



SAE STANDARD

SAE1025™

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Failure Mode and Effects Analysis (FMEA)
Includes Criticality Analysis and Design, Supportability, Software, and Process FMEA

RATIONALE

There are many different Failure Mode and Effects Analysis (FMEA) and Failure Mode, Effects, and Criticality Analysis (FMECA) standards currently being used across many industries, but none of them constitute a complete, authoritative, and up-to-date resource for practitioners. This standard was created to establish a widespread practice for effective design, supportability, and process risk identification, assessment, mitigation, and prevention. This standard establishes contracting and performance requirements for the use of Design Failure Mode and Effects Analysis (DFMEAs), Software Failure Mode and Effects Analysis (SwFMEAs), Supportability Failure Mode and Effects Analysis (SupFMEAs), Process Flow Diagrams (PFDs), Process Failure Mode and Effects Analysis (PFMEAs), and Control Plans (CPs) throughout the product life cycle. It defines a methodology to mitigate risk using DFMEA, SwFMEA, SupFMEA, PFD, PFMEA, and CP. This standard also provides requirements for those organizations directed to complete Quantitative Criticality Analysis.

The four types of FMEA covered in this standard are inclusive of other sub-types. For example, MIL-STD-1629A introduces two FMEA approaches, depending on variation in design complexity and available data: functional approach and hardware approach. In this standard, both of these approaches are included within the framework of Design FMEA. Other FMEA standards include System FMEA, which focuses on early design concepts, with emphasis on high-level functions and interfaces, and is also included within the framework of Design FMEA.

This standard is intended to be used as a replacement for MIL-STD-1629A. Despite being cancelled in 1998, MIL-STD-1629A is still a key reference in the aerospace and Department of War (DoW) sectors. It has steadfastly guided engineering practices for over four decades. Yet, despite its extensive use and critical role, it has not been revised in more than 40 years. This standard recognizes the importance of MIL-STD-1629A, the need for its modernization, and the proposed approach to updating this standard to align with current industry's best practices and technological advancements. The last four decades have witnessed significant technological advancements. New engineering tools and techniques have emerged, offering more efficient and accurate methods for conducting FMEA. However, these advancements are not reflected in the current version of MIL-STD-1629A. Starting with MIL-STD-1629A as a baseline, this standard incorporates these new tools and techniques essential for maintaining its relevance and effectiveness.

While this standard is identified as an FMEA standard, it includes Criticality Analysis and therefore the process previously called FMECA. The terms FMEA and FMECA have caused confusion in the past, with some industries, such as defense, recognizing a difference between the two and others, such as automotive, including a Criticality Analysis element in FMEA. Criticality Analysis is an integral part of FMEA and is necessary to take full advantage of the benefits of FMEA. For clarity and consistency, this standard identifies FMEA as the overall process which includes criticality analysis.

This standard was also developed to provide a common approach to meet the requirements of AS9145. Companies and organizations that use this standard shall meet the DFMEA, PFMEA, PFD, and Control Plan requirements of AS9145. AS9145 is a critical framework designed to enhance product quality and reliability within the aerospace and automotive industries and has been adopted by many other organizations and industries. This standard integrates Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) methodologies into a cohesive and systematic approach, ensuring that all products meet stringent aerospace and automotive requirements. Its purpose is to minimize risks, improve communication, and ensure that products are delivered on time and within budget.

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This standard establishes the timing to complete FMEAs within the product development process and requires continued updates as products, processes, and operations change throughout the product life cycle. This standard is focused on the usefulness of FMEA as a Design Tool and its role in the Decision-Making Process early in the product development process and maintaining configuration control throughout the life cycle of the product. FMEAs should be initiated as soon as the design or process concept is established. One of the key purposes of FMEA is the early identification of failure modes. By assessing potential failure modes during the preliminary design stages, designers can implement corrective actions before the system is fully developed. This proactive approach helps prevent costly redesigns and ensures that the final product meets reliability and safety standards. The standard also focuses on the usefulness of FMEA in the operational phases of the life cycle, providing recommendations for changes to design, processes, and support as operating experience is accrued.

FOREWORD

This standard is intended to be used when establishing, performing, evaluating, or improving the FMEA process. When appropriately and effectively applied, FMEA provides a positive impact on every aspect of the product life cycle. FMEA is a comprehensive process for establishing and maintaining reliability of any product's performance, functional and physical attributes with its requirements, design, and operational information.

This standard provides the rational basis upon which to apply good judgment in both planning for and executing FMEAs. This requires an understanding of what to do and also why it is necessary to tailor the application of the selected FMEA type to meet the program requirements. SAE is publishing one standard to define the application of FMEA for DFMEAs, SwFMEAs, SupFMEAs, and PFMEAs.

To assure customer satisfaction, the automotive, aviation, space, and defense industries and other organizations must produce and continually improve safe, reliable products that equal or exceed customer and regulatory authority requirements. The globalization of the industry and the resulting diversity of regional/national requirements and expectations have complicated this objective. End-product organizations face the challenge of assuring the quality and integration of products purchased from suppliers throughout the world and at all levels within the supply chain. Industry suppliers face the challenge of delivering products to multiple customers, having varying quality expectations and requirements. The principles defined within this standard also apply to other companies or organizations that design or manufacture a product (i.e., medical devices, consumer lifestyle products, electronics, and batteries).

The usefulness of FMEA as a design tool in the decision-making process is dependent upon the effectiveness with which problem information is communicated for early design attention. The greatest criticism of FMEA has been its limited use in improving designs due to untimeliness and isolated performance without adequate input to the design process. Timeliness is the key factor in differentiating between effective and ineffective implementation of FMEA. The primary objective of FMEA is to identify all modes of failure within a system design, with the early identification of catastrophic and critical failure possibilities being its first purpose. FMEA should be initiated as soon as preliminary design information is available at the higher system levels and extended to the lower levels as more information becomes available. Although FMEA is an essential reliability task, it also provides information for maintainability, safety analysis, survivability and vulnerability, logistics support analysis, maintenance planning analysis, and failure detection and isolation subsystem design. This concurrent use must be considered in planning the FMEA effort to prevent the proliferation of requirements and the duplication of efforts within the same program.

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1. SCOPE

FMEA is a systematic approach aimed at identifying and mitigating potential risks in the design, manufacture, and maintenance of a product. Implementing FMEA provides a range of benefits, such as:

- Preventing potential failures early in the life cycle.
- Identifying risk - establishing clear linkages ensures that no potential failure mode is overlooked across the life cycle of the product.
- Improving product safety, reliability, performance, and supportability.
- Enhancing collaboration - the framework fosters cross-functional communication, enabling design, manufacturing, and maintenance teams to work in harmony.
- Achieving effectiveness - by integrating analyses and plans, organizations can streamline workflows and reduce redundancies.
- Reducing costs associated with product failures.
- Enhancing customer satisfaction through consistent quality and reliability.
- Improving product quality - comprehensive linkage reduces errors and ensures a robust design and manufacturing process.
- Providing the basis for developing product support requirements through supportability analysis

FMEA is versatile and shall be applied across various dimensions of product and process management. This standard provides terms, definitions, defined data elements, and essential information within each category of FMEA. There are many types of FMEA, but the primary types defined in this standard include:

- DFMEA: Focuses product design deficiencies during the design phase of a product and is updated based on product design changes throughout the life of the product design.
- SwFMEA: Addresses risks and issues specific to software during the design phase of a product and is updated based on software changes throughout the life of the product design.
- SupFMEA: Evaluates factors affecting product support and maintenance during the design phase of a product and is updated throughout the life of the product design.
- PFMEA: Concentrates on manufacturing and operational processes to identify and mitigate risks during the design phase of a product and is updated based on product or process changes throughout the life of the product design.
- Quantitative Criticality Analysis: Focuses on determining the risk of failure based on calculated or estimated failure rates.

An essential part of the FMEA process is to identify and communicate potential issues that need to be addressed. When significant risks are discovered, it is incumbent on the FMEA team to communicate quickly to key stakeholders so that the project team can address as soon as feasible and not wait until the contracted deliverable is completed. FMEA is a dynamic and living process, the result of which is improved designs, manufacturing processes, and supportability, not forms or databases that are filled out.

This standard applies to any product, process, or software in all phases of their life cycle. As a standard, this document contains requirements ("shall") and recommendations ("should") to guide the user through FMEA methods.

1.1 Responsibility for performing FMEAs.

There are two primary applications for FMEA projects that are within the scope of this standard.

1.1.1 FMEAs Performed to Fulfill the Requirements of a Contract

FMEA services may be contracted for independently or as part of a larger system acquisition. This section is intended to only address the requirements for the contracting for FMEA services whether it is part of a larger contract or for FMEA services only. When developing a contract for completion of FMEAs, two terms will be used:

- The Contracting Authority, or equivalent organization (**Acquirer**), establishes and controls the functional and performance requirements for completion of FMEAs
- The Contractor, or Supplier (**Supplier**), executes the defined functional and performance requirements for completion of FMEAs.

Responsibility of Acquirer

The **Acquirer** is responsible for defining the FMEA requirements and associated deliverables in contracts (or other agreements) with its Suppliers. The **Acquirer** establishes and controls the functional and performance requirements, controls the Supplier agreement, and has oversight and agreement compliance monitoring responsibility during product design, development, manufacturing, deployment, operation, upgrade/modification, maintenance, and disposal.

NOTE: The **Acquirer** is expected to create a set of tailored requirements from this standard that are included as part of internal agreements for enterprises, programs, and projects.

Responsibility of Supplier

The **Supplier** is responsible for complying with the requirements cited in this document, as tailored by the **Acquirer**. In addition, the **Supplier** is responsible for ensuring that their sub-suppliers also conduct FMEAs in such a manner that these requirements are met completely and efficiently.

NOTE: The **Supplier** is responsible for complying with, or requesting that the **Acquirer** grant relief from, the requirements contained in this standard as tailored by the **Acquirer** and documented in the agreement.

Applicability

This document applies to Acquirers and their Suppliers covered by the contract and/or statement of work. FMEA is implemented on programs throughout the product life cycle or as specified in the contract.

1.1.2 FMEAs that are Done within Organization Based on Internal Requirements

When performing FMEAs based only on internal requirements and/or procedures, there is no Acquirer and Supplier relationship.

Responsibility of Organization

The Organization is responsible for defining the FMEA requirements and associated deliverables to each product program/project. The Organization establishes and controls the functional and performance requirements and has oversight and compliance monitoring responsibility during product design, development, manufacturing, deployment, operation, upgrade/modification, maintenance, and disposal.

NOTE: The Organization is expected to create a set of tailored requirements from this standard that are included as part of internal agreements for enterprises, programs, and projects.

1.2 Contracting for FMEA

This document offers a clear description of how to utilize the SAE1025 standard, highlights its key elements, and provides essential information for both contracting and conducting the distinct types of FMEA defined within. FMEA is a critical methodology within all Organizations' (government and commercial) contracting framework. It ensures that potential failure modes in products and processes are systematically identified, assessed, and mitigated. This methodology is indispensable for achieving stringent performance and reliability standards mandated by the Organization. The integration of FMEA projects into the product life cycle phases establishes a robust pathway for risk management, design validation, production readiness, and product support.

It is incumbent upon the Organization to review the contractual requirements to avoid duplication of effort between the reliability program and other program efforts such as safety, maintainability, manufacturing, human engineering, test and evaluation, survivability and vulnerability, maintenance planning, and integrated logistics support. Identification of the concurrent use of FMEA results by the reliability program and other disciplinary areas is required in the FMEA plan or other appropriate program documentation to avoid duplication of effort by the Organization and the Supplier.

The Role of FMEA in Contracting

FMEA occurs during the planning, development, production, and operations and support phases of projects. By systematically identifying potential failure modes, assessing their effects, and prioritizing corrective actions, FMEA enhances decision-making processes at every stage of development.

Developmental Requirements and their FMEA Integration

The contracting framework incorporates FMEA into three key deliverables: FMEA Plan, Completed FMEA(s), and Updated FMEA(s). These deliverables that are produced within the product life cycle phases constitute a structured approach to advance designs, production readiness, and support while maintaining a focus on risk mitigation.

1.2.1 The FMEA Plan

The FMEA Plan shall be submitted to and approved by the Acquirer. The contracting process begins with the development of an FMEA Plan. At this stage, project teams outline the scope and identify and plan the set of FMEAs. This phase emphasizes the importance of aligning FMEA activities with project goals and regulatory requirements. The FMEA Plan lays the foundation for subsequent deliverables and ensures that all stakeholders are aligned on objectives and methodologies. Key aspects and requirements for the FMEA Plan are defined in 4.1.1.

Deliverable: The FMEA Plan

1.2.2 Conduct FMEAs and Present Risk

Conducting FMEAs represents the transition from planning to execution where FMEA directly influences design and process decisions and supports the pursuit of technical excellence. This deliverable is the result of completing FMEA Steps 2 through 5 for each of the FMEAs that are identified in the FMEA Plan. Since program cost and schedule constraints require that available resources be used where they are most cost-effective, the earliest possible availability of FMEA results is important so that the impact on cost and schedule can be minimized. Key aspects and requirements for FMEA Steps 2 through 5 are defined in 4.1.2.

Deliverable: Completed FMEA(s)

1.2.3 Provide Ongoing FMEA Updates

Once FMEAs have been completed, they need to be updated to ensure risk remains acceptable through the product life cycle. This deliverable is the result of completing FMEA Step 6 for each of the FMEAs that are identified in the FMEA Plan. Key aspects and requirements for FMEA Step 6 are defined in 4.1.2.

Deliverable: Updated FMEA(s)

1.3 Tailoring for FMEA Applications and Usage

Tailoring is the process of modifying the FMEA requirements to meet the needs of the Organization and their enterprises in their operations and/or for the products and services that they provide, as well as to provide agreement in a contract. All “shall” statements are required unless otherwise agreed to between the Organization and the Supplier completing the distinct types of FMEA.

1.3.1 Tailoring for Requirements for the “FMEA Plan”

The requirements for the development of an FMEA Plan can vary depending on the specific program. This makes it necessary to tailor the requirements for the FMEA Plan to each individual program. Tailoring requires that the Organization understands which requirements are optional and those that require approval for tailoring. Key contracting aspects and requirements for the FMEA Plan are defined in 1.2.

The following are some topics for consideration when tailoring the “FMEA Plan:”

- Scope of deliverables
- Formatting of FMEAs
- How will FMEAs be delivered?
- When will the FMEAs be delivered?

Output: Agreed upon set of requirements to finalize the “FMEA Plan”

1.3.2 Tailoring for Requirements for “Completed FMEAs”

The tailoring of FMEA requirements is specified in the contractual provisions by the organization responsible. Tailoring of requirements may take the form of deletion, addition, or alteration to the statements in Sections 6 (DFMEA), Section 7 (SupFMEA), Section 8 (SwFMEA), and Section 9 (PFMEA) and any specified tasks to adapt the requirements of a specific program or Organization. Tailoring may also include limiting the application of FMEA to specific parts of the product.

The following are some topics for consideration when tailoring requirements for completing FMEAs.

- Which “should” statements will be included as data elements
- Any “shall” statements that will not be included based on agreement between the contracting authority and contractor
- Severity and Occurrence (SO) versus Severity and Occurrence and Discovery (SOD)
- How FMEA risks will be confirmed as reduced to acceptable levels
- How is acceptable risk defined?

Output: The requirements for Completing FMEAs

1.3.3 Tailoring for “Ongoing FMEA Updates”

Tailoring for this process involves adapting the frequency, format, and detail of FMEA summaries and updates to best fit the project’s complexity, stakeholder requirements, and life cycle phase, ensuring effective communication and continuous risk management throughout the product life cycle. Key contracting aspects and requirements for summarizing FMEAs and completing Ongoing FMEA Updates are defined in 1.2.

The following are some topics for consideration when tailoring “Ongoing FMEA updates.”

- When is an update required?
- How are updates defined?
- How risk is tracked
- When the FMEA is retired

Output: The requirements for updating FMEAs are defined.

1.4 The Purpose of SAE1025

Project teams responsible for product design, software, supportability, and manufacturing and assembly processes need to identify and reduce technical risks. The purpose of this standard is to assist those teams by providing appropriate terms, requirements, data elements, and essential elements of FMEA methodology that can be tailored to meet their internal and customer requirements.

FMEA is started early in the product development process and uses a qualitative criticality analysis process as defined in Sections 6, 7, 8, and 9. This standard recommends starting with and maintaining the FMEA throughout the product life cycle using a company-defined configuration management and version control procedure.

1.4.1 SAE1025 Enhancements that will Modernize MIL-STD-1629

- Clearly defining specific causes and associated potential Special Product Characteristics and Key Control Characteristics. This is significant in order to clearly define actions to improve the product design.
- Addition of a recommended actions to enable the FMEA team to identify actions to improve the product design, test actions to improve the test, and process action to improve the manufacturing process. This section is important to drive critical thinking to challenge the product and process designs ability to meet the defined requirements.
- Addition of a specific Supportability FMEA section (Section 7) to define a common SupFMEA application.
- Addition of a specific Software FMEA section (Section 8) to define a common SwFMEA application.
- Addition of a specific Process FMEA section (Section 9) to define a common application of developing Process Flow Diagrams (PFDs), PFMEAs, and Control Plans (CPs). This section will commonize the approach between aerospace, land vehicles, and other industries.
- Enhances the requirements for a tailorable and contractable FMEA Plan, so that contracting authority and supplier can agree on the set of FMEAs and resources to meet program objectives.
- Provides defined FMEA quality objectives, supporting an optional audit process, so that contracting authorities can purchase FMEAs that meet defined quality standards, and internal management can implement high value FMEAs.

1.4.2 SAE1025 Enhancements to the Current SAE J1739 FMEA Standard Used for Land Vehicles

- Update the rating tables from a 10-point to a 5-point table to align with MIL-STD-1629A and other industries.
- Add Preliminary Maintenance Actions to improve reliability during product usage and support development of SupFMEAs (see 6.3.8)
- Replace the MSR Section of SAE J1739 with Compensating Provisions to align with MIL-STD-1629A and reduce complexity (see 6.3.11, 6.3.12, and 6.3.13)
- Add Fault Isolation Methods to improve reliability during product usage (see 6.3.14).
- Recommend the elimination of RPN as a form of Criticality Analysis and use the tables in Section E.1.



1.4.3 SAE1025 Ensures Products Meet Functional Safety Criteria Defined in MIL-STD-882E and ISO 26262

FMEA is a cornerstone methodology for risk management, enabling organizations to deliver quality products while meeting customer expectations. Its adaptability across various categories ensures that risks are addressed comprehensively, from design and manufacturing to support and maintenance. By embedding FMEA within the product life cycle, companies can achieve greater efficiency and reliability, safeguarding their success in a competitive market.

The Functional Safety objective of MIL-STD-882E is to formulate the Level of Rigor (LOR) tasks related to the prevention or mitigation of hazardous events to avoid unreasonable risk. Given the LOR defined by the Software Criticality Matrix, SwFMEA supports the required analysis to provide a level of confidence in safety-significant software and document causal factors and hazards that may require mitigation.

2. APPLICABLE DOCUMENTS

The following publications form a part of this document to the extent specified herein. The latest issue of SAE publications shall apply. The applicable issue of other publications shall be the issue in effect on the date of the purchase order. In the event of conflict between the text of this document and references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specific exemption has been obtained.

2.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (U.S. and Canada only) or +1 724-776-4970 (outside U.S. and Canada), www.sae.org.

AS6500	Manufacturing Management Program
AS9103	Aerospace Series - Quality Management Systems - Variation Management of Key Characteristics
AS9138	Aerospace Series - Quality Management Systems, Statistical Product Acceptance Requirements
AS9145	Aerospace Series - Requirements for Advanced Product Quality Planning and Production Part Approval Process
AS13002	Requirements for Developing and Qualifying Alternate Inspection Frequency Plans
AS13003	Measurement Systems Analysis Requirements for the Aero Engine Supply Chain
AS13004	Process Failure Mode and Effects Analysis (PFMEA) and Control Plans
SAE J1739	Potential Failure Mode and Effects Analysis (FMEA), Including Design FMEA, Supplemental FMEA-MSR, and Process FMEA
EIA-649	Configuration Management Standard
GEIA-STD-0007	Logistics Product Data

2.2 ISO Publications

Copies of these documents are available online at www.iso.org/store.

ISO 26262	Road vehicles - Functional safety
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2.3 NASA Publications

Copies of these documents are available online at <https://ntrs.nasa.gov>.

NASA-STD-8739.8A Software Assurance and Software Safety

2.4 NAVAIR Publications

Available from Naval Air Systems Command, 47123 Buse Road, Building 2272, Suite 540, Patuxent River, MD 20670, www.navair.navy.mil.

DI-SESS-81495C Failure Mode, Effects, and Criticality Analysis

DI-SESS-82426 Model-Based Engineering Failure Mode, Effects, and Criticality Analysis Profile (SysML Version)

2.5 U.S. Government Publications

Copies of these documents are available online at <https://quicksearch.dla.mil>.

MIL-HDBK-896A Manufacturing Management Program Guide

MIL-STD-882E System Safety

MIL-STD-1629A Procedures for Performing a Failure Mode Effects and Criticality Analysis

MIL-STD-31000 Technical Data Packages

2.6 Other Publications

Best Practices to Achieve Better Reliability and Maintainability Estimates for DoD Systems. Office of Systems Engineering and Architecture, Office of the Under Secretary of Defense for Research and Engineering. Available at <https://www.cto.mil/wp-content/uploads/2025/02/Best-Practices-RM-Estimates-Feb2025.pdf>.

Common Weakness Enumeration (CWE) - A community-developed list of SW & HW weaknesses that can become vulnerabilities. The Mitre Corporation. Available at <https://cwe.mitre.org/>.

Neufelder, A.M. (2023). *Software FMEA and the Common Defect Enumeration*. 2023 Annual Reliability and Maintainability Symposium (RAMS).

3. DEFINITIONS, TERMS, VIEWPOINTS, AND ACRONYMS

3.1 Definitions

FMEA definitions for the FMEA data elements, and many of the associated terms, are unique to each of the four FMEA types. DFMEA definitions are in Section 6; SupFMEA definitions are in Section 7; SwFMEA definitions are in Section 8; and PFMEA definitions are in Section 9.

3.1.1 DESIGN FLOWS

Design flows identify the states, sequences, timing, and data definitions for the software. A “design flow” is a systematic, step-by-step process used in engineering and design to transform a concept into a final product, whether it’s a physical device, a software application, or a built environment. It involves a series of specific stages and methodologies that ensure the design meets requirements, is thoroughly tested, and is optimized for functionality and reliability, accounting for both typical and peak loads.

3.1.2 FAULT

A fault is the occurrence or existence of an abnormal condition that can lead to an undesired state of an item. In the context of FMEA, some causes of failure may be considered faults.

3.1.3 FMEA DIAGRAM (for SwFMEA)

The FMEA Diagram is a pictorial tool to facilitate an analysis of a software system that includes the system functions and the data flows between them. The diagram illustrates the operation, interrelationships, and interdependencies of functional entities. These behaviors include functional flow timing, data flow, control flow, and resource utilization for each user interaction, software operation, and interface transaction. The accuracy and suitability of these diagrams must be confirmed as a suitable interpretation of the requirements.

3.1.4 SYSTEM HIERARCHY

A “system” is an integrated set of constituent parts that are combined in an operational or support environment to accomplish a defined objective. System definition should include the interfaces between the subsystems/components and may include the interfaces with adjacent systems. Defining the system is a key part of identifying the scope of the FMEA project.

A “hierarchy” is a partitioning scheme that establishes an ordered relationship between the items in a system, where the items are represented as being “above,” “below,” or “at the same level as” one another. Each level of indentation, from system to subsystem to component to part, comprises the hierarchy of the system.

3.1.5 TEST PLAN

The test plan provides the methodology to assure design verification and production validation of systems, assemblies, and components through application of a concise, yet comprehensive, test planning and test results reporting system. The test plan itemizes all tests and evaluations necessary to assure that functional (performance) and reliability (performance over time) criteria and target requirements are defined in specific measurable terms. The plan also specifies test responsibility, test quantities, and timing requirements.

3.2 Terms

For the purposes of this document, the following terms apply:

- “Shall” indicates a requirement.
- “Should” indicates a recommendation.
- “May” indicates a permission.
- “Can” indicates a possibility.

Information marked as “NOTE:” is for clarifying the associated requirement or improve understanding.

3.3 Viewpoints

In the context of an SwFMEA, “viewpoints” are the different perspectives or levels of focus used by an analyst to identify potential failure modes. A viewpoint determines what aspects of the software system are being analyzed for potential errors or defects.

The common viewpoints include system, functional, interface, and detailed design. Other documented viewpoints can be considered for analysis. These include maintenance, usability, serviceability, vulnerability (aka cybersecurity), and software process.

Using different viewpoints helps ensure a comprehensive analysis by systematically investigating the software from multiple angles. Since modern software systems are too large and complex for an exhaustive analysis, viewpoints allow the SwFMEA to be risk-based and tailored to the specific product and its goals.

3.4 Acronyms

The acronyms subsection gathers actual and related short forms and initialisms used within the document for easy reference.

AIAA	American Institute of Aeronautics and Astronautics
APQP	Advanced Product Quality Planning
ARP	Aerospace Recommended Practice
AS	Aerospace Standard
BIT	Built-in Test
CA	Criticality Analysis
CP	Control Plan
CWE	Common Weakness Enumeration
DFMEA	Design Failure Mode and Effects Analysis
DoW	Department of War
FHA	Functional Hazard Assessment
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects, and Criticality Analysis
FRACAS	Failure Reporting and Corrective Action System
GR&A	Ground Rules and Assumptions
HMI	Human-Machine Interface
ICD	Interface Control Documents
IRS	Interface Requirements Specification
KCC	Key Control Characteristic
LORA	Level of Repair Analysis
LOR	Level of Rigor
LPD	Logistics Product Data
MBSE	Model-Based Systems Engineering
MBE	Model-Based Engineering
MFA	Manufacturing Feasibility Assessment
MRO	Maintenance, Repair, and Overhaul

MSA	Measurement System Analysis
MSR	Monitoring and System Response
MTA	Maintenance Task Analysis
PFD	Process Flow Diagram
PFMEA	Process FMEA
PPAP	Production Part Approval Process
PSA	Product Supportability Analyses
R&M	Reliability and Maintainability
RCM	Reliability Centered Maintenance
RPN	Risk Priority Number
SC	Special Product Characteristic
S	Severity
SO	Severity and Occurrence
[SO]	Severity and Occurrence Matrix
SOD	Severity and Occurrence and Discovery
[SOD]	Severity and Occurrence and Discovery Matrix
SOE	Software Operating Environment
SPC	Statistical Process Control
SupFMEA	Supportability FMEA
SwFMEA	Software FMEA
SysML	Systems Modeling Language

4. GENERAL REQUIREMENTS

FMEA shall be planned and performed in accordance with the general requirements of this standard and any specific tasks mandated by the procuring activity, customer, or internal company guidelines. A well-structured FMEA process entails collaboration among stakeholders, detailed analysis, and adherence to predefined guidelines.

4.1 FMEA Process and Procedure

FMEAs shall be performed according to the six defined steps of the FMEA Process (see Figure 1), which serves as a comprehensive framework for identifying, analyzing, and mitigating potential risks within a system or project. This method begins with meticulous planning in Step 1, where a clear scope is defined, the set of FMEAs tailored to the specific needs of the project are identified, and a comprehensive FMEA Plan is developed and approved. Steps 2 through 5 delve deeply into the application of the FMEA for each identified type, ensuring a thorough examination of potential failure modes and their effects, and resulting in FMEA risk being reduced to an acceptable level. Finally, Step 6 consolidates the results by presenting key findings based on risk assessments, evaluating the effectiveness of the FMEA process through established audit criteria, and addressing change management and version control requirements to maintain consistency and traceability. Together, these steps provide a structured approach to proactive risk management and system optimization.

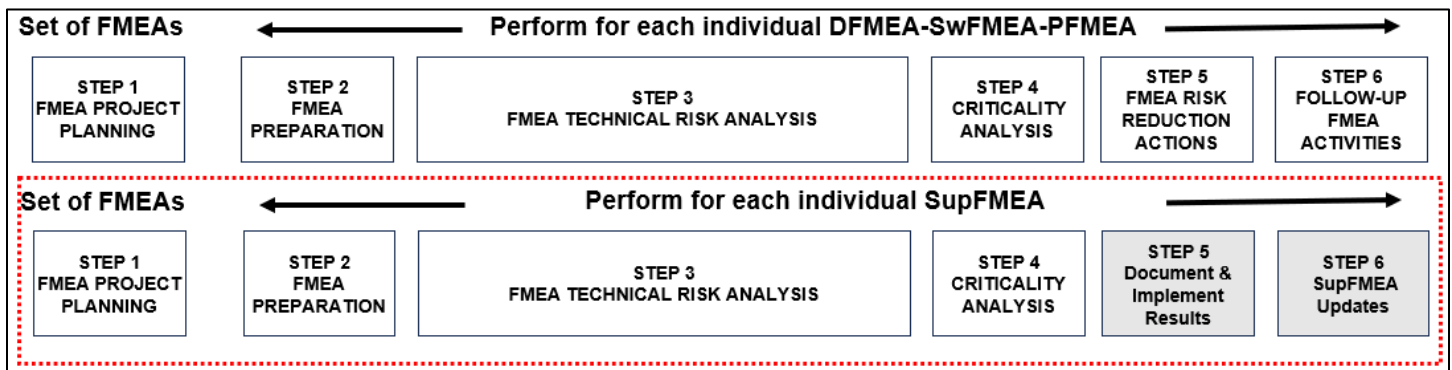


Figure 1 - FMEA process map (six steps)

NOTE: The six steps are the same for DFMEA, SwFMEA, and PFMEA, but Step 5 and Step 6 in SupFMEA are unique.

The procedures for DFMEA, SupFMEA, SwFMEA, and PFMEA are contained in the corresponding section of the standard. Section 6 has the procedure for DFMEA, Section 7 has the procedure for SupFMEA, Section 8 has the procedure for SwFMEA, and Section 9 has the procedure for PFMEA.

4.1.1 Step 1: FMEA Project Planning

An FMEA Plan shall be developed to identify, prioritize, and schedule the set of FMEAs that need to be performed during the product development timeframe to support the safety, reliability, and performance objectives of the project. The plan shall also identify all resources necessary to perform the analyses, including personnel, financial, computer/software, and source data.

Essential Elements:

The FMEA Plan should be coordinated within the organization so that FMEA “best practice” planning is consistent with existing program plans. For example, the execution of Configuration Management per the FMEA planning documentation is essential to successfully maintain consistency between product configuration information and the product. Organizations can reference documents such as EIA-649 for additional information on Configuration Management.

Planning is the foundation of the FMEA process and is critical to the success of the overall project. This phase involves setting objectives, defining scope, and allocating resources.

At minimum, the Plan should include:

- Project scope
- Project schedule
- Project team(s) composition and interfaces
- Required funding and personnel resources
- Required software tools
- Identification of applicable references, specifications, and data sources
- Change management and version control

4.1.1.1 Define the Scope of the Project

A summary statement of the scope of the FMEA Project shall be provided.

Essential Elements:

The FMEA project is the entire set of FMEAs that need to be performed during the product development timeframe to support the safety, reliability, and performance objectives of the product.

The scope of the project can be described textually, along with the appropriate level of detail about the project definition. The scope can also be visually represented by the system hierarchy, detailing the levels of indenture. The aim of the project scope definition is to provide clear input for the development of the FMEA Plan. The FMEA plan shall clearly identify which systems, interfaces, components, parts, and process steps will be the subject of the analysis. The scope summary should include a general description of the level of indenture at which the analysis will be performed.

4.1.1.2 Identify Set of FMEAs and Schedule

The specific FMEAs that will be performed as part of the FMEA project shall be determined and scheduled. The set of FMEAs will include the necessary DFMEAs, SwFMEAs, SupFMEAs, and PFMEAs.

Essential Elements:

Using a method such as Preliminary Risk Assessment (see Sections G.1, I.1, and J.1), the list of potential FMEAs can be identified and prioritized, allowing the project team to determine which FMEAs to do, and their schedule, so they can be scheduled. Emphasis is on conducting FMEAs which present the greatest risk to the project based on the results of the preliminary risk assessment. SupFMEA should include all items that may require repair or replacement unless specifically excluded.

4.1.1.3 Identify Resources and Funding

- a. **Personnel:** The appropriate FMEA(s) team shall be identified. FMEA is a team effort, and each team member contributes with their unique knowledge and experience. The FMEA team should include cross-functional members who understand the details and history of the design, as well as support personnel that understand the operating conditions and environment the product will be used in. On an as-needed basis, the team(s) can also include members from safety, quality, designers, reliability, support engineers, operators, and maintainers. An FMEA review and approval process that includes appropriate stakeholders should be clearly documented.
- b. **Computer and Software:** The complex data developed through FMEA lends itself well to the use of relational databases. Whether using commercially available FMEA software or bespoke databases or spreadsheets, the FMEA plan should address the use of software tools and data storage to ensure data is stored safely and securely with appropriate access for team members.
- c. **Financial:** FMEA is a significant undertaking. Appropriate budgets should be developed and resources allocated. Cost estimates for the FMEA team(s) should be identified to include considerations for external support from other organizational elements. Costs for required software tools, data, and training should also be identified.
- d. **Data:** All data sources for the project should be identified. Typical data sources such as design data, drawings, models, maintenance and failure data, and data for “like and similar” products should be included. Access requirements should be identified.
- e. **Training.** Training and competency in the use of the tools and methodologies defined within this standard is essential to ensure effective process risk identification, assessment, mitigation, and prevention. The organization shall determine and document specific competency and training requirements relevant to its ability to comply with this standard.

4.1.1.4 Define Initial Ground Rules & Assumptions

An initial set of Ground Rules & Assumptions (GR&A) shall be developed prior to performing any analysis.

Essential Elements:

Every effort shall be made to identify and record all ground rules and analysis assumptions prior to initiation of the analysis; however, ground rules and analysis assumptions may be added or modified if requirements change. Additional ground rules and analysis assumptions shall be documented and separately identified for inclusion in the specific type of FMEA. The initial GR&A shall include, at a minimum, the specified elements.

- **Environmental profiles.** The environmental profiles that present the anticipated environmental conditions for the project shall be defined. When a system will be utilized in more than one environment, each different environmental profile shall be described. The intended use, through time, of the product should be developed from engineering specifications for each environmental profile.
- **Mission phases and operational modes.** Identify all mission phases and operating modes that may impact how the equipment can fail or change the failure effects when failure occurs.

- Product breakdown structure. Identify the product breakdown structure (level of indenture) to be used in the analysis. The structure shall have a mapping between engineering, product support, and maintenance ID systems.
- Failure definition. The statements on what constitutes a failure of the item should include performance parameters and allowable limits for each specified function. Failure definitions shall be included in the ground rules submitted with the FMEA plan. The general statements shall not conflict with any failure definitions specified by the procuring activity. Each single item failure, as its effects are analyzed, is to be considered the only failure in the system. Where a single item failure is non-detectable, the analysis shall be extended to determine the effects of a second failure, which, in combination with the first undetectable failure, could result in a catastrophic or critical failure condition. Passive and multiple failures that may result in catastrophic or critical conditions shall also be identified. When safety, redundant, or backup items exist, failure assumptions shall be broadened to include the failure conditions that resulted in the need for the safety, redundant, or backup item. Design or process changes or special control measures shall be identified and defined for all catastrophic and critical failure modes.
- Effects of failure. The organization or FMEA team shall determine whether all End Effects are assessed for severity classification or if only the worst potential consequences (worst case) are assessed.
- Risk assessment. The risk ranking and criticality evaluation criteria must be agreed upon as part of the FMEA Plan, and can be tailored if needed, based on customer requirements or organization's FMEA policy. Recommended evaluation criteria are located in Appendices B through E.
- Metadata/Header format. Metadata and header formats shall be defined by the organization or company completing the document. The owner of the document is responsible to ensure the header information meets all customer and regulatory requirements.

If Quantitative Criticality Analysis is required by the customer, this decision should be included in GR&A. When doing Quantitative Criticality Analysis, see Appendix A for the template and guidance.

4.1.1.5 Change Management and Version Control

The FMEA Plan shall define and implement FMEA Change Management and Version Control.

Change Management and Version Control of FMEAs, as required by this standard, refers to the systematic process of managing and tracking all changes, approvals, and versions of FMEAs within an organization. The FMEA and its results must be retained according to the organization's record retention policy and requirements. Determination of which FMEA versions to retain, whether by status level, program timing, management, or customer review, rests with the Acquirer, Organization, or Supplier. Version control ensures that any updates to the FMEA, prompted by product or process changes after initial approval, are documented, controlled, and preserved in alignment with organizational and contractual obligations. Organizations can reference documents such as EIA-649 for additional information on Change Management and Version Control.

4.1.1.6 Develop Preliminary FMEA Plan

The preliminary FMEA Plan shall be developed, if not addressed, as part of a higher level plan.

Essential Elements:

Essential elements of the FMEA Plan include the set of FMEAs that will be performed, the types of FMEAs, when each FMEA needs to start and complete, who will lead the FMEA teams, worksheet or database formats, any specific contractor procedures, ground rules and assumptions, failure definitions, how change management and version control will be applied, and any other project information that will ensure the right FMEAs are identified and completed according to this standard.

The FMEA plan shall describe the procedures for implementing the specified requirements of this standard, updating the FMEA to reflect design changes, and use of the analysis results to provide design guidance. Sample worksheet formats, ground rules, analysis assumptions, identification of the lowest indenture level of analysis, coding system description, failure definitions, and identification of coincident use of the FMEA by the reliability organization and other organization elements shall be included in the plan.

The time-phasing of the FMEA effort is important and should be identified in the FMEA plan to ensure that analysis results will be available to support the project decision points during system development. See 4.2.

4.1.1.7 Approval of the FMEA Plan

The proposed FMEA Plan shall be reviewed and approved by the key stakeholders.

Essential Elements:

The proposed FMEA Plan contains the set of FMEAs that need to be done to achieve the project requirements, including FMEA types, timing, resources, and other items identified in this section. The FMEA Plan needs to be reviewed and approved by the contracting authority if the FMEAs are part of a contract or by internal management of the organization that will be performing the FMEAs for internal projects. The plan needs to be adjusted to be acceptable before proceeding with execution.

4.1.2 Steps 2 through 6: Performed for Each Individual FMEA

Steps 2 through 6 are essential to the execution of each specific type of FMEA detailed in the FMEA Plan established in Step 1. The implementation of these steps is tailored to the type of FMEA being performed.

- Design FMEAs (DFMEA) shall be performed according to the specific requirements in Section 6.
- Supportability FMEAs (SupFMEA) shall be performed according to the specific requirements in Section 7.
- Software FMEAs (SwFMEA) shall be performed according to the specific requirements in Section 8.
- Process FMEAs (PFMEA) shall be performed according to the specific requirements in Section 9.

These sections provide requirements and essential elements customized to the unique processes of each FMEA type, ensuring a comprehensive and systematic approach to risk management and quality assurance.

For DFMEAs, SwFMEAs, and PFMEAs, design and process changes or special control measures shall be identified and defined for all catastrophic and critical failure modes. For SupFMEAs, any catastrophic or critical failure modes that have not been mitigated to acceptable levels through design or process changes or special control measures shall be evaluated through RCM analysis to identify additional mitigations, such as preventive maintenance or operational restrictions.

4.2 Product Life Cycle Timing

To realize maximum benefits, FMEA requirements within this standard shall follow the timing requirements as outlined in this timing section for the appropriate product life cycle pathway.

Phases of a Product Life Cycle

The product life cycle is typically divided into six distinct phases, each with specific goals and outputs. The specific names of each of the phases in the product life cycle model can vary by organization or industry.

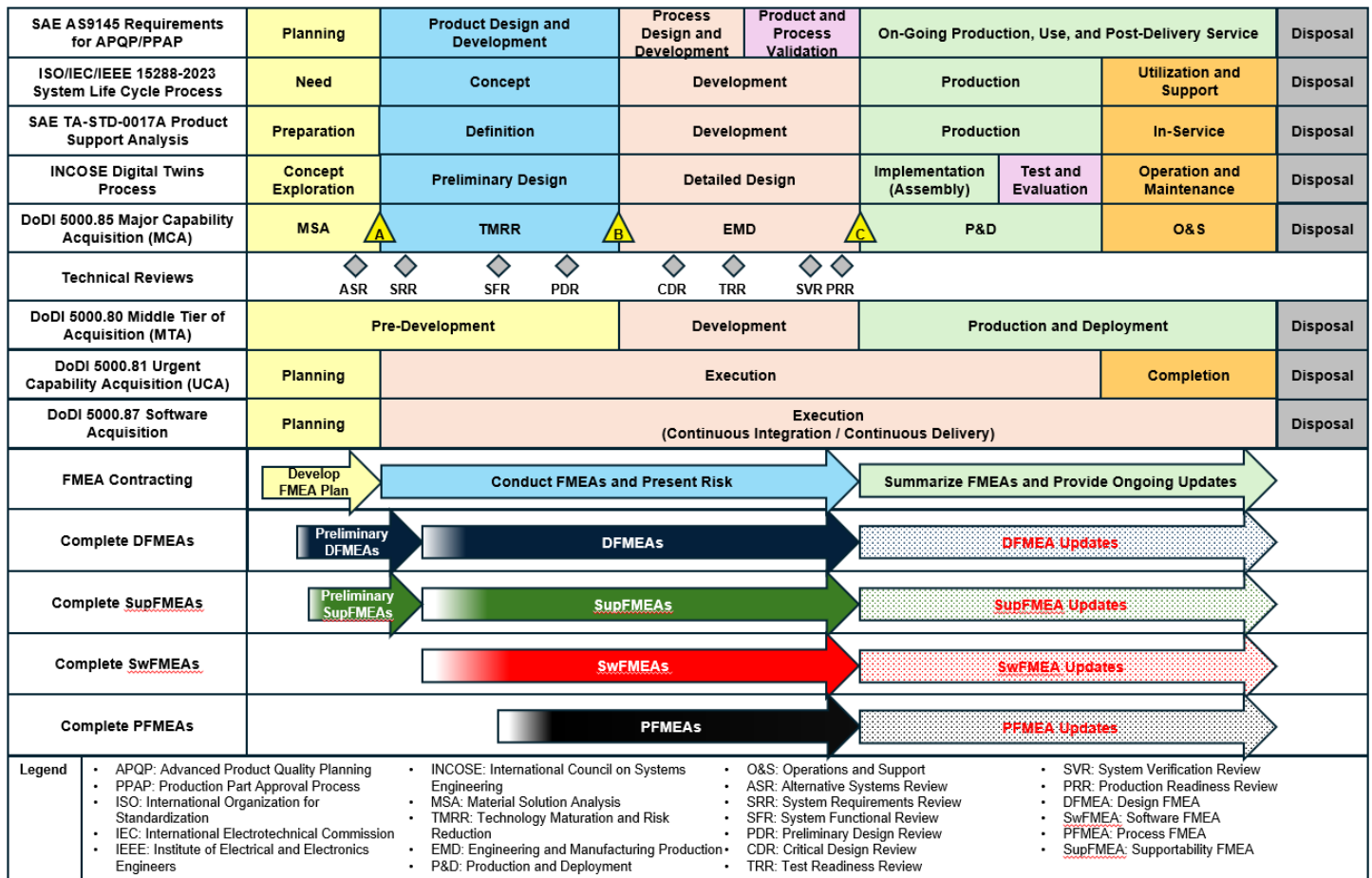


Figure 2 - Product life cycle phase chart

FMEAs should be done early in the conceptual phase when design criteria, mission requirements, and conceptual designs are being developed to evaluate the design approach and to compare the benefits of competing design configurations. Timely FMEAs can provide visibility of critical failure modes and identify potential single failure points, some of which can be eliminated with minimal design effort. As the program and design definitions become more refined, FMEAs can be expanded to successively more detailed levels. When changes are made in system design to remove or reduce the impact of the identified failure modes, FMEAs must be updated for the redesigned portions to ensure that all predictable failure modes in the new design are considered.

Each type of FMEA is applied within the context of designing, manufacturing, and maintaining a product design, ensuring comprehensive updates throughout the product life cycle. FMEA is an essential design, supportability, or manufacturing process evaluation procedure that should not be limited to the phase traditionally thought of as the design phase. The specific life cycle model may vary across organizations; however, these phases collectively ensure the product's journey from conception to disposal, depending on the organization.

5. MODEL-BASED SYSTEMS ENGINEERING

Model-Based Systems Engineering (MBSE) uses modeling to support system requirements, design, verification, and validation from the conceptual phase through the life cycle. It employs digital representations of physical systems to enhance engineering processes. Systems Modeling Language (SysML) is a general-purpose modeling language used in MBSE designed to specify, design, verify, and communicate the structure, behavior, and requirements of complex systems.

Using the Model-Based Engineering (MBE) FMECA SysML profile from DI-SESS-82426 supports the move from static document delivery to interactive model delivery of FMEA data. This SysML profile contains standard data elements needed to generate MBE FMEA design views. These include, but are not limited to, item function, failure mode and effects, failure detection and isolation, compensating provisions, maintenance actions, failure propagation, criticality analysis (including severity, occurrence, and discovery classification), and summary FMEA table. The SysML profile data elements are tailorable to select only those views needed for the program.

Organizations adopting MBSE principles and intending to develop interactive FMEA models shall modify or create their own MBE FMEA SysML profile, provided it captures the required FMEA data elements and design views.

Integrating FMEA into MBSE improves analysis accuracy and depth. Furthermore, the MBSE-based FMEA enables associated data to be dynamically provided to various stakeholders, allowing quicker engagement, decreasing design cycle times, and increasing design influence. MBSE system models detail physical components and interactions, staying updated with design changes and operational data, keeping the FMEA process relevant. This integration fosters interdisciplinary collaboration, as models provide a common framework for communication and insight sharing. MBSE system models enable reliability and other engineering functions to continuously exchange information to identify and eliminate or control failure modes throughout a system's life cycle and apply the information as a basis for detecting and isolating faults, determining operator and maintainer actions, and identifying test requirements. Continuous verification and validation of FMEA results against real-world data (e.g., maintenance management system or Failure Reporting, Analysis, and Corrective Action System [FRACAS] data) should be performed to maintain model accuracy and ensure consistency with system design and performance.

Integrating FMEA into MBSE improves analysis accuracy and depth.

6. DESIGN FMEA

Purpose of Design FMEA

The purpose of Design FMEA (DFMEA) is to analyze the product design, focusing on potential design-related deficiencies, with emphasis on improving the product design and the effectiveness of tests, helping to ensure product operation is safe and reliable during useful life.

What is Design FMEA?

DFMEA is an engineering method performed by a cross-functional team of subject matter experts that identifies and analyzes potential failure modes, their causes, and the effects of failure at the system or end-user level. It uses a risk assessment procedure to prioritize risk for corrective actions and recommends and implements the approved actions to address the most serious concerns. The end result of DFMEA is design risk reduced to an acceptable level.

DFMEA improves the product design by providing support for the decision-making process. If the analysis fails to provide usable information at or before a project decision point, then it has made no contribution and is untimely. It must not become a "check-box" or "fill-out-the-form" activity. A properly performed DFMEA is invaluable to those who are responsible for making program decisions regarding the feasibility and adequacy of a design approach. The time-phasing of the DFMEA effort is important and should be identified in the FMEA plan to assure that analysis results will be available to support the project decision points during system development.

DFMEA is an essential function in design, from concept through development. To be effective, the DFMEA must be iterative to correspond with the nature of the design process itself. The extent of effort and sophistication of approach used in the DFMEA will be dependent upon the nature and requirements of the individual program.

This Design FMEA section is applicable to different approaches and sub-types. An example is the functional and hardware approach covered in MIL-STD-1629A. These two approaches depend on variation in design complexity and available data, and the requirements in this section apply to both approaches. Another example is called System FMEA, which is a Design FMEA performed at the system level and focuses on early design concepts, emphasizing high-level functions and interfaces. The requirements in this section apply to System FMEA and a variety of other FMEA sub-types, either as is or when tailored as appropriate.

Design FMEA Process Steps

According to 4.1.2, DFMEAs shall be performed according to the specific requirements in Section 6. The steps in the DFMEA process are visually shown in the DFMEA process map (see Figure 3). Each sub-step in the DFMEA Process is described in Section 6 with the corresponding requirement, definitions, data elements, and Essential Elements.

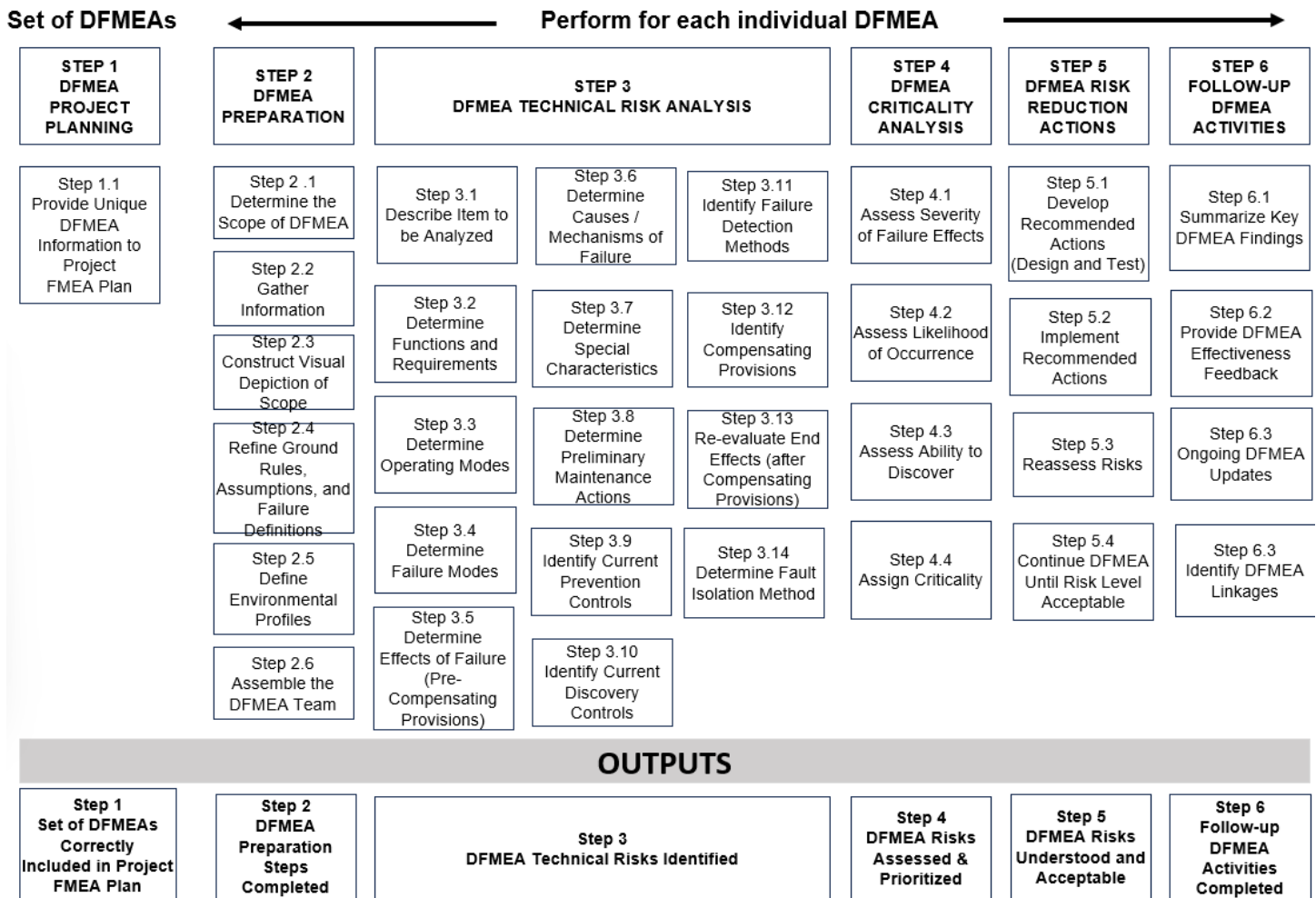


Figure 3 - DFMEA process map

6.1 DFMEA Project Planning (Step 1)

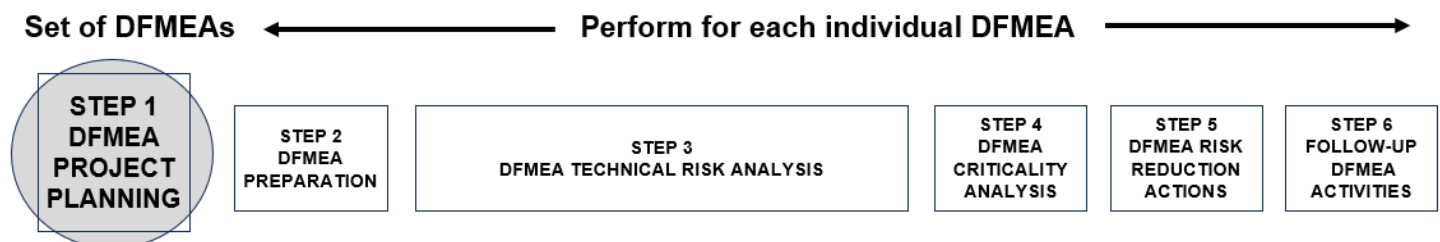


Figure 4 - Step 1 of the DFMEA six-step process map

Output: Set of DFMEAs correctly included in the Project FMEA Plan

6.1.1 DFMEA Contribution to the Project FMEA Plan

Unique information that is relevant only to DFMEA planning shall be included in the Project FMEA Plan, as outlined in 4.1.1.

When identifying the set of DFMEAs that are part of the FMEA Plan, see Section G.1 for information on the use of Preliminary Risk Assessment.

6.2 DFMEA Preparation (Step 2)

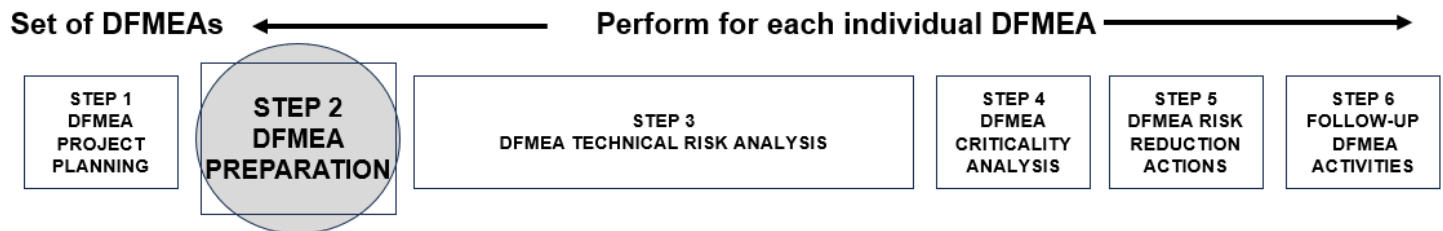


Figure 5 - Step 2 of the DFMEA six-step process map

Output: DFMEA Preparation Steps Completed

6.2.1 Determine Scope of Individual DFMEA

For each DFMEA that will be performed, the scope of the DFMEA shall be determined.

Essential Elements:

The scope of a DFMEA is defined by using diagrams, system hierarchy, bills-of-material, technical specifications, and illustrations or similar tools that represent the item or items being analyzed. The DFMEA team is empowered to choose the scope of the analysis, with management and customer concurrence.

The item is the subject of the analysis. The item (system, subsystem, component, or software unit “algorithm”) must be specified in the DFMEA. Once the item has been determined to be within the scope of the analysis, then the team can identify the functions and requirements for that item. The scope should define the hardware or software for which the team is responsible for designing. This defines the item that will be analyzed. This is the item for which the engineering team has design ownership and risk reduction responsibility.

6.2.2 Gather Information

The necessary information that is input to the DFMEA shall be gathered.

Essential Elements:

One of the more important steps in DFMEA preparation is gathering all the relevant information, as available. If this step is missed or done inadequately, DFMEA meetings can be burdened with extra tasks related to missing information, and DFMEA results are potentially compromised.

The following are some of the categories of information to research and gather prior to the first DFMEA meeting and as needed. The specific list of information that needs to be gathered when preparing for a DFMEA can be determined by the company or organization.

- Technical specifications and development plans. Technical specifications and development plans describe what constitutes and contributes to the various types of system failure. These will state the system objectives and specify the design and test requirements for operation, reliability, and maintainability. A definition of the operational and environmental stresses the system is expected to undergo, as well as failure definitions, will either be provided or can be developed.
- Trade-off study reports. These reports should identify areas of marginal and state-of-the-art design and explain any design compromises and operating restraints agreed upon. This information will aid in determining the possible and most probable failure modes and causes in the system.
- Design data and drawings. Design data and drawings identify each item and the item configuration that perform each of the system functions. System design data and drawings will usually describe the system's internal and interface functions beginning at system level and progressing to the lowest indenture level of the system.
- Reliability data. The determination of the possible and probable failure modes requires an analysis of reliability data, when available.

Other categories of information may include:

- Bill of Materials
- Past DFMEAs with similar scope to the selected DFMEA
- Warranty, recalls, and other field history, preferably prioritized, so the DFMEA team knows the most critical issues
- Applicable government or safety regulations
- Test procedures
- Lessons learned/best practices
- Industry standards
- Preliminary Design Verification Plan
- FMEA Block Diagram
- List of specific design changes and changes to operating environment
- List of concerns relating to the item being analyzed
- Other documents and information that highlight the nature of the design concept

6.2.3 Construct Visual Depiction of the Scope

A visual depiction of the scope of the selected DFMEA, called FMEA Block Diagram or Functional Block Diagram, shall be provided.

Essential Elements:

An FMEA Block Diagram or Functional Block Diagram illustrates the operation, interrelationships, and interdependencies of functional entities. All system interfaces shall be indicated. See Section H.1 and Figure H1 for more details on the development of a Block Diagram.

The Block Diagram is a pictorial tool to facilitate analysis of system or subsystem. In the context of the selected DFMEA, the Block Diagram does the following:

- Visually depicts scope of analysis.
- Identifies internal and external interfaces that are within the scope of the analysis, which can then be shown as Functions in DFMEA.
- Enables application of system, subsystem, and component hierarchy.

Block Diagrams are created as early as possible in the product development cycle; as soon as a basic definition of the system or subsystem exists, they can be refined as the design matures.

6.2.4 Refine Ground Rules and Assumptions

Ground rules and analysis assumptions for the DFMEA shall be provided.

Essential Elements:

Ground rules, assumptions, and engineering information help the DFMEA team conduct the analysis in an efficient and effective manner.

The DFMEA Team agrees on a set of Ground Rules and Assumptions (GR&A) for the analysis. These include the GR&A from 4.1.1.4 as well as the unique GR&A that are unique to the DFMEA being performed. Examples of DFMEA-specific ground rules and assumptions might include:

- Keep the focus of the DFMEA on the item identified in the Preliminary Risk Assessment and stay within the agreed-upon scope.
- The Block Diagram will be updated based on additions and changes during the development of the DFMEA.
- The DFMEA should address the design intent and assume the design will be manufactured/assembled to this intent.

The DFMEA, as an analytical engineering tool, records the ideas and concerns of a design team; therefore, it is understood that failures shown in the DFMEA are potential.

6.2.5 Assemble the FMEA Team

The appropriate DFMEA team shall be agreed upon and assembled prior to commencing the analysis.

Essential Elements:

The owner of the DFMEA will establish the DFMEA team, as necessary, to suit the needs of the scope and ensure timely analysis. DFMEA is a team effort, and each team member contributes with their unique knowledge and experience to identify risk in the design. The DFMEA team should include a core team, as appropriate, who meet regularly and understand the details and history of the design to take the analysis from start to finish.

The reason for a cross-functional team is because one person cannot know everything. Multiple disciplines minimize the potential for “blind spots” while conducting the analysis. One of the indispensable values of DFMEA is the journey of discovery. The cross talk and synergy between team members allows them to discover things that individuals often miss.

6.3 DFMEA Technical Risk Analysis (Step 3)

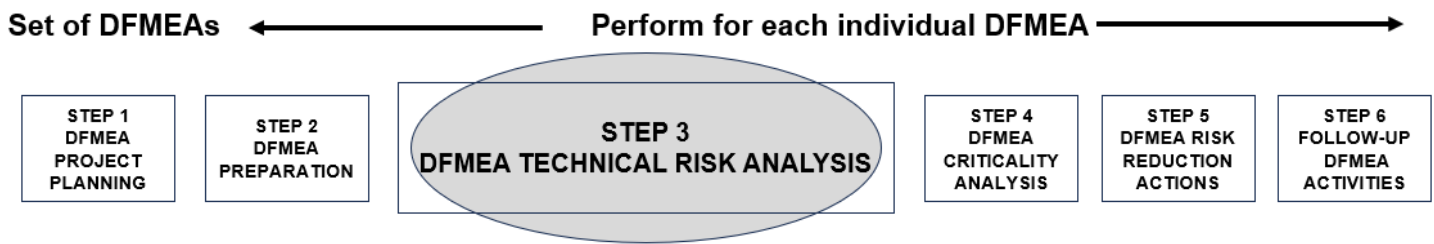


Figure 6 - Step 3 of the DFMEA six-step process map

Output: DFMEA Technical Risks Identified

The Technical Risk Analysis portion of the DFMEA is accomplished by completing the approved data elements of the DFMEA process map. Figure 7 provides the recommended data elements to complete the Technical Risk Analysis of a DFMEA, and an abbreviated example can be found in Section I.1.

Technical Risk Analysis																
Item Nomenclature	Item Identification #	Function(s)	Operating Mode(s)	Failure Mode(s)	Effect(s) of Failure (LOCAL)	Effect(s) of Failure (NEXT)	Effect(s) of Failure (END)	Potential Cause(s) / Mechanism(s) of Failure	Special product characteristic(s)	Preliminary Maintenance Actions	Current Design Controls (Prevention)	Current Design Controls (Discovery)	Failure Detection Method(s)	Compensating Provisions (design or operator)	End Effects (Re-evaluated)	Fault Isolation Method
6.3.1	6.3.1.1	6.3.2	6.3.3	6.3.4	6.3.5			6.3.6	6.3.7	6.3.8	6.3.9	6.3.10	6.3.11	6.3.12	6.3.13	6.3.14

Figure 7 - DFMEA technical risk analysis

6.3.1 Describe the Item to be Analyzed.

The Item Nomenclature shall be entered in the analysis.

Data Element: Item Nomenclature

Definition: Item Nomenclature is a short textual description of the system, subsystem, or component of the design that is being analyzed.

Essential Elements:

For each DFMEA that is selected for analysis, clearly describe the item that will be analyzed. The Item Nomenclature should be consistent with the Item identified in 6.2.1. Determine the scope of the individual DFMEA. If a DFMEA is performed on a System, the Item Nomenclature is "System Name." It is important to keep the item at the defined level of analysis, such as: the nomenclature of the system for a DFMEA at the system level, the nomenclature of the subsystem for a DFMEA of a subsystem, or the nomenclature of the component for a DFMEA of a component.

6.3.1.1 Assign Identification Number

A serial number or other reference designation identification number should be assigned for traceability purposes.

Data Element: Item Identification #

Definition: Item identification number is a logical numbering system that uniquely identifies the item being analyzed and reflects location on system hierarchy

Essential Elements:

For each item being analyzed with DFMEA, a unique identification number can be assigned for traceability purposes. It is attached to the Item Nomenclature.

The identification number should be consistent with those used for the block diagrams, schematics, and other drawings to ensure DFMEA traceability between items, functions and failure modes.

6.3.2 Determine Functions and Requirements

Functional descriptions, including any relevant associated requirements, shall be developed for the item selected for analysis.

Data Element: Function(s)

Definition: The function describes the purpose of the item, along with corresponding requirements. This shall include both the basic function(s) of the item, as well as interface function(s).

Essential Elements:

Functional descriptions are developed for each mission, mission phase, and operational mode and include basic and interface functions. The functional descriptions should include associated requirements. Function statements in the form of “action verb” followed by “measurable noun” are key to accurately describe the functions of the item.

A requirement is a measurable characteristic of a function. A product function may have multiple requirements. Product requirements (at a system and subsystem level) relate to the desired output of a function, such as power or fluid flow. Product requirements (at a component or part level) relate to product characteristics, such as features on a product drawing.

Basic functions are what the item is supposed to do (including associated requirements) and come from technical specifications or subject matter experts. Interface functions are what the identified interface is supposed to do (including associated requirements) and come from reviewing the FMEA Block Diagram.

An item (e.g., product) may have more than one function. Organizations may prioritize which functions are considered in the DFMEA. Functions are developed with attention to the operational mode. The more precise the function and associated requirements, the easier it is to identify potential failure modes.

Where possible, measurable values for requirements are preferred in the DFMEA, as they help define acceptance criteria for the test plan. Measurable values may be obtained from the product drawings and/or technical specifications.

6.3.3 Determine Operating Modes

For each function, the associated Operating Mode(s) or Mission Phase shall be determined.

Data Element: Operating Mode(s)

Definition: The operating mode is a concise statement of the mode of operation for performing the function in which the failure occurs.

Essential Elements:

In order to ensure that no important functions or failure modes are missed, the DFMEA team identifies relevant operational modes. This may encompass the entire life cycle of the asset or a single phase of a mission or operational mode. The mode should encompass the relevant function(s) and the most definitive timing information where the anticipated item function(s) occur.

When more than one method of performing a particular function is available, the alternative operational modes shall be identified.

The timing information may consider the conditions, circumstances, durations, influences, profiles, scenarios, environment, stresses, timings, and combinations thereof surrounding and affecting the item under analysis. The Operational Modes include, but are not limited to, Operating, Non-Operating, and Inactive, which are defined as follows.

Operating: an item state where the item is performing at least one operating function (example: operation, uptime maintenance, captive carry, mission phases, test, hot standby, sorties).

Non-Operating: an item state where the item is non-operating but is assumed to be operable (example: dormant life, downtime maintenance, cold standby).

Inactive: an item state where the item is assumed to be inoperable (example: transportation, storage, held in reserve for potential future inventory assignment).

6.3.4 Determine Failure Mode(s)

For each function, the associated failure modes shall be determined.

Data Element: Failure Mode(s)

Definition: A failure mode is the manner in which an item could potentially fail to meet or deliver the intended function.

Essential Elements:

Potential failure modes shall be determined by examination of the item's ability to perform the intended function and achieve the stated requirements. Each potential failure mode is considered separately from other failure modes, allowing the team to address the unique reasons (causes) for that failure mode.

All predictable failure modes for the item function being analyzed shall be identified and described on the basis of the stated requirements in the system definition narrative and the failure definitions included in the system's/item's ground rules.

As covered in 4.1, passive and multiple failures that may result in catastrophic or critical conditions shall also be identified. When safety, redundant, or backup items exist, failure assumptions shall be broadened to include the failure conditions that resulted in the need for the safety, redundant, or backup item.

In order to ensure no important failure modes are missed, potential failure modes can be examined in relation to the following conditions:

- Premature operation.
- Failure to operate at a prescribed time.
- Intermittent operation.
- Failure to cease operation at a prescribed time.
- Loss of output or failure during operation.
- Degraded output or operational capability.
- Other unique failure conditions, as applicable, based on system characteristics and operational requirements or constraints.

NOTE: Not all categories will always result in failure modes.

6.3.5 Failure Effects

The impact of each assumed failure mode on item operation, function, or status shall be identified, evaluated, and recorded. The failure under consideration may impact several indenture levels in addition to the indenture level under analysis; therefore, "local," "next higher level," and "end" effects shall be evaluated. Failure effects shall also consider the mission objectives, maintenance requirements, and personnel and system safety.

6.3.5.1 Determine Local Effect(s) of Failure

For each failure mode, the local effect(s) of failure shall be identified and documented.

Data Element: Local Effect(s) of Failure

Definition: Local effect of failure means the impact a failure mode has on the operation, function, or status of the specific item being analyzed.

Essential Elements:

The impact of each assumed failure mode on item operation, function, or status shall be identified, evaluated, and recorded. Failure effects shall focus on the specific block diagram element that is affected by the failure under consideration,

Local effects concentrate specifically on the impact an assumed failure mode has on the operation and function of the item in the indenture level under consideration. The impact of the defined local effect helps determine the impact on the next higher indenture level above the indenture level under consideration.

6.3.5.2 Determine Next-Level Effect(s) of Failure

For each failure mode, once the local effect(s) of failure are documented, the next-level effect(s) of failure should be identified and documented.

Data Element: Next-Level Effect(s) of Failure

Definition: Next-level effect of failure means the impact a failure mode has on the operation, functions, or status of the items in the next higher indenture level above the indenture level under consideration.

Essential Elements:

If the item being analyzed is sufficiently high on the system hierarchy, and it is therefore not feasible to identify an effect at the next-higher level, enter "not applicable" in the field. In this case, the DFMEA team will only evaluate the local and end effects. Otherwise, the next higher level effect should be entered.

6.3.5.3 Determine End Effects of Failure (Pre-Compensating Provisions)

For each failure mode, once the local effect(s) of failure and next-level effect(s) are documented, the end effect(s) of failure shall be identified and documented.

Data Element: End Effect(s) of Failure (Pre-Compensating Provisions)

Definition: End effect of failure means the impact a failure mode has on the operation, function, system, or owner/operator of the highest indenture level. The end effect described could be the impact of multiple failure event.

Essential Elements:

End effects evaluate and define the total effect an assumed failure has on the final product and the end user/customer (product operator). End effects should provide an orderly and thorough evaluation of the effects of foreseeable failures and other events, including what the user might notice or experience. They shall clearly state if the effect of a failure mode could impact safety or noncompliance to regulations, when applicable. As required, where a single item failure is non-detectable in operation, the analysis shall be extended to determine the effects of a second failure, which in combination with the first undetectable failure could result in a catastrophic or critical failure condition. Passive and multiple failures that may result in catastrophic or critical conditions shall also be identified.

The end effect described may be the result of a double failure. For example, failure of a safety device may result in a catastrophic end effect only in the event that both the prime function goes beyond limit for which the safety device is set and the safety device fails. Those end effects resulting from a double failure shall be indicated on the DFMEA worksheets or entered in the DFMEA database.

As indicated in the data element heading, the end effect at this point in the DFMEA is determined without regard to compensating provisions. Once compensating provisions are identified, the end effect will be reevaluated.

6.3.6 Determine Cause(s)/Mechanism(s) of Failure

For each failure mode, the most probable causes associated with the postulated failure mode shall be identified and described.

Data Element: Failure Cause(s)/Mechanism(s)

Definition: A cause is the potential design deficiency that results in the failure mode. A failure mechanism is the physical, chemical, electrical, thermal, or other process that results in failure.

Essential Elements:

Since a failure mode may have more than one cause, all probable independent causes for each failure mode shall be identified and described. Causes are often described in terms of product characteristics, such as dimensions, weight, orientation, hardness, strength, etc., where the potential design deficiency is associated with a product characteristic.

Causes should be listed as concisely and completely as possible so that remedial efforts (controls and actions) can be aimed at appropriate causes.

The "Cause" description can also include the underlying failure mechanism. Failure mechanisms are the physical, chemical, electrical, thermal, or other processes that result in failure. For a system, the failure mechanism is the process of error propagation following a component failure that leads to a system failure. Including failure mechanisms in the cause description of DFMEAs leads to a more thorough understanding of the physics of failure, resulting in effective resolution of potential design deficiencies.

It is important that engineers consider foreseeable misuse when evaluating factors that can lead to potential failure modes and causes, especially when there is a direct interface between the customer/user/operator and the system, subsystem, or component being reviewed. Although potential misuse is not a cause by itself, a design can potentially be made robust to misuse that is reasonably foreseen. Potential misuse should be considered in the context of defining requirements.

6.3.7 Identify Potential Special Product Characteristic(s)

Potential Special Product Characteristics should be identified and defined for all catastrophic and critical failure modes.

Data Element: Potential Special Product Characteristic(s)

Definitions: A product characteristic is a feature of a product (e.g., dimension, relationship, finish, property, orientation, appearance, composition, chemistry, performance, function) that is defined on a design requirement document (engineering drawing and specification) and can be measured using variable or attribute measurement methods once the product has been produced.

A special product characteristic is a feature of a product that requires special care because incorrect nominal values/tolerances and corresponding manufacturing/assembly variation may have significant influence on product safety, performance, and service life.

Essential Elements:

The purpose of selecting Special Product Characteristic is to communicate the risk to manufacturing, assembly, and/or other interfacing design disciplines. Risks identified in the DFMEA are INPUTS (but not exclusive) to the special characteristic selection process.

The purpose of identifying a potential Special Product Characteristic is to communicate the risk to manufacturing, assembly, and/or other interfacing design disciplines for special controls. DFMEA causes of failure, properly expressed as potential design deficiencies, can be an input to special characteristic identification, provided the associated risk meets company special characteristic policy. The process for determining the classification of characteristics (standard or special) is company specific; therefore, identified special product characteristics should be entered in DFMEA Recommended Actions so they can be confirmed.

6.3.8 Determine Preliminary Maintenance Actions

For each failure mode and associated cause, the DFMEA team should determine preliminary maintenance actions.

Data Element: Preliminary Maintenance Actions

Definitions:

Preliminary Maintenance Actions are corrective or preventive maintenance actions that the DFMEA team would like to communicate to the SupFMEA team.

Essential Elements:

The DFMEA team should consider and provide potential maintenance actions that can be performed to reduce the likelihood of the cause or failure mode or extend the useful life of the item under consideration. These are preliminary recommendations and will be reviewed and updated as appropriate by the supportability team. In particular, the DFMEA team should identify those potential maintenance actions that are inherent in the design and/or specified by the designer, such as servicing, lubrication, or calibration requirements. Other design-intent-related maintenance requirements or procedures, such as those for modular replacement, should also be included.

6.3.9 Identify Current Prevention Controls (Prevention)

For each failure mode and associated cause, the FMEA team should identify and document current prevention controls.

Data Element: Current Design Controls (Prevention)

Definitions: Prevention-type design controls describe how a failure mode and/or cause is prevented, based on methods currently planned or in place.

Essential Elements:

The DFMEA team lists, as applicable, prevention-type design controls that are currently planned or in place. The focus of prevention-type design controls is on actions that are taken during the design process to mitigate design risks.

Prevention-type controls may not be applicable for every failure mode and/or cause; but where identified, they can be part of the basis for determining the occurrence rating. They are not intended to reduce the severity of a failure, which is the province of compensating provisions. Emphasis on strong prevention actions is encouraged, as such actions often can be completed earlier in the project with the resulting efficiency and effectiveness.

The focus of prevention-type design controls is on prevention, not discovery. Prevention-type controls may not be applicable for every failure mode and/or cause. If there are no currently planned prevention-type design controls for a given failure mode and associated cause, the team can enter "none."

6.3.10 Identify Current Discovery Controls

For each failure mode and associated cause, the DFMEA team should identify and document current discovery controls.

Data Element: Current Design Controls (Discovery)

Definitions: Discovery-type design controls describe how the item's failure mode and/or associated cause is discovered based on analytical or physical test methods that are currently planned or in place before the product is released for production.

Essential Elements:

The DFMEA team lists, as applicable, discovery-type design controls that are currently planned or in place. The focus of discovery-type design controls is on the physical tests or virtual analyses that are currently planned or in place.

NOTE: Current Discovery Controls are not the same as in-service or in-operation detection of a potential failure by the system or the operator.

Discovery-type Design Controls are used as input to the discovery rating and are intended to increase the likelihood that the failure mode or associated cause will be discovered and/or prove design intent is confirmed before it is released for production.

6.3.11 Identify Failure Detection Methods

A description of the methods by which occurrence of the failure mode is detected by the operator shall be recorded. In addition, where applicable, a description of indications which are evident to an operator that a system has malfunctioned or failed, other than the identified warning devices, shall also be recorded.

Data Element: Failure Detection Method(s)

Definition: A Failure Detection Method is a description of the method by which occurrence of the failure mode is detected in operation by operator or monitoring system.

Essential Elements:

The failure detection means, such as visual inspection, audible warning devices, automatic sensing devices (onboard or off-board), sensing instrumentation, tactile or other unique indications, or none, shall be identified.

Describe any monitoring or warning device that will provide an indication of impending failure and any planned tests or inspections that could detect occurrence of the failure mode. Identify to what indenture level failures can be isolated using built-in test features and indicate when ancillary test equipment will be required for fault isolation.

Proper correlation of a system malfunction or failure may require identification of normal indications as well as abnormal indications. If no indication exists, identify if the undetected failure will jeopardize the mission objectives or personnel safety. If the undetected failure allows the system to remain in a safe state, a second failure situation should be explored to determine whether or not an indication will be evident to an operator. Indications to the operator should be described as follows:

- a. Normal. An indication that is evident to an operator when the system or equipment is operating normally.
- b. Abnormal. An indication that is evident to an operator when the system has malfunctioned or failed.
- c. Incorrect. An erroneous indication to an operator due to the malfunction or failure of an indicator (i.e., instruments, sensing devices, visual or audible warning devices, etc.).

This field can be left blank if there are no applicable failure detection methods.

6.3.12 Identify and Evaluate Compensating Provisions

Compensating provisions, either design provisions and/or operator actions, shall be identified and evaluated.

Data Element: Compensating Provisions (Design or Operator)

Definition: Compensating provisions are either design provisions and/or operator actions, which circumvent or mitigate the effect of the failure.

Essential Elements:

This step is required to record the true behavior of the item in the presence of an internal malfunction or failure.

Design Provisions:

Compensating provisions that are provisions of the design shall be identified and evaluated. Design provisions are features of the design at any indenture level that will nullify the effects of a malfunction or failure, control or deactivate system items to halt generation or propagation of failure effects or activate backup or standby items or systems. Design compensating provisions include:

- Redundant items that allow continued and safe operation.
- Safety or relief devices such as monitoring or alarm provisions that permit effective operation or limit damage.
- Alternative modes of operation such as backup or standby items or systems.

Operator Actions:

Compensating provisions that require operator action to circumvent or mitigate the effect of the postulated failure shall be identified and evaluated. The compensating provision that best satisfies the indication(s) observed by an operator when the failure occurs shall be determined. This may require the investigation of an interface system to determine the most correct operator action(s). The consequences of any probable incorrect action(s) by the operator in response to an abnormal indication should be considered and the effects recorded.

Compensating provisions shall be evaluated as to how well they circumvent or mitigate the effect of failure.

Evaluation criteria:

- If the DFMEA team believes the Compensating Provisions are sufficiently robust and will result in mitigating the effect of failure, they should revise the End Effects description accordingly. "Sufficiently robust" means the performance of the monitoring system regarding detection and response or the result of the operator action responding to a warning or alert message is such that the original (i.e., uncompensated) impact of the failure event is avoided with a high degree of certainty.
- If the DFMEA team believes the Compensating Provisions are not sufficiently robust and will not always result in mitigating the effect of failure, they should leave the End Effects description unrevised.
- If the DFMEA team determines that action is needed to improve the Compensating Provisions in order to better mitigate the effects of failure, they should recommend appropriate actions and enter in the Recommended Actions column.

6.3.13 Reevaluate End Effects (after Compensating Provisions)

Once the Compensating Provisions have been identified and evaluated, the end effects shall be reevaluated.

Data Element: End Effects (Reevaluated)

Definition: Reevaluating end effects means determining how well the current compensating provisions circumvent or mitigate the end effects to see if there is valid reason to reduce the severity.

Essential Elements:

Based on the results of the evaluations in the Compensating Provisions step, the DFMEA team reevaluates the end effects and enters the revised end effects.

6.3.14 Determine Fault Isolation Method

The DFMEA team should enter the fault isolation method that will be used by an operator to isolate the malfunction or failure.

Data Element: Fault Isolation Method

Definition: A fault isolation method is a specific action or series of actions by an operator or maintainer that isolates the malfunction or failure.

Essential Elements:

Fault isolation procedures are critical to allow an operator and/or maintainer to conduct fault isolation to fix the issue that caused the failure.

Fault isolation procedures require a specific action or series of actions by an operator or maintainer, followed by a check or cross reference either to instruments, control devices, circuit breakers, or combinations thereof. Identify to what indenture level failures can be isolated by the use of built-in test (BIT) features and indicate when ancillary test equipment will be required to complete fault isolation. An operator or maintainer may only know the initial symptoms of failure until further specific action is taken, such as performing a more detailed BIT. The failure being considered in the analysis may be of lesser importance or likelihood than another failure that could produce the same symptoms, and this should be considered. This procedure is followed until a satisfactory course of action is determined.

6.4 DFMEA Criticality Analysis (Step 4)

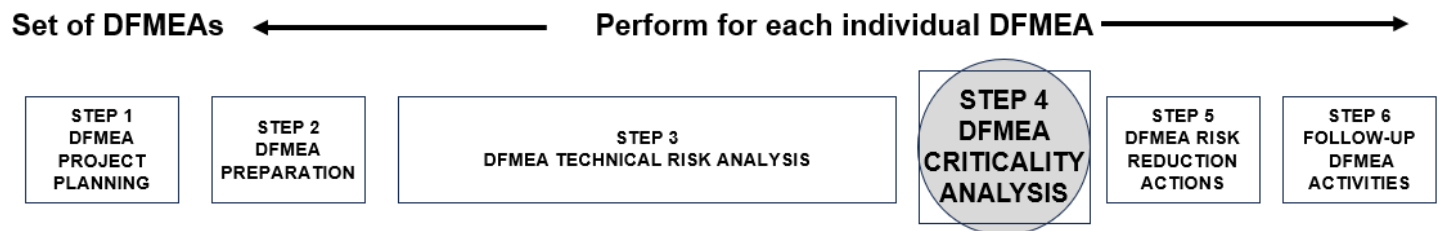


Figure 8 - Step 4 of the DFMEA six-step process map

Output: DFMEA Risks Assessed and Prioritized

The Criticality Analysis portion of the DFMEA is accomplished by completing the approved data elements of the DFMEA process map. Figure 9 provides the recommended data elements to complete the Criticality Analysis of a DFMEA.

Technical Risk Analysis																	Criticality Analysis			
Item Nomenclature	Item Identification #	Function	Operating Mode(s)	Failure Mode(s)	Effect(s) of Failure (LOCAL)	Effect(s) of Failure (NEXT)	Effect(s) of Failure (END)	Potential Cause(s) / Mechanism of Failure	Special product characteristic(s)	Preliminary Maintenance Actions	Current Design Controls (Prevention)	Current Design Controls (Discovery)	Failure Detection Method(s)	Compensating Provisions (design or operator)	End Effects (Re-evaluated)	Fault Isolation Method	Severity	Occurrence	Discovery	Criticality
6.3.1	6.3.1.1	6.3.2	6.3.3	6.3.4	6.3.5			6.3.6	6.3.7	6.3.8	6.3.9	6.3.10	6.3.11	6.3.12	6.3.13	6.3.14	6.4.1	6.4.2	6.4.3	6.4.4

Figure 9 - DFMEA criticality analysis

6.4.1 Assess Severity of Failure Effects

A severity classification category shall be assigned to the most serious effect for a given failure mode.

Data Element: Severity

Definition of Severity classification as a principle:

As a principle, Severity considers the most serious consequences of a failure, classified by the degree of injury, property damage, system damage, and mission loss that could occur.

Definition of Severity classification as a Data Element:

As a Data Element, Severity classification is a rating associated with the most serious effect for a given failure mode for the function being evaluated.

Essential Elements:

As required in 4.1, Severity classifications are assigned to the effects of each failure mode to provide a basis for establishing corrective action priorities. Severity classification should be assigned to the most serious of the end effect(s) of each failure mode, after consideration of compensating provisions, according to 6.3.13.

Severity should be estimated using the criteria in Section B.1 (see Figure B1).

Reference Ground Rules and Assumptions as to whether all End Effects are assessed for severity classification or if only the worst potential consequences (worst cases) are assessed.

6.4.2 Assess Likelihood of Occurrence

NOTE: If the Project FMEA Plan, as documented in 4.1.1, includes a requirement to use Quantitative Criticality Analysis, the procedure is outlined in Appendix A.

Likelihood of Occurrence rating shall be assigned to each failure mode and associated cause.

Data Element: Occurrence

Definition of Occurrence as a principle:

As a principle, Occurrence is an assessment of the likelihood that the item will experience a potential failure mode due to a specific cause during a specified period.

Definition of Occurrence as a Data Element:

As a Data Element, Occurrence is a rating assigned to each failure mode cause and/or mechanism based on the likelihood that the failure mode and associated cause will occur during the Specified Period, such as design life of the product.

Essential Elements:

The assessment of occurrence considers, as applicable, all relevant field or test experiences, prevention controls, safeguards, and degree of change. The initial assessment of occurrence is performed prior to any recommended actions and testing and does not consider mitigation. The Occurrence rating has a relative meaning rather than an absolute value and should be assessed independently of severity.

The Occurrence rating should be assessed using the criteria in Section C.1 (see Figure C1). In the referenced table, likelihood of occurrence numbers are grouped into distinct, logically defined levels, which establish the qualitative likelihood of occurrence for the failure cause. While the table should meet the needs of most applications, the team shall agree on an evaluation criteria using a 1 to 5 rating system that is consistent, even if modified for individual analysis.

A specified period is a defined interval measured in units to describe events, usage, or time (hours, rounds, miles, cycles, missions, design life) for the application of the item under analysis. The period is used to bound the associated analysis or assessment window to a specific set of system objectives, requirements, and operating modes where the assumed item failures occur.

6.4.3 Assess Ability to Discover

The DFMEA team should assess the ability of the current design controls to discover a failure mode or cause during the development stage.

Data Element: Discovery

Definition of Discovery as a principle:

As a principle, Discovery is the ability to discover, using currently planned tests or analyses, the presence of a failure mode or cause within the design development process.

This document uses the term “Discovery” rather than the term “Detection” to differentiate from Detection in operation.

Definition of Discovery as a Data Element:

As a Data Element, Discovery is the rating associated with the likelihood that the currently planned Discovery Controls will discover the failure mode and/or associated cause, according to defined criteria, during product development.

Essential Elements:

In DFMEA, it is strongly recommended that SOD is used, as there is risk associated with inability to discover a failure mode or cause during product development time frame. The use of Discovery assesses the goodness of discovery controls and allows the team to utilize the DFMEA to improve tests and analyses.

The Discovery rating should be assessed using the criteria in Section D.1 (see Figure D1).

The Discovery assessment considers the Current Discovery Controls, including the stage of development, the robustness of the discovery controls in revealing the design weaknesses/failures within specifications, and the timing of the findings within the cycle of the process being assessed. The initial assessment of Discovery is performed prior to any recommended actions and testing. The Discovery rating has a relative meaning rather than an absolute value and should be assessed independently of severity.

In the Discovery Evaluation table, the Ability to Detect rating numbers are grouped into distinct, logically defined levels. While the table should meet the needs of most applications, the team shall agree on an evaluation criteria using a 1 to 5 rating system that is consistent, even if modified for individual analysis.

6.4.4 Assign Criticality (Combined Impact of Severity, Occurrence, and Discovery)

Application note: This step is not applicable for Quantitative Criticality Analysis. For application of Quantitative Criticality Analysis, see Appendix A.

The DFMEA team shall assign a Criticality, which assesses the combined impact of the rankings from SOD, using approved methodology, in order to prioritize risk and related recommended actions.

Data Element: Criticality

Definition: Criticality is the combined SOD impact, based on a procedure using a visual representation of the positional relationship for Severity, Occurrence, and Discovery, establishing criticality for individual failure modes/causes.

Essential Elements:

The criticality matrix provides a means of characterizing the risk associated with a combination of SOD. The matrix is constructed by combining [SOD] in matrix locations representing the Severity, Occurrence, and Discovery.

Color-coding can be applied based on parameters determined by the organization, providing grouping of failure modes as high, medium, and low with regard to potential impact on mission success, performance, safety, and maintainability.

[SOD] Matrix combines Severity, Occurrence, and Discovery ratings with suggested priority levels for identification of potential actions to reduce risk based on High (H), Medium (M), and Low (L) assessments. Individual organizations may develop their own criteria for H, M, and L.

See Section E.1 and Figure E1 for an example of [SOD] Matrix.

Once the Criticality is assigned for the given failure mode and cause, the result, such as High, Medium, or Low, can be entered into the corresponding Criticality data field in the DFMEA.

NOTE: The represented importance of high (red), medium (yellow), and low (green) can be modified by the organization or contracting agent.

6.5 DFMEA Risk Reduction Actions (Step 5)

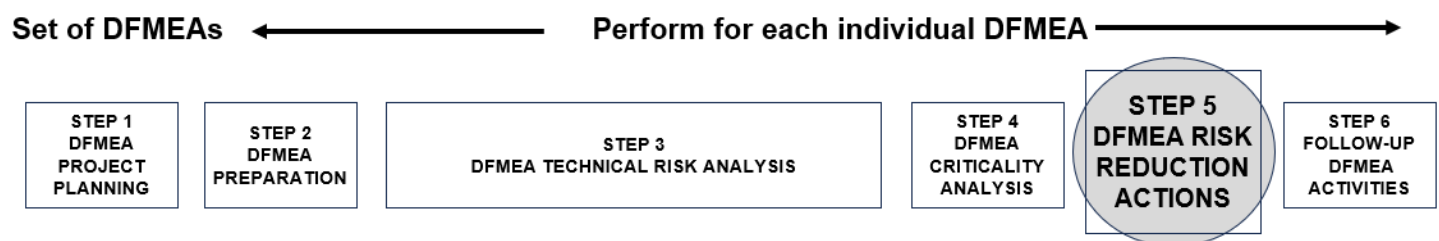


Figure 10 - Step 5 of the DFMEA six-step process map

Output: DFMEA Risks Understood and Acceptable

The Risk Reduction Actions portion of the DFMEA is accomplished by completing the approved data elements of the DFMEA process map. Figure 11 provides the recommended data elements to complete the Risk Reduction Actions of a DFMEA.

Technical Risk Analysis																Criticality Analysis				Risk Reduction Actions						
Item Nomenclature	Item Identification #	Function	Operating Mode(s)	Failure Mode(s)	Effect(s) of Failure (LOCAL)	Effect(s) of Failure (NEXT)	Effect(s) of Failure (END)	Potential Cause(s) / Mechanism of Failure	Special Design characteristic(s)	Preliminary Maintenance Actions	Current Design Controls (Prevention)	Current Design Controls (Discovery)	Failure Detection Method(s)	Compensating Provisions (design of operator)	End Effects (Re-evaluated)	Fault Isolation Method	Severity	Occurrence	Discovery	Criticality	Recommended Actions (Design and Test)	Actions Taken	Severity	Occurrence	Discovery	Criticality
6.3.1	6.3.1.1	6.3.2	6.3.3	6.3.4	6.3.5			6.3.6	6.3.7	6.3.8	6.3.9	6.3.10	6.3.11	6.3.12	6.3.13	6.3.14	6.4.1	6.4.2	6.4.3	6.4.4						

Figure 11 - DFMEA risk reduction actions

6.5.1 Develop Recommended Actions (Design and Test)

The DFMEA team shall recommend product design improvements and/or test improvements that are sufficient to reduce the identified risk to an acceptable level.

Data Element: Recommended Actions (Design and Test)

Definition: Recommended Actions (Design and Test) are specific tasks that are recommended by the Design FMEA team to improve the product design or improve the capability of the test or analyze, based on criticality analysis.

Essential Elements:

For each failure mode and associated cause where the DFMEA team has prioritized risk and determined that the risk is not acceptable, the DFMEA team recommends actions that are intended to reduce risk to an acceptable level. These actions can be design-improvement actions or test-improvement actions or both. They include the person who is responsible for implementation as well as the target completion date.

Recommended Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions that could theoretically be taken. The purpose of documenting Recommended Actions is to formally commit to reducing risks and improving the design or test.

As covered in 4.1, design changes or special control measures shall be identified and defined for all catastrophic and critical failure modes. Similarly, where the loss of input or output at a lower indenture level is critical to the operational success of the higher indenture level, action shall be taken to eliminate or control the identified failure modes.

The intent of recommended actions are to improve the ability to prevent, mitigate, or discover a failure. This is achieved by mitigating the effect of failure by design change (reducing Severity risk), reducing the likelihood of failure by design modification or controls (reducing Occurrence risk), and improving the ability to discover failures during product development time frame through improvements to tests or analyses (reducing Discovery risk).

6.5.2 Management Review of High-Risk Failure Modes

Management shall review the DFMEA high-risk failure modes and corresponding recommended actions.

Essential Elements:

It is essential that the DFMEA recommended actions are agreed upon and implemented, with the desired outcome. Therefore, DFMEA high-risk failure modes and their corresponding Recommended Actions shall be reviewed and approved by management. The DFMEA team shall provide all necessary supporting information for management review of the high-risk failure modes, effects, and causes, along with their recommendations on how risk can be reduced to an acceptable level.

The management review of high-risk failure modes ensures understanding, buy-in, support, and adequacy of the recommended actions. If agreed by management, the recommended actions are supported, as needed, so that they will be executed. If management does not agree with any of the recommended actions, specific feedback goes back to the DFMEA team, with revised recommended actions developed and presented by the DFMEA team, until management accepts and disposes of the risk reduction tasks. The end result is a set of agreed-upon actions and tasks that, when implemented, will reduce risk to an acceptable level.

The organization can define the level of management that conducts this review at the level that is responsible for the risk and the project. The defined management review team can be included as part of GR&A.

6.5.3 Implement Recommended Actions

Each Recommended Action shall be implemented, and the specific action that was taken shall be documented.

Data Element: Actions Taken

Definition: An action taken is the specific and verifiable action that was taken, based on the Recommended Action.

Essential Elements:

For each recommended action, a brief description of the specific action that was taken is recorded. The team may wish to include the effective completion date. If an action is not implemented, note the rationale.

Actions Taken should not include routine execution of Current Prevention Controls or Current Discovery Controls but should focus on the results of actions recommended.

6.5.4 Reassess Risks

Once the Actions Taken have been implemented and documented, Severity, Occurrence and Discovery values shall each be reassessed, and the revised Criticality shall be assigned.

Definition (as covered in 6.4.1 through 6.4.4)

Essential Elements:

Severity, Occurrence, and Discovery values are reassessed, and revised Criticality assigned, when the action has been completed (action taken). The action taken is the rationale for modifying the ratings. If "No Action" is taken, S, O, and D ratings remain as originally assigned. Recommended Actions must be completed and documented prior to any S, O, and D re-ratings.

The DFMEA serves as a historical record for the design; therefore, the original Severity, Occurrence, and Discovery numbers are not modified once actions have been taken. The completed analysis becomes a repository to capture the progression of design and test refinements.

6.5.5 Continue DFMEA Until Risk Level Acceptable

Based on the results of the reassessed risk, the DFMEA shall be continued until risk is acceptable.

Essential Elements:

A DFMEA is completed when an acceptable level of risk has been achieved and agreed upon by the DFMEA team and management. Until this point, the DFMEA is continued until the risk represented by each of the S, O, and Ds is reduced to a level that is deemed acceptable by the organization, considering input or requirements from the customer.

6.6 Follow-Up DFMEA Activities (Step 6)

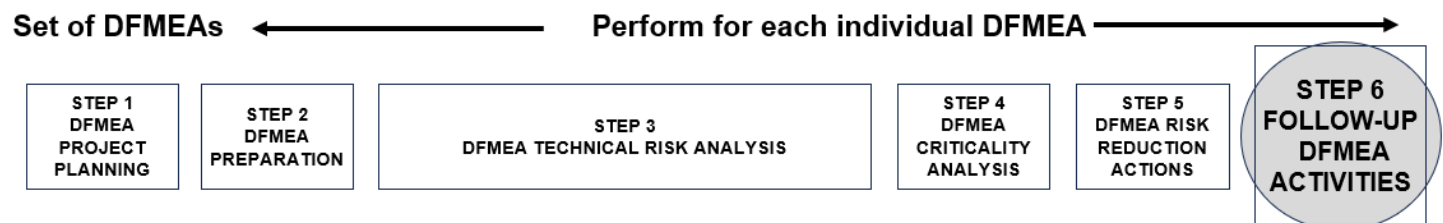


Figure 12 - Step 6 of the DFMEA six-step process map

Output: Follow-up DFMEA Activities Completed

6.6.1 Summarize DFMEA Key Findings

When DFMEA is required by contract, the results of the DFMEA shall be documented in a report provided to the Contracting Authority or equivalent organization (Acquirer).

The FMEA Report shall provide the following:

- The item being analyzed and at what indenture level
- The design version being analyzed
- The ground rules, analysis assumptions, and FMEA block diagrams
- System definition narrative
- Access, as required, to DFMEA records, in the form of worksheets or database records
- Catastrophic and critical failure modes that are unmitigated, along with estimated occurrence, and rationale for not eliminating the failure modes
- Potential single failure points that could not be eliminated, along with corresponding criticality

- A summary of any final conclusions and recommendations based on the analysis
- Plans for ongoing DFMEA updates
- Results of any DFMEA effectiveness evaluation

6.6.2 Provide DFMEA Effectiveness Feedback

An evaluation form or audit checklist should be used during the development of a DFMEA to ensure the quality of the analysis.

DFMEA Quality Objectives can be used as follows:

- Become part of DFMEA training
- Reviewed at each DFMEA meeting
- Incorporated as an essential part of DFMEA quality audits
- Consider leaving the DFMEA open until quality objectives are met
- Review of supplier FMEAs

See Appendix I for a list of DFMEA Quality Objectives.

6.6.3 Provide Ongoing DFMEA Updates

DFMEA shall be updated, as needed, throughout the life cycle of the product.

Essential Elements:

Once the initial DFMEA is completed and an acceptable level of risk is agreed upon by the DFMEA team and management, DFMEA updates shall be completed when indicated, based on the following types of changes:

- Changes to the product design
- Changes to the operating environment
- Changes to the use of the product
- Previously unidentified failure modes

Any of these items may warrant a change to the DFMEA and subsequent action taken to address residual risk. A systematic process for reviewing and updating the DFMEA compared to these changes should be adopted.

See 4.1.1.5 for requirements for managing and tracking of all changes, approvals, and versions of DFMEA within the organization. The DFMEA and its results must be retained according to the organization's record retention policy and requirements.

6.6.4 Identify DFMEA Linkages

This standard also defines the interfaces between the DFMEA and other processes. The linkages include:

- DFMEA linkage with SupFMEA, J.1.3 (see Figure J3)
- DFMEA linkage with the PFD, J.1.1 (see Figure J1)
- DFMEA linkage with PFMEA, J.1.2 (see Figure J2)

7. SUPPORTABILITY (SUP) FMEA

Purpose of Supportability FMEA

The purpose of Supportability FMEA (SupFMEA) is to analyze the product design from a supportability viewpoint, with two main objectives: (1) provide the basis for supportability analysis to determine all of the support requirements when the system is fielded and (2) identify additional potential design improvement opportunities to increase reliability or decrease downtime and support costs by reducing the need for, or complexity of, support requirements. Additionally, the SupFMEA is used to update the analysis of support requirements as in-service experience is gained. SupFMEA is used to identify failures that may occur in service so that appropriate support resources, including maintenance tasks, may be identified and acquired to correct or mitigate those failures. SupFMEA is also used to identify failures that may warrant design changes to improve the support posture of the system through reductions in the need for support resources, either through improved reliability or reduced support requirements. The SupFMEA provides the basis for all subsequent Supportability Analysis, such as Reliability-Centered Maintenance (RCM) Analysis, Maintenance Task Analysis (MTA), Level of Repair Analysis (LORA), and Spares Parts Provisioning Analysis.

Supportability FMEA General Requirements

The Supportability FMEA shall be initiated in the early design phase of a product life cycle as described in the General Requirements (see Section 4) and shall be updated to reflect the current state of the design throughout the product life cycle. The initial SupFMEA shall be started in the conceptual phase when design criteria, mission requirements, and conceptual designs are being developed to compare the supportability impacts of competing design configurations, evaluate different potential support concepts, and evaluate design versus supportability trade studies. As the design is solidified, the initial SupFMEA is completed and shall be used to begin other Supportability Analyses. The SupFMEA shall consider operational changes and accrued operating experience as the product or system is fielded. Significant benefits can be realized by periodically or continuously refining supportability analysis throughout the operations and support phase of the product life cycle.

The SupFMEA shall consider known or like operating conditions and scenarios based on the experience of operators and maintenance personnel who will operate and maintain the analyzed system or similar systems.

The SupFMEA analysis shall be performed at the indenture level at which support actions will occur with consideration given to the maintenance concept of the upper level system and all relevant subsystems and components. Analysis shall be performed at the indenture level at which support actions will occur.

The SupFMEA shall identify all failures that may potentially occur in service when a system is fielded. Unlike the DFMEA, PFMEA, and SwFMEA, which focus on eliminating critical or undesirable failures, the SupFMEA will identify those failures that may require correction or mitigation should they occur. The SupFMEA should also identify any critical failures identified in the DFMEA that were not fully eliminated or mitigated by the DFMEA process to ensure appropriate preventive maintenance requirements or other mitigation strategies are considered.

Supportability FMEA Process Steps

The SupFMEA shall be performed in accordance with the requirements specified in the SupFMEA Process Steps as detailed in Figure 13.