build in the appropriate level of prevention and detection controls in manufacturing.

失效分析（步骤四）				PFMEA 风险分析（步骤五）						
1.对于上一较高级别要素和/或最终用户的失效影响（FE）	失效影响（FE）的严重度（S）	2.关注要素的失效模式（FM）	3.工作要素的失效模式（FC）	对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	PFMEA AP	特殊特性	筛选器代码（可选）
您的工厂：间隙太小无法安装轴 发运至工厂：无 最终用户： 舒适模式关闭时间过长	8	不能实现烧结轴承的轴向定位	设备在达到最终位置前停止	根据数据表调整力的大小	5	根据规范 MRKJ5038 对电机性能曲线进行完全检测	2	M		

图 3.5-3 PFMEA 风险分析表格示例

3.5.10 顾客和供应商之间的协作（严重度）

风险分析的输出是顾客和供应商对技术风险达成的一致理解。协作的方法从口头报告到正式报告不一。共享的信息量取决于项目的需要、公司政策、合同协议等。共享的信息内容取决于公司在供应链中的位置。下面列出了一些示例：

1. OEM 可将整车级 DFMEA 的设计功能、失效影响和严重度与一级供应商的 DFMEA 进行比较。

2. 一级供应商通过产品图纸和/或规范或其他方式传达有关产品特性的必要信息，包括对标准或特殊特性和严重度的指定。此信息用作二级供应商 PFMEA 以及一级供应商内部 PFMEA 的输入。当设计团队传达"产品特性超出规范"的相关风险时，过程团队可以在制造过程中建立适当水平的预防和探测控制。

3.5.11 Basis for Optimization

The output of Steps 1, 2, 3, 4, and 5 of the 7-step FMEA process is used to determine if additional design or testing action is needed. The process reviews, customer reviews, management reviews, and cross-functional team meetings lead to Step 6 Optimization.

3.6 Process FMEA 6th Step: Optimization

3.6.1 Purpose



The purpose of the Process Optimization Step is to determine actions to mitigate risk and assess the effectiveness of those actions. The end result is a process which minimizes the risk of producing and delivering products that do not meet the customer and stakeholder expectations.

The main objectives of a Process Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures
- Basis for refinement of the product and/or process requirements and prevention and detection controls

The primary objective of optimization is to develop actions that reduce risk by improving the process. In this step, the team reviews the results of the risk analysis and assigns actions to lower the occurrence of the failure cause or increase the ability to detect the failure cause or failure mode. Actions may also be assigned which improve the process but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls, and are already considered in the initial risk analysis. All actions should have a responsible individual and a target completion time associated with the action.

If the team decides that no further actions are necessary, "No further action is needed" is written in the Remarks field to show the risk analysis was completed.

3.5.11 优化的基础

FMEA七步骤中前五个步骤的输出用于确定是否需要额外的设计或测试措施。过程评审、顾客评审、管理评审和跨职能团队会议为步骤六"优化"提供基础。

3.6过程 FMEA 步骤六：优化

3.6.1 目的



过程优化步骤旨在确定降低风险的措施并评估这些措施的有效性。该步骤的最终成果是实现一个这样的过程：能够将生产和交付不符合顾客和利益相关方预期的产品的风险降至最低。

过程优化的主要目标包括：

- 确定降低风险的必要措施
- 为措施实施分配职责和期限
- 实施措施并将其形成文件，包括对所实施措施的有效性的确认以及采取措施后的风险评估
- FMEA 团队、管理层、顾客和供应商在潜在失效方面的协作
- 提高产品和/或过程要求以及预防和探测控制的基础

优化的主要目标是通过改善过程，确定降低风险的措施。在该步骤中，团队将评审风险分析的结果并确定适当措施，以降低失效起因的发生频率或提高探测失效起因或失效模式的能力。团队也可以确定能够改善过程但并不一定降低风险评估评级的措施。措施指承诺采取具体、可衡量和可实现的措施，而不是制定出可能永远无法实施的潜在措施。措施不适用于已经计划的活动，因为它们已经记录在预防或探测控制文件中，且已经在初步风险分析中得到分析。所有措施都应确定具体的负责人以及相关的目标完成时间。

若团队决定不需要采取进一步措施，则应在"备注"栏中填写"无需采取进一步措施"，以表明风险分析已经完成。

The PFMEA can be used as the basis for continuous improvement of the process.

The optimization is most effective in the following order:

- Process modifications to eliminate or mitigate a Failure Effect (FE)
- Process modifications to reduce the Occurrence (O) of the Failure Cause (FC).
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).
- In the case of process modifications, all impacted process steps are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different manufacturing concept.

The PFMEA can be used as the basis for continuous improvement of the process.

3.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

3.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

PFMEA 可作为过程持续改进的基础。

优化最有效的顺序如下：

- 消除或减轻失效影响（FE）的过程变更。
- 降低失效起因（FC）频度（O）的过程变更。
- 提高探测（D）失效起因（FC）或失效模式（FM）的能力。
- 如进行过程变更，则需要重新评估所有受影响的过程步骤。

若出现了概念变更，则需针对 FMEA 所有步骤中受影响的部分进行评审。这是必要的，因为初始分析基于不同的制造概念，因而不再有效。

PFMEA 可作为过程持续改进的基础。

3.6.2 责任分配

每个措施都应该有负责人和与之相关的目标完成日期(TCD)。

负责人应确保措施的状态保持更新。如果措施被确认，那么该负责人也要对措施的实施情况负责。

应记录预防和探测措施的实际完成日期，包括措施实施的日期。

目标完成日期应切合实际（例如，按照产品开发计划、在过程验证之前、在生产开始之前）。

3.6.3 措施的状态

关于措施的状态，建议分为以下几类：

尚未确定

没有确定的措施。

尚未决策（可选）

措施已经确定，但还没有决定。正在创建决策文件。

尚未执行（可选）

已对措施作出决定，但尚未执行。

已完成

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions.

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product. Actions are open loops that need to be closed in writing.

3.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Process FMEA Occurrence and Detection rating tables.

3.6.5 Continual Improvement

The PFMEA serves as an historical record for the process. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or at a minimum available and accessible as part of version history. The completed analysis becomes a repository to capture the progression of process decisions and design refinements. However, original S, O, D ratings may be modified for foundation, family or generic PFMEAs because the information is used as a starting point for an - process specific analysis.

已完成状态是指措施已经被执行，其有效性已经被证明和记录，并已经进行了最终评估。

不执行

当决定不执行某项措施时，就会分配"不执行"的状态。如果实践和技术限制超出当前能力，就会发生这种情况。

只有当 FMEA 团队评估了每一项的措施优先级，并接受风险水平或记录措施关闭时，FMEA 工作才算完成。

若"不采取措施"，那么措施优先级就不会降低，失效风险会被转移到产品中。对于具有开放性目标的措施，需以书面形式将其关闭。

3.6.4 措施有效性评估

当措施完成时，频度和探测度值将被重新评估，一个新的措施优先级可能要被确定。

新的措施将获得一个初始措施优先等级，作为对有效性的预测。

然而，该措施将一直保持"尚未执行"的状态，直到其有效性得到测试为止。测试完成后，初步评估必须得到确认或在必要时调整。然后，措施的状态从"尚未执行"改为"已完成"。

重新评估应基于采取的预防和探测措施的有效性，并且新的值应基于过程 FMEA 频度和探测度评级表中的定义。

3.6.5 持续改进

PFMEA 是过程的历史记录。因此，初始严重度、频度和探测度（S、O、D）数值需显示可见，或至少可作为历史记录一部分使用和访问。分析完成后将形成一个存储库，能够记录过程决策和设计改进的进展。但是，基础、系列或一般 PFMEA 的初始 S、O、D 评级可能被修改，因为这些信息被用作过程分析的起点。

3.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures

Communication between the FMEA team, management, customers and suppliers during the development of the technical risk analysis and/or when the PFMEA is initially complete brings people together to improve their understanding of product and process functions and failures. In this way, there is a transfer of knowledge that promotes risk reduction.

PFMEA RISK ANALYSIS (STEP 5)							PFMEA OPTIMIZATION (STEP 6)												
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks
Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038.	2	M			Selected press with position control sensor	Selected press with force monitoring	Process Engineer Mr. Paul Duncan	dd. mm. yyyy	open			8	3	2		L	

Figure 3.6-1 Example of PFMEA Optimization with new Risk Evaluation Form

3.7 Process FMEA 7th Step: Results Documentation

3.7.1 Purpose



The purpose of the results documentation step is to summarize and communicate the results of the Failure Mode and Effects Analysis activity.

The main objectives of Process Results Documentation are:

- Communication of results and conclusions of the analysis
- Establishment of the content of the documentation
- Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Communication of actions taken to reduce risks, including within the organization, and with customers and/or suppliers as appropriate
- Record of risk analysis and risk reduction to acceptable levels

3.6.6 FMEA 团队、管理层、顾客和供应商之间针对潜在失效的协作

在技术风险分析期间和/或当 PFMEA 初步完成时，FMEA 团队、管理层、顾客和供应商之间的沟通会将相关人员聚在一起，以共同提高各自对产品和过程功能和失效的理解。通过这种方式可以使得“如何降低风险”的知识得以传播。

PFMEA 风险分析（步骤五）							PFMEA 优化（步骤六）												
对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	PFMEA AP	特殊特性	筛选器代码（可选）	预防措施	检测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	特殊特性	PFMEA AP	备注
根据数据表调整力的大小	5	根据规范 MRKJ5038 对电机性能曲线进行完全探测	2	M			带位置控制传感器的选择性压装	带压力监测的选择性压装	过程工程师 Paul Duncan 先生	年月日	尚未确定			8	3	2		L	

图 3.6-1 进行最新风险评估的 PFMEA 优化表格示例

3.7 过程 FMEA 步骤七：结果文件化

3.7.1 目的



“结果文件化”步骤的目的是，针对 FMEA 活动的结果进行总结和交流。

“将过程结果形成文件”的主要目标是：

- 对结果和分析结论进行沟通
- 建立文件内容
- 记录采取的措施，包括对实施的措施的效果进行确认、采取措施后进行风险评估
- 在组织内部，以及与客户和/或供应商之间（如需）针对降低风险的措施进行沟通
- 记录风险分析和风险降低到的可接受水平

3.7.2 FMEA Report



The scope and results of an FMEA should be summarized in a report. The report can be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the PFMEA details when requested by management, customers, or suppliers. It is meant to be a summary for the PFMEA team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfills the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan

   a. FMEA Intent – Purpose of this FMEA?

   b. FMEA Timing – FMEA due date?

   c. FMEA Team – List of participants?

   d. FMEA Task - Scope of this FMEA?

   e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (e.g. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

F. A plan and commitment of timing for ongoing FMEA improvement actions.

   a. Commitment and timing to close open actions.

   b. Commitment to review and revise the PFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)

   c. Commitment to capture "things gone wrong" in foundation PFMEAs for the benefit of future analysis reuse, when applicable. (Refer to section 1.3.6 Foundation and Family FMEAs)

3.7.2 FMEA 报告



该报告可用作公司内部或公司之间的沟通使用。当管理层、顾客或供应商要求时，该报告不应取代对 PFMEA 的评审。它是 PFMEA 团队和其他人员的总结，以确认每个任务都已完成、并评审分析结果。

文件的内容应满足组织、预期读者和利益相关方的要求，这一点很重要。具体细节可由各方商定。这样，还可以确保分析的所有细节和知识产权都由编制 PFMEA 的公司保留。

文件的格式可根据具体公司而定。但是，报告应指出失效的技术风险，并将其视为为开发计划和项目里程碑的一部分。报告可包括以下内容：

A. 相较于第 1.5 节"项目计划"中的初始目标，说明一下最终状态。

   a. FMEA 目的 – FMEA 的目的是什么?

   b. FMEA 时间安排 – FMEA 的截止日期?

   c. FMEA 团队 – 参与人员清单?

   d. FMEA 任务 - FMEA 的范围?

   e. FMEA 工具 – 如何使用所采取的分析方法?

B. 总结分析范围并确认新的内容。

C. 对功能的开发过程进行总结。

D. 至少对团队确定的高风险失效进行总结，并提供一份具体的 S/O/D 评级表和措施优先排序方法（如措施优先级表）。

E. 对已采取的和/或计划中的措施进行总结（包括这些措施的状态），以解决高风险的失效。

F. 为进行中的 FMEA 改进措施制定计划和时间安排。

   a. 对尚未确定的措施进行关闭做出承诺和时间安排。

   b. 承诺在批量生产期间对 PFMEA 进行评审和修订，以确保相对于生产设计来说，分析是准确和完整的（例如，根据公司程序，由设计变更、纠正措施等引起的修订）。（参见第 1.4 节"案例 3"中的 FMEA 修订）

   c. 承诺在"基础 DFMEA"中找到"出差错的地方"，以便在将来适用时可以再次用于分析。（参见第 1.3.6 节"基础和家族 FMEA"）

4 SUPPLEMENTAL FMEA FOR MONITORING AND SYSTEM RESPONSE (FMEA-MSR)

In a Supplemental FMEA for Monitoring and System Response, potential Failure Causes which might occur under customer operating conditions are analyzed with respect to their technical effects on the system, vehicle, people, and regulatory compliance. The method considers whether or not Failure Causes or Failure Modes are detected by the system, or Failure Effects are detected by the driver. Customer operation is to be understood as end-user operation or in-service operation and maintenance operations.

FMEA-MSR includes the following elements of risk:

a) Severity of harm, regulatory noncompliance, loss or degraded functionality, and unacceptable quality; represented by (S)
b) Estimated frequency of a Failure Cause in the context of an operational situation; represented by (F)
c) Technical possibilities to avoid or limit the Failure Effect via diagnostic detection and automated response, combined with human possibilities to avoid or limit the Failure Effect via sensory perception and physical reaction; represented by (M)

The combination of F and M is an estimate of the probability of occurrence of the Failure Effect due to the Fault (Failure Cause) and resulting malfunctioning behavior (Failure Mode).

NOTE: The overall probability of a Failure Effect to occur may be higher, because different Failure Causes may lead to the same Failure Effect.

FMEA-MSR adds value by assessing risk reduction as a result of monitoring and response. FMEA-MSR evaluates the current state of risk of failure and derives the necessity for additional monitoring by comparison with the conditions for acceptable residual risk. The analysis can be part of a Design FMEA in which the aspects of Development are supplemented by aspects of Customer Operation. However, it is usually only applied when diagnostic detection is necessary to maintain safety or compliance.

Detection in DFMEA is not the same as Monitoring in Supplemental FMEA-MSR. In DFMEA, Detection controls document the ability of testing to demonstrate the fulfillment of requirements in development and validation. For monitoring that is already part of the system design, validation is intended to demonstrate that diagnostic monitoring and system response works as intended. Conversely, Monitoring in FMEA-MSR assesses the effectiveness of fault detection performance in customer operation, assuming that specifications are fulfilled. The Monitoring rating also comprehends the safe performance and reliability of system reactions to monitored faults. It contributes to the assessment of the fulfillment of Safety Goals and may be used for deriving the Safety Concept.

4 监视及系统响应的补充 FMEA（FMEA-MSR）

关于对系统、车辆、人员和法规遵从性的技术影响，监视及系统响应的补充 FMEA 对顾客操作条件下可能出现的潜在失效起因进行了分析。该方法考虑到失效起因或失效模式是否由该系统探测到或失效影响是否由驾驶员探测到。顾客操作将理解为最终用户操作或运行操作以及维护操作。

FMEA-MSR 涵盖了以下风险要素：

a） 伤害的严重程度、不符合法规、功能丧失或退化，以及不可接受的质量，由（S）表示

b） 在运行情况下估计的失效起因频率，由（F）表示

c） 通过诊断探测和自动响应避免或限制失效影响的技术可能性，以及通过感官知觉和物理响应避免或限制失效影响的人为可能性，由（M）表示

F 和 M 的组合系指由于失效（失效起因）和由此产生的故障行为（失效模式）所导致的失效影响发生概率的估计。

注：发生失效影响的总体概率可能更高，原因在于不同的失效起因可能导致相同的失效影响。

FMEA-MSR 通过评估因监视和响应所产生的降低风险的方式增值。FMEA-MSR 通过与可接受的残余风险条件进行比较并评估当前的失效风险状态，得出额外监视的必要性。该分析可以属于设计 FMEA 的一部分，设计 FMEA 中该分析的开发方面从顾客操作方面进行补充分析。但它仅在需要诊断探测维持安全性或合规性时才加以应用。

DFMEA 的探测与补充 FMEA-MSR 的监视不同。在 DFMEA 中，探测控制记录了可证明满足开发和确认要求的试验能力。对于已成为系统设计一部分的监视功能，确认旨在证明诊断监视和系统响应按预期运作。相反，假设满足相应的规范的情况下，FMEA-MSR 中的监视评估了顾客操作中的故障探测性能的效果。监视评级也可理解为安全性能以及系统对监视到的故障的响应的可靠性。它有利于评估是否实现安全目标，且可用于获得安全概念。

Supplemental FMEA-MSR addresses risks that in DFMEA would otherwise be assessed as High, by considering more factors which accurately reflect lower assessed risk according to the diagnostic functions of the vehicle operating system. These additional factors contribute to an improved depiction of risk of failure (including risk of harm, risk of noncompliance, and risk of not fulfilling specifications).

FMEA-MSR contributes to the provision of evidence of the ability of the diagnostic, logical, and actuation mechanisms to achieve and maintain a safe or compliant state (in particular, appropriate failure mitigation ability within the maximum fault handling time interval and within the fault tolerant time interval).

FMEA-MSR evaluates the current state of risk of failure under end-user conditions (not just risk of harm to persons). The detection of faults/failures during customer operation can be used to avoid the original failure effect by switching to a degraded operational state (including disabling the vehicle), informing the driver and/or writing a diagnostic trouble code (DTC) into the control unit for service purposes. In terms of FMEA, the result of RELIABLE diagnostic detection and response is to eliminate (prevent) the original effect, and replace it with a new, less severe effect.

FMEA-MSR is useful in deciding whether the system design fulfills the performance requirements with respect to safety and compliance. The result may be i.e.

- additional sensor(s) may be needed for monitoring purposes
- redundancy in processing may be needed
- plausibility checks may reveal sensor malfunctions

4.1 FMEA-MSR 1st Step: Planning and Preparation

4.1.1 Purpose



The main objectives of Planning and Preparation in FMEA-MSR are:

- Project identification
- Project plan (InTent, Timing, Team, Tasks, Tools (5T))
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline DFMEA
- Basis for the Structure Analysis step

根据车辆操作系统的诊断功能，通过考虑更多的、可精确地反映所评估到的较低级别风险的因素，补充的 FMEA-MSR 可以解决 DFMEA 中被评为高级别的风险。这些附加因素有利于提高对失效风险（包括伤害风险、不合规风险、不遵守规范的风险）的描述。

FMEA-MSR 有利于提供诊断、逻辑和驱动机制实现和维持安全或合规状态的能力的证据（特别是在最大故障处理时间间隔内和容错时段内的适当失效缓解能力）。

FMEA-MSR 评估最终用户条件下的当前失效风险状态（不仅仅是对人员造成伤害的风险）。顾客操作期间的故障/失效探测可用于通过切换到降级的运行状态（包括禁用车辆），通知驾驶员和/或将诊断故障代码（DTC）写入服务用控制单元来避免初始的失效影响。就 FMEA 而言，可靠的诊断探测和响应最终消除（预防）原始影响，并将其替换为新的，不太严重的影响。

FMEA-MSR 可用于确定系统设计是否满足安全性和合规性方面的性能要求。结果可能如下：

- 出于监视的目的考虑，可能需要额外的传感器
- 可能需要处理冗余
- 真实性检查可能显示传感器故障

4.1 FMEA-MSR 步骤一：规划和准备

4.1.1 目的



FMEA-MSR 规划和准备的主要目标：

- 项目确定
- 项目计划（目的、时间安排、团队、任务、工具（5T））
- 分析边界：分析中包括什么、不包括什么
- 基准 DFMEA 的确定
- 结构分析步骤的基础

4.1.2 FMEA-MSR Project Identification and Boundaries

FMEA-MSR Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the FMEA-MSRs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

The following may assist the team in defining FMEA-MSR projects, as applicable:

- Hazard Analysis and Risk Assessment
- Legal Requirements
- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary/System)
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products

Answers to these questions and others defined by the company help create the list of FMEA-MSR projects needed. The FMEA- MSR project list assures consistent direction, commitment and focus.

Below are some basic questions that help identify FMEA-MSR boundaries:

(1) After completing a DFMEA on an Electrical / Electronic / Programmable Electronic System, are there effects that may be harmful to persons or involve regulatory noncompliance?

(2) Did the DFMEA indicate that all of the causes which lead to harm or noncompliance can be detected by direct sensing, and/or plausibility algorithms?

(3) Did the DFMEA indicate that the intended system response to any and all of the detected causes is to switch to a degraded operational state (including disabling the vehicle), inform the driver and/or write a Diagnostic Trouble Code (DTC) into the control unit for service purposes?

FMEA for Monitoring and System Response may be used to examine systems which have integrated fault monitoring and response mechanisms during operation. Typically, these are more complex systems composed of sensors, actuators and logical processing units. The diagnosis and monitoring in such systems may be achieved through hardware and/or software.

4.1.2 FMEA-MSR 项目确定和边界

项目确定包括明确了解需要评估的内容。这涉及到确定顾客项目所需的 FMEA-MSR 的决策过程。分析中需要不包括和包括的内容一样重要。

如适用，以下内容可帮助团队确定 FMEA-MSR 项目：

- 危害分析和风险评估
- 法律要求
- 技术要求
- 顾客需要/需求/期望（外部和内部顾客）
- 要求规范
- 图表（方块/边界图/系统）
- 原理图、图纸和/或 3D 模型
- 物料清单（BOM）、风险评估
- 类似产品以往的 FMEA

对这些问题以及公司定义的其它问题的回答，将帮助创建所需的 FMEA-MSR 项目清单。FMEA-MSR 项目清单确保了方向、承诺和工作重点的一致性。

以下基本问题可帮助确定 FMEA-MSR 边界：

（1）在电气/电子/可编程电子系统上完成 DFMEA 后，是否存在可能对人员伤害或涉及法规不符合的影响？

（2）DFMEA 是否表明可通过直接感知和/或合理算法探测到将引起伤害或不合规行为的所有起因？

（3）DFMEA 是否表明对任何和所有探测到的起因的预期系统响应是切换到降级的运行状态（包括禁用车辆），通知驾驶员和/或将诊断故障代码（DTC）写入服务用控制单元？

监视及系统响应补充 FMEA 可用于检验已集成运行期间的故障监视和响应机制的系统。通常这些属于更加复杂的系统，它们是由传感器、执行器和逻辑处理单元构成。此类系统中的诊断和监视功能可通过硬件和/或软件实现。

Systems that may be considered in a Supplemental FMEA for Monitoring and System Response consist in general of at least a sensor, a control unit, and an actuator or a subset of them and are called mechatronic systems. Systems in-scope may also consist of mechanical hardware components (i.e. pneumatics and hydraulics).



Figure 4.1-1 Generic block diagram of an Electrical / Electronic / Programmable Electronic System

The scope of a Supplemental FMEA for Monitoring and System Response may be established in consultation between customer and supplier. Applicable scoping criteria may include, but are not limited to:

1. System Safety relevance
2. ISO Standards, i.e. Safety Goals according to ISO 26262
3. Documentation requirements from legislative bodies, i.e. UN/ECE Regulations, FMVSS/CMVSS, NHTSA, and On Board Diagnostic Requirements (OBD) Compliance.

4.1.3 FMEA-MSR Project Plan

A plan for the execution of the FMEA-MSR should be developed once the FMEA-MSR project is known.

It is recommended that the 5T method (Intent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The plan for the FMEA-MSR helps the company be proactive in starting the FMEA-MSR early. The FMEA-MSR activities (7-step process) should be incorporated into the overall design project plan.

可视为属于监视及系统响应的补充 FMEA 的一部分的系统通常由至少一个传感器、一个控制单元和一个执行器或者其一部分组成，并且称为机械电子系统。范围内系统还可能包含机械硬件要素（例如：气动和液压组件）。



图 4.1-1 电气/电子/可编程电子系统的一般方块图

可在顾客和供应商协商的基础上确定监视及系统响应的补充 FMEA 的范围。适用范围标准可能包括但不限于：

1. 系统安全关联性
2. ISO 标准，例如：根据 ISO 26262 的安全目标
3. 立法机构的文件要求，例如：UN/ECE 法规、FMVSS/CMVSS、NHTSA 和车载诊断要求（OBD）合规性

4.1.3 FMEA-MSR 项目计划

确定 FMEA-MSR 项目后，应立即制定 FMEA-MSR 的执行计划。

建议使用本手册第 1.5 节中所述的 5T 方法（目的、时间安排、团队、任务、工具）。FMEA-MSR 计划有助于公司提早启动 FMEA-MSR。FMEA-MSR 活动（七步法过程）应纳入总体设计项目计划中。

4.2 FMEA-MSR 2nd Step: Structure Analysis

4.2.1 Purpose



The main objectives of Structure Analysis in FMEA-MSR are:

- Visualization of the analysis scope
- Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts
- Identification of design interfaces, interactions
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

Depending on the scope of analysis, the structure may consist of hardware elements and software elements. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity.

The scope of the FMEA-MSR is limited to the elements of the system for which the baseline DFMEA showed that there are causes of failure which can result in hazardous or noncompliant effects.

In order to visualize a system structure, two methods are commonly used:

- Block (Boundary) Diagrams
- Structure Trees

For more details, refer to Section 2.2 Design FMEA

4.2.2 Structure Trees

In a Supplemental FMEA for Monitoring and System Response, the root element of a structure tree can be at vehicle level, i.e. for OEMs which analyze the overall system (see Figure 4.2-1) or at the system level, i.e. for suppliers which analyze a subsystem or component (see Figure 4.2-2).

Root element at vehicle level



Figure 4.2-1 Example of a structure tree of a window lift system for investigating erroneous signals, monitoring, and system response

4.2 FMEA-MSR 步骤二：结构分析

4.2.1 目的



FMEA-MSR 结构分析的主要目标：

- 分析范围的可视化
- 结构树或其它：方块图、边界图、数字模型、实体零件
- 确定设计接口、交互作用
- 顾客和供应商工程团队之间的协作（接口职责）
- 功能分析步骤的基础

根据分析范围，结构可能包含硬件要素和软件要素。复杂结构可分成几个结构（工作包）或不同的方块图层，并出于组织原因的考虑单独分析或确保足够的清晰度。

FMEA-MSR 的范围仅限于系统的要素，其中根据该系统的基准 DFMEA 所示，存在可能导致危险或不合规影响的失效起因。

为实现系统结构的可视化，通常使用以下两种方法：

- 方块（边界）图
- 结构树

详见设计 FMEA 第 2.2 节

4.2.2 结构树

在监视及系统响应的补充 FMEA 中，结构树的根要素可能处于整车层面（例如：分析整个系统（见图 4.2-1）或 OEM）或处于系统层面（即对子系统或组件进行分析的供应商（见图 4.2-2））。

整车层面的根要素

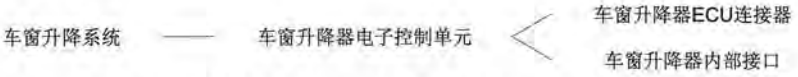


图 4.2-1车窗升降系统结构树的示例，用于调查错误信号、监视及系统响应

The sensor element and the control unit may also be part of one component (smart sensor). Diagnostics and monitoring in such systems may be realized by hardware and/or software elements.

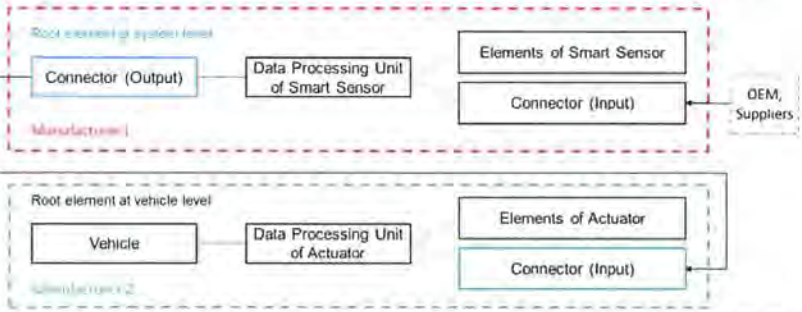


Figure 4.2-2 Example of a structure tree of a smart sensor with an internal sensing element and output to an interface

In case there is no sensor within the scope of analysis, an Interface Element is used to describe the data/current/voltage received by the ECU. One function of any ECU is to receive signals, i.e. via a connector. These signals can be missing or erroneous. With no monitoring, you get erroneous output.

In case there is no actuator within the scope of analysis, an Interface Element is used to describe the data/current/voltage sent by the ECU. Another function of any ECU is to send signals, i.e. via a connector. These signals can also be missing or erroneous. It can also be "no output" or "failure information.

The causes of erroneous signals may be within a component which is outside the scope of responsibility of the engineer or organization. These erroneous signals may have an effect on the performance of a component which is within the scope of responsibility of the engineer or organization. It is therefore necessary to include such causes in the FMEA-MSR analysis.

NOTE: Ensure that the structure is consistent with the Safety Concept (as applicable).

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lift System	ECU Window Lifter	Connector ECU Window Lifter

Figure 4.2-3 Example of Structure Analysis in the FMEA-MSR Form

传感器元件和控制单元可能也是一个组件（智能传感器）的一部分。此类系统中的诊断和监视功能可通过硬件和/软件要素实现。

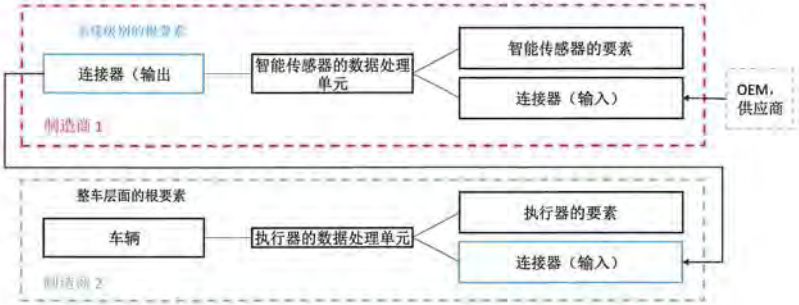


图 4.2-2 带内部感测元件和接口输出的智能传感器结构树示例

如果分析范围内未提供传感器，则使用接口要素来描述 ECU 接收的数据/电流/电压。任何 ECU 的功能之一便是接收信号，即通过连接件接收信号。这些信号可能丢失或错误。在没有监视的情况下，获得的输出可能有误。

如果分析范围内未提供执行器，则使用接口要素来描述 ECU 发送的数据/电流/电压。任何 ECU 的其他功能之一便是发送信号，即通过连接器发送信号。这些信号也可能丢失或错误。也可能是"无输出"或"失效信息"。

错误信号可能是由工程师或组织的责任范围之外的组件所致。这些错误信号可能对工程师或组织责任范围内组件的性能产生影响，因此 FMEA-MSR 分析中需要涵盖这些原因。

注：确保该结构与安全概念（如适用）保持一致。

结构分析（步骤二）		
1.上一较高级别	**2.关注要素**	**3.下一较低级别或特性类型**
车窗升降系统	ECU 车窗升降器	ECU 车窗升降器用连接器

图 4.2-3 FMEA-MSR 表格中的结构分析示例

4.3 FMEA-MSR 3rd Step: Function Analysis

4.3.1 Purpose



The main objectives of Function Analysis in FMEA-MSR are:

- Visualization of functions and relationships between functions
- Function tree/net, or equivalent function matrix parameter diagram (P-diagram)
- Cascade of customer (external and internal) functions with associated requirements
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

In a Supplemental FMEA for Monitoring and System Response, monitoring for failure detection and failure responses are considered as functions. Hardware and software functions may include monitoring of system states.

Functions for monitoring and detection of faults/failures may consist of, for example: out of range detections, cyclic redundancy checks, plausibility checks and sequence counter checks.

Functions for failure reactions may consist of, for example, provision of default values, switching to a limp home mode, switching off the corresponding function and/or display of a warning.

Such functions are modeled for those structural elements that are carriers of these functions, i.e. control units or components with computational abilities like smart sensors.

Additionally, sensor signals can be considered which are received by control units. Therefore, functions of signals may be described as well.

Finally, functions of actuators can be added, which describe the way the actuator or vehicle reacts on demand.

Performance requirements are assumed to be the maintenance of a safe or compliant state. Fulfillment of requirements is assessed through the risk assessment.

In case sensors and/or actuators are not within the scope of analysis, functions are assigned to the corresponding interface elements (consistent with the Safety Concept-as applicable).

4.3 FMEA-MSR 步骤三：功能分析

4.3.1 目的



FMEA-MSR 功能分析的主要目标：

- 功能及各功能之间的关系的可视化
- 功能树/网络或等效功能矩阵参数图（P 图）
- 顾客（外部和内部）功能与相关要求的关联
- 要求或特性与功能的关联
- 工程团队（系统、安全和组件）之间的协作
- 失效分析步骤的基础

在监视及系统响应的补充 FMEA 中，对失效探测和失效响应的监视视为其具有的功能。硬件和软件功能可能包括监视控制状态的功能。

故障/失效的监视和探测功能可能包括超出范围的探测、循环冗余校验、真实性检查和序列计数器检查等功能。

针对失效响应的功能可能包括提供默认值、切换到跛行模式、关闭相应功能和/或显示警告等功能。

这些功能被建模为那些作为这些功能载体的结构要素，即具有计算能力的控制单元或组件，如智能传感器。

此外，可考虑由控制单元接收的传感器信号。因此，也可以描述信号的功能。
最后，执行器的功能可添加，这说明了执行器或车辆按需响应的方式。

假设性能要求是维护安全或合规状态。通过风险评估，对相关要求的履行情况进行评估。

如果传感器和/或执行器不在分析范围内，则将功能分配给相应的接口要素（与适用安全概念相符）。

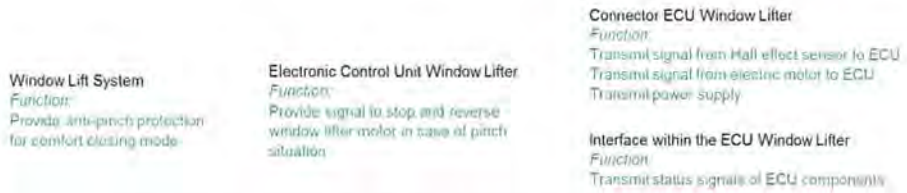


Figure 4.3-1 Example of a structure tree with functions Structure Tree

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU

Figure 4.3-2 Example of Function Analysis in FMEA-MSR Form

4.4 FMEA-MSR 4th Step: Failure Analysis

4.4.1 Purpose

The purpose of Failure Analysis in FMEA-MSR is to describe the chain of events which lead up to the end effect, in the context of a relevant scenario.

The main objectives of Failure Analysis in FMEA-MSR are:

- Establishment of the failure chain
- Failure Cause, Monitoring, System Response, Reduced Failure Effect
- Identification of product Failure Causes using a parameter diagram or failure network
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

4.4.2 Failure Scenario

A Failure Scenario is comprised of a description of relevant operating conditions in which a fault results in malfunctioning behavior and possible sequences of events (system states) that lead to an end system state (Failure Effect).

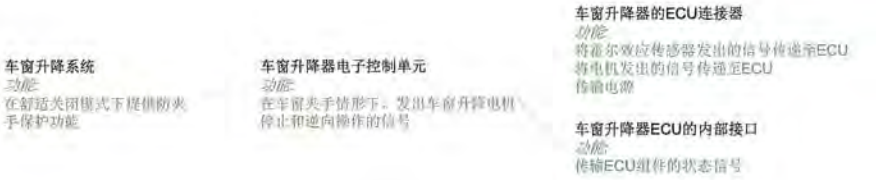


图 4.3-1 含功能结构树的结构树示例

功能分析（步骤三）		
1.上一较高级别功能及要求	**2.关注要素功能及要求**	**3.下一较低级别功能及要求或特性**
在舒适关闭模式下提供防夹手保护功能	在车窗夹手情形下，发出车窗升降电机停止和逆向操作的信号	将霍尔效应传感器发出的信号传递至 ECU

图 4.3-2 FMEA-MSR 表格中的功能分析示例

4.4 FMEA-MSR 步骤四：失效分析

4.4.1 目的

在相关的场景下，FMEA-MSR 的失效分析旨在说明导致最终影响的事件链。

FMEA-MSR 失效分析的主要目标：

- 建立失效链
- 失效起因、监视、系统响应、减轻的失效影响
- 使用参数图或失效网确定产品失效起因
- 顾客与供应商之间的协作（失效影响）
- FMEA 表格和风险分析步骤中失效记录的基础

4.4.2 失效场景

失效场景由相关操作条件的描述组成，在这些条件中，故障导致错误行为并且可能导致最终系统状态（失效影响）的事件序列（系统状态）。

It starts from defined Failure Causes and leads to the Failure Effects. (See Figure 4.4-1)

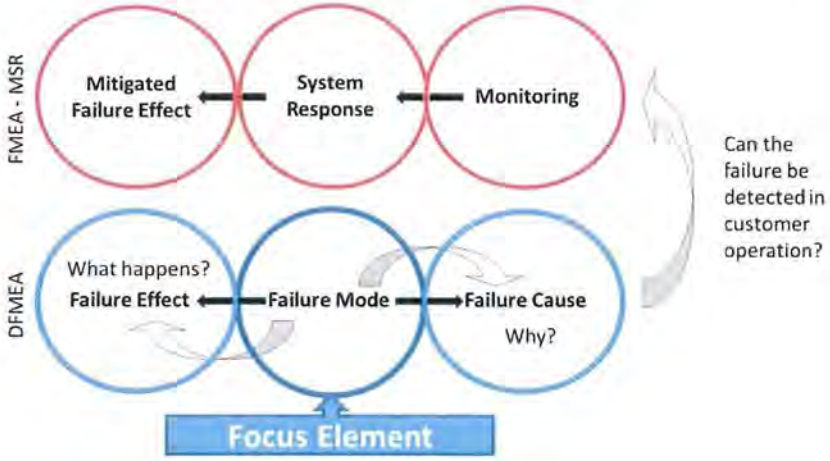


Figure 4.4-1 Theoretical failure chain model DFMEA and FMEA-MSR

The focus of the analysis is a component with diagnostic capabilities, i.e. an ECU.

If the component is not capable of detecting the fault/failure, the Failure Mode will occur which leads to the end effect with a corresponding degree of Severity.

However, if the component can detect the failure, this leads to a system response with a Failure Effect with a lower Severity compared to the original Failure Effect. Details are described in the following scenarios (1) to (3).

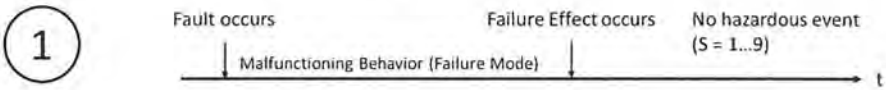


Figure 4.4-2 Failure Scenario (1) - Non-Hazardous

Failure Scenario (1) describes the malfunctioning behavior from the occurrence of the fault to the Failure Effect, which in this example is not hazardous but may reach a non-compliant end system state.

它的起点为确定的失效起因，而其终点为失效影响。（见图 4.4-1）

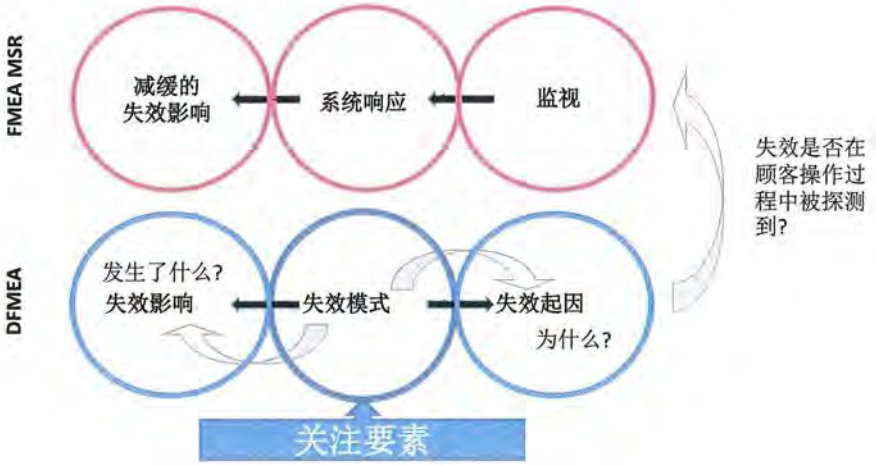


图 4.4-1 理论失效链模型 DFMEA 和 FMEA-MSR

分析的焦点在具有诊断能力的组件，即 ECU。

如果组件无法探测到故障/失效，则会发生失效模式，从而导致相应严重程度的最终结果。

但如果组件可探测到失效，这会产生系统响应，其失效影响与初始的失效影响相比，其严重度更低。在以下场景（1）至（3）中对相关细节进行了说明。

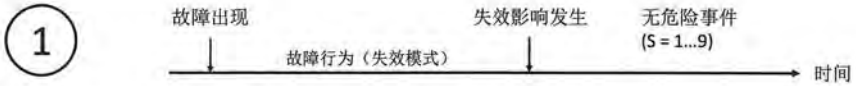


图 4.4-2 失效场景（1）——无危险事件

失效场景（1）说明了从故障出现到失效影响发生过程中所产生的故障行为，其中在本示例中，失效影响虽然不会造成危险，但可能达到不合规的最终系统状态。

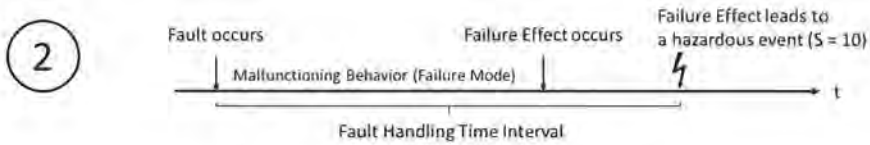


Figure 4.4-3 Failure Scenario (2) - Hazardous

Failure Scenario (2) describes the malfunctioning behavior from the occurrence of the fault to the Failure eEfect, which in this example leads to a hazardous event.

As an aspect of the Failure Scenario, it is necessary to estimate the magnitude of the Fault Handling Time Interval (time between the occurrence of the fault, and the occurrence of the hazard / noncompliant Failure Effect).

The Fault Handling Time Interval is the maximum time span of malfunctioning behavior before a hazardous event occurs, if the safety mechanisms are not activated.

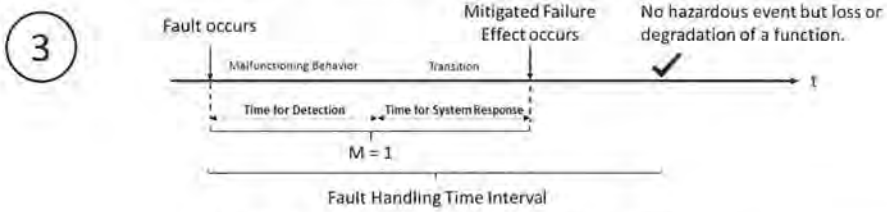


Figure 4.4-4 Failure Scenario (3) - Mitigated (Effect)

Failure Scenario (3) describes the malfunctioning behavior from the occurrence of the fault to the mitigated Failure Effect, which in this example leads to a loss or degradation of a function instead of the hazardous event.

4.4.3 Failure Cause

The description of the Failure Cause is the starting point of the Failure Analysis in a Supplemental FMEA for Monitoring and System Response. The Failure Cause is assumed to have occurred and is not the true Failure Cause (root cause). Typical Failure Causes are electrical/electronic faults (E/E faults) (Refer to Appendix C2). Root causes may be insufficient robustness when exposed to various factors such as the external environment, vehicle dynamics, wear, service, stress cycling, data bus overloading, and erroneous signal states, etc. Failure Causes can be derived i.e. from the DFMEA, catalogues for failures of E/E components, and network communication data descriptions.

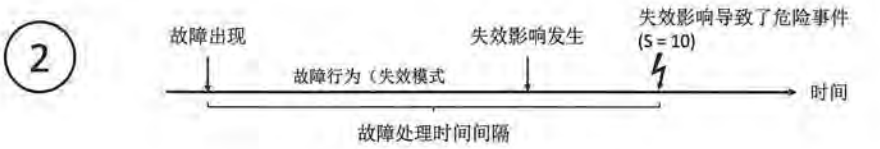


图 4.4-3 失效场景（2）——危险事件

失效场景（2）说明了从故障出现到失效影响发生的过程中所产生的故障行为，其中在本示例中，失效影响导致了危险事件。

作为失效场景的一个方面，需要估算故障处理时间间隔的大小（故障发生与危险/不合规失效影响发生之间的时间间隔）。

故障处理时间间隔系指危险事件发生前故障行为的最大时间跨度，前提是安全机制未激活。

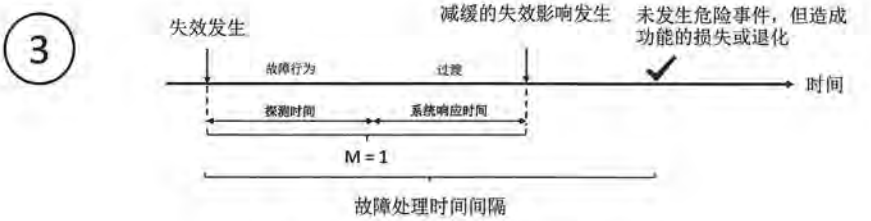


图 4.4-4 失效场景（3） - 减缓（影响）

失效场景（3）说明了从故障出现到减缓的失效影响出现的过程中所产生的故障行为，其中在本示例中，失效影响导致了功能的损失或退化而非危险事件。

4.4.3 失效起因

失效起因的描述是指监视及系统响应的补充 FMEA 失效分析的起点。假设失效起因已发生且并非真正的失效起因（根本原因）。典型失效起因系指电气/电子故障（E/E 故障）（参阅附录 C2）。当受到诸如外部环境、车辆动力学、磨损、服务、应力循环、数据总线过载和错误信号状态等各种因素的影响时，根本原因可能也变得不够稳健。失效起因可以是从 DFMEA、E/E 组件失效目录和网络通信数据说明中获得的。

NOTE: In FMEA-MSR, diagnostic monitoring is assumed to function as intended. (However, it may not be effective.) Therefore, Failure Causes of diagnostics are not part of FMEA-MSR but can be added to the DFMEA section of the form. These include:

√ Failed to detect fault

√ Falsely detected fault (nuisance)

√ Unreliable fault response (variation in response capability)

Teams may decide not to include failures of diagnostic monitoring in DFMEA because Occurrence ratings are most often very low (including "latent failures" Ref. ISO 26262). Therefore, this analysis may be of limited value. However, the correct implementation of diagnostic monitoring should be part of the test protocol.

Prevention Controls of diagnostics in a DFMEA describe how reliable a mechanism is estimated to detect the Failure Cause and reacts on time with respect to the performance requirements.

Detection Controls of diagnostics in a DFMEA would relate back to development tests which verify the correct implementation and the effectiveness of the monitoring mechanism.

4.4.4 Failure Mode

A Failure Mode is the consequence of the fault (Failure Cause). In

FMEA-MSR two possibilities are considered:

a. In case of failure scenarios (1) and (2) the fault is not detected or the system reaction is too late. Therefore, the Failure Mode in FMEA-MSR is the same as in DFMEA. (see Figure 4.4-5).

b. Different is failure scenario (3), where the fault is detected and the system response leads to a mitigated Failure Effect. In this case a description for the diagnostic monitoring and system response is added to the analysis. Because the failure chain in this specific possibility consists of a fault/failure and a description of an intended behavior, this is called a hybrid failure chain or hybrid failure network (see Figure 4.4-6).

注：　在 FMEA-MSR 中，假定诊断监视按预期运作。（但它可能无效。）因此，诊断的失效起因并不属于 FMEA-MSR 的一部分，但可添加到表格的 DFMEA 部分。这些失效起因包括：

√ 未探测到故障

√ 错误探测到故障（危害）

√ 不可靠的故障响应（响应能力的变差）

团队可能决定在 DFMEA 中排除诊断监视的失效，原因在于该失效的发生率通常非常低（包括"潜在失效"（参考 ISO 26262））。因此，本分析的价值可能有限。但是，准确地实现诊断监视应属于测试协议的一部分。

DFMEA 中的诊断的预防控制说明了探测失效起因机制的可靠性以及该机制可根据性能要求及时作出反应。

DFMEA 中的诊断的探测控制应当与开发测试相关，其中这些开发测试验证了监视机制的准确实现及其有效性。

4.4.4 失效模式

失效模式是故障（失效起因）所导致的后果。在 FMEA-MSR 中，考虑到以下两种可能性：
FMEA-MSR 有两种可能性：

a. 如果是失效场景（1）和（2），未探测到故障或系统反应太晚。因此，FMEA-MSR 中的失效模式与 DFMEA 中的相同（见图 4.4-5）。

b. 在失效场景（3）中具体的表现不同，其中探测到故障并且系统响应产生了减缓的失效影响。在这种情况下，诊断监视和系统响应的说明将添加到分析中。由于这一特定可能性中的失效链包括故障/失效及预期行为说明，因此称为混合失效链或混合失效网（见图 4.4-6）。

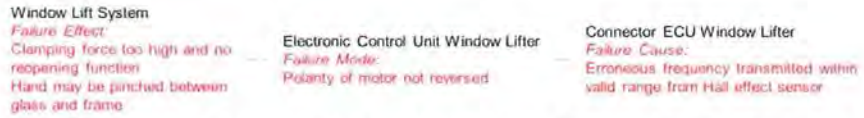


Figure 4.4-5 Example of a structure with failure chain without a monitoring or with a monitoring which is only partially effective (scenario (1) and (2)).



Figure 4.4-6 Example of a structure with hybrid failure chain including a monitoring which always is effective and switches the system to a mitigated Failure Effect (scenario (3)

4.4.5 Failure Effect

A Failure Effect is defined as the consequence of a Failure Mode. Failure Effects in FMEA-MSR are either a malfunctioning behavior of the system or an intended behavior after detection of a Failure Cause. The end effect may be a "hazard" or "noncompliant state" or, in case of detection and timely system response, a "safe state" or "compliant state" with loss or degradation of a function.

The severity of Failure Effects is evaluated on a ten point scale according to Table MSR1 and Table D1, respectively.

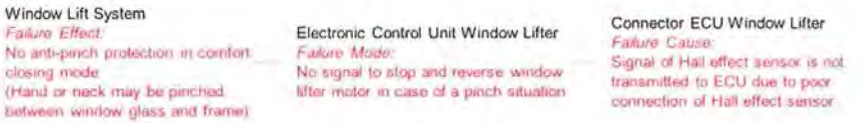


Figure 4.4-7 Example of a failure network

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Next Lower Element or Characteristic**
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	No signal to stop and reverse window lifter motor in case of a pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor

Figure 4.4-8 Example of Failure Analysis in FMEA-MSR Form

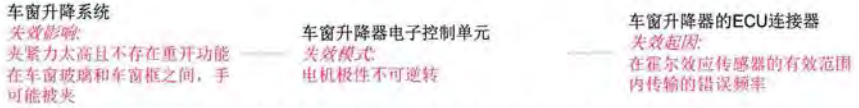


图 4.4-5 具有或不具有或仅部分有效的监视功能的失效链结构示例（场景（1）和（2））

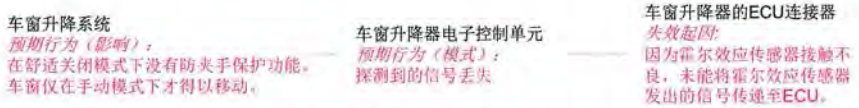


图 4.4-6 具有始终有效且将系统切换到减缓失效影响的监视功能的混合失效链结构示例（场景（3）

4.4.5 失效影响

失效影响被定义为失效模式的后果。FMEA-MSR 中的失效影响系指系统的故障行为或探测到故障原因后的预期行为。最终效果可以是“危险”或“不合规状态”，或者在探测和及时系统响应的情况下，可以是功能的丢失或退化的“安全状态”或“合规状态”。

根据表 MSR1 和表 D1，分别采用十分制量表对失效影响的严重度进行评估。

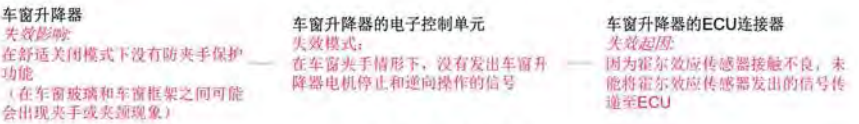


图 4.4-7 失效网示例

失效分析（步骤四）		
1.上一较高级别功能及要求	**2.关注要素功能及要求**	**3.下一较低级别功能及要求或特性**
在舒适关闭模式下没有防夹手保护功能 （在车窗玻璃和车窗框架之间可能会出现夹手或夹颈现象）	在车窗夹手情形下，没有发出车窗升降器电机停止和逆向操作的信号	因为霍尔效应传感器接触不良，未能将霍尔效应传感器发出的信号传递至 ECU

图 4.4-8 FMEA-MSR 表格中的失效分析示例

4.5 FMEA-MSR 5th Step: Risk Analysis

4.5.1 Purpose



The purpose of Risk Analysis in FMEA-MSR is to estimate risk of failure by evaluating Severity, Frequency, and Monitoring, and prioritize the need for actions to reduce risk.

The main objectives of the FMEA-MSR Risk Analysis are:

- Assignment of existing and/or planned controls and rating of failures
- Assignment of a Rationale for Frequency Rating
- Assignment of Monitoring Controls
- Analysis of provisions for functional safety and regulatory compliance
- Rating of Severity, Frequency and Monitoring for each failure chain.
- Collaboration between customer and supplier (Severity and Frequency)
- Evaluation of Action Priority
- Basis for the product Optimization step

4.5.2 Evaluations

Each Failure Mode, Cause and Effect relationship (failure chain or hybrid network)) is assessed by the following three criteria:

Severity (S): represents the Severity of the Failure Effect

Frequency (F): represents the Frequency of Occurrence of the Cause in a given operational situation, during the intended service life of the vehicle

Monitoring (M): represents the Detection potential of the Diagnostic Monitoring functions (detection of Failure Cause, Failure Mode and/or Failure Effect)

Evaluation numbers from 1 to 10 are used for S, F, and M respectively, where 10 stands for the highest risk contribution.

By examining these ratings individually and in combinations of the three factors the need for risk-reducing actions may be prioritized.

4.5.3 Severity (S)

The Severity rating (S) is a measure associated with the most serious Failure Effect for a given Failure Mode of the function being evaluated and is identical for DFMEA and FMEA-MSR.

4.5 FMEA-MSR 步骤五：风险分析

4.5.1 目的

FMEA-MSR 中的风险分析旨在通过评估严重度、频率和监视来评估失效的风险，并对需要采取降低风险的措施进行优先排序。

FMEA-MSR 风险分析的主要目标：



- 分配现有和/或计划的控制措施、并对失效进行评级
- 对频率评级分配理由
- 分配监视控制措施
- 分析功能安全和法规合规性的规定
- 对每个失效链进行严重度、频率和监视评级
- 顾客与供应商之间的协作（严重度和频率）
- 评估措施优先级
- 产品优化步骤的基础

4.5.2 评估

每种失效模式、因果关系（失效链或混合网络）是通过以下三个标准评估的：

严重度（S）： 表示失效影响的严重程度

频率（F）： 表示在给定的运行情况下，车辆的预期使用寿命期间发生失效起因的频率

监视（M）： 表示诊断监视功能的潜在探测度（探测失效起因、失效模式和/或失效影响）

1 到 10 的评估数字分别用于 S、F 和 M，其中 10 代表最高风险。

通过单独检查这些评级并结合三个因素，可优先考虑降低风险的措施。

4.5.3 严重度（S）

严重度评级（S）是一种与所评估功能在既定失效模式下的最严重失效影响相关联的度量，并且 DFMEA 和 FMEA-MSR 的严重度评级是相同的。

Severity should be estimated using the criteria in the Severity Table MSR1. The table may be augmented to include product- specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent even if modified for individual design analysis.

The Severity evaluations of the Failure Effects should be transferred by the customer to the supplier, as needed.

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible Failure Effect.	

Note: This table is identical to Table D1 - DFMEA SEVERITY (S)

Table MSR1 - Supplemental FMEA-MSR SEVERITY (S)

4.5.4 Rationale for Frequency Rating

In a Supplemental FMEA for Monitoring and System Response, the likelihood of a failure to occur in the field under customer operating conditions during service life is relevant.

严重度应采用严重度表 MSR1 中的标准进行评估。可扩增该表，使其包含产品特定示例。FMEA 项目团队应就评估标准和评级体系达成一致，即使根据单个设计分析做了修改，该标准和体系也是一致的。

失效影响的严重度评估应按需要通过顾客转移给供应商。

产品一般评估标准严重度			
根据以下标准对潜在失效影响进行评级。			空白，由使用人员填写
S	**影响**	**严重度标准**	**公司或产品系列示例**
10	**非常高**	影响到车辆和/或其他车辆的操作安全，驾驶员、乘客、交通参与者或行人的健康状况。	
9		不符合法规。	
8	**高**	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	
6	**中**	**失去**车辆次要功能	
5		**降低**车辆次要功能	
4		外观、声音、振动、粗糙度或触感令人感觉非常不舒服。	
3	**低**	外观、声音、振动、粗糙度或触感令人感觉一般性的不舒服。	
2		外观、声音、振动、粗糙度或触感令人略微感觉不舒服。	
1	**非常低**	没有可觉察到的影响。	

注：　本表与表 D1 DFMEA 严重度（S）相同

表 MSR1——FMEA-MSR 严重度（S）补充表

4.5.4　频率评级的理由

监视及系统响应的补充 FMEA 中，在使用寿命期间内，在顾客操作条件下，频率评级的理由是和现场发生失效的可能性相关。

Analysis of end user operation requires assumptions that the manufacturing process is adequately controlled in order to assess the sufficiency of the design.

Examples on which a rationale may be based on:

- Evaluation based on the results of Design FMEAs
- Evaluation based on the results of Process FMEAs
- Field data of returns and rejected parts
- Customer complaints
- Warranty databases
- Data handbooks

The rationale is documented in the column "Rationale for Frequency Rating" of the FMEA-MSR form.

4.5.5 Frequency (F)

The Frequency rating (F) is a measure of the likelihood of occurrence of the cause in relevant operating situations during the intended service life of the vehicle or the system using the criteria in Table MSR2.

If the Failure Cause does not always lead to the associated Failure Effect, the rating may be adapted, taking into account the probability of exposure to the relevant operating condition (according to Table MSR2.1). In such cases the operational situation and the rationale are to be stated in the column "Rationale for Frequency Rating".

Example: From field data it is known how often a control unit is defective in ppm/year. This may lead to F=3. The system under investigation is a parking system which is used only a very limited time in comparison to the overall operating time. So harm to persons is only possible when the defect occurs during the parking maneuver. Therefore, Frequency may be lowered to F=2.

Frequency Potential (F) for the Product			
Frequency criteria (F) for the estimated occurrence of the Failure Cause in relevant operating situations during the intended service life of the vehicle			Blank until filled in by user
F	**Estimated Frequency**	**Frequency criteria - FMEA-MSR**	**Corporate or Product Line Examples**
10	**Extremely high or cannot be determined**	Frequency of occurrence of the Failure Cause is unknown or known to be unacceptably high during the intended service life of the vehicle	
9	**High**	Failure Cause is likely to occur during the intended service life of the vehicle	
8		Failure Cause may occur often in the field during the intended service life of the vehicle	
7	**Medium**	Failure Cause may occur frequently in the field during the intended service life of the vehicle	
6		Failure Cause may occur somewhat frequently in the field during the intended service life of the vehicle	

最终用户操作的分析需要假设制造过程得到足够的控制，以便评估设计的适用性。

理由可基于以下的示例：

- 基于设计 FMEA结果的评估
- 基于过程 FMEA结果的评估
- 使用现场的退货和拒收产品数据
- 顾客投诉
- 保修数据库
- 数据手册

理由记录在 FMEA-MSR 表格的"频率评级理由"列中。

4.5.5 频率（F）

频率评级（F）是指，使用表 MSR2 中的标准，对在车辆或系统预期使用寿命期间相关操作中发生失效起因的可能性的衡量。

如果失效起因并不总是导致相关联的失效影响，考虑暴露于相关运行条件的可能性（根据表 MSR2.1），可以考虑调整评级。在这种情况下，运行情况和基本原理应在"频率评级的理由"列中说明。

示例：从使用现场数据中知悉，控制单元有缺陷的频率以 ppm /年为单位。这可能导致 F = 3。研究中的系统为一种停车系统，与整个运行时间相比，该系统使用的时间较短。因此，只有在停车操作期间发生缺陷时才可能对人员造成伤害。因此，频率可降低到 F = 2。

产品的潜在频率(F)			
频率标准（F），用于在车辆预期使用寿命周期内与运行状况相关失效起因的估计频度			空白，由使用人员填写
F	**估计频率**	**频率标准 - FMEA-MSR**	**公司或产品系列示例**
10	**极高或不能确定**	在车辆预期使用寿命周期内，失效起因的发生频率未知，或已知很高而无法接受	
9	**高**	失效起因在车辆预期使用寿命周期内可能会出现	
8		在车辆预期使用寿命周期内，失效起因可能在车辆使用中经常出现	
7	**中**	在车辆预期使用寿命周期内，失效起因可能在车辆使用中频繁出现	
6		在车辆预期使用寿命周期内，失效起因可能在车辆使用中略微频繁地出现	

5		Failure Cause may occur occasionally in the field during the intended service life of the vehicle.	
4	**Low**	Failure Cause is predicted to occur rarely in the field during the intended service life of the vehicle. At least ten occurrences in the field are predicted.	
3	**Very low**	Failure Cause is predicted to occur in isolated cases in the field during the intended service life of the vehicle. At least one occurrence in the field is predicted.	
2	**Extremely low**	Failure Cause is predicted not to occur in the field during the intended service life of the vehicle based on prevention and detection controls and field experience with similar parts. Isolated cases cannot be ruled out. No proof it will not happen.	
1	**Cannot Occur**	Failure Cause cannot occur during the intended service life of the vehicle or is virtually eliminated. Evidence that Failure Cause cannot occur. Rationale is documented.	

Percentage of relevant operating condition in comparison to overall operating time	**Value by which F may be lowered**
< 10%	1
< 1%	2

NOTE: Probability increases as number of vehicles are increased

Reference value for estimation is one million vehicles in the field

Table MSR2 - Supplemental FMEA-MSR FREQUENCY (F)

5		在车辆预期使用寿命周期内，失效起因可能在车辆使用中偶尔出现。	
4	低	在车辆预期使用寿命周期内，预计失效起因在车辆使用中极少出现。预计在使用中至少发生十次。	
3	非常低	在车辆预期使用寿命周期内，预计失效起因在孤立事例的车辆使用中会出现。预计在使用中至少发生一次。	
2	极低	在车辆预期使用寿命周期内，在应用预防及探测控制措施以及相似零件现场使用经验的基础上，预计失效起因在车辆使用中不会出现。不能排除孤立事例。没有证明表明这种现象不会发生。	
1	不会出现	失效起因在车辆预期使用寿命周期内不会出现，或几乎排除这种可能。证据表明失效起因不会出现。其起因已进行记录。	

相关运行条件占总运行时间的比例	F 可以随之降低的值
< 10%	1
< 1%	2

注：　随着车辆数量的增加，可能性也随之增加
估计参考值为一百万台使用中的车辆

表 MSR2 - 补充 FMEA-MSR 频率(F)表

4.5.6 Current Monitoring Controls

All controls that are planned or already implemented and lead to a detection of the Failure Cause, the Failure Mode or the Failure Effect by the system or by the driver are entered into the "Current Monitoring Controls" column. In addition, the fault reaction after detection should be described, i.e. provision of default values, (if not already sufficiently described by the Failure Effect).

Monitoring evaluates the potential that the Failure Cause, the Failure Mode or the Failure Effect can be detected early enough so that the initial Failure Effect can be mitigated before a hazard occurs or a noncompliant state is reached. The result is an end state effect with a lower severity.

4.5.7 Monitoring (M)

The Monitoring rating (M) is a measure of the ability of detecting a fault/failure during customer operation and applying the fault reaction in order to maintain a safe or compliant state.

The Monitoring Rating relates to the combined ability of all sensors, logic, and human sensory perception to detect the fault/failure; and react by modifying the vehicle behavior by means of mechanical actuation and physical reaction (controllability). In order to maintain a safe or compliant state of operation, the sequence of fault detection and reaction need to take place before the hazardous or noncompliant effect occurs. The resulting rating describes the ability to maintain a safe or compliant state of operation.

Monitoring is a relative rating within the scope of the individual FMEA and is determined without regard for severity or frequency. Monitoring should be estimated using the criteria in Table MSR3. This table may be augmented with examples of common monitoring. The FMEA project team should agree on an evaluation criteria and rating system which is consistent, even if modified for individual product analysis.

The assumption is that Monitoring is implemented and tested as-designed. The effectiveness of Monitoring depends on the design of the sensor hardware, sensor redundancy, and diagnostic algorithms that are implemented. Plausibility metrics alone are not considered to be effective. Refer to Table MSR3.

Implementation of monitoring and the verification of effectiveness should be part of the development process and therefore may be analyzed in the corresponding DFMEA of the product. (see NOTE for Failure Causes in Section 4.4.1).

The effectiveness of diagnostic monitoring and response, the fault monitoring response time, and the Fault Tolerant Time Interval need to be determined prior to rating. Determination of the effectiveness of diagnostic monitoring is addressed in detail in ISO 26262-5:2018 Annex D.

4.5.6 当前监视控制

所有计划中的或已实施的、能使系统或驾驶人探测到失效起因、失效模式或失效影响的控制，应填入"当前监视控制"列中。另外，应对探测后的失效反应进行说明，例如：提供默认值（前提是还没有通过失效影响进行适当的说明）。

监视评估可及早探测到失效起因、失效模式或失效影响的可能性，以便在危险发生或达到不合规状态之前可减缓初始失效影响。结果是较低严重度的最终状态影响。

4.5.7 监视（M）

监视评级（M）是对顾客操作期间探测故障/失效并应用故障响应来维持安全或合规状态能力的度量。

监视评级涉及所有传感器、逻辑和人类感知的组合能力，旨在探测故障/失效，并通过机械驱动和物理反应（可控性）改变车辆行为的方式作出响应。为保持安全或合规的运行状态，需要在发生危险或不合规的影响之前进行故障探测和响应的排序。最终评级说明了维持安全或合规运行状态的能力。

监视评级是在单个 FMEA 范围内的相对评级，并且在不考虑严重度或频率的情况下确定。应使用表 MSR3 中的标准评估监视情况。可使用常见监视的示例来扩充该表。FMEA 项目团队应就评估标准和评级体系达成一致，即使根据单个产品分析做了修改，该标准和体系也是一致的。

假设是按照设计实现和测试监视。监视的有效性取决于传感器硬件的设计、传感器冗余以及采用的诊断算法。仅真实性指标不被认为是有效的。请参阅表 MSR3。

监视的执行及有效性的验证应当属于开发过程的一部分，因此可在产品的相应 DFMEA 中进行分析（见 4.4.1 节中的失效起因注释）。

要在评级前确定诊断监视和响应、故障监视响应时间和容错时段的有效性。ISO 26262-5:2018 附录 D 详细说明了诊断监测有效性的确定。

In practice, three different monitoring/response cases may be distinguished:

(1) No fault/failure monitoring

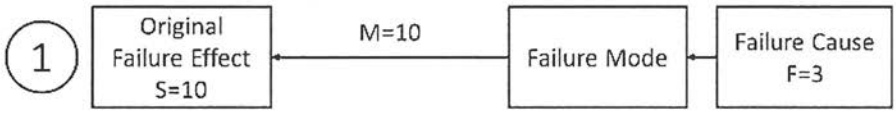


Figure 4.5-1 FMEA-MSR Monitoring not implemented or not considered

If there is no monitoring control, or if monitoring and response do not occur within the Fault Handling Time Interval, then Monitoring should be rated as Not Effective (M=10).

(2) Reliable fault/failure monitoring and system response

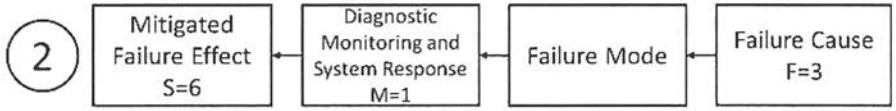


Figure 4.5-2 FMEA-MSR Reliable Diagnostic Monitoring

The original Failure Effect is virtually eliminated. Only the mitigated Failure Effect remains relevant for the risk estimation of the product or system. In this instance only, the mitigated FE is relevant for the Action Priority rating, not the original FE.

The assignment of Monitoring Ratings to Failure Causes and their corresponding Monitoring Controls can vary depending on:

a. Variations in the Failure Cause or Failure Mode
b. Variations in the hardware implemented for diagnostic monitoring
c. The execution timing of the safety mechanism, i.e. failure is detected during "power up" only
d. Variations in system response
e. Variations in human perception and reaction
f. Knowledge of implementation and effectiveness from other projects (newness)

实际上，三种不同监视/响应情况可加以区别。

（1）不存在故障/失效监视

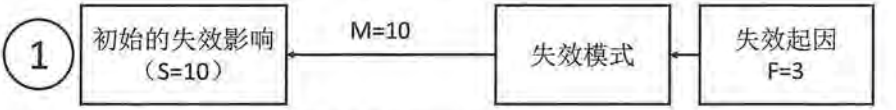


图 4.5-1 未实施或未考虑使用的 FMEA-MSR 监视

如果不存在监视控制或在故障处理间隔时间未发生监视和响应，则监视应评为无效（M=10）。

（2）可靠的故障/失效监视及系统响应

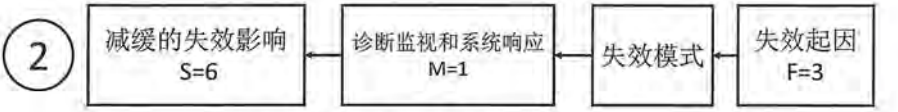


图 4.5-2 FMEA-MSR 可靠的诊断监测

几乎消除了初始的失效影响。仅减缓的失效影响仍与产品或系统的风险评估相关。仅在这一情况下，减缓的 FE 与措施优先级相关，而不是与原始的 FE 相关。

失效起因的监视评级及其相应的监视控制可取决于以下几个方面：

a. 失效起因或失效模式的变差
b. 实现诊断监视的硬件的变差
c. 安全机制的执行时间安排，例如：仅在"通电"期间探测到失效
d. 系统响应的变差
e. 人类感知和反应的变差
f. 其他项目实施和有效性的知识（新颖性）

Depending on these variations or execution timing, Monitoring Controls may not be considered to be RELIABLE in the sense of M=1.

(3) Less-than reliable fault/failure monitoring

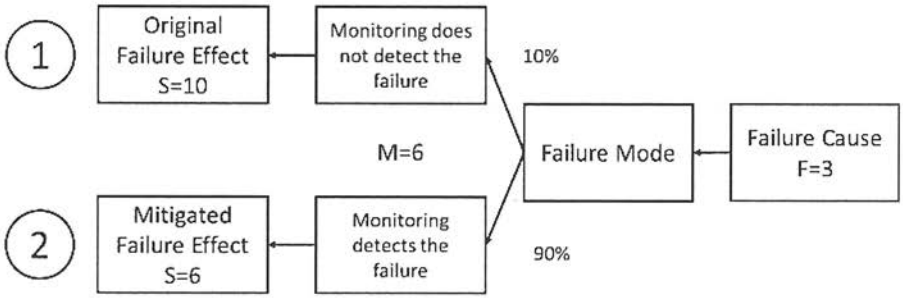


Figure 4.5-3 FMEA-MSR Diagnostic Monitoring partially effective

The original Failure Effect occurs less often. Most of the failures are detected and the system response leads to a mitigated Failure Effect. The reduced risk is represented by the Monitoring rating. The most serious Failure Effect remains S=10.

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
10	**Not effective**	The fault/failure cannot be detected at all or not during the Fault Handling Time Interval; by the system, the driver, a passenger, or service technician.	No response during the Fault Handling Time Interval.	
9	**Very Low**	The fault/failure can almost never be detected in relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Minimal diagnostic coverage.	The reaction to the fault/failure by the system or the driver may not reliably occur during the Fault Handling Time Interval.	

根据这些变化或执行时间安排，在 M=1 时，监视控制措施不被认为是可靠的。

（3）不太可靠的故障/失效监视

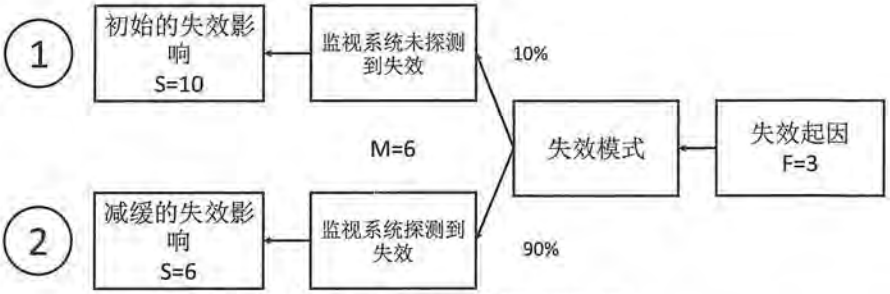


图 4.5-3 部分有效的 FMEA-MSR 诊断监视

初始的失效影响发生的次数较少。大多数的失效均被探测到，并且系统响应使失效影响得到了降低。降低的风险按监测评级表示。最严重的失效影响仍为 S = 10。

监视及系统响应(M) 的补充 FMEA				
在顾客操作中用于监视失效起因、失效模式和失效影响的监视标准(M)。在监视或系统响应中使用与最低效的标准相关的评级				空白，由使用人员填写
M	**监视控制及系统响应的有效性**	**诊断监视/感知标准**	**系统响应/人体反应标准**	**公司或产品系列示例**
10	**无效**	在容错时段内，系统、驾驶员、乘客或维修技术人员根本无法探测或未探测到故障/失效现象。	在容错时段内没有反应。	
9	**非常低**	在相关运行条件下几乎从未探测到故障/失效现象。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率低。	在容错时段内，系统或驾驶员不能以可靠的方式对故障/失效进行反应。	

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
8	**Low**	The fault/failure can be detected in very few relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated <60%.	The reaction to the fault/failure by the system or the driver may not always occur during the fault tolerant time interval.	
7	**Moderately Low**	Low probability of detecting the fault/failure during the fault tolerant time interval by the system or the driver. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated >60%.	Low probability of reacting to the detected fault/failure during the fault tolerant time interval by the system or the driver.	
6	**Moderate**	The fault/failure will be automatically detected by the system or the driver only during power-up, with medium variance in detection time. Diagnostic coverage estimated >90%.	The automated system or the driver will be able to react to the detected fault/failure in many operating conditions.	
5		The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in very many operating conditions. Diagnostic coverage estimated between 90% - 97%.	The automated system or the driver will be able to react to the detected fault/failure in very many operating conditions.	
4	**Moderately High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in most operating conditions. Diagnostic coverage estimated >97%.	The automated system or the driver will be able to react to the detected fault/failure during the fault tolerant time interval, in most operating conditions.	
3	**High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval with very low variance in detection time, and with a high probability. Diagnostic coverage estimated >99%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval in most operating conditions with very low variance in system response time, and with a high probability.	

监视及系统响应(M) 的补充 FMEA				
在顾客操作中用于监视失效起因、失效模式和失效影响的监视标准(M)。在监视或系统响应中使用与最低效的标准相关的评级				空白，由使用人员填写
M	**监视控制及系统响应的有效性**	**诊断监视/感知标准**	**系统响应/人体反应标准**	**公司或产品系列示例**
8	低	在极少数的相关运行条件下故障/失效能够被探测到。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率预计低于 60%。	在容错时段内，系统或驾驶员不能总是对故障/失效进行反应。	
7	较低	在容错时段内，系统或驾驶员探测到故障/失效的机率低。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率预计高于 60%。	在容错时段内，系统或驾驶员对故障/失效进行反应的机率低。	
6	中	只有在打开电源状态下，系统或驾驶员才能自动探测到故障/失效，探测时间的变化为中等程度。诊断覆盖率预计高于 90%。	在多种运行条件下，自动化系统或驾驶员能够对探测到的故障/失效进行反应。	
5		在容错时段内，系统能够自动探测到故障/失效，探测时间的变化为中等程度或者驾驶员可在多种运行条件下探测到故障/失效。诊断覆盖率预计在 90-97% 之间。	在很多种运行条件下，自动化系统或驾驶员能够对探测到的故障/失效进行反应。	
4	较高	在容错时段内，系统能够自动探测到故障/失效，探测时间的变化一般，或者驾驶员在大多运行条件下可以探测到故障/失效。诊断覆盖率预计高于 97%。	在容错时段内，自动化系统或驾驶员在大多运行条件下能够对探测到的故障/失效进行反应。	
3	高	在容错时段内，系统能够自动探测到故障/失效，探测时间的变化很小，并且机率高。诊断覆盖率预计高于 99%。	在容错时段内，系统在大多运行条件下能够自动探测到故障/失效，系统反应的时间变差很小，并且机率高。	

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
2	**Very High**	The fault/failure will be detected automatically by the system with very low variance in detection time during the fault tolerant time interval, and with a very high probability. Diagnostic coverage estimated > 99.9%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval with very low variance in system response time, and with a very high probability.	
1	**Reliable** and acceptable for elimination of original failure effect	The fault/failure will always be detected automatically by the system. Diagnostic coverage estimated to be significantly greater than 99.9%.	The system will always automatically react to the detected fault/failure during the fault tolerant time interval.	

Table MSR3 - Supplemental FMEA-MSR MONITORING (M)

监视及系统响应(M) 的补充 FMEA				
在顾客操作中用于监视失效起因、失效模式和失效影响的监视标准(M)。在监视或系统响应中使用与最低效的标准相关的评级				空白，由使用人员填写
M	**监视控制及系统响应的有效性**	**诊断监视/感知标准**	**系统响应/人体反应标准**	**公司或产品系列示例**
2	**非常高**	在容错时段内，系统能够自动探测到故障/失效，探测时间变化很小，并且机率很高。诊断覆盖率预计高于 99.9%。	在容错时段内，系统能够自动探测到故障/失效，系统反应的时间变差很小，并且机率很高。	
1	在消除原有的失效影响方面**可靠**并可接受	系统总是可以自动探测到故障/失效。故障覆盖率预计大大高于 99.9%。	在容错时段内，系统总是能够对故障/失效进行自动反应。	

表 MSR 补充 FMEA-MSR 监视(M)表

4.5.8 Action Priority (AP) for FMEA-MSR

The Action Priority is a methodology which allows for the prioritization of the need for action, considering Severity, Frequency, and Monitoring (SFM).

This is done by the assignment of SFM ratings which provide a basis for the estimation of risk.

See previous chapters for discussion of reducing risk first by S, then F, then M.

Priority High (H): Highest priority for review and action.

The team needs to either identify an appropriate action to lower frequency and/or to improve monitoring controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action.

The team should identify appropriate actions to lower frequency and/or to improve monitoring controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action.

The team could identify actions to lower frequency and/or to improve monitoring controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

This is not the prioritization of High, Medium, or Low risk. It is the prioritization of the need for actions to reduce risk.

If the team decides that no further actions are necessary, "No further action is needed" is written in the Remarks field to show the risk analysis was completed.

4.5.8 FMEA-MSR 的措施优先级（AP）

措施优先级是指，在考虑严重度、频率和监视（SFM）的情况下，确定需要采取措施优先顺序的一种方法。

这是通过分配 SFM 评级来完成的，其中这些评级为风险评估提供了依据。

有关将风险依次降低 S、F、M 的讨论，请参阅前面的章节。

优先级高（H）：评审和措施的最高优先级。

团队需要确定适当的措施来降低频率和/或改进监视控制，或证明并记录为何当前的控制足够有效。

优先级中（M）：评审和措施的中等优先级。

团队应该确定适当的措施来降低频率和/或改进监视控制，或者由公司自行证明并记录为何当前的控制措施足够有效。

优先级低（L）：评审和措施的低优先级。

该团队可以确定措施来降低频率和/或改进监视控制。

对于潜在的严重度为 9-10 且措施优先级为高和中的失效影响，建议至少应由管理层评审，包括所采取的任何建议措施。

这不是对高、中、低风险的优先排序，而是对降低风险的措施的优先排序。

如果团队决定不需要采取进一步措施，则在“备注”列中填入“无需进一步措施”，以表明已经完成风险分析。

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect High	**10**	Medium - Extremely high	5-10	Reliable - Not effective	1-10	H
		Low	4	Moderately high - Not effective	4-10	H
				Very high - High	2-3	H
				Reliable	1	M
		Very low	3	Moderately high - Not effective	4-10	H
				Very high - High	2-3	M
				Reliable	1	L
		Extremely low	2	Moderately high - Not effective	4-10	M
				Reliable - High	1-3	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect High	**9**	Low - Extremely high	4-10	Reliable - Not effective	1-10	H
		Extremely low - Very low	2-3	Very high - Not effective	2-10	H
				Reliable - High	1	L
		Cannot occur	1	Reliable - Not effective	1-10	L

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响度	**S**	**在车辆使用寿命内对发生失效起因的预测**	**F**	**监视有效性**	**M**	**措施优先级 (AP)**
对产品的影响度高	10	中 - 极高	5-10	可靠 - 无效	1-10	H
		低	4	较高 - 无效	4-10	H
				很高 - 高	2-3	H
				可靠	1	M
		非常低	3	较高 - 无效	4-10	H
				很高 - 高	2-3	M
				可靠	1	L
		极低	2	较高 - 无效	4-10	M
				可靠 - 高	1-3	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度高	9	低 - 极高	4-10	可靠 - 无效	1-10	H
		极低 - 很低	2-3	很高 - 无效	2-10	H
				可靠 - 高	1	L
		不会出现	1	可靠 - 无效	1-10	L

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Moderately high	**7-8**	Medium - Extremely high	6-10	Reliable - Not effective	1-10	H
		Medium	5	Moderately high - Not effective	5-10	H
				Reliable - Moderately high	1-4	M
		Low	4	Moderately low - Not effective	7-10	H
				Moderately high - Moderate	4-6	M
				Reliable - High	1-3	L
		Very low	3	Very low - Not effective	9-10	H
				Moderately low - Low	7-8	M
				Reliable - Moderate	1-6	L
		Extremely low	2	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Moderately Low	**4-6**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderate - Not effective	6-10	H
				Reliable - Moderately high	1-5	M
		Extremely low - Low	2-4	Very low - Not effective	9-10	M
				Moderately high - Moderate	7-8	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响度	**S**	**在车辆使用寿命内对发生失效起因的预测**	**F**	**监视的有效性**	**M**	**措施优先级 (AP)**
对产品的影响度较高	**7-8**	中-极高	6-10	可靠 - 无效	1-10	H
		中	5	较高 - 无效	5-10	H
				可靠 - 较高	1-4	M
		低	4	较低 - 无效	7-10	H
				较高 - 中	4-6	M
				可靠 - 高	1-3	L
		非常低	3	很低 - 无效	9-10	H
				较低 - 低	7-8	M
				可靠 - 中	1-6	L
		极低	2	较低 - 无效	7-10	M
				可靠 - 中	1-6	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度较低	**4-6**	高 - 极高	7-10	可靠 - 无效	1-10	H
		中	5-6	中 - 无效	6-10	H
				可靠 - 较高	1-5	M
		极低 - 低	2-4	很低 - 无效	9-10	M
				较高 - 中	7-8	M
				可靠 - 中	1-6	L
		不会出现	1	可靠 - 无效	1-10	L

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Low	**2-3**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Extremely low - Low	2-4	Reliable - Not effective	1-10	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Very low	**1**	Cannot occur - Extremely high	1-10	Reliable - Not effective	1-10	L

NOTE: If M=1, the Severity rating of the Failure Effect after Monitoring and System Response is to be used for determining MSR Action Priority. If M is not equal to 1, then the Severity Rating of the original Failure Effect is to be used for determining MSR Action Priority.

Table AP – ACTION PRIORITY FOR FMEA-MSR

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响度	**S**	**在车辆使用寿命内对发生失效起因的预测**	**F**	**监视的有效性**	**M**	**措施优先级 (AP)**
对产品的影响度低	**2-3**	高 - 极高	7-10	可靠 - 无效	1-10	H
		中	5-6	较低 - 无效	7-10	M
				可靠 - 中	1-6	L
		极低 - 低	2-4	可靠 - 无效	1-10	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度很低	**1**	不会出现 - 极高	1-10	可靠 - 无效	1-10	L

注：　如果 M=1，在确定 MSR 措施优先级时，应使用监视及系统响应后的失效影响严重度评级。如果 M 不等于 1，在确定 MSR 措施优先级时，应使用最初的失效影响严重度评级。

AP 表 - FMEA-MSR 措施优先级

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)
The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None	Window will close with full clamping force.	10	Hand or neck may be pinched between glass and frame	10	10	M	

Figure 4.5-4 Example of FMEA-MSR Risk Analysis - Evaluation of Current Risk Form

4.6 FMEA-MSR 6th Step: Optimization

4.6.1 Purpose



The primary objective of Optimization in FMEA-MSR is to develop actions that reduce risk and improve safety. In this step, the team reviews the results of the risk analysis and evaluates action priorities.

The main objectives of FMEA-MSR Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and target completion dates for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures

补充 FMEA-MSR 风险分析（步骤五）									
频率评级的理由	失效起因的发生频率（F）	当前的诊断监视	当前的系统响应	监视（M）	在系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度（S）	在失效分析中初始失效影响的严重度（步骤四）	MSR AP	筛选器代码（可选）
根据 xyz 标准将霍尔效应传感器和 ECU 进行连接的原理	2	无	车窗将在最大夹持力状态下关闭。	10	在玻璃和车窗框架之间可能会出现夹手或夹颈现象	10	10	M	

图 4.5-4 FMEA-MSR 风险分析示例——当前风险评估表

4.6 FMEA-MSR 步骤六：优化

4.6.1 目的

FMEA-MSR 优化的主要目标在于制定降低风险和提高安全性的措施。在此步骤中，团队将评审风险分析的结果并评估措施优先级。



FMEA-MSR 优化的主要目标：

- 确认降低风险的必要措施
- 为措施实施分配职责和目标完成日期
- 实施措施并将其形成文件，包括对所实施措施的有效性的确认以及采取措施后的风险评估
- 确认降低风险的必要措施
- 为措施实施分配职责及截止日期
- FMEA 团队、管理层、顾客和供应商在潜在失效方面的协作

- Basis for refinement of the product requirements and prevention/detection controls

High and medium action priorities may indicate a need for technical improvement.

Improvements may be achieved by introducing more reliable components which reduce the occurrence potential of the Failure Cause in the field or introduce additional monitoring which improve the detection capabilities of the system. Introduction of monitoring is similar to design change. Frequency of the Failure Cause is not changed. It may also be possible to eliminate the Failure Effect by introducing redundancy.

If the team decides that no further actions are necessary, "No further action is needed" is written in the Remarks field to show the risk analysis was completed.

The optimization is most effective in the following order:

- Component design modifications in order to reduce the Occurrence (O) of the Failure Cause (FC)
- Component design modifications in order to reduce the occurrence of the Failure Cause (FC).
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).

In the case of design modifications, all impacted design elements are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different design concept.

4.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

- 为改进产品要求和预防/探测控制提供基础

中、高措施优先级可能表明需要技术改进。

可通过引入更可靠的、可降低使用现场失效起因潜在发生的组件，或者引入额外的可提高系统探测能力的监视，实现改进。监视的引入类似于设计变更。失效起因的频率不会改变。同样可通过引入冗余的方式来消除失效影响。

如果团队决定不需要采取进一步措施，则在"备注"一列填入"无需进一步措施"，以表明已经完成风险分析。

优化的最有效顺序如下：

- 修改组件的设计，以减少失效起因（FC）的频度（O）
- 修改组件的设计，以减少失效起因（FC）的发生
- 提高探测（D）失效起因（FC）或失效模式（FM）的能力

在发生设计修改的情况下，所有受影响的设计要素都要重新评估。

在概念变更的情况下，FMEA 的所有步骤都要针对受影响的部分进行评审。这是必要的，因为初始分析是基于不同的设计概念，已不再有效。

4.6.2 责任分配

每个措施都应该有负责人和与之相关的目标完成日期。

负责人应确保措施的状态保持更新。如果措施被确认，那么该负责人也要对措施的实施情况负责。

应记录措施的实际完成日期，包括措施实施的日期。

目标完成日期应切合实际（例如，按照产品开发计划、在过程确认之前、在生产开始之前）。

4.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No Action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions. Closure of all actions should be documented before the FMEA is released at Start of Production (SOP).

Describe the actual preventive and detection actions regarding design change, test procedure, test plan, process change, control plan, or other documents.

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product design.

4.6.4 Assessment of Action Effectiveness

When an action has been completed, Frequency, and Monitoring values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

4.6.3 措施状态

措施的状态，建议分为以下几类：

尚未确定

没有确定的措施。

尚未决策（可选）

措施已经确定，但还没有决定。正在创建决策文件。

尚未执行（可选）

已对措施作出决定，但尚未执行。

已完成

已完成状态是指措施已经被执行，其有效性已经被证明和记录，并已经进行了最终评估。

不执行

当决定不执行某项措施时，就会分配"不执行"的状态。如果实践和技术限制超出当前能力，就会发生这种情况。

只有当 FMEA 团队评估了每个项目的措施优先级，并接受风险水平或记录所有措施关闭时，FMEA 工作才算完成。在生产开始（SOP）时发布 FMEA 之前，应记录所有措施的完成情况。

说明有关设计变更、测试程序、测试计划、过程变更、控制计划或其他文档的实际预防和探测措施。

如果"不采取措施"，那么"措施优先级"就不会降低，失效风险就会继续进入产品设计。

4.6.4 措施有效性评估

当措施完成时，频率和监视值将重新评估，一个新的措施优先级可能要被确定。

新的措施将获得初步措施优先级评估，作为对有效性的预测。

然而，该措施将一直保持"尚未执行"的状态，直到其有效性得到测试为止。测试完成后，初步评估必须得到确认或在必要时调整。然后，措施的状态从"尚未执行"改为"已完成"。

The reassessment should be based on the effectiveness of the MSR Preventive and Diagnostic Monitoring Actions taken and the new values are based on the definitions in the FMEA-MSR Frequency and Monitoring rating tables.

4.6.5 Continuous Improvement

FMEA-MSR serves as an historical record for the design. Therefore, the original Severity, Frequency, and Monitoring (S, F, M) numbers are not modified once actions have been taken.

The completed analysis becomes a repository to capture the progression of design decisions and design refinements.

However, original S, F, M ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

SUPPLEMENTAL FMEA-MSR OPTIMIZATION (STEP 6)													
MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	MSR AP	Remarks
None	Introduction of plausibility check between motor current and loss of signal from Hall effect sensor.	Comfort closing mode disabled	Loss of convenience function "Comfort closing". The window only moves in manual mode.	6	Test engineer Mr. Warren Watchful	dd.mm.yy yy	implem entation pending			2	1	L	

Figure 4.6-1 Example of FMEA-MSR Optimization with new Risk Evaluation Form

重新评估应基于采取的 MSR 预防和诊断监视措施的有效性，并且新值应基于 FMEA-MSR 频率和监视评级表中的定义。

4.6.5 持续改进

FMEA-MSR 是设计的历史记录。因此，一旦采取措施，初始严重度、频率和监视（S、F、M）的评分将不会被修改。

分析完成后将形成一个存储库，能够记录设计决策和设计改进的进展。

然而，对于基础、系列或一般 DFMEA，初始的严重度、频率和监视（S、F、M）评级可能被修改，因为这些信息在特定应用中被用作应用分析的起点。

补充 FMEA-MSR 优化（步骤六）													
MSR 预防措施	诊断监视措施	系统响应	系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度（S）	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	频率（F）	监视（M）	MSR AP	备注
无	在电机电流和霍尔效应传感器丢失信号之间采用真实性核查	禁用舒适关闭模式	失去便捷的"舒适关闭"功能。车窗仅在手动模式下升降	6	测试工程师 Warren Watchful 先生	_年_月_日	尚未执行			2	1	L	

图 4.6-1 进行最新风险评估的 FMEA-MSR 优化表格示例

4.7 FMEA-MSR 7th Step: Results Documentation

4.7.1 Purpose



The purpose of the results documentation step is to summarize and communicate the results of the Failure Mode and Effects Analysis activity.

The main objectives of FMEA - MSR Results Documentation are:

- Communication of results and conclusions of the analysis
- Establishment of the content of the documentation
- Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Communication of actions taken to reduce risks, including within the organization, and with customers and/or suppliers as appropriate
- Record of risk analysis and reduction to acceptable levels

4.7.2 FMEA Report

The scope and results of an FMEA should be summarized in a report. The report can be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the FMEA-MSR details when requested by management, customers, or suppliers. It is meant to be a summary for the FMEA-MSR team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfill the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan
   a. FMEA Intent – Purpose of this FMEA?
   b. FMEA Timing – FMEA due date?
   c. FMEA Team – List of participants?
   d. FMEA Task - Scope of this FMEA?
   e. FMEA Tool – How do we conduct the analysis Method used?

4.7 FMEA-MSR 步骤七：结果文件化

4.7.1 目的



“结果文件化”步骤的目的是，针对 FMEA 活动的结果进行总结和交流。

“将 FMEA-MSR 结果形成文件”的主要目标是：

- 对结果和分析结论进行沟通
- 建立文件内容
- 记录采取的措施，包括对实施的措施的效果进行确认、采取措施后进行风险评估
- 在组织内部，以及与客户和/或供应商之间（如需）针对降低风险的措施进行沟通
- 记录风险分析和风险降低到的可接受水平

4.7.2 FMEA 报告

FMEA 的范围和结果应在报告中进行总结。该报告可用作公司内部或公司之间的沟通使用。当管理层、顾客或供应商要求时，该报告不应取代对 FMEA-MSR 细节的审查。它是 FMEA-MSR 团队和其他人员的总结，以确认每个任务都已完成、并评审分析结果。

文件的内容应满足组织、预期读者和利益相关方的要求，这一点很重要。具体细节可由各方商定。这样，还可以确保分析的所有细节和知识产权都由编制 FMEA 的公司保留。

文件的格式可根据具体公司而定。但是，报告应指出失效的技术风险，并将其视为为开发计划和项目里程碑的一部分。报告可包括以下内容：

A. 相较于第 1.5 节“项目计划”中的初始目标，说明一下最终状态。

a. FMEA 目的——FMEA 的目的是什么？
b. FMEA 时间安排——FMEA 的截止日期？
c. FMEA 团队——参与人员清单？
d. FMEA 任务——FMEA 的范围？
e. FMEA 工具——如何使用所采取的分析方法？

B. A summary of the scope of the analysis and identify what is new.
C. A summary of how the functions were developed.
D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/F/M rating tables and method of action prioritization (e.g. Action Priority table).
E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.
F. A plan and commitment of timing for ongoing FMEA improvement actions.
    a. Commitment and timing to close open actions.
    b. Commitment to review and revise the FMEA-MSR during mass production to ensure the accuracy and completeness of the analysis as compared with the original production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)
    c. Commitment to capture "things gone wrong" in foundation FMEA-MSRs for the benefit of future analysis reuse, when applicable. (Refer to section 1.3.6 Foundation and Family FMEAs)

B. 总结分析范围并确定新内容。

C. 对功能是如何开发的进行总结。

D. 至少对团队确定的高风险失效进行总结，并提供一份具体的 S/F/M 评级表和措施优先排序方法（如措施优先级表）

E. 对采取的和/或计划中的措施进行总结（包括这些措施的状态），以解决高风险的失效。

F. 为进行中的 FMEA 改进措施制定计划和时间安排，并承诺完成。

   a. 对尚未确定的措施进行关闭做出承诺和时间安排

   b. 承诺在批量生产期间对 FMEA-MSR 进行评审和修订，以确保相对于最初的生产设计来说，分析是准确和完整的（例如，根据公司程序，由设计变更、纠正措施等引起的修订）。（参考第 1.4 节案例 3 FMEA 修订）

   c. 承诺在"基础 FMEA-MSR"中找到"出差错的地方"，以便在将来适用时可以再次用于分析。（参见第 1.3.6 节基础和家族 FMEA。）

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A Sample FMEA Form Sheets

A1 DFMEA Form Sheets

- Form A: Standard DFMEA Form Sheet
  - AIAG & VDA Form Sheet Supporting 7 Step Approach

- Form B: Alternate DFMEA Form Sheet
  - With "Next Higher Level" and "Next Higher Level and Function and Requirement" in a single row and not prepared in all rows.

- View A: DFMEA Software View.

A FMEA 表格示例

A1 DFMEA 表格

- 表格 A: 标准 DFMEA 表格
  - AIAG & VDA 七步法辅助表格

- 表格 B: 其它 DFMEA 表格
  - “上一较高级别”和“上一较高级别以及功能和要求”在同一行中，不在所有行中

- 视图 A: DFMEA 软件视图

Design Failure Mode and Effects Analysis (DESIGN FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____
Engineering Location: _____
Customer Name: _____
Model Year / Platform: _____

Subject: _____
DFMEA Start Date: _____
DFMEA Revision Date: _____
Cross-Functional Team: _____

DFMEA ID Number: _____
Design Responsibility: _____
Confidentiality Level: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
Issue #	History / Change Authorization (As Applicable)	1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type	1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

DFMEA RISK ANALYSIS (STEP 5)						DFMEA OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Filter Code (Optional)	Remarks

Form A: Standard DFMEA Form Sheet

规划和准备 (步骤一)

公司名称:
工程地点:
顾客名称:
车型 / 平台:

项目:
DFMEA 开始日期:
DFMEA 修订日期:
跨职能团队:

DFMEA ID编号:
设计职责:
保密级别:

项目编号	持续改善	结构分析 (步骤二)			功能分析 (步骤三)			失效分析 (步骤四)			
	历史 / 变更授权 (适用时)	1. 上一较高级别	2. 关注要素	3.下一较低级别或特性类型	1.上一较高级别功能及要求	2.关注要素功能及要求	3.下一较低级别功能及要求或特性	1.对于上一较高级别要素和/或最终用户的失效影响 (FE)	失效影响的严重度 (S)	2. 关注要素的失效模式 (FM)	3.下一较低级别要素或特性的失效起因 (FC)

DFMEA 风险分析 (步骤五)						DFMEA 优化 (步骤六)											
当前的对失效起因的预防措施 (PC)	失效起因/失效模式的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	筛选器代码(可选)	DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度 (S)	频度 (O)	探测度 (D)	DFMEA 措施优先级	筛选器代码(可选)	备注

表格 A: 标准 DFMEA 表格

Design Failure Mode and Effects Analysis (DESIGN FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____
Engineering Location: _____
Customer Name: _____
Model Year / Platform: _____

Subject: _____
DFMEA Start Date: _____
DFMEA Revision Date: _____
Cross-Functional Team: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)		FAILURE ANALYSIS (STEP 4)			
		1. Next Higher Level		1. Next Higher Level Function and Requirement					
Issue #	History / Change Authorization (As Applicable) (This column is optional)	2. Focus Element	3. Next Lower Level or Characteristic Type	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

DFMEA ID Number: _____
Design Responsibility: _____
Confidentiality Level: _____

RISK ANALYSIS (STEP 5)						OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Special Characteristics	Remarks

Form B: Alternate DFMEA Form Sheet

设计失效模式及影响分析 (设计 FMEA)

规划和准备 (步骤一)

公司名称:
工程地点:
顾客名称:
车型 / 平台:

项目:
DFMEA 开始日期:
DFMEA 修订日期:
跨职能团队:

	持续改善	结构分析 (步骤二)		功能分析 (步骤三)		失效分析 (步骤四)			
		1. 上一较高级别		1.上一较高级别功能及要求					
问题 #	历史 / 变更授权 (适用时)	2. 关注要素	3.下一较低级别或特性类型	2.关注要素功能及要求	3.下一较低级别功能及要求或特性	1.对于上一较高级别要素和/或最终用户的失效影响 (FE)	失效影响的严重度 (S)	2. 关注要素的失效模式 (FM)	3.下一较低级别要素或特性的失效起因 (FC)

DFMEA ID编号:
设计责任:
保密级别:

DFMEA 风险分析 (步骤五)						DFMEA 优化 (步骤六)												
当前的对失效起因的预防措施(PC)	失效起因/失效模式的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	筛选器代码(可选)	预防措施	探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度 (S)	频度 (O)	探测度 (D)	DFMEA 措施优先级	特殊特性	备注

表格 B: 备选 DFMEA 表格

VIEW A: DFMEA Software View

Design Failure Mode and Effects Analysis (Design FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name:	Subject:	Page of
Engineering Location:	DFMEA Start Date:	DFMEA ID Number:
Customer Name:	DFMEA Revision Date:	Design Responsibility:
Model Year / Platform:	Cross-Functional Team:	Confidentiality Level:

STRUCTURE ANALYSIS (STEP 2)

1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type

FUNCTION ANALYSIS (STEP 3)

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

FAILURE ANALYSIS (STEP 4)

DFMEA RISK ANALYSIS (STEP 5) and DFMEA OPTIMIZATION (STEP 6)

Issue #	History / Change Authorization (As Applicable)	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of DC/PM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
						DFMEA CURRENT CONTROLS											
						DFMEA OPTIMIZATION											

设计失效模式及影响分析 (设计 FMEA)

规划和准备 (步骤一)		
公司名称:	项目:	页 of
工厂地点:	DFMEA 开始时间:	DFMEA ID 编号:
顾客名称:	DFMEA 修改日期:	设计负责人
车型 / 平台:	跨职能团队:	保密级别:

结构分析 (步骤二)

1. 上一较高级别	2. 关注要素	3.下一较低级别或特性类型

功能分析 (步骤三)

1. 上一较高级别功能及要求	2.关注要素功能及要求	3.下一较低级别功能及要求或特性

失效分析 (步骤四)

DFMEA 风险分析 (步骤五) 和DFMEA 优化 (步骤六)

# 项目	历史 / 变更授权 (适用时)	1.对于上一较高级别要素和/或最终用户的失效影响 (FE)	失效影响的严重度 (S)	2. 关注要素的失效模式 (FM)	3.下一较低级别要素或特性的失效起因 (FC)	当前的预防失效起因的预控措施 (PC)	失效起因的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的排查度 (D)	DFMEA 措施优先级	降低排代码 (可选)	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	备注
						DFMEA 当前的控制措施											
						DFMEA 优化											

A2 PFMEA Form Sheets

- Form C: Standard PFMEA Form Sheet
  - AIAG & VDA Form Sheet Supporting 7 Step Approach

- Form D: Alternate PFMEA Form Sheet
  - With "Process Item" and "Function of the Process Item" in a single row and not prepared in all rows

- Form E: Alternate PFMEA Form Sheet
  - With "Function of the Process Step and Product Characteristics" and "Function of Process Work Element and Process Characteristics" split into multiple columns in order to make each column a unique category of information

- Form F: Alternate PFMEA Form Sheet
  - Adjustments from Form D and Form E combined.

- Form G: Alternate PFMEA Form Sheet
  - With modifications to the Structure Analysis and Failure Analysis sections.

- View B: PFMEA Software View

A2 PFMEA 表格

- 表格 C：标准 PFMEA 表格
  - AIAG & VDA 七步法辅助表格
- 表格 D：备选 PFMEA 表格
  - "过程项目"和"过程项目功能"在同一行中，而不是在所有行中
- 表格 E：备选 PFMEA 表格
  - "过程步骤的功能和产品特性"和"过程工作要素的功能和过程特性"被拆分为多个列，以使每个列成为唯一的信息类别
- 表格 F：备选 PFMEA 表格
  - 表格 D 和表格 E 的调整组合
- 表格 G：备选 PFMEA 表格
  - 对"结构分析"和"失效分析"章节进行了修改
- 视图 B: PFMEA 软件视图

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____
Plant Location: _____
Customer Name: _____
Model Year / Platform: _____

Subject: _____
PFMEA Start Date: _____
PFMEA Revision Date: _____
Cross-Functional Team: _____

PFMEA ID Number: _____
Process Responsibility: _____
Confidentiality Level: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
Issue #	History / Change Authorization (As Applicable) (This column is optional)	1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

RISK ANALYSIS (STEP 5)							OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Special Characteristics	Remarks

Form C: Standard PFMEA Form Sheet

过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)			
公司名称:		项目:	PFMEA ID编号:
工程负责:		PFMEA 开始日期:	设计责任:
责任名称:		PFMEA 修订日期:	保密级别:
车型 / 平台:		跨职能团队:	

	持续改善	结构分析 (步骤二)			功能分析 (步骤三)			失效分析 (步骤四)			
问题 #	历史 / 变更授权 (适用时)) (这一类是可选项!)	1. 过程项 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素4M	1.过程名称的功能 系统、子系统、零件要素或过程的功能	2.过程步骤的功能和产品特性 (最值为可选项)	3.过程工作要素的功能和过程特性	1.对于上一较高级别要素和/或终端用户的失效影响 (FE)	失效影响的严重度 (S)	2.关注要素的失效模式 (FM)	3.工作要素的失效起因 (FC)

PFMEA 风险分析 (步骤五)							PFMEA 优化 (步骤六)											
当前的对失效起因的预防措施(PC)	失效起因/失效模式的频度	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度	DFMEA 措施优先级	特殊特性	筛选器代码(可选)	预防措施	探测措施	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成时间	严重度 (S)	频度 (O)	探测度 (D)	PFMEA AP	特殊特性	备注

表格 C: 标准 PFMEA 表格

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____
Plant Location: _____
Customer Name: _____
Model Year / Platform: _____

Subject: _____
PFMEA Start Date: _____
PFMEA Revision Date: _____
Cross-Functional Team: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)		FAILURE ANALYSIS (STEP 4)			
		1. Process Item System, Subsystem, Part Element or Name of Process		1. Function of the Process Item Function of System, Subsystem, Part Element or Process	Your Plant: Ship to Plant: End User:				
Issue #	History / Change Authorization (As Applicable) (This column is optional)	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

PFMEA ID Number: _____
Process Responsibility: _____
Confidentiality Level: _____

RISK ANALYSIS (STEP 5)							OPTIMIZATION (STEP 6)										
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Special Characteristics	Remarks

Form D: Alternate PFMEA Form Sheet

过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)

公司名称:
工程地点:
顾客名称:
车型 / 平台:

项目:
PFMEA 开始日期:
PFMEA 修订日期:
跨职能团队:

	持续改善	结构分析 (步骤二)		功能分析 (步骤三)		失效分析 (步骤四)			
		1. 过程名称 系统、子系统、零件要素或过程名称		1.过程名称的功能 系统、子系统、零件要素或过程的功能	我的工厂: 交付工厂: 其他顾客:				
问题 #	历史 / 变更授权 (适用时)) (这一类是可选项!)	2. 过程步骤 工位编号和关注要素名称	3. 过程工作 要素4M	2.过程步骤的功能和产品特性 (量值为可选项)	3.过程工作要素的功能和过程特性	1.对于上一较高级别要素和/或终端用户的失效影响 (FE)	失效影响的严重度 (S)	2.关注要素的失效模式 (FM)	3.工作要素的失效起因 (FC)

PFMEA ID编号:
设计职责:
保密级别:

PFMEA 风险分析 (步骤五)							PFMEA 优化 (步骤六)											
当前的对失效起因的预防措施 (PC)	失效起因/失效模式的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	特殊特性	筛选器代码(可选)	预防措施	探测措施	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成时间	严重度 (S)	频度 (O)	探测度 (D)	PFMEA 措施优先级	特殊特性	备注

表格 D:备选 PFMEA 表格

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____ Subject: _____ FPMEA ID Number: _____
Plant Location: _____ FPMEA Start Date: _____ Process Responsibility: _____
Customer Name: _____ FPMEA Revision Date: _____ Confidentiality Level: _____
Model Year / Platform: _____ Cross-Functional Team: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)					FAILURE ANALYSIS (STEP 4)			
Issue #	History / Change Authorization (As Applicable) (This column is optional)	1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2.a Function of the Process Step	2.b Product Characteristic as applicable (Quantitative value is optional)	3.a Function of the Process Work Element "What is being done"	3.b Process Characteristic as applicable (Quantitative value is optional)	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

RISK ANALYSIS (STEP 5)							OPTIMIZATION (STEP 6)										
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FM	Current Detection Controls (DC) of FC	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Special Characteristics	Remarks

Form E: Alternate PFMEA Form Sheet

过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)

结构分析 (步骤二)				功能分析 (步骤三)					失效分析 (步骤四)			
历史 / 变更原因 (适用时) (这一步是可选项)	1. 过程名称 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素4M	1.过程名称的功能 系统、子系统、零件要素或过程的功能	2.a 过程步骤的功能	2.b产品特性（适用时） （重复为可选项）	3.a 过程工作要素的功能 "在做什么"	3.b 过程特性（适用时） （重复为可选项）	1. 失效影响 (FE)	失效影响的严重度 (S)	2.关注要素的失效模式 (FM)	3.工作要素的失效起因 (FC)

PFMEA 风险分析 (步骤五)								PFMEA 优化 (步骤六)											
当前的对对失效起因的预防措施 (PC)	失效起因/失效模式的频度 (O)	当前的针对失效模式的探测措施	当前的对对失效起因的探测措施	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	特殊特性	筛选器代码(可选)	预防措施	探测措施	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成时间	严重度 (S)	频度 (O)	探测度 (D)	PFMEA AP	特殊特性	备注

表格 E: 备选 PFMEA 表格

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____ Subject: _____ FMEA ID Number:
Plant Location: _____ FMEA Start Date: _____ Process Responsibility:
Customer Name: _____ FMEA Revision Date: _____ Confidentiality Level:
Model Year / Platform: _____ Cross-Functional Team: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)				FAILURE ANALYSIS (STEP 4)			
		1. Process Item System, Subsystem, Part Element or Name of Process		1. Function of the Process Item Function of System, Subsystem, Part Element or Process							
Issue #	History / Change Authorization (As Applicable) (This column is optional)	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	2.a Function of the Process Step	2.b Product Characteristic as applicable (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic as applicable (Quantitative value is optional)	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

RISK ANALYSIS (STEP 5)								OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FM	Current Detection Controls (DC) of FC	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Special Characteristics	Remarks

Form F: Alternate PFMEA Form Sheet

过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)

公司名称:		项目:		PFMEA ID编号:	
工程地点:		PFMEA 开始日期:		设计职责:	
顾客名称:		PFMEA 修订日期:		保密级别:	
车型 / 平台:		跨职能团队:			

	持续改善	结构分析 (步骤二)		功能分析 (步骤三)				失效分析 (步骤四)			
		1. 过程名称 系统、子系统、零件要素或过程名称		1.过程名称的功能 系统、子系统、零件要素或过程的功能	供给工厂: 接收工厂: 最终顾客:						
问题 #	历史 / 变更授权 (适用时)) (这一类是可选项)	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素4M	2.a 过程步骤的功能	2.b产品特性 (适用时) (量值为可选项)	3.a 过程工作要素的功能 "在做什么"	3.b 过程特性 (适用时) (量值为可选项)	1. 失效影响 (FE)	失效影响的严重度 (S)	2.关注要素的失效模式 (FM)	3.工作要素的失效起因 (FC)

PFMEA 风险分析 (步骤五)								PFMEA 优化 (步骤六)											
现有的对失效起因的预防措施 (PC)	失效起因/失效模式的频度 (O)	现有的针对失效模式的探测措施	现有的针对失效起因的探测措施	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	特殊特性	建议的代码 (可选)	预防措施	探测措施	负责人姓名	目标完成时间	状态	采取基于过程的措施	完成时间	严重度 (S)	频度 (O)	探测度 (D)	PFMEA AP	特殊特性	备注

表格 F: 备选 PFMEA 表格

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____ Subject: _____ PFMEA ID Number: _____
Plant Location: _____ PFMEA Start Date: _____ Process Responsibility: _____
Customer Name: _____ PFMEA Revision Date: _____ Confidentiality Level: _____
Model Year / Platform: _____ Cross-Functional Team: _____

	CONTINUOUS IMPROVEMEN	STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
		2. Process Step Station No. and Name of Focus Element	Process Description (Verb / Noun) (Function or Outcome of the Process Step)	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Process Work Element 4M Type	3. Function of the Process Work Element and Process Characteristic	2. Failure Mode (FM) of the Process Step	1. Failure Effects (FE)	Severity (S)	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC

RISK ANALYSIS (STEP 5)							OPTIMIZATION (STEP 6)											
Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	SxO (Reference)	SxD (Reference)	OxD (Reference)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Remarks

Form G: Alternate PFMEA Form Sheet

过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)

公司名称:
工程地点:
服务名称:
年型 / 平台:

项目:
PFMEA 开始日期:
PFMEA 修订日期:
跨职能团队:

PFMEA ID编号:
设计职责:
保密级别:

	持续改善	结构分析 (步骤二)			功能分析 (步骤三)			失效分析 (步骤四)			
问题 #	历史 / 变更授权 (适用时) (这一类是可选项!)	2. 过程步骤 工位编号和关注要素名称	过程描述 (动词 / 名词) (过程步骤的功能或输出)	2.过程步骤的功能和产品特性 (量值为可选项)	3. 过程工作要素4M	3. 过程工作要素和过程特性的功能	2. 过程步骤的失效模式 (FM)	1. 失效影响 (FE)	严重度(S)	3. 工作要素的失效起因(FC)	当前的失效起因的控制措施(PC)

PFMEA 风险分析 (步骤五)							PFMEA 优化 (步骤六)										
频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的	DFMEA 措施优先级	SxO (参考)	SxD (参考)	OxD (参考)	预防措施	探测措施	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成时间	严重度 (S)	频度 (O)	探测度 (D)	PFMEA 措施优先级	备注

表格 G: 备选 PFMEA 表格

VIEW B: PFMEA Software View

Process Failure Mode and Effects Analysis (Process FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name:	Subject:	Page of
Plant Location:	PFMEA Start Date:	PFMEA ID Number:
Customer Name:	PFMEA Revision Date:	Process Responsibility:
Model Year / Platform:	Cross-Functional Team:	Confidentiality Level:

STRUCTURE ANALYSIS (STEP 2)

1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

FUNCTION ANALYSIS (STEP 3)

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

FAILURE ANALYSIS (STEP 4) and **RISK ANALYSIS CURRENT CONTROLS (STEP 5) and OPTIMIZATION (STEP 6)**

Issue #	History / Change Authorization (As Applicable)	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remark
						PFMEA CURRENT CONTROLS											
						PFMEA OPTIMIZATION											



过程失效模式及影响分析 (过程 FMEA)

规划和准备 (步骤一)

公司名称:	项目:	页 of
工厂地点:	PFMEA 开始时间:	PFMEA ID 编号:
编号名称:	PFMEA 修改日期:	过程负责人:
年度 / 平台:	跨职能团队:	保密级别:

结构分析 (步骤二)

1. 过程名称 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作 要素4M

功能分析 (步骤三)

1. 过程名称 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作 要素4M

失效分析 (步骤四)

PFMEA 风险分析 (步骤五) 和PFMEA 优化 (步骤六)

# 项目	历史 / 变更授权 (适用时)) (这一类是可选项!)	1. 失效影响 (FE)	严重度(S)	2. 过程步骤的失效模式 (FM)	3. 工作要素的失效起因(FC)	失效起因的预防措施 (PC)	失效起因的频度 (O)	失效起因/失效模式的探测措施(DC)	失效起因/失效模式的探测度 (D)	PFMEA 措施优先级	特殊特性	所选择代码(可选)	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成时间	备注
						PFMEA 当前的控制措施												
						PFMEA 优化												

A3 FMEA – MSR Form Sheets

- Form H Standard FMEA-MSR Form Sheet
  - AIAG & VDA Form Sheet Supporting 7 Step Approach
- View C: FMEA – MSR Software View

A3 FMEA – MSR 表格

- 表格 H 标准 FMEA-MSR 表格
  - AIAG & VDA 七步法辅助表格
- 视图 C: FMEA – MSR 软件视图

Design Failure Mode and Effects Analysis (DESIGN FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name: _____
Engineering Location: _____
Customer Name: _____
Model Year / Platform: _____

Subject: _____
DFMEA Start Date: _____
DFMEA Revision Date: _____
Cross-Functional Team: _____

DFMEA ID Number: _____
Design Responsibility: _____
Confidentiality Level: _____

	CONTINUOUS IMPROVEMENT	STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
Issue #	History / Change Authorization (As Applicable)	1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type	1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

_____
_____
_____

DFMEA RISK ANALYSIS (STEP 5)						DFMEA OPTIMIZATION (STEP 6)									
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrance (O)	Detection (D)	DFMEA AP

with Supplemental FMEA-MSR Analyses

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									SUPPLEMENTAL FMEA-MSR OPTIMIZATION (STEP 6)												
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)	MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Remarks

Form H: Standard FMEA-MSR Form Sheet

规划和准备 (步骤一)

公司名称:
工程地点:
顾客名称:
车型 / 平台:

项目:
DFMEA 开始日期:
DFMEA 修订日期:
跨职能团队:

DFMEA ID编号:
设计职责:
保密级别:

	持续改善	结构分析 (步骤二)			功能分析 (步骤三)			失效分析 (步骤四)			
Issue #	History / Change Authorization (As Applicable)	1. 上一较高级别	2. 关注要素	3.下一较低级别或特性类型	1.上一较高级别功能及要求	2.关注要素功能及要求	3.下一较低级别功能及要求或特性	1.对于上一较高级别要素和/或最终用户的失效影响 (FE)	失效影响的严重度 (S)	2. 关注要素的失效模式 (FM)	3.下一较低级别要素或特性的失效起因 (FC)

DFMEA 风险分析 (步骤五)						DFMEA 优化 (步骤六)										
当前的对失效起因的预防措施(PC)	失效起因/失效模式的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	筛选器代码(可选)	DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度 (S)	频度 (O)	探测度 (D)	DFMEA 措施优先级

补充的 FMEA-MSR 分析

补充 FMEA-MSR 风险分析 (步骤五)									补充 FMEA-MSR 优化 (步骤六)											
顾客功能或要求	失效链预防措施 (P)	当前的诊断措施	当前的检测机制	频度 (O)	失效链或失效模式	在 MSR 之前失效链或失效模式严重度	在分析中识别失效链或失效模式严重度 (步骤四)	MSR 措施优先级	筛选器代码 (可选)	MSR 预防措施	诊断测试策略	测试机制	在MSR后的失效模式严重度(S)	在MSR后的失效链或失效模式	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度 (S)	频度 (O)	失效分析的失效链或失效模式的探测度 (D) (步骤五)	MSR 措施优先级	备注

表格 H: 标准 FMEA-MSR 表格

VIEW C: FMEA-MSR Software View

Design Failure Mode and Effects Analysis (Design FMEA)

PLANNING and PREPARATION (STEP 1)

Company Name:	Subject:	Page of
Engineering Location:	DFMEA Start Date:	DFMEA ID Number:
Customer Name:	DFMEA Revision Date:	Design Responsibility:
Model Year / Platform:	Cross-Functional Team:	Confidentiality Level:

STRUCTURE ANALYSIS (STEP 2)

1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type

FUNCTION ANALYSIS (STEP 3)

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

FAILURE ANALYSIS (STEP 4) | **DFMEA RISK ANALYSIS (STEP 5) and DFMEA OPTIMIZATION (STEP 6)**

Issue #	History / Change Authorization (As Applicable)	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
	HINTS - this row can be hidden					DFMEA CURRENT CONTROLS											
						DFMEA OPTIMIZATION											
						SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5) and OPTIMIZATION (STEP 6)												
						Rationale for Frequency	Frequency (F) of FC	Diagnostic Monitoring and System Response	Monitoring (M)	MSR AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
						FMEA-MSR CURRENT CONTROLS											
						FMEA-MSR OPTIMIZATION											

设计失效模式及影响分析 (设计 FMEA)

规划和准备 (步骤一)

公司名称:	项目:	页 of
工厂地点:	DFMEA 开始时间:	DFMEA ID 编号:
顾客名称:	DFMEA 修改日期:	设计负责人
年型 / 平台:	跨职能团队:	保密级别:

结构分析（步骤二）

1. 上一较高级别	2. 关注要素	3.下一较低级别或特性类型

功能分析（步骤三）

1. 上一较高级别功能及要求	2.关注要素功能及要求	3.下一较低级别功能及要求或特性

FAILURE ANALYSIS (STEP 4)

DFMEA 风险分析（步骤五）和DFMEA 优化 (步骤六)

问题 #	历史 / 变更授权 (适用时)	1.对于上一较高级别要素和/或最终用户的失效影响（FE）	失效影响的严重度 (S)	2. 关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）	当前的对失效起因的预防措施 (PC)	失效起因的频度 (O)	当前的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度 (D)	DFMEA 措施优先级	筛选器代码(可选)	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	备注
	提示：这一行可以隐藏					DFMEA 当前的控制措施											
						DFMEA 优化											
						补充 FMEA-MSR 风险分析（步骤五）和补充 FMEA-MSR 优化（步骤六）											
						频率评级的理由	失效起因的频率 (F)	诊断监视和系统响应	监测 (M)	MSR 措施优先级	筛选器代码（可选）	负责人姓名	目标完成时间	状态	采取基于证据的措施	完成日期	备注
						FMEA-MSR 当前的控制措施											
						FMEA-MSR 优化											

B Form Sheets – Step by Step Hints

B1 DFMEA Form Sheet Hints

B1.1 DFMEA Form Sheet Hints: Step 1

Design Failure Mode and Effects Analysis (Design FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for DFMEA	**Subject:**	Name of DFMEA Project (System, Subsystem and/or Component)	**DFMEA ID Number:**	Determined by Company
Engineering Location:	Geographical Location	**DFMEA Start Date:**	Start Date	**Design Responsibility:**	Name of DFMEA owner
Customer Name:	Name of Customer(s) or Product Family	**DFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross-Functional Team:**	Team Roster needed		

Figure B1.1-1 DFMEA Form Sheet with Hints: Step 1

B 表格 — 各步骤有提示。

B1 DFMEA 表格提示

B1.1 DFMEA 表格提示：步骤一

设计失效模式与影响分析（设计FMEA）					
规划与准备（步骤一）					
公司名称：	负责 DFMEA 的公司名称	项目：	DFMEA 项目名称（系统、子系统和/或组件）	**DFMEA ID 编号：**	由公司确定
工程地点：	地理位置	**DFMEA 开始日期：**	开始日期	**设计职责：**	DFMEA 所有人姓名
顾客名称：	顾客名称或产品系列	**DFMEA 修订日期：**	最后修订日期	**保密级别：**	商业应用、专有、保密
年型/项目：	顾客应用或公司模式/类型	**跨职能团队：**	所需的团队成员名单		

图 B1.1-1 带提示的 DFMEA 表格：步骤一

B1.2 DFMEA Form Sheet Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Subsystem, System, Array of Systems, Vehicle	Subsystem, Component or Interface Name	Component or Interface Name or Characteristic Characteristic Type: Geometry, Material, Surface Finish, Coatings, etc.

Figure B1.2-1 DFMEA Form Sheet with Hints: Step 2

B1.3 DFMEA Form Sheet Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Function of Vehicle, System or Subsystem and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Subsystem, Component or Interface and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Component or Interface or Characteristic Description (Quantitative value is optional, one Characteristic per row)

Figure B1.3-1 DFMEA Form Sheet with Hints: Step 3

B1.2 DFMEA 表格提示 步骤二

结构分析（步骤二）		
1.上一较高级别	2.关注要素	3.下一较低级别或特性类型
子系统、系统、系统阵列、车辆	子系统、组件或接口名称	组件或接口名称或特性 特性类型： 形状、材料、表面光洁度、涂层，等

图 B1.2-1 带提示的 DFMEA 表格：步骤二

B1.3 DFMEA 表格提示 步骤三

功能分析（步骤三）		
1.上一较高级别功能及要求	2.关注要素功能及要求	3.下一较低级别功能及要求或特性
车辆、系统或子系统的功能，以及其必须满足的要求或预期输出的描述 （量值为可选项，每行一个要求）	子系统、组件或接口的功能，以及以及其必须满足的要求或预期输出的描述 （量值为可选项，每行一个要求）	组件或接口的功能或特性描述 （量值为可选项，每行一个特性）

图 B1.3-1 带提示的 DFMEA 表格：步骤三

B1.4 DFMEA Form Sheet Hints: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. Include potential effects to the vehicle (End User) level and regulations, as applicable	1-10	How the Subsystem, Component or Interface could fail to perform the Function described as the Focus Element and lead to the Failure Effects Failure Analysis can begin with the FM, FE or FC as long as there is an accurate Failure Chain	How the Subsystem, Component or Interface could fail to perform the Function described as the Next Lower level and lead to the Failure Mode

Figure B1.4-1 DFMEA Form Sheet with Hints: Step 4

B1.5 DFMEA Form Sheet Hints: Step 5

DFMEA RISK ANALYSIS (STEP 5)					
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
Initial State - Past controls proven and/or controls committed to	1-10	Initial State - Past controls proven and/or controls committed to	1-10	H, M, L, NA	LL

Figure B1.5-1 DFMEA Form Sheet with Hints: Step 5

B1.4 DFMEA 表格提示 步骤四

失效分析（步骤4）			
1.对于上一较高级别要素和/或车辆最终用户的失效影响（FE）	失效影响的严重度	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）
车辆、系统或子系统如何未能实现上一较高级别中描述的功能。在适用情况下，包括对车辆（最终用户）级别和法规的潜在影响	1-10	子系统、组件或接口如何未能实现作为关注要素所应具备的功能并导致失效影响 当存在准确的失效链时，可对失效模式、失效影响或失效起因进行失效分析	子系统、组件或接口如何未能实现下一较低级别中描述的功能，并导致失效模式。

图 B1.4-2 带提示的 DFMEA 表格：步骤四

B1.5 DFMEA 表格提示 步骤五

DFMEA风险分析（步骤五）					
对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	DFMEA AP	筛选器代码（可选）
初始状态 - 过去经过验证的控制和/或将要采用的控制	1-10	初始状态 - 过去经过验证的控制和/或将要采用的控制	1-10	H、M、L、NA	LL

图 B1.5-1 带提示的 DFMEA 表格：步骤五

B1.6 DFMEA Form Sheet Hints: Step 6

DFMEA OPTIMIZATION (STEP 6)												
DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Filter Code (Optional)	Remarks
Additional Actions needed to reduce Occurrence	Additional Actions needed to improve Detection	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA	LL	For DFMEA team use

Figure B1.6-1 DFMEA Form Sheet with Hints: Step 6

B1.7 DFMEA Form Sheet: Step 7

DFMEA Step 7 is independently handled by each organization and is not recorded on the DFMEA form sheet.

B1.6 DFMEA 表格提示 步骤六

DFMEA 优化（步骤六）												
DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	DFMEA AP	筛选器代码（可选）	备注
为降低频度所需的附加措施	为改善探测所需的附加措施	姓名，不是职称 或 部门	__年__月或__年__月__日	尚未确定，尚未决策（可选），尚未执行（可选），已完成，不执行	已采取措施的描述以及文档编号、报告名称和日期，等	__年__月或__年__月__日	1-10	1-10	1-10	H, M, L, NA	LL	供 DFMEA 团队使用

图 B1.6-1 带提示的 DFMEA 表格：步骤六

B1.7 DFMEA 表格提示 步骤七

DFMEA 步骤七由各组织单独管理，不在 DFMEA 表格中记录。

B1.8 DFMEA Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter	Commutation System	Brush Card Base Body
FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Convert electrical energy into mechanical energy acc. to Parameterization	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Torque and rotating velocity of the window lifter motor too low	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush

Figure B1.8-1 DFMEA Failure Structure (Software View)

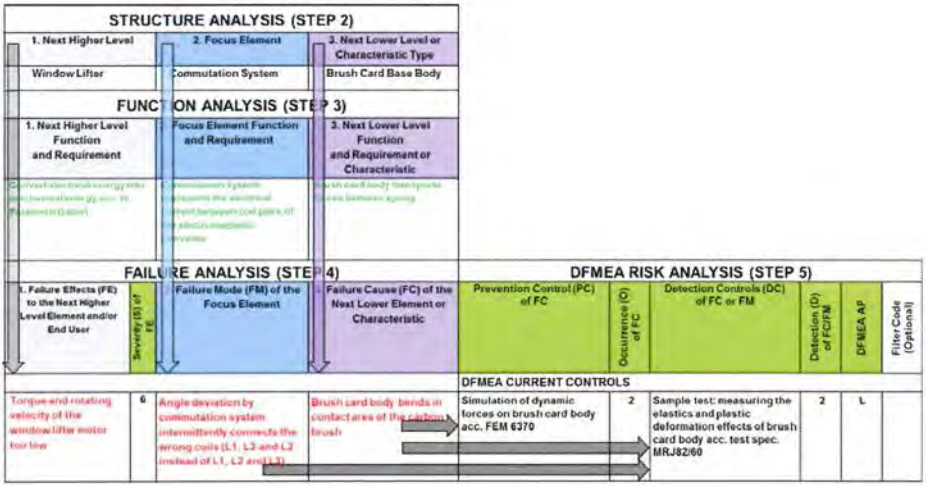


Figure B1.8-2 DFMEA Risk Analysis (Software View)

B1.8 DFMEA 软件示例



图 B1.8-1 DFMEA 失效结构（软件视图）



图 B1.8-2 DFMEA 风险分析（软件视图）

FAILURE ANALYSIS (STEP 4)				DFMEA RISK ANALYSIS (STEP 5) and DFMEA OPTIMIZATION (STEP 6)												
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Prevention Control (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				DFMEA CURRENT CONTROLS											
Window does not lower	6	Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L							
				DFMEA OPTIMIZATION											
				None		final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	1	L		Test Engineer Mr. Max Mueller	dd.mm.yyyy	planned			

Figure B1.8-3 DFMEA Optimization with new Risk Evaluation (Software View)

失效分析（步骤四）				DFMEA 风险分析（步骤五）和 DFMEA 优化（步骤六）												
1.对于上一较高级别要素和/或车辆最终用户的失效影响（FE）	失效影响的严重度	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）	对失效起因的预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的探测控制（DC）	失效起因/失效模式的探测度（D）	DFMEA AP	筛选器代码（可选）	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	备注
				DFMEA 当前控制											
车窗未能降下	6	换向系统间歇性错误连接线圈（L1、L3和L2，而不是L1、L2和L3）	电刷盒的碳刷接触部位弯曲	根据FEM 6370标准进行的电刷盒动态受力模拟	2	抽样测试：依据测试规范MRJ 82/60测量电刷盒的弹性和塑性变形影响	2	L							
				DFMEA优化											
				无		最终产品测试：根据测试规范MRJ1140在最苛刻条件下测量电流	1	L		测试工程师Max Mueller先生	__年__月__日	已计划			

图 B1.8-3 进行最新风险评估的 DFMEA 优化（软件视图）

B2 PFMEA Form Sheet Hints

B2.1 PFMEA Form Sheet Hints: Step 1

Process Failure Mode and Effects Analysis (Process FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for PFMEA	**Subject:**	Name of PFMEA Project	**PFMEA ID Number:**	Determined by Company
Manufacturing Location:	Geographical Location	**PFMEA Start Date:**	Start Date	**Process Responsibility:**	Name of PFMEA Owner
Customer Name:	Name of Customer(s) or Product Family	**PFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross Functional Team:**	Team Roster needed		

Figure B2.1-1 PFMEA Form Sheet with Hints: Step 1

B2.2 PFMEA Form Sheet Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	**2. Process Step Station No. and Name of Focus Element**	**3. Process Work Element 4M Type**
The name of the process being analyzed e.g. electrical motor assembly line which is the end result of all successfully completed process steps May also be a non-direct manufacturing process e.g. shipping	The operation or station to be analyzed that produces the Process Item e.g. OP 30 Sintered bearing press-in process	Use the 4M's to identify types of variation that have an influence on the operation or station being analyzed. 4M Types: Man, Machine, Material (Indirect), Milieu (Environment) List a single "M" for each line. Types may vary by company

Figure B2.2-1 PFMEA Form Sheet with Hints: Step 2

B2 PFMEA 表格提示

B2.1 PFMEA 表格提示 步骤一

过程失效模式与影响分析（过程FMEA ）					
规划与准备（步骤一）					
公司名称：	负责 PFMEA 的公司名称	项目：	PFMEA 项目名称	DFMEA ID 编号：	由公司确定
制造地址：	地理位置	PFMEA 开始日期：	开始日期	过程职责：	PFMEA 所有人姓名
顾客名称：	顾客名称或产品系列	PFMEA 修订日期：	最后修订日期	保密级别：	商业应用、专有、保密
年型/项目：	顾客应用或公司模式/类型	跨职能团队：	所需的团队成员名单		

图 B2.1-1 带提示的 PFMEA 表格：步骤一

B2.2 PFMEA 表格提示 步骤二

结构分析（步骤二）		
1. 过程项 系统、子系统、零件要素或过程名称	**2. 过程步骤 工位编号和关注要素名称**	**2. 过程工作要素 4M类型**
正在分析中的过程的名称，例如电机装配线，其是已成功完成所有过程步骤的最终结果 也可以是间接的制造过程，例如运送	待分析的过程项的操作或工位，例如OP 30烧结轴承的压装过程	使用4M类型找出对正在分析中的操作或工位产生影响的不同管理方法。 4M类型：人员、设备、材料（非直接）、环境 在每行列出一个4M项。 各个公司的管理方法可能不同

图 B2.2-1 带提示的 PFMEA 表格：步骤二

B2.3 PFMEA Form Sheet Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item Function of System, Subsystem, Part Element or Process	**2. Function of the Process Step and Product Characteristic (Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**
A description of what the Process Item is expected to achieve broken down into several categories. Some categories may be unknown and listed as Not Applicable (NA). These expectations can be referred to when completing Failure Effects (FE). These expected results may apply for the entire Process Item e.g. electrical motor assembly line.	A description of what the operation or station must achieve e.g. Axial position sintered bearing in pole housing. This is the positive Product Characteristic and must be detectable/measurable in the product after the product has been produced. The Failure Mode or Failure Modes will be the negative or negatives of the positive Product Characteristic.	A positive description of how the work is completed including the positive process characteristic related to each 4M. The negative of these positives will be used for the Failure Cause column. The more detail used here, more positives, will produce more Failure Causes. Quantitative value/specification optional, refer to process documents. Examples: Press force, machine temperature, wash concentration, speed, etc. Process characteristics are measured when the process is running.

Figure B2.3-1 PFMEA Form Sheet with Hints: Step 3

B2.4 PFMEA Form Sheet Hints: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**Severity (S) of FE**	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Next Lower Element or Characteristic**
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. When considering Effects, consider items listed in "Function of the Process Item" and the "Failure Mode" and how they can Effect the 3 areas being considered (Your Plant, Ship-to plant, Process Item, End User) It is recommended to list the Severity Rating next to each of the 3 areas (Your Plant, Ship to plant, Process Item, End User) being considered and use the highest Rating for the Severity. Rank. One area, such as End User, may not always have the highest Severity Rating	1-10	Failure mode must be detectable/measureable in the product (defect) The Failure Mode will be the negative or negatives of the positive Product Characteristic.	The Failure Cause is the negative of the positive listed in "Function of the Process Work Element and Process Characteristic" Cause must be detectable in the process (error) and lead to the Failure Mode.

Figure B2.4-1 PFMEA Form Sheet with Hints: Step 4

B2.3 PFMEA 表格提示 步骤三

功能分析（步骤三）		
1. 过程项的功能 系统、子系统、零件要素或过程的功能	2.过程步骤的功能和产品特性（量值为可选项）	3.过程工作要素的功能和过程特性
对过程项的预期功能按几个细分类别分开描述 一些类别可能未知并列为不适用（NA） 在填写失效影响（FE）时可以提到这些预期。 这些预期结果可以应用于所有过程名称，例如，电机装配线。	操作或工位必须达到功能的描述，例如烧结轴承在电机壳内的轴向位置。 这些是正面的产品特性，在产品生产出来后必须可以对其进行探测/测量。 与正面产品特性相反的是一种或多种失效模式。	对如何完成工作的正面描述包括与 4M类型每个项目相关的正面的过程特性。 与这些正面描述相反的描述则用于失效起因列内。在此处描述越为详细，正面描述越多，失效起因也将会更多。 量值/规格为可选项，请参看过程文档。例如：压力、机器温度、冲洗液浓度、速度等。在过程进行中可对过程特性进行测量。

图 B2.3-1 带提示的 PFMEA 表格：步骤三

B2.4 PFMEA 表格提示 步骤四

失效分析（步骤四）			
1.对于上一较高级别要素和/或最终用户的失效影响（FE）	失效影响的严重度(S)	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）
车辆、系统或子系统如何未能实现上一较高级别中描述的功能。 在考虑影响的时候，应考虑"过程项的功能"和"失效模式"中列出的项目，以及它们如何影响正在考虑的三个方面……您的工厂、发运至工厂、过程项、最终用户） 建议在三个考虑方面（您的工厂、发运至工厂、过程项、最终用户）旁边列出严重度评级，并使用最高的严重度评级。例如，最终用户的某个方面可能并不总是获得最高的严重度评级。	1-10	失效模式在产品（缺陷）中必须可以进行探测/测量 与正面产品特性相反的是失效模式。	在"过程工作要素的功能和过程特性"中所列正面描述的反面为失效起因 在过程（错误）中必须可以探测到失效起因，并且失效起因会导致失效模式。

图 B2.4-1 带提示的 PFMEA 表格：步骤四

B2.5 PFMEA Form Sheet Hints: Step 5

PFMEA RISK ANALYSIS (STEP 5)						
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Sp Prod Char	Filter Code (Optional)
Initial State - Past controls proven and/or controls committed to	1-10	Initial State - Past controls proven and/or controls committed to	1-10	H, M, L, NA	CC	LL

Figure B2.5-1 PFMEA Form Sheet with Hints: Step 5

B2.6 PFMEA Form Sheet Hints: Step 6

OPTIMIZATION (STEP 6)												
Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	SpProd Cha	PFMEA AP	Remarks
Additonal Actions needed to reduce Occurrence	Additional Actions needed to improve Detection	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc	mmyy or ddmmyy	1-10	1-10	1-10	CC SC	H, M, L, NA	For PFMEA team use

Figure B2.6-1 PFMEA Form Sheet with Hints: Step 6

B2.7 PFMEA Form Sheet Hints: Step 7

PFMEA Step 7 is independently handled by each organization and is not recorded on the PFMEA form sheet.

B2.5 PFMEA 表格提示 步骤五

PFMEA 风险分析（步骤五）						
对失效起因的当前预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的当前探测控制（DC）	失效起因/失效模式的探测度（D）	PFMEAAP	产品特性	筛选器代码（可选）
初始状态 - 过去经过验证的控制和/或将要采用的控制	1-10	初始状态 - 过去经过验证的控制和/或将要采用的控制	1-10	H、M、L、NA	CC	LL

图 B2.5-1 带提示的 PFMEA 表格：步骤五

B2.6 PFMEA 表格提示 步骤六

优化（步骤六）												
预防措施	探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	产品特性	PFMEA 措施优先级	备注
为降低频度所需的附加措施	为改善探测所需的附加措施	姓名，不是职称或部门	_年__月__或__年__月__日	尚未确定，尚未决策（可选），尚未执行（可选），已完成，不执行	已采取措施的描述以及文档编号、报告名称和日期，等	_年__月__或__年__月__日	1-10	1-10	1-10	CC SC	H、M、L、NA	供 PFMEA 团队使用

图 B2.6-1 带提示的 PFMEA 表格：步骤六

B2.7 PFMEA 表格提示 步骤七

PFMEA 步骤七由各组织单独管理，不在 PFMEA 表格中记录。

B2.8 PFMEA Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item **System, Subsystem, Part Element or Name of Process**	**2. Process Step** **Station No. and Name of Focus Element**	**3. Process Work Element** **4M Type**
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item **Function of System, Subsystem, Part Element or Process**	**2. Function of the Process Step and Product Characteristic** **(Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door without any stoppage, skirt or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator press the button of machine for initiating the press-in process when loading is completed
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Work Element**
Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure B2.8-1 PFMEA Failure Structure (Software View)

B2.8 PFMEA 软件示例

结构分析（步骤二）		
1. 过程项 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作 要素4M类型
电机装配线	[OP 30] 烧结轴承压装过程	操作人员
功能分析（步骤三）		
1. 过程项的功能 系统、子系统、零件要素或过程的功能	2. 过程步骤的功能和产品特性（量值为可选项）	3.过程工作要素的功能和过程特性
您的工厂： 将轴安装至电机壳总成内 发运至工厂： 在无需作业线停顿、分拣或隔离情况下将电机安装至车门上 最终用户： 升起和降下车窗	压装烧结轴承，在每次压装时实现电机壳内的轴向定位保留最大间隙	在完成装料后，操作员按下机器按钮以启动压装过程
失效分析（步骤四）		
1.对于上一较高级别要素和/或最终用户的失效影响（FE）	2.关注要素的失效模式（FM）	3.工作要素的失效起因（FC）
您的工厂： 间隙太小无法安装轴 发运至工厂： 无法将电机安装至车门上 最终用户： 舒适模式关闭时间过长	不能实现烧结轴承的轴向定位	设备在达到最终位置前停止

图 B2.8-1 PFMEA 失效结构（软件视图）

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item: Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to ensure does without loss leakage out of containment End User: Window wipers and blades	Press in sintered bearing to achieve axial position of pole housing to max gap per print	Operator pulls the button of machine for starting the press-in process and machine starts working if completed

FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5)							
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)
				PFMEA CURRENT CONTROLS						
Your Plant: Assembly of shaft is not possible because clearance too small Ship to Plant: None End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position	None	10	Lot Release Protocol Objective (Effectivity: 100%): Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator. Detection indicator: OK/NOK (RED/GREEN area). 100% check of motor performance curve acc. spec. MRKJ5038	2	H		

Figure B2.8-2 PFMEA with Risk Analysis (Software View)

结构分析（步骤二）		
1. 过程项系统、子系统、零件要素或过程名称	2. 过程步骤工位编号和关注要素名称	3. 过程工作要素4M类型
电机装配线	[OP 30] 烧结轴承压装过程	操作人员

功能分析（步骤三）		
1. 过程项的功能系统、子系统、零件要素或过程的功能	2.过程步骤的功能和产品特性（量值为可选项）	3.过程工作要素的功能和过程特性
您的工厂： 将轴安装至电机壳总成内 发运至工厂： 在无需作业线停顿、分拣或隔离情况下将电机发送至车门上 最终用户： 升起并降下车窗	压装烧结轴承：在每次压装时实现电机壳内的轴向定位保留最大间隙	在完成装料后，操作员按下机器按钮以启动压装过程

失效分析（步骤四）				FFMEA 风险分析（步骤五）						
1.对于上一较高级别要素和/或最终用户的失效影响（FE）	失效影响的严重度(S)	2.关注要素的失效模式（FM）	3.工作要素的失效起因（FC）	对失效起因的预防控制（PC）	失效起因的频度（O）	对失效起因或失效模式的探测控制（DC）	失效起因/失效模式的探测度（D）	PFMEA AP	特性	筛选器代码（可选）
				PFMEA 当前控制						
您的工厂： 因为间隙过小无法安装轴 发运至工厂： 无 最终用户： 舒适模式关闭时间过长	8	不能实现烧结轴承的轴向定位	设备在达到最终位置前停止	无	10	批签发协议目标（有效性：100%）；操作员使用观测计探测轴承和电机壳之间的轴向间隙；探测指标：好/不好（红色/绿色区域）；根据规范MRKJ5038 对电机性能曲线进行完全探测	2	H		

图 B2.8-2 进行风险分析的 PFMEA（软件视图）

FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5) and PFMEA OPTIMIZATION (STEP 6)												
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				PFMEA CURRENT CONTROLS												
Your Plant: Assembly of shaft is not possible because clearance too small Next to Plant: None End User: Comfort closing time too long	8	Axial position of outboard bearing is not reached	Machine stops before reaching final position	Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5039	3	M								
				PFMEA OPTIMIZATION												
				Selected press with position control sensor	3	Selected press with force monitoring	2	L			Process Engineer Mr. Paul Duncan	dd.mm.yyyy	open			

Figure B2.8-3 PFMEA Optimization with new Risk Evaluation (Software View)

失效分析（步骤四）				PFMEA 风险分析（步骤五）和PFMEA 优化（步骤六）												
1. 对于上一较高级别要素和/或终端用户的失效影响（FE	失效影响的严重度(S)	2. 关注要素的失效模式（FM）	3. 工件要素的失效起因（FC）	现有的对失效起因的预防措施(PC)	失效起因发生度(O)	现有的失效起因/失效模式的探测措施 (DC)	失效起因/失效模式的探测度(D)	DFMEA 风险优先数	特殊特性	建议措施(PA)	负责人姓名	目标完成时间	状态	针对证据所采取的措施	完成时间	备注
				PFMEA 当前控制												
[illegible]	8	[illegible]	[illegible]	按照数据表调整压入力	5	根据规范 MRKJ5039 对电机性能曲线进行 100%检测	3	M								
				PFMEA 优化												
				带记忆检测传感器的选择性压装	3	压压力监测的选择性压装	2	L			过程工程师 Paul Duncan 先生	__年__月__日	尚未确定			

图 B2.8-3 进行最新风险评估的 PFMEA 优化（软件视图）

B3 FMEA-MSR Form Sheet Hints

B3.1 FMEA-MSR Form Sheet Hints: Step 1

Design Failure Mode and Effects Analysis (Design FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for DFMEA	**Subject:**	Name of DFMEA Project (System, Subsystem and/or Component)	**DFMEA ID Number:**	Determined by Company
Engineering Location:	Geographical Location	**DFMEA Start Date:**	Start Date	**Design Responsibility:**	Name of DFMEA owner
Customer Name:	Name of Customer(s) or Product Family	**DFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross-Functional Team:**	Team Roster needed		

Figure B3.1-1 FMEA-MSR Form Sheet with Hints: Step 1

B3.2 FMEA-MSR Form Sheet Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	**2. Focus Element**	**3. Next Lower Level or Characteristic Type**
Subsystem, System, Array of Systems, Vehicle	**Subsystem, Component or Interface Name**	**Component or Interface Name or Characteristic** **Characteristic Type:** **Geometry, Material, Surface Finish, Coatings, etc.**

Figure B3.2-1 FMEA-MSR Form Sheet with Hints: Step 2

B3.3 FMEA-MSR Form Sheet Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	**2. Focus Element Function and Requirement**	**3. Next Lower Level Function and Requirement or Characteristic**
Function of Vehicle, System or Subsystem and a description of the Requirement or Intended Output it must fulfill **(Quantitative value is optional, one Requirement per row)**	**Function of Subsystem, Component or Interface and a description of the Requirement or Intended Output it must fulfill** **(Quantitative value is optional, one Requirement per row)**	**Function of Component or Interface or Characteristic Description** **(Quantitative value is optional, one Characteristic per row)**

Figure B3.3-1 FMEA-MSR Form Sheet with Hints: Step 3

B3 FMEA-MSR 表格提示

B3.1 FMEA-MSR 表格提示 步骤一

设计失效模式与影响分析（设计FMEA ）					
规划与准备（步骤一）					
公司名称：	负责DFMEA的公司名称	项目：	DFMEA项目名称（系统、子系统和/或组件）	DFMEA ID编号：	由公司确定
工程地点：	地理位置	DFMEA开始日期：	开始日期	设计职责：	DFMEA所有人姓名
顾客名称：	顾客名称或产品系列	DFMEA修订日期：	最后修订日期	保密级别：	商业应用、专有、保密
年型/项目：	顾客应用或公司模式/类型	跨职能团队：	所需的团队成员名单		

图 B3.1-1 带提示的 FMEA-MSR 表格：步骤一

B3.2 FMEA-MSR 表格提示 步骤二

结构分析（步骤二）		
1.上一较高级别	**2.关注要素**	**3.下一较低级别或特性类型**
子系统、系统、系统阵列、车辆	子系统、组件或接口名称	组件或接口名称或特性 特性类型： 形状、材料、表面光洁度、涂层等

图 B3.2-1 带提示的 FMEA-MSR 表格：步骤二

B3.3 FMEA-MSR 表格提示 步骤三

功能分析（步骤三）		
1.上一较高级别功能及要求	2.关注要素 功能及要求	3.下一较低级别 功能和要求 或特性
车辆、系统或子系统的功能，以及其必须满足的要求或预期输出的描述 （量值为可选项，每行一个要求）	子系统、组件或接口的功能，以及其必须满足的要求或预期输出的描述 （量值为可选项，每行一个要求）	组件或接口的功能或特性描述 （量值为可选项，每行一个特性）

图 B3.3-1 带提示的 FMEA-MSR 表格：步骤三

B3.4 FMEA-MSR Form Sheet Hints: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. Include potential effects to the vehicle (End User) level and regulations, as applicable	1-10	How the Subsystem, Component or Interface could fail to perform the Function described as the Focus Element and lead to the Failure Effects Failure Analysis can begin with the FM, FE or FC as long as there is an accurate Failure Chain	How the Subsystem, Component or Interface could fail to perform the Function described as the Next Lower level and lead to the Failure Mode

Figure B3.4-1 FMEA-MSR Form Sheet with Hints Sheet: Step 4

B3.5 FMEA-MSR Form Sheet Hints: Step 5

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Most Severe FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)
Internal comments about the reasons for the Frequency rating	1-10	Error detection methods during vehicle use	Error response action during vehicle use	1-10	The new Vehicle, System or Subsystem potential effects to the End User level after monitoring and system response controls are in place	1-10	1-10	H, M, L, NA If M=1 use "Severity after MSR"	LL

Figure B3.5-1 FMEA-MSR Form Sheet with Hints: Step 5

B3.4 FMEA-MSR 表格提示 步骤四

失效分析（步骤四）			
1.对于上一较高级别要素和/或车辆最终用户的失效影响（FE）	失效影响的严重度	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）
车辆、系统或子系统如何未能实现上一较高级别中描述的功能。在适用情况下，包括对车辆（最终用户）级别和法规的潜在影响	1-10	子系统、组件或接口如何未能实现作为关注要素所应具备的功能并导致失效影响 当存在准确的失效链时，可对失效模式、失效影响或失效起因进行失效分析	子系统、组件或接口如何未能实现下一较低级别中描述的功能，并导致失效模式。

图 B3.4-1 带提示的 FMEA-MSR 表格：步骤四

B 3.5 FMEA-MSR 表格提示 步骤五

补充FMEA-MSR风险分析（步骤五）									
频率评级基本原理	失效起因的发生频率（F）	当前的诊断监视	当前的系统响应	监视（M）	在系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度	在失效分析中最严重失效影响的严重度（步骤四）	MSRAP	筛选器代码（可选）
关于频率评级原因的内部评论	1-10	在车辆使用中的故障探测方法	车辆使用过程中的故障响应措施	1-10	监视和系统响应控制就位后，新车辆、系统或子系统对最终用户层面的潜在影响	1-10	1-10	H、M、L、NA 如果 M=1 使用"MSR 后的严重度	L L

图 B3.5-1 带提示的 FMEA-MSR 表格：步骤五

B3.6 FMEA-MSR Form Sheet Hints: Step 6

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 6)														
MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	Severity (S) of Most Severe FE from Failure Analysis (Step 4)	MSR A P	Remarks
Additonal Actions needed to reduce Frequency	Additional error detection methods during vehicle use	Additonal Actions needed to reduce Frequency	The Vehicle, System or Subsystem potential effects to the End User level after monitoring and system response are in place	1-10	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA If M=1 use "Severity after MSR"	For FMEA-MSR team use

Figure B3.6-1 FMEA-MSR Form Sheet with Hints: Step 6

B3.7 FMEA-MSR Form Sheet Hints: Step 7

FMEA-MSR Step 7 is independently handled by each organization and is not recorded on the FMEA-MSR form sheet.

B3.8 FMEA-MSR Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lift System	ECU Window Lifter	Connector ECU Window Lifter
FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.

Figure B3.8-1 FMEA-MSR Failure Structure (Software View)

B3.6 FMEA-MSR 表格提示 步骤六

补充FMEA-MSR 风险分析（步骤六）													
MSR 预防措施	诊断监视措施	系统响应	系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	频率（F）	监视（M）	在失效分析中最严重失效影响的严重性（步骤四）	MS RAP	备注
为减少发生频率所需的附加措施	车辆使用过程中其他的故障探测方法	为减少发生频率所需的附加措施	监视和系统响应就位后车辆、系统或子系统对最终用户层面的潜在影响	1-10	姓名，不是职称或部门	__年__月或__年__月__日	尚未确定、尚未决策（可选）、尚未执行（可选）、已完成、不执行	已采取措施的描述以及文档编号、报告名称和日期，等	__年__月或__年__月__日	1-10	1-10	1-10	H，M，L，NA 如果 M=1 使用"MSR 后的严重度"	供 FMEA-MSR 团队使用

图 B3.6-1 带提示的 FMEA-MSR 表格：步骤六

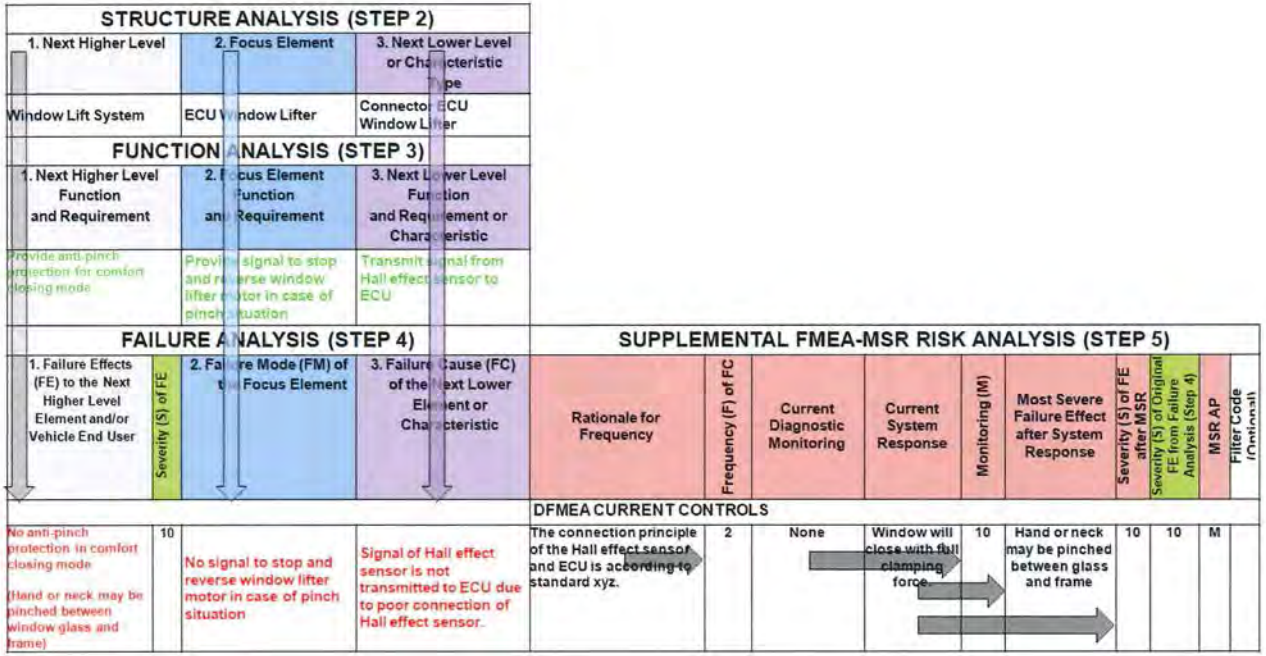
B3.7 FMEA-MSR 表格步骤七

FMEA-MSR 步骤七由各组织单独管理，不在 FMEA-MSR 表格中记录。

B3.8 FMEA-MSR 软件示例

结构分析（步骤二）		
1. 上一较高级别	2. 关注要素	3. 下一较低级别或特性类型
车窗升降系统	车窗升降器的电子控制单元	车窗升降器的ECU连接器
功能分析（步骤三）		
1. 上一较高级别功能及要求	2. 关注要素功能及要求	3. 下一较低级别功能及要求或特性
在舒适关闭模式下提供防夹手保护功能	在车窗夹手情形下，发出车窗升降电机停止和逆向操作的信号	霍尔效应传感器发出的信号传递至ECU
失效分析（步骤四）		
1. 对于上一较高级别要素和/或终端用户的失效影响（FE）	2. 关注要素的失效模式（FM）	3. 下一较低级别要素或特性的失效起因（FC）
在舒适关闭模式下没有防夹手保护功能 （在车窗玻璃和车窗框架之间可能会出现夹手或夹颈现象	在车窗夹手情形下，没有发出车窗升降电机停止和逆向操作的信号	因为霍尔效应传感器接触不良，未能将霍尔效应传感器发出的信号传递至ECU。

图 B3.8-1 FMEA-MSR 失效结构（软件视图）



STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lift System	ECU Window Lifter	Connector ECU Window Lifter

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU

FAILURE ANALYSIS (STEP 4)				SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)
				DFMEA CURRENT CONTROLS									
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	10	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.	The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None	Window will close with full clamping force	10	Hand or neck may be pinched between glass and frame	10	10	M	

Figure B3.8-2 FMEA-MSR Risk Analysis (Software View)

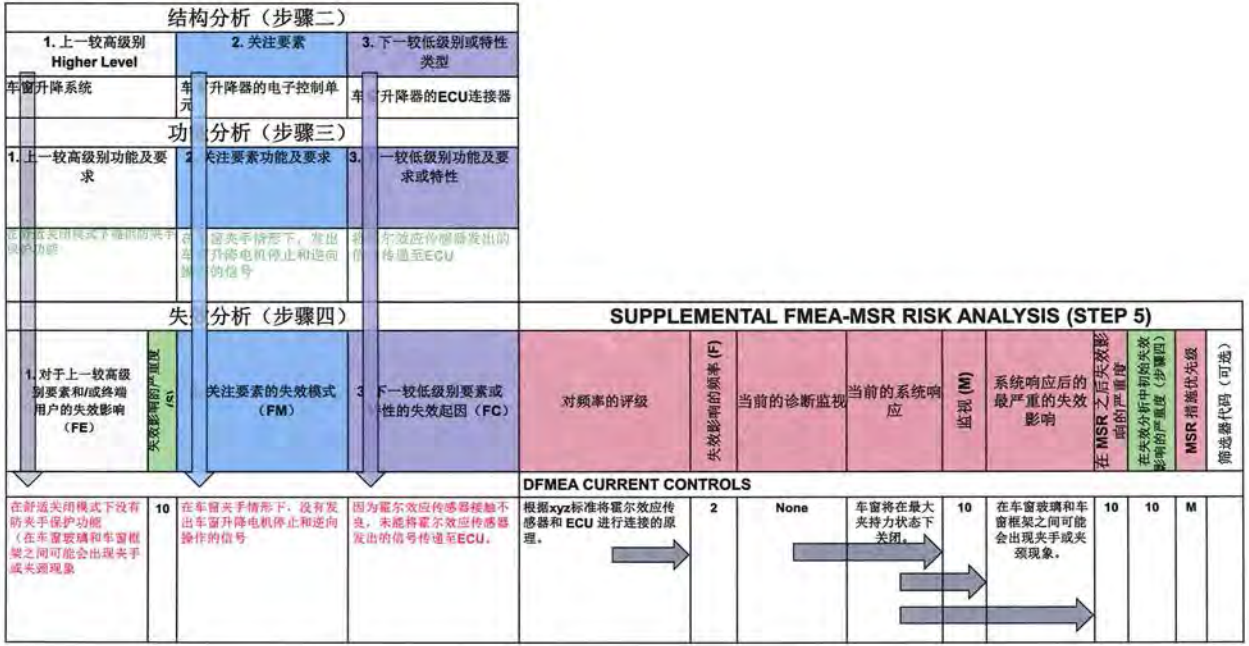


图 B3.8-2 FMEA-MSR 风险分析（软件视图）

Figure B3.8-3 FMEA-MSR Optimization with new Risk Evaluation (Software View)

FAILURE ANALYSIS (STEP 4)				SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5) and OPTIMIZATION (STEP 6)											
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Rationale for Frequency	Frequency (F) of FC	Diagnostic Monitoring and System Response	Monitoring (M)	MSR AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				FMEA-MSR CURRENT CONTROLS											
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	6	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.	The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None Window will close with full clamping force.	10	M							
				FMEA-MSR OPTIMIZATION											
				None	2	Introduction of plausibility check between motor current and loss of signal from Hall effect sensor. Comfort closing mode disabled	1	L		Test engineer Mr. Warren Watchful	dd.mm.yyyy	implementation pending			

图 B 3.8-3 进行最新风险评估的 FMEA-MSR 优化（软件视图）

失效分析（步骤四）				补充 FMEA-MSR 风险分析（步骤五）和优化（步骤六）											
1. 对于上一较高级别要素和/或终端用户的失效影响（FE）	失效影响的严重度 (S)	2. 关注要素的失效模式（FM）	3. 下一较低级别要素或特性的失效起因（FC）	频率评级的理由	失效影响的频率 (F)	诊断监视及系统响应	监视 (M)	MSR 措施优先级	筛选器代码（可选）	负责人姓名	目标完成时间	状态	针对证据采取的措施	完成日期	注
				FMEA-MSR 现有的控制											
在舒适关闭模式下没有防夹手保护功能（在车窗玻璃和车窗框架之间可能会出现夹手或夹器现象	10	在车窗夹手情形下，没有发出车窗升降电机停止和逆向操作的信号	因为霍尔效应传感器接触不良，未能将霍尔效应传感器发出的信号传递至ECU。	霍尔效应传感器和ECU的连接原理符合标准xyz。	2	无 车窗将在最大夹持力状态下关闭。	10	M							
				FMEA-MSR 优化											
				无	2	在电机电流和霍尔效应传感器丢失信号之间采用真实性核查 禁用舒适关闭模式	1	L		测试工程师 Warren Watchful 先生	__年__月__日	尚未执行			

C: Severity, Occurrence, Detection and Action Priority Tables

C1 DFMEA SOD and AP Tables

C1.1 DFMEA SEVERITY (S)

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect.	

Table C1.1 - DFMEA SEVERITY (S)

C: 严重度、频度、探测度及措施优先级表

C1 DFMEA SOD 表和 AP 表

C1.1 DFMEA 严重度(S)

产品一般评估标准严重度(S)			
根据以下标准对潜在失效影响进行评级。			空白，由使用人员填写
S	**影响**	**严重度标准**	**公司或产品系列示例**
10	非常高	影响到车辆和/或其他车辆的操作安全，驾驶员、乘客、交通参与者或行人的健康状况。	
9		不符合法规。	
8	高	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	
6	中	**失去**车辆次要功能	
5		**降低**车辆次要功能	
4		外观、声音、振动、粗糙度或触感令人感觉非常不舒服。	
3	低	外观、声音、振动、粗糙度或触感令人感觉中度的不舒服。	
2		外观、声音、振动、粗糙度或触感令人略微感觉不舒服。	
1	非常低	没有可觉察到的影响。	

表 C1-1 DFMEA 严重度 (S)

C1.2 DFMEA OCCURRENCE (O)

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**Extremely high**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**Very high**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8		**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	
7	**High**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6		**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	

C1.2 DFMEA 频度 (O)

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	**对失效起因发生的预测**	**频度标准 - DFMEA**	**公司或产品系列示例**
10	**极高**	在没有操作经验和/或在运行条件不可控制的情况下的任何地方对新技术的**首次**应用。没有对产品进行验证和/或确认的经验。 不存在标准，且尚未确定最佳实践。预防控制不能预测使用现场绩效或不存在预防控制。	
9	**非常高**	在公司内**首次**应用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 预防控制不是针对确定特定要求的性能。	
8		在新应用内**首次**使用具有技术创新或材料的设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 极少存在现有标准和最佳实践，不能直接用于该设计产品。预防控制不能可靠地反映使用现场绩效。	
7	**高**	根据相似技术和材料的**新型**设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 标准、最佳实践和设计规则符合基础设计要求，但不适用于创新产品。防预防控制提供了有限的性能指标。	
6		应用现有技术和材料，与之前设计**相似**。类似应用，工作周期或运行条件有改变。之前的测试或使用现场经验。 存在标准和设计规则，但不足以确保不会出现失效起因。预防控制提供了预防失效起因的部分能力。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
5	Moderate	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4		**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	Low	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause and predict conformance of production design.	
2	Very low	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	Extremely low	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table C1.2 - DFMEA Occurrence (O)

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
5	中	应用成熟技术和材料，与之前设计相比有**细节**上的变化。类似的应用、工作周期或运行条件。之前的测试或使用现场经验，或为具有与失效相关测试经验的新设计。 在之前设计中所学到的与解决设计问题相关的教训。在本设计中对最佳实践进行再评估，但尚未经过验证。预防控制能够发现与失效起因相关的产品缺陷，并提供部分性能指标。	
4		与短期现场使用暴露几乎相同的设计。类似应用，工作周期或运行条件有细微变化。之前测试或使用现场经验。之前设计和为新设计而进行的改变符合最佳实践、标准和规范要求。 预防控制能够发现与失效起因相关的产品缺陷，很可能地反映设计符合性	
3	低	对已知设计（相同应用，在工作周期或操作条件方面）和测试或类似运行条件下的现场经验的细微变化或成功完成测试程序的新设计。 考虑到之前设计的经验教训，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并预测了与生产设计的一致性。	
2	非常低	与长期现场暴露几乎相同的设计。相同应用，具备类似的工作周期或运行条件。在类似运行条件下的测试或使用现场经验。 考虑到之前设计的经验教训并对其具备充足的信心，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并显示出对设计符合性的信心。	
1	极低	失效通过预防控制消除，通过设计失效起因不可能发生。	

产品经验：在公司内使用产品的历史（新品设计、应用或使用案例）。已经完成的探测控制结果提供了设计经验。

预防控制：在产品设计中使用最佳实践、设计规则、公司标准、经验教训、行业标准、材料规范、政府规定，以及以预防为导向的分析工具的有效性（分析工具包括计算机辅助工程、数学建模、模拟研究、公差叠加和设计安全边际）。

注：频度 10、9、8、7 可根据产品验证活动降低。

表 C1-2 DFMEA 频度 (O)

C1.3 Alternative DFMEA Occurrence (O) Tables

C1.3.1 DFMEA OCCURRENCE (O): Incidents per Thousand Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate			Blank until filled by user
O	**Incidents per 1000 items/vehicles**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**≥ 100 per thousand >/= 1 in 10**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**50 per thousand, 1 in 20**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8	**20 per thousand, 1 in 50**	**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	
7	**10 per thousand 1 in 100**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6	**2 per thousand 1 in 500**	**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	

C1.3 备选DFMEA频度 (O) 表

C1.3.1 DFMEA 频度 (O)，带每千台车故障率

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑产品经验和预防控制。			空白，由使用人员填写
O	每千件产品/车辆的故障率	频度标准 - DFMEA	公司或产品系列示例
10	≥ 千分之一百 >/= 十分之一	在无操作经验和/或在运行条件不可控制的情况下，在任何地方对新技术的首次应用。没有对产品进行验证和/或确认的经验。 不存在标准，并尚未确定最佳实践。预防控制不能预测使用现场绩效或不存在预防控制。	
9	千分之五十， 二十分之一	在公司内首次应用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 预防控制不是针对确定特定要求的性能。	
8	千分之二十， 五十分之一	在新应用内首次使用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 极少存在现有标准和最佳实践，不能直接用于该设计产品。预防控制不能可靠地反映使用现场绩效。	
7	千分之十， 百分之一	根据相似技术和材料的新型设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 标准、最佳实践和设计规则符合基础设计要求，但不适用于创新产品。预防控制提供了有限的性能指标。	
6	千分之二， 五百分之一	应用现有技术和材料，与之前设计相似。类似应用，工作周期或运行条件有改变。之前的测试或使用现场经验。 存在标准和设计规则，但不足以确保不会出现失效起因。预防控制提供了预防失效起因的部分能力。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate			Blank until filled by user
5	**.5 per thousand 1 in 2000**	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4	**.1 per thousand 1 in 10,000**	**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	**.01 per thousand 1 in 100,000**	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.	
2	**≤ .001 per thousand 1 in 1,000,000**	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	**Preventive controls eliminate failure**	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table C1.3.1 - Alternate DFMEA Occurrence (O)

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
5	千分之 0.5，二千分之一	应用成熟技术和材料，与之前设计相比有细节上的变化。类似的应用、工作周期或运行条件。之前的测试或使用现场经验，或为具有与失效相关测试经验的新设计。 在之前设计中所学到的与解决设计问题相关的教训。在本设计中对最佳实践进行再评估，但尚未经过验证。预防控制能够发现与失效起因相关的产品缺陷，并提供部分性能指标。	
4	千分之 0.1，一万分之一	与短期现场使用暴露几乎相同的设计。类似应用，工作周期或运行条件有细微变化。之前的测试或使用现场经验。 之前设计和为新设计而进行的改变符合最佳实践、标准和规范要求。预防控制能够发现与失效起因相关的产品缺陷，很可能地反映设计符合性。	
3	千分之 0.01，十万分之一	对已知设计（相同应用，在工作周期或操作条件方面）和测试或类似运行条件下的现场经验的细微变化或成功完成测试程序的新设计。 考虑到之前设计的经验教训，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并预测了与生产设计的一致性。	
2	≤ 千分之 0.001，一百万分之一	与长期现场暴露几乎相同的设计。相同应用，具备类似的工作周期或运行条件。在类似运行条件下的测试或使用现场经验。 考虑到之前设计的经验教训并对其具备充足的信心，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并显示出对设计符合性的信心。	
1	通过预防控制避免失效	失效通过预防控制消除，通过设计失效起因不可能发生。	

产品经验：在公司内使用产品的历史（新品设计、应用或使用案例）。已经完成的探测控制结果提供了设计经验。

预防控制：在产品设计中使用最佳实践、设计规则、公司标准、经验教训、行业标准、材料规范、政府规定，以及以预防为导向的分析工具的有效性（分析工具包括计算机辅助工程、数学建模、模拟研究、公差叠加和设计安全边际）。

注：频度 10、9、8、7 可根据产品验证活动降低。

表 C1.3.1 - 备选 DFMEA 频度 (O)

C1.3.2 DFMEA Occurrence (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**Every time**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**Almost every time**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8	**More than once per shift**	**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	

C1.3.2 DFMEA 频度 (O)，基于时间的失效预测值

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	**基于时间的失效起因预测**	**频度标准 - DFMEA**	**公司或产品系列示例**
10	**每次**	在无操作经验和/或在运行条件不可控制的情况下，在任何地方对新技术的首次应用。没有对产品进行验证和/或确认的经验。 不存在标准，并尚未确定最佳实践。预防控制不能预测使用现场绩效或不存在预防控制。	
9	**几乎每次**	在公司内首次应用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 预防控制不是针对确定特定要求的性能。	
8	**每班超过一次**	在新应用内首次使用具备创新技术的设计产品或材料。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 极少存在现有标准和最佳实践，不能直接用于该设计产品。预防控制不能可靠地反映使用现场绩效。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
7	**More than once per day**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6	**More than once per week**	**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	
5	**More than once per month**	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4	**More than once per year**	**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	**Once per year**	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.	

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	基于时间的失效起因预测	频度标准 - DFMEA	公司或产品系列示例
7	每日超过一次	根据相似技术和材料的**新型**设计。新应用，或工作周期/运行条件有改变。没有对产品进行验证和/或确认的经验。 标准、最佳实践和设计规则符合基础设计要求，但不适用于创新产品。预防控制提供了有限的性能指标。	
6	每周超过一次	应用现有技术和材料，与之前设计**相似**。类似应用，工作周期或运行条件有改变。之前的测试或使用现场经验。 存在标准和设计规则，但不足以确保不会出现失效起因。预防控制提供了预防失效起因的部分能力。	
5	每月超过一次	应用成熟技术和材料，与之前设计相比有**细节**上的变化。类似的应用、工作周期或运行条件。之前的测试或使用现场经验，或为具有与失效相关测试经验的新设计。 在之前设计中所学到的与解决设计问题相关的教训。在本设计中对最佳实践进行再评估，但尚未经过验证。预防控制能够发现与失效起因相关的产品缺陷，并提供部分性能指标。	
4	每年超过一次	与短期现场使用暴露几乎相同的设计。类似应用，工作周期或运行条件有细微变化。之前的测试或使用现场经验。 之前设计和为新设计而进行的改变符合最佳实践、标准和规范要求。预防控制能够发现与失效起因相关的产品缺陷，很可能地反映设计符合性。	
3	每年一次	对已知设计（相同应用，在工作周期或操作条件方面）和测试或类似运行条件下的现场经验的细微变化或成功完成测试程序的新设计 考虑到之前设计的经验教训，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并预测了与生产设计的一致性。	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
2	**≤ .001 per thousand 1 in 1,000,000**	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	**Preventive controls eliminate failure**	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table C1.3.2 – Alternate DFMEA Occurrence (O)

产品的潜在频度 (O)			
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度（定性评级）时应考虑产品经验和预防控制。			空白，由使用人员填写
O	基于时间的失效起因预测	频度标准 - DFMEA	公司或产品系列示例
2	每年少于一次	与长期现场暴露几乎相同的设计。相同应用，具备类似的工作周期或运行条件。在类似运行条件下的测试或使用现场经验。 考虑到之前设计的经验教训并对其具备充足的信心，设计预计符合标准和最佳实践。预防控制能够发现与失效起因相关的产品缺陷，并显示出对设计符合性的信心。	
1	从未发生	失效通过预防控制消除，通过设计失效起因不可能发生	

产品经验：在公司内使用产品的历史（新品设计、应用或使用案例）。已经完成的探测控制结果提供了设计经验。

预防控制：在产品设计中使用最佳实践、设计规则、公司标准、经验教训、行业标准、材料规范、政府规定，以及以预防为导向的分析工具的有效性 （分析工具包括计算机辅助工程、数学建模、模拟研究、公差叠加和设计安全边际）。

注：频度 10、9、8、7 可根据产品验证活动降低。

表 C1.3.2 备选 DFMEA 频度 (O)

C1.4 DFMEA DETECTION (D)

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	Very low	Test procedure yet to be developed.	Test method not defined	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	
8	Low	New test method; not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or re-tooling.	Pass-Fail Testing	
6	Moderate		Test-to-Failure	
5			Degradation Testing	
4	High	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	Very high	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to **always** detect the failure mode or failure cause.		

Table C1.4 - DFMEA DETECTION (D)

C1.4 DFMEA 探测度（D）

用于产品设计验证的潜在探测度 (D)				
根据探测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
10	非常低	测试程序尚未开发。	测试方法尚未定义	
9		没有为探测失效模式或失效起因而特别地设计测试方法。	通过/不通过测试、失效测试、老化测试	
8	低	新测试方法，尚未经过验证。	通过/不通过测试、失效测试、老化测试	
7		已经验证的测试方法，该方法用于功能性验证或性能、质量、可靠性以及耐久性确认；测试计划时间在产品开发周期内较迟，如果测试失败将导致重新设计、重新开模具导致生产延迟。	通过/不通过测试	
6	中		失效测试	
5			老化测试	
4	高	已经验证的测试方法，该方法用于功能性验证或性能、质量、可靠性以及耐久性确认；计划时间充分，可以在开始生产之前修改生产工装。	通过/不通过测试	
3			失效测试	
2			老化测试	
1	非常高	之前测试证明不会出现失效模式或失效起因，或者探测方法经过实践验证**总是**能够探测到失效模式或失效起因。		

表 C1.4 DFMEA 探测度(D)

C1.5 ACTION PRIORITY TABLE FOR DFMEA

Action Priority (AP) for DFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**Action Priority (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	

C1.5 DFMEA 措施优先级表

DFMEA 措施优先级 (AP)							
措施优先级是以严重度、频度以及探测度评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	**S**	**对失效起因发生的预测**	**O**	**探测能力**	**D**	**措施优先级 (AP)**	**备注**
对产品或工厂的影响度非常高	9-10	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	

Action Priority (AP) for DFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**Action Priority (AP)**	**Comments**
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

DFMEA 的措施优先级 (AP)							
措施优先级是以严重度、频度以及检测评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	**S**	**对失效起因发生的预测**	**O**	**探测能力**	**D**	**措施优先级 (AP)**	**备注**
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度高	7-8	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	M	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	

Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	

对产品或工厂的影响度中等	4-6	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	M	
				非常高	1	M	
		高	6-7	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	M	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	M	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	

		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No Discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table C1.5 – ACTION PRIORITY FOR DFMEA

		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度低	2-3	非常高	8-10	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		高	6-7	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
没有可觉察到的影响。	1	非常低 - 非常高	1-10	非常高 - 非常低	1-10	L	

表 C1.5 DFMEA 措施优先级

C2 PFMEA SOD and AP Tables

C2.1 PFMEA SEVERITY (S)

Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations.	
8	**Moderately high**	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	

C2 PFMEA SOD 表和 AP 表

C2.1 PFMEA 严重度 (S)

过程一般评估标准严重度 (S)					
根据以下标准对潜在失效影响进行评级。					空白，由使用人员填写
S	**影响**	**对您的工厂的影响**	**对发运至工厂的影响（在已知情况下）**	**对最终用户的影响（在已知情况下）**	**公司或产品系列示例**
10	**高**	失效可能会导致从事生产或组装作业的工人面临严重的健康和/或安全风险	失效可能会导致从事生产或组装作业的工人面临严重的健康和/或安全风险	影响到车辆和/或其他车辆的操作安全性，驾驶员、乘客、交通参与者或行人的健康状况。	
9		失效可能会导致厂内不符合法规	失效可能会导致厂内不符合法规	不符合法规。	
8	**较高**	生产运行 100%会受到影响，产品不得不报废。失效可能会导致厂内不符合法规，或导致从事生产或组装作业的工人面临慢性健康和/或安全风险	生产线停工超过一个完整的班次；可能停止发货；需要使用现场返修或更换（装配线到终端用户），并且不符合法规。失效可能会导致厂内不符合法规，或导致从事生产或组装作业的工人面临慢性健康和/或安全风险。	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		产品可能需要进行分拣，其中一部分（少于 100%）会报废；主要过程有偏差；生产过程速度降低或增加劳动力	生产线停工从 1 小时起到一个完整的班次；可能停止发货；需要使用现场返修或更换（装配线到终端用户），并且不符合法规。	在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	

Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
6	**Moderately low**	100% of production run may have to be reworked off line and accepted	Line shutdown up to one hour	**Loss** of secondary vehicle function.	
5		A portion of the production run may have to be reworked off line and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect	No discernible effect or no effect	No discernible effect.	

Table C2-1 - PFMEA SEVERITY (S)

过程一般评估标准严重度 (S)					
根据以下标准对潜在失效影响进行评级。					空白，由使用人员填写
S	影响	对您的工厂的影响	对发运至工厂的影响（在已知情况下）	对最终用户的影响（在已知情况下）	公司或产品系列示例
6	较低	100%的产品可能需要线下返工后才能被接受	生产线停工不超过一个小时	失去车辆次要功能	
5		部分产品可能需要线下返工后才能被接受	少于100%的产品受到影响；极有可能出现额外的缺陷产品；需要分拣；生产线没有停工	降低车辆次要功能	
4		100%的产品可能需要在工位上返工后才能继续加工	缺陷产品缺陷产品会触发重大应对计划的启动；可能不会出现额外的瑕疵产品；不需要分拣	外观、声音、振动、粗糙度或触感令人感觉非常不舒服。	
3	低	部分产品可能需要在工位上返工后才能继续加工	缺陷产品会触发次要应对计划的启动；可能不会出现额外的缺陷产品；不需要分拣	外观、声音、振动、粗糙度或触感令人感觉一般性的不舒服。	
2		会导致过程、操作或操作人员的不方便	缺陷产品不会触发应对计划的启动；可能不会出现额外的缺陷产品；不需要分拣；需要向供应商提供反馈	外观、声音、振动、粗糙度或触感令人略微感觉不舒服。	
1	非常低	没有可觉察到的影响	没有可觉察到的影响或没有影响	没有可觉察到的影响。	

表 C2-1 PFMEA 严重度 (S)

C2.2 PFMEA OCCURRENCE (O)

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Extremely high**	None	No prevention controls.	
9	**Very high**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8				
7	**High**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6				
5	**Moderate**		Prevention controls are effective in preventing failure cause.	
4				
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very low**			
1	**Extremely low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table C2.2 - PFMEA OCCURRENCE (O)

C2.2 PFMEA 频度 (O)

<table>
<tr><th colspan="5">过程的潜在频度 (O)</th></tr>
<tr><td colspan="4">根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑预防控制。频度是在评估时进行的预估定性评级，可能不能反映真实的频度。频度评级得分是在 FMEA（正在评估的过程）范围内进行的相对评级数值。针对多个频度评级中的预防控制而言，可以使用最能反映控制有效性的评级。</td><td>空白，由使用人员填写</td></tr>
<tr><th>O</th><th>对失效起因发生的预测</th><th>控制类型</th><th>预防控制</th><th>公司或产品系列示例</th></tr>
<tr><td>10</td><td>极高</td><td>无</td><td>没有预防控制。</td><td></td></tr>
<tr><td>9</td><td rowspan="2">非常高</td><td rowspan="2">行为控制</td><td rowspan="2">预防控制在防止失效起因出现的方面起到的作用很小。</td><td></td></tr>
<tr><td>8</td><td></td></tr>
<tr><td>7</td><td rowspan="2">高</td><td rowspan="4">行为或
技术控制</td><td rowspan="2">预防控制在防止失效起因出现的方面可以起到一定的作用。</td><td></td></tr>
<tr><td>6</td><td></td></tr>
<tr><td>5</td><td rowspan="2">中</td><td rowspan="2">预防控制在防止失效起因出现的方面可以起到有效的作用。</td><td></td></tr>
<tr><td>4</td><td></td></tr>
<tr><td>3</td><td>低</td><td rowspan="2">最佳实践：行为或技术控制</td><td rowspan="2">预防控制在防止失效起因出现的方面可以起到高度有效的作用。</td><td></td></tr>
<tr><td>2</td><td>非常低</td><td></td></tr>
<tr><td>1</td><td>极低</td><td>技术控制</td><td>预防控制在预防失效起因设计（例如零件形状）或过程（如夹具或模具设计）而发生的失效起因方面极其有效。预防控制的目的 - 失效模式不会因失效起因而实际发生。</td><td></td></tr>
</table>

预防控制的有效性：在确定预防控制的有效性时，应考虑预防控制是否为技术措施（依靠机械设备、工具寿命、工具材料等），或应用最佳实践（夹具、工装设计、校准程序、防错确认、定期检修、工作说明、统计流程控制表、过程监视、产品设计等），或行为措施（依靠持有证书或未持有证书的操作人员、技术工人、团队领导等）。

表 C2. 2 PFMEA 频度 (O)

C2.3 Alternative PFMEA Occurrence (O) Tables

C2.3.1 PFMEA Occurrence (O) with Incidents per Thousand Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**≥ 100 per thousand >/= 1 in 10**	None	No prevention controls.	
9	**50 per thousand 1 in 20**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**20 per thousand 1 in 50**			
7	**10 per thousand 1 in 100**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**2 per thousand 1 in 500**			
5	**.5 per thousand 1 in 2000**		Prevention controls are effective in preventing failure cause.	
4	**.1 per thousand 1 in 10,000**			
3	**.01 per thousand 1 in 100,000**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**< .001 per thousand 1 in 1,000,000**			
1	**Failure is eliminated through preventive control**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table C2.3.1 – Alternate PFMEA OCCURRENCE (O)

C2.3 备选 PFMEA 频度 (O) 表

C2.3.1 PFMEA 频度 (O)，每千台车故障率

过程的潜在频度 (O)				
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑预防控制。频度是在评估时进行的预估定性评级，可能不能反映真实的频度。频度评级得分是在 FMEA（正在评估的过程）范围内进行的相对评级数值。针对多个频度评级中的预防控制而言，可以使用最能反映控制有效性的评级。				空白，由使用人员填写
O	**每千件产品/车辆的故障率**	**控制类型**	**预防控制**	**公司或产品系列示例**
10	≥ 千分之一百 >/= 十分之一	无	没有预防控制。	
9	千分之五十 二十分之一	行为控制	预防控制在防止失效起因出现的方面起到的作用很小。	
8	千分之二十 五十分之一			
7	千分之十 百分之一	行为或技术控制	预防控制在防止失效起因出现的方面可以起到一定的作用。	
6	千分之二 五百分之一			
5	千分之 **0.5** 二千分之一		预防控制在防止失效起因出现的方面可以起到有效的作用。	
4	千分之 **0.1** 万分之一			
3	千分之 **0.01** 十万分之一	最佳实践：行为或技术控制	预防控制在防止失效起因出现的方面可以起到非常有效的作用。	
2	< 千分之 **0.001** 百万分之一			
1	**通过预防控制避免失效**	技术控制	预防控制在预防失效起因设计（例如零件形状）或过程（如夹具或模具设计）而发生的失效起因方面极其有效。预防控制的目的 - 失效模式不会因失效起因而实际发生。	

预防控制的有效性：在确定预防控制的有效性时，应考虑预防控制是否为技术措施（依靠机械设备、工具寿命、工具材料等），或应用最佳实践（夹具、工装设计、校准程序、防错验证、定期检修、工作说明、统计流程控制表、过程监视、产品设计等），或行为措施（依靠持有证书或未持有证书的操作人员、技术工人、团队领导等）。

表 C2.3.1 备选 PFMEA 频度 (O)

C2.3.2 PFMEA OCCURRENCE (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Every time**	None	No prevention controls.	
9	**Almost every time**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**More than once per shift**			
7	**More than once per day**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**More than once per week**			
5	**More than once per month**		Prevention controls are effective in preventing failure cause.	
4	**More than once per year**			
3	**Once per year**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Less than once per year**			
1	**Never**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table C2.3.2 – Alternate PFMEA OCCURRENCE (O)

C2.3.2 PFMEA 频度 (O)，基于时间的失效预测值

过程的潜在频度 (O)				
根据以下标准对潜在失效起因进行的评级。在确定最佳预估频度时应考虑预防控制。频度是在评估时进行的预估定性评级，可能不能反映真实的频度。频度评级得分是在 FMEA （正在评估的过程）范围内进行的相对评级数值。针对多个频度评级中的预防控制而言，可以使用最能反映控制有效性的评级。				空白，由使用人员填写
O	**基于时间的失效起因预测**	**控制类型**	**预防控制**	**公司或产品系列示例**
10	每次	无	没有预防控制。	
9	几乎每次	行为控制	预防控制在防止失效起因出现的方面起到的作用很小。	
8	每班超过一次			
7	每日超过一次	行为或技术控制	预防控制在防止失效起因出现的方面可以起到一定的作用。	
6	每周超过一次			
5	每月超过一次		预防控制在防止失效起因出现的方面可以起到有效的作用。	
4	每年超过一次			
3	每年一次	最佳实践：行为或技术控制	预防控制在防止失效起因出现的方面可以起到非常有效的作用。	
2	每年少于一次			
1	从未发生	技术控制	预防控制在预防失效起因设计（例如零件形状）或过程（如夹具或模具设计）而发生的失效起因方面极其有效。预防控制的目的 - 失效模式不会因失效起因而实际发生。	

预防控制的有效性：在确定预防控制的有效性时，应考虑预防控制是否为技术措施（依靠机械设备、工具寿命、工具材料等），或应用最佳实践（夹具、工装设计、校准程序、防错验证、定期检修、工作说明、统计流程控制表、过程监视、产品设计等），或行为措施（依靠持有证书或未持有证书的操作人员、技术工人、团队领导等）。

表 C2.3.2 备选 PFMEA 频度 (O)

C2.4 PFMEA DETECTION (D)

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	Very low	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	Low	Test or inspection method **has not been** proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	
6	Moderate	Test or inspection method **has been** proven to be effective and reliable (e.g. plant has experience with method, gauge R&R results are acceptable on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

C2.4 PFMEA 探测度 (D)

用于过程设计验证的潜在探测度(D)				
根据检测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
10	非常低	尚未建立或有已知的测试或检验方法。	不能或无法探测到失效模式。	
9		测试或检验方法不可能探测到失效模式。	通过任意或不定时的审核很难探测到失效模式。	
8	低	测试或检验方法**尚未**经过实践证明为有效和可靠（例如，工厂在测试或检验方法方面没有或很少有经验，有关类似过程或本程序的测量可重复性和再现性分析结果接近边际值等）。	可以探测失效模式或失效起因的人工检验（视觉、触觉、听觉）方法，或使用人工检验（计数或计量）方式。	
7			以设备为基础的检验方式（采用光学、蜂鸣器等装置的自动化或半自动化方式），或使用可以探测失效模式或失效起因的检验设备，例如坐标测量机。	
6	中	测试或检验方法**已**经过实践证明为有效和可靠（例如，工厂在测试或检验方法方面具备经验，有关类似过程或本程序的测量可重复性和再现性结果可以接受等）。	可以探测失效模式或失效起因（包括产品样本检查）的人工检验（视觉、触觉、听觉）方法，或使用人工检验（计数或计量）方式。	
5			以设备为基础的探测方式（采用光学、蜂鸣器等装置的半自动化方式），或使用可以探测失效模式或失效起因（包括产品样本检查）的检验设备，例如坐标测量机。	

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
4	High	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode **downstream**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect the failure mode **in-station**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
2		Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.).	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	Very high	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

Table C2.4 - PFMEA DETECTION (D)

用于过程设计验证的潜在探测度 (D)				
根据检测方法成熟度和探测机会对探测控制进行评级。				空白，由使用人员填写
D	**探测能力**	**探测方法成熟度**	**探测机会**	**公司或产品系列示例**
4	高	已经过实践证明为有效或可靠的系统（例如工厂在关于相同过程或本程序的测试或探测方法方面具备经验），测量可重复性和再现性结果可以接受等。	以设备为基础的自动化探测方法，其可以在**下游**探测到失效模式，进而避免进一步加工、或系统可以识别差异产品，并允许其在过程中自动前进，直至到达指定的不合格品卸载区。差异产品将在一个有效的系统内受到监视，避免这些产品从工厂内流出。	
3			以设备为基础的自动化探测方法，其可以**在工位上**探测到失效模式，进而避免进一步加工、或系统可以识别差异产品并允许其在过程中自动前进，直至到达指定的不合格品卸载区。差异产品将在一个有效的系统内受到监视，避免这些产品从工厂内流出。	
2		探测方法已经经过实践证明为有效或可靠（例如工厂在探测方法、防错确认措施方面具备经验等）。	以设备为基础的探测方法，其可以探测失效起因并避免出现失效模式（差异零件）。	
1	非常高	根据设计或加工过程而不会实际出现失效模式，或者探测方法经过实践验证**总是**能够探测到失效模式或失效起因。		

表 C2.4 PFMEA 探测度(D)

C2.5 ACTION PRIORITY TABLE FOR PFMEA

Action Priority (AP) for PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

C2.5 PFMEA 措施优先级表

PFMEA 措施优先级 (AP)							
措施优先级是以严重度、频度以及探测度评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。							空白，由使用人员填写
影响	S	对失效起因发生的预测	O	探测能力	D	措施优先级 (AP)	备注
对产品或工厂的影响度非常高	9-10	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度高	7-8	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	H	
		高	6-7	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	H	
				非常高	1	M	
		中	4-5	低 - 非常低	7-10	H	
				中	5-6	M	
				高	2-4	M	
				非常高	1	M	
		低	2-3	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)	Comments
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No Discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table C2.5 – ACTION PRIORITY FOR PFMEA

影响	S	对失效起因发生的预测	O	探测能力	D	措施优先级 (AP)	备注
对产品或工厂的影响度中	4-6	非常高	8-10	低 - 非常低	7-10	H	
				中	5-6	H	
				高	2-4	M	
				非常高	1	M	
		高	6-7	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	M	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	M	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
对产品或工厂的影响度低	2-3	非常高	8-10	低 - 非常低	7-10	M	
				中	5-6	M	
				高	2-4	L	
				非常高	1	L	
		高	6-7	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		中	4-5	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		低	2-3	低 - 非常低	7-10	L	
				中	5-6	L	
				高	2-4	L	
				非常高	1	L	
		非常低	1	非常高 - 非常低	1-10	L	
没有可觉察到的影响。	1	非常低 - 非常高	1-10	非常高 - 非常低	1-10	L	

表 C2.5 PFMEA 措施优先级

C3 FMEA-MSR SFM and AP Tables

C3.1 Supplemental FMEA-MSR SEVERITY (S)

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible Failure Effect.	

Note: This table is identical to Table C1.1 - DFMEA SEVERITY (S)

Table C3-1 - Supplemental FMEA-MSR SEVERITY (S)

C3 PFMEA-MSR SFM 表和 AP 表

C3.1 补充 FMEA-MSR 严重度 (S) 表

产品一般评估标准严重度			
根据以下标准对潜在失效影响进行评级。			空白，由使用人员填写
S	**影响**	**严重度标准**	**公司或产品系列示例**
10	**非常高**	影响到车辆和/或其他车辆的操作安全性，驾驶员、乘客、交通参与者或行人的健康状况。	
9		不符合法规。	
8	**高**	在预期使用寿命内，**失去**正常驾驶所必需的车辆主要功能。	
7		在预期使用寿命内，**降低**正常驾驶所必需的车辆主要功能。	
6	**中**	**失去**车辆次要功能	
5		**降低**车辆次要功能	
4		外观、声音、振动、粗糙度或触感令人感觉非常不舒服	
3	**低**	外观、声音、振动、粗糙度或触感令人感觉一般性的不舒服。	
2		外观、声音、振动、粗糙度或触感令人略微感觉不舒服	
1	**非常低**	没有可觉察到的失效影响。	

注：该表格与 D1 DFMEA 严重度(S) 表格相同

表 C3-1 补充 FMEA-MSR 严重度(S)表

C3.2 Supplemental FMEA-MSR FREQUENCY (F)

Frequency Potential (F) for the Product			
Frequency criteria (F) for the estimated occurrence of the Failure Cause in relevant operating situations during the intended service life of the vehicle			Blank until filled in by user
F	**Estimated Frequency**	**Frequency criteria - FMEA-MSR**	**Corporate or Product Line Examples**
10	**Extremely high or cannot be determined**	Frequency of occurrence of the Failure Cause is unknown or known to be unacceptably high during the intended service life of the vehicle	
9	**High**	Failure Cause is likely to occur during the intended service life of the vehicle	
8		Failure Cause may occur often in the field during the intended service life of the vehicle	
7	**Medium**	Failure Cause may occur frequently in the field during the intended service life of the vehicle	
6		Failure Cause may occur somewhat frequently in the field during the intended service life of the vehicle	
5		Failure Cause may occur occasionally in the field during the intended service life of the vehicle.	
4	**Low**	Failure Cause is predicted to occur rarely in the field during the intended service life of the vehicle. At least ten occurrences in the field are predicted.	
3	**Very low**	Failure Cause is predicted to occur in isolated cases in the field during the intended service life of the vehicle. At least one occurrence in the field is predicted.	
2	**Extremely low**	Failure Cause is predicted not to occur in the field during the intended service life of the vehicle based on prevention and detection controls and field experience with similar parts. Isolated cases cannot be ruled out. No proof it will not happen.	
1	**Cannot Occur**	Failure Cause cannot occur during the intended service life of the vehicle or is virtually eliminated. Evidence that Failure Cause cannot occur. Rationale is documented.	

Percentage of relevant operating condition in comparison to overall operating time	Value by which F may be lowered
< 10%	1
< 1%	2

NOTE: Probability increases as number of vehicles are increased

Reference value for estimation is one million vehicles in the field

Table C3-2 - Supplemental FMEA-MSR FREQUENCY (F)

C3.2 补充 FMEA-MSR 频率(F)表

产品的潜在频率(F)			
频率标准（F），用于在车辆预期使用寿命周期内与运行状况相关失效起因的估计频度			空白，由使用人员填写
F	**估计频率**	**频率标准 - FMEA-MSR**	**公司或产品系列示例**
10	**极高或不能确定**	在车辆预期使用寿命周期内，失效起因的发生频率未知，或已知很高而无法接受	
9	**高**	失效起因在车辆预期使用寿命周期内可能会出现	
8		在车辆预期使用寿命周期内，失效起因可能在车辆使用中经常出现	
7	**中**	在车辆预期使用寿命周期内，失效起因可能在车辆使用中频繁出现	
6		在车辆预期使用寿命周期内，失效起因可能在车辆使用中略微频繁地出现	
5		在车辆预期使用寿命周期内，失效起因可能在车辆使用中偶尔出现。	
4	**低**	在车辆预期使用寿命周期内，预计失效起因在车辆使用中极少出现。预计在使用中至少发生十次。	
3	**非常低**	在车辆预期使用寿命周期内，预计失效起因在孤立事例的车辆使用中会出现。预计在使用中至少发生一次。	
2	**极低**	在车辆预期使用寿命周期内，在应用预防及探测控制措施以及相似零件现场使用经验的基础上，预计失效起因在车辆使用中不会出现。不能排除孤立事例。没有证明表明这种现象不会发生。	
1	**不会出现**	失效起因在车辆预期使用寿命周期内不会出现，或几乎排除这种可能。证据表明失效起因不会出现。其理由已进行记录。	

相关运行条件占总运行时间的比例	F 可以随之降低的值
< 10%	1
< 1%	2

注：随着车辆数量的增加，可能性也随之增加
估计参考值为一百万台使用中的车辆

表 C3-2 补充 FMEA-MSR 频率(F)表

C3.3 Supplemental FMEA-MSR MONITORING (M)

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
10	**Not effective**	The fault/failure cannot be detected at all or not during the fault tolerant time interval; by the system, the driver, a passenger, or service technician.	No response during the fault tolerant time interval.	
9	**Very Low**	The fault/failure can almost never be detected in relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Minimal diagnostic coverage.	The reaction to the fault/failure by the system or the driver may not reliably occur during the fault tolerant time interval.	
8	**Low**	The fault/failure can be detected in very few relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated <60%.	The reaction to the fault/failure by the system or the driver may not always occur during the fault tolerant time interval.	
7	**Moderately Low**	Low probability of detecting the fault/failure during the fault tolerant time interval by the system or the driver. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated >60%.	Low probability of reacting to the detected fault/failure during the fault tolerant time interval by the system or the driver.	
6	**Moderate**	The fault/failure will be automatically detected by the system or the driver only during power-up, with medium variance in detection time. Diagnostic coverage estimated >90%.	The automated system or the driver will be able to react to the detected fault/failure in many operating conditions.	
5		The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in very many operating conditions. Diagnostic coverage estimated between 90% - 97%.	The automated system or the driver will be able to react to the detected fault/failure in very many operating conditions.	

C3.3 补充 FMEA-MSR 监视(M)表

监视及系统响应(M) 的补充 FMEA				
在顾客操作中用于监视失效起因、失效模式和失效影响的监视标准(M)。在监视或系统响应中使用与最低效的标准相关的评级				空白，由使用人员填写
M	监视控制及系统响应的有效性	诊断监视/感知标准	系统响应/人体反应标准	公司或产品系列示例
10	无效	在容错时段内，系统、驾驶员、乘客、或维修技术人员根本无法探测或未探测到故障/失效现象。	在容错时段内没有反应。	
9	非常低	在相关运行条件下几乎从未探测到故障/失效现象。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率低。	在容错时段内，系统或驾驶员不能以可靠的方式对故障/失效进行反应。	
8	低	在极少数的相关运行条件下故障/失效能够被探测到。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率预计低于 60%。	在容错时段内，系统或驾驶员不能总是对故障/失效进行反应。	
7	较低	在容错时段内，系统或驾驶员探测到故障/失效的机率低。监视控制非常低效，具有很高的变化性和不确定性。诊断覆盖率预计高于 60%。	在容错时段内，系统或驾驶员对故障/失效进行反应的机率低。	
6	中	只有在打开电源状态下，系统或驾驶员才能自动探测到故障/失效，探测时间的变化为中等程度。诊断覆盖率预计高于 90%。	在多种运行条件下，自动化系统或驾驶员能够对探测到的故障/失效进行反应。	
5		在容错时段内，系统能够自动探测到故障/失效，探测时间的变化为中等程度，或者驾驶员可在多种运行条件下探测到故障/失效。诊断覆盖率预计在 90-97% 之间。	在很多种运行条件下，自动化系统或驾驶员能够对探测到的故障/失效进行反应。	

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
4	**Moderately High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in most operating conditions. Diagnostic coverage estimated >97%.	The automated system or the driver will be able to react to the detected fault/failure during the fault tolerant time interval, in most operating conditions.	
3	**High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval with very low variance in detection time, and with a high probability. Diagnostic coverage estimated >99%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval in most operating conditions with very low variance in system response time, and with a high probability.	
2	**Very High**	The fault/failure will be detected automatically by the system with very low variance in detection time during the fault tolerant time interval, and with a very high probability. Diagnostic coverage estimated > 99.9%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval with very low variance in system response time, and with a very high probability.	
1	**Reliable** and acceptable for elimination of original failure effect	The fault/failure will always be detected automatically by the system. Diagnostic coverage estimated to be significantly greater than 99.9%.	The system will always automatically react to the detected fault/failure during the fault tolerant time interval.	

Table C3-3 - Supplemental FMEA-MSR MONITORING (M)

监视及系统响应(M) 的补充 FMEA				
在顾客操作中用于监视失效起因、失效模式和失效影响的监视标准(M)。在监视或系统响应中使用与最低效的标准相关的评级				空白，由使用人员填写
M	**监视控制及系统响应的有效性**	**诊断监视/感知标准**	**系统响应/人体反应标准**	**公司或产品系列示例**
4	较高	在容错时段内，系统能够自动探测到故障/失效，探测时间的变化一般，或者驾驶员在大多运行条件下可以探测到故障/失效。诊断覆盖率预计高于 97%。	在容错时段内，自动化系统或驾驶员在大多运行条件下能够对探测到的故障/失效进行反应。	
3	高	在容错时段内，系统能够自动探测到故障/失效，探测时间的变化很小，并且机率高。诊断覆盖率预计高于 99%。	在容错时段内，系统在大多运行条件下能够自动探测到故障/失效，系统反应的时间变差很小，并且机率高。	
2	非常高	在容错时段内，系统能够自动探测到故障/失效，探测时间变化很小，并且机率很高。诊断覆盖率预计高于 99.9%。	在容错时段内，系统能够自动探测到故障/失效，系统反应的时间变差很小，并且机率很高。	
1	在消除原有的失效影响方面可靠并可接受	系统总是可以自动探测到故障/失效。故障覆盖率预计大大高于 99.9%。	在容错时段内，系统总是能够对故障/失效进行自动反应。	

表 C3-3 补充 FMEA-MSR 监视(M)表

C3.4 ACTION PRIORITY FOR FMEA-MSR

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect High	**10**	Medium - Extremely high	5-10	Reliable - Not effective	1-10	H
		Low	4	Moderately high - Not effective	4-10	H
				Very high - High	2-3	H
				Reliable	1	M
		Very low	3	Moderately high - Not effective	4-10	H
				Very high - High	2-3	M
				Reliable	1	L
		Extremely low	2	Moderately high - Not effective	4-10	M
				Reliable - High	1-3	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect High	**9**	Low - Extremely high	4-10	Reliable - Not effective	1-10	H
		Extremely low - Very low	2-3	Very high - Not effective	2-10	H
				Reliable - High	1	L
		Cannot occur	1	Reliable - Not effective	1-10	L

C3.4 FMEA-MSR 措施优先级

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响	S	在车辆使用寿命内对发生失效起因的预测	F	监视有效性	M	措施优先级 (AP)
对产品的影响度高	10	中 - 极高	5-10	可靠 - 无效	1-10	H
		低	4	较高 - 无效	4-10	H
				很高 - 高	2-3	H
				可靠	1	M
		非常低	3	较高 - 无效	4-10	H
				很高 - 高	2-3	M
				可靠	1	L
		极低	2	较高 - 无效	4-10	M
				可靠 - 高	1-3	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度高	9	低 - 极高	4-10	可靠 - 无效	1-10	H
		极低 - 很低	2-3	很高 - 无效	2-10	H
				可靠 - 高	1	L
		不会出现	1	可靠 - 无效	1-10	L

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Moderately high	**7-8**	Medium - Extremely high	6-10	Reliable - Not effective	1-10	H
		Medium	5	Moderately high - Not effective	5-10	H
				Reliable - Moderately high	1-4	M
		Low	4	Moderately low - Not effective	7-10	H
				Moderately high - Moderate	4-6	M
				Reliable - High	1-3	L
		Very low	3	Very low - Not effective	9-10	H
				Moderately low - Low	7-8	M
				Reliable - Moderate	1-6	L
		Extremely low	2	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Moderately Low	**4-6**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderate - Not effective	6-10	H
				Reliable - Moderately high	1-5	M
		Extremely low - Low	2-4	Very low - Not effective	9-10	M
				Moderately high - Moderate	7-8	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响	S	在车辆使用寿命内	F	监视的有效性	M	措施优先级
对产品的影响度较高	7-8	中-极高	6-10	可靠 - 无效	1-10	H
		中	5	较高 - 无效	5-10	H
				可靠 - 较高	1-4	M
		低	4	较低 - 无效	7-10	H
				较高 - 中	4-6	M
				可靠 - 高	1-3	L
		非常低	3	很低 - 无效	9-10	H
				较低 - 低	7-8	M
				可靠 - 中	1-6	L
		极低	2	较低 - 无效	7-10	M
				可靠 - 中	1-6	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度较低	4-6	高 - 极高	7-10	可靠 - 无效	1-10	H
		中	5-6	中 - 无效	6-10	H
				可靠 - 较高	1-5	M
		极低 - 低	2-4	很低 - 无效	9-10	M
				较高 - 中	7-8	M
				可靠 - 中	1-6	L
		不会出现	1	可靠 - 无效	1-10	L

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Low	2-3	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Extremely low - Low	2-4	Reliable - Not effective	1-10	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Very low	1	Cannot occur - Extremely high	1-10	Reliable - Not effective	1-10	L

NOTE: If M=1, the Severity rating of the Failure Effect after Monitoring and System Response is to be used for determining MSR Action Priority. If M is not equal to 1, then the Severity Rating of the original Failure Effect is to be used for determining MSR Action Priority.

Table C3.4 – ACTION PRIORITY FOR FMEA-MSR

FMEA-MSR 的措施优先级 (AP)						
措施优先级是以严重度、频率以及监视评级的综合为基础的，目的是为降低风险而对各项措施进行优先排序。						
影响	**S**	**在车辆使用寿命内对发生失效起因的预测**	**F**	**监视的有效性**	**M**	**措施优先级 (AP)**
对产品的影响度低	**2-3**	高 - 极高	7-10	可靠 - 无效	1-10	H
		中	5-6	较低 - 无效	7-10	M
				可靠 - 中	1-6	L
		极低 - 低	2-4	可靠 - 无效	1-10	L
		不会出现	1	可靠 - 无效	1-10	L
对产品的影响度很低	**1**	不会出现 - 极高	1-10	可靠 - 无效	1-10	L

注：　如果 M=1，在确定 MSR 措施优先级时，应使用监视及系统响应后的失效影响严重度评级。如果M不等于1，在确定 MSR 措施优先级时，应使用最初的失效影响严重度评级。

表 C3.4 - FMEA-MSR 措施优先级

D Additions

D1 Special Characteristics

Special Characteristics are intended to provide information regarding design characteristics which require particular attention to process controls. Characteristics which lead directly to a failure of a product function in regard to safety, fit, form, performance, further processing of the product, or compliance to government regulations and industry standards may be identified as Special Characteristics.

Special Characteristics are identified to reduce the instances of scrap, rework, non-conforming parts, and assembly errors. The likelihood of customer complaints, product warranty claims, and government recalls is thereby mitigated by specifying Special Characteristics to ensure effective process controls. Special Characteristics are marked with abbreviations or symbols* in documents such as Product documents (as required), Process FMEA (Special Characteristics column) and Control Plans. Evidence for the implementation of process controls for Special Characteristics should be monitored, documented, and accessible.

In the Design FMEA, the Filter Code column replaces the Classification column because Special Characteristics are not required to be shown in the DFMEA.

The Design FMEA is one of several inputs to the selection of Special Characteristics. The team may use the Design FMEA to highlight when process controls may be needed to ensure conformance to specifications. The Design FMEA Form Sheet column named "Filter Code (Optional)" may be used to document that information.

To properly identify Special Characteristics, the Process FMEA team considers how variation in the manufacturing process can affect the functionality of the product. In other words, characteristics may be sensitive to manufacturing/assembly variation (Special Characteristic) or not sensitive to manufacturing/assembly variation (Standard Characteristic).

The Process FMEA contains the column titled "Classification". This column may be used to specify Special Characteristics (e.g. critical, key, major, significant) that require additional process controls.

*NOTE: Special Characteristics may be company-specific or customer-specific designations. Customer specified Special Characteristics symbols can be translated into the organization's symbols for Special Characteristics (e.g. in a correlation table).

D2 FMEA and Functional Safety

D2.1 Linkage between Functional Safety and Supplemental FMEA for Monitoring and System Response (FMEA-MSR)

The Hazard Analysis and Risk Assessment (HARA) (see ISO26262- 3:2018 Clause 6.4) provides Safety Goals relative to safety-related functions. It also assigns Automotive Safety Integrity Levels (ASILs) which are used to identify the mitigation and are applied to ensure a socially acceptable residual risk of malfunctioning behavior. The Functional Safety Concept (FSC) further defines requirements to ensure the Safety Goals are met by the design. It defines the Warning and Degradation Concept, and the Test Cases which are necessary to demonstrate that the design fulfills the Safety Goals and Safety Requirements. However, ISO 26262 refers to FMEA (along with Systems Theoretic Process Analysis (STPA) and Fault Tree Analysis (FTA) as methods to identify potential causes of malfunctioning behavior. FMEA-MSR may be used to supplement the DFMEA by analyzing the effectiveness of diagnostic monitoring and system response in maintaining functional safety. In addition to safety considerations, the method can also be used for analysis of regulatory compliance topics.

D 新增内容

D1 特殊特性

特殊特性旨在提供需要特别注意过程控制的设计特性的有关信息。直接导致产品功能在安全、配合、组装、性能、产品的进一步加工或符合政府法规和行业标准方面失效的特性可视为特殊特性。

确定特殊特性，旨在减少报废、返工、不合格零件和装配错误的情况。因此，通过规定特殊特性来确保有效的过程控制，以降低顾客投诉、产品保修索赔和政府召回的可能性。特殊特性用缩写或符号*标注在文件中，如产品文件（根据需要）、过程 FMEA（“特殊特性“列）和控制计划。应监视、记录并获取执行特殊特性过程控制的证据。

在设计 FMEA 中，“筛选器代码“列之所以替换了“分类”列，原因在于不需要在 DFMEA 中显示特殊特性。

设计 FMEA 是选择特殊特性的几个输入项之一。团队可使用设计 FMEA 来强调何时可能需要过程控制来确保符合规范。名为“筛选器代码（可选）”的设计 FMEA 表格列可用于记录该信息。

为了正确识别特殊特性，过程 FMEA 团队应考虑制造过程中的变差如何影响产品的功能。换句话说，特性可能对制造/装配变差敏感(特殊特性)，也可能对制造/组装变差不敏感(标准特性)。

过程 FMEA 包含标题为“分类”的列。此列可用于规定需要额外过程控制的特殊特性（例如：至关重要的、关键的、主要的、显著的）。

*注意：特殊特性可以有公司或顾客特定的名称。可以把顾客指定的特殊特征符号转换为组织的特殊特性符号(例如：在对照表中)。

D2 FMEA 和功能安全

D2.1 功能安全与监视及系统响应的补充 FMEA（FMEA-MSR）之间的关联性

危害分析和风险评估（HARA）（见 ISO26262- 3:2018 第 6.4 条）提供了与安全功能相关的安全目标。该评估还分配了汽车安全完整性级别（ASIL），确定风险降低的情况，并确保社会可接受的失效行为的残余风险。功能安全概念（FSC）进一步确定了确保设计满足安全目标的要求，且定义了警告和降级的概念，以及证明设计满足安全目标和安全需求所必需的测试用案例。但 ISO 26262 将 FMEA（以及系统理论过程分析（STPA）和故障树分析（FTA）作为确定故障行为潜在起因的方法。FMEA-MSR 可用于通过分析诊断的有效性来补充 DFMEA 在维护功能安全方面的监控和系统响应。除了安全考虑，该方法还可以用于分析法规符合性的主题。

D2.2 Linkage between Frequency (F) and Exposure in ISO 26262

Exposure in ISO 26262 refers to the duration or frequency of an operational situation. However, Frequency in FMEA-MSR refers to the occurrence of a fault during an operational situation. Therefore, the two metrics are related, but not equivalent.

D2.3 Linkage between Frequency (F) and FIT Rates in ISO 26262

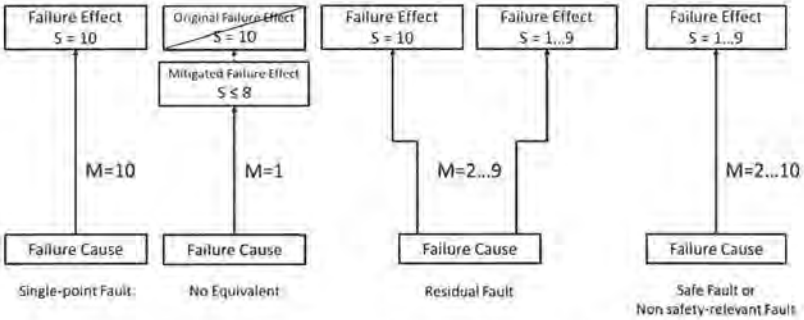
Frequency is a qualitative estimation of how often the considered failure cause may occur during an operational situation. FIT Rates are a quantitative assessment of the measured reliability of an E/E component, based on exposure of the component to specific test conditions. Therefore, the two metrics are related, but not equivalent.

D2.4 Linkage between Monitoring (M) and Diagnostic Coverage in ISO 26262

Monitoring (M) considers the ability of persons and/or the system to detect a specific cause (fault or failure), and react to that detected fault or failure within the Fault Tolerant Time Interval (FTTI). Diagnostic Coverage in ISO 26262 refers to the ability of the system to detect a percentage of all possible faults, and react to a fault within the Fault Tolerant Time Interval (FTTI). Therefore, the Monitoring rating in FMEA-MSR has a wider scope of detection, but relates only to a specific cause.

D2.5 Linkage between Failures in FMEA-MSR to Faults/Errors/Failures in ISO 26262

A Failure Cause in FMEA-MSR is equivalent to a Fault in ISO 26262. However, it is not necessarily a root cause, depending on whether the scope of analysis is a component or a system. A Failure Mode in FMEA-MSR is equivalent to an "Error" in ISO 26262. A Failure Effect in FMEA-MSR is equivalent to a "Failure" in ISO 26262 (Ref. Part 10, Clause 4.3.1).



NOTE: Multiple-point Faults are not in scope of FMEA-MSR

Figure D2-1 Linkage between Failure Causes in FMEA-MSR to Faults in ISO 26262

D2.6 Applicability of FMEA-MSR to manufacturers of microcontrollers

FMEDA is the recommended method for quantitative analysis of microcontrollers. FMEA-MSR may be used for qualitative analysis, but may not provide any additional value.

D2.2 频率（F）与 ISO 26262 中的暴露时间之间的关联性

ISO 26262 中的暴露时间系指某种运行况的持续时间或频率。但 FMEA-MSR 中的频率系指运行期间故障发生的频次。因此这两个指标相关，但并非等同的。

D2.3 频率（F）与 ISO 26262 中的 FIT 比率之间的关联性

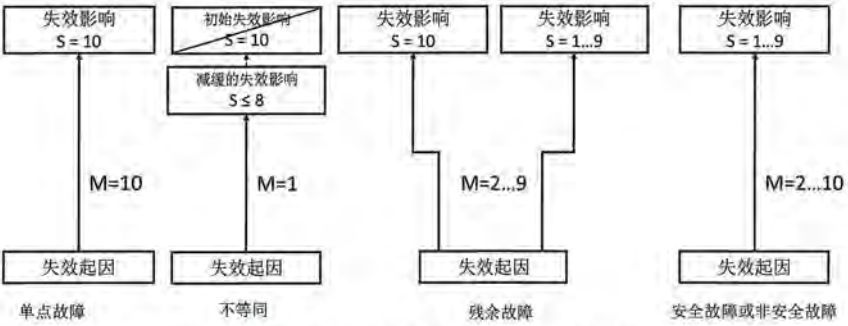
频率系指运行期间所考虑到的失效起因可能发生频率的定性估算。根据组件在特定测试条件下的暴露时间，FIT 比率系指测量 E/E 组件可靠性的定量估计。因此这两个指标相关，但并非等同的。

D2.4 监视（M）与 ISO 26262 中的诊断覆盖率之间的关联性

监控（M）考虑的是人员和/或系统探测特定起因（故障或失效）的能力，并在容错时段（FTTI）内对探测到的故障或失效作出反应。ISO 26262 中的诊断覆盖率是指系统能够探测到所有可能故障的百分比，并在容错时段（FTTI）内对故障作出响应。因此，虽然 FMEA-MSR 中的监控评级的探测范围更广，但它仅涉及特定原因。

D2.5 FMEA-MSR 中的失效与 ISO 26262 中的故障/错误/失效之间的关联性

FMEA-MSR 中的失效起因等同于 ISO 26262 中的故障。但它不一定是根本原因，这具体取决于分析范围是组件还是系统。FMEA-MSR 中的失效模式等同于 ISO 26262 中的“错误”。FMEA-MSR 中的失效影响等同于 ISO 26262 中的“失效”（参考第 10 部分，第 4.3.1 条）。）。



注：多点失效不在 FMEA-MSR 的范围之内

图 D2-1 FMEA-MSR 中的失效起因与 ISO 26262 中的失效之间的关联性

D2.6 FMEA-MSR 对微控制器制造商适用

FMEDA 是微控制器定性分析的推荐方法。FMEA-MSR 可用于定性分析，但可能不会产生任何附加值。

E Further Application Fields

With the DFMEA and PFMEA described, all application fields can be covered.

The procedure is also transferable to suppliers of the automotive industry of other industrial branches. The special features and specific procedures are to be taken into account.

E1 FMEA for Software Scopes

The functions of a system are realized more and more often by software. A Design FMEA examines the functional capability of a system, and therefore the inspection of software scopes is a part of this. The system and its effect relationships should be inspected as a whole in the analysis of the software scope.

When inspecting software scopes, special problems can occur that are considered in the following sections.

NOTE: The term "Software FMEA" is misleading, since not the software but the functions that are realized by the software are to be examined in the system context.

E2 Objective of the Software Scopes Inspection

Analysis of the software requirements:

Demand from the complete system

Checking the basis information/boundary conditions/specifications

Systematical actions for risk reduction, e.g. concept change, avoidance, detection.

Analysis of possible faults in software scopes:

Effect on the complete system

Depiction of the interaction of software modules in the complete system

Risk assessment of the of software modules.

E 更多应用领域

在 DFMEA 和 PFMEA 的说明范围内，可涵盖所有应用领域。

该程序可用于汽车行业以及其它行业的供应商。这时，应考虑其特殊性和特定程序。

E1 FMEA 软件范围

由软件实现系统功能的现象越来越为常见用软件来实现系统的功能越来越为常见。 设计 FMEA 对系统的功能进行检查， 所以对软件范围进行检验是该工作的部分内容。在对软件范围进行分析时，应对系统及其影响之间的关系进行完整的检验。

在对软件范围进行检验时，可能会出现以下方面的特殊问题，对此应注意可能会出现一些特殊问题，应在以下方面给予考虑。

注： "软件 FMEA"这一术语具有误导性，因为在系统背景中需要检验的并不是软件，而是由软件实现的功能。

E2 软件范围的检验目标

软件要求的分析：

整个系统的需求

检查基础信息/边界条件/规范说明

降低风险的系统性措施，如：变更概念、避免风险、探测风险。

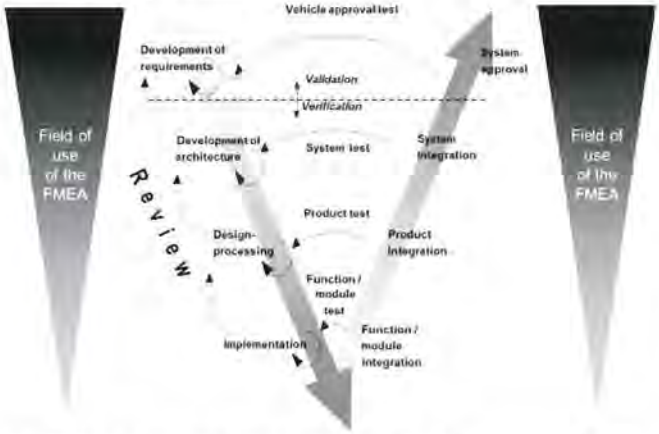
在软件范围内对可能的故障进行分析：

对整个系统的影响

对软件各个模块在整个系统中的相互作用进行描述

对软件模块进行风险评估。

E3 FMEA in the Software Development Process



The FMEA is especially suited for the analysis of requirements and for the validation of the implementation. Therefore its field of application is primarily in the upper part of the model shown.

E4 FMEA for Machine and Facility Manufacturers

The DFMEA of a machine is sometimes referred to as a "Machine FMEA" in the literature.

Starting from a PFMEA in which a machine was identified as a risk, a DFMEA can be prepared for the machine.

In the PFMEA, the requirements on the functions/abilities of the machine are identified in the analysis of the machine.

Separate evaluation tables are to be developed for this Machine FMEA.

At the end the Machinery FMEA follows the rules as Design or Process FMEA.

E3 软件开发过程中的 FMEA



FMEA 特别适用于要求分析和实施验证 。因此其应用领域主要位于该显示模型的上部区域因此其应用领域主要在所显示模型的上部区域。

E4 用于机械和设备制造商的 FMEA

有关机械设备的 DFMEA 在文献中有时也被称为"设备 FMEA"。

从设备设备被视为风险的 PFMEA 开始，可以设备编制 DFMEA。

制作 PFMEA 过程中，在分析设备时应识别设备的功能/性能要求。

针对设备 FMEA，应另行编制评估表。

最后，设备 FMEA 应遵循设计或过程 FMEA 中的规则。

F Change Point Summaries

F1 AIAG 4th Edition FMEA Reference Manual to AIAG & VDA FMEA Handbook

F1.1 AIAG 4th Edition DFMEA to AIAG & VDA FMEA Handbook DFMEA

The AIAG & VDA FMEA method is described by a 7-Step approach. The steps are the synthesis of AIAG and VDA DFMEA process steps. For example, Block/Boundary Diagrams are shown as Step 2 of the 7-Step approach and the same deliverable is shown as a prerequisite in the 4th Edition.

Special Characteristics are removed from DFMEA but stay in PFMEA, see Annex D1 Special Characteristics.

For continuous Improvement a History/Change Authorization column is added (For use as applicable)

The linkage between DFMEA and PFMEA is explained and FMEA Collaboration (Customer – Tier n – Tier n+1).

1st Step: Planning and Preparation

Preparation is partly considered in the 4th Edition General FMEA Guidelines, Chapter II Overview of FMEA, and Chapter III DFMEA. Step 1 includes definition of the "5T's": InTent, Timing, Team, Task, and Tool to be used to document the analysis as well as identification of the analysis subject and baseline DFMEA as appropriate.

FMEA Form Sheet header is defined within Step 1 and the following changes apply:

i. **Company Name** added
ii. Marking of **System, Subsystem or Component** removed
iii. **Engineering Location** added
iv. **Customer Name** added
v. **Model Year(s)/Program(s)** changed to **Model Year/Platform**
vi. **Subject** added
vii. **Key Date** removed
viii. **Revision Date** added
ix. **FMEA Number** changed to **DFMEA ID Number**
x. **Page Number** of **Page Number** removed
xi. **Prepared By** changed to **Design Responsibility**
xii. **FMEA Date (orig.)** changed to **Start Date**
xiii. **Core Team** changed to **Cross-Functional Team**
xiv. **Confidentiality Level** added

Reason for change: To use common terms and include necessary information for record management

F 变更点总结

F1 AIAG 第四版 FMEA 参考手册变更为 AIAG & VDA FMEA 手册

F1.1 AIAG 第四版 DFMEA 变更为 AIAG & VDA FMEA 手册 DFMEA

AIAG & VDA FMEA 方法按七步法过程进行说明。这些步骤为 AIAG & VDA DFMEA 过程步骤的综合。例如，方块图/边界图显示为七步法过程的步骤 2，并且同一交付结果在第 4 版中则显示为先决条件。

在 DFMEA 中删除了特殊特性，但在 PFMEA 中，却保留了特殊特性（见附录 D1 特殊特性）。

为进行持续改进，添加了"历史/变更授权"列（供适用时使用）

解释了 DFMEA 与 PFMEA 之间的关联以及 FMEA 的协作（顾客——第 n 级 ——第 n + 1 级）。

步骤一：规划和准备

第 4 版《基础 FMEA 指南》的第二章"FMEA 概述"和第三章"DFMEA"涉及部分准备工作。步骤 1 包括"5T"的定义：将用于记录分析的目的、时间安排、团队、任务和工具以及适当时分析项目和基准 DFMEA 的确定。

步骤 1 中确定了 FMEA 表头，进行了以下变更：

i. 添加了**公司名称**
ii. 删除了**系统、子系统或组件**标记
iii. 添加了**工程地点**
iv. 添加了**顾客名称**
v. **年型/项目变更**为**年型/平台**
vi. 添加了**项目**
vii. 删除了**关键日期**
viii. 添加了**修订日期**
ix. **FMEA 编号**变更为 **DFMEA ID 编号**
x. 删除了**页码/页数**
xi. **编制人**变更为**设计责任人**
xii. **FMEA 日期（初始日期）**已变更为**开始日期**
xiii. **核心团队**变更为**跨职能团队**
xiv. 添加了**保密级别**

变更原因：使用一般术语并载入记录管理所需的信息

2nd Step: Structure Analysis

For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT with SYSTEM as Next Higher Level, SYSTEM ELEMENT as Focus Element, and COMPONENT ELEMENT as Next Lower Level or Characteristic Type.

Collaboration between customer and supplier is defined and added.

Reason for change: To correctly identify the system, subsystem, component and/or characteristic in relation to the item (focus element) being analyzed. This information is needed for Step 3, Function Analysis.

1. Next Higher Level SYSTEM	2. Focus Element SYSTEM ELEMENT	3. Next Lower Level or Characteristic Type COMPONENT ELEMENT

3rd Step: Function Analysis

AIAG 4TH Edition Form Sheet A and C: Item/Function and Requirement are split so that Item is part of Step 1 and Function and Requirement space is available for each of the levels defined in Step 2.

The description is more detailed how to formulate functions.

Detailed definition of requirements / characteristics and usage of P-Diagram explained.

Collaboration between engineering teams is described.

Reason for change: To establish the functions for each Item/System Element to demonstrate an understanding of how each level contributes to the functionality of the next higher level. Considering and listing the positive Functions and Requirements of the Product leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

Important note: AIAG Form Sheet A and C: Item/Function needed correction due to instances where customers have received DFMEAs showing an Item description and Failure Mode with no Function or Requirement identified. The expectation is that a Function and Requirement are necessary for an understanding of how the Function could fail.

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

步骤二：结构分析

对于 DFMEA，项目扩展为系统、系统要素以及组件要素，其中系统为上一较高级别，系统要素为关注要素，而组件要素为下一较低级别或特性类型。

定义并增加了顾客与供应商之间的协作。

变更原因：分析了正确识别与项目（关注元件）相关的系统、子系统、组件和/或特性。步骤 3"功能分析"需要此信息。

1. 上一较高级别	2. 关注要素	3.下一较低级别或特性类型
系统	系统要素	组件要素

步骤三：功能分析

AIAG 第四版表格 A 和 C：项目/功能和要求是分开的，因此项目纳入步骤 1 中，"功能和要求"空白处可用于步骤 2 中确定的各个级别。

该描述更详细地说明了如何表达各功能。

详细定义了所述参数图（P-图）的要求/特性和用法。

对工程团队之间的协作进行了说明。

变更原因： 确定每个项目/系统要素的功能，以展示对"各级别是如何贡献给上一更高级别的功能"的理解。考虑并列出产品的正向功能和要求后，可列出负面因素、失效影响以及失效起因。

重要注释：AIAG 表格 A 和 C：之所以项目/功能需要更正，原因在于，顾客已收到显示项目描述和未确定功能或要求的失效模式的 DFMEA。按照预期，功能和要求是理解功能如何失效所必需的。

1. 上一较高级别功能及要求	2. 关注要素功能及要求	3. 下一较低级别功能及要求或特性

4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

i. **Potential Failure Mode** changed to: **Failure Mode (FM) of the Focus Element**

ii. **Potential Failure Effect** changed to: **Failure Effects (FE) to the Next Higher level Element and/or End User**

iii. **Potential Failure Cause** changed to: **Failure Cause (FC) of the Next Lower Element or Characteristic**

iv. Order of columns changed from **FM, FE, FC** to **FE, FM, FC**

> Important note: Although the order of columns changed, the order of creating the analysis using a spreadsheet remains the same. It is necessary to identify first the (FM), then either the (FE) or (FC) depending on the team. When using FMEA-dedicated software the team may perform the DFMEA in a different way e.g. identifying failures and then linking them in a proper failure chain of (FE), (FM), (FC).

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Reason for change: To promote the cause and effect analysis in terms of a chain of potential events. The structure, function, and failure sections of the form sheet are designed using a pattern that leads to three levels of a failure chain (FE), (FM), (FC).

5th Step: Risk Analysis

The term "ranking" replaced by "rating" because each failure is rated according to the criteria defined in the rating charts. Each rating chart has a new column to add company-specific examples

i. **Severity** rating – Ten-point scale with similar definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR when rating the (FE) to the end user level.

ii. **Occurrence** rating – Ten-point scale with added emphasis on Prevention Controls as input to the Occurrence rating.

iii. **Detection** rating – Ten-point scale that considers Ability to Detect, Detection Method Maturity, and Opportunity for Detection.

iv. **Action Priority (AP)** is offered as a replacement for Risk Priority Number (RPN) – Reference AP table for High-Medium-Low assignments. There is a common AP table for DFMEA and PFMEA.

v. **Classification** replaced with **Filter Code (Optional)** – The Filter Code column may be used to flag potential special characteristics or other information designated by the company.

步骤四：失效分析

关注要素的概念确定了分析的重点。

i. **潜在失效模式**变更为：**关注要素的失效模式（FM）**

ii. **潜在失效影响**变更为：**对上一较高级别要素和/或最终用户的失效影响（FE）**

iii. **潜在失效原因**变更为：**下一较低级别要素或特性的失效起因（FC）**

iv. **各列顺序从 FM、FE、FC 变更为 FE、FM、FC**

> 重要注释：虽然各列顺序已发生变更，但使用电子表格创建分析的顺序保持不变。首先需要确定（FM），然后由团队确定（FE）或（FC）。当使用 FMEA 专用软件时，团队可采用不同的方式执行 DFMEA，例如，确定失效，然后在（FE）、（FM）、（FC）的适当失效链中将其联系起来。

通过对问题解决方法的系统说明来确定失效。

更详细的说明如何通过示例来表示失效影响、失效模式和失效起因。

呈现了 PFMEA 和 DFMEA 之间的关系。

对表格中可能的视图进行了说明。

对顾客和供应商之间的协作进行了解释。

1. 对上一较高级别要素和/或最终用户的失效影响（FE）	2. 关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）

变更原因：根据一系列潜在事件进行因果分析。表格的结构、功能和失效部分使用形成失效链(FE)、(FM)、（FC）三个级别的模式进行了设计。

步骤五：风险分析

之所以术语"排名"替换为"评级"，原因在于，失效均根据评级表中确定的标准进行评级。每个评级表都有一个新列，用于添加公司特定的示例

i. **严重度**评级——对各个级别均定义了新的十分制量表。评级 10 和 9 与功能安全组对应（无论警告如何，安全评级为 10，而法规评级为 9）。在（FE）评级为最终用户级别时，DFMEA、PFMEA 和 FMEA-MSR 采用相同的量表。

ii. **频度**评级——十分制量表，并额外强调将预防控制作为频度评级的输入。

iii. **探测度**评级——考虑探测能力、探测方法成熟度和探测机会的十分制量表。

iv. 提供**措施优先级（AP）**，以替代风险顺序数（RPN）——参考高-中-低分配的 AP 表。AP 表对 DFMEA 和 PFMEA 通用。

v. **分类**替换为**筛选器代码（可选）**——"筛选器代码"列可用于标记潜在特殊特性或公司指定的其他信息。

Reason for change: Rating charts revised for global use by automotive OEMs and suppliers to encourage more effective and efficient DFMEAs by using common rating criteria. The AP table considers the importance of Severity, then Occurrence, then Detection when prioritizing actions for risk reduction as described in the AIAG 4th Edition FMEA Manual. The AP (H-M-L) considers the ratings of S, O, and D at the same time and applies logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

Classification of failures as shown on product drawings and/or specifications (standard or special type) is not a requirement of DFMEA, therefore the column was removed and replaced with a Filter Code column.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

More detailed evaluation tables for occurrence and detection with examples.

Collaboration between customer and supplier explained.

1. Failure Effects (FE) to the Next Higher- Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)

6th Step: Optimization

The definition of optimization is detailed in the AIAG & VDA FMEA Handbook.

i. Recommended Action split into two columns: **Preventive Action and Detection Action**

ii. New: **Status** (Suggested status levels: Open, Completed, Discarded)

iii. Changed: **Action Taken with Pointer to Evidence**

iv. New: **Remarks** (for DFMEA team or internal use)

New assessment of action effectiveness defined.

Continual improvement described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change: The information helps the user with visual management to be sure each piece of information is included and correct. Important is the "Pointer to Evidence" for follow-up reasons.

DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks

变更原因：为便于全球使用，汽车 OEM 和供应商通过使用一般评级标准修订的评级表旨在提高 DFMEA 的效果和效率。在为 AIAG 第 4 版 FMEA 手册中所述的降低风险措施进行优先排序时，AP 表依次考虑了严重度、频度和探测度的重要性。AP（H-M-L）同时考虑 S、O 和 D 的评级，并应用逻辑来确定措施优先级。该表还就三个 AP 级别的工作方式提出了相应的建议。

产品图纸和/或规范（标准或特殊类型）中所示的失效分类并非 DFMEA 的要求，因此删除了该列并替换为"筛选器代码"列。

即使是在未来使用，当前控制也构成风险分析的一部分。对于频度和探测度，给出了更详细的、带示例的评估表。

对顾客和供应商之间的协作进行了解释。

1.对上一较高级别要素和/或最终用户的失效影响（FE）	FE 严重度（S）	2.关注要素的失效模式(FM)	3.下一较低级别要素或特性的失效起因（FC）	FC 的当前预防控制（PC）	FC 的频度（O）	FC 或 FM 的当前探测控制	FC/FM 的探测度（D）	PFMEA 措施优先级	筛选器代码（可选）

步骤六：优化

优化的定义详见 AIAG & VDA FMEA 手册。

i. 建议的措施分为两列：**预防措施和探测措施**

ii. 新增内容：状态（建议状态级别：尚未确定、已完成、已弃用）

iii. 变更内容：**采取基于证据的措施**

iv. 新增内容：**备注**（供 DFMEA 团队或内部使用）

措施有效性的新评估已确定。

对持续改进进行了说明。

对 FMEA 团队、管理层、顾客和供应商之间的协作进行了解释。

变更原因：该信息可帮助用户进行可视化管理，以确保所有的信息均被纳入且准确无误。由于跟踪的原因，重要的是"采取基于证据的措施"。

DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	DFMEA 措施优先级	筛选器代码（可选）

7th Step: Result Documentation

Step 7 summarizes the scope and results of the DFMEA in a report for review by internal management and/or the customer. The AIAG 4th Edition FMEA manual indicates that management owns the FMEA process and has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process including timing. These statements are found in Chapter 2, Strategy, Planning, Implementation. However, the 4th Edition does not provide additional guidance on how to engage management in the DFMEA team. Step 7 provides recommendations for what to include in results documentation. This report should indicate the technical risk of failure as a component of the development plan and project milestones.

F1.2 AIAG 4th Edition PFMEA to AIAG & VDA FMEA Handbook PFMEA

The AIAG & VDA FMEA method is described by a 7-Step approach. The descriptions below compare these 7-Steps to the current AIAG process. The comparisons include all form sheets used in both manuals. As appropriate, it will be pointed out why (Reason for change or Reason for use) the change can help lead to a more complete PFMEA.

1st Step: Planning & Preparation -

i. **Define the Scope** changed to **1st Step: Planning & Preparation**

2nd Step: Structure Analysis -

i. **Item** changed to **Process Item System, Subsystem, Part Element or Name of Process**
Note: Different form formats, allow this to be listed a single place or on each line.

ii. **Process Step** changed to **Process Step Station No.** and **Name of Focus Element**

iii. **Process Work Element 4M Type has been added.**

Reason for use: This added step (4M) requires the users to consider the 4M's while reviewing the activity taking place within the process.

1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

Or alternate form sheet

1. Process Item System, Subsystem, Part Element or Name of Process	
2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

步骤七：结果文件化

步骤七总结了报告中 DFMEA 的范围和结果，供内部管理层和/或顾客评审。据 AIAG 第四版 FMEA 手册所述，FMEA 过程归管理层所有，并最终负责资源的选择和应用，并确保时间安排等风险管理过程有效。这些说明见第 2 章“战略、规划、实施”。然而，第 4 版并没有就如何在 DFMEA 团队中进行管理提供额外的指导。步骤七还给出了有关“结果文件化”的建议。本报告应指出失效发生的技术风险，以视作组件开发计划和项目里程碑的一部分。

F1.2 AIAG 第四版 PFMEA 变更为 AIAG & VDA FMEA 手册 PFMEA

AIAG & VDA FMEA 方法按七步法过程进行说明。以下说明将这七个步骤与当前的 AIAG 进行比较。比较内容包括两本手册中使用的所有表格。适当时，将指出变更（变更原因或使用原因）有助于实现更完整的 PFMEA 的原因。

步骤一：规划和准备 -

i. **范围定义**变更为**步骤一：规划和准备：**

步骤二：结构分析-

i. **项目**已更改为**过程项 系统、子系统、零件要素或过程名称**
注：不同的表单格式可将其列在单独的位置或各行。

ii. **过程步骤**变更为**过程步骤 工位编号和关注要素名称**

iii. **添加了过程工作要素 4M 类型。**

使用原因：此增加的步骤（4M）要求用户在评审该过程中发生的活动时，对 4M 加以考虑。

1. 过程项 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素 4M 类型

或替代表格

1.过程项 系统、子系统、零件要素或过程名称	
2. 过程步骤工位编号和关注要素名称	3. 过程工作要素4M类型

3rd Step: Function Analysis

i. **Function of the Process Item Function of System, Subsystem, Part Element or Process has been added.**
Reason for use - Listing the positive functions of the process helps to identify the negatives, which are the Failure Effects.

ii. **Function** (one column) and its **Requirement / Product** (one column) changed to **Function of the Process Step** and **Product Characteristic** (single column) or **Function of the Process Step** (one column) and **Product Characteristic** (one column), depending on form sheet used.

iii. **Function** (one column) and its **Requirements / Process** (one column) changed to **Function of the Process Work Element** and **Process Characteristic** (single column) or **Function of the Process Work Element** (one column) and **Process Characteristic** (one column), depending on form sheet used.

Note: AIAG Form Sheets G and H, added an additional column to list the Requirements / Process. While the form sheets include this additional column, it did not include an additional column for the Function / Process. The intent, while not stated, was to list Function / Process in the single Function column.

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

Or alternate form sheet

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	
2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

Or alternate form sheet

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)

步骤三：功能分析

i. **添加了过程项的功能系统、子系统、零件要素或过程的功能。**

使用原因—列出该过程的正向功能有助于确定负面因素，即失效影响。

ii. 根据使用的表格，**功能**（一列）及其**要求/产品**（一列）变更为**过程步骤**的**功能和产品特性**（单列）或**过程步骤**（一列）的**功能**和**产品特性**（一列）。

iii. 根据使用的表格，**功能**（一列）及其**要求/过程**（一列）更改为**过程工作要素的功能和过程特性**（单列）或**过程工作要素**（一列）**功能**和**过程特性**（一列）。

> 注：　AIAG 表格 G 和 H 添加了一个附加列，以列出要求/过程。虽然这些表格包含此附加列，但它不包含功能/过程的附加列。虽然未进行说明，但其目的在于在单个"功能"列中列出功能/过程。

1. 过程项的功能 系统、子系统、零件要素或过程的功能	2.过程步骤的功能和产品特性 （量值为可选项）	3. 过程工作要素的功能和过程特性

或替代表格

1. 过程项的功能 系统、子系统、零件要素或过程的功能	
2. 过程步骤的功能和产品特性 （量值为可选项）	3. 过程工作要素的功能和过程特性

或替代表格

1. 过程项的功能 系统、子系统、零件要素或过程的功能	2.a 过程步骤的功能	2.b 产品特性(量值为可选项)	3.a 过程工作要素的功能	3.b 过程特性 （量值为可选项）

4th Step: Failure Analysis -

i. **Potential Effect(s) of Failure** changed to **Failure Effects (FE)** to the next **Higher Level Element** and/or **Vehicle End User**

ii. **Severity** changed to **Severity (S) of FE**
Note: The AIAG Severity Table was based on **Effect on Customer** and **Effect on Manufacturing**, while AIAG & VDA Severity table is also based on **Effect End User**, it divides **Effect on Manufacturing** into two sections, **Impact to Your Plant** and **Impact to Ship-to Plant (when known)**.

Reason for change: The division of manufacturing requires the user to consider the internal impact and external impact to manufacturing.

iii. **Potential Failure Mode** changed to **Failure Mode (FM) of the Focus Element**.

iv. **Potential Cause(s) of Failure** changed to **Failure Cause (FC) of the Work Element.**



5th Step: Risk Analysis -

i. **Current Process Controls – Prevention** changed to **Current Prevention Control (PC) of FC.**

ii. **Occurrence** changed to **Occurrence (O) of the FC.**

Note: The AIAG Occurrence Table was based on "Likelihood of Failure" and "Incidents items / vehicles" while the AIAG & VDA Table is based on "Prediction of Failure Cause Occurring", "Type of Control", and "Prevention Controls".

Reason for Change: The AIAG & VDA is based on the robustness of the Prevention Controls and can be applied to any production rate.

iii. **Current Detection Process Controls / Cause** and **Current Detection Process Controls / Failure Mode (Form Sheet E)** is changed to **Current Detection Controls (DC) of FC or FM.**

iv. **Detection** changed to **Detection (D) of the FC / FM**".

Note: The AIAG Detection Table was based on "Opportunity for Detection", "Likelihood of Detection by Process Control" and "Likelihood of Detection, while the AIAG & VDA Table is based on "Detection Method Maturity", "Opportunity for Detection" and "Ability to Detect". Both tables are based on a 1 to 10 scale.

v. **RPN** changed to **PFMEA AP**.

Reason for Change: The RPN scale is 1 to 1,000 based on the simple multiplication of S, O and D and does apply logic. The AP (Action Priority) scale is L (Low), M (Medium) and H (High) and is based on taking into account the rating of S, O, and D at the same time and applies logic to determine the priority of action.

vi. **Classification** changed to **Special Characteristics**.

Note: Special Characteristics and Filter Code are sub-categories of AIAG Classification.

vii. **Filter Code (Optional)** new for AIAG & VDA Handbook.



步骤四：失效分析-

i. **潜在失效影响**已变更为**上一较高级别要素**和/或**车辆最终用户的失效影响（FE）**

ii. **严重度**已变更为 **FE 的严重度（S）**

注：AIAG 严重度表基于**对顾客及制造的影响**，而 AIAG&/VDA 严重度表则基于**最终用户的影响**，它将对制造的影响分为两部分：**对工厂的影响**和**对发运至工厂的影响**（已知悉时）。

变更原因：制造业的分工要求用户考虑对制造业的内部影响和外部影响。

iii. **潜在失效模式**已更改为**关注要素的失效模式（FM）**。

iv. **潜在失效起因**已变更为**工作要素的失效起因（FC）**。



步骤五：风险分析-

i. **当前过程控制——预防**已变更为 **FC 的当前预防控制（PC）**。

ii. **频度**变更为 FC 的**频度**（O）。

注：AIAG 频度表基于"失效可能性"和"事故项目/车辆"，而 AIAG/VDA 表基于"失效起因发生的预测"、"控制类型"和"预防控制"。

变更原因：AIAG&/VDA 基于预防控制的稳健性，可应用于任何生产方式。

iii. **当前探测过程控制/原因和当前探测过程控制/失效模式（E 表格）**变更为 **FC 或 FM 的当前探测控制（DC）**。

iv. **探测**变更为 **FC/FM 的探测度（D）**。

注：AIAG 探测表基于"探测机会"、"过程控制探测的可能性"和"探测可能性"，而 AIAG & VDA 表基于"探测方法成熟度"、"探测概率"和"探测能力"。两个表均采用十分制量表。

v. **RPN** 变更为 **PFMEA AP**。

变更原因：基于 S、O 和 D 的简单乘法，RPN 量表范围在 1 到 1,000 之间，并且应用逻辑。AP（措施优先级）量表分为 L（低）、M（中）和 H（高）级别，并且同时考虑 S、O 和 D 的评级并且应用逻辑来确定措施优先级。

vi. **分类**变更为**特殊特性。**

注：特殊特性和筛选器代码为 AIAG 分类的子类别。

vii. AIAG & VDA 新增的**筛选器代码（可选）**。



6th Step: Optimization -

i. Recommended Action changed to Prevention Action and Detection Action

Reason for change: The division of information helps the user with visual management of actions related to Prevention and Detection.

ii. **Responsibility & Target Completion Date** changed to **Responsible Persons Name** and **Target Completion Date.**

Reason for change: Requires a name rather than a department.

iii. **Status** new for AIAG & VDA Handbook.

Reason for change: Users can track the percentage of completion.

iv. **Action Results - Actions Taken Completion Date and Actions Taken & Effective Date** (Form Sheets A ~ H) is changed to Action Taken with Pointer to Evidence and Completion Date.

Reason for change: In addition to listing actions taken, a direction to evidence is required.

v. **Severity / Occurrence / Detection / RPN** changed to **Severity / Occurrence / Detection / AP.**

vi. **Special Characteristics** new for AIAG & VDA Handbook.

vii. **Remarks** new for AIAG & VDA Handbook.

Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks

7th Step: Results Documentation –

Step 7 summarizes the scope and results of the DFMEA in a report for review by internal management and/or the customer. The AIAG 4th Edition FMEA manual indicates that management owns the FMEA process and has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process including timing. These statements are found in Chapter 2, Strategy, Planning, Implementation. However, the 4th Edition does not provide additional guidance on how to engage management in the DFMEA team. Step 7 provides recommendations for what to include in results documentation. This report should indicate the technical risk of failure as a component of the development plan and project milestones.

步骤六：优化

i. 建议措施已变更为"预防措施和探测措施"

变更原因：信息的划分有助于用户可视化管理与预防和探测相关的措施。

ii. **责任及目标完成日期**已变更为**负责人姓名及目标完成日期。**

变更原因：需要一个姓名而非部门。

iii. AIAG-VDA 新增的**状态。**

变更原因：用户可跟踪完成的百分比。

iv. **措施结果——采取的措施完成日期和采取的措施及生效日期（表格 A~H）**变更为采取基于证据的措施和完成日期。

变更原因：除了列出所采取的行动外，还需要对应证据。

v. **严重度/频度/探测度/ RPN** 变更为**严重度/频度/探测度/AP。**

vi. AIAG-VDA 新增的**特殊特性。**

vii. AIAG-VDA 新增的**备注。**

预防措施	探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	特殊特性	PFMEA 措施优先级	备注

步骤七：结果文件化 –

步骤七总结了报告中 DFMEA 的范围和结果，供内部管理层和/或顾客评审。据 AIAG 第四版 FMEA 手册所述，FMEA 过程归管理层所有，并最终负责资源的选择和应用，并确保时间安排等风险管理过程有效。这些说明见第 2 章"战略、规划、实施"。然而，第 4 版并没有就如何在 DFMEA 团队中进行管理提供额外的指导。步骤七还给出了有关"结果文件化"的建议。本报告应指出失效发生的技术风险，以视作组件开发计划和项目里程碑的一部分。

F2 VDA Volume 4, Chapter Product and Process FMEA to AIAG & VDA FMEA Handbook

F2.1 VDA Volume 4, Chapter Product DFMEA to AIAG & VDA FMEA Handbook

The FMEA Method is described by seven-step approach, similar to the previous five-step approach in VDA Volume 4, Product and Process FMEA.

The section Definition is the new first step Preparation and Project Planning. The result documentation is added as step seven.

1. Preparation and Project Planning
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimization
7. Result Documentation

Special Characteristics are removed from the DFMEA Form Sheet but stay in the PFMEA Form Sheet. See Annex D1 Special Characteristics.

For continuous Improvement history column is added and the authorization column changed.

The linkage between DFMEA and PFMEA is explained and the FMEA Collaboration (Customer – Tier n – Tier n+1).

The comparison below shows the format of FMEA Form Sheets listed in the VDA Volume 4 to the form sheets listed in the AIAG & VDA Handbook including those listed in the Appendices.

As appropriate, it will be pointed out why (**Reason for change**) the format can help lead to a more complete DFMEA.

1st Step: Planning and Preparation

"Definition - D" is replaced by **"1st Step: Planning and Preparation"**. Preparation is partly considered in definition. Both sections define the depth of what will be included in the document.

FMEA Form Sheet header is defined within step 1 and new columns are changed or added.

i. Changed: Model Year(s) / Program(s)
ii. Changed: Subject
iii. Changed: Start Date and Revision Date
iv. Changed: Cross Functional Team
v. Changed: DFMEA ID Number
vi. Changed: Design Responsibility
vii. Added: Company Name
viii. Added: Engineering Location
ix. Added: Customer Name
x. Added: Confidentiality Level

F2 VDA 第四卷产品和过程 FMEA 变更为 AIAG & VDA FMEA 手册

F2.1 VDA 第四卷"产品 DFMEA"一章变更为 AIAG & VDA FMEA 手册

FMEA 方法按七步法进行说明，类似于 VDA 第四卷《产品和过程 FMEA》中的五步法。

"定义"部分为新的第一步：准备和项目规划。添加了结果文件化将作为步骤七。

1. 项目规划和准备
2. 结构分析
3. 功能分析
4. 失效分析
5. 风险分析
6. 优化
7. 结果文件化

在 DFMEA 中删除了特殊特性，但在 PFMEA 中，却保留了特殊特性（见附录 D1 特殊特性）。

为进行持续改进，添加了"历史/变更授权"列（供适用时使用）

对 DFMEA 和 PFMEA 之间的联系进行了解释以及 FMEA 协作（顾客——第 n 层 ——第 n + 1 层）。

如下所示，对 VDA 第 4 卷中列出的 FMEA 表格格式和 AIAG-VDA 手册中列出的表格（包括附录中列出的表格）进行了比较。

适当时，将指出为什么（**变更原因**）格式可以帮助形成更完整的 DFMEA 的原因。

步骤一：规划和准备

"定义（D）"替换为**"步骤一：规划和准备"**。 在定义中考虑了一部分准备工作。这两个部分都定义了文档中包含的内容。

步骤一中确定了 FMEA 表头，并且变更或添加新列。

i. 变更内容： 年型/项目
ii. 变更内容： 项目
iii. 变更内容： 开始日期和修订日期
iv. 变更内容： 跨职能团队
v. 变更内容： DFMEA ID 编号
vi. 变更内容： 设计职责
vii. 添加内容： 公司名称
viii. 添加内容： 工程地点
ix. 添加内容： 顾客名称
x. 添加内容： 保密级别

2nd Step: Structure Analysis

For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT with SYSTEM as Next Higher Level, SYSTEM ELEMENT as Focus Element, and COMPONENT ELEMENT as Next Lower Level or Characteristic Type.

1. Next Higher Level SYSTEM	2. Focus Element SYSTEM ELEMENT	3. Next Lower Level or Characteristic Type COMPONENT ELEMENT

Connection description with process flow diagram and structure tree.

Possible views in form sheet are described.

Collaboration between customer and supplier is defined and added.

Reason for change:

This focuses the FMEA team on the Element to analyze. The Next Higher and Lower Level help to identify the Effect of Failure, and the Causes of Failure link in the defined SYSTEM.

3rd Step: Function Analysis

For DFMEA, FUNCTION/REQUIREMENT is expanded to Function and Requirement or Intended Output of System (Next Higher Level), Function and Requirement and Intended Performance Output of System Element (Focus Element), and Function and Requirement or Characteristic or Intended Function or Characteristics of Component Element (Next Lower Level or Characteristic Type).

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

The description is more detailed how to formulate functions.

Detailed definition of requirements / characteristics and usage of P-Diagram explained.

Possible view in form sheet is described

Collaboration between engineering teams is described.

Reason for change:

Considering and listing the positive Functions and Requirements of the Product, leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

步骤二：结构分析

对于 DFMEA，项目扩展为系统、系统要素以及组件要素，其中系统为上一较高级别，系统要素为关注要素，而组件要素为下一较低级别或特性类型。

1. 上一较高级别 系统	2. 关注要素 系统要素	3.下一较低级别或特性类型 组件要素

对过程流程图和结构树的关联进行了说明。

对表格中可能的视图进行了说明。

定义并增加了顾客与供应商之间的协作。

变更原因：

这使 FMEA 团队专注于要素的分析。上一较高和较低级别有助于识别确定系统中的失效影响和失效起因的联系。

步骤三：功能分析

对于 DFMEA，功能/要求扩展到系统的功能和要求或预期输出（上一较高级别）、系统要素的功能和要求或预期性能输出（关注要素），以及组件要素的功能和要求或特性或预期功能或特性（下一较低级别或特性类型）。

1. 上一较高级别功能及要求	2. 关注要素功能及要求	3. 下一较低级别功能及要求或特性

该描述更详细地说明如何解释各功能。

详细定义了所述参数图（P-图）的要求/特性和用法。

对表格中可能的视图进行了说明。

对工程团队之间的协作进行了说明。

变更原因：

考虑并列出产品的正向功能和要求后，可列出负面因素、失效影响以及失效起因。

4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The Failure Effects (FE) to the Next Higher Level Element and/or End User, the Failure Mode (FM) of the Focus Element, and the Failure Cause (FC) of the Next Lower Element or Characteristic are aligned in the SYSTEM.

5th Step: Risk Analysis

Severity (S) rating:

Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Occurrence (O) rating:

Ten point scale with new definitions for each level. Emphasis on Prevention Controls as input to the Occurrence rating added.

Detection (D) rating:

Ten point scale with new definitions for each level. Ability to detect and timing considered.

Action Priority (AP):

Risk Priority Number (RPN) with Action Priority (AP) replaced. The same table is used for DFMEA und PFMEA. The Action Priority is shown by 'high', 'medium' and 'low'.

步骤四：失效分析

关注要素概念确定了分析的焦点。

1. 对上一较高级别要素和/或最终用户的失效影响（FE）	2. 关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）

通过对问题解决方法的系统说明来确定失效。

更详细的说明如何通过示例来表示失效影响、失效模式和失效起因。

呈现了 PFMEA 和 DFMEA 之间的关系。

对表格中可能的视图进行了说明。

对顾客和供应商之间的协作进行了解释。

变更原因：

在系统中，对上一较高级别要素和/或最终用户的失效影响（FE）、关注要素的失效模式（FM）和下一较低级别要素或特性的失效起因（FC）进行调整。

步骤五：风险分析

严重度（S）评级：

对各个级别均定义了新的十分制量表。评级 10 和 9 与功能安全组对应（无论警告如何，安全评级为 10，而法规评级为 9）。DFMEA、PFMEA 和 FMEA-MSR 使用相同的量表。

频度（O）评级：

十分制量表，附带各级别的新定义。强调预防控制措施作为添加的频度评级的输入。

探测度（D）评级：

十分制量表，附带各级别的新定义。探测能力和时间安排考虑在内。

措施优先级（AP）：

风险顺序数（RPN）替换为措施优先级（AP）——DFMEA 和 PFMEA 使用同一个表。措施优先级按"高"、"中"和"低"表示。

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)

More detailed definition of current prevention and current detection controls with examples instead of prevention and detection actions.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

New and more detailed described evaluation table of severity of "end user".

More detailed described evaluation tables occurrence and detection with examples.

AP as replacement of RPN introduced with Action Priority high, medium, and low.

New column "Filter Code (Optional)" introduced.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The AP (Action Priority) scale is L (Low), M (Medium), and H (High) is based on taking into account the rating of S, O, and D at the same time and applying logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

6th Step: Optimization

Definition of optimization detailed.

DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the "Pointer to Evidence" for follow-up reasons.

1.对上一较高级别要素和/或最终用户的失效影响（FE）	FE 严重度（S）	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）	FC 的当前预防控制（PC）	FC 的频度（O）	FC 或 FM 的当前探测控制	FC/FM 的探测度（D）	PFMEA AP	筛选器代码（可选）

通过实例而不是预防和探测措施，更详细地定义了当前预防和探测控制。

即使未来会实施，当前控制仍属于风险分析的一部分。

对新增更详细的"最终用户"严重度评估表的进行了说明。

通过示例更详细地说明了频度和探测度的评估表。

RPN 替换为通过高、中、低等措施优先级引入的 AP。

新引入的"筛选器代码（可选）"列。

对表格中可能的视图进行了说明。

对顾客和供应商之间的协作进行了解释。

变更原因：

基于同时考虑 S、O 和 D 的级别并应用逻辑来确定措施优先级，AP（措施优先级）量表划分为 L（低）、M（中）、H（高）三个级别。该表还就三个 AP 级别的解决方法提出了建议。

步骤六：优化

对优化定义进行了详细说明。

DFMEA 预防措施	DFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	DFMEA 措施优先级	筛选器代码（可选）

定义了不同措施的状态。

定义了措施有效性的重新新评估；

对持续改进进行说明。

备注列添加到文档内部意见、注释和筛选器列，以处理数据。

对表格中可能的视图进行了说明。

对 FMEA 团队、管理层、顾客和供应商之间的协作进行了解释。

变更原因：

该信息可帮助用户进行可视化管理，确保所有的信息均被纳入且准确无误。由于跟踪原因，重要的是"基于证据"。

7th Step: Result Documentation

The added step seven summarizes the scope and results of an FMEA in a report.

This report should indicate the technical risk of failure as a component of the development plan and project milestones.

F2.2 VDA Volume 4, Chapter Process PFMEA to AIAG & VDA FMEA Handbook

The FMEA Method is described by seven-step approach, similar to the previous five-step approach in VDA Volume 4, Product and Process FMEA.

The section Definition is the new first step Preparation and Project Planning. The result documentation is added as step seven.

1. Preparation and Project Planning
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimization
7. Result Documentation

Special Characteristics stay in the PFMEA Form Sheet but are removed from the DFMEA Form Sheet. See Annex C1 Special Characteristics.

For continuous Improvement history column is added and the authorization column changed.

The linkage between DFMEA and PFMEA is explained and the FMEA Collaboration (Customer – Tier n – Tier n+1).

The comparison below shows the format of FMEA Form Sheets listed in the VDA Volume 4 to the forms listed in the AIAG & VDA Handbook including those listed in the Appendices.

As appropriate, it will be pointed out why (**Reason for change**) the format can help lead to a more complete PFMEA.

1st Step: Planning and Preparation

"**Definition - D**" is replaced by "**1st Step: Planning and Preparation**". Preparation is partly considered in definition. Both sections define the depth of what will be included in the document.

FMEA Form Sheet header is defined within step 1 and new columns are changed or added.

i. Changed: Model Year(s) / Program(s)
ii. Changed: Subject
iii. Changed: Start Date and Revision Date
iv. Changed: Cross Functional Team
v. Changed: PFMEA ID Number
vi. Changed: Process Responsibility
vii. Added: Company Name
viii. Added: Customer Name
ix. Added: Manufacturing Location
x. Added: Confidentiality Level

步骤七：结果文件化

增加的步骤七总结了报告中 FMEA 的范围和结果。

本报告应指出失效发生的技术风险，作为部件开发计划和项目里程碑的一部分。

F2.2 DA 第四卷过程 FMEA 变更为 AIAG & VDA FMEA 手册

FMEA 方法按七步法进行说明，类似于 VDA 第四卷《产品和过程 FMEA》中的五步法。

"定义"部分为新的第一步（准备和项目规划）。结果文件化将作为步骤七予以添加。

1. 项目规划和准备
2. 结构分析
3. 功能分析
4. 失效分析
5. 风险分析
6. 优化
7. 结果文件化

PFMEA 表格中保留了特殊特性，但在 DFMEA 删除了它。见附录 D1 特殊特性。

为进行持续改进，添加了"历史/变更授权"列（供适用时使用）

对 DFMEA 和 PFMEA 之间的联系进行了解释以及 FMEA 协作（顾客——第 n 级 ——第 n + 1 级）。

如下所示，对 VDA 第 4 卷中列出的 FMEA 表格格式和 AIAG-VDA 手册中列出的表格（包括附录中列出的表格）进行了比较。

在适当的情况下，将指出为什么（**变更原因**）格式可以帮助形成更完整的 DFMEA 的原因。

步骤一：规划和准备

"定义（D）"替换为**"步骤一：规划和准备"**。在定义中部分考虑了准备工作。这两个部分都定义了文档中包含的内容的深度。

步骤一中确定了 FMEA 表头，并且变更或添加新列。

i.	变更内容：	年型/项目
ii.	变更内容：	项目
iii.	变更内容：	开始日期和修订日期
iv.	变更内容：	跨职能团队
v.	变更内容：	PFMEA ID 编号
vi.	变更内容：	过程职责
vii.	添加内容：	公司名称
viii.	添加内容：	工程地点
ix.	添加内容：	顾客名称
x.	添加内容：	保密级别

2nd Step: Structure Analysis

For PFMEA, ITEM is expanded to PROCESS ITEM with System, Subsystem, Part Element or Name of Process, PROCESS STEP with Station No. and Name of Focus Element, and PROCESS WORK ELEMENT with 4M Type. PROCESS WORK ELEMENT labels added: Machine, Man, Material (Indirect), EnvironMent (Milieu), etc.

1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

Connection description with process flow diagram and structure tree.

4M especially Material (indirect) is more clarified and detailed explained;

Possible views in form sheet are described.

Collaboration between customer and supplier is defined and added.

Reason for change:

This focuses the FMEA team on the Element to analyze. The Process Item and Process Work Element help to identify the Effect of Failure, and the Causes of Failure link in the defined PROCESS.

3rd Step: Function Analysis

For PFMEA, FUNCTION of Process Item is expanded to Function of System, Subsystem, Part Element or Process, FUNCTION OF PROCESS STEP is expanded to Function of System, Subsystem, Part Element or Process, and FUNCTION OF WORK ELEMENT to Function of the Process Work Element and Process Characteristic.

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

The description is more detailed how to formulate functions.

Detailed definition of functions / characteristics and usage of P-Diagram explained.

Possible view in form sheet is described

Collaboration between engineering teams is described.

Reason for change:

Considering and listing the positive Functions / characteristics of the Process, leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

步骤二：结构分析

对于 PFMEA，项目扩展为过程项包括系统、子系统、零件要素或过程名称、过程步骤包括工位编号和关注要素名称以及过程工作要素包括 4M 类型。添加的过程工作要素标签：设备、人员、材料（间接）、里程碑（环境）等

1. 过程项 系统、子系统、零件要素或过程名称	2. 过程步骤 工位编号和关注要素名称	3. 过程工作要素 4M 类型

过程流程图和结构树的关联说明。

4M，尤其是材料（间接）的解释更明确且更详细。

对表格中可能的视图进行了说明。

顾客与供应商之间的协作经确认并予以添加。

变更原因：

这使 FMEA 团队专注于要素的分析。过程名称和过程工作要素有助于识别确定系统中的失效影响和失效起因的联系。

步骤三：功能分析

对于 PFMEA，过程项的功能扩展到系统、子系统、零件要素或过程的功能、过程步骤的功能扩展到系统、子系统、零件要素或过程的功能，以及工作要素的功能扩展到过程工作要素的功能和过程特性。

1. 过程项的功能 系统、子系统、零件要素或过程的功能	2. 过程步骤的功能和产品特性（量值为可选项）	3. 过程工作要素的功能和产品特性

该描述更详细地说明如何解释各功能。

详细定义了所述参数图（P-图）的要求/特性和用法。

对表格中可能的视图进行了说明。

对工程团队之间的协作进行了说明。

变更原因：

考虑并列出过程的正向功能和特性后，可列出负面因素、失效影响以及失效起因。

4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Effects between "your plant", "ship-to-plant" and "end user" defined.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The Failure Effects (FE) to the Next Higher Level Element and/or End User, the Failure Mode (FM) of the Focus Element, and the Failure Cause (FC) of the Next Lower Element or Characteristic are aligned in the SYSTEM.

5th Step: Risk Analysis

Severity (S) rating:

Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Occurrence (O) rating:

Ten point scale with new definitions for each level. Emphasis on Prevention Controls as input to the Occurrence rating added.

Detection (D) rating:

Ten point scale with new definitions for each level. Ability to detect and timing considered.

Action Priority (AP):

Risk Priority Number (RPN) with Action Priority (AP) replaced. The same table is used for DFMEA und PFMEA. The Action Priority is shown by 'high', 'medium' and 'low'.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)

步骤四：失效分析

关注要素概念确定了分析的重点。

1. 对上一较高级别要素和/或最终用户的失效影响（FE）	2. 关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）

通过对问题解决方法的系统说明来确定失效。

更详细地描述了如何通过实例来制定失效影响、失效模式和失效起因。

确定了"您的工厂"、"发运至工厂"和"最终用户"之间的影响。

呈现了 PFMEA 和 DFMEA 之间的关系。

对表格中可能的视图进行了说明。

对顾客和供应商之间的协作进行了解释。

变更原因：

在系统中，对上一较高级别要素和/或最终用户的失效影响（FE）、关注要素的失效模式（FM）和下一较低级别要素或特性的失效起因（FC）进行调整。

步骤五：风险分析

严重度（S）评级：

对各个级别均定义了新的十分制量表。评级 10 和 9 与功能安全组对应（无论警告如何，安全评级为 10，而法规评级为 9）。在（FE）评级为最终用户级别时，DFMEA、PFMEA 和 FMEA-MSR 使用相同的量表。

频度（O）评级：

十分制量表，附带各级别的新定义。强调预防控制作为添加的频度评级的输入。

探测度（D）评级：

十分制量表，附带各级别的新定义。探测能力和时间安排考虑在内。

措施优先级（AP）：

风险顺序数（RPN）替换为措施优先级（AP）——DFMEA 和 PFMEA 使用同一个表。措施优先级按"高"、"中"和"低"表示。

1.对上一较高级别要素和/或最终用户的失效影响（FE）	FE 严重度（S）	2.关注要素的失效模式（FM）	3.下一较低级别要素或特性的失效起因（FC）	FC 的当前预防控制（PC）	FC 的频度（O）	FC 或 FM 的当前探测控制	FC/FM 的探测度（D）	PFMEA AP	特殊特性	筛选器代码（可选）

More detailed definition of current prevention and current detection controls with examples instead of prevention and detection actions.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

New and more detailed described evaluation table of severity with differentiation of "your plant", "ship-to-plant" and "end user".

More detailed described evaluation tables occurrence and detection with examples.

AP as replacement of RPN introduced with Action Priority high, medium, and low.

New column "Filter Code (Optional)" introduced.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The AP (Action Priority) scale is L (Low), M (Medium), and H (High) is based on taking into account the rating of S, O, and D at the same time and applying logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

6th Step: Optimization

Definition of optimization detailed.

PFMEA Preventive Action	PFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the "Pointer to Evidence" for follow-up reasons.

7th Step: Result Documentation

The added step seven summarizes the scope and results of an FMEA in a report.

This report should indicate the technical risk of failure as a component of the development plan and project milestones.

通过实例而不是预防和探测措施，更详细地定义了当前的预防和探测控制。

即使未来会实施，当前控制仍属于风险分析的一部分。

对新增更详细的"最终用户"严重度评估表进行了说明。

通过示例更详细地说明了频度和探测度的评估表。

RPN 替换为通过高、中、低等措施优先级引入的 AP 。

新引入的"筛选器代码（可选）"列。

对表格中可能的视图进行了说明。

对顾客和供应商之间的协作进行了解释。

变更原因：

在同时考虑到 S、O 和 D 的级别并应用逻辑来确定措施优先级，AP（措施优先级）量表被划分为 L（低）、M（中）、H（高）三个级别。该表还就三个 AP 级别的解决方法提出了建议。

步骤六：优化

对优化定义进行了详细说明。

PFMEA 预防措施	PFMEA 探测措施	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	严重度（S）	频度（O）	探测度（D）	DFMEA AP	筛选器代码（可选）

定义了不同措施的状态。

定义了措施有效性的重新评估；

对持续改进进行说明。

备注列添加到文档内部意见、注释和筛选器列，以处理数据。

对表格中可能的视图进行了说明。

对 FMEA 团队、管理层、顾客和供应商之间的协作进行了解释。

变更原因：

该信息可帮助用户进行可视化管理，确保所有的信息均被纳入且准确无误。 由于跟踪原因，重要的是"基于证据 "。

步骤七：结果文件化

增加的步骤七总结了报告中 FMEA 的范围和结果。

本报告应指出失效发生的技术风险，作为组件开发计划和项目里程碑的一部分。

F2.3 VDA Volume 4, Chapter FMEA for Mechatronical Systems to AIAG & VDA FMEA Handbook Supplemental FMEA for Monitoring and System Response (FMEA-MSR)

The VDA Volume 4, Chapter FMEA for Mechatronical Systems" is replaced by "Supplemental FMEA for Monitoring and System Response (FMEA-MSR)".

The FMEA-MSR supplements the Design FMEA. It shows the linkage between Functional Safety and Supplemental FMEA for Monitoring and System Response (FMEA-MSR).

This methodology evaluates the effects of monitoring and system response in a system or product.

Changes to DFMEA are in step five and six.

5th Step: Risk Analysis

Severity (S) rating:

Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Frequency (F) rating:

Ten point scale with new definitions for each level. FMEA-MSR replaces the Occurrence rating scale of a Design FMEA with a Frequency rating scale. Frequency of a failure cause to occur is estimated under customer operating conditions.

Monitoring (M) rating:

Ten point scale with new definitions for each level. FMEA-MSR replaces the Detection rating scale of a Design FMEA with a Monitoring rating scale. Consider capability to monitor and system response.

Action Priority (AP):

Risk Priority Number (RPN) with Action Priority (AP) replaced. The Action Priority is shown by 'high', 'medium' and 'low'.

Supplement of FMEA-MSR Risk Analysis:

Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)

The Supplement shows detailed definition of Rationale for Frequency, Current Diagnostic Monitoring and System Response, Most Severe Failure Effect after System Response, Severity (S) of FE after MSR, Severity (S) of Original FE from Failure Analysis (Step 4), and MSR AP.

MSR AP introduced with Action Priority high, medium, and low.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The FMEA-MSR is a supplement to DFMEA and takes aspects of road vehicle safety in account.

F2.3 VDA 第四卷，机电系统 FMEA 一章变更为 AIAG & VDA FMEA 手册 监视及和系统响应的补充 FMEA（FMEA- MSR）

VDA 第四卷"产品和过程 FMEA"一章的"机电系统的 FMEA"一节替换为"监视及系统响应的补充 FMEA（FMEA- MSR）。

FMEA-MSR 对设计 FMEA 进行了补充。它表现了功能安全与监视及系统响应的补充 FMEA（FMEA-MSR）之间的联系。

该方法评估系统或产品中监视和系统响应的影响。

对 DFMEA 的变更发生在步骤五和步骤六。

步骤五：风险分析

严重度（S）评级：

对各个级别均定义了新的十分制量表。评级 10 和 9 与功能安全组对应（无论警告如何，安全评级为 10，而法规评级为 9）。在（FE）评级为最终用户级别时，DFMEA、PFMEA 和 FMEA-MSR 使用相同的量表。

频率评级：

对各个级别均适用的、且具有新定义的十分制量表。FMEA-MSR 将设计 FMEA 的频度评级量表替换为频率评级量表。在顾客操作条件下估算了失效起因发生的频率。

监视评级：

对各个级别均适用的、且具有新定义的十分制量表。FMEA-MSR 将设计 FMEA 的诊断评级量表替换为监视评级量表。顾客监视能力及系统响应。

措施优先级（AP）：

风险顺序数（RPN）替换为措施优先级（AP）。措施优先级按"高"、"中"、"低"级别表示。

补充 FMEA-MSR 风险分析

频率评级的理由	失效起因的发生频率（F）	当前的诊断监视	当前的系统响应	监视（M）	在系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度	在失效分析中初始失效影响的严重度（S）（步骤四）	MSR 措施优先级	筛选器代码（可选）

补充部分为 MSR AP 详细定义了频率评级理由、当前的诊断监视和系统响应、系统响应后最严重的失效影响、MSR 后 FE 的严重度（S）、失效分析（步骤四）中的初始 FE 的严重度（S）。

MSR AP 引入了高、中、低级别的措施优先等级。

对表格中可能的视图进行了说明

对顾客与供应商之间的协作进行了解释。

变更原因:

FMEA-MSR 是对 DFMEA 的补充，并且考虑了道路车辆安全因素。

6th Step: Optimization

Definition of optimization detailed.

MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	MSR AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the "Pointer to Evidence" for follow-up reasons.

步骤六：优化

对优化定义进行了详细说明。

MSR 预防措施	诊断监视措施	系统响应	系统响应后最严重的失效影响	在 MSR 之后失效影响的严重度	负责人姓名	目标完成日期	状态	采取基于证据的措施	完成日期	频率（F）	监视（M）	MSR 措施优先级	备注

定义了不同措施的状态。

定义了对措施有效性的重新评估；

对持续改进进行说明。

备注列添加到文档内部意见、注释和筛选器列，以处理数据。

对表格中可能的视图进行了说明。

对 FMEA 团队、管理层、顾客和供应商之间的协作进行了解释。

变更原因：

该信息可帮助用户进行可视化管理，确保所有的信息均被纳入且准确无误。由于后续原因，重要的是~~基~~于证据"。

G References and Suggested Readings

- IATF 16949: 2016 Quality management systems
  Particular requirements for the application of ISO 9001
  for automotive production and relevant service part organizations
- ISO 9001 Quality management systems - Requirements
- ISO 26262 Road vehicles - Functional safety
- SAE°J1739 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)
- VDA Volume 2 Quality Assurance of Supplies
- VDA Maturity Level Assurance for New Parts
- AIAG APQP Advanced Production and Quality Planning
- AIAG PPAP Production Part Approval Process

H Glossary

Cyber-Physical Systems: a mechanism that is controlled or monitored by computer-based algorithms, tightly integrated with the Internet and its users

Diagnostic coverage: per ISO 26262-1:2018, the percentage of the failure rate of a hardware element, or percentage of the failure rate of a failure mode of a hardware element that is detected or controlled by the implemented safety mechanism, the diagnostic figures are determined by the hardware functional safety analysis

Failure Chain: A failure chain consists of a Failure Effect, a Failure Mode, and a Failure Cause.

Failure Network: A failure network is the connection of one or more failure chains that can represent failures at multiple levels such that a Failure Cause at one level is a Failure Mode at the next lower level.

Focus Element: The subject of the analysis. In a hierarchically described system, a focus element has a next higher level element and at least one next lower element. A focus element may be a System Element (item), a function of a system element, or a failure to provide a function as specified.

Hybrid Failure Chain: A hybrid failure chain consists of a Failure Cause or Failure Mode, intended Monitoring Controls, and a mitigated failure effect.

Mechatronics: technology combining electronics and mechanical engineering

Operational situation: per ISO 26262-1:2018, a scenario that can occur during a vehicle's life (e.g. driving at high speed; parking on a slope; maintenance)

Primary Vehicle Function: a function that is essential to fulfil the basic purpose of a vehicle, e.g. steering, braking, propulsion, and visibility

Residual Risk: The risk(s) remaining after the deployment of safety measures. See ISO26262-1:2018.

Secondary Vehicle Function: a function that enhances or enables a primary vehicle function as well as the user experience, e.g. safety, comfort, convenience, interface, diagnostic, and serviceability

Service life: the intended design life of the item (FMEA-MSR: the intended design life of the vehicle)

Structure Tree: A graphical depiction of the hierarchical links between system elements and its dependencies.

System Element: elements of a system that are represented in the structure tree

System response: the system's reaction to a detected fault, usually in the form of degrading or disabling of a function and/or warning the operator and setting a fault code

Useful life: the operating interval in which a function is correctly provided, and the failure rate is within acceptable tolerance

Zero Mileage / Zero km / Zero Hours: vehicle has not left the assembly plant

G 参考资料及推荐阅读资料

- IATF 16949 质量管理体系 - 汽车生产件及相关服务件组织应用 ISO 9001 的特殊要求
- ISO 9001 质量管理体系 - 要求
- ISO 26262 道路车辆 - 功能安全
- SAE J1739 设计潜在失效模式与影响分析（设计 FMEA），制造及组装过程的潜在失效模式与影响分析（过程 FMEA）
- VDA 第 2 卷 供应商质量保证
- VDA 新零件的成熟度保障
- AIAG APQP 先期产品质量策划
- AIAG PPAP 生产件批准程序

H 词汇表

网络物理系统：一种通过互联网与系统用户紧密地融合在一起的，基于计算机算法进行控制或监控的机制。

诊断覆盖率：根据 ISO 26262-1:2018 标准，由实施的安全机制所探测或监视到的硬件要素失效率的百分数、或硬件要素失效模式失效率的百分数，诊断数值由硬件功能安全分析确定。

失效链：失效链包括失效影响、失效模式、以及失效起因。

失效网：失效网由一个或多个失效链连接在一起，这些失效链可以在多个层级对失效现象进行显示，这样在某个层级的失效起因在相邻较低层级则为失效模式。

关注要素：位于分析中心的对象；在按层级描述的系统中，关注要素拥有一个上级系统要素，以及至少一个下级系统要素。

混合失效链：混合失效链包括失效起因或失效模式、预期的监测控制，以及缓解的失效影响。

机械电子工程：将电子工程和机械工程结合在一起的技术。

运行状况：根据 ISO 26262-1:2018 标准，在车辆寿命周期内发生的情形（例如：高速驾驶；在坡道上驻车；维修保养）

车辆主要功能：实现车辆基础用途所必需的功能，例如：转向、制动、传动、以及视野要求

残余风险：在部署安全措施之后的剩余风险。请参看 ISO26262- 1:2018。

车辆次要功能：一种能够增强或确保车辆主要功能及良好用户体验的功能，例如：安全性、舒适性、便利性、接口功能、诊断功能，以及可服务性。

使用寿命：商品的预期设计寿命（FMEA-MSR：车辆的预期设计寿命）

结构树：以图解形式描述系统要素及其附属要素之间的层级联系。

系统要素：在结构树中显示的系统内要素

系统响应：系统对探测到的故障的回应，通常以功能降级或禁用和/或向操作人员发出警示信息并设置故障代码方式进行回应

使用寿命：一个可以提供正常功能，并且失效率在可接受公差范围内的操作时间段

0 公里：尚未离开组装厂的车辆

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