SURFACE VEHICLE STANDARD

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(R) Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA-MSR, and Process FMEA

RATIONALE

This standard has been revised to emphasize the process of FMEA selection, creation, documentation, reporting, and change management. New additions include the table of contents, supplemental DFMEA for monitoring and system response (DFMEA-MSR) with rating criteria for frequency and monitoring, and an introduction of the action priority method. The standard includes more information about how information flows from DFMEA to validation planning and PFMEA to control planning. Revisions have been made to the rating criteria for severity, occurrence, and detection for both DFMEA and PFMEA. This standard serves as a common starting point for the development of an effective DFMEA and PFMEA.

This document contains content from the AIAG and VDA Handbook, First Edition, 2019.

FOREWORD

This document was revised by a balanced committee and represents current thoughts and practices on the subject from the viewpoint of OEMs (original equipment manufacturers), suppliers, and consultants. The rating charts and action priority charts are part of harmonization efforts between SAE, AIAG, and VDA. This document serves as a standard that includes requirements and additional recommendations for best practices in the application of FMEA. The goal of this document is to adhere to basic principles of FMEA knowing that procedures for how to perform FMEA will vary by company. This document is referenced in other publications by IATF, ISO, SAE, AIAG, and VDA.

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TO PLACE A DOCUMENT ORDER: **Tel: 877-606-7323 (inside USA and Canada)**
Tel: +1 724-776-4970 (outside USA)
Fax: 724-776-0790
Email: CustomerService@sae.org
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1. SCOPE

This FMEA standard describes potential failure mode and effects analysis in design (DFMEA), supplemental FMEA-MSR, and potential failure mode and effects analysis in manufacturing and assembly processes (PFMEA). It assists users in the identification and mitigation of risk by providing appropriate terms, requirements, rating charts, and worksheets. As a standard, this document contains requirements—"must"—and recommendations—"should"—to guide the user through the FMEA process. The FMEA process and documentation must comply with this standard as well as any corporate policy concerning this standard. Documented rationale and agreement with the customer are necessary for deviations in order to justify new work or changed methods during customer or third-party audit reviews.

1.1 Purpose

To assist designers and manufacturers in the identification and reduction of technical risk by providing appropriate terms, requirements, evaluation criteria, and worksheet formats.

2. REFERENCES

The following documents are additional references on the subject of this standard. Unless otherwise indicated, the latest issue of the SAE publications shall apply.

2.1 SAE Publications

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

ARP5580 Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications

AS9103 Aerospace Series - Quality Management Systems - Variation Management of Key Characteristics

AS13004 Process Failure Mode and Effects Analysis (PFMEA) and Control Plans

2.2 ISO Publications

Copies of these documents are available online at http://webstore.ansi.org/.

ISO 26262 Road Vehicles - Functional Safety

2.3 Other Publications

AIAG and VDA FMEA Handbook, First Edition, June 2019, available from Automotive Industry Action Group, 4400 Town Center, Southfield, MI 48075, Tel: 248-358-3570, www.aiag.org.

IATF 16949, "Automotive Quality Management System Standard," International Automotive Task Force (IATF), Supplement to, and in conjunction with, ISO 9001:2015. IATF 16949:2016 was revised as a standard, cancels and replaces ISO/TS 16949:2009.

3. DEFINITIONS, EXAMPLES, TERMS

The purpose of terms and definitions is to add clarity to some words used in this document that are not otherwise defined in the body of the text.

3.1 DESIGN FMEA FOR MECHANICAL AND ELECTRICAL

Design FMEA is a type of FMEA that analyzes the product design, focusing on potential design-related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during useful life.

3.2 DESIGN FMEA FOR SOFTWARE

Software FMEA is a type of design FMEA that analyzes the software elements, focusing on potential software-related deficiencies, with emphasis on improving the software design and ensuring product operation is safe and reliable during useful life.

3.3 SUPPLEMENTAL FMEA FOR MONITORING AND SYSTEM RESPONSE

Supplemental FMEA for monitoring and system response (FMEA-MSR) enhances the DFMEA for selected mechatronic systems by providing a means of assessing risk reduction through diagnostic detection and response during customer operation.

3.4 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 DFMEA, some causes of failure may be considered faults.

3.5 DESIGN VERIFICATION/VALIDATION

Analysis or testing executed to demonstrate that new or modified designs, or new applications of existing designs, will meet customer expectations, in the intended environment, over the useful life of the product.

3.6 DIAGNOSTIC MONITORING

Monitoring in FMEA-MSR assesses the effectiveness of fault detection performance in customer operation, assuming that specifications are fulfilled. The Monitoring rating also comprehends the safe performance and reliability of system reactions to monitored failures.

3.7 FAILURE MODE AND EFFECTS ANALYSIS

FMEA is a qualitative and systematic analysis method intended to identify, prioritize, and reduce technical risks of product or process failures to an acceptable level. Failures shown in FMEA are considered potential and may or may not occur.

3.8 GENERIC FMEA

A generic FMEA contains both historical and potential failure modes, causes, controls, etc., not related to a specific project. It is used as a starting point for a new DFMEA or PFMEA because, when maintained, it reflects failures that occur after product and process validation and start of regular production and beyond. Other commonly used terms for generic FMEAs include core, template, baseline, gold standard, etc., based on company procedures.

3.9 MECHATRONIC SYSTEM

Technology combining mechanical, electrical, and software into a single product. A mechatronic system is a set of components or subsystems that relates at least a sensor, a controller, and an actuator with one another.

NOTE: The related sensor or actuator can be included in the system or can be external to the system. Refer to ISO 26262-1:2018.

3.10 PROCESS FMEA

Process FMEA is a type of FMEA that analyzes the manufacturing or assembly process, focusing on potential manufacturing-related deficiencies, with emphasis on improving the manufacturing process and ensuring the product is built to design requirements in a safe manner, with minimal downtime, scrap and rework, etc.

3.11 RISK MITIGATION

The implementation of changes to designs that changes the effect and therefore reduces the severity of the effects of failure.

3.12 PRODUCT VALIDATION

Engineering analysis or testing executed to demonstrate that products made from production tools and processes will meet customer expectations, in the intended environment, over the useful life of the product. PV is a requirement for the production part approval process (PPAP). Production validation is separate from plant equipment qualification and process control planning.

3.13 RISK REDUCTION

The primary objective of the FMEA process is to identify potential high risks and try to keep those high risks from occurring in the end product; or, if that cannot be accomplished, then to minimize the risk effect(s) to the end product user.

3.14 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.

3.15 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.

3.16 TEST REPORT

The test report provides a means for reporting progress and test results made toward design targets specified by the plan. The test plan and test report may be contained within a single document, the design verification plan and report (DVP&R) form. The plan and reporting system cover the entire test development and quality/reliability growth period, inception through ongoing refinement.

3.17 Examples in this Standard

This edition of SAE J1739 will be using a series of examples to illustrate the concept of various portions of FMEA. The examples will be a single-line excerpt from different FMEAs. The following example excerpts will be used:

1. Windshield wiper system FMEA
2. Windshield wiper arm design FMEA
3. Windshield wiper motor design FMEA
4. Washer fluid-level sensing software FMEA
5. Windshield wiper motor FMEA-MSR

It is important to note that there is a one-to-many relationship between the different portions of the FMEA. Each item can potentially have many functions. Each function can potentially have many failure modes. Each failure mode can have many causes, etc. The single-line example excerpts are meant to show the various portions of FMEA in order to help the reader understand the concept being described and should not be construed to mean there is only one line in the FMEA. It is also important to understand that the example excerpts are not an actual FMEA. An actual FMEA must be done by the correct team, with all the correct inputs. The example excerpts are for illustration purposes.

For example, the scope of the wiper motor DFMEA was expanded beyond the motor itself to include motor grounding, in order to illustrate a failure mode and cause relating to the grounding interface. The FMEA-MSR example was chosen to show the relationship between the wiper motor DFMEA and wiper motor FMEA-MSR, in order to illustrate how a supplemental FMEA for monitoring and system response flows from a DFMEA.

For these example FMEA excerpts, selected portions of FMEA preparation procedure were used, including a wiper system FMEA block/boundary diagram, assumptions about wiper system operating conditions, a wiper assembly process flow, and others.

Each of the five example excerpts are shown in the appropriate section of the standard, with only the portion of the example excerpt up to the sectional topic. For example, in the cause section, the five example excerpts will be shown up to cause (item, function/requirement, failure mode, effect, cause).

3.18 Terms

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

- “MUST” indicates a requirement.
- “SHOULD” indicates a recommendation.
- “MAY” indicates a permission.
- “CAN” indicates a possibility.

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

4. GENERAL REQUIREMENTS

4.1 What is FMEA?

The fundamental value of the FMEA process is to identify potential risks, prioritize those risks, and then reduce risks over time to an acceptable level. Three categories of technical risks discussed during the FMEA process include design risks (i.e., risks related to requirements and specifications, engineering calculations, material selection, labelling, etc.), process risks (i.e., risks related to manufacturing, assembly, testing, rework, etc.), and monitoring and response risks (i.e., risks related to diagnostics, warnings, etc.).

FMEA is a qualitative and systematic analysis intended to:

a. Prepare for risk analysis: FMEA preparation steps including FMEA block/boundary diagram, functional analysis, gather information, etc.

b. Identify technical risks: Identify potential failures of a product/process and the effects and causes of failure.

c. Prioritize risks: Assess the risks of failure using subjective criteria and prioritize the need for action.

d. Reduce risks: Identify and execute actions in order to reduce risk to an acceptable level.

e. Communicate results: Document the analysis and communicate risk reduction strategy.

FMEA is:

- An analysis of potential technical risk of failure of a product or process.
- A method to analyze single-point failures (i.e., failure A or failure B may occur).
- A qualitative (subjective) discussion method.

- Uses inductive reasoning (i.e., likelihood of future failure is based on occurrence of past failures and does not predict future failure with certainty).
- Uses deductive reasoning (i.e., development of conclusions based on premises agreed to by the team).

FMEA is not:

- Intended as an assessment tool for business, cost, or timing risk.
- A method to analyze multi-point failures that occur in tandem (i.e., failure A and B may occur together).
- A quantitative (computed) analysis.
- Intended for use as a validation test plan, or an advanced product quality planner.

4.2 Why FMEA?

The intended purpose of DFMEA and PFMEA is to ensure design and process robustness by thoroughly documenting and reducing the potential risks of failure to provide the intended functions and meet the necessary requirements of the product that is delivered to the customer.

4.3 Who Performs FMEA?

Although responsibility for the preparation of the FMEA varies by organization, FMEA should be a cross-functional team effort. A team of knowledgeable individuals should be consulted (e.g., engineers with expertise in design, analysis/testing, manufacturing, assembly, service, recycling, quality, reliability, and FMEA facilitation). The FMEA should be a catalyst to stimulate the interchange of ideas between the functions affected and thus promote a team approach.

4.3.1 Management

Management must establish a corporate policy regarding the application of FMEA as related to the corporation's product development program from concept design through validation, start of production, and beyond. This includes FMEA planning in relation to engineering project management.

Management has the authority to manage resources and set priorities to delegate tasks for FMEA completion. Management must establish design and process FMEA ownership for each analysis. Management is responsible for supporting the cross-functional team by showing interest in project status and team attendance, participating in the management reviews, and asking thought-provoking questions.

Each company must establish ownership for FMEA procedures and methodology. Company procedures must take into account external FMEA requirements such as ISO, IEC, SAE, and VDA standards. Individual project teams must understand OEM (customer-specific) FMEA requirements in order to reach an agreement on an approach that will meet the basic elements of FMEA (identify risk, prioritize risk, reduce risk) and establish the acceptance criteria for FMEA reviews in order to avoid FMEA rework late in the process.

Management must ensure a system is in place for storage and retrieval of FMEA documents. Management or the FMEA owner must determine when a FMEA is deemed Confidential.

NOTE: Proprietary, confidential, and secret document handling is not prescribed by this document.

4.3.2 Owner

The project engineer (system engineer, design engineer, etc.) is responsible for the technical content of a DFMEA. The manufacturing engineer (process engineer, assembly engineer, etc.) is responsible for the technical content of a PFMEA. The owner of the DFMEA is the person responsible for the design (i.e., product drawing/specification). The owner of the PFMEA is the person responsible for the process design (i.e., tooling specification, manufacturing process layout). Owners of FMEA are responsible for kicking off of the FMEA, technical leadership during the FMEA, and wrapping up meetings at completion of analysis: management review, review of related documents (e.g., test plans and control plans), summary of identified risks and assigned actions presented for information, consensus, and acceptance. They are responsible for recruiting the team and the facilitator.

4.3.3 Facilitator (Moderator)

The FMEA facilitator (moderator, coordinator, coach, etc.) is responsible for application of the FMEA method. In some cases, the technical content owner is also the facilitator. Facilitators determine the meeting agenda, session duration, and reoccurring schedules for the team to meet project timing. They invite core and support team members based on each agenda. They keep records of attendance and topics discussed. The facilitator works closely with the FMEA owner to complete each step of the analysis and report out to management and/or the customer.

4.3.4 Team Members

The owner of the FMEA will establish the FMEA team, as necessary, to suit the needs of the scope and ensure timely analysis. A team consists of knowledgeable individuals who perform the FMEA analysis. This may include, but is not limited to, representatives from: design (mechanical, electrical, software, safety), manufacturing, validation, suppliers, materials, service, quality, reliability and technical experts. Team members are responsible for preparing and participating during FMEA meetings.

NOTE: Due to logistics and responsibility differences, the entire team may not be able to meet at the same time. It is recommended to establish a core team where participation is required and a support team where participation is based on the agenda for a meeting or workshop.

4.3.5 Customer

Customer-specific requirements for FMEA should be discussed at the beginning of a new customer program: scope, timing, deliverables, special rating charts, special forms, etc. The customer is responsible for providing an FMEA audit worksheet at the beginning of a project if planned to be used to review the FMEA at the end of a project (to avoid misunderstandings).

4.3.6 Fully Owned Risks versus Partnership Interface Risks

When the product design is fully owned by an engineering group, the technical risk can be reduced or removed through adding preventive/detective controls or changing the design. For fully owned design risks, there is a single owner that owns this risk analysis.

“Fully owned” risks are defined as having sole responsibility for the risk by owning:

1. The engineering design responsibility, and

2. The key preventive control(s), and

3. The key detective controls to complete the mitigation process.

When the product design is not fully owned by an engineering group because of interfaces with products owned by others outside of their group, then partnership interfaces and multiple owners exist. Additional communication must be made about interface risks to understand and ensure that the risk mitigation process is thorough and completed. Poor communication or bad assumptions could lead to design deficiencies or manufacturing errors. Any uncertainties should be addressed in the Recommended Actions within the FMEA document.

“Partnership interface” risks are defined as owning only one or two of the three risk mitigating responsibilities (i.e., engineering/manufacturing design, preventive and/or detective controls).

Key partnership interface risks are poor interaction, communication or bad assumptions between risk partners. In other words, incorrect or missing information “sent by YOU” to your risk partner(s), or incorrect or missing information “received by YOU” from your risk partner(s).

4.4 When is the FMEA Created?

One of the most crucial factors for the successful implementation of an FMEA program is timeliness. The FMEA is meant to be a “before-the-event” action, not an “after-the-fact” exercise. To achieve the greatest value, the FMEA should be done before a product or process failure mode has been incorporated into a product or process. Upfront time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises. An FMEA can reduce or eliminate the chance of implementing a preventive/corrective change that could create an even larger concern (safety or regulatory).

4.4.1 Start

The FMEA should be started as soon as the design or process concept has been established. In general, a DFMEA for the product is started before the PFMEA. The company’s product development timeline shows the timing for design, validation, machine qualification, and production of the product. This timeline is useful for establishing milestones for DFMEA and PFMEA.

4.4.2 Completion

The FMEA should be completed through action plan identification before the design or process has been finalized. In general, a DFMEA should be finished before validation testing begins. A process FMEA should be finished before machine qualification begins. Tracking of actions is based on their due dates. Refer to internal company procedures for target completion timing.

4.4.3 Revisions

See 5.6 and 6.6 for more information about when the DFMEA and PFMEA should be revised after is has been completed.

4.5 FMEA Worksheet

The steps of FMEA are created by using tools that provide structure to perform the analysis (e.g., FMEA form column headings or FMEA software). These worksheets can be modified to meet company or customer requirements (e.g., add or move columns). See Appendices L, M, N for recommended forms.

4.6 FMEA Rating Criteria

A suggested rating criteria for severity, occurrence, detection, frequency, and monitoring is included in this standard. Rating criteria should be agreed to at the beginning of a project with the customer to avoid rework late in the development process. The team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual analysis. The rating criteria must be included in the FMEA documentation.

4.7 FMEA Risk Prioritization

A risk prioritization method should be agreed-to at the beginning of a project to avoid rework later in the development process.

4.8 FMEA Process Steps

In general, FMEAs should be guided by the steps shown in Figure 1. The actual flow of analysis activities may be iterative, not necessarily sequential. Section 5 DFMEA and FMEA-MSR and Section 6 PFMEA define the details of each step.

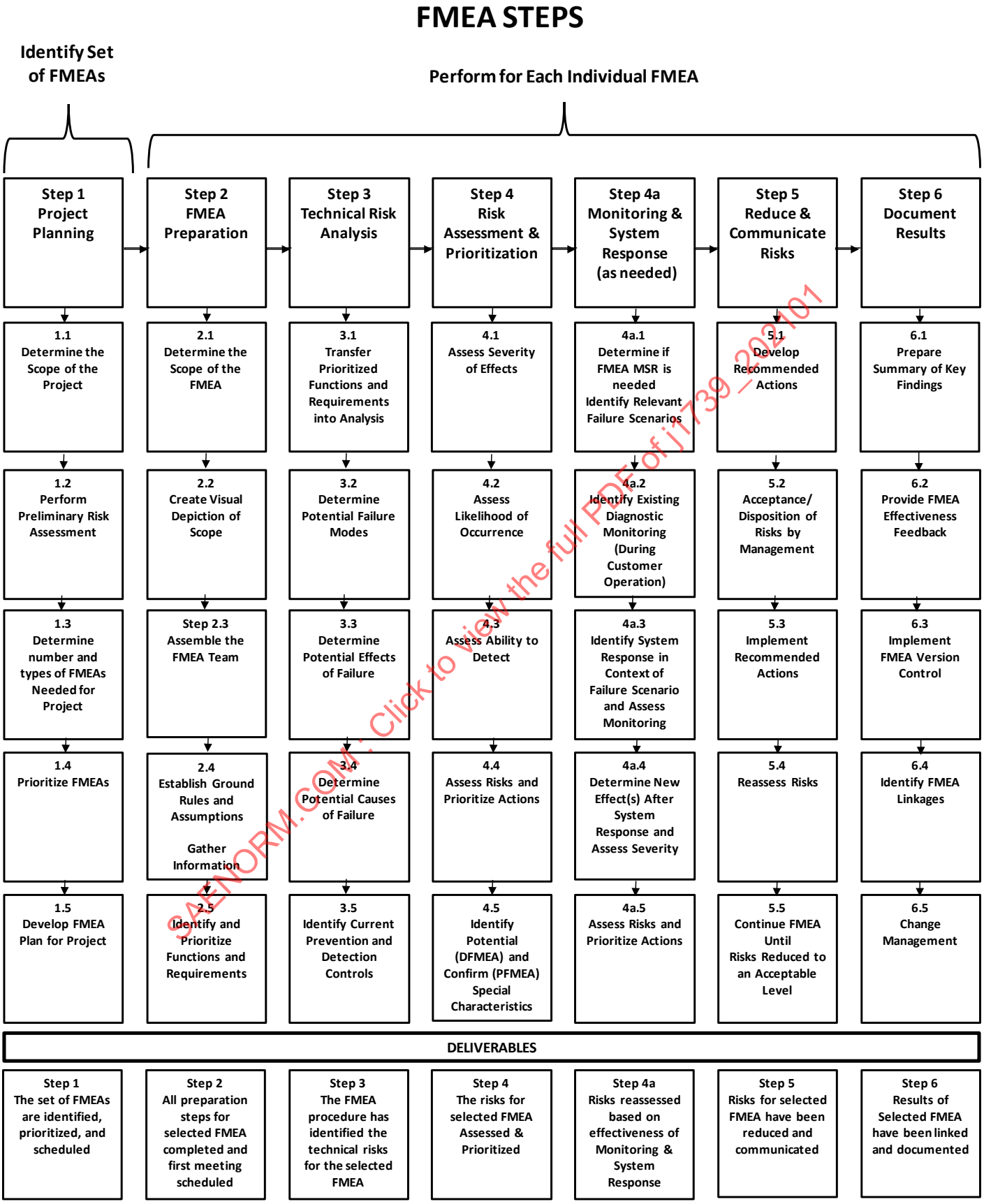

Figure 1 - FMEA six-step process map

5. DESIGN FMEA

5.1 Project Planning (Step 1)

Figure 1A - Step 1 of the FMEA six-step process map

Deliverables: The set of DFMEAs are identified, prioritized, and scheduled.

5.1.1 Determine the Scope of the Project

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

For system and design FMEAs, the scope of the project can be described textually, such as new widget project, along with appropriate level of detail about the project definition. It can also be visually represented by the system hierarchy, sometimes called the bill of materials.

System hierarchy is defined as follows:

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.

The partitioning of the overall project into individual FMEAs depends on who is responsible for the design. For system and design FMEAs, the general rule is whomever has design responsibility has ownership for the corresponding system or design FMEAs. If company “A” has responsibility for the windshield washer system, then they have responsibility for the System FMEA on the windshield washer system. If they also have responsibility for the wiper arm and wiper motor, they would also have responsibility for any needed DFMEAs on the wiper arm and motor. System FMEAs are a type of design FMEA that focus on functions that are unique to the system, and interfaces between subsystems and adjacent systems (which may include multiple ownership responsibilities). Software FMEAs are a type of design FMEA that focus on functions (sometimes referred to as vehicle features such as lane keeping assist) that require software to perform the function.

When defining the scope of an FMEA project, a portion of the system configuration could look like Figure 2, with as many subsystems and components as needed.

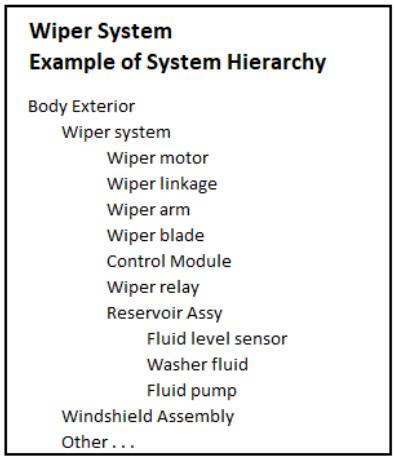

Figure 2 - System hierarchy example for windshield wiper system

Although the scope of the project is visually depicted by the system hierarchy (e.g., use of a structure tree), 5.1.2 and 5.1.3 describe how to select which FMEAs will be done from the system hierarchy.

5.1.2 Perform Preliminary Risk Assessment for Design FMEA

DFMEAs can be resource intensive. They should be performed when a certain level of change or other risk factors can be effectively addressed by the DFMEA methodology. New product designs can include hundreds or even thousands of subsystems and components. Few companies have the resources to properly do DFMEAs on everything. New or modified designs usually require a system FMEA. Lower-level FMEA projects can be identified based on well-defined selection criteria.

Some companies consider three basic cases for which DFMEAs are generated, each with a different scope or focus.

Case 1: New designs or new technology. The scope of the DFMEA is the complete design.

Case 2: Modifications to existing design (assumes there is a DFMEA for the existing design). The scope of the revision efforts should focus on the modification to design, possible interactions due to the modification, and field performance. Modifications include removal or addition of new parts. Modifications also include changes to existing product functions or performance requirements.

Case 3: Use of existing design in a new environment, location, or application (assumes there is an DFMEA for the existing design). The scope of the revision is the impact of the new environment, location, application, duty cycle, or usage profile of the existing design.

Cases 1, 2, and 3 provide some guidance for scope identification; however, additional factors should be considered. The preliminary risk assessment can be used to determine which DFMEAs need to be done, to support prioritization, and to enhance the use of Cases 1, 2, and 3 for DFMEA project planning.

Preliminary risk assessment has three stages:

1. Companies identify important criteria and weight for selection of DFMEA projects. Example selection criteria may include:
    - Potential for safety issues
    - Degree of new technology
    - Degree of design or application change
    - History of significant field problems

- Potential for important regulation issues
- Supplier capability
- Other risk criteria such as complexity, cybersecurity issues, safety-related software functions, high-risk interfaces, etc.

2. The risk criteria can each be assessed on a variable scale (such as high 3, moderate 2, or low 1) for each of the items being considered for FMEAs. Preliminary risk assessment criteria can be tailored to the unique needs of any company. The prioritization metric column is a multiplication of the risk columns.

3. Based on this assessment, the team can select FMEAs to be performed on the wiper project. The team may choose to do all the FMEAs or select ones that have the highest scores. Determine number and types of FMEAs needed for project.

Figure 3 shows a fictitious example of preliminary risk assessment done on a wiper system. The example above applies to system or design FMEAs.

Preliminary Risk Assessment
Wiper System Example
Method:
1. Project team agrees on risk factors
2. For each level of system hierarchy, assess risk related to associated risk factor (1, 2, 3*)
3. Multiply risk assessments together to get prioritization metric
4. When the team decides which items will receive an FMEA, enter Y/N in last column
* Assessment key: 1 = low risk, 2 = moderate risk, 3 = high risk

Item	Safety Concerns	New Technology	Degree of Change	Field Problems	Regulatory Risk	Supplier Concerns	Other risk factors[1]	Prioritization Metric	Create/update DFMEA Y/N
Wiper system	3	3	2	3	2	3		324	Y
Wiper motor	2	3	2	3	2	3		216	Y
Wiper linkage	1	1	1	2	1	2		4	N
Wiper arm	3	1	3	3	2	2		108	Y
Wiper blade	2	2	1	2	2	1		16	N
Control Module	2	1	1	1	1	1		2	N
Wiper relay	3	1	1	2	2	3		36	N
Reservoir Assy (incl sensor)	2	2	2	3	2	3		144	Y

[1] Project team may add other risk factors, as well as modify above risk factors.

Figure 3 - Preliminary risk assessment example for windshield wiper system

5.1.3 Determine Number and Types of FMEAs Needed for Project

The project team, with management agreement, determines the number and type of FMEAs needed for the project based on the preliminary risk assessment. The number of FMEAs is influenced by scope and responsibilities within or outside the organization. Types of DFMEAs include system, subsystem, or component and can include designation of mechanical, electrical, or software.

5.1.4 Prioritize Design FMEAs

Prioritization should emphasize conducting FMEAs for which the scopes are of greatest risk to the project based on the results of a preliminary risk assessment. Prioritization allows the project team to determine which FMEAs to do and define the order so they can be scheduled.

5.1.5 Develop DFMEA Plan for Project

The FMEA plan is the output of prioritization with added detail. By definition, a “plan” is a written account of intended future course of action aimed at achieving specific goal(s) or objective(s) within a specific timeframe. It explains in detail what needs to be done, when, how, and by whom.

An FMEA plan is the set of FMEAs that need to be done on a given program, including the types of FMEA (system, design, process, DFMEA-MSR, supplier FMEAs, or others), when they will be done, and by whom.

5.2 DFMEA Preparation (Step 2)

Figure 1B - Step 2 of the FMEA six-step process map

Deliverables: All preparation steps for selected DFMEA have been completed and first meeting scheduled.

5.2.1 Determine the Scope of the FMEA

The scope of a DFMEA can be defined by using diagrams, system hierarchy, bills-of-material, illustrations, or similar tools that represent items (also referred to as system elements) being analyzed to facilitate the analysis of interfaces and close clearance conditions. 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 (e.g., per the block/boundary diagram or bill-of-material) 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.

Examples of items include: wiper system, wiper arm, wiper motor, wash fluid-level sensing software, etc.

There are assemblies and components that are outside a company’s design and development responsibility. The common term is “black box.” The team may use the FMEA block/boundary diagram to show which components are make/buy.

5.2.2 Create Visual Depiction of Scope

A visual depiction can be achieved using a block/boundary diagram. A system hierarchy created from a part list or bill-of-material is recommended as an input to the block/boundary diagram.

5.2.2.1 Block/Boundary Diagram

The block/boundary diagram is a pictorial tool to facilitate analysis of system or subsystem. A block/boundary diagram is required.

In the context of the selected DFMEA, the block/boundary diagram does the following:

- Visually depicts scope of analysis
- Provides a foundation for Interface analysis, item/function analysis, P-diagram, and DFMEA
- Identifies internal and external interfaces which can then be shown as functions in DFMEA
- Enables application of system, sub-system, and component hierarchy

The diagram may be in the form of boxes connected by lines as shown in Figure 4. Each box corresponding to a major sub-system/component of a product. The lines correspond with how the product sub-systems/components are related to, or interface with, each other; for additional clarity, arrows can be used at the end point(s) to indicate the direction of flow, when appropriate. It is recommended to label the blocks and interfaces with an alpha-numeric label.

Interfaces and interactions may be analyzed using an interface FMEA or included in a component, subsystem, or system analysis. Additional interfaces and interactions include human-machine interface (HMI) and human-vehicle interface (HVI). This diagram illustrates the primary relationship between the items covered in the analysis.

Types of relationships:

- P: Physically touching
  - Welded, bolted, clamped, adhesion, clearance
- E: Energy transfer
  - Electricity, heat, kinetic energy, torque, force
- I: Information/data transfer
  - Data, CAN messages, analogue signals, tell-tales
- M: Material exchange
  - Coolants, fuels, liquids/gases/solid, material abrasion

Block/boundary diagrams are created as early as possible in the product development cycle—as soon as a basic definition of the system or subsystem exists. Block/boundary diagrams are steadily refined as the design matures.

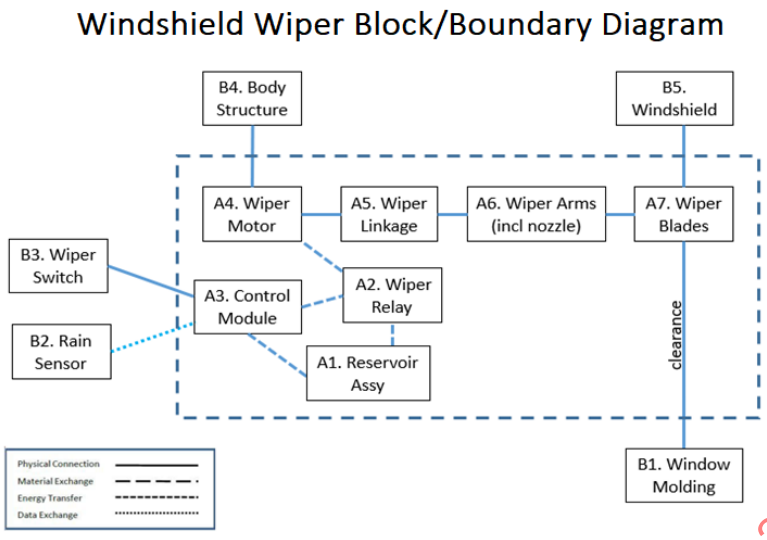

Figure 4 - Block/boundary diagram example for windshield wiper system

5.2.3 Assemble the FMEA Team

The owner of the FMEA will establish the FMEA team, as necessary, to suit the needs of the scope and ensure timely analysis. The DFMEA team consists of subject matter experts who represent cross functional knowledge associated with the design and are trained in the DFMEA process. DFMEA is a team effort and each team member contribute 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 functional safety engineer and on-board diagnostic engineer may be added to the FMEA-MSR core team as needed. This core team should expand based on the needs of the team (e.g., add disciplines, add more experienced people, etc.). See 4.3 for more information.

The reason for a cross-functional team is simply because one person cannot know everything. Multiple disciplines minimize the potential for “blind spots” while conducting the analysis. The project leader, who may be a system/product engineer, quality engineer, or DFMEA engineer (facilitator/moderator) should develop a team roster that includes resources assigned to the overall project/program along with additional subject matter experts to ensure the proper expertise is applied to the DFMEA. 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.

5.2.4 Establish Ground Rules and Assumptions/Gather FMEA Information

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

5.2.4.1 Ground Rules

Suggested ground rules to help DFMEA teams operate efficiently 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/boundary diagram will be updated based on additions and changes during the development of the DFMEA
- Identify potential failures that are reasonable and controllable by design
- Work within the team’s knowledge and ask for input from others when needed

5.2.4.2 Assumptions

The DFMEA should address the design intent and assume the design will be manufactured/assembled to this intent. The PFMEA should address manufacturing and assembly risk. 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. As such, failures described in the DFMEA may or may not occur. The DFMEA team should agree on a set of assumptions for the analysis. These assumptions are used to keep the team focused on what they have control over.

5.2.4.3 Gather Information

The purpose of this step is to gather the information that is necessary to perform the technical risk analysis for the selected FMEA.

One of the more important steps in FMEA preparation is gathering all the relevant information, as available. If this step is missed or done inadequately, FMEA meetings can be burdened with extra tasks related to missing information, and FMEA results potentially compromised. The specific list of information that needs to be gathered when preparing for an FMEA should be determined by the company. The following are some of the categories of information to research and gather prior to the first FMEA meeting.

- Bill of materials, as covered in 5.2.1
- Past DFMEAs and/or generic DFMEA, with similar scope to the selected FMEA
- Warranty, recalls, and other field history, preferably prioritized, so the FMEA team knows the most important issues
- Engineering requirements (functional, performance, functional safety, operating environments, etc.)
- Drawings, schematics, software architecture models
- Applicable government or safety regulations
- Test procedures
- Lessons learned/best practices
- Industry standards
- Preliminary design verification plan
- FMEA block/boundary diagram
- P-diagram (if performed)
- 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

NOTE: If new DFMEA being built from a past or generic DFMEA, the team needs to ensure it is an adequate DFMEA to be used as a starting point.

5.2.4.4 Identifying Information

The DFMEA documentation contains important information about the analysis. The identifying information must include a project name, latest revision date, organization, department, and group or individual who is design responsible. Additional information such as DFMEA number, start date, model year, program number, system/sub-system/component, core and support team member names, and team facilitator, etc., may be documented to provide useful information for tracking or storage and retrieval purposes. A team member list including names and departments is recommended.

5.2.5 Identify and Prioritize Functions and Requirements

Functions and requirements provide a foundation for each of the selected items to be analyzed.

5.2.5.1 Functions

The function describes what the item is intended to do. An item (e.g., product) may have more than one function. Function statements in the form of “action verb” followed by “measurable noun” are key to accurately describe the functions of the items. Examples for the windshield wiper DFMEA are shown in Figure 5.

System and DFMEAs must consider basic and interface functions. Basic functions are what the item is supposed to do (including associated requirements) and can be summarized 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/boundary diagram.

The more precise the function, the easier it is to identify potential failure modes for preventive/corrective action. If the item has more than one function with different potential modes of failure, then the functions should be listed separately.

5.2.5.2 Requirements

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. Examples for the Windshield Wiper DFMEA are shown in Figure 5.

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

Item	Function(s)	Requirement(s)
Wiper System	Clear windshield of debris and water on all wiper speed settings	1. Wipe quality is defined in document #XYZ 2. Blades must not contact windshield or body moldings at any time. 3. Reference FMVSS 104
Wiper arm	Transfer angular motion from wiper pivot to wiper blade	1. Blade-glass pressure X 2. Wiper arm length Y 3. Wiper arm bending stiffness Z [Reference wiper arm specification #abc]
Low washer fluid-level warning software	Communicate low fluid level to instrument display	Send 5 volt signal to the instrument display when the fluid level goes below 25% of its reservoir capacity
Wiper Motor (includes motor grounding)	Provides operational power to operate the wiper system.	1. Minimum output torque "X" Nm 2. maximum current (Amps) 3. minimum rotational RPM Y

DFMEA columns truncated

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Figure 5 - Functions and requirements examples for windshield wiper DFMEA

5.2.5.3 Design for Assembly/Manufacturing

The DFMEA team should consider the design and its characteristics that help ensure the design can easily be manufactured without failures. One example might be a requirement to align two parts in a manner that is error proofed. In this example there needs to be a self-aligning feature. This can be described by a function/requirement.

DFMEA function: product assembly of Part A attaches to Part B with the requirement of A and B parallel edges. The measurable requirement might be: Part A to Part B parallel edges within 0.2 mm.

The DFMEA for this function/requirement would identify potential failure modes, effects, causes and possibly end up with a design improvement with the use of recesses or bosses to properly locate components in a self-aligning manner.

5.2.5.4 Item/Function Matrix

An item/function matrix is a tool to identify and prioritize functions and requirements. Items that are graphically displayed on the block/boundary diagram are correlated to the appropriate function. The windshield wiper item/function matrix example is shown in Figure 6.

An item/function matrix has the following objectives:

1. Provide a visual listing of the basic and interface functions (and associated requirements) for the item being analyzed.

2. Provide a visual listing of lower-level items from the FMEA block/boundary diagram, and associated functions/requirements for those lower-level items that will be getting FMEAs (see preliminary risk assessment).

3. Provide a visual listing of the interfaces and type of interface (from FMEA block/boundary diagram) and list the associated interface function for the highest-priority interfaces.

4. Prioritize each of the listed basic and interface functions for the item being analyzed (for inclusion in the FMEA), as well as the lower-level functions that will be getting FMEAs.

An item/function matrix is developed as follows:

1. List the items from the FMEA block/boundary diagram.
2. List the basic functions for the item being analyzed.
3. List the lower-level items that will be receiving FMEAs, based on preliminary risk assessment. Other items that will not be getting FMEAs (such as component FMEAs) can be grayed out.
4. List the functions and associated requirements for each of the lower-level items that will be getting FMEAs.
5. List the interfaces from FMEA block/boundary diagram and identify the type of interface.
6. Prioritize the basic and interface functions, based on company-specific criteria, such as past field problems, changes to the design, and new technology.
7. Assign the interface type for each of the interfaces based on FMEA block/boundary diagram.
8. List the functions for each of the higher-priority interfaces.

Wiper System Item-Function Matrix Example

Interface Key: Physical connection = P, Material exchange = M, Energy transfer = E, Data exchange = D, Physical clearance = P_C

Items / Interfaces	Functions (for items considered higher risk based on prelim risk assessment)	Requirements	Function Priority	External Interface Type	Internal Interface Type
Item: Wiper System	Clear windshield of precipitation on all wiper speed settings	1. Wipe quality defined in doc. #XYZ 2. Blades must not contact windshield or body moldings at any time. 3. Swept Area (Reference FMVSS 104) 4. Cyclic wipe rate on low speed, high speed, and intermittent settings	H		
	Provide quiet operation	Noise less than X decibels	M		
A1. Reservoir Assy	Contain supply of washer fluid	Contains X liters of washer fluid	L		
	Deliver washer fluid to nozzle	Delivers X ml/sec of washer fluid	M		
	Detect low washer fluid level	Detects 25% volume threshhold	H		
A2. Wiper Relay	Complete circuit to supply power to wiper motor when signal from controller is present	1. 5 V signal 2. 12 V XX A fused power 3. Isolated ground	M		
A3. Control Module			L		
A4. Wiper Motor	Provide operational power to articulate the wiper system	1. Torque specification 2. Stall resistance performance specification	H		
A5. Wiper Linkage			L		
A6. Wiper Arm	Transfer motion from wiper pivot to wiper blade	1. Force-Deflection Spec 2. Wind Lift Spec 3. Blade angle Spec 4. Durability	H		
A7. Wiper Blade	Sweep precipitation from windshield	1. Contact glass throughout sweep, along entire blade 2. Durability	M		
Interface: B1-A6 Wdo Mldg-Wiper Blade	Maintain Clearance on all wipe cycles	1. 25 mm clearance spec	M	P_C	
Interface: A1-A3 Ctrl Mod - Reservoir	Communicates signal from fluid level sensor	1. 0.XX voltage drop max	H	E	
Interface: A2-A3 Ctrl Mod - Wpr Relay	Send signal to wiper relay according to wiper switch position	1. 5 V signal	M	E	
Interface: A4-B4 Body Struct - Wiper Motor	Locate, secure, and isolate wiper motor	1. Noise transmission requirements 2. Electrical grounding	H	P	
Interface: B5-A7 Windshield - Wiper Blade	Clear windshield of precipitation	1. Blade angle specification 2. SAE Blade pivot spec	M	P	
Interface: A2-A4 Wpr Relay - Wpr Motor	Switch wiper motor power supply according to stalk switch position	1. 5V input, 12V Output 2. Durability	M		E
Interface: A4-A5 Wpr Mtr - Wpr Linkage	Actuate linkage by converting motor torque to reciprocating motion	1. Splined joint 2. Nut tightening torque	H		P
Interface: A5-A6 Wpr Linkage - Wpr Arm			L		P
Interface: A6-A7 Wiper Arm - Wiper Blade			L		P

Figure 6 - Item/function matrix example for windshield wiper system

5.2.5.5 Prioritization of Functions

A final step in FMEA preparation is to identify and prioritize the functions that relate to the item being analyzed. These become candidate functions to be brought into the FMEA. See 5.3.1.

Once basic and interface functions are listed, prioritizing the functions can be done based on company-specific criteria, such as past field problems, changes to the design, and new technology. If the functions are prioritized (high, medium, low), the FMEA team can begin with the high-priority functions and proceed with other priorities based on company or customer guidance. Functions of greatest concern to the team should be discussed first, and in greatest detail. Not all functions need to be included in the DFMEA.

5.2.5.6 Parameter Diagram for select Functions

A parameter (P) diagram is a graphical representation of the environment in which an item exists. Parameters are attributes of the behavior of a function. A P-diagram includes factors which influence the transfer function between inputs and outputs, focusing on design decisions necessary to optimize output. An example of a parameter diagram is shown in Figure 7.

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

A P-diagram focuses on achievement of function. It clearly identifies all influences on that function including what can be controlled (control factors), and what cannot reasonably be controlled (noise factors). The P-diagram is a key input for robust DFMEA analysis. It enables teams to understand transformations and how they are influenced. Information gained through developing a P-diagram provides input to the test plan.

The P-diagram, completed for specific ideal functions, assists in the identification of:

- Factors, levels, responses, and signals necessary for system optimization
- Functions which can be inputs to the FMEA
- Control and noise factors which could affect functional performance
- Failure modes and unintended system outputs (diverted outputs)
- Potential effects of failure
- Recommended actions

P-diagrams are a useful way of illustrating system behavior:

- Sources of variation
- Ways of controlling performance
- Links between failure modes and noise factors

As P-diagrams are completed on a specific function, there may be multiple P-diagrams for one DFMEA; in this case, attach all of the P-diagrams to the DFMEA.

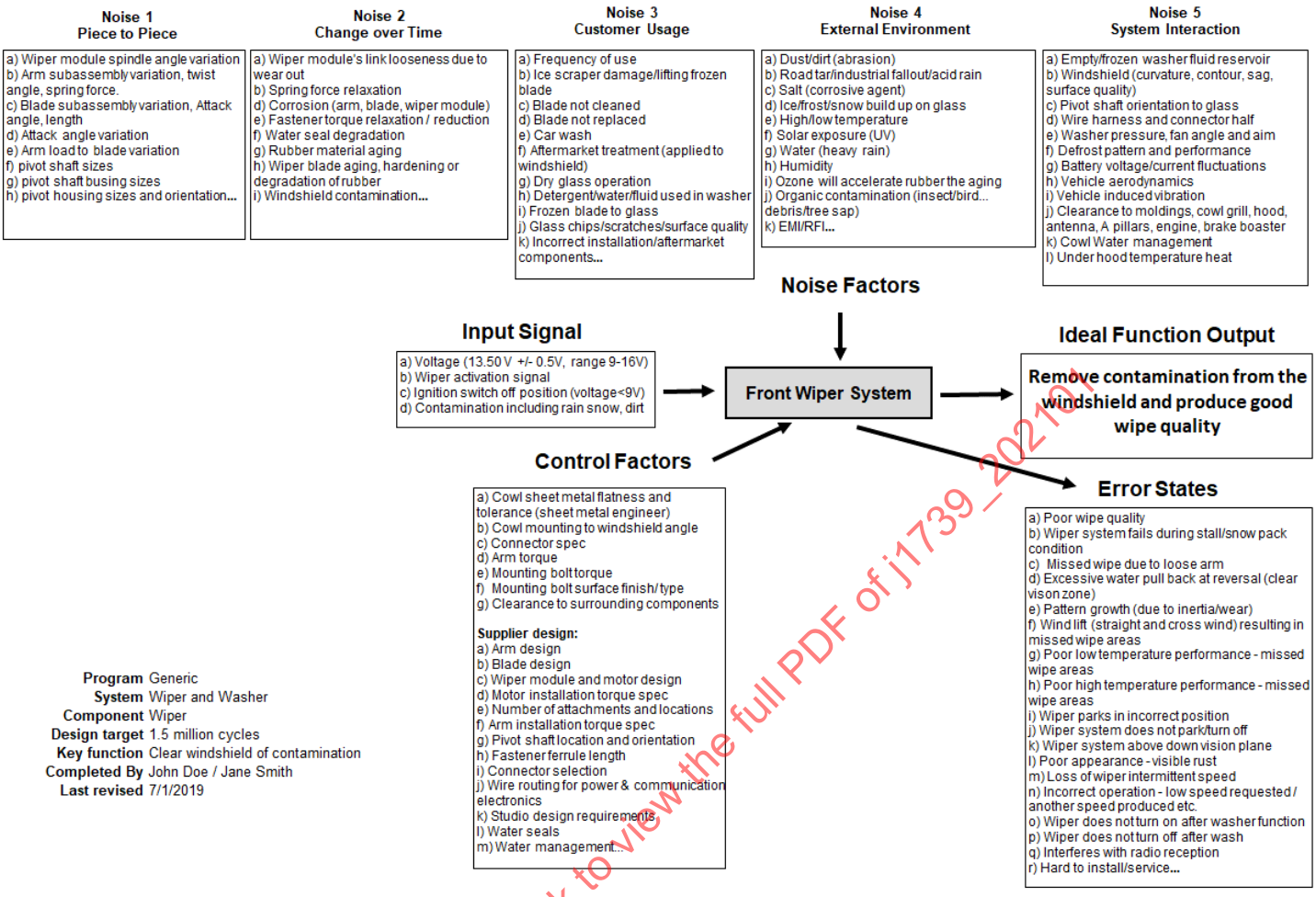

Figure 7 - Parameter diagram example on windshield wiper system

5.3 Technical Risk Analysis (Step 3)

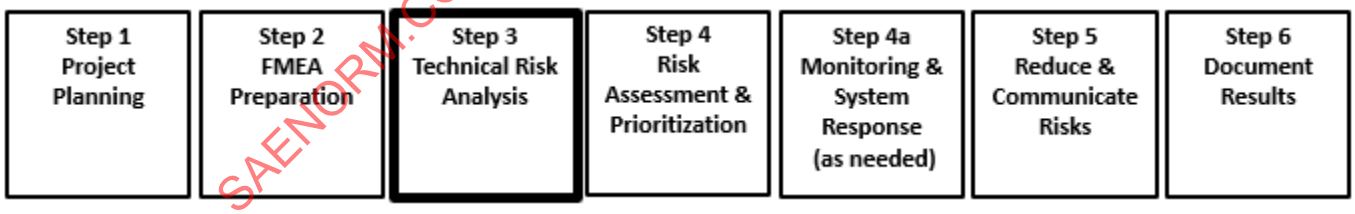

Figure 1C - Step 3 of the FMEA six-step process map

Deliverables: The DFMEA procedure has identified the technical risks for the selected DFMEA.

5.3.1 Transfer Prioritized Functions and Requirements into Analysis

The team can begin the technical risk analysis once the item, functions, and requirements have been selected and transferred to the DFMEA.

5.3.2 Determine Potential Failure Modes

A potential failure mode is the manner in which an item could potentially fail to meet or deliver the intended function. Each potential failure mode is considered separately from other failure modes allowing the team to address the unique reasons (causes) for that failure mode. List each potential failure mode separately in the DFMEA worksheet. Examples for the windshield wiper DFMEA are shown in Figure 8.

There are several categories (thought starters) of potential failure modes, including:

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

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

Item	Function(s)	Requirement(s)	Potential Failure Mode(s)
Wiper System	Clear windshield of debris and water on all wiper speed settings	1. Wiper quality is defined in document #XYZ 2. Blades must not contact windshield or body moldings at any time. 3. Reference FMVSS 104	Windshield is not clear of debris and water
Wiper arm	Transfer angular motion from wiper pivot to wiper blade	1. Blade-glass pressure X 2. Wiper arm length Y 3. Wiper arm bending stiffness Z [Reference wiper arm specification #abc]	Wiper arm bends
Low washer fluid-level warning software	Communicate low fluid level to instrument display	Send 5 volt signal to the instrument display when the fluid level goes below 25% of its reservoir capacity	Does not send low-fluid level indication to display when below threshold
Wiper Motor (includes motor grounding)	Provides operational power to operate the wiper system.	1. Minimum output torque "X" Nm 2. maximum current (Amps) 3. minimum rotational RPM Y	Insufficient power to overcome static friction in system

DFMEA columns truncated

DFMEA rows truncated

Figure 8 - Potential failure mode examples for windshield wiper DFMEA

5.3.3 Determine Potential Effects of Failure

The effects of failure are consequences or results of each failure mode. The effect(s) are listed in the DFMEA for each failure mode. The effects of the failure mode should be considered against the next level up assembly, the final product, and the end user/customer (product operator). End effects should state what the user might notice or experience. They should clearly state if the effect of a failure mode could impact safety or non-compliance to regulations, when applicable. The intent is to forecast the potential effect(s) of failure consistent with the team's level of knowledge. In some cases, the team conducting the analysis may not know the end user effect (e.g., commodity parts such as catalogue parts or off-the-shelf parts). When this information is not known, the effects should be defined in terms of the part function and specification. The system integrator has the responsibility to ensure the commodity item addresses integration risks. Examples for the windshield wiper DFMEA are shown in Figure 9.

Item	Function(s)	Requirement(s)	Potential Failure Mode(s)	Potential Effect(s) of Failure
Wiper System	Clear windshield of debris and water on all wiper speed settings	1. Wipe quality is defined in document #XYZ 2. Blades must not contact windshield or body moldings at any time. 3. Reference FMVSS 104	Windshield is not clear of debris and water	Possible reduction of driver visibility and potential violation of FMVSS 104
Wiper arm	Transfer angular motion from wiper pivot to wiper blade	1. Blade-glass pressure X 2. Wiper arm length Y 3. Wiper arm bending stiffness Z [Reference wiper arm specification #abc]	Wiper arm bends	Wiper blade angle changes resulting in blade chatter; glass not fully cleared but partially degraded visibilty, without safety implications (no violation of FMVSS 104)
Low washer fluid-level warning software	Communicate low fluid level to instrument display	Send 5 volt signal to the instrument display when the fluid level goes below 25% of its reservoir capacity	Does not send low-fluid level indication to display when below threshold	Empty washer fluid container leading to insufficient clearing of windshield with potential reduced forward visibility
Wiper Motor (includes motor grounding)	Provides operational power to operate the wiper system.	1. Minimum output torque "X" Nm 2. maximum current (Amps) 3. minimum rotational RPM Y	Insufficient power to overcome static friction in system	Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104

DFMEA columns truncated

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Figure 9 - Potential effects of failure examples for windshield wiper DFMEA

NOTE: Some words may be part of the description of a failure mode, effect, or cause depending on the function and requirements of a system, subsystem, or component (e.g., leaks).

5.3.4 Determine Potential Cause(s) of Failure

For each failure mode, the FMEA team identifies the causes. A "cause" is the specific reason for the failure, preferably found by asking "why" until the root cause is determined. For DFMEAs, the cause is the design deficiency that results in the failure mode. For process FMEAs, the cause is the manufacturing or assembly deficiency (or source of variation) that results in the failure mode. If a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode. The cause should be described in actionable terms; i.e., something that can be corrected or controlled. Examples for the windshield wiper DFMEA are shown in Figure 10.

Where possible the FMEA team should continue asking "why" until identifying the "root" cause. The only exception to this is for higher levels of analysis, such as system FMEAs, in which the cause may remain at a higher level, such as a component failure, and not carried all the way down to the reason for the component failure, which the subsequent DFMEA would analyze for the component. It is often useful to use the phrase "due to" to help get the root cause. For example, in the case of the projector lamp shattering, a possible cause could be "over pressure due to wrong gas."

When a system FMEA is being performed, and a supplier has responsibility for a subassembly or component, the system FMEA team may need to request access to appropriate FMEA information, in order to be certain risk has been identified, and high-risk issues are properly addressed.

In DFMEAs, root causes are often described in terms of product characteristics, such as dimensions, weight, orientation, hardness, strength, etc., where the 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.

When identifying causes, it is useful to review the assumptions for the DFMEA, such as the following:

1. The DFMEA team may assume the part is manufactured or assembled within engineering specifications. Based on this assumption, failure modes may be caused by potential deficiencies in design.

2. The DFMEA team may assume the part design may include a deficiency that could cause unacceptable variation in the manufacturing or assembly process. Based on this assumption, failure modes may be a result of manufacturing or assembly mis-builds, but the mis-builds are due to potential design deficiencies.

In the SAE J1739 DFMEA worksheet, the cause column 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 FMEAs leads to a more thorough understanding of the physics of failure, resulting in effective resolution of potential design deficiencies.

It is helpful to emphasize the difference between failure mode, cause, and failure mechanism. A failure mode is the manner in which the item or assembly could fail to meet the intended function and its requirements. A cause is the specific reason for the failure, expressed as a potential design deficiency. A failure mechanism is the actual physical phenomenon behind the failure mode or the process of degradation or chain of events leading to and resulting in a particular failure mode.

Wherever possible, for high-risk issues the FMEA team should define the cause at the failure mechanism level. This means for system FMEAs or subsystem FMEAs, the FMEA team should either proceed with a component FMEA that can drill down to the precise root cause and failure mechanism that explains the failure mode and place it in the cause column or continue with the “five whys” until isolating the cause at the mechanism level. No matter how the FMEA team chooses to proceed, wherever possible the FMEA team should properly define the cause at the failure mechanism level for high-risk issues.

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, sub-system, 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.

Incorrect cause wording (not actionable): Using wiper system to clear ice or deep snow from windshield.

Correct cause wording (actionable): Insufficient robustness to wiper blade blockage specified.

Item	Function(s)	Requirement(s)	Potential Failure Mode(s)	Potential Effect(s) of Failure	Potential Cause(s) of Failure
Wiper System	Clear windshield of debris and water on all wiper speed settings	1. Wipe quality is defined in document #XYZ 2. Blades must not contact windshield or body moldings at any time. 3. Reference FMVSS 104	Windshield is not clear of debris and water	Possible reduction of driver visibility and potential violation of FMVSS 104	Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade
Wiper arm	Transfer angular motion from wiper pivot to wiper blade	1. Blade-glass pressure X 2. Wiper arm length Y 3. Wiper arm bending stiffness Z [Reference wiper arm specification #abc]	Wiper arm bends	Wiper blade angle changes resulting in blade chatter; glass not fully cleared but partially degraded visibilty, without safety implications (no violation of FMVSS 104)	Wiper arm has insufficient stiffness due to wrong arm material
Low washer fluid-level warning software	Communicate low fluid level to instrument display	Send 5 volt signal to the instrument display when the fluid level goes below 25% of its reservoir capacity	Does not send low-fluid level indication to display when below threshold	Empty washer fluid container leading to insufficient clearing of windshield with potential reduced forward visibility	Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability
Wiper Motor (includes motor grounding)	Provides operational power to operate the wiper system.	1. Minimum output torque "X" Nm 2. Maximum current (Amps) 3. Minimum rotational RPM Y	Insufficient power to overcome static friction in system	Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104	Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified

DFMEA columns truncated

DFMEA rows truncated

Figure 10 - Potential causes of failure examples for windshield wiper DFMEA

Failure causes in the DFMEA may, or may not, relate to failure modes in the PFMEA. A failure cause such as Part A to Part B misaligned may be a failure mode in the PFMEA such as Part A to Part B misoriented. The DFMEA would consider the reason for misalignment from a design perspective and the PFMEA would consider the reason for misalignment from a process perspective. In both cases, the FMEA teams discuss what is within their own control (i.e., the design or the process).

5.3.5 Identify Current Prevention and Detection Controls

In DFMEAs, design controls are actions or methods that are currently planned or in place to reduce or eliminate the risk associated with each potential failure mode and cause. Examples for the windshield wiper DFMEA are shown in Figure 11.

5.3.5.1 Prevention Design Controls

Prevention-type design controls describe how a failure mode, cause, or effect is prevented, based on actions or methods currently planned or in place. Prevention controls may not be applicable for every failure mode, cause, or effect; but they are part of the basis for determining the occurrence rating. Table 1 provides examples of types of prevention controls that have an influence on the reduction of field failure.

Table 1 - Prevention control examples for DFMEA

Standards and Best Practices	Analysis Activities Used for Design Decisions	Design Intent
Company design standards that have been previously validated and used (bill-of-design, template drawings, heat treat standards, established best practices, etc.)	Finite element analysis Tolerance stack analysis Margin of safety analysis that ensures robustness regardless of manufacturing method Design of experiments	Protection against environmental conditions (cold, hot, humidity), driving conditions (water, sand, rocks), etc., in mechanical systems
Catalog specifications (use cases, recommended applications, load limits, temperature ranges, etc.)	Worst case circuit analysis methods (extreme value analysis, root-sum-squared, Monte Carlo analysis)	Protection against electro-magnetic interference, etc., in electrical systems
External design standards (ISO, SAE, etc.)	Virtual analysis methods	Protection against undefined states, malicious code, corrupted code/data (e.g., dual core processing or secondary sensing), hardware design errors, etc., in software

NOTE: FMEA teams should use caution when describing a prevention control as “carryover design.” The use of “carryover design” can be a prevention-control strategy to the degree that the following criteria are in place: (1) the previous design has a proven field history, (2) the new design is similar in content to the previous design, (3) the new design is similar in conditions of use to the previous design, and (4) the new design has no new technology. Deviations to any of these criteria can lessen the value of “carryover design” as a valid prevention control.

Document numbers, when used, are for reference only as pointers to the associated documents at the time the analysis is created. Company policy may determine whether these document numbers must be kept up to date as they may change during the life of the program.

5.3.5.2 Detection Design Controls

Detection-type design controls describe how the item’s failure mode and/or associated cause is detected based on analytical or physical methods that are currently planned or in place, before the product is released for production. Detection-type design controls are used as input to the detection rating and are intended to increase the likelihood that the problem will be detected and/or prove design intent is confirmed, before it is released for production.

A detection control may not be applicable for every cause and/or failure mode. When listing detection controls, it is important to be detailed enough for subsequent reviewer to confirm how well that the design control will, in fact, detect the failure should it occur. Details should include test name, test number, and the paragraph or procedural step that will be used to detect the failure. Table 2 provides examples of types of detection controls.

Table 2 - Detection control types for DFMEA

Analytical Methods	Physical Methods
Use of correlated models to determine if system or component requirements are met Use of simulations to determine if system or component requirements are met Use of analytical methods to determine if system or component requirements are met	Use of physical system/component testing to determine if reliability requirements are met Use of physical system/component testing to determine if performance requirements are met Use of design of experiments to determine if requirements are met Use of functionality testing to determine if functional requirements are met

The DFMEA may include additional recommended actions to add additional testing to the test plan, or to modify tests in the test plan.

NOTE: Manufacturing process controls (those test and inspection activities that are done a manufacturing plant) are not valid detection-type design controls.

Item		Potential Failure Mode(s)	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Current Design Controls - Prevention (P)	Current Design Controls - Detection (D)	
Wiper System	DFMEA columns truncated	Windshield is not clear of debris and water	Possible reduction of driver visibility and potential violation of FMVSS 104	Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade	1. Supplier best practice standard for linkage 2. Specification for isolator material	1. Wiper system assembly cyclic durability test 2. Vehicle level reliability test #123	DFMEA columns truncated
Wiper arm		Wiper arm bends	Wiper blade angle changes resulting in blade chatter; glass not fully cleared but partially degraded visibilty, without safety implications (no violation of FMVSS 104)	Wiper arm has insufficient stiffness due to wrong arm material	1. W/S Wiper Design Guide #123 2. Wiper arm force-deflection study / simulation	1. Wiper arm force-deflection test #123 2. Wind load test #456 3. Wiper blade start-up test (check frozen to blade) #789	
Low washer fluid-level warning software		Does not send low-fluid level indication to display when below threshold	Empty washer fluid container leading to insufficient clearing of windshield with potential reduced forward visibility	Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability	1. Software designed to display message when 5 volt signal is received by ECU 2. Software architecture design 3. Modelling of signal flow (i/o matrix)	1. Functional test of ECU processor 2. Software in loop (SIL) 3. Hardware in loop (HIL)	
Wiper Motor (includes motor grounding)		Insufficient power to overcome static friction in system	Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104	Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified	1. Wiper Motor design guide	1. Durability test of the motor, including harness ground 2. Environmental Exposure - Vehicle Summer/Winter Test	

DFMEA rows truncated

Figure 11 - Current design control examples for windshield wiper DFMEA

5.4 Risk Assessment and Prioritization (Step 4)

Figure 1D - Step 4 of the FMEA six-step process map

Deliverables: The risks for the selected DFMEA have been assessed and prioritized.

The purpose of risk assessment and prioritization is to identify and prioritize risk areas that require special attention through design reviews, DVP&R, design changes, and other recommended actions. There are three types of criteria used in DFMEA to assess risks of failure. They are: severity, occurrence, and detection. Examples for the windshield wiper DFMEA are shown in Figure 12.

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

5.4.1 Assess Severity of Effects

Severity is a rating number associated with the most serious effect for a given failure mode for the function being evaluated. It is a relative rating within the scope of the individual FMEA and is determined without regard for occurrence or detection.

Severity should be estimated using the criteria in Appendix A. The table may be augmented to include product-specific examples. The team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual design analysis (e.g., passenger car, truck, motorcycle, tractor, golf cart, etc.).

Assessment of severity depends on the team's understanding of product safety, product functions, and functional requirements as related to the vehicle and sub-assembly or part being supplied. Assessing the severity may lie outside the immediate design engineer's/team's field or experience or knowledge. In these cases, assumptions regarding intended applications may be documented, or an interfacing system team or customer should be consulted in order to comprehend the propagation of effects.

In the case of commodity parts (e.g., design-responsible for screws, bolts, connectors, etc.), the severity rating criteria will be limited to the immediate function and its related requirements so that severity reflects the impact on fit/finish, partial function, and loss of function rather than the impact on the system or end user.

One of the goals of the FMEA process is to mitigate risk or lessen the impact of a potential failure mode. The severity rating itself can not be changed without changing the design to reduce the effect to a lesser impact or eliminating the failure mode and its effects (e.g., use of monitoring and system response). In addition, other techniques include fail-safe, fail-operational, and fault tolerance methods.

5.4.2 Assess Likelihood of Occurrence

Likelihood of occurrence is a rating number associated with each cause for a given failure mode being evaluated. The occurrence rating considers the likelihood of occurrence during the design life of the product. The occurrence rating number has a relative meaning rather than an absolute value and is determined without regard for severity or detection. The DFMEA team may consider prevention controls, field history for similar items, and degree of change as input to the occurrence rating.

NOTE: The team should agree on an evaluation criteria and rating system that is consistent, even if modified for individual analysis. Any modifications to the table should add value to the risk-mitigation process.

5.4.2.1 Application of DFMEA Likelihood Evaluation Criteria

Occurrence should be estimated using the criteria in Appendix B. The occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The assessment of likelihood of occurrence for a specific cause can be identified by the DFMEA team using a qualitative (subjective) method.

When assessing likelihood of occurrence, the DFMEA team considers prevention controls, field history for similar items (when applicable), and degree of change as factors influencing the occurrence rating. This subjective assessment can be made by using the word descriptions from the columns of the table in Appendix B.

5.4.3 Assess Ability to Detect

Detection is the rating associated with the likelihood of detecting the failure mode and/or associated cause, according to defined criteria.

One of the goals of the DFMEA process is to increase the ability to validate a design prior to start of production. The FMEA team has a responsibility to determine how well a specific simulation, test, or function check can detect the failure mode, or the cause which results in the failure mode.

The detection rating scale combines considerations for both the robustness of the detection method in revealing design weaknesses within specifications, and the timing of the findings within the design cycle. When no detection control has been identified, a rating of 10 is used, and a recommended action is written to address the deficiency.

5.4.3.1 Application of DFMEA Detection Evaluation Criteria

DFMEA detection should be estimated using the criteria in Appendix C. This table may be augmented with examples of common detection methods used by the company.

Assessment of “ability to detect” is accomplished by assessing the likelihood that the current detection-type design controls will be able to detect the failure mode or associated cause. This can be done by one of two methods:

1. In Method One, the DFMEA team considers the capabilities of all the current detection-type design controls (together) for a given cause and/or failure mode and enters the resultant “ability to detect” rating in the detection column of the DFMEA. In other words, if all the current detection controls are implemented, what is the likelihood that the failure mode or cause will be detected? The “detection method maturity” and “opportunity for detection” columns in Appendix C provide guidance in making this assessment. However, the key is for the DFMEA team to arrive at the “ability to detect” rating using the best thinking of the team. Figure 12 represents Method One.

2. In Method Two, the DFMEA team assesses the “ability to detect” for each of the current detection-type design controls. If this method is used, the team considers the likelihood that the failure mode or cause will be detected by each of the detection controls separately. Like the first method, the “detection method maturity” and “opportunity for detection” columns in Appendix C provide guidance in making this assessment, but the DFMEA team arrives at the “ability to detect” rating using the best estimate of the team. When using this method, it is a good practice to include the detection rating in parenthesis next to each of the detection methods in the “current design controls - detection” column, and the lowest value is used.

Item	DFMEA columns truncated	Potential Cause(s) of Failure	Current Design Controls - Prevention (P)	Current Design Controls - Detection (D)	SEV (S)	OCC (O)	DET (D)	DFMEA columns truncated
Wiper System		Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade	1. Supplier best practice standard for linkage 2. Specification for isolator material	1. Wiper system assembly cyclic durability test 2. Vehicle level reliability test #123	9	4	3	
Wiper arm		Wiper arm has insufficient stiffness due to wrong arm material	1. W/S Wiper Design Guide #123 2. Wiper arm force-deflection study / simulation	1. Wiper arm force-deflection test #123 2. Wind load test #456 3. Wiper blade start-up test (check frozen to blade) #789	7	5	3	
Low washer fluid-level warning software		Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability	1. Software designed to display message when 5 volt signal is received by ECU 2. Software architecture design 3. Modelling of signal flow (i/o matrix)	1. Functional test of ECU processor 2. Software in loop (SIL) 3. Hardware in loop (HIL)	7	5	5	
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified	1. Wiper Motor design guide	1. Durability test of the motor, including harness ground 2. Environmental Exposure - Vehicle Summer/Winter Test	9	7	5	
DFMEA rows truncated								

Figure 12 - Assignment of severity, occurrence, detection

5.4.4 Assess Risks and Prioritize Actions

The purpose of risk prioritization is to help the team understand relative risk within an analysis. There are many methods that have been used to assess combinations of severity (S), occurrence (O), and detection (D) ratings to prioritize risk and determine action priority. These methods include risk priority number (RPN), SO, criticality analysis (CA), and action priority.

Organizations should adopt a prioritization system which may include one or more of the techniques described in this standard.

5.4.4.1 RPN

The risk priority number (RPN) is the product of the severity (S), occurrence (O), and detection (D) rating. Within the scope of the individual FMEA, this value is between “1” and “1000.” The use of RPN is optional.

RPN = (S) x (O) x (D)

Example: (S) 7, (O) 3, (D) 5 = RPN 105

A benefit of RPN is that it provides an indicator of improvement (before and after actions taken) that reduces any one factor of severity, occurrence, or detection. It shows the distribution of RPN values for a project (pareto) giving a high-level overview of the risk assessment.

A disadvantage of using RPN is that the final RPN ratings are relative to a particular analysis and are subjective; therefore, selecting an RPN threshold is not an acceptable practice. Thresholds give the impression that values below the threshold do not need improvement action. In other words, there is no value above which it is mandatory to take a recommended action or below which the team is automatically excused from an action.

Establishing such thresholds may promote the wrong behavior causing team members to spend time trying to justify a lower occurrence or detection rating value to reduce the RPN. This type of behavior avoids addressing the real problem that underlies the cause of the failure mode and merely keeps the RPN below the threshold. It is important to recognize that determining reasonable risk is desirable, it should be based on an analysis of severity, occurrence, and detection and not through the application of RPN thresholds.

Another concern with RPN is that equal RPN values may not have equal risk levels due to the fact that S, O, and D are not of equal importance. Severity should be assessed first then occurrence for prevention and then detection to stop the failure mode from getting to the customer. High severity, low RPN can be high risk.

The focus of the FMEA should be to identify opportunities to continually improve the product and customer satisfaction beyond thresholds. Care should be taken to understand the limitations of RPN.

5.4.4.2 SO

The “SO” number is the product of the severity (S) and occurrence (O) ratings. Within the scope of the individual FMEA, this value is between “1” and “100.” The use of the SO number as a supplement to RPN is optional.

SO = (S) x (O)

Example: (S) 7, (O) 3, (D) 5 = SO 21

A benefit of SO is that it gives additional information about equal RPN values. The organization may focus on how to reduce SO by reducing the value of “O” through preventive actions. Furthermore, this may lead to subsequent detection improvements for those with the highest SO value.

The disadvantage of using SO is similar to that of RPN; i.e., thresholds. Table 3 illustrates how the SO can provide useful information about RPN. While it helps prioritize equal RPN results for action, it does not consider the detection rating.

Table 3 - Contrast between RPN and SO

S, O, D Rating	RPN	SO
8, 10, 2	160	80
8, 2, 10	160	16
10, 8, 2	160	80
10, 2, 8	160	20
2, 10, 8	160	20
2, 8, 10	160	16

5.4.4.3 Criticality Analysis (CA)

Criticality analysis (CA) is terminology used in aerospace and military handbooks and guidelines (i.e., MIL-STD-1629a, ARP5580, AS9145). CA is a procedure by which each potential failure mode is ranked according to the combined influence of severity and likelihood of occurrence. CA is performed concurrently as part of the product development process and is updated as the design, manufacturing, and assembly processes evolve to production release. Criticality analysis risk assessment supports identification of those items that could be defined as special characteristics.

Criticality Analysis may be visually shown as a "S&O risk graph." This allows for a non-linear approach to characterize levels of risk such as high (red), medium (yellow), and low (green). Figure 13 shows an example of a S&O risk graph. AN S&D and/or O&D risk graph may also be used. The use of risk graphs is optional.

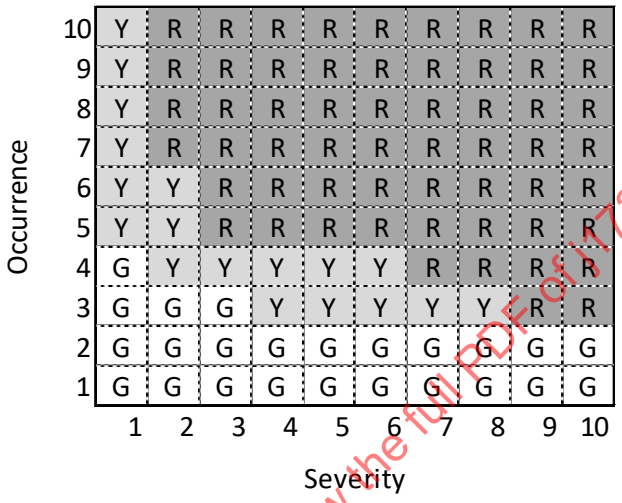


Figure 13 - Sample S&O risk graph

When using a risk graph, it is up to the company or customer to assign R, Y, and G and make the resulting table available to the DFMEA team.

5.4.4.4 Action Priority (AP)

Action priority (AP) table combines severity (S), occurrence (O), and detection (D) ratings with suggested priority levels for identification of potential actions to reduce risk based on high (H), medium (M), and low (L) assessments. Individual companies may develop their own criteria for H, M, and L and make the company-specific action priority table available to the DFMEA team and customer or supplier. The use of action priority is optional.

A complete AP table example is shown in Appendix I and is not meant to be automatically used by companies without review and agreement. The table used to support the action priority method should reflect a company's needs for action prioritization. The S, O, D rating charts provide the structure for the groupings as shown in Appendix J. If the organization chooses to modify the S, O, D, rating criteria for specific products, processes, or projects, the AP table should also be carefully reviewed for alignment. An example of an AP table used by the windshield wiper system project team is shown as Figure 14. The AP assessment is shown in the risk prioritization section of the DFMEA.

The benefit of action priority is that it does not treat severity, occurrence, and detection as equal values (as RPN, SO does). The principle of risk reduction through efforts to reduce severity, then occurrence, then detection drives the action priority levels of high (H), medium (M), and low (L). The AP table provides an action prioritization system to focus the team's time and resources.

The disadvantage of using action priority is that action taken to reduce risk may or may not change the action priority level. In other words, it is difficult to see incremental improvements.

Care should be taken to avoid automatic action based on a combination of S, O, D that would require or eliminate the need for action. For example, an AP assessment of low does not mean action should not be considered. The high, medium, or low assessment should be used to prioritize action, not presume action is not necessary.

No.	Effect	SEV	Likelihood of Failure Cause Occurring	OCC	Ability to Detect	DET	ACTION PRIORITY (AP)
Action Priority rows truncated							
9	Product or plant effect very high	9-10	Moderate	4-5	Low - Very low	7-10	H
10					Moderate	5-6	H
11					High	2-4	H
12					Very high	1	M
13			Low	2-3	Low - Very low	7-10	H
14					Moderate	5-6	~~M~~ H*
15					High	2-4	~~L~~ M*
16					Very high	1	L
17			Very low	1	Very low - Very high	1-10	L
Action Priority rows truncated							

* The windshield washer project team reviewed the action priority table in Appendix R and agreed to make two changes raising the AP level from Medium to high and low to medium in two instances for their application. This is an example of how a company or project team can use the AP method.

Figure 14 - Example of Appendix I - action priority table modified for windshield wiper system

The example in Figure 15 is based on using a final "risk prioritization" rating of high (H), medium (M), and low (L).

Item	DFMEA columns truncated	Potential Cause(s) of Failure	Current Design Controls - Prevention (P)	Current Design Controls - Detection (D)	SEV (S)	OCC (O)	DET (D)	Risk Prioriti-zation	DFMEA columns truncated
Wiper System		Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade	1. Supplier best practice standard for linkage 2. Specification for isolator material	1. Wiper system assembly cyclic durability test 2. Vehicle level reliability test #123	9	4	3	M	
Wiper arm		Wiper arm has insufficient stiffness due to wrong arm material	1. W/S Wiper Design Guide #123 2. Wiper arm force-deflection study / simulation	1. Wiper arm force-deflection test #123 2. Wind load test #456 3. Wiper blade start-up test (check frozen to blade) #789	7	5	3	M	
Low washer fluid-level warning software		Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability	1. Software designed to display message when 5 volt signal is received by ECU 2. Software architecture design 3. Modelling of signal flow (i/o matrix)	1. Functional test of ECU processor 2. Software in loop (SIL) 3. Hardware in loop (HIL)	7	5	5	M	
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified	1. Wiper Motor design guide	1. Durability test of the motor, including harness ground 2. Environmental Exposure - Vehicle Summer/Winter Test	9	7	5	H	
DFMEA rows truncated									

Figure 15 - Assignment of risk prioritization

For the purpose of assessing risks and prioritizing actions, individual companies should determine the method that suits their goals for technical risk analysis and internal management or customer requirements.

The DFMEA team may choose to generate action plans at any time during the DFMEA development even prior to having RPN, SO, criticality analysis, or AP assessment.

NOTE: It is recommended that potential severity 9 and 10 and potential effect(s) regardless of action priority assessment be reviewed by management including any recommended actions that were identified.

5.4.5 Identify Potential Special Characteristics

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. Standard product characteristics will be produced to specifications using appropriate manufacturing methods and controls. Standard product characteristics are NOT typically treated as special characteristics.

A special product (design) 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, fit, and service life. The purpose of selecting special product characteristic is to communicate the risk to manufacturing, assembly, and/or other interfacing design disciplines.

The DFMEA is pivotal in providing information about the severity of a potential failure effect. The DFMEA team can flag requirements and/or failures/causes that are candidates for special characteristic designation during the risk analysis. The process for determining the classification of characteristics (standard or special) is company specific.

Finalized special product characteristics are normally shown on design records (e.g., engineering drawings or specifications) using a specific symbol or typographic label defined by the company. These symbols and/or labels are not required in the DFMEA since the DFMEA is one of the inputs to the selection process of a special characteristics.

Potential special characteristics can be identified in the DFMEA by describing the product characteristic as shown in Figure 16. Customer specific symbols used to designate special characteristics in the DFMEA are not required. Risks identified in the DFMEA are **INPUTS** (but not exclusive) to the special characteristic selection process. Potential 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.

Item	DFMEA columns truncated	Potential Cause(s) of Failure	Current Design Controls - Prevention (P)	Current Design Controls - Detection (D)	SEV (S)	OCC (O)	DET (D)	Risk Prioriti-zation	Potential Special Characteristic(s)	DFMEA columns truncated
Wiper System		Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade	1. Supplier best practice standard for linkage 2. Specification for isolator material	1. Wiper system assembly cyclic durability test 2. Vehicle level reliability test #123	9	4	3	M	Dimensional placement of isolalators with respect to wiper linkage	
Wiper arm		Wiper arm has insufficient stiffness due to wrong arm material	1. W/S Wiper Design Guide #123 2. Wiper arm force-deflection study / simulation	1. Wiper arm force-deflection test #123 2. Wind load test #456 3. Wiper blade start-up test (check frozen to blade) #789	7	5	3	M	1. Wiper arm material specification 2. Wiper arm length	
Low washer fluid-level warning software		Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability	1. Software designed to display message when 5 volt signal is received by ECU 2. Software architecture design - Modelling of signal flow (i/o matrix)	1. Functional test of ECU processor 2. Software in loop (SIL) 3. Hardware in loop (HIL)	7	5	5	M		
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified	1. Wiper Motor design guide	1. Durability test of the motor, including harness ground 2. Environmental Exposure - Vehicle Summer/Winter Test	9	7	5	H	Ground tightening torque spec	
DFMEA rows truncated										

Figure 16 - Potential special characteristics examples for windshield wiper DFMEA

5.4.6 Supplemental FMEA for Monitoring and System Response (as needed)

Figure 1E - Step 4a of the FMEA six-step process map

Deliverables: The risks are re-assessed based on the effectiveness of monitoring and system response.

5.4.6.1 FMEA-MSR - What is it?

Supplemental FMEA for monitoring and system response (FMEA-MSR) is an extension of the DFMEA. Figure 17 shows the linkage between DFMEA and FMEA-MSR. FMEA-MSR provides a means of assessing risk reduction due to diagnostic detection with a subsequent response during customer operation. These additional factors contribute to an improved depiction of risk of failure (including risk of harm, risk of noncompliance, and risk of not fulfilling requirements). As applicable, the malfunctioning behaviors, hazards, and relevant operating situations that are identified in the hazard analysis and risk assessment may be associated with functions and/or requirements in the FMEA-MSR (refer to ISO 26262-3:2018).

In an FMEA-MSR, potential failure modes and causes that may occur under customer operating conditions are analyzed with respect to their technical effects on the system, vehicle, people, and regulatory compliance. The method considers whether failure modes or causes are detected, and whether the behavior of the system can be changed prior to the formation of an undesirable effect. Customer operation is to be understood as end-user operation or in-service operation and maintenance operations.

The detection of failure modes and causes during customer operation can be used to avoid the original effect of failure by switching to a degraded operational state (including disabling the vehicle) and informing the driver. In terms of FMEA, the result of RELIABLE diagnostic detection and response is to eliminate (prevent) the original effect, and replace it with a new, less severe effect.

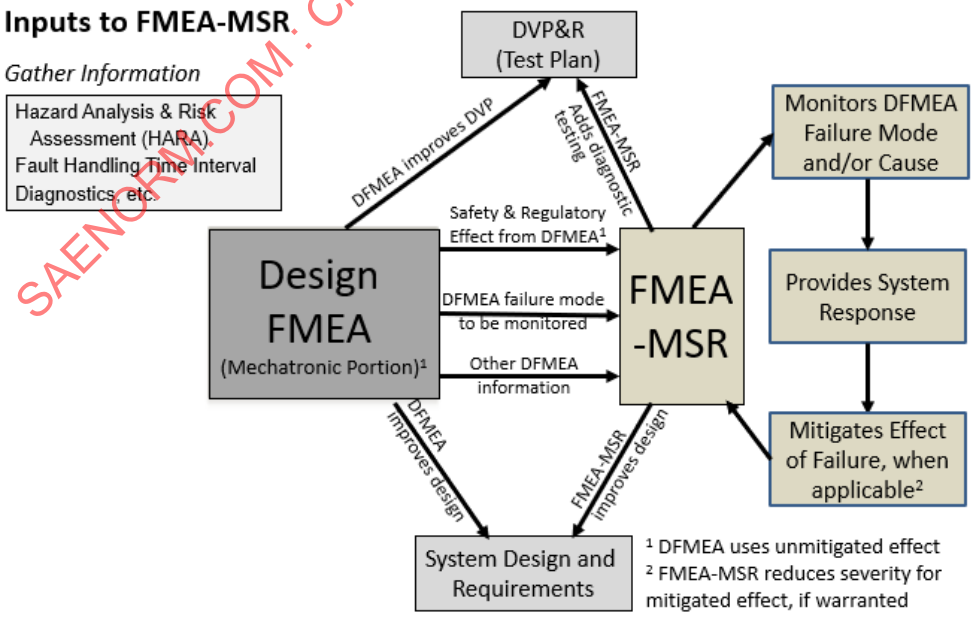


Figure 17 - DFMEA to FMEA-MSR linkages

The value of FMEA-MSR is effect mitigation during customer operation. Monitoring and system response have three key attributes:

1. Sensing: System must be able to detect that a problem condition has occurred or will occur.

2. Control (e.g., micro-processor): Using preprogrammed logical alternatives (mechanical, electrical, or SW based, etc.), one or more risk mitigating actions must be available.

3. Response (affects system and/or driver behavior): One or more responses must reliably act in time to ensure that the original effect is mitigated.

5.4.6.2 Determine if FMEA-MSR is Needed

The decision-making process begins by understanding when the mechatronic system meets the criteria for the application of FMEA-MSR. See 3.9. A mechatronic system includes the signal flow from the sensor to the controller to the actuator. However, a mechanical actuator may be external to the mechatronic system. In this case, a sensor or diagnostic algorithm may be used to detect a change of state of the external actuator.

Supplemental FMEA for monitoring and system response is most commonly applied when there are potential effect(s) of failure in the DFMEA that may be harmful to persons, involve regulatory noncompliance, or disable the vehicle. However, FMEA-MSR may be used to assess the mitigation of other performance-related effects that may occur during customer operation.

When a DFMEA identifies a hazard or noncompliance that can be prevented or mitigated by the application of a diagnostic detection and response, supplemental FMEA-MSR is used to assess the effectiveness of the diagnostic. Failures of diagnostic hardware and software are considered in the DFMEA, but not in FMEA-MSR. Figure 18 illustrates the decision-making process for the application of the supplemental FMEA-MSR.

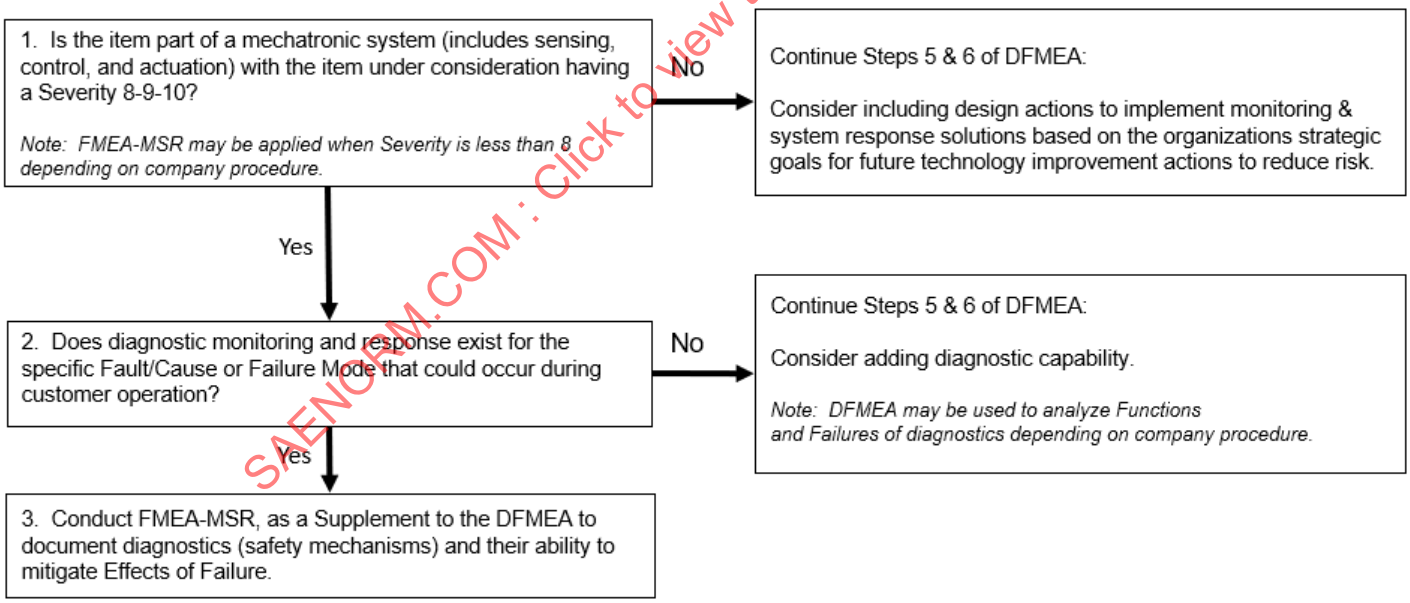


Figure 18 - FMEA-MSR decision-making process

The windshield wiper motor is part of the windshield wiper system which includes sensing, control, and actuation; therefore, is considered a mechatronic system and is a good candidate for the application of FMEA-MSR. The FMEA-MSR wiper motor example will be used to demonstrate the FMEA-MSR decision-making process, using two scenarios: (A) no existing diagnostic monitoring related to cause or failure mode in DFMEA, and (B) diagnostic monitoring exists related to cause or failure mode in DFMEA.

Scenario A: Cannot detect wiper motor over temp threshold (no existing diagnostic monitoring related to cause or failure mode in DFMEA).

1. Is the item part of a mechatronic system (includes sensing, control, and actuation) with the item under consideration having a severity of 8, 9, or 10?

   a. Yes—go to next question.

   b. No—continue DFMEA.

   Answer: “Yes” (loss of windshield wiping function; e.g., severity 9). Go to question 2.

2. Does diagnostic monitoring and response exist for the specific fault/cause or failure mode that could occur during customer operation?

   a. Yes—consider adding MSR to DFMEA.

   b. No—consider adding diagnostic capability.

   Answer: “No” (cannot detect wiper motor over temp threshold—consider adding diagnostic capability and consider doing DFMEA on new diagnostics; see recommended actions).

Scenario B: Wiper motor over temp diagnostic monitoring exists related to cause or failure mode in DFMEA.

1. Is the item part of a mechatronic system (includes sensing, control, and actuation) with the item under consideration having a severity of 8, 9, or 10?

   a. Yes—go to next question.

   b. No—continue DFMEA.

   Answer: “Yes” (loss of windshield wiping function; e.g., severity 9). Go to question 2.

2. Does diagnostic monitoring and response exist for the specific fault/cause or failure mode that could occur during customer operation?

   a. Yes—go to next question.

   b. No—consider adding diagnostic capability.

   Answer: “Yes” (a temp sensor is part of the wiper motor assembly, and an algorithm has been developed to read the temp sensor signal and trigger intermittent wiping once the temp threshold has been reached—the infrastructure exists). Go to question 3.

3. Conduct FMEA-MSR, as a supplement to the DFMEA.

   Result: FMEA-MSR will be done to assess the effectiveness of the diagnostic monitoring and response FMEA-MSR and recommended actions for MSR.

5.4.6.3 Identify Relevant Failure Scenarios

A failure scenario is comprised of a description of relevant operating conditions in which a cause results in malfunctioning behavior that leads to an undesired system state (effect of failure). Relevant operating situations from the hazard analysis and risk assessment (refer to ISO 26262-3:2018), and other relevant use cases form the basis for the identification of FMEA-MSR failure scenarios. The description of the cause of failure and corresponding failure mechanism from the DFMEA is essential to the description of the failure scenario in FMEA-MSR. Examples for the windshield wiper DFMEA are shown in Figure 19.

5.4.6.4 Assess Frequency

Next, estimate the frequency of a cause of failure in the context of an operational situation, relevant throughout the service life of the vehicle, represented by (F) (see Appendix D).

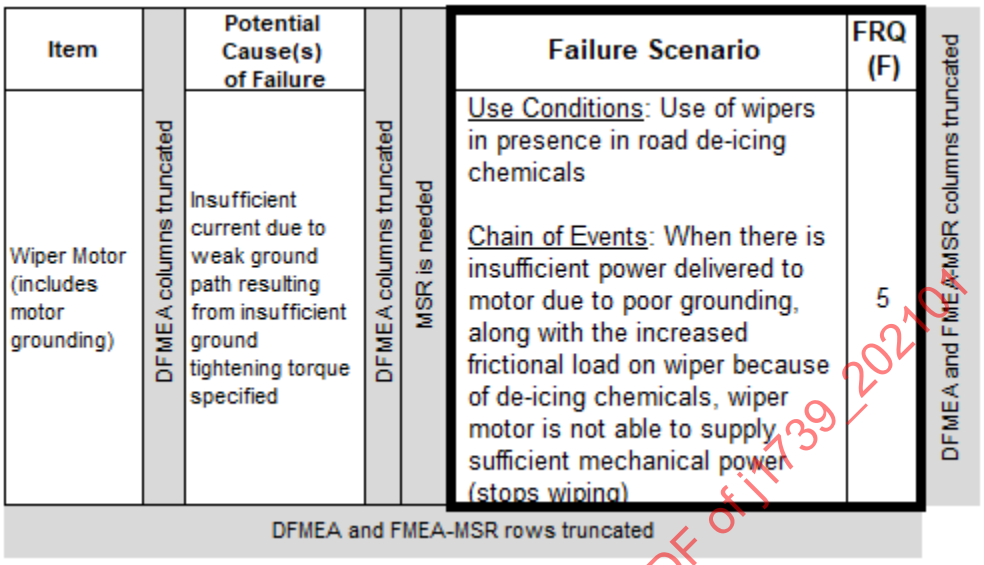


Figure 19 - Failure scenario example for windshield wiper DFMEA

5.4.6.5 Identify Existing Diagnostic Monitoring (During Customer Operation)

Diagnostic monitoring is the detection of an abnormal condition that leads to an undesired state of operation of a vehicle function. Diagnostic monitoring of the performance of a function may be provided by direct sensing, plausibility algorithm(s), or a combination of these. For example: sensor out of range detections, cyclic redundancy checks, plausibility checks, and sequence counter checks. Examples for the windshield wiper DFMEA are shown in Figure 20.

If the diagnostics are not capable of reliably detecting the cause or failure mode that leads to the undesired effect, the effect may occur, with a corresponding degree of severity. However, if the diagnostic can reliably detect the failure, this leads to a consistent system response. If the response also reliably occurs prior to the effect occurring, the new effect of failure has a lower severity compared to the original effect of failure. While it is beneficial to detect the cause or mode, an unreliable diagnostic will not result in a lower severity rating.

In DFMEA, detection controls describe how the item's failure mode and/or associated cause is detected based on analytical or physical methods that are currently planned or in place, before the product is released for production. Monitoring in FMEA-MSR assesses the effectiveness of fault detection performance in customer operation, assuming that specifications are fulfilled. The monitoring rating also comprehends the reliability of system reactions to detected faults. It contributes to the assessment of the fulfillment of safety goals and the functional safety concepts.

NOTE: In FMEA-MSR, the effectiveness of diagnostic monitoring and system response is assumed to have been validated. Failures of diagnostics are not part of FMEA-MSR but can be added to the DFMEA section of the form. These include:

- Does not detect failure
- Falsely detects failure (nuisance)
- Unreliable response to failure detection (variation in response capability)

NOTE: If diagnostic monitoring is not available, enter "none" and consider recommended actions.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	none	
DFMEA and FMEA-MSR rows truncated								

Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	Function: Monitor motor current (amps) Requirement: motor current over X amps initiates system response	

Figure 20 - Diagnostic monitoring example for windshield wiper DFMEA

5.4.6.6 Identify System Response in Context of Failure Scenario

Considering the failure scenario, the DFMEA team documents the anticipated system response to a monitored cause of failure or failure mode. The intent of a system response is to help achieve the goal of having a safe or compliant operational state. System responses may consist of, for example, switching to a limp home mode, switching off the corresponding function and/or display of a warning, transitioning to a different mode of operation, etc. Examples for the windshield wiper DFMEA are shown in Figure 21.

5.4.6.7 Assess Monitoring

The monitoring value (M) rates technical possibilities to avoid or limit the effect via diagnostic detection and automated response, combined with human possibilities to avoid or limit the effect via sensory perception and physical reaction. Monitoring evaluates the potential that the cause, the failure mode, or the effect can be detected early enough so that the initial effect can be mitigated before a hazard occurs or a noncompliant state is reached. The result of effective monitoring and response is an end state effect with a lower severity. (See Appendix E.)

NOTE: The effectiveness of diagnostic monitoring, the fault tolerant time interval, the fault handling time interval, and the fault handling (detection/reaction) time need to be determined by a functional safety subject matter expert (refer to ISO 26262-5:2018 Annex D for details) prior to rating (M) by the FMEA-MSR team. For all other non-human harm effects (e.g., OBD compliance), a different subject matter expert would be needed.

In practice, three different monitoring/response cases may be distinguished:

1. No monitoring. If there is no monitoring control, or if monitoring and response do not occur within the fault handling time interval, then monitoring should be rated as not effective (M = 10).

2. Reliable monitoring and system response. The original effect is virtually eliminated. Only the mitigated effect remains relevant for the risk estimation of the product or system. In this instance only, the mitigated effect is relevant for the risk assessment rating, not the original effect.

3. Less-than reliable monitoring. The original effect occurs less often. Most of the failures are detected and the system response leads to a mitigated effect. However, the most serious effect retains the original severity.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	none	none	10	
DFMEA and FMEA-MSR rows truncated										

Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	Function: Monitor motor current (amps) Requirement: motor current over X amps initiates system response	When motor current amperage reaches threshhold, transition to intermittent wipe setting (3 cycles / min)	2	
DFMEA and FMEA-MSR rows truncated										

Figure 21 - System response example for windshield wiper DFMEA

5.4.6.8 Determine New Effect(s) After System Response

Considering the proposed diagnostic monitoring, the DFMEA team documents the new effect(s) of failure after system response. The new effects after system response may consist of, for example, diminished capacity of a function, partial function, disabling a function, etc., while maintaining a safe or compliant operating state. Examples for the windshield wiper DFMEA are shown in Figure 22.

5.4.6.9 Reassess Severity

Severity of harm, regulatory noncompliance, loss or degraded functionality, and unacceptable quality are represented by an “S.” (See Appendix A.)

In order to reduce the severity rating, the diagnostic must detect the fault. The fault reaction must also occur prior to the unintended effect. Depending on the effectiveness of the diagnostic monitoring and response, the end effect would occur less often. However, the occurrence of the cause does not change. Company policy, customer requirements, and/or management decision may be necessary to determine if the effectiveness of monitoring is acceptable, and whether the effect may be changed as a result of fault monitoring.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	New Effect(s) of Failure after System Response	SEV (S) after MSR	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	none	none	10	SAME: Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104	9	
DFMEA and FMEA-MSR rows truncated												

Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	New Effect(s) of Failure after System Response	SEV (S) after MSR	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	Function: Monitor motor current (amps) Requirement: motor current over X amps initiates system response	When motor current amperage reaches threshhold, transition to intermittent wipe setting (3 cycles / min)	2	Wiper system operates intermittently instead of reaching thermal threshhold (which would stop the motor)	7	
DFMEA and FMEA-MSR rows truncated												

Figure 22 - New effect(s) after system response example for windshield wiper DFMEA

5.4.6.10 Assess Risks and Prioritize Actions

The purpose of risk assessment and prioritization in FMEA-MSR is to qualitatively estimate the effectiveness of diagnostic monitoring and response in reducing the risk of failure to an acceptable level. Risk is measured by evaluating severity, frequency, and monitoring, and prioritizing the need for actions to reduce risk. Examples for the windshield wiper DFMEA are shown in Figure 23. A sample MSR action prioritization is described in Appendix K.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	New Effect(s) of Failure after System Response	SEV (S) after MSR	MSR Risk Prioriti-zation	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	none	none	10	SAME: Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104	9	H	
DFMEA and FMEA-MSR rows truncated													

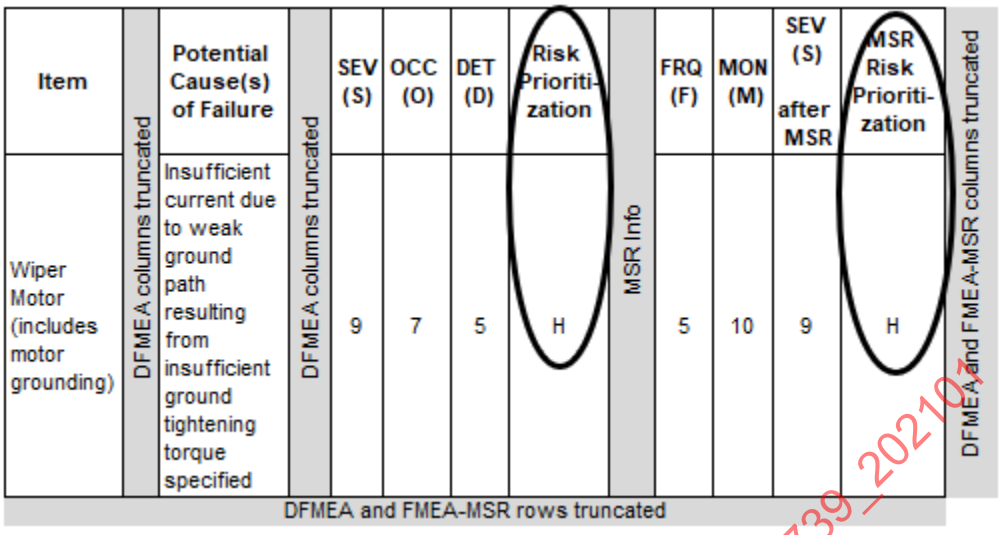
Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	MSR is needed	Failure Scenario	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	New Effect(s) of Failure after System Response	SEV (S) after MSR	MSR Risk Prioriti-zation	DFMEA and FMEA-MSR columns truncated
Wiper Motor (includes motor grounding)		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified			Use Conditions: Use of wipers in presence in road de-icing chemicals Chain of Events: When there is insufficient power delivered to motor due to poor grounding, along with the increased frictional load on wiper because of de-icing chemicals, wiper motor is not able to supply sufficient mechanical power (stops wiping)	5	Function: Monitor motor current (amps) Requirement: motor current over X amps initiates system response	When motor current amperage reaches threshhold, transition to intermittent wipe setting (3 cycles / min)	2	Wiper system operates intermittently instead of reaching thermal threshhold (which would stop the motor)	7	M	
DFMEA and FMEA-MSR rows truncated													

Figure 23 - MSR risk prioritization example for windshield wiper DFMEA

The DFMEA and MSR risk prioritization are two separate indicators as shown in Figure 24.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA



Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

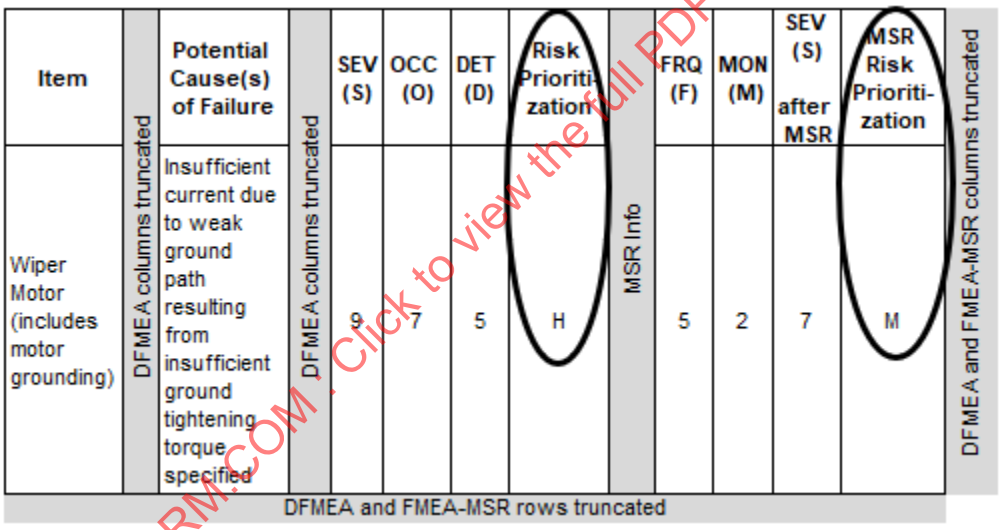


Figure 24 - DFMEA and MSR risk prioritization example

5.5 Reduce and Communicate Risks (Step 5)

Figure 1F - Step 5 of the FMEA six-step process map

Deliverables: Risks for the selected DFMEA are reduced and communicated.

5.5.1 Develop Recommended Actions

The intent of a recommended action is to improve the ability to prevent, mitigate, or detect a failure. This is achieved by reducing the likelihood of failure (occurrence), improving the ability to detect failures prior to production release (detection), and/or mitigating the effect of failure by changing the design (severity).

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. It is not recommended to include actions that are already documented in the prevention or detection controls, and are already considered in risk prioritization.

For each line of analysis, the recommended actions field must include verbiage to reflect the fact that each risk was critically evaluated. If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering “none” in the recommended actions field. Without a written comment, it may be construed that the risk associated with the line item was overlooked. An entry of “none” indicates that the assessed risk is acceptable. Single-line excerpts of recommended actions for the wiper system FMEA-MSR example are shown in Figure 25.

5.5.1.1 Application of Recommended Actions for DFMEA

For DFMEA, if the risk prioritization as influenced by severity, occurrence, and detection is acceptable, no action is needed. If not, the DFMEA team needs to consider recommended actions. The intent of a DFMEA recommended action is to improve the product design by reducing the likelihood of occurrence of the cause of failure, improving the ability to detect failures prior to production release, and/or mitigating the effect of failure by changing the design.

The DFMEA team may also add recommended actions to communicate questions to technical interface risk partners (e.g., gather input about potential effects of failures, gather input about testing or performance feedback, gather information about interfacing geometry, material composition, etc.) or for other tasks that are needed to accomplish DFMEA objectives.

5.5.1.2 Application of Recommended Actions for FMEA-MSR

For FMEA-MSR, if the MSR risk prioritization as influenced by frequency, monitoring, and severity is acceptable, no action is needed. If not, the DFMEA team needs to consider MSR-related recommended actions. The intent of an MSR recommended action is to improve the ability to detect and react to a fault during customer operation before it leads to failure. This may be achieved by adding new diagnostic capability or improving existing diagnostic capability.

5.5.1.3 Responsibility and Target Completion Date

Recommended actions represent assignments given to specific individuals. When a recommended action is to be performed by a supplier company, the name of an individual from the target company is also written, as a means of assigning an oversight role and to ensuring closed loop completion of the activity. The individual to whom the action is assigned should be well aware of commitment and should be present for the relevant aspects of the risk assessment discussion. A due date is also required for each action. The due date represents acceptance of a commitment to take action by a certain date. If the recommended action is not completed by the due date, then a new due date may be assigned.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	SEV (S)	OCC (O)	DET (D)	Risk Prioriti-zation	Potential Special Characteristic(s)	Recommended Action(s)	DFMEA columns truncated
Wiper System		Wiper linkage assembly clearance to windshield molding is reduced over time as linkage isolators degrade		9	4	3	M	Dimensional placement of isolalators with respect to wiper linkage	1. Review supplier DFMEA for linkage design and ensure linkage degradation is root caused and addressed. 2. Review supplier test profile and test resutls to ensure no linkage isolator deformation	
Wiper arm		Wiper arm has insufficient stiffness due to wrong arm material		7	5	3	M	1. Wiper arm material specification 2. Wiper arm length	1. FEA to determine proper wiper arm stiffness 2. If FEA shows deficient stiffness, change the arm material to meet stiffness requirement 3. Modify Wiper Design Guide #123 to include correct arm material	
Low washer fluid-level warning software		Algorithm does not recognize faulty signal from fluid-level sensor due to missing fault-detection capability		7	5	5	M		1. Develop fault-detection algorithm that will accurately identify faulty washer fluid-level sensor. 2. Add Fault injection testing of sensor system response to signal. 3. Move from two algorithm input strategy to a four algorithm input strategy.	
DFMEA rows truncated										

Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Potential Cause(s) of Failure	DFMEA columns truncated	SEV (S)	OCC (O)	DET (D)	Risk Prioriti-zation	Potential Special Character-istic(s)	MSR Info	FRQ (F)	Identify Existing Diagnostic Monitoring	System Response	MON (M)	New Effect(s) of Failure after System	SEV (S) after	MSR Risk Prioriti-zation	Recommended Action(s)	DFMEA columns truncated
Wiper Motor (includes motor grounding) SCENARIO A*		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified		9	7	5	H	Ground tightening torque spec		5	none	none	10	SAME: Wiper arm stops (thermal overload interrupts circuit); loss of wiping with potential non-compliance with FMVSS 104	9	H	DMEA Actions: 1. Increase ground tightening torque spec to ensure grounding integrity over anticipated loads 2. Consider using conductive grease to improve current carrying capacity of circuit MSR Actions: 1. Add diagnostic capability to monitor motor current and respond in a safe manner 2. Perform DFMEA on the new diagnostic capability 3. Perform FMEA-MSR to see if this new diagnostic capability is adequate to reduce severity	
Wiper Motor (includes motor grounding) SCENARIO B*		Insufficient current due to weak ground path resulting from insufficient ground tightening torque specified		9	7	5	H	Ground tightening torque spec		5	Function: Monitor motor current (amps) Requirement: motor current over X amps initiates system response	When motor current amperage reaches threshhold, transition to intermittent wipe setting (3 cycles / min)	2	Wiper system operates intermittently instead of reaching thermal threshhold (which would stop the motor)	7	M	DMEA Actions: 1. Increase ground tightening torque spec to ensure grounding integrity over anticipated loads. 2. Consider using conductive grease to improve current carrying capacity of circuit MSR Actions: None	
DFMEA rows truncated																		

Figure 25 - Recommended actions example for windshield wiper DFMEA

5.5.2 Acceptance/Disposition of Risks by Management

The company's FMEA procedure should describe how DFMEA is reviewed and/or approved by management. Risk prioritization methods allow review with others outside the team who share ownership/responsibility for the risk mitigation.

5.5.3 Implement Recommended Actions

Implementation of recommended actions is completed by entering a brief description of the action taken and effective date. Documenting the closure of a recommended action is as important as writing the recommended action. If an action is not implemented, note that is was rejected/discarded with reason given.

Closure of recommended actions should be documented before start of regular production (SORP). Missing closure information may be challenged if the DFMEA is subjected to legal discovery.

5.5.4 Reassess Risks

Severity, occurrence, and detection values are re-assessed 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, D ratings remain as originally assigned. Recommended actions must be completed and documented prior to any S, O, D re-ratings. Examples for the windshield wiper DFMEA are shown in Figure 26.

The occurrence rating itself may not be changed without changing the design, experience in testing, and field exposure to decrease the chance of the failure cause and subsequent failure mode from happening. The detection rating itself cannot be improved without changing the sensitivity to detect failure modes during validation and/or verification activities as well as the timing of such activities.

The DFMEA serves as a historical record for the design, therefore the original severity, occurrence, and detection numbers are not modified once actions have been taken. The completed analysis becomes a repository to capture the progression of design and design refinements. However, original severity, occurrence, and detection ratings may be modified for generic or product family DFMEAs because the information is used as a starting point for an application-specific analysis.

Scenario A - No existing diagnostic monitoring related to cause or failure mode in DFMEA

Item	DFMEA columns truncated	Recommended Action(s)	Action(s) Taken & Effective Date		New (S)	New (O)	New (D)	New Risk Prioriti-zation
Wiper System		1. Review supplier DFMEA for linkage design and ensure linkage degradation is root caused and addressed. 2. Review supplier test profile and test results to ensure no linkage isolator deformation	1. Review of supplier DFMEA was completed; Supplier took action to ensure linkage degradation was root caused and addressed. 2. Subsequent review of supplier test profile and test results confirmed there was no deformation of linkage isolators.	1. 3/1/2019 2. 4/1/2019	9	2	2	L
Wiper arm		1. FEA to determine proper wiper arm stiffness 2. If FEA shows deficient stiffness, change the arm material to meet stiffness requirement 3. Modify Wiper Design Guide #123 to include correct arm material	1. FEA confirmed wiper arm material does not meet stiffness requirements 2. Stiffer wiper arm material implemented	1. 3/2/2019 2. 4/1/2018 3. 5/2/2019	7	2	3	L
Low washer fluid-level warning software		1. Develop fault-detection algorithm that will accurately identify faulty washer fluid-level sensor. 2. Add Fault injection testing of sensor system response to signal. 3. Move from two algorithm input strategy to a four algorithm input strategy.	1. Updated software to include fault-detection code to monitor fluid-level sensor and send error code if fluid level does not change during operation. 2. Added fault injection testing of sensor system response to 5 volt signal.	1. 3/2/2019 2. 4/1/2019	7	2	2	L
DFMEA rows truncated								

Scenario B - Diagnostic monitoring exists related to cause or failure mode in DFMEA

Item	DFMEA and MSR columns truncated	Recommended Action(s)	Action(s) Taken & Effective Date		New (S)	New (O)	New (D)	New Risk Prioriti-zation
Wiper Motor (includes motor grounding) SCENARIO A*		DMEA Actions: 1. Increase ground tightening torque spec to ensure grounding integrity over anticipated loads 2. Consider using conductive grease to improve current carrying capacity of circuit MSR Actions: 1. Add diagnostic capability to monitor motor current and respond in a safe manner 2. Perform DFMEA on the new diagnostic capability 3. Perform FMEA-MSR to see if this new diagnostic capability is adequate to reduce severity	1. Change authorization 123 (increase ground terminal fastener tightening spec to XYZ) 2. Diagnostic capability added to monitor motor current and respond in a safe manner. 3. DFMEA completed on new diagnostic capability. 4. FMEA-MSR completed with severity reduced to lower value	1. 4/15/2019 2. 4/22/2019 3. 4/30/2109 4. 4/30/2019	7	2	2	L
Wiper Motor (includes motor grounding) SCENARIO B*		DMEA Actions: 1. Increase ground tightening torque spec to ensure grounding integrity over anticipated loads. 2. Consider using conductive grease to improve current carrying capacity of circuit MSR Actions: None	1. Change authorization 123 (increase ground terminal fastener tightening spec to XYZ) 2. FMEA-MSR completed with severity reduced to lower value	1. 4/15/2019 2. 4/15/2019	7	2	2	L
DFMEA rows truncated								

Figure 26 - Action results examples for windshield wiper DFMEA

5.5.5 Continue FMEA Until Risks Have Been Reduced to an Acceptable Level

It is worthwhile to ask, “When is an FMEA completed?” Is an FMEA completed when each of the columns or sections have been filled out? The answer is no. An FMEA is not completed merely by filling out the various columns or sections of the FMEA.

Is an FMEA completed when the FMEA team has recommended and executed specific actions, based on risk prioritization? The answer is no, not necessarily. An FMEA is not necessarily completed when all the actions have been executed.

The correct answer is an FMEA is completed when an acceptable level of risk has been achieved and agreed upon by the FMEA team and management. Until this point, the FMEA 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 company, considering input or requirements from the customer.

As each of the FMEA recommended actions are executed, the FMEA team enters what was done in the actions taken column or section, and re-scores the S, O, and D. If the combination of re-scored S, O, and Ds are deemed acceptable by the FMEA team, based on company policy and considering input or requirements from the customer, the risk related to that specific issue is addressed for the purposes of the FMEA. If the risk represented by the re-scored S, O, and Ds are not deemed acceptable, the FMEA team continues to recommend and execute actions to reduce risk, until an acceptable level of risk is achieved.

When all the FMEA recommended actions have been executed, and the re-scored S, O, Ds are acceptable, the FMEA is considered complete for the purpose of the FMEA project. In the future, the FMEA may be updated, as appropriate, based on guidance or policy covered in 5.6.5.

5.6 Document Results (Step 6)

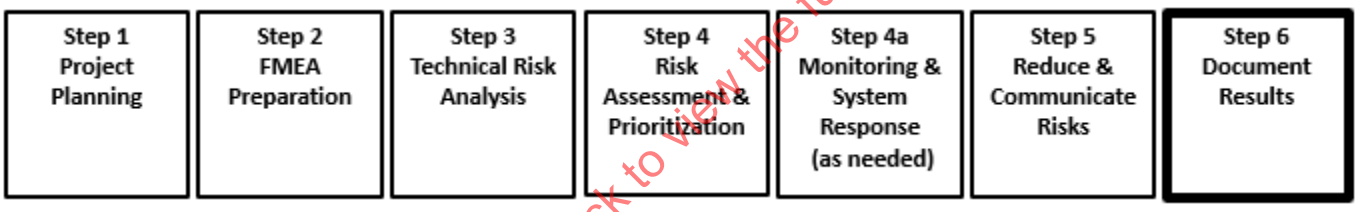


Figure 1G - Step 6 of the FMEA six-step process map

Deliverables: The results of the selected DFMEA are linked and documented.

5.6.1 Prepare Summary of Key Findings

A summary of the DFMEA results can be created and archived with the DFMEA. It highlights the high risk potential failures and associated design actions. The content of the summary is company-specific and represents the DFMEA at a certain time interval (e.g., end of DFMEA project). It may include key findings determined by the team and management, such as the definition of new functions, requirements, rating criteria (severity, occurrence, detection), risk prioritization method, risk analysis summary, actions to reduce risk, special characteristics, and conclusions; e.g., potential risks are reduced to an acceptable level as determined by management.

5.6.2 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:

1. Become part of DFMEA training
2. Reviewed at each DFMEA meeting
3. Incorporated as an essential part of DFMEA quality audits
4. Consider leaving the DFMEA open until quality objectives are met

A recommended approach is to consider effectiveness criteria that is aligned with the six-step process, such as:

Step 1: Project Planning

Deliverable: Set of FMEAs are identified, prioritized, and scheduled.

FMEA plan: The right set of FMEAs have been identified and prioritized, based on company policy, and organized into an executable FMEA plan.

Step 2: FMEA Preparation

Deliverable: All preparation steps for selected FMEA have been completed and first meeting scheduled.

Scope: The scope for the selected DFMEA is correctly defined, focused on areas of highest concern/value, and properly reflected in the FMEA block/boundary diagram.

Interfaces: The DFMEA scope includes integration and interface failure modes in both block diagram and analysis.

Lessons learned: The DFMEA considers all major “lessons learned” (such as high warranty, campaigns, etc.) as input to failure mode identification.

Team: The right people are identified and participate as part of the cross functional DFMEA team throughout the analysis and are adequately trained in FMEA methods.

Step 3: Technical Risk Analysis

Deliverable: The FMEA procedure has identified the technical risks for the selected FMEA.

Technical risk analysis: Each portion of the technical risk assessment has been properly performed, based on correct FMEA fundamentals and procedure.

Step 4: Risk Assessment and Prioritization

Deliverable: The risks for the selected FMEA have been assessed and prioritized.

High-risk failures identified: All potential high-risk failure modes and associated causes are properly identified and prioritized, including past field issues (for similar items) and potential new issues.

Special characteristics: The DFMEA identifies appropriate special characteristics candidates, based on company policy.

Step 5: Reduce and Communicate Risks

Deliverable: Risks for selected FMEA have been reduced and communicated.

Design improvements: The DFMEA drives actions to improve product designs as the primary objective.

Test improvements: The DFMEA drives actions to improve the design verification plan and report (DVP&R), as a secondary objective.

High-risk failures addressed: The DFMEA addresses all high-risk failure modes, as identified by the FMEA team, with executable action plans. The result is risk reduced to an acceptable level.

Timing: The DFMEA is completed during the “window of opportunity” where it could most efficiently impact the product design, the DVP&R, and the manufacturing process.

Step 6: Document Results

Deliverable: Results of selected FMEA have been linked and documented.

Documentation: Each portion of the DFMEA document is properly and completely filled out “by the book,” including “action taken” and new risk prioritization values. The document is archived for future reference.

Time usage: Time spent by the DFMEA team, as early as possible and focused on areas of concern, is an effective and efficient use of time, with a value-added result.

This evaluation or “self-assessment” may be company specific or customer specified.

5.6.3 Implement DFMEA Version Control

The DFMEA must be retained by the organization according to the organization’s record retention policy and customer requirements. It is up to the company to determine what version(s) of the DFMEA must be retained (e.g., based on status level, program timing, management review, customer review, PPAP, etc.). In any case, a good document management system will show only the most recent version with history available.

5.6.4 Identify DFMEA Linkages

The DFMEA is related to other documents such as the product design documents, design verification plan, and process FMEA. There is a two-way feedback loop in some cases. Recommended inputs and outputs covered in this standard are shown in Figure 27.

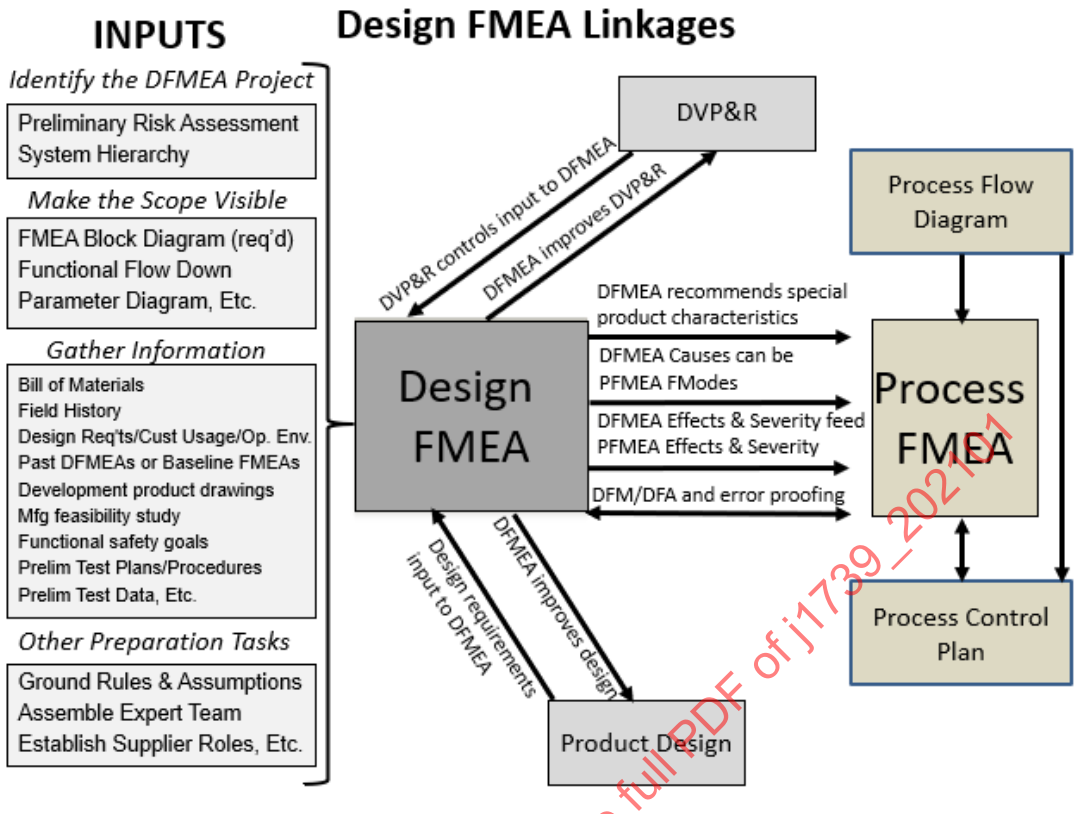


Figure 27 - DFMEA linkages

5.6.4.1 Linkage between DFMEA and Product Design

DFMEA improves design: The causes of the DFMEA are fixed or corrected by improving the design of the system or product.

Design requirements input to DFMEA: Product design requirements are input to the functions and corresponding requirements, for the DFMEA.

5.6.4.2 Linkage between DFMEA and Design Verification Plan and Report (DVP&R)

DVP&R controls are input to DFMEA: The FMEA team includes representation from the testing department, in order to ensure that the team considers all needed input from testing as part of the analysis. An example of a DVP&R for the windshield wiper DFMEA is shown in Figure 28.

Design Verification Plan and Report (DVP&R) Example												
System : Wiper System			Supplier Name : ABC Wipers LLC			Department : Wipers			DVP Number : AB123			
Component :			Supplier Code : AB123			Prepared By : Joe Smith			Original Date : 12/1/2019			
Application : 2022 ZZ Program			Part Number :			Design Engineer : Sally Jones			Revision Date : 1/22/2020			
Test Plan											Test Report	
Test Number	Test Name	Test Specification	Acceptance Criteria	Test Method	Test Responsibility	Test Phase	Sample Size	Sample Type	Test Start	Test Completion	Test Results	Comments
1	Wiper System assembly cyclic Durability	Wiper Performance standard # PS-6543, Section 9.2 Cyclic durability	Blades must not contact body moldings at any time for xxxx cycles	Degradation Test	Wiper Lab	DV PV	6 5	Prototype Pre Production	1/1/2020 9/1/2020	3/1/2020 1/1/2021		
2	Vehicle Level Reliability	Vehicle Reliability Test Procedure AB1234	Blades must not contact body moldings	Pass / Fail	Vehicle Durability	DV PV	6 5	Prototype Pre Production	3/1/2020 9/1/2020	8/1/2020 2/1/2021		
3	Wiper Arm force Deflection	Wiper Arm specification # XY657	Wiper Arm bending stiffness Z +/- xx	Test to Failure	Wiper Arm Supplier	DV PV	6 6	Prototype Pre Production	3/1/2020 9/1/2020	3/15/2020 9/15/2020		
4	Wind Load	Wiper Vehicle test WT-8765 , section 7.3	The wiper system shall wipe 100 percent of the vision area as specified in FMVSS104 at a relative wind speed equal to 160 kmh.	Pass / Fail	Wind Tunnel	Proto Vehicle	3	Prototype	7/1/2020	7/15/2020		
5	Functional test of ECU Processor	Wiper ECU specification # 98789 Section 7.6 , Fluid level signal	Send 5 volt signal to the instrument display when fluid level goes below 25% of reservoir capacity	Pass/ Fail	ECU Supplier	DV PV	3 3	Prototype Pre Production	2/1/2020 10/1/2020	3/1/2020 11/1/2020		
6	Software in Loop (SIL)	Wiper ECU specification # 98789 Section 7.6 , Fluid level signal	Send 5 volt signal to the instrument display when fluid level goes below 25% of reservoir Capacity	Pass/ Fail	E/E Lab	DV PV	1 1	Prototype Pre Production	4/1/2020 10/1/2020	4/15/2020 10/15/2020		
7	Continued...											

Figure 28 - DVP&R example for windshield wiper DFMEA

DFMEA improves DVP&R: When the FMEA team identifies failure modes and associated causes that are not currently well detected in test plans or procedures, the test plans and procedures should be updated and improved (using the recommend actions column) so all failure modes of concern are detected during testing. The design verification plan and report (DVP&R) provides input to the detection-type design controls of the DFMEA. Additionally, the DFMEA may identify additional or modified tests to be documented in the DVP&R. See Figure 29.

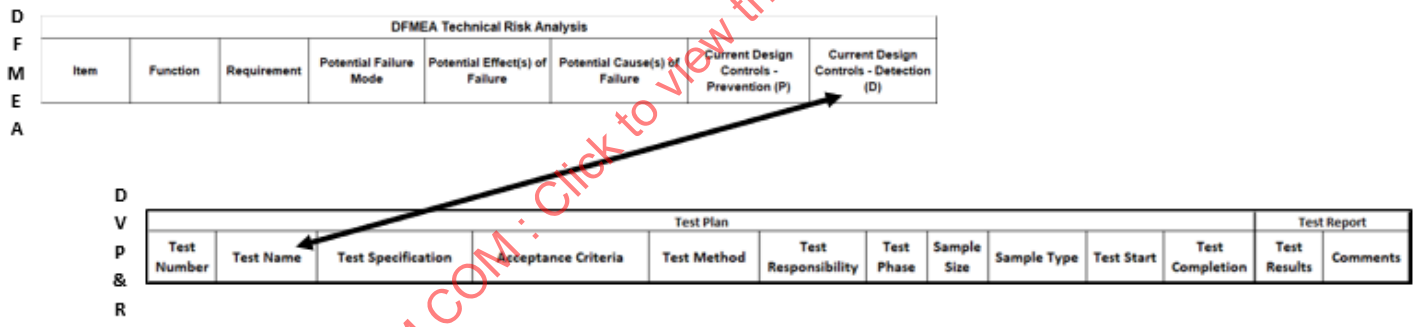


Figure 29 - DFMEA and DVP&R connection

5.6.4.3 Linkage between DFMEA and PFMEA

DFMEA recommends potential special product characteristics: Properly defined causes in the DFMEA can become inputs to identification of potential special product characteristics, based on company policy.

DFMEA causes can be PFMEA failure modes: Causes in the DFMEA become inputs to identification of failure modes in the PFMEA. See 6.3.2.

DFMEA effects can be PFMEA effects: Effects in the DFMEA become inputs to identification of product-related effects in the PFMEA. When the effect of a potential failure mode is a safety hazard to the end-user, it is important that these potential effects are clearly communicated to the manufacturing organizations and suppliers for consideration in the PFMEA. The method for communicating issues from the DFMEA to the PFMEA may vary by company. See 6.3.2.

DFM/DFA and error proofing: Product designs must be able to be manufactured and assembled, and this can be supported by the DFMEA team considering design improvements that help ensure the design can easily be manufactured without failures.

5.6.5 Change Management

Changes to the DFMEA are necessary to make sure the analysis reflects the design at start of production. Changes after start of production may be necessary based on a review of the design change.

5.6.5.1 Update DFMEA to Reflect a Design Change

When design changes occur, the preliminary risk assessment may be used to determine if the DFMEA needs to be updated.

5.6.5.2 Update DFMEA with Lessons Learned

The company should determine the best method to secure and benefit from what was learned when something failed in the past in order to avoid making the same failure again.

The company may:

a. Reference lessons learned in the DFMEA itself at the start of the project.

b. Update a generic DFMEA and not revise all the variants that exist.

c. Update all the variants as a look-across (without the existence of a generic DFMEA).

d. Maintain a database of lessons learned separately from the DFMEA used as input at the start of a new DFMEA (e.g., campaigns, recalls, high warranty, etc.).

NOTE: A generic DFMEA includes data not related to a specific customer, but is used as a starting point for a new DFMEA. It is revised based on failures that occur after validation is complete, after start of regular production, and beyond based on company policy. Generic DFMEAs should be revised to comprehend product and process lessons learned based on internal quality issues, warranty, campaigns, etc.

6. PROCESS FMEA

This standard defines a method for the identification, assessment, mitigation, and prevention of technical risks of failure in manufacturing and assembly processes using process flow diagrams (PFDs), process failure mode and effects analysis (PFMEA), and process control plans (PCPs) throughout the life cycle of a product. Section 6.6.4 identifies linkages between these tools.

6.1 PFMEA Planning (Step 1)

Figure 1A - Step 1 of the FMEA six-step process map

Deliverables: The set of PFMEAs are identified, prioritized, and scheduled.

6.1.1 Determine the Scope of the Project

A PFMEA project is the entire set of PFMEAs that need to be performed during the process development timeframe to support the quality objectives of the manufacturing/assembly processes and how they relate to the safety, reliability, and performance objectives of the product design.

The scope should define the process operations required to manufacture and assemble the hardware, electrical, or software for which the team is responsible. The partitioning of the overall project into individual PFMEAs depends on who is responsible for the manufacturing, assembly, or aftermarket operations. The general rule is whomever has process responsibility has ownership for the corresponding PFMEAs. If company “A” has responsibility for the assembly of the windshield washer system, then they have responsibility for the windshield washer system assembly PFMEA. Companies responsible for manufacturing individual components will have responsibility for completing the manufacturing PFMEAs.

6.1.2 Perform Preliminary Risk Assessment for Process FMEAs

PFMEAs can include hundreds of operations and be resource intensive. Few companies have the resources to properly do PFMEAs on everything. PFMEAs should be performed when a certain level of change or other risk factors can be effectively addressed. Therefore, companies can consider three basic cases for which PFMEAs are generated, each with a different scope or focus:

Case 1: New plant layout, new machines or new processing technology. The scope of the PFMEA is the affected manufacturing or assembly process.

Case 2: Modifications to an existing process (assumes there is a PFMEA for the existing process). The scope of the revision efforts should focus on the modifications, or interactions due to the modifications to the manufacturing or assembly processes. Modifications include removal or addition of processing operations or changes in tooling or equipment to achieve the process functions or performance requirements.

Case 3: Use of existing process in a new environment, location, or application (assumes there is a PFMEA for the existing process). The scope of the revision is the impact of the new environment, location, or application on the existing process.

Cases 1, 2, and 3 provide some guidance for scope identification; however, additional factors should be considered. Field performance issues can be an indicator of manufacturing problems. The preliminary risk assessment can be used to determine which PFMEAs need to be done to support prioritization, and to enhance the use of Cases 1, 2, and 3 for PFMEA project planning.

Preliminary risk assessment has four stages:

1. The manufacturing and assembly processes are defined at the macro level (Figure 30 shows a fictitious example of Windshield Wiper System assembly plant layout that will be used for preliminary risk assessment).

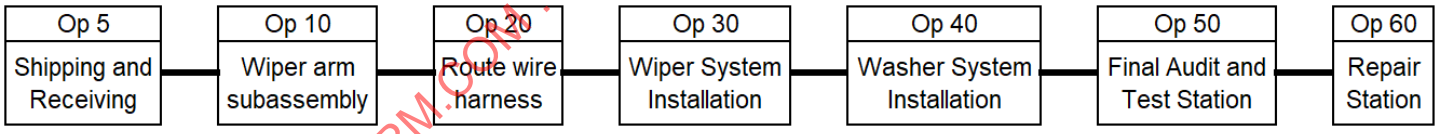


Figure 30 - Example for windshield wiper system macro assembly process

2. Companies identify important criteria for selection of PFMEA projects. Example selection criteria may include:
   - Potential for safety issues
   - Degree of new technology
   - Degree of design or application change
   - History of significant field problems
   - History of manufacturing or assembly problems
   - New tooling or product complexity

- Potential for important regulation issues
- Supplier capability
- Other risk criteria such as traceability, complexity, packaging, supplier concerns, cybersecurity issues, safety-related software functions, etc.

3. The risk criteria can be assessed on a variable scale (such as high 3, moderate 2, or low 1) for each of the items being considered for PFMEAs. Preliminary risk assessment criteria can be tailored to the unique needs of any company. The prioritization metric column is a multiplication of the criteria columns.

4. Based on this assessment, the team can select which macro-level processes require PFMEAs to be performed. The team may choose to do PFMEAs on all processes or select ones that have the highest scores.

Figure 31 shows a fictitious example of PFMEA preliminary risk assessment done on a wiper system.

Preliminary Risk Assessment
Wiper System Assembly Example
Method:
1. Document the process steps at the macro level
2. Project team agrees on risk factors
3. For each macro-level process, assess risk related to associated risk factor (1, 2, 3*)
4. Multiply risk assessments together
5. Select the processes requiring PFMEAs to be performed

* Assessment key: 1 = low risk, 2 = moderate risk, 3 = high risk (project teams may modify the assessment key)

Op-Seq	Process Description	Degree of Change	Safety Concerns	New Technology	Manufacturing &	Field Problems	Regulatory Risk	Special Characteristics	Other Risk Criteria	Prioritization Metric	Create / Update PFMEA Y/N?
5	Shipping and Receiving	1	1	1	1	1	1			1	N
10	Wiper arm subassembly	1	2	1	1	2	2			8	N
20	Route wire harness	1	1	1	1	1	1			1	N
30	Wiper System Installation	2	3	1	2	3	2			72	Y
40	Washer system installation	1	1	1	1	1	1			1	N
50	Final Audit and Test Station	2	3	1	1	3	2			36	Y
60	Repair Station	1	2	1	2	2	1			8	N

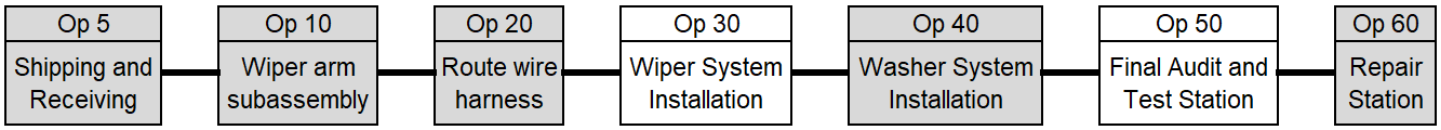
* Project team may add/modify risk factors.

Figure 31 - Preliminary risk assessment example for windshield wiper system assembly process

6.1.3 Determine the Processes that Require PFMEAs for a Project

The project team, with management agreement, determines the specific processes that require PFMEAs, based on the preliminary risk assessment. The decision by the project team as to which specific processes will receive PFMEAs is influenced by scope and responsibilities within or outside the organization.

In the windshield wiper preliminary risk assessment example, Operations 30 and 50 were identified as requiring PFMEAs. However, the PFD, PFMEA, and PCP examples will only focus on Op 30 analysis. See Figure 32.



Macro operations not requiring PFMEA are shaded gray.

Figure 32 - Preliminary risk assessment defines windshield wiper system macro operations requiring PFMEA

6.1.4 Prioritize PFMEAs

PFMEA Prioritization should emphasize conducting PFMEAs for which the scopes are of greatest risk to the project based on the results of a preliminary risk assessment. Prioritization allows the project team to determine which PFMEAs to do and define the order so they can be scheduled. However, written customer requirements may supersede the decision and require PFMEAs on all operations.

6.1.5 Develop PFMEA Plan for Project

The PFMEA plan is the output of prioritization with added detail. By definition, a “plan” is a written account of an intended future course of action aimed at achieving specific goal(s) or objective(s) within a specific timeframe. It explains in detail what needs to be done, when, how, and by whom.

6.2 PFMEA Preparation (Step 2)

Figure 1B - Step 2 of the FMEA six-step process map

Deliverables: All preparation steps for selected PFMEA have been completed and first meeting scheduled.

6.2.1 Determine the Scope of the PFMEA

The process flow diagram (PFD) is a representation of the sequential steps of the process which includes all operations from receipt of the material through to storage, packaging, and shipment. The scope of a PFMEA, as determined by the preliminary risk assessment, is further defined in the PFD from a macro level to the detailed incremental operation steps (micro level) for a single operation. A PFD on a single operation (for example, Op 30 wiper system installation) includes the primary process flow operations as well as secondary operations such as off-line inspection, off-line repair, or material movement.

The PFD may not reflect all processes. For example, what companies call a “hidden factory” is not shown on the PFD. A hidden factory step occurs when the material or product is handled other than in accordance with the planned PFD (any operation not included in a PFD such as rework/repair, scrap, material movement, etc.). Other hidden factory examples include: ad hoc repairs in a storage facility, handling of parts that have failed in-process tests, material returned to storage due to cancelled (cut) product assembly, and extra parts at a station. Analysis of hidden factory processes may contribute to the identification of failure modes (product defects) or errors in a manufacturing or assembly process (causes) because a hidden factory is not documented and therefore not controlled. Hidden factory operations of concern to the PFMEA team (e.g., hand torque due to equipment being down for repair) should be added to the micro PFD for prioritization and inclusion in a PFMEA.

6.2.2 Create Visual Depiction of Scope

A visual depiction of scope can be achieved using a process flow diagram. Companies can decide if they want to include all operations within one PFD or if they want to limit the PFD to each macro operation with associated micro operation steps. Figure 33 illustrates what the PFD would look like for just the wiper system installation (Op 30).

Process Flow Diagram
Operation 30

Inspection Key
A=Automatic
M=Manual
V=Visual
Q=Quality Audit

Changeover Key
P=Product
T=Tooling
S=Softw are
D=Dunnage
L=Label

Part # WS-2021-rev b
Customer Part # WprSys-2024
Product: Wiper System
Rev Date: 1/25/2020
Prepared By: Bill Haughey; Rhonda Brender; Mike Bucala; Paul Baird, Ryan Winnicki; Ed Myzienski; Mike Dow n; Carl Carlson; Lee Daw son; Mary Row zee; MaryBeth Soloy

Organization: Manufacturing Engineering
Department: Wiper System - Quality

			Operation Type												
Op-Seq	Process Characteristics Sources of Variation (Inputs)	Special Process Characteristic	Administration (A) Traceability (T)	Fabrication / Transformation	Move / Transport	Lift / Get / Store	Inspect / Verify	Rework	Scrap / Contain	Packaging Interaction	Changeover	Operation Description (Process Function) (Do This - To This - With This) (Purpose of Operation)	Process Function Priority	Product Characteristics (Outputs)	Special Product Characteristic	Comments
30												Wiper System Installation	H			
30.05	Bar Code reader Bin Placard		A / T			X						Get w iper linkage	L	1) Correct w iper linkage 2) No damage		Traceability
30.07	Placement of isolators			X								Get and manually install isolators	L	Alignment of isolators to w indshield molding	Dimensional placement of isolators w ith respect to w iper linkage	
30.10	Torque tool setting			X								Orient and secure w iper linkage to body structure w ith battery torque tool	H	1) Alignment of Linkage to w indshield molding 2) Torque w ithin design specification	Clearance to w indshield	Speed control, rotation control, torque control
30.15	Bar Code reader		T			X						Get w iper motor	L	1) Correct w iper motor 2) No damage		Traceability w ill be needed
30.20	Locating feature in tray design Battery torque tool			X								Orient and secure w iper motor to body and w iper linkage w ith battery torque tool	L	1) Correct alignment of motor to vehicle 2) Torque w ithin design specification	Secured w ith correct torque	Speed control, rotation control, torque control
30.30	1) Operation layout to enable connector orientation 2) Torque tool setup 2) Torque tool calibration	1: KCC Degree of connector rotation 2: KCC Tool RPM		X								Orient and secure w iper motor ground w ire to vehicle w ith battery torque tool	H	1) Error proof design to prevent connector rotation 2) Torque	1: CC Connector orientation 2: CC Ground w ire fastener torque spec	Speed control, rotation control, torque control

Figure 33 - Example of a micro-level process flow diagram for wiper system installation (Op 30)

The PFMEA team defines and evaluates each micro level operation step to determine level of risk. The process function priority column adds the H-M-L as a clear designation of risk assessment for both the macro and micro level of operations (see 6.2.2.9). Operation steps are shaded when defined as "low risk" and will not require further details in the PFMEA. It is important to understand the PFD is part of the continuous improvement process. As the PFMEA and PCP are completed additional information will be identified that could add, modify, or delete defined operation steps and priority ranking within the PFD. Regardless of ranking level, each macro PFD operation step is populated within the PFMEA (operation description).

The following sections define the typical content of a PFD and the order of which they are logically completed. These sections are not intended to prescribe a mandatory PFD development sequence.

6.2.2.1 Identifying Information

The PFD, PFMEA, and PCP documentation contains important information about the analysis and is consistent between the manufacturing processes. The identifying information for each of the documents must include a project name, latest revision date, organization, department, and group or individual responsible for the operation. Additional information such as PFMEA number, start date, model year, program number, system/sub-system/component, core and support team member names, and team facilitator, etc., may be documented to provide useful information for tracking or storage and retrieval purposes. A team member list including names and departments is recommended.

6.2.2.2 Operation Description

Operation description defines what is happening to the material, product, or assembly. Wording of the operation description should consider the operation purpose ("do this"), the part or material ("to this"), and how the operation is being performed ("with this"). The more precise the description of the operation (process functions), the easier it is to identify potential failure modes for preventive/corrective controls and actions. If the operation has more than one step with different potential modes of failure, list each of the detailed steps separately in the PFD worksheet.

6.2.2.3 Outputs (Product Characteristics or Other Process Outputs)

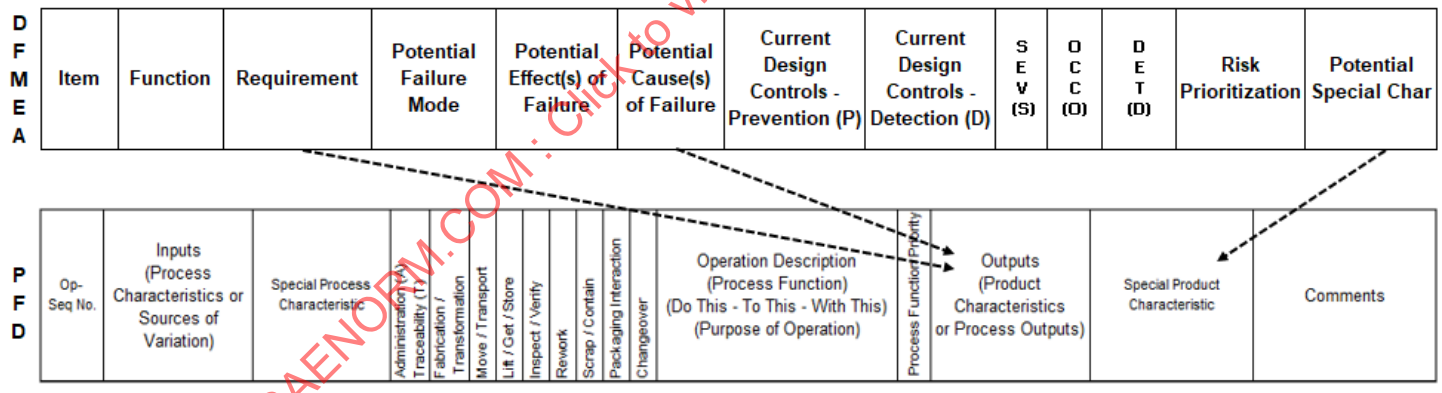
Outputs may include product characteristics (such as adhesive thickness or metal thickness) or other process outputs (such as no damage to paint during assembly). For example, scrap/contain may not have product characteristic outputs, but would have process outputs (e.g., bad product quarantined).

Product characteristics define the primary desired outcome of the fabrication/transformation operations. Examples of product characteristics are spline length, surface finish, width, quantity, and torque. They are dimensional, visual, functional, mechanical, and material features or properties which describe and constitute the design of the article, as specified by drawing or digital product definition requirements. These characteristics can be measured, inspected, tested, or verified to determine conformance to the design requirements. The product characteristics in the PFD feed the product characteristics in the control plan (PCP). The values for the product characteristics are shown on the product drawings and specifications to define the acceptance criteria for the control plan (PCP).

Other process outputs are documented in the PFD worksheet as the desired result of the operation and are considered when defining the requirements in the PFMEA. There may be operation steps that are performed to accomplish a process output (i.e., remove a part for repair, service equipment or tooling, etc.).

As shown in Figure 34, the DFMEA (when available) can provide valuable information as inputs to the PFD to help define the outputs (product characteristics) for a given operation.

- The engineer or team uses engineering judgement to establish/define the requirements from the DFMEA into the PFD outputs (product characteristics).
- The engineer or team uses engineering judgement to establish/define the outputs that are intended to address potential cause(s) defined in the DFMEA. These are documented as the PFD Outputs (product characteristics).
- The engineer or team uses engineering judgement to establish/define the potential special characteristics from the DFMEA into the PFD special product characteristics.



Dashed lines indicate engineering judgement is used to convert information from DFMEA to PFD.

Figure 34 - DFMEA and PFD connection

6.2.2.4 Special Product Characteristics

Finalization of a special product characteristic is an iterative process between engineering and manufacturing. The DFMEA along with other design tools provide input to potential special product characteristics (candidates). The PFD, PFMEA, and PCP may begin with special product characteristic candidates and result in the agreed upon (final) special product characteristics.

See 5.4.5 for information on special product characteristics.

6.2.2.5 Inputs (Process Characteristics or Sources of Variation)

Inputs are process characteristics or sources of variation. A process characteristic is a characteristic such as temperature, speed, feed, chemical concentration, pressure, voltages, etc., that is measured while the process is running. Lack of control of a process characteristic can directly influence the ability to achieve the product characteristics (e.g., press load influences a part being fully seated). Sources of variation are process variables that are defined from categories of a fishbone diagram: man (human factors), machine, methods (systems), mother nature (environment), measurements, and materials.

6.2.2.6 Special Process Characteristics

A special process characteristic is a parameter that requires special care. Special process characteristics are monitored during manufacturing/assembly. The purpose of the special process characteristic is to ensure the process is monitored to maintain validated settings and identify variation anomalies requiring attention. Monitoring process characteristics is preferred over measuring the correlated product characteristics.

6.2.2.7 Comments

Comments are collected during the development of the process flow diagram (PFD), the team might identify a concern, control, or action necessary to ensure the operation step will meet the product requirements. These ideas can be captured and considered during the development of the PFMEA and/or PCP in the comments section of the PFD.

6.2.2.8 Operation Sequence Number

The process step operation sequence number is an identification of the operation, or steps in an operation, being analyzed and must be written in the PFD. The process step identification (e.g., department number, operation number, work element number, etc.) should be consistent with other process documents including the PFMEA, PCP, and standardized work instructions (SWI). A process step includes deviations from the main process flow.

6.2.2.9 Process Function Priority (Optional)

Process function priority builds on the preliminary risk assessment process and will identify and prioritize which detailed operations require additional risk analysis to be documented in the PFMEA. The priority is optional and criteria is company specific. A high-medium-low prioritization may be used.

6.2.2.10 Process Categories (Operation Types)

Process categories are the starting point for comprehensive analysis of the manufacturing process. The PFD categories type(s) will relate to the defined scope of the analysis. Companies can modify these suggested categories to meet their internal requirements. Operation categories define common tasks to enable variation reduction and error proofing. They can also be an input to the process function priority.

6.2.2.10.1 Administration/Traceability

Administration and traceability activities are tasks that include verification of product delivery, movement, or shipment. The tasks can be in the form of signing or scanning a document that defines the receipt or movement of material or confirmation that the output of the process step was completed. These tasks are done in conjunction with another operation type. (i.e., material receiving and shipping, getting, movement, storage, inspection or verification, quarantine parts that require rework or scrap, etc.).

6.2.2.10.2 Fabrication - Transformation

“Fabrication - transformation” refers to value-added activities that change the state of the material, product, or assembly (i.e., assembly, machining, welding, paint, labeling, etc.). In a manufacturing operation, the outputs of these activities are related to the product features (characteristics) identified on the product drawing. In an assembly operation, the output of this activity is related to an interface as defined in 5.2.2.1 or on the drawing. These outputs are documented in the “product requirements - outputs” section of the PFD.

6.2.2.10.3 Move - Transport

“Move - transport” refers to the movement (i.e., hand-carried, fork truck, conveyor, or machine indexed) of material from storage locations, between stations, or departments. Often there is a requirement to confirm the product is delivered to the correct location by stamping the traveler. It may be necessary to ensure precautions are taken to protect the product during transportation to the new location.

6.2.2.10.4 Lift - Get - Store

“Lift - get” is the act of retrieving product or tool from a storage location, a presentation device, or unloading a product from a tool, fixture, or machine. “Store” is the act of installing or placing a product or tool in a particular location. Location can be defined as where the product or tool is physically placed (i.e., presentation device, supermarket, storage dunnage, rack, pallet, conveyor, or parts tray).

6.2.2.10.5 Inspect - Verify

“Inspect - verify” refers to any process step that evaluates the product for conformance to specifications (i.e., visual inspection, physical measurement, functional testing, automatic gauging, etc.). With any verification step, there is an associated task of documenting the results of the test on a company-specific form.

Types of inspections can be classified by:

A = Automatic, or machine inspected (i.e., leak tester, vision system, torque controlled)

M = Manually inspected by the operator (i.e., hand gage)

V = Visually inspected by the operator

Q = Quality audit, control plan check

6.2.2.10.6 Rework

“Rework” refers to process steps required to replace or repair rejected material. Rework operations can include, but are not limited to, repair, teardown, reload, replace parts, etc.

6.2.2.10.7 Scrap - Contain

“Scrap” refers to permanently removing rejected material from the value stream and placing it into a scrap container (i.e., red container, tote, basket, etc).

“Contain” refers to suspect or reject material that is temporarily held until it can be reworked or scrapped.

6.2.2.10.8 Packaging Interface

“Packaging interface” considers the protection of the product or assembly from damage (i.e., packing a opening with material to prevent damage during debur process, packaging a product for shipment, etc.). A packaging interface step is typically associated with an operation that has an output of getting or storing of a component or assembly from line side dunnage.

6.2.2.10.9 Changeover

It is important to flag the process steps that are affected by changeover activities. Not controlling changeover activities can lead to a potential cause of failure.

Possible changeover activities can be classified as:

P = Product, material

T = Tooling, hard setup changes (adjustments)

S = Software, soft setup (menu, selector switches), job instructions

D = Dunnage, packaging

L = Labels (in-process labels, product labels, etc.)

6.2.2.10.10 Other

Companies can identify additional (other) types of operation categories not defined previously or modify any the defined operation types to meet their business criteria.

6.2.3 Assemble the PFMEA Team

The owner or facilitator/moderator of the PFMEA will establish the PFMEA Team, as necessary, to suit the needs of the scope and ensure timely analysis. The PFMEA team consists of subject matter experts who represent cross-functional knowledge associated with the manufacturing, assembly, or service operations and are trained in the PFMEA process. PFMEA is a team effort and each team member contributes with their unique knowledge and experience to identify risk in the design. The PFMEA team should include a core team, as appropriate, who meet regularly and understand the details and history of the manufacturing or assembly operations to take the analysis from start to finish. The core team should expand based on the needs of the team (e.g., add disciplines, add more experienced people, etc.). See 4.3 for more information.

The reason for a cross-functional team is simply because one person cannot know everything. Multiple disciplines minimize the potential for “blind spots” while conducting the analysis. The project leader, who may be a manufacturing engineer, quality engineer, or PFMEA engineer (facilitator/moderator), should develop a team roster that includes resources assigned to the overall project/program along with additional subject matter experts to ensure the proper expertise is applied to the PFMEA. One of the indispensable values of PFMEA is the journey of discovery. The cross talk and synergy between team members allows them to discover things that individuals often miss.

6.2.4 Establish Ground Rules and Assumptions/Gather FMEA Information

Ground rules, assumptions, and engineering Inputs/Information help the PFMEA team conduct the analysis in an efficient and effective manner.

6.2.4.1 Ground Rules

Suggested ground rules to help PFMEA teams operate efficiently include:

- The high level PFD steps are used to complete the preliminary risk assessment but the PFMEA analysis is completed at the detailed operation level as defined by the PFD
- The PFD operation steps will be updated based on additions and changes during the development of the PFMEA and control plan
- Stay focused on operator safety and meeting the requirements of the operation
- There should be one or more special process characteristics for each agreed upon special product characteristic

6.2.4.2 Assumptions

The PFMEA team should document the assumptions they made while completing the PFMEA. The PFMEA, as an analytical engineering tool, records the ideas and concerns of a process team; therefore, it is understood that failures shown in the PFMEA are potential failures which may or may not occur. The PFMEA should address manufacturing and assembly risks, while assuming that the product will meet the design intent. It is assumed that parts/materials coming into the operation from previous steps will conform to product specifications. Exceptions can be made as experience dictates (e.g., known deficiencies in incoming part quality). These assumptions are used to keep the team focused on what they have control over.

6.2.4.3 Gather Information

The PFMEA team gathers information necessary to perform the technical risk analysis for the selected PFMEA. Product design documents include parts list, product functions and requirements, drawings specifications, warranty and field history, and DFMEA (if available). Process related documents include current PFDs, PFMEAs, and control plans, plant issues, tooling and fixtures, preventive maintenance schedules, manufacturing feasibility studies, and verification test procedures. These are all inputs to the PFMEA based on the level of analysis (i.e., final assembly, subsystem assembly, component manufacturing). If this step is missed or done inadequately, FMEA meetings can be burdened with extra tasks related to missing information, and FMEA results may be compromised.

6.2.5 Identify and Prioritize Functions and Outputs (Requirements)

Identify functions and requirements in the PFMEA provides a foundation for each of the selected/prioritized operations to be analyzed. The operation description (6.2.2.2) in the PFD becomes the function within the PFMEA and the outputs (product characteristics) (6.2.2.3) defined in the PFD establish/define the requirements in the PFMEA. Priorities for the functions and requirements come from 6.2.2.9.

6.3 Technical Risk Analysis (Step 3)

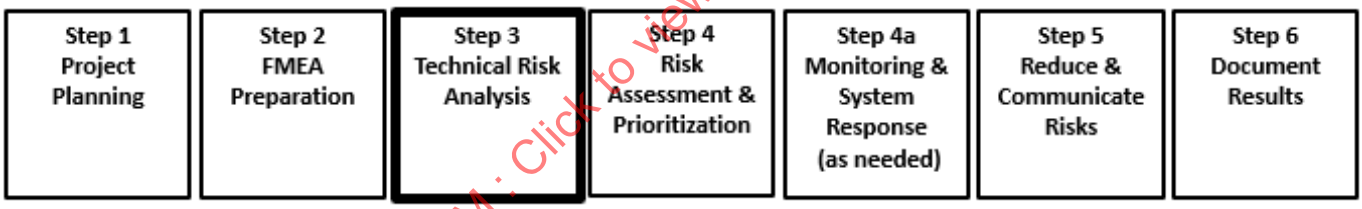


Figure 1C - Step 3 of the FMEA six-step process map

Deliverables: The PFMEA procedure has identified the technical risks for the selected DFMEA.

The PFMEA identifies the risks of failure of the operation steps to deliver the intended output. The primary purpose is to manufacture or assemble the product to design specifications (product characteristics); however, there are some operations that have an output that is not related to a product characteristic, such as contain, scrap, inspect, or verify.

The team should discuss and document the interfaces between operations where past problems have been identified. Additional interfaces and interactions include the human-machine interface (HMI). The responsibility for each interface and interaction must be defined either within the PFMEA team or between PFMEA teams. The PFMEA must take the technical/physical limits of a manufacturing or assembly process into consideration, for example:

a. Operators might have trouble distinguishing similar parts (e.g., size, color, selection of software)

b. Operators might have trouble controlling variation of process characteristics (e.g., time, temperature, location)

c. Nonconforming products must be controlled

d. Operators could be injured based on repetitive work

e. Error proofing is a continuous improvement process

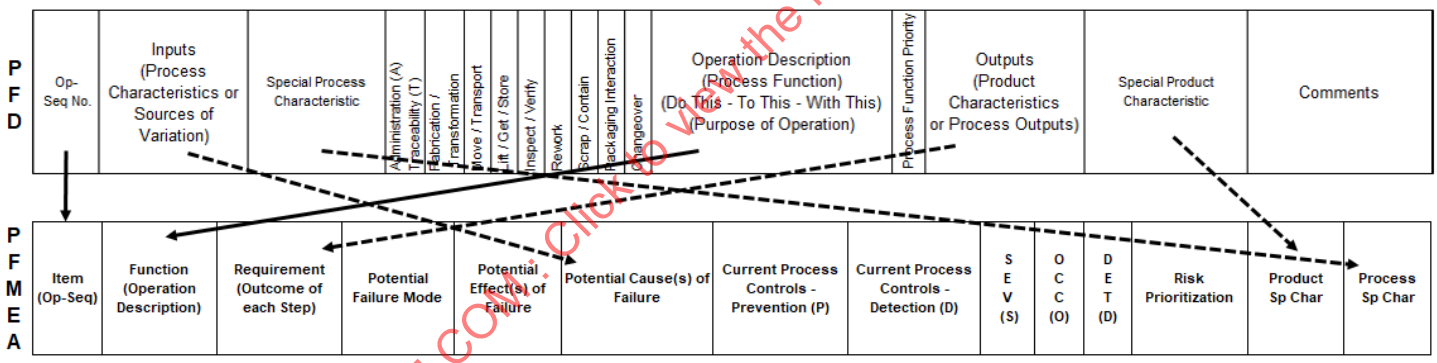
f. Need to verify correct completion of assembly process

Operations of greatest concern to the team should be discussed first, and in greatest detail. Other operations should receive less, but appropriate, focus.

6.3.1 Transfer Prioritized Functions and Requirements into Analysis

Transfer of Prioritized Functions and Requirements by a designated team member (owner of the operation in scope) initiates the PFMEA. To minimize the time in the PFMEA meetings, the information in the PFD (see Figure 35) is used to populate the Item, Function, and Requirements section of the PFMEA analysis. Once the PFMEA is populated with all of the operation steps, the team can define which operation steps will be discussed first.

- The operation sequence number in the PFD becomes the item (Op-Seq) in the PFMEA
- The process characteristics in the PFD are used by the engineer and/or the PFMEA team to define the causes in the PFMEA
- The operation description becomes the function in the PFMEA
- The product characteristics in the PFD are used by the engineer and/or the PFMEA team to define the requirements in the PFMEA
- The product special characteristics in the PFD are entered as product special characteristics in the PFMEA



Solid lines indicate exact copy and paste from PFD to PFMEA and dashed lines indicate engineering judgement is used to convert information.

Figure 35 - PFD and PFMEA connection

Based on the preliminary risk assessment, Figure 36 provides an example for the windshield wiper PFMEA. This example shows how to transfer the Item (OP-Seq number), function (operation description), and requirements (outputs of each operation step) from the PFD to the PFMEA. These linkages initiate the PFMEA technical risk analysis step 3.

6.3.1.1 Item (Process Operation Sequence Number)

The item (process operation sequence number) is a direct copy from the PFD (see Figure 36). This is the first linkage of the PFD to the PFMEA.

6.3.1.2 Process Function

The process function describes what is happening to the part within a detailed step of a given operation. The process function should be identical to the operation description in the PFD. This enables the ability to connect the analysis of each process operation and know when the scope is complete (see Figure 36). The team determines the priority with which to analyze functions (6.2.2.9).

6.3.1.3 Requirements

Requirements (see Figure 36) relate to the output of the function, such as length, depth, surface finish, torque, quarantine, etc. A requirement is a measurable characteristic of a function which may be qualitative. It is recommended that quantitative values for requirements, such as torque specifications and product specifications, only be included in the process control plan and not the PFD or PFMEA. Therefore, as specifications change over time, only one document needs to be updated with the new specification.

Item (Op-Seq)	Process Function	Requirements
30.1	Orient and secure wiper linkage to body structure with battery torque tool	Torque within design specification
30.3	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Ground wire alignment to body
30.3	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Torque within design specification

Figure 36 - PFMEA example for Operation 30 (wiper system installation)

6.3.2 Determine Potential Failure Modes

Potential failure modes are the manner in which the manufacturing and assembly process could potentially fail to meet the defined outputs of the operation step, called “requirements” in PFMEA. It is a description of a product defect as a result of the process failure (product non-conformance) within a specific operation. Potential failure modes can be in-process related when the process function and requirement are specific to process outcomes or a potential product defect when the function and requirement is related to a product outcome. Examples for the windshield wiper PFMEA are shown in Figure 37.

Each potential failure mode should be considered independently of other potential failure modes. This enables the team to address the unique reasons (potential causes of failure) independently of other failure modes.

There are several categories of potential failure modes, including:

- Does not meet function
- Over-achieving function (i.e., operation output above acceptable threshold)
- Under-achieving function (i.e., operation output under acceptable threshold)
- Intermittent function (i.e., operation output randomly in and out of specification)
- Unintended function (i.e., operator safety)

Item (Op-Seq)	Process Function	Requirements	Potential Failure Mode
30.10	Orient and secure wiper linkage to body structure with battery torque tool	Torque within design specification	Torque too high
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Ground wire alignment to body	Ground wire damaged during torque operation
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Torque within design specification	Torque too low

PFMEA Columns Truncated

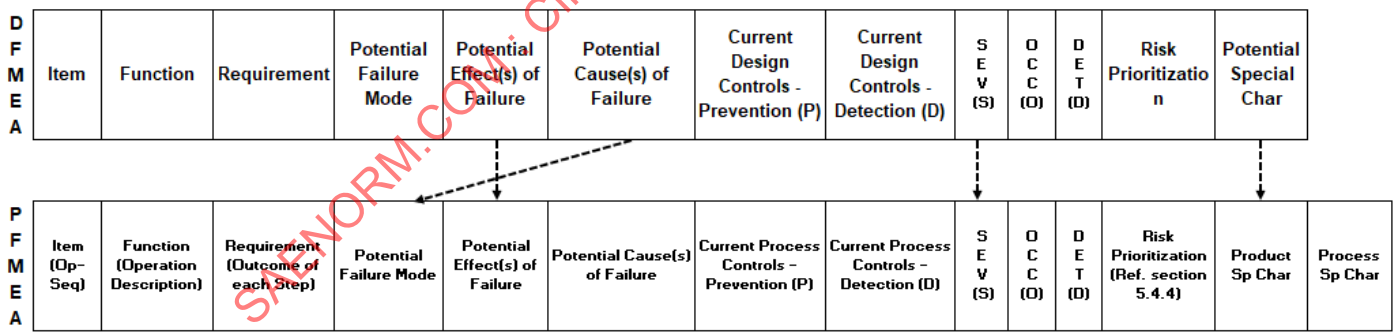
PFMEA Rows Truncated

Figure 37 - Potential failure mode examples for windshield wiper PFMEA

The DFMEA also has information the PFMEA team should consider when completing the analysis (see Figure 38).

- The PFMEA team use engineering judgement to establish/define the failure mode in the PFMEA from the cause in the DFMEA (product characteristic).
- The PFMEA team use engineering judgement to establish/define product effects and severity ratings in the PFMEA from the product effects and severity ratings DFMEA. The PFMEA considers two types of effects: product effects and process effects. The higher severity rating of all the effects is used for risk assessment.
- The PFMEA team use engineering judgement to establish/define potential special product characteristics in the PFMEA from the special product characteristic candidates in the DFMEA.

NOTE: The linkage between DFMEA to PFMEA does not apply to purchased catalog parts; i.e., springs, bolts, capacitors, etc. There is no linkage between the product (application) DFMEA and the catalog part manufacturing PFMEA.



Dashed lines indicate engineering judgement is used to convert information from the DFMEA to the PFMEA.

Figure 38 - DFMEA and PFMEA connection

6.3.3 Determine Potential Effect(s) of Failure

Effects are consequences or results of each potential failure mode and must be listed in the PFMEA. The effects, for each potential failure mode, can be the effect at the operation, subsequent operations, customer operations, as well as the end customer (operator of the vehicle). If known, the effects of a potential failure mode can include what the customer might notice or experience such as the impact safety or non-compliance to regulations (as applicable). The intent is to forecast the potential effect(s) of failure consistent with the team's level of knowledge. Examples for the windshield wiper PFMEA are shown in Figure 39.

Item (Op-Seq)	Process Function	Requirements	Potential Failure Mode	Potential Effects of Failure
30.10	Orient and secure wiper linkage to body structure with battery torque tool	Torque within design specification	Torque too high	* In station repair to replace stripped fasteners (4) * Wiper blade angle changes leading to partial loss of visibility (9)
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Ground wire alignment to body	Ground wire damaged during torque operation	* Major repair out of station station (8) * Intermittent ground leads intermittent loss of visibility (9) * Potential injury to operator fingers (10)
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Torque within design specification	Torque too low	* In station repair to retorque fasteners (4) * Intermitten ground connection leads to intermittent loss of visiblity (9)

PFMEA Columns Truncated

PFMEA Rows Truncated

Figure 39 - Potential effects of failure examples for windshield wiper PFMEA

6.3.4 Determine Potential Cause(s) of Failure

A potential cause of failure is an indication of why the potential failure mode could occur. It is defined in terms of the inability to meet or achieve the process function and requirement; as an indication of a process weakness, the consequence of which is the failure mode. Identify, to the extent possible, every potential cause for each failure mode. Each failure mode may have multiple causes. List each potential cause separately in order to identify specific prevention/detection controls. Causes should be defined in actionable terms (i.e., instead of "operator error," use "operator selects wrong drill or operator release torque tool trigger prior to achieving torque"). It is important that engineers consider "foreseeable user/operator error" as a casual factor, especially when there is a direct interface between the user/operator and the system, sub-system, or component being reviewed. All realistic potential causes should be listed in the PFMEA. Examples for the windshield wiper DFMEA are shown in Figure 40.

Use of the following 6M typical cause categories may help with discussion leading to specific causes for a given potential failure mode.

- Machine/equipment (machine capability, initial setup adjustment, machine wear over time, inadequate gating/venting, inadequate or no lubrication, tool wear over time, tool breakage, tool-to-tool differences, fixture tolerance, fixture adjustment, fixture wear over time, chip on locator, worn locator, weld current too high or low, weld pressure, heat treat temperature too high or low, conveyor speed too fast or too slow, equipment maintenance including repair, replacement, reassembly, and adjustment, inspection gauging failures including inaccuracies, and ineffectiveness, etc.)
- Methods/systems (sequence, procedures, layout, off-line rework/repair, off-line inspection, material flow, process control programming, scrap containment, etc.)
- Material/components (part missing, part mislocated, incoming raw material, purchased parts, previous operations)
- Manpower/operator (manual over torque, manual under torque, operator skill, ergonomic factors, time, missing or inadequate visual aids, lack of concentration, etc.)
- Measurements (gauge wear out, gauge out of calibration, etc.)
- Mother nature (environment) (e.g., plant temperature, lighting, humidity, dust, noise, etc.)

NOTE: The above examples represent categories. Specific details need to be added to complete the cause description. Only specific errors or malfunctions (e.g., part installed upside down) should be listed; ambiguous phrases (e.g., operator error, machine malfunction) should not be used. The PFMEA team has direct or indirect responsibility towards mitigating the causal risk. Three core risk management tools may be applied to reduce risk. These are: (1) error proof the process or change the design, (2) add a preventative control, (3) add a detective control. Documenting very specific causes makes the analysis more concise and useful.

Two assumptions for causes:

- The incoming item is manufactured and assembled within engineering specifications.
- The design may include a deficiency that may cause unacceptable variation (mis-builds, errors, etc.); in these cases, adequate warning(s) should be considered to mitigate the risk.

Item (Op-Seq)	Process Function	Requirements	Potential Failure Mode	Potential Effects of Failure	Potential Cause(s) of Failure
30.10	Orient and secure wiper linkage to body structure with battery torque tool	Torque within design specification	Torque too high	* In station repair to replace stripped fasteners (4) * Wiper blade angle changes leading to partial loss of visibility (9)	Fastener joint degradation due to torque tool out of calibration
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Ground wire alignment to body	Ground wire damaged during torque operation	* Major repair out of station station (8) * Intermittent ground leads intermittent loss of visibility (9) * Potential injury to operator fingers (10)	Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisting during torque operation
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	Torque within design specification	Torque too low	In station repair to retorque fasteners (4) Intermitten ground connection leads to intermittent loss of visiblity (9)	Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)

PFMEA Columns Truncated

PFMEA Rows Truncated

Figure 40 - Potential causes of failure examples for windshield wiper PFMEA

6.3.5 Identify Current Prevention and Detection Controls

In PFMEAs, process controls are actions or methods that are currently planned or in place to reduce or eliminate the risk associated with each potential failure mode and associated cause.

6.3.5.1 Prevention Controls

Prevention controls should be considered when developing the PFMEA, as applicable. A prevention control describes how a cause, failure mode or effect is prevented based on the current or planned actions, but may not be applicable for every cause and/or failure mode. Prevention process controls are based on the application of standards, specifications, process rules, process guides, lessons learned, process norms or best practices, etc., as a means to prevent the occurrence of the cause. Product and process error proofing features and devices and automated process controls are examples of prevention controls. When not applicable, the prevention controls field can be left blank.

Document numbers, when used, are for reference only as pointers to the associated documents at the time the analysis is created. Company policy determines whether these document numbers must be kept up to date as they may change during the life of the program.

6.3.5.2 Detection Controls

Detection controls describe how the operation failure mode and/or cause is detected based on automated or manual methods that are currently planned or in place, before the manufacturing or assembly process is released for production. The detection control assumes a failure has occurred and describes how a cause and/or failure mode is detected during the production process. The process control may occur at the subject operation or at subsequent operations and are used as an input to the detection ranking. When not known or not applicable, the detection controls field can be left blank and should be rated according to the detection rating criteria (i.e., detection 10).

A detection control may not be applicable for every cause and/or failure mode. When listing detection controls, it is important to be detailed enough for subsequent reviewer to confirm how well that the process control will, in fact, detect the failure mode and/or cause should it occur. Details should include the type of automated or mechanical equipment/tooling, operator inspection, and when the detection will occur (in-station or subsequent operation).

The PFMEA form shown in Appendix N has two columns for the process controls (i.e., separate columns for prevention controls and detection controls) to assist the team in clearly distinguishing between these two types of process controls. This allows for a quick visual determination that both types of process controls have been considered. Examples for the windshield wiper PFMEA are shown in Figure 41.

Item (Op-Seq)	PFMEA Columns Truncated	Potential Failure Mode	Potential Effects of Failure	Potential Cause(s) of Failure	Current Process Controls - Prevention (P)	Current Process Controls - Detection (D)	PFMEA Columns Truncated
30.10		Torque too high	* In station repair to replace stripped fasteners (4) * Wiper blade angle changes leading to partial loss of visibility (9)	Fastener joint degradation due to torque tool out of calibration	Preventive Maintenance Schedule (PM-2020-R1)	* Visual inspection of calibration Sticker on Torque Tool * First piece verification during torque calibration	
30.30		Ground wire damaged during torque operation	* Major repair out of station station (8) * Intermittent ground leads intermittent loss of visibility (9) * Potential injury to operator fingers (10)	Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisiting during torque operation	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel of ground wire twisting during toque operations	
30.30		Torque too low	* In station repair to retorque fasteners (4) * Intermitten ground connection leads to intermittent loss of visiblity (9)	Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel torque tool stopped	
PFMEA Rows Truncated							

Figure 41 - Current prevention and detection control examples for windshield wiper PFMEA

6.4 Risk Assessment and Prioritization (Step 4)

Figure 1D - Step 4 of the FMEA six-step process map

Deliverables: The risks for the selected PFMEA have been assessed and prioritized.

The purpose of risk assessment and prioritization is to identify and prioritize risk areas that require special attention through process reviews, process changes, process control planning, and other recommended actions. There are three types of criteria used in PFMEA to assess risks of failure. They are: severity, occurrence, and detection. Examples for the windshield wiper PFMEA are shown in Figure 42.

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

6.4.1 Assess Severity of Effects

Severity of effects is a rating number associated with the most serious effect for a given failure mode for the operation being evaluated. It is a relative rating within the scope of the individual PFMEA and is determined without regard for occurrence or detection.

Severity should be estimated using the criteria in Appendix A. The table may be augmented to include product/process specific examples. The team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual process analysis.

Assessment of severity depends on the team's understanding of the consequences of failure for each operation and the intended output (requirements). If the customer affected by a failure mode is the next manufacturing or assembly plant or the product user, assessing the severity may lie outside the PFMEA team's field of experience or knowledge. In these cases, the design engineer, and/or subsequent manufacturing or assembly plant process engineer, should be consulted in order to comprehend the propagation of effects.

One of the goals of the PFMEA process is to mitigate risk or lessen the impact of a potential failure mode. The PFMEA can have both process related effects and product related effects. For the process related effects, the severity rating can be reduced by changing the manufacturing or assembly process. Writing the individual severity number within the description of each effect is recommended if multiple effects are identified for a given potential failure.

6.4.2 Assess Likelihood of Occurrence

Likelihood of occurrence is a rating number associated with each cause for a given failure mode being evaluated. The occurrence rating considers the likelihood of occurrence during production. The occurrence rating number has a relative meaning rather than an absolute value and is determined without regard for severity or detection. The occurrence rating takes into account the prevention-type process controls. The PFMEA team considers prevention controls, plant history for similar items, and degree of change as input to the occurrence rating.

The occurrence rating itself may not be changed without changing the process (or influencing change to the design; e.g., error proofing or DFM/DFA) to decrease the chance of the failure cause and subsequent failure mode from happening.

NOTE: The team should agree on an evaluation criteria and rating system that is consistent, even if modified for individual process analysis. Any modifications to the table should add value to the risk reduction process, and be documented in the report of PFMEA results (step 6).

6.4.2.1 Application of DFMEA Likelihood Evaluation Criteria

Occurrence should be estimated using the criteria in Appendix G. The occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The assessment of likelihood of occurrence for a specific cause, can be identified using either a qualitative (subjective) method (Method One), or a quantitative (objective) method (Method Two).

In Method One, the PFMEA team considers prevention controls, plant history for similar items, and degree of change as input to the occurrence rating. This method is used when there are sufficient changes to the manufacturing or assembly processes that the occurrence assessment cannot be made from the new processes directly and quantitatively. When using Method One, a subjective assessment can be made by using the word descriptions from the first three columns of the table in Appendix G.

In Method Two, the PFMEA team considers the statistical performance of the process being evaluated, using objective, measurable data relating to the process causes. This method is used when the process has not changed significantly and quantitative data for the current process is available. When using Method Two, an objective assessment can be made by using the fourth column in Appendix G.

The best practice for the selection of the likelihood of occurrence rating should be applied at the most objective data driven level possible, given the degree of change or the processes that are being analyzed. It should be an organization's goal to capture knowledge of process performance and reuse the data to improve predictive capability relentlessly and continuously.

The statistical performance and behavior of the process parameters can be used instead of a product conformance approach. Monitoring the process parameters correlated to product characteristics permits a faster response to an event that could result in a defective product. Reacting to parameter instability is more effective for the prevention of product failure than identifying defective products “after the fact” through traditional quality control.

6.4.3 Assess Ability to Detect

Detection is the rating associated with the likelihood of detecting the failure mode and/or associated cause, according to defined criteria.

Ability to detect is the rating number associated with the combined capabilities of all the current process controls for a given cause and/or failure mode. Do not automatically presume the detection rating is low because the occurrence rating is low, instead assume the failure has occurred, then assess the capabilities of all the detection-type design controls to detect low-frequency failure modes and/or causes. The detection rating is identified without regard for severity or occurrence.

Detection is a relative rating, within the scope of the individual FMEA. Detection should be estimated using the criteria in Appendix H. This table may be augmented with examples of common detection methods used by the company. The team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual process analysis.

One of the goals of the PFMEA process is to increase the ability to validate a manufacturing or assembly process prior to start of regular production. The detection rating itself cannot be improved without changing the sensitivity to detect failure modes during process validation activities, as well as the timing of such activities. The PFMEA team has a responsibility to determine how well a specific process control check can detect the failure mode, or the cause which results in the failure mode. The detection rating scale combines considerations for both the robustness of the detection method in revealing process weaknesses within specifications, and the timing of the findings.

6.4.3.1 Application of PFMEA Detection Evaluation Criteria

PFMEA detection should be estimated using the criteria in Appendix H. This table may be augmented with examples of common detection methods used by the company.

Assessment of “ability to detect” is accomplished by assessing the likelihood that the current detection-type process controls will be able to detect the failure mode or associated cause. This can be done by one of two methods:

In Method One, the PFMEA team considers the capabilities of all the current detection-type process controls (together) for a given cause and/or failure mode and enters the resultant “ability to detect” rating in the detection column of the PFMEA. In other words, if all of the current detection controls are implemented, what is the likelihood that the failure mode or cause will be detected? The “detection method maturity” and “opportunity for detection” columns in Appendix N provide guidance in making this assessment. However, the key is for the PFMEA team to arrive at the “ability to detect” rating using the best thinking of the team. Figure 42 represents Method One.

In Method Two, the PFMEA team assesses the “ability to detect” for each of the current detection-type process controls. If this method is used, the team considers the likelihood that the failure mode or cause will be detected by each of the detection controls separately. Similar to the first method, the “detection method maturity” and “opportunity for detection” columns in Appendix N provide guidance in making this assessment; but the PFMEA team arrives at the “ability to detect” rating using the best estimate of the team. When using this method, it is a good practice to include the detection rating in parenthesis next to each of the detection methods in the “current process controls - detection” column, and the lowest value is used.

Item (Op-Seq)	PFMEA Columns Truncated	Potential Cause(s) of Failure	Current Process Controls - Prevention (P)	Current Process Controls - Detection (D)	Sev	Occ	Det	PFMEA Columns Truncated
30.10		Fastener joint degradation due to torque tool out of calibration	Preventive Maintenance Schedule (PM-2020-R1)	* Visual inspection of calibration Sticker on Torque Tool * First piece verification during torque calibration	9	4	6	
30.30		Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisiting during torque operation	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel of ground wire twisting during toque operations	10	7	7	
30.30		Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel torque tool stopped	9	4	7	
PFMEA Rows Truncated								

Figure 42 - Assignment of severity, occurrence, detection examples for windshield wiper PFMEA

6.4.4 Assess Risks and Prioritize Actions

The purpose of assessing risks and prioritization of actions is to help the team understand relative risk within an analysis. There are many methods that have been used to assess combinations of S, O, and D ratings to prioritize risk and determine action priority. Organizations should select a prioritization method such as: risk priority number (RPN), SO, criticality analysis (CA), action priority (AP), or develop an internal process that better fits company and industry requirements. An organization may find value in performing more than one prioritization method.

In addition to risk assessment methods being used to prioritize PFMEA recommended actions, they can also be used to identify issues for review by management.

6.4.4.1 RPN

The risk priority number (RPN) is the product of the severity (S), occurrence (O), and detection (D) rating. Within the scope of the individual FMEA, this value is between “1” and “1000”. The use of RPN is optional.

$$RPN = (S) \times (O) \times (D)$$

Example: (S) 7, (O) 3, (D) 5 = RPN 105

A benefit of RPN is that it provides an indicator of improvement (before and after actions taken) that reduces any one factor of severity, occurrence or detection. It shows the distribution of RPN values for a project (pareto) giving a high-level overview of the risk assessment.

A disadvantage of using RPN is that the final RPN ratings are relative to a particular analysis and are subjective; therefore, selecting an RPN threshold is not an acceptable practice. Thresholds give the impression that values below the threshold do not need improvement action. In other words, there is no value above which it is mandatory to take a recommended action or below which the team is automatically excused from an action.

Establishing such thresholds may promote the wrong behavior causing team members to spend time trying to justify a lower occurrence or detection rating value to reduce the RPN. This type of behavior avoids addressing the real problem that underlies the cause of the failure mode and merely keeps the RPN below the threshold. It is important to recognize that determining reasonable risk is desirable, it should be based on an analysis of severity, occurrence, and detection, and not through the application of RPN thresholds.

Another concern with RPN is that equal RPN values may not have equal risk levels due to the fact that S, O, and D are not of equal importance. Severity should be assessed first then occurrence for prevention and then detection to stop the failure mode from getting to the customer. High severity, low RPN can be high risk. The focus of the PFMEA should be to identify opportunities to continually improve the manufacturing and assembly processes. Care should be taken to understand the limitations of RPN.

6.4.4.2 SO

The “SO” number is the product of the severity (S) and occurrence (O) ratings. Within the scope of the individual FMEA, this value (between “1” and “100”). The use of the SO number as a supplement to RPN is optional.

$$SO = (S) \times (O)$$

Example: (S) 7, (O) 3, (D) 5 = SO 21

A benefit of SO is that it gives additional information about equal RPN values. The organization may focus on how to reduce SO by reducing the value of “O” through preventive actions. Furthermore, this may lead to subsequent detection improvements for those with the highest SO value.

The disadvantage of using SO is similar to that of RPN, i.e., thresholds. Table 4 illustrates how the SO can provide useful information about RPN. While it helps prioritize equal RPN results for action, it does not consider the detection rating.

Table 4 - Contrast between RPN and SO

S, O, D Rating	RPN	SO
8, 10, 2	160	80
8, 2, 10	160	16
10, 8, 2	160	80
10, 2, 8	160	20
2, 10, 8	160	20
2, 8, 10	160	16

6.4.4.3 Criticality Analysis (CA)

Criticality analysis (CA) is terminology used in aerospace and military handbooks and guidelines (i.e., MIL-STD-1629a, ARP5580, AS9145). CA is a procedure by which each potential failure mode is ranked according to the combined influence of severity and likelihood of occurrence. CA is performed concurrently as part of the product development process and is updated as the design, manufacturing, and assembly processes evolve to production release. Criticality analysis risk assessment supports identification of those items that could be defined as special characteristics.

Criticality analysis may be visually shown as a “S&O risk graph.” This allows for a non-linear approach to characterize levels of risk such as high (red), medium (yellow), and low (green). Figure 43 shows an example of a S&O risk graph. A S&D and/or O&D risk graph may also be used. The use of risk graphs is optional.

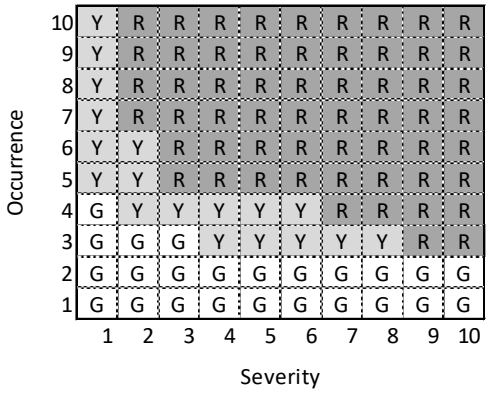


Figure 43 - Sample S&O risk graph

When using a risk graph, it is up to the company or customer to assign R, Y, and G and make the resulting table available to the PFMEA team.

6.4.4.4 Action Priority

Action priority (AP) table combines severity (S), occurrence (O), and detection (D) ratings with suggested priority levels for identification of potential actions to reduce risk based on high (H), medium (M), and low (L) assessments. Individual companies may develop their own criteria for H, M, and L and make the company-specific action priority table available to the DFMEA team and customer or supplier. The use of action priority is optional.

A complete AP table example is shown in Appendix I and is not meant to be automatically used by companies without review and agreement. The table used to support the action priority method should reflect a company's needs for action prioritization. The S, O, D rating charts provide the structure for the groupings as shown in Appendix J. If the organization chooses to modify the S, O, D, rating criteria for specific products, processes, or projects, the AP table should also be carefully reviewed for alignment. An example of an AP table used by the windshield wiper system project team is shown as Figure 44. The AP assessment is shown in the risk prioritization section of the DFMEA. Figure 45 provides an example based on using a final "risk prioritization" rating of high (H), medium (M), and low (L).

The benefit of action priority is that it does not treat severity, occurrence, and detection as equal values (as RPN, SO does). The principle of risk reduction through efforts to reduce severity, then occurrence, then detection drives the action priority levels of high (H), medium (M), and low (L). The AP table provides an action prioritization system to focus the team's time and resources.

The disadvantage of using action priority is that action taken to reduce risk may or may not change the action priority level. In other words, it is difficult to see incremental improvements.

Care should be taken to avoid automatic action based on a combination of S, O, D that would require or eliminate the need for action. For example, an AP assessment of low does not mean action should not be considered. The high, medium, or low assessment should be used to prioritize action, not presume action is not necessary.

No.	Effect	SEV	Likelihood of Failure Cause Occurring	OCC	Ability to Detect	DET	ACTION PRIORITY (AP)
9	Product or plant effect very high	9-10	Moderate	4-5	Low - Very low	7-10	H
10					Moderate	5-6	H
11					High	2-4	H
12					Very high	1	M
13			Low	2-3	Low - Very low	7-10	H
14					Moderate	5-6	~~M~~ H*
15					High	2-4	~~L~~ M*
16					Very high	1	L
17			Very low	1	Very low - Very high	1-10	L

* The windshield washer project team reviewed the action priority table in Appendix R and agreed to make two changes raising the AP level from medium to high and low to medium in two instances for their application. This is an example of how a company or project team can use the AP method.

Figure 44 - Example of Appendix I - action priority table modified for windshield wiper system

Item (Op-Seq)	PFMEA Columns Truncated	Potential Cause(s) of Failure	Current Process Controls - Prevention (P)	Current Process Controls - Detection (D)	Sev	Occ	Det	Risk Prioriti-zation	PFMEA Columns Truncated
30.10		Fastener joint degradation due to torque tool out of calibration	Preventive Maintenance Schedule (PM-2020-R1)	* Visual inspection of calibration Sticker on Torque Tool * First piece verification during torque calibration	9	4	6	H	
30.30		Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisiting during torque operation	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel of ground wire twisting during toque operations	10	7	7	H	
30.30		Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel torque tool stopped	9	4	7	H	
PFMEA Rows Truncated									

Figure 45 - Assignment of risk prioritization for the windshield wiper system

For the purpose of assessing risks and prioritizing actions individual companies should determine the method that suits their goals for technical risk analysis and internal management or customer requirements.

The PFMEA team may choose to generate action plans at any time during the PFMEA development even prior to having RPN, SO, criticality analysis, or AP assessment.

Note: It is recommended that potential Severity 9-10 and potential effect(s) regardless of action priority assessment be reviewed by management including any recommended actions that were identified.

6.4.5 Confirm Special Characteristics

The PFMEA must include agreed upon special product characteristic(s) to determine process causes/mechanisms which can result in the production of nonconforming products. The PFMEA process controls strategy is to:

- Prevent failure through error proofing (product and process design).
- Reduce variation through process selection, variation reduction and product tolerance design.
- Develop Detection Controls to ensure nonconformances are identified and removed.

The PFMEA identifies the special process characteristic, when applicable, that contribute to the process controls strategy. special process characteristics influence the conformance of a special product characteristic.

A special process characteristic is a parameter that requires special care which identifies where variation must be controlled to ensure process performance remains stable. The purpose of the special process characteristic is to ensure the process is monitored to maintain validated settings and identify variation anomalies requiring attention. These characteristics are measured while the process is running; e.g., machine settings, temperature, pressure, current, fluid level, speed, etc. Process characteristics may be standard or special as shown on a control plan.

Product and process special characteristics must be shown in their respective sections of the PFMEA (see Figure 46). If special product or process characteristics have not been defined, the PFMEA entry for product or process special characteristic may be left blank. Company policy may direct the PFMEA team to enter “none” or “standard” in the PFMEA.

All special product characteristics and special process characteristics must be shown on the process control plan.

Item (Op-Seq)	PFMEA Columns Truncated	Potential Cause(s) of Failure	Current Process Controls - Prevention (P)	Current Process Controls - Detection (D)	Sev	Occ	Det	Risk Prioriti-zation	Product Sp Char	Process Sp Char	PFMEA Columns Truncated
30.10		Fastener joint degradation due to torque tool out of calibration	Preventive Maintenance Schedule (PM-2020-R1)	* Visual inspection of calibration Sticker on Torque Tool * First piece verification during torque calibration	9	4	6	H			
30.30		Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisiting during torque operation	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel of ground wire twisting during toque operations	10	7	7	H	CC Connector orientation	KCC Degree of connector rotation	
30.30		Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)	1) Work Instructions (SAE-2019-TorqueXYZ) 2) Operator training (Form-2019-123xy)	Tactile feel torque tool stopped	9	4	7	H	CC Ground wire fastener torque spec	KCC Tool RPM	
PFMEA Rows Truncated											

CC - Critical Characteristic, KCC - Key Control Characteristic

Figure 46 - Special characteristics examples for windshield wiper PFMEA

6.5 Reduce and Communicate Risks (Step 5)

Figure 1F - Step 5 of the FMEA six-step process map

Deliverables: Risks for the selected PFMEA are reduced and communicated.

6.5.1 Develop Recommended Actions

Development of recommended actions represent a commitment to take a specific, measurable, and achievable action, not potential actions that could be taken. The primary objectives of the recommended actions of the PFMEA are to reduce risks and increase customer satisfaction by improving the manufacturing or assembly process and/or improving the process controls. It is not recommended to include actions that are already documented in the prevention or detection controls and are already considered in risk prioritization. Single-line excerpts of recommended actions for the wiper system PFMEA example are shown in Figure 47.

For each line of analysis, the recommended actions field must include verbiage to reflect the fact that each risk was critically evaluated. If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering “none” in the recommended actions field. Without a written comment, it may be construed that the risk associated with the line item was overlooked. An entry of “none” indicates that the assessed risk is acceptable.

Recommended actions may either be preventative or detective. Prevention-type recommended actions reduce the likelihood of occurrence of a cause and its resulting failure mode and/or effect by removing or controlling one or more causes of failure through revision of process (e.g., addition of a fail-safe mechanism to protect an operator) or error proofing. Detection-type recommended actions increase the ability to detect the cause and/or failure mode at the subject operation or at a subsequent verification operation prior to shipping the product during production.

The order of precedence for recommended actions:

Actions for prevention:

- Prevent the characteristic from being incorrect (cannot make bad part—error proofing)
- Reduce variation (increase process capability)
- Review product design for process optimization

Actions for detection (when prevention actions are not effective or feasible):

- Communicate the need for developing detection methods to expose nonconforming parts.
- Mistake proof (cannot pass a bad part) (e.g., ability to detect the failure mode and not allow product acceptance)
- Increase the sensitivity of simulation/testing to exhibit the failure mode
- Emphasis should be placed on preventing causes of failures (i.e., reducing the occurrence) rather than detecting them
- Responsibility and target completion date

It is acceptable to include the name of an organization or department with a recommended action. However, since recommended actions represent a commitment by an individual to do something, recommended actions should be assigned to one person who is present for the discussion; or subsequently agreed-to by someone who was not present for the discussion. A due date is also required. The due date represents acceptance of a commitment to take action by a certain date. If the recommended action is not completed by the due date, then a new due date may be assigned. A history of due date extensions may be preserved by striking through the original date and entering the new date below (in the same cell).

Item (Op-Seq)	PFMEA Columns Truncated	Potential Cause(s) of Failure	PFMEA Columns Truncated	Sev	Occ	Det	Risk Prioritization	Product Sp Char	Process Sp Char	Recommended Action (P or D)	Responsibility	Target Date	PFMEA Columns Truncated
30.10		Fastener joint degradation due to torque tool out of calibration		9	4	6	H			Change from battery torque tool to Digital Controlled (DC) torque tool	Carl Carlson	01/05/20	
30.30		Wire damaged during torque operation due to inadequate design to prevent the ground wire connector from twisiting during torque operation		10	7	7	H	CC Connector orientation	KCC Degree of connector rotation	Add an anti-rotation feature on the ground wire connector and body to prevent ground wire damage during torque operation	Ed Myzienski	10/06/19	
30.30		Wiper ground wire not torqued to specification due to torque tool trigger released too soon to protect against connector twisting in operator hand (human factors)		9	4	7	H	CC Ground wire fastener torque spec	KCC Tool RPM	Change the torque to a 2 speed torque tool to prevent twisting the connector during torque operation	Bill Haughey	10/15/19	
PFMEA Rows Truncated													

Figure 47 - Recommended actions example for windshield wiper PFMEA

6.5.2 Acceptance/Disposition of Risks by Management

The company's FMEA procedure should describe how PFMEA is reviewed and/or approved by management. Risk prioritization methods allow review with others outside the team who share ownership/responsibility for the risk mitigation.

Management acceptance/disposition of risks methods for the manufacturing and assembly processes should describe how the PFD, PFMEA, and process control plan (PCP) are reviewed and/or approved by management within the company's FMEA procedure.

6.5.3 Implement Recommended Actions

Implementation of recommended actions is completed by entering a brief description of the action taken and effective date. Documenting the closure of a recommended action is as important as writing the recommended action. If an action is not implemented, note that is was rejected/discarded with reason given.

Closure of recommended actions should be documented before start of regular production (SORP). Missing closure information may be challenged if the PFMEA is subjected to legal discovery. After SORP, new recommended actions to implement product design changes that impact the process should be validated with the same degree of robustness as the original process; e.g., production trial run.

6.5.4 Reassess Risks

Reassessment of risks is when severity, occurrence, and detection values are re-scored when the action has been completed. If no actions were taken, leave the related rating columns blank. Examples for the windshield wiper PFMEA are shown in Figure 48.

In order to reassess the risks, the following can to be considered:

a. Severity may be reduced as the result of a design change impacting the end user.

b. Severity may be reduced as a result of a process change impacting the plant operator.

c. Occurrence may be reduced by removing or controlling one or more of the causes of the failure mode through a process revision.

d. Detection may be reduced by changing detection methods or increasing the process capability to detect the failure mode or cause.

Item (Op-Seq)	PFMEA Columns Truncated	Recommended Action (P or D)	PFMEA Columns Truncated	Actions Taken	Effective Date	New (S)	New (O)	New (D)	New Risk Prioriti-zation
30.10		Change from battery torque tool to Digital Controlled (DC) torque tool		Replaced all battery torque tools for severity 9 or 10 with digital controlled torque tools.	02/04/20	9	2	2	L
30.30		Add an anti-rotation feature on the ground wire connector and body to prevent ground wire damage during torque operation		Changed wire connector to include anti-rotation tab and added anti-rotation tab location hole to position the connector.	10/06/19	8	2	2	L
30.30		Change the torque to a 2 speed torque tool to prevent twisting the connector during torque operation		Added 2 speed DC torque tool to ensure ground wire is torqued to specification and avoid wire damage during torque operation	10/15/19	9	2	2	L
PFMEA Rows Truncated									

Figure 48 - Action results example for windshield wiper PFMEA

6.5.5 Continue FMEA Until Risks Have Been Reduced to an Acceptable Level

It is worthwhile to ask, “When is a PFMEA completed?” Is the PFMEA completed when each of the columns or sections have been filled out? The answer is no. PFMEA is not completed merely by filling out the various columns or sections of the FMEA spreadsheet or software.

Is a PFMEA completed when the PFMEA team has recommended and executed specific actions, based on risk prioritization? The answer is no, not necessarily. PFMEA is not necessarily completed when all the actions have been executed.

The correct answer is a PFMEA is completed when an acceptable level of risk has been achieved and agreed upon by the PFMEA team and management. Until this point, the PFMEA 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 company, considering input or requirements from the customer.

As each of the PFMEA recommended actions are executed, the PFMEA team enters what was done in the actions taken column or section, and rescores the S, O, and D. If the combination of rescored S, O, and Ds are deemed acceptable by the PFMEA team, based on company policy and considering input or requirements from the customer, the risk related to that specific issue is addressed for the purposes of the PFMEA. If the risk represented by the rescored S, O, and Ds are not deemed acceptable, the PFMEA team continues to recommend and execute actions to reduce risk, until an acceptable level of risk is achieved.

When all the PFMEA recommended actions have been executed, and the rescored S, O, and Ds are acceptable, the PFMEA is considered complete for the purpose of the PFMEA project. In the future, the PFMEA may be updated, as appropriate, based on guidance or policy covered in 6.6.5.

6.6 Document Results (Step 6)

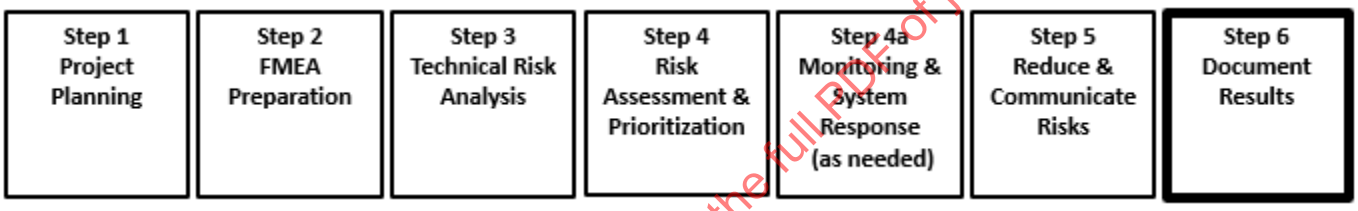


Figure 1G - Step 6 of the FMEA six-step process map

Deliverables: The results of the selected PFMEA are linked and documented.

6.6.1 Prepare Summary of Key Findings

A summary of the PFMEA results can be created and archived with the PFMEA. It highlights the high risk potential failures and associated process actions. The content of the summary is company-specific and represents the PFMEA at a certain time interval (e.g., end of PFMEA project). It may include key findings determined by the team and management, such as the definition of new manufacturing and assembly operations, new outputs of operations (requirements), new process controls (technology, equipment, detection methods, etc.), rating criteria (severity, occurrence, detection), risk prioritization method, risk analysis summary, actions to reduce risk, special product and process characteristics, and conclusions; e.g., potential risks are reduced to an acceptable level as determined by management.

6.6.2 Provide PFMEA Effectiveness Feedback

An evaluation form or audit checklist may be used during the development of a PFMEA to ensure the quality of the analysis. This evaluation or self-assessment may be company specific or customer specified.

PFMEA quality objectives can be used as follows:

1. Become part of PFMEA training
2. Reviewed at each PFMEA meeting
3. Incorporated as an essential part of PFMEA quality audits
4. Consider leaving the PFMEA open until quality objectives are met

A recommended approach is to consider effectiveness criteria that is aligned with the six-step process, such as:

Step 1: Project Planning

Deliverable: Set of PFMEAs are identified, prioritized, and scheduled.

PFMEA plan: The right set of PFMEAs have been identified and prioritized, based on company policy, and organized into an executable PFMEA plan.

Step 2: FMEA Preparation

Deliverable: All preparation steps for selected PFMEA have been completed and first meeting scheduled.

Scope: The scope for the selected PFMEA is correctly defined, focused on areas of highest concern/value, and properly reflected in the PFMEA process flow diagram.

Interfaces: The PFMEA scope includes integration and interface between the PFD, PFMEA, and PCP.

Lessons learned: The PFMEA considers all major “lessons learned” (such as high warranty, campaigns, plant issues, manufacturing guidelines, etc.) as input to failure mode identification.

Team: The right people are identified and participate as part of the cross functional PFMEA team throughout the analysis and are adequately trained in PFD, PFMEA, and PCP methods.

Step 3: Technical Risk Analysis

Deliverable: The PFMEA procedure has identified the technical risks for the selected PFMEA.

Technical risk analysis: Each portion of the technical risk assessment has been properly performed, based on correct PFMEA fundamentals and procedure.

Interfaces: The PFMEA includes integration of information from the PFD and the DFMEA and/or product design.

Step 4: Risk Assessment and Prioritization

Deliverable: The risks for the selected PFMEA have been assessed and prioritized.

High-risk failures identified: All potential high-risk failure modes and associated causes are properly identified and prioritized, including past field issues (for similar items) and potential new issues.

Special characteristics: The PFMEA identifies appropriate special product characteristics and special process characteristics, based on company policy.

Interfaces: The PFMEA team and management also use information from the control plan (PCP) to assess and prioritize risk.

Step 5: Reduce and Communicate Risks

Deliverable: Risks for selected PFMEA have been reduced and communicated.

Process improvements: The PFMEA drives actions to improve process designs as the primary objective.

High-risk failures addressed: The PFMEA addresses all high-risk failure modes, as identified by the PFMEA team, with executable action plans. The result is risk reduced to an acceptable level.

Timing: The PFMEA is completed during the “window of opportunity” where it could most efficiently impact the manufacturing and/or assembly processes.

Step 6: Document Results

Deliverable: Results of selected FMEA have been linked and documented.

Documentation: Each portion of the PFMEA document is properly and completely filled out “by the book,” including “action taken” and new risk prioritization values. The document is archived for future reference.

Time usage: Time spent by the PFMEA team, as early as possible and focused on areas of concern, is an effective and efficient use of time, with a value-added result.

This evaluation or self-assessment may be company specific or customer specified.

6.6.3 Implement PFMEA Version Control

The PFMEA must be retained by the organization according to the organization’s record retention policy and customer requirements. It is up to the company to determine what version(s) of the PFMEA must be retained (e.g., based on status level, program timing, management review, customer review, PPAP, etc.). In any case, a good document management system will show only the most recent version with history available.

6.6.4 Identify PFMEA Linkages

The PFMEA is related to other documents such as the product design documents, DFMEA, process flow diagram, process control plans, inspection records, and operator work instructions. The PFD, PFMEA, and PCP work together to identify, assess, mitigate, and prevent technical risks of failure in the manufacturing and assembly processes.

A process control plan (PCP) provides written descriptions of the systems used for controlling parts and processes. It can be component or process specific, or family where multiple parts are produced using the same processing line. The control plan describes the actions that are required at each phase and detailed operation of the process including receiving, processing, material handling, and periodic requirements to assure that all process outputs will be in control. The control plan provides the process monitoring and control methods that will be used to control product or process characteristics. Typical PCP types include prototype, pre-launch and production. An example of a process control plan for the windshield wiper installation is shown in Figure 49.

The process control plan should place emphasis on pro-active controls at the point of manufacture. Good manufacturing practice should consider: the control of the process inputs to obtain the desired product outputs; employ prevention rather than detection (e.g., use of error-proofing instead of operator dependent work or inspection); and verification of output at the earliest possible operation/step within the process.

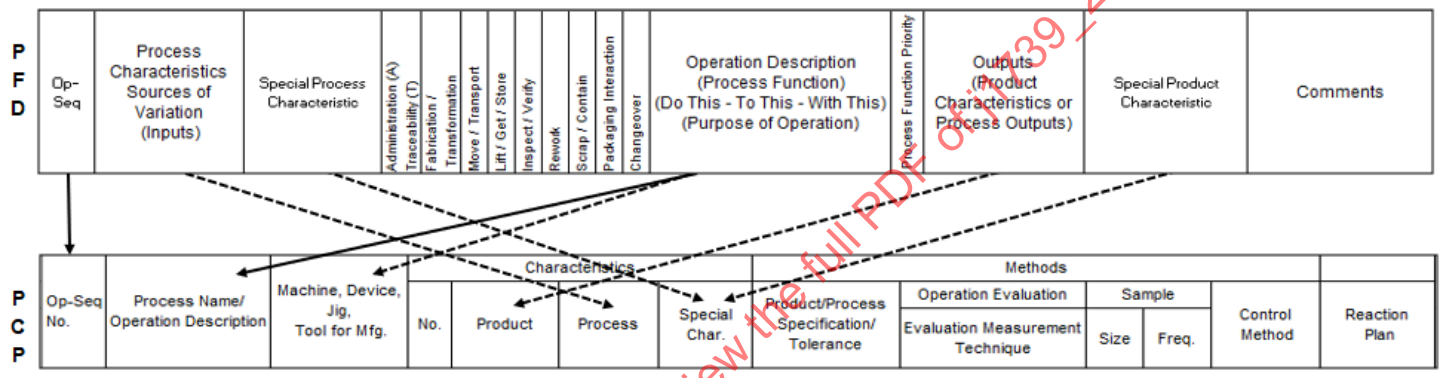
CONTROL PLAN

Part Number/Latest Change Level			Key Contact/Phone							Control Plan No:	WWS-Op-30-rev b		
WS-2021-rev b			Bill Haugher / 810-516-1157							Date (Orig.) 12/3/2019	Date (Rev.) 1/21/2020		
Customer Part Number			Core Team							Customer Engineering Approval/Date (If Req'd.)			
			Mike Bucala; Paul Baird, Ryan Winnicki; Ed Myzienski; Mike Down; Lee Dawson; Mary Rowzee							Rhonda Brender - 1/21/2020			
Part Name/Description			Supplier/Plant Approval/Date							Customer Quality Approval/Date (If Req'd.)			
Wiper System Installation			MaryBeth Soloy - 1/21/2020							Carl Carlson - 1/21/2020			
Supplier/Plant	Supplier Code		Other Approval/Date (If Req'd.)							Other Approval/Date (If Req'd.)			
			N/A							N/A			
Op-Seq No.	Process Name/ Operation Description	Machine, Device, Jig, Tool for Mfg.	Characteristics			Special Char. Class	Methods					Control Method	Reaction Plan
			No.	Product	Process		Product/Process Specification/ Tolerance	Operation Evaluation Evaluation Measurement Technique	Sample Size	Sample Freq.			
30	Wiper System Installation												
31.10	Orient and secure wiper linkage to body structure with battery torque tool	Battery torque tool		Torque specification			Torque spec 10nm to 12nm	Operator torques fastener until the battery torque tool stops and light turns green	100%	N/A		Light on the torque tool QC audit every shift	Quarintine product since last audit and change torque tool
32.10	Orient and secure wiper linkage to body structure with battery torque tool				Battery torque tool calibration		Torque spec 10nm to 12nm	First piece to confirm torque calibration meets specifications	1	Each Shift		Calibrate procedure TT-SAE-2018RA Calibration label Battery charging procedure	Quarintine product since last audit and calibrate torque tool
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	2 speed DC Torque tool	5	Torque specification		CC Ground wire fastener torque spec	Torque spec: 15 +/-2 NM	Tighten until torque tool completes cycle and light turns green	Each part	100%		Tool Calibration Procedure (SAE.PM.2019.567) Nonconforming material Procedure (SAE NCM ABC123)	Inspect all assemblies since last calibration check.
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool	2 speed DC Torque tool	5		Tool RPM	KCC Tool RPM	200 RPM - Two turns 80 RPM - Final Torque	QC completes torque tool calibration	1	Each Shift		Tool calibration procedure SAE.2019.DC123 Form signed off and dated Update calibration sticker on torque tool	Replace torque tool if incapable of achieving torque
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool		5	Connector orientation		CC Connector orientation	Connector oriented per drawing (SAE-1739-2020)	Operator aligns anti-rotation feature into location hole	Each part	100%		Design anti-rotation error proofing feature	Realign per SWI-SAE-2024
30.30	Orient and secure wiper motor ground wire to vehicle with battery torque tool		5		Degree of connector rotation	KCC Degree of connector rotation	Connector oriented per drawing (SAE-1739-2020)	Error Proofed by design	100%	N/A		Design anti-rotation error proofing feature	Realign per SWI-SAE-2025

Figure 49 - Process control plan example for the windshield wiper system

The flow of information is shown in Figure 50 between the PFD and the PCP.

- The operation sequence number in the PFD becomes the operation sequence number in the PCP
- The operation description in the PFD becomes the operation description in the PCP
- The operation description in the PFD identifies the machine, device, jig, tool in the PCP (the “with this”)
- The engineer or PFMEA team uses engineering judgement to convert process characteristics in the PFD to the process characteristics in the PCP
- The engineer or PFMEA team uses engineering judgement to convert product characteristics in the PFD to the product characteristics in the PCP
- The engineer or PFMEA team uses engineering judgement to convert special product characteristics in the PFD to the special characteristics in the PCP

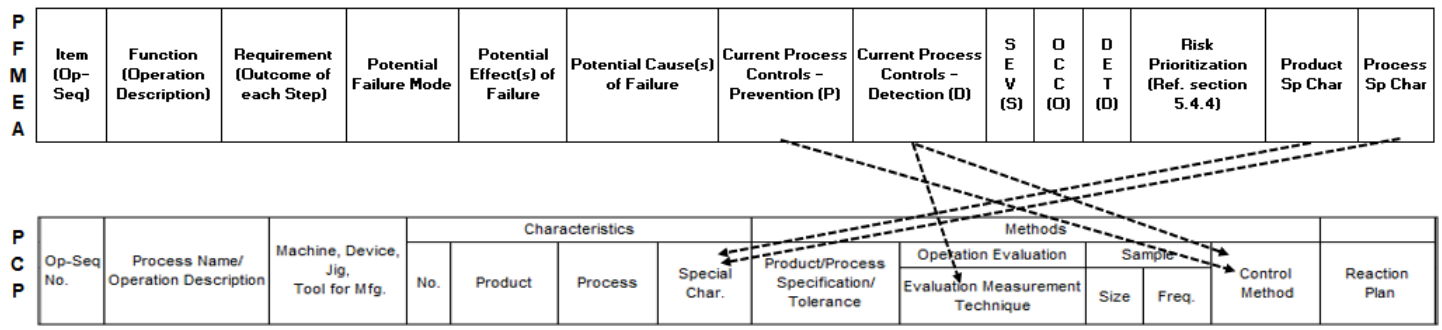


Solid lines indicate exact copy and paste from PFD to PCP and dashed lines indicate engineering judgement is used to convert information.

Figure 50 - PFD and PCP connection

The flow of information is shown in Figure 51 between the PFMEA and the PCP.

- The engineer or PFMEA team uses engineering judgement to convert prevention controls in the PFMEA to the control methods in the PCP
- The engineer or PFMEA team uses engineering judgement to convert detection controls in the PFMEA to the evaluation measurement technique and the control methods in the PCP
- The engineer or PFMEA team uses engineering judgement to convert product and process special characteristics identified in the PFMEA to the special characteristics in the PCP



Dashed lines indicate engineering judgement is used to convert information.

Figure 51 - PFMEA and PCP connection