

SURFACE VEHICLE RECOMMENDED PRACTICE

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**(R) Potential Failure Mode and Effects Analysis in Design (Design FMEA),
Potential Failure Mode and Effects Analysis in Manufacturing and Assembly
Processes (Process FMEA), and Potential Failure Mode and Effects Analysis
for Machinery (Machinery FMEA)**

1. Scope—General Information

- 1.1 Overview**—This SAE Recommended Practice was jointly developed by DaimlerChrysler Corporation, Ford Motor Company, and General Motors Corporation.

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

All FMEA's focus on the design, whether it be of the product, the process or the machinery used to build the product. An Applications Section (see Section 5) has been added to provide information on applying the FMEA technique to plant machinery and equipment using the Machinery FMEA (MFMEA).

- 1.2 Recommended Practice Format**—For ease of use, this reference document presents the two basic types of FMEA (Design FMEA and Process FMEA) in their own separate sections. This document also contains an Applications Section (Section 5) which discusses in some detail how an FMEA is applied to Plant Machinery and Equipment (Machinery FMEA).

The Machinery FMEA (MFMEA) information has been provided due to the importance of Plant Machinery, Tooling, and Equipment functioning as intended in manufacturing and assembly plants. The use of the MFMEA, on Plant Machinery, Tooling, and Equipment, will assist with the identification of potential failure modes, so that design and processing alternatives can be considered, prior to finalizing the Plant Machinery, Tooling, and Equipment Designs.

It should be noted that this document is a recommended practice, and as such, each Team is free to use the guidelines listed herein in the manner which will be most effective for a given situation.

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Figure 1 illustrates an approximate time line where the Design FMEA (DFMEA) for the product is started somewhat before the Process FMEA (PFMEA) for producing the product. Figure 1 shows that the Machinery FMEA (MFMEA) should be started at about the same time as the PFMEA. The "OEM Product Development Time Line" refers to the "Original Equipment Manufacturer's Time Line" which is used for the design, development, and production of the product. In some situations, all three FMEAs (i.e., DFMEA, PFMEA, and MFMEA) might be started at the same time. In general, the earlier that FMEAs are started, the better the chances of optimizing the various activities/designs/processes in a cost and time effective manner.

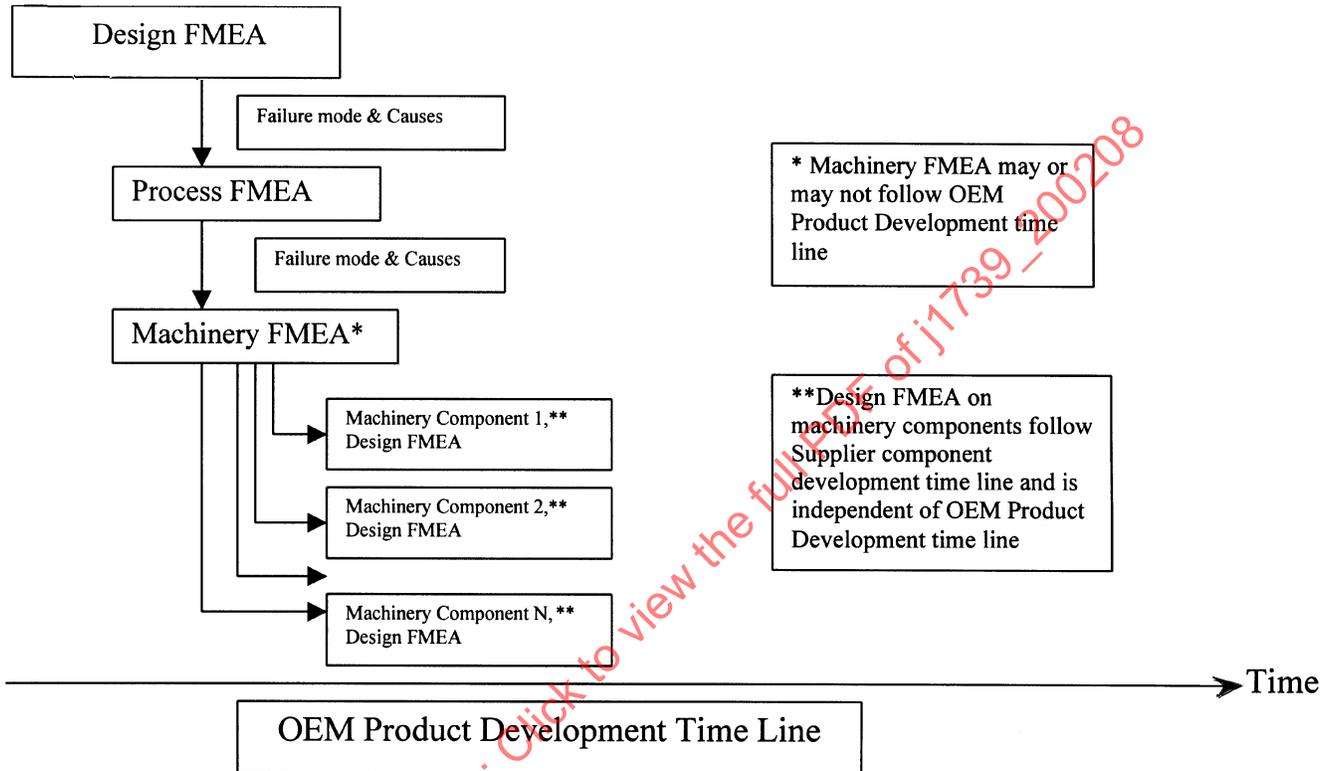


FIGURE 1—OEM PRODUCT DEVELOPMENT TIME LINE

- 1.3 What is an FMEA?**—An FMEA can be described as a systematic group of activities intended to: (a) recognize and evaluate the potential failure of a product/process and the effects of that failure, (b) identify actions that could eliminate or reduce the chance of the potential failure occurring, and (c) document the process. It is complementary to the process of defining what a design or process must do to satisfy the customer.
- 1.4 FMEA Implementation**—Because of the general industry trend to continually improve products and processes whenever possible, using the FMEA as a disciplined technique to identify and help minimize potential concern is as important as ever. Studies of vehicle campaigns have shown that fully implemented FMEA programs could have prevented many of the campaigns.

One of the most important factors for the successful implementation of an FMEA program is timeliness. It is meant to be a "before-the-event" action, not an "after-the-fact" exercise. To achieve the greatest value, the FMEA must be done before a product or process failure mode has been incorporated into a product or process. Up front 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 which would create an even larger concern. Communication and coordination should occur between all types of FMEAs (i.e., Design - DFMEA, Process - PFMEA, and Machinery - MFMEA). (See Figure 1).

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS SEQUENCE

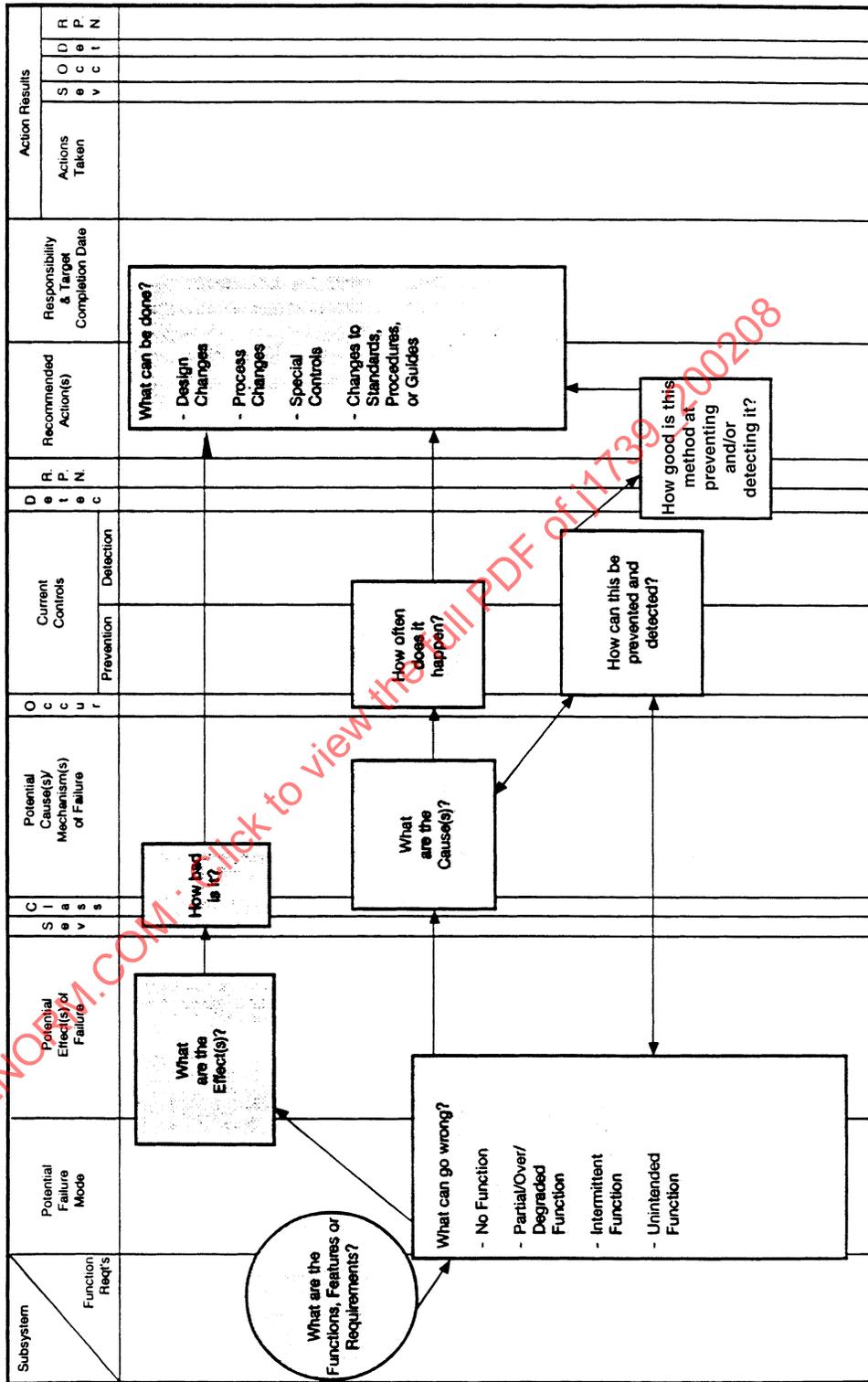


FIGURE 2—FMEA PROCESS SEQUENCE

Figure 2 depicts the sequence in which an FMEA should be performed. It is not simply a case of filling out the column, but rather understanding the process in order to eliminate risk and plan the appropriate controls to ensure customer satisfaction.

There are three basic cases for which FMEA's are generated, each with a different scope or focus:

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

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

Case 2: Modifications to existing design or process (assumes there is a FMEA for the existing design or process).

The scope of the FMEA should focus on the modification to design or process, possible interactions due to the modification, and field history.

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

Although responsibility for the preparation of the FMEA is usually assigned to an individual, FMEA input should be a team effort. A team of knowledgeable individuals should be assembled (e.g., engineers with expertise in Design, Analysis/Testing, Manufacturing, Assembly, Service, Recycling, Quality, and Reliability). The FMEA is initiated by the engineer from the responsible activity, which can be the Original Equipment Manufacturer (i.e., produces the final product), a supplier, or a subcontractor.

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

A review of the FMEA document against FMEA quality objectives (see Appendix A and Appendix B) is recommended including a management review.

1.5 Follow-Up—The need for taking effective, preventive/corrective actions, with appropriate follow-up on those actions cannot be overemphasized. A thoroughly thought out and well developed FMEA will be of limited value without positive and effective preventive/corrective actions.

The responsible engineer is in charge of assuring that all recommended actions have been implemented or adequately addressed. The FMEA is a living document and should always reflect the latest level, as well as the latest relevant actions, including those occurring after the start of production.

The responsible engineer has several means of assuring that recommended actions are implemented. They include, but are not limited to the following:

- a. Reviewing designs, processes, and/or machinery to ensure that recommended actions have been implemented
- b. Review of engineering drawings, product/process specifications, and process flow,
- c. Confirmation of incorporation of changes to design/assembly/manufacturing documentation, and
- d. Review of Design/Process FMEAs, special FMEA applications such as Machinery FMEA and Build and Installation FMEA, Control Plans, and Operation Instructions.

2. References—There are no referenced publications specified herein.

**POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS IN DESIGN
(DESIGN FMEA)**

System _____ FMEA Number _____
 Subsystem _____ Page _____ of _____
 Component _____ Prepared By _____
 Model Year(s)/Program(s) _____ Design Responsibility _____ FMEA Date (Orig.) _____ (Rev.) _____
 Core Team _____ Key Date _____

Item	Function	Potential Failure Mode	Potential Effect(s) of Failure	Classifications	Potential Cause(s)/Mechanism(s) of Failure	Occurrence	Current Design Controls — Prevention — Detection	Detection	Recommended Action(s)	Responsibility & Target Completion Date	Action Results Actions Taken	S O D R.				
												S	O	D	R.	

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FIGURE 3B—POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS IN DESIGN (DESIGN FMEA)
 — ONE COLUMN, CURRENT DESIGN CONTROLS —

3. **Potential Failure Mode and Effects Analysis in Design (Design FMEA)**

3.1 Introduction—A Design potential FMEA is an analytical technique utilized primarily by a Design-Responsible Engineer/Team as a means to ensure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. End items, along with every related system, subassembly, and component, should be evaluated. In its most rigorous form, an FMEA is a summary of the team's thoughts (including an analysis of items that could go wrong based on experience) as a component, subsystem, or system is designed. This systematic approach parallels, formalizes, and documents the mental disciplines that an engineer normally goes through in any design process.

The Design potential FMEA supports the design process in reducing the risk of failures (including unintended outcomes) by:

- a. Aiding in the objective evaluation of the design, including functional requirements and design alternatives.
- b. Evaluating the initial design for manufacturing, assembly, service, and recycling requirements.
- c. Increasing the probability that potential failure modes and their effects on system and vehicle operation have been considered in the design/development process.
- d. Providing additional information to aid in the planning of thorough and efficient design, development, and validation programs.
- e. Developing a ranked list of potential failure modes according to their effect on the "customer," thus establishing a priority system for design improvements, development, and validation testing/analysis.
- f. Providing an open issue format for recommending and tracking risk reducing actions.
- g. Providing future reference (e.g., lessons learned), to aid in analyzing field concerns, evaluating design changes, and developing advanced designs.

3.1.1 CUSTOMER DEFINED—The definition of "CUSTOMER" for a Design potential FMEA is not only the "END USER," but also the design-responsible engineers/teams of the vehicle or higher level assemblies, and/or the manufacturing/process-responsible engineers in activities such as Manufacturing, Assembly, and Service.

3.1.2 TEAM EFFORT—During the initial Design potential FMEA process, the responsible engineer is expected to directly and actively involve representatives from all affected areas. These areas of expertise and responsibility should include, but are not limited to assembly, manufacturing, design, analysis/test, reliability, materials, quality, service, and suppliers, as well as the design area responsible for the next higher or lower assembly or system, sub-assembly or component. The FMEA should be a catalyst to stimulate the interchange of ideas between the functions affected and thus promote a team approach.

Unless the responsible engineer is experienced with FMEA and team facilitation, it is helpful to have an experienced FMEA Facilitator assist the team in its activities.

The Design FMEA is a living document and should:

- a. Be initiated before or at design concept finalization,
- b. Be continually updated as changes occur or additional information is obtained throughout the phases of product development, and
- c. Be fundamentally completed before the production drawings are released for tooling.

Considering that manufacturing/assembly needs have been incorporated, the Design FMEA addresses the design intent and assumes the design will be manufactured/assembled to this intent. Potential failure modes and/or causes/mechanisms that can occur during the manufacturing or assembly process need not, but may, be included in a Design FMEA. When not included, their identification, effect, and control are covered by the Process FMEA.

The Design FMEA does not rely on process controls to overcome potential design weaknesses, but it does take the technical/physical limits of a manufacturing/assembly process into consideration, for example:

- a. Necessary mold drafts
- b. Limited surface finish
- c. Assembling space/access for tooling
- d. Limited hardenability of steels
- e. Tolerances/process capability/performance

The Design FMEA can also take into consideration the technical/physical limits of product maintenance (service) and recycling, for example:

- a. Tool access
- b. Diagnostic capability
- c. Material classification symbols (for recycling)

3.2 Development of a Design FMEA—The design responsible engineer has at his/her disposal a number of documents that will be useful in preparing the Design FMEA. The process begins by developing a listing of what the design is expected to do, and what it is expected not to do, i.e., the design intent. Customer wants and needs — as may be determined from sources such as Quality Function Deployment (QFD), Vehicle Requirements Documents, known product requirements and/or manufacturing/assembly/service/recycling requirements — should be incorporated. The better the definition of the desired characteristics, the easier it is to identify potential failure modes for preventive/corrective action.

A Design FMEA should begin with a block diagram, for the system, subsystem, and/or component being analyzed.

An example block diagram is shown in Appendix C. The block diagram can also indicate the flow of information, energy, force, fluid, etc. The objective is to understand the deliverables (input) to the block, the process (function) performed in the block, and the deliverables (output) from the block.

The diagram illustrates the primary relationship between the items covered in the analysis and establishes a logical order to the analysis. Copies of the diagrams used in FMEA preparation should accompany the FMEA.

In order to facilitate documentation of the analysis of potential failures and their consequences, a blank form is available in Appendix D.

An example of a completed form is contained in Appendix E, including numbered headings (1) – (22) for ease of reference to the following descriptions.

- 3.2.1 (1) FMEA NUMBER—Enter the FMEA document number, which may be used for tracking. (See Figure 3A or 3B.)
- 3.2.2 (2) SYSTEM, SUBSYSTEM, OR COMPONENT NAME AND NUMBER—Indicate the appropriate level of analysis and enter the name and number of the system, subsystem, or component being analyzed. The FMEA team must decide on what constitutes a system, subsystem, or component for their specific activities. The actual boundaries that divide a System, Subsystem, and Component are arbitrary and must be set by the FMEA team. Some descriptions are provided below and some examples are provided in Appendix F (See Figure 3A or 3B.)

- 3.2.2.1 *System FMEA Scope*—A system can be considered to be made up of various subsystems. These subsystems often have been designed by different teams. Some typical System FMEAs might cover the following systems: Chassis System, or Powertrain System, or Interior System, etc. Thus, the focus of the System FMEA is to ensure that all interfaces and interactions between the various subsystems that make up the system as well as interfaces to other vehicle systems and the customer are covered.
- 3.2.2.2 *Subsystem FMEA Scope*—A subsystem FMEA is generally a sub-set of a larger system. For example, the front suspension subsystem is a sub-set of the chassis system. Thus, the focus of the Subsystem FMEA is to ensure that all interfaces and interactions between the various components that make up the subsystem are covered in the Subsystem FMEA.
- 3.2.2.3 *Component FMEA Scope*—A component FMEA is generally an FMEA focused on the sub-set of a subsystem. For example, a strut is a component of the front suspension (which is a subsystem of the chassis system.)
- 3.2.3 (3) DESIGN RESPONSIBILITY—Enter the OEM, department, and group. Also include the supplier name if applicable. (See Figure 3A or 3B.)
- 3.2.4 (4) PREPARED BY—Enter the name, telephone number, and company of the engineer responsible for preparing the FMEA. (See Figure 3A or 3B.)
- 3.2.5 (5) MODEL YEAR(S)/PROGRAM(S)—Enter the intended model year(s) and program(s) that will utilize and/or be affected by the design being analyzed (if known). (See Figure 3A or 3B.)
- 3.2.6 (6) KEY DATE—Enter the initial FMEA due date, which should not exceed the scheduled production design release date. (See Figure 3A or 3B.)
- 3.2.7 (7) FMEA DATE—Enter the date the original FMEA was compiled, and the latest revision date. (See Figure 3A or 3B.)
- 3.2.8 (8) CORE TEAM—List the names of the responsible individuals and departments which have the authority to identify and/or perform tasks. (It is recommended that each team member's name, department, telephone number, address, etc., be included on a distribution list). (See Figure 3A or 3B.)
- 3.2.9 (9) ITEM/FUNCTION—Enter the name and other pertinent information (e.g., the number, the part class, etc.) of the item being analyzed. Use the nomenclature and show the design level as indicated on the engineering drawing. Prior to initial release (e.g., in the conceptual phases), experimental numbers should be used. (See Figure 3A or 3B.)

Enter, as concisely as possible, the function of the item being analyzed to meet the design intent. Include information (metrics/measurables) regarding the environment in which this system operates (e.g., define temperature, pressure, humidity ranges, design life). If the item has more than one function with different potential modes of failure, list all the functions separately.

- 3.2.10 (10) POTENTIAL FAILURE MODE—Potential Failure Mode is defined as the manner in which a component, subsystem, or system could potentially fail to meet or deliver the intended function described in the item/function column (i.e., intended function fails). The potential failure mode may also be the cause of a potential failure mode in a higher level subsystem, or system, or be the effect of one in a lower level component. (See Figure 3A or 3B.)

List each potential failure mode associated with the particular item and item function. The assumption is made that the failure could occur, but may not necessarily occur. A recommended starting point is a review of past things-gone-wrong, concerns, reports, and group brainstorming.

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Potential failure modes that could only occur under certain operating conditions (i.e., hot, cold, dry, dusty, etc.) and under certain usage conditions (i.e., above average mileage, rough terrain, only city driving, etc.) should be considered.

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

cracked	deformed	loosened
leaking	sticking	oxidized
fractured	does not transmit torque	slips (does not hold full torque)
no support (structural)	inadequate support (structural)	harsh engagement
disengages too fast	inadequate signal	intermittent signal
no signal	EMC/RFI	drift

NOTE—Potential failure modes should be described in “physical” or technical terms, not as a symptom necessarily noticeable by the customer.

3.2.11 (11) **POTENTIAL EFFECT(S) OF FAILURE**—Potential Effects of Failure are defined as the effects of the failure mode on the function, as perceived by the customer. (See Figure 3A or 3B and 3.1.1)

Describe the effects of the failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user. State clearly if the function could impact safety or non-compliance to regulations. The effects should always be stated in terms of the specific system, subsystem, or component being analyzed. Remember that a hierarchical relationship exists between the component, subsystem, and system levels. For example, a part could fracture, which may cause the assembly to vibrate, resulting in an intermittent system operation. The intermittent system operation could cause performance to degrade, and ultimately lead to customer dissatisfaction. The intent is to forecast the failure effects, to the team's level of knowledge.

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

Noise	Rough	Leaks
Erratic Operation	Inoperative	Regulatory Non-Compliance
Poor Appearance	Unpleasant Odor	
Unstable	Operation Impaired	
Intermittent Operation	Thermal Event	

3.2.12 (12) **SEVERITY (S)**—Severity is the rank associated with the most serious effect for a given failure mode. Severity is a relative ranking, within the scope of the individual FMEA. A reduction in Severity Ranking index can be effected only through a design change. Severity should be estimated using Table 1 as a guideline.

3.2.12.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for individual product analysis. (See Table 1.)

NOTE 1—It is not recommended to modify criteria ranking values of 9 and 10. Failure Modes with rank Severity 1, should not be analyzed further.

NOTE 2—High Severity Rankings can sometimes be reduced by making design revisions that compensate or mitigate the resultant severity of failure. For example, “run flat tires” can mitigate the severity of a sudden tire blowout and “seat belts” can mitigate the severity of a vehicle crash.

TABLE 1—SUGGESTED DFMEA SEVERITY EVALUATION CRITERIA

Effect	Criteria: Severity of Effect	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Very High	Vehicle/item inoperable (loss of primary function).	8
High	Vehicle/Item operable, but at a reduced level of performance. Customer very dissatisfied.	7
Moderate	Vehicle/Item operable, but Comfort/Convenience item(s) inoperable. Customer dissatisfied.	6
Low	Vehicle/Item operable, but Comfort/Convenience item(s) operable at a reduced level of performance. Customer somewhat dissatisfied.	5
Very Low	Fit and Finish/Squeak and Rattle item does not conform. Defect noticed by most customers (greater than 75%).	4
Minor	Fit and Finish/Squeak and Rattle item does not conform. Defect noticed by 50% of customers.	3
Very Minor	Fit and Finish/Squeak and Rattle item does not conform. Defect noticed by discriminating customers (less than 25%).	2
None	No discernible effect.	1

- 3.2.13 (13) CLASSIFICATION—This column may be used to classify any special product characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional design or process controls. (See Figure 3A or 3B.)

This column may also be used to highlight high-priority failure modes for engineering assessment, if the Team finds this helpful, or if local management requires same.

Special Product or Process Characteristic symbols and their usage is directed by specific company policy and is not standardized in this document.

- 3.2.14 (14) POTENTIAL CAUSE(S)/MECHANISM(S) OF FAILURE—Potential Cause of Failure is defined as an indication of a design weakness, the consequence of which is the failure mode. (See Figure 3A or 3B.)

List, to the extent possible, every potential cause and/or failure mechanism for each failure mode. The cause/mechanism should be listed as concisely and completely as possible so that remedial efforts can be aimed at pertinent causes.

Typical failure causes may include, but are not limited to:

Incorrect Material Specified	Inadequate Design Life Assumption
Over-stressing	Insufficient Lubrication Capability
Inadequate Maintenance Instructions	Incorrect Algorithm
Improper Maintenance Instructions	Improper Software Specification
Improper Surface Finish Specification	Inadequate Travel Specification
Improper Friction Material Specified	Excessive Heat
Improper Tolerance Specified	

Typical failure mechanisms may include, but are not limited to:

Yield	Chemical Oxidation
Fatigue	Electromigration
Material Instability	
Creep	
Wear	
Corrosion	

- 3.2.15 (15) OCCURRENCE (O)—Occurrence is the likelihood that a specific cause/mechanism will occur during the design life. The likelihood of occurrence ranking number has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design change or design process change (e.g., design checklist, design review, design guide) is the only way a reduction in the occurrence ranking can be effected. (See Figure 3A or 3B.)

Estimate the likelihood of occurrence of potential failure cause/mechanism on a “1” to “10” scale. In determining this estimate, questions such as the following should be considered:

- What is the service history/field experience with similar components, subsystems, or systems?
- Is component carryover or similar to a previous level component, subsystem, or system?
- How significant are changes from a previous level component, subsystem, or system?
- Is component radically different from a previous level component?
- Is component completely new?
- Has the component application changed?
- What are the environmental changes?
- Has an engineering analysis (e.g., reliability) been used to estimate the expected comparable occurrence rate for the application?
- Have preventive controls been put in place?

A consistent occurrence ranking system should be used to ensure continuity. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence.

3.2.15.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual product analysis. (See Table 2.) Occurrence should be estimated using Table 2 as a guideline:

NOTE—The ranking value of 1 is reserved for “Remote: Failure Is unlikely”.

TABLE 2—SUGGESTED DFMEA OCCURRENCE EVALUATION CRITERIA

Probability of Failure	Likely Failure Rates Over Design Life	Ranking
Very High: Persistent failures	≥100 per thousand vehicles/items	10
	50 per thousand vehicles/items	9
High: Frequent failures	20 per thousand vehicles/items	8
	10 per thousand vehicles/items	7
Moderate: Occasional failures	5 per thousand vehicles/items	6
	2 per thousand vehicles/items	5
	1 per thousand vehicles/items	4
Low: Relatively few failures	0.5 per thousand vehicles/items	3
	0.1 per thousand vehicles/items	2
Remote: Failure is unlikely	≤ 0.01 per thousand vehicles/items	1

3.2.16 (16) **CURRENT DESIGN CONTROLS**—List the prevention, design validation/verification (DV), or other activities which are completed or committed to and that will assure the design adequacy for the failure mode and/or cause/mechanism under consideration. Current controls (e.g., road testing, design reviews, fail/safe designs such as a pressure relief valve, mathematical studies, rig/lab testing, feasibility review, prototype tests, fleet testing) are those that have been or are being used with the same or similar designs. (See Figure 3A and 3B.) The Team should always be focused on improving design controls; for example, the creation of new system tests in the lab, or the creation of new system modeling algorithms, etc.

There are two types of Design Controls to consider:

- a. Prevention: Prevent the cause/mechanism of failure or the failure mode from occurring, or reduce the rate of occurrence,
- b. Detection: Detect the cause/mechanism of failure or the failure mode, either by analytical or physical methods, before the item is released to production.

The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent. The initial detection rankings will be based on design controls that either detect the cause/mechanism of failure, or detect the failure mode.

The Design FMEA form in Figure 3A has two columns for the design controls (i.e., separate columns for Prevention Controls and Detection Controls) to assist the team in clearly distinguishing between these two types of design controls. This allows for a quick visual determination that both types of design controls have been considered. Use of this two-column form is the preferred approach. (See Figure 3A.)

NOTE— In the example included here, it is clear that the team has not identified any prevention controls. This could be due to prevention controls not having been used on the same or similar designs.

If a one-column (for design controls) form is used, then the following prefixes should be used. For prevention controls, place a ‘P’ before each prevention control listed. For detection controls, place a ‘D’ before each detection control listed. (See Figure 3B.)

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Once the design controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised.

3.2.17 (17) **DETECTION (D)**—Detection is the rank associated with the best detection design control from the list in the previous column. Detection is a relative ranking, within the scope of the individual FMEA. In order to achieve a lower ranking, generally the planned design control (e.g., validation, and/or verification activities) has to be improved.

3.2.17.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual product analysis. (See Table 3.)

TABLE 3—SUGGESTED DETECTION EVALUATION CRITERIA

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
Absolute Uncertainty	Design Control will not and/or can not detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control	10
Very Remote	Very remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	9
Remote	Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	8
Very Low	Very Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	7
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	6
Moderate	Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	2
Almost Certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode.	1

3.2.17.2 It is best to have detection design controls in place as early as possible in the design development process.

NOTE—After making the Detection Ranking, the Team should review the Occurrence Ranking and ensure that the Occurrence Ranking is still appropriate

Detection should be estimated using Table 3 as a guideline:

NOTE—The ranking value of 1 is reserved for “almost certain.”

3.2.18 (18) **RISK PRIORITY NUMBER (RPN)**—The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. (See Figure 3A or 3B.)

$$\text{RPN} = (\text{S}) \times (\text{O}) \times (\text{D}) \quad (\text{Eq. 1})$$

Within the scope of the individual FMEA, this value (between “1” and “1000”) can be used to rank order the concerns in the design (e.g., in Pareto fashion).

- 3.2.19 (19) **RECOMMENDED ACTION(S)**—Engineering assessment for preventive/corrective action should be first directed at high severity, high RPN, and other items designated by the team. The intent of any recommended action is to reduce rankings, in the following preference order: severity, occurrence, and detection rankings. (See Figure 3A or 3B.)

In general practice when the severity is a “9” or “10”, special attention must be given to assure that the risk is addressed through existing design controls or preventive/corrective action(s), regardless of the RPN. In all cases where the effect of an identified potential failure mode could be a hazard to the end-user, preventive/corrective actions should be considered to avoid the failure mode by eliminating, mitigating, or controlling the cause(s).

After special attention has been given to Severity Rankings of 9 or 10, the team then addresses other Failure Modes, with the intent of reducing Severity, then Occurrence, and then Detection.

Actions such as, but are not limited to, the following should be considered:

- a. Revised Design Geometry and/or tolerances,
- b. Revised Material Specification,
- c. Design of experiments (particularly when multiple or interactive causes are present)/or other problem solving techniques, and
- d. Revised Test Plan.

The primary objective of recommended actions is to reduce risks and increase customer satisfaction by improving the design.

Only a design revision can bring about a reduction in the severity ranking. A reduction in the occurrence ranking can be effected only by removing or controlling one or more of the causes/mechanisms of the failure mode through a design revision. An increase in design validation/verification actions will result in a reduction in the detection ranking only. Increasing the design validation/verification actions is a less desirable engineering action since it does not address the severity or occurrence of the failure mode.

If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering a “NONE” in this column.

- 3.2.20 (20) **RESPONSIBILITY (FOR THE RECOMMENDED ACTION)**—Enter the name of the organization and individual responsible for the recommended action and the target completion date. (See Figure 3A or 3B.)
- 3.2.21 (21) **ACTIONS TAKEN**—After an action has been implemented, enter a brief description of the actual action and effective date. (See Figure 3A or 3B.)
- 3.2.22 (22) **REVISED RATINGS**—After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the related ranking columns blank. (See Figure 3A or 3B.)

All revised ratings should be reviewed. If further action is considered necessary, repeat the analysis. The focus should always be on continuous improvement.

- 3.2.23 **FOLLOW-UP ACTIONS**—See 1.5.

**POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)**

FMEA Number _____

Page _____ of _____

Prepared By _____

FMEA Date (Orig.) _____ (Rev.) _____

Item _____ Process Responsibility _____

Model Year(s)/Program(s) _____ Key Date _____

Core Team _____

Process Function Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Cause(s) Mechanism(s) of Failure	Occurrence	Current Process Controls Prevention	Current Process Controls Detection	D e t e c t i o n	R e p a r t u r e	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Action Results						
													S	O	D	R			
													S	O	D	R			
													e	c	e	P			
													v	c	i	N			

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FIGURE 4A—POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS IN MANUFACTURING AND ASSEMBLY PROCESSES (PROCESS FMEA) – TWO COLUMNS, CURRENT PROCESS CONTROLS –

**POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
IN MANUFACTURING AND ASSEMBLY PROCESSES
(PROCESS FMEA)**

FMEA Number _____
 Page _____ of _____
 Prepared By _____
 FMEA Date (Orig.) _____ (Rev.) _____

Item _____
 Model Year(s)/Program(s) _____
 Core Team _____
 Process Responsibility _____
 Key Date _____

Process Function Requirements	Potential Failure Mode	Potential Effect(s) of Failure	C I S a s e s	P o t e n t i a l C a u s e (s) M e c h a n i s m (s) o f F a i l u r e	O c c u r r e n c e	C u r r e n t P r o c e s C o n t r o l s — Prevention — Detection	D e t e r m i n e d C o n t r o l s	R e c o m m e n d e d A c t i o n (s)	R e s p o n s i b i l i t y & T a r g e t C o m p l e t i o n D a t e	A c t i o n s T a k e n	A c t i o n R e s u l t s	
											S e v e r i t y	D e t e c t i o n

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FIGURE 4B—POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS IN MANUFACTURING AND ASSEMBLY PROCESSES (PROCESS FMEA) – ONE COLUMN, CURRENT PROCESS CONTROLS –

4. **Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)**

4.1 Introduction—A Process potential FMEA is an analytical technique utilized by a Manufacturing/Assembly Responsible Engineer/Team as a means to assure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. In its most rigorous form, an FMEA is a summary of the engineer's/team's thoughts (including an analysis of items that could go wrong based on experience) as a process is developed. This systematic approach parallels and formalizes the mental discipline that an engineer normally goes through in any manufacturing planning process.

The Process potential FMEA:

- a. Identifies the process functions and requirements,
- b. Identifies potential product and process related failure modes,
- c. Assesses the effects of the potential failures on the customer,
- d. Identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction or detection of the failure conditions,
- e. Identifies process variables on which to focus process controls,
- f. Develops a ranked list of potential failure modes, thus establishing a priority system for preventive/corrective action considerations, and
- g. Documents the results of the manufacturing or assembly process.

4.1.1 **CUSTOMER DEFINED**—The definition of “CUSTOMER” for a Process potential FMEA should normally be seen as the “END USER.” However, customer can also be a subsequent or downstream manufacturing or assembly operation, a service operation, as well as government regulations.

4.1.2 **TEAM EFFORT**—During the initial Process potential FMEA development, the responsible engineer is expected to directly and actively involve representatives from all affected areas. These areas should include, but are not limited to design, assembly, manufacturing, materials, quality, service, and suppliers, as well as the area responsible for the next assembly. The FMEA should be a catalyst to stimulate the interchange of ideas between the areas affected and thus promote a team approach.

Unless the responsible engineer is experienced with FMEA and team facilitation, it is helpful to have an experienced FMEA Facilitator assist the team in its activities.

The Process FMEA is a living document and should be initiated:

- a. Before or at the feasibility stage,
- b. Prior to tooling for production, and
- c. Take into account all manufacturing operations, from individual components to assemblies.

The PFMEA should be addressed according to the 3 cases outlined in 1.4.

Early review and analysis of new or revised processes is promoted to anticipate, resolve, or monitor potential process concerns during the manufacturing planning stages of a new model or component program.

The Process FMEA assumes the product, as designed, will meet the design intent. Potential failure modes which can occur because of a design weakness may be included in a Process FMEA. Their effect and avoidance is covered by the Design FMEA.

The Process FMEA does not rely on product design changes to overcome weaknesses in the process. However, it does take into consideration a product's design characteristics relative to the planned manufacturing or assembly process to assure that, to the extent possible, the resultant product meets customer needs and expectations.

4.2 Development of a Process FMEA—The process-responsible engineer has at his or her disposal a number of documents that will be useful in preparing the Process FMEA. The FMEA begins by developing a listing of what the process is expected to do, and what it is expected not to do, i.e., the process intent.

The Process FMEA should begin with a flow chart of the general process. This flow chart should identify the product/process characteristics associated with each operation. Identification of some product effects from the corresponding Design FMEA, should be included, if available. Copies of the flow chart used in FMEA preparation should accompany the FMEA.

In order to facilitate documentation of the analysis of potential failures and their consequences, a Process FMEA form has been developed and is in Appendix G.

An example of a completed form is contained in Appendix H, including numbered headings (1) – (22) for ease of reference to the following descriptions.

- 4.2.1 (1) FMEA NUMBER—Enter the FMEA document number, which may be used for tracking. (See Figure 4A or 4B.)
- 4.2.2 (2) ITEM—Enter the name and number of the system, subsystem, or component, for which the process is being analyzed. (See Figure 4A or 4B.)
- 4.2.3 (3) PROCESS RESPONSIBILITY—Enter the OEM, department, and group. Also include the supplier name if known. (See Figure 4A or 4B.)
- 4.2.4 (4) PREPARED BY—Enter the name, telephone number, and company of the engineer responsible for preparing the FMEA. (See Figure 4A or 4B.)
- 4.2.5 (5) MODEL YEAR(S)/PROGRAM(S)—Enter the intended model year(s)/program(s) that will use and/or be affected by the design/process being analyzed (if known). (See Figure 4A or 4B.)
- 4.2.6 (6) KEY DATE—Enter the initial FMEA due date, which should not exceed the scheduled start of production date. (See Figure 4A or 4B.)
- NOTE— In the case of a supplier, the initial FMEA due date should not exceed the customer required Production Part Approval Process (PPAP) submission date.
- 4.2.7 (7) FMEA DATE—Enter the date the original FMEA was compiled, and the latest revision date. (See Figure 4A or 4B.)
- 4.2.8 (8) CORE TEAM—List the names of the responsible individuals and departments which have the authority to identify and/or perform tasks. (It is recommended that each team member's name, department, telephone number, address, etc., be included on a distribution list.) (See Figure 4A or 4B.)
- 4.2.9 (9) PROCESS FUNCTION/REQUIREMENTS—Enter a simple description of the process or operation being analyzed (e.g., turning, drilling, tapping, welding, assembling). The team should review applicable performance, material, process, environmental, and safety standards. Indicate as concisely as possible the purpose of the process or operation being analyzed, including information about the design (metrics/measurables) describing the system, subsystem, or component. Where the process involves numerous operations (e.g., assembling) with different potential modes of failure, it may be desirable to list the operations as separate elements. (See Figure 4A or 4B.)

4.2.10 (10) **POTENTIAL FAILURE MODE**—Potential Failure Mode is defined as the manner in which the process could potentially fail to meet the process requirements and/or design intent as described in the process function/requirements column. It is a description of the nonconformance at that specific operation. It can be a cause associated with a potential failure mode in a subsequent (downstream) operation or an effect associated with a potential failure in a previous (upstream) operation. However, in preparation of the FMEA, the assumption may be made that the incoming part(s)/material(s) are correct. Exceptions can be made by the FMEA team where historical data indicates deficiencies in incoming part quality. (See Figure 4A or 4B.)

List each potential failure mode for the particular operation in terms of a component, subsystem, system, or process characteristic. Assume that the failure could occur, but may not necessarily occur. The process engineer/team should be able to pose and answer the following questions:

- a. How can the process/part fail to meet specifications?
- b. Regardless of engineering specifications, what would a customer (end user, subsequent operations, or service) consider objectionable?

Start by comparing similar processes and reviewing customer (end user and subsequent operation) claims relating to similar components. In addition, a knowledge of the design intent is necessary. Typical failure modes could be, but are not limited to:

Bent	Burred	Hole off-location
Cracked	Hole too shallow	Hole missing
Handling damage	Dirty	Hole too deep
Surface too rough	Deformed	Surface too smooth
Open Circuited	Short Circuited	Mis-labeled

NOTE— Potential failure modes should be described in “physical” or technical terms, not as a symptom noticeable by the customer.

4.2.11 (11) **POTENTIAL EFFECT(S) OF FAILURE**—Potential Effects of Failure are defined as the effects of the failure mode on the customer(s). (See Figure 4A or 4B and 4.1.1.)

Describe the effects of the failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user. State clearly if the failure mode could impact safety or cause noncompliance to regulations. The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the vehicle owner. Each must be considered when assessing the potential effect of a failure.

For the End User, the effects should always be stated in terms of product or system performance, such as:

Noise	Rough	Erratic Operation	Excessive Effort
Inoperative	Unpleasant Odor	Unstable	Operation Impaired
Draft	Intermittent Operation	Poor Appearance	Leaks
Vehicle Control Impaired	Rework/Repairs	Customer Dissatisfaction	Scrap

If the customer is the next operation or subsequent operation(s)/location(s), the effects should be stated in terms of process/operation performance, such as:

Can not fasten	Does not fit	Can not bore/tap	Does not connect
Can not mount	Does not match	Can not face	Causes Excessive tool wear
Damages equipment	Endangers operator		

4.2.12 (12) SEVERITY(S)—Severity is the rank associated with the most serious effect for a given failure mode. Severity is a relative ranking, within the scope of the individual FMEA. A reduction in Severity Ranking index can be effected through a design change to system, subsystem or component, or a redesign of the process. (See Figure 4A or 4B.)

If the customer affected by a failure mode is the manufacturing or assembly plant or the product user, assessing the severity may lie outside the immediate process engineer's/team's field of experience or knowledge. In these cases, the design FMEA, design engineer, and/or subsequent manufacturing or assembly plant process engineer, should be consulted.

4.2.12.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual process analysis. (See Table 4.)

Severity should be estimated using Table 4 as a guideline:

NOTE—It is not recommended to modify criteria for ranking values of 9 and 10. Failure Modes with rank Severity 1, should not be analyzed further.

TABLE 4—SUGGESTED PFMEA SEVERITY EVALUATION CRITERIA

Effect	Criteria: Severity of Effect	Criteria: Severity of Effect	Ranking
	This ranking results when a potential failure mode results in a final customer and/or a manufacturing/assembly plant defect. The final customer should always be considered first. If both occur, use the higher of the two severities. (Customer Effect)	This ranking results when a potential failure mode results in a final customer and/or a manufacturing/assembly plant defect. The final customer should always be considered first. If both occur, use the higher of the two severities. (Manufacturing/Assembly Effect)	
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	Or may endanger operator (machine or assembly) without warning.	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	Or may endanger operator (machine or assembly) with warning.	9
Very High	Vehicle/item inoperable (loss of primary function).	Or 100% of product may have to be scrapped, or vehicle/item repaired in repair department with a repair time greater than one hour.	8
High	Vehicle/Item operable but at a reduced level of performance. Customer very dissatisfied.	Or product may have to be sorted and a portion (less than 100%) scrapped, or vehicle/item repaired in repair department with a repair time between half an hour and an hour.	7
Moderate	Vehicle/Item operable but Comfort/Convenience item(s) inoperable. Customer dissatisfied.	Or a portion (less than 100%) of the product may have to be scrapped with no sorting, or vehicle/item repaired in repair department with a repair time less than half an hour.	6
Low	Vehicle/Item operable but Comfort/Convenience item(s) operable at a reduced level of performance. Customer somewhat dissatisfied.	Or 100% of product may have to be reworked, or vehicle/item repaired off-line but does not go to repair department.	5
Very Low	Fit & finish/Squeak and rattle item does not conform. Defect noticed by most customers (greater than 75%).	Or the product may have to be sorted, with no scrap, and a portion (less than 100%) reworked.	4
Minor	Fit & finish/Squeak and rattle item does not conform. Defect noticed by 50% of customers.	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, on-line but out-of-station.	3
Very Minor	Fit & finish/Squeak and rattle item does not conform. Defect noticed by discriminating customers (less than 25%).	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, on-line but in-station.	2
None	No discernible effect.	Or slight inconvenience to operation or operator, or no effect.	1

4.2.13 (13) CLASSIFICATION—This column may be used to classify any special product or process characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional process controls. (See Figure 4A or 4B.)

This column may also be used to highlight high priority failure modes for engineering assessment.

If a classification is identified in the Process FMEA, notify the design responsible engineer since this may affect the engineering documents concerning control item identification.

Special Product or Process Characteristic symbols and their usage is directed by specific company policy and is not standardized in this document.

4.2.14 (14) POTENTIAL CAUSE(S)/MECHANISM(S) OF FAILURE—Potential Cause of Failure is defined as how the failure could occur, described in terms of something that can be corrected or can be controlled. (See Figure 4A or 4B.)

List, to the extent possible, every failure cause assignable to each potential failure mode. If a cause is exclusive to the failure mode, i.e., if correcting the cause has a direct impact on the failure mode, then this portion of the FMEA thought process is completed. Many causes, however, are not mutually exclusive, and to correct or control the cause, a design of experiments, for example, may be considered to determine which root causes are the major contributors and which can be most easily controlled. The causes should be described so that remedial efforts can be aimed at those causes which are pertinent. Typical failure causes may include, but are not limited to:

Improper torque - over, under	Improper weld - current, time, pressure
Inaccurate gauging	Improper heat treat - time, temperature
Inadequate gating/venting	Inadequate or no lubrication
Part missing or mislocated	Worn locator
Worn tool	Chip on locator
Broken tool	Improper machine setup
Improper programming	

Only specific errors or malfunctions (e.g., operator fails to install seal) should be listed; ambiguous phrases (e.g., operator error, machine malfunction) should not be used.

4.2.15 (15) OCCURRENCE (O)—Occurrence is the likelihood that a specific cause/mechanism of failure will occur. The likelihood of occurrence ranking number has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design or process change is the only way a reduction in the occurrence ranking can be effected. (See Figure 4A or 4B.)

Estimate the likelihood of occurrence of potential failure cause/mechanism on a “1” to “10” scale.

A consistent occurrence ranking system should be used to ensure continuity. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence.

The “Possible Failure Rates” are based on the number of failures which are anticipated during the process execution. If statistical data are available from a similar process, the data should be used to determine the occurrence ranking. In all other cases, a subjective assessment can be made by using the word descriptions in the left column of the table, along with any historical data available for similar processes.

4.2.15.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, that is consistent, even if modified for individual process analysis. (See Table 5.)

Occurrence should be estimated using the following table as a guideline:

NOTE—The ranking value of 1 is reserved for “Remote: Failure Is unlikely.”

TABLE 5—SUGGESTED PFMEA OCCURRENCE EVALUATION CRITERIA

Probability	Likely Failure Rates ⁽¹⁾	Ranking
Very High: Persistent failures	≥100 per thousand pieces	10
	50 per thousand pieces	9
High: Frequent failures	20 per thousand pieces	8
	10 per thousand pieces	7
Moderate: Occasional failures	5 per thousand pieces	6
	2 per thousand pieces	5
	1 per thousand pieces	4
Low: Relatively few failures	0.5 per thousand pieces	3
	0.1 per thousand pieces	2
Remote: Failure is unlikely	≤ 0.01 per thousand pieces	1

1. For associated Ppk calculations and values, see Appendix M.

4.2.16 (16) **CURRENT PROCESS CONTROLS**—Current Process Controls are descriptions of the controls that either prevent to the extent possible the failure mode/cause from occurring or detect the failure mode or cause should it occur. These controls can be process controls such as error/mistake proofing or Statistical Process Control (SPC), or can be post-process evaluation. The evaluation may occur at the subject operation or at subsequent operations. (See Figure 4A or 4B.)

There are two types of Process Controls/features to consider:

- a. Prevention: Prevent the cause/mechanism or failure mode/effect from occurring, or reduce their rate of occurrence
- b. Detection: Detect the cause/mechanism or failure mode, and lead to corrective action(s)

The preferred approach is to first use prevention controls if possible. The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the process intent. The initial rankings for detection will be based on process controls that either detect the cause/mechanism of failure, or detect the failure mode.

The Process FMEA form in Figure 4A 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. Use of this two-column form is the preferred approach. (See Figure 4A.)

If a one-column (for process controls) form is used, then the following prefixes should be used. For prevention controls, place a ‘P’ before each prevention control listed. For detection controls, place a ‘D’ before each detection control listed. (See Figure 4B.)

Once the process controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised.

4.2.17 (17) **DETECTION (D)**—Detection is the rank associated with the best detection control listed in the process control column. Detection is a relative ranking, within the scope of the individual FMEA. In order to achieve a lower ranking, generally the planned process control has to be improved. (See Figure 4A or 4B.)

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Assume the failure has occurred and then assess the capabilities of all “Current Process Controls” to prevent shipment of the part having this failure mode or defect. Do not automatically presume that the detection ranking is low because the occurrence is low (e.g., when Control Charts are used), but do assess the ability of the process controls to detect low frequency failure modes or prevent them from going further in the process.

Random quality checks are unlikely to detect the existence of an isolated defect and should not influence the detection ranking. Sampling done on a statistical basis is a valid detection control.

4.2.17.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, that is consistent, even if modified for individual product analysis. (See Table 6.)

Detection should be estimated using Table 6 as a guideline:

NOTE—The ranking value of 1 is reserved for “Controls certain to Detect.”

TABLE 6—SUGGESTED PFMEA DETECTION EVALUATION CRITERIA

Detection	Criteria	Inspection Type A ⁽¹⁾	Inspection Type B ⁽¹⁾	Inspection Type C ⁽¹⁾	Suggested Range of Detection Methods	Ranking
Almost Impossible	Absolute certainty of non-detection			X	Cannot detect or is not checked.	10
Very Remote	Controls will probably not detect			X	Control is Achieved with indirect or random checks only.	9
Remote	Controls have poor chance of detection			X	Control is achieved with visual inspection only.	8
Very Low	Controls have poor chance of detection			X	Control is achieved with double visual inspection only.	7
Low	Controls may detect.		X	X	Control is achieved with charting methods, such as SPC {Statistical Process Control}	6
Moderate	Controls may detect		X		Control is based on variable gauging after parts have left the station, OR Go/No Go gauging performed on 100% of the parts after parts have left the station.	5
Moderately High	Controls have a good chance to detect	X	X		Error detection in subsequent operations, OR gauging performed on set-up and first-piece check (for set-up causes only).	4
High	Controls have a good chance to detect	X	X		Error detection in-station, OR error detection in subsequent operations by multiple layers of acceptance: supply, select, install, verify. Can not accept discrepant part.	3
Very High	Controls almost certain to detect.	X	X		Error detection in-station (automatic gauging with automatic stop feature). Can not pass discrepant part.	2
Certain	Controls certain to detect.	X			Discrepant parts can not be made because item has been error proofed by process/product design.	1

1. Inspection Types:
 A. Error Proofed
 B. Gauging
 C. Manual Inspection

NOTE—X's indicate the inspection type(s) used for a given rank.

4.2.18 (18) **RISK PRIORITY NUMBER (RPN)**—The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. (See Figure 4A or 4B.)

$$RPN = (S) \times (O) \times (D) \quad \text{(Eq. 2)}$$

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Within the scope of the individual FMEA, this value (between “1” and “1000”) can be used to rank order the concerns in the process (e.g., in Pareto fashion).

- 4.2.19 (19) **RECOMMENDED ACTION(S)**—Engineering assessment for corrective action should be first directed at high severity, high RPN, and other items designated by the team. The intent of any recommended action is to reduce rankings, in the following preference order: severity, occurrence, and detection rankings. (See Figure 4A or 4B).

In general practice when the severity is “9” or “10”, special attention must be given to assure that the risk is addressed through existing design actions/controls or process preventive/corrective action(s), regardless of the RPN. In all cases where the effect of an identified potential failure mode could be a hazard to manufacturing/assembly personnel, preventive/corrective actions should be taken to avoid the failure mode by eliminating or controlling the cause(s), or appropriate operator protection should be specified.

After special attention has been given to Severity Rankings of 9 or 10, the team then addresses other Failure Modes, with the intent of reducing Severity, then Occurrence, and then Detection.

Actions such as, but not limited to, the following should be considered:

- a. To reduce the probability of occurrence, process and/or design revisions are required. An action-oriented study of the process using statistical methods could be implemented with an ongoing feedback of information to the appropriate operations for continuous improvement and defect prevention.
- b. Only a design and/or process revision can bring about a reduction in the severity ranking.
- c. To increase the probability of detection, process and/or design revisions are required. A preferred method for generating possible process and/or design revisions, to increase the probability of detection, is Error/Mistake Proofing. Generally, improving detection controls is costly and ineffective for quality improvements. Increasing quality controls inspection frequency is not an effective preventive/corrective action and should only be utilized as a temporary measure, since permanent preventive/corrective action is required. In some cases, a design change to a specific part may be required to assist in the detection. Changes to the current control system may be implemented to increase this probability.
Emphasis must, however, be placed on preventing defects (i.e., reducing the occurrence) rather than detecting them. An example would be the use of Statistical Process Control and process improvement rather than random quality checks or associated inspection.

If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering a “NONE” in this column.

- 4.2.20 (20) **RESPONSIBILITY (FOR THE RECOMMENDED ACTION)**—Enter the individual responsible for the recommended action, and the target completion date. (See Figure 4A or 4B.)
- 4.2.21 (21) **ACTIONS TAKEN**—After an action has been implemented, enter a brief description of the action and effective date. (See Figure 4A or 4B.)
- 4.2.22 (22) **REVISED RATINGS**—After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the related ranking columns blank. (See Figure 4A or 4B.)

All revised ratings should be reviewed and if further action is considered necessary, repeat the analysis. The focus should always be on continuous improvement.

- 4.2.23 **FOLLOW-UP ACTIONS**—See 1.5.

**POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(MACHINERY FMEA)**

System _____ FMEA Number _____
 Subsystem _____ Page _____ of _____
 Component _____ Prepared By _____
 Program(s)/Plant(s) _____ Design Responsibility _____ FMEA Date (Orig.) _____ (Rev.) _____
 Core Team: _____ Key Date _____

Item Function Reqs	Potential Failure Mode	Potential Effect(s) of Failure	C I S e s	Potential Cause(s) Mechanism(s) of Failure	O c c u r	C u r r e n t Machinery Controls —Prevention —Detection	D e t R. e P. c N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results Actions Taken	S O D R. e c e P. v c t N.		

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FIGURE 5B—MACHINERY FMEA FORM
— ONE COLUMN, CURRENT MACHINERY DESIGN CONTROLS —

5. *Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA). An Application of Design FMEA to Plant Machinery, Tooling, and Equipment.*

5.1 Introduction—Failure Mode and Effects Analysis concepts can be applied to machinery (the term machinery, as used throughout this text includes tooling and equipment) to reduce the probability that potential failure modes, related to machinery, will occur. The Machinery potential FMEA (MFMEA) supports the machinery design process from design development through design approval. The MFMEA is a thorough review of each step, or function, in the overall operation of the machinery. This section addresses the concepts used to develop an effective MFMEA, which is an application of a Design FMEA (Section 3) for Plant Machinery, Tooling, and Equipment.

This section on MFMEA includes unique “Machinery Tables” for Severity, Occurrence, and Detection Rankings.

It should be noted that a Process FMEA can also be applied to Machinery for the “Build/Installation Process.” The information provided for Process FMEA (Section 4) can be used for the creation of “Build/Installation Process FMEA,” but an application is not listed here-in. The Build/Installation Process FMEA should be initiated prior to the creation of any machinery that will be used for production. The MFMEA is a design output used to evaluate and improve the reliability, maintainability, and the durability of the machinery.

A Machinery potential FMEA (MFMEA) for plant machinery, tooling, and equipment is an analytical technique utilized primarily by a Machinery-Responsible Engineer/Team. The purpose of the FMEA is to assure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. In its most rigorous form, an FMEA is a summary of the team’s thoughts (including analysis of items that could go wrong based on experience) as the machinery is designed. The systematic approach parallels, formalizes, and documents the mental disciplines that an engineer/team normally goes through in any design/development process.

Since the MFMEA should be used as an input to the machinery preventive maintenance program, and used to assist in the determination of machinery controls that will be used, it is impossible to develop an effective MFMEA without the plant machinery personnel and the various supplier field service activities represented on the team. The team (see 5.1.2) should also focus on improving the reliability, durability, maintainability, and availability of the machine while conducting the analysis.

The Machinery Potential FMEA supports the design process in reducing risk of failures by:

- a. Aiding in the objective evaluation of equipment functions and sequence of steps, design requirements, and design alternatives;
- b. Increasing the probability that potential failure modes and their effects on the customer (see 5.1.1) and the “End User” have been considered in the design and development process;
- c. Providing additional information to aid in the planning of thorough and efficient design, validation, and development programs, including the planning of an efficient and effective process for preventive maintenance;
- d. Developing a ranked list of potential failure modes ranked according to their effect on the “customer”, thus establishing a priority system for design improvements, development, and validation testing/analysis;
- e. Providing future reference, e.g., lessons learned to aid in analyzing field concerns, evaluating design changes, and developing advanced machinery designs;
- f. Improving the reliability and durability of the machinery, resulting in reduced life cycle costs;
- g. Improving machinery maintainability, resulting in reduced mean time to repair; and,
- h. Improving reliability, durability, and maintainability, resulting in increased availability.

When fully implemented, the MFMEA discipline can be performed on new, modified, or carry-over designs in new applications or environments. An engineer from the responsible design source should initiate the MFMEA process, which for a proprietary design, may be the supplier.

5.1.1 CUSTOMER DEFINED—The definition of “Customer” for a MFMEA is the manufacturing facility where the machinery is to be installed for production. The manufacturing facility includes plant engineers, maintenance, production, and other plant support personnel.

5.1.2 TEAM EFFORT—During the MFMEA process, the machinery-responsible engineer is expected to actively involve representatives from all affected areas. These areas should include, but are not limited to production, manufacturing engineering, safety, quality, suppliers, product engineering, and the “customer” of the machinery as described in 5.1.1. The MFMEA should be a catalyst to stimulate the interchange of ideas between activities affected and thus promote a team approach. In addition, for any commercial “Catalog” components, the responsible representative from the component supplier should be consulted as required.

Unless the responsible engineer is experienced with FMEA and team facilitation, it is helpful to have an experienced FMEA Facilitator assist the team in its activities.

The Machinery FMEA is a living document and should:

- a. Be initiated during machinery design concept development,
- b. Be continually updated as changes occur or additional information is obtained throughout the phases of machinery development, and
- c. Should be completed before engineering release for construction.

The MFMEA analyzes functions, design requirements, needs, and assumes the machinery will be built to specification. The focus of the MFMEA is to eliminate potential failures by removing design weaknesses before the machinery is built as opposed to relying on machinery controls and/or preventive maintenance to reduce the occurrence of the failures.

5.2 Development of a Machinery FMEA—The machinery design responsible engineer has at his/her disposal a number of formal and informal documents that will be useful in the preparation of the Machinery FMEA. The process of preparing the MFMEA begins with the full understanding of what the machinery is expected to do or not to do, in a given environment, under stated conditions, and for a defined period of time. These expectations may be determined from sources such as the Reliability and Maintainability specification statement, design requirements, performance reports, preventive/corrective action reports, maintenance history, program objectives, and federal or local regulatory requirements.

Prior to beginning the MFMEA, the team should have at their disposal a minimum of:

- a. Detailed description of the sequence of steps in the overall operation of the machinery,
- b. Equipment literature,
- c. Engineering drawings of the machinery, and,
- d. Machinery reliability and maintainability information (estimated or actual).

A Machinery FMEA should begin by prioritizing the subsystem improvements necessary to meet the overall system expectations.

A Machinery FMEA should begin with a block diagram for the system or subsystem being analyzed. An example of the block diagram is shown in Appendix C.

In order to facilitate documentation of the Machinery FMEA, a form is available in Appendix I.

An example of a completed form is contained in Appendix K.

5.2.1 FMEA NUMBER—Enter the FMEA document number, which may be used for tracking. (See Figure 5A or 5B.)

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- 5.2.2 MACHINERY/SYSTEM, SUBSYSTEM, OR COMPONENT NAME—Indicate the appropriate level of analysis and enter the name and identification number of the system, subsystem, or component being analyzed. The FMEA team members must decide on what constitutes a system, subsystem, or component for their specific activities. The actual boundaries that divide a system, subsystem, and component are arbitrary and must be set by the FMEA team. (See Figure 5A or 5B and Appendix F.)
- 5.2.2.1 *System FMEA Scope*—A system can be considered to be made up of various subsystems. These subsystems often have been designed by different teams. Some typical Machinery System FMEAs might cover the following systems: Underbody Welding System, or Chassis Decking/Marriage System, etc. Thus, the focus of the System FMEA is to ensure that all interfaces and interactions are covered among the various subsystems that make up the system.
- 5.2.2.2 *Subsystem FMEA Scope*—A Subsystem FMEA is generally a sub-set of a larger system. For example, the robots are a sub-set of the underbody welding system. Thus, the focus of the Machinery Subsystem FMEA is to ensure that all interfaces and interactions are covered among the various components that make up the subsystem.
- 5.2.2.3 *Component FMEA Scope*—A Component FMEA is generally an FMEA focused on the sub-set of a subsystem. For example, end-of-arm tooling (e.g., weld gun, sealer gun, gripper) is a component of the robot (which is a subsystem of the underbody welding system.)
- 5.2.3 DESIGN RESPONSIBILITY—Enter the OEM, department, group, and the supplier name as applicable. (See Figure 5A or 5B.)
- 5.2.4 PREPARED BY—Enter the name, telephone number, and the company of the engineer responsible for preparing the MFMEA document. (See Figure 5A or 5B.)
- 5.2.5 PROGRAM(S)/PLANT(S)—Enter the intended programs(s) and plant(s) that will utilize and/or be affected by the machinery being analyzed. (See Figure 5A or 5B.)
- 5.2.6 KEY DATE—Enter the initial MFMEA due date, which should not exceed the scheduled engineering release date for construction. (See Figure 5A or 5B.)
- 5.2.7 FMEA DATE—Enter the date the original MFMEA was compiled, and the latest revision date. (See Figure 5A or 5B.)
- 5.2.8 CORE TEAM—List the names of the responsible individuals and departments that have the authority to identify and/or perform tasks. (It is recommended that each team member's name, department, telephone number, address, etc., be included on the distribution list.) (See Figure 5A or 5B.)
- 5.2.9 ITEM/FUNCTION REQUIREMENTS—Enter the name of the item and enter a simple description of the step, or function, that is being analyzed. The team should review applicable performance, material, process, environmental, and safety standards. Indicate as concisely as possible the purpose/requirements of the step, or function, being analyzed, including information about the design (metrics/measurables) describing the system, subsystem or component.

If the subsystem has more than one function with different potential modes of failure, it may be desirable to list the functions as separate elements.

Performance Requirement Examples:

- To pump sealant to panel at the rate of X cubic centimeters per minute
- To pump coolant to work piece at not less than X gallons per minute
- To achieve a torque of X N-m in Y seconds
- To ramp up to X degree Celsius in Y seconds and maintain temperature for Z seconds
- To transfer power from point A to point B
- To move product X meters in Y minutes

5.2.10 POTENTIAL FAILURE MODE—Potential Failure Mode is defined as the manner in which the machinery could potentially fail to meet or deliver its intended function described in Item/Function Requirements column (i.e., intended function fails). (See Figure 5A or 5B.)

The potential failure mode is a description of the nonconformance at that specific step, or function. It can be a cause associated with a potential failure mode in a subsequent (downstream) step or an effect associated with a potential failure in a previous (upstream) step. However, in preparation of the MFMEA, the following assumptions should be made:

- a. Incoming parts and materials are correct,
- b. Machinery will be built, installed, adjusted, and maintained to specifications, and,
- c. All preceding steps in the sequence of operations have been executed to specifications.

List each potential failure mode associated with the particular item and item function or step. The assumption is made that the failure could occur, but may not necessarily occur. A recommended starting point is a review of machinery supplier correction action reports, lessons learned documents (including end user and subsequent operations reports), machinery down time logs and group brainstorming.

Potential failure modes that could only occur under certain operating conditions (e.g., temperature extremes, high humidity, external shock/vibration) and under certain usage conditions (increased line rate) should be considered.

The machinery engineer/team should be able to pose and answer the following questions:

- a. How can the machinery/sequence step fail to meet engineering specifications?
- b. What could fail to meet customer (end user, subsequent steps of functions, or field service) expectations?

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

Bent	Broken	Worn
Cracked	Warped	Short circuit
Dirty	Binding	Open circuit
Grounded		

5.2.11 POTENTIAL EFFECTS OF FAILURE—The effects should be stated in terms of a specific system, subsystem, or component being analyzed. Any impact of the failure mode on upstream and downstream processes should also be stated.

State clearly if the function could impact safety or noncompliance to regulations and if operators and safety are potentially affected. The effects should always be stated in terms of what the customer might notice or experience (see 5.1.1). List all effects and rank the most severe effect.

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

Machinery breakdowns	Increased cycle time
Degraded Output	Impaired performance
Inadequate torque	Loss of production during operation
Intermittent operation	Partial or complete loss of function
Excessive Noise	Excessive vibration
Excessive effort required	Lack of repeatability
Endangers operator/technician	Excessive backlash

5.2.12 SEVERITY—Severity is the rank associated with the most serious effect for a given failure mode. Severity is a relative ranking, within the scope of the individual FMEA.

A reduction in Severity Ranking index can be effected only through a machinery design change. Severity should be estimated using Table 7.

5.2.12.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for an individual system. (See Table 7.)

NOTE—It is not recommended to modify criteria for ranking values of 9's and 10's. Failure Modes with a Severity rank of 1 should not be analyzed further.

TABLE 7—SUGGESTED SEVERITY EVALUATION CRITERIA

Effect	Severity of Effect	Ranking
Hazardous – Without Warning	Very high severity ranking – Affects operator, plant or maintenance personnel, safety, and/or affects non-compliance with government regulations, without warning.	10
Hazardous – With Warning	High severity ranking – Affects operator, plant or maintenance personnel, safety, and/or affects non-compliance with government regulations with warning.	9
Very High	Downtime of more than 8 h or the production of defective parts for more than 4 h.	8
High	Downtime of between 4 and 8 h or the production of defective parts for between 2 and 4 h.	7
Moderate	Downtime of between 1 and 4 h or the production of defective parts for between 1 and 2 h.	6
Low	Downtime of between 30 min and 1 h or the production of defective parts for up to 1 h.	5
Very Low	Downtime of between 10 and 30 min, but no production of defective parts.	4
Minor	Downtime of up to 10 min, but no production of defective parts	3
Very Minor	Process parameter variability not within specification limits. Adjustment or other process controls need to be taken during production. No downtime and no production of defective parts.	2
None	Process parameter variability within specification limits. Adjustment or other process controls can be done during normal maintenance	1

5.2.13 CLASSIFICATION—This column may be used to classify any special product characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional design or process controls. (See Figure 5A or 5B.)

This column may also be used to highlight high-priority failure modes for engineering assessment, if the Team finds this helpful, or if local management requires same.

Special Product or Process Characteristic symbols and their usage is directed by specific company policy and is not standardized in this document.

5.2.14 POTENTIAL CAUSES/MECHANISM'S OF FAILURE—Potential Cause of Failure is defined as an indication of a design weakness, the consequence of which is the failure mode. (See Figure 5A or 5B.)

List, to the extent possible, every potential cause and/or failure mechanism for each failure mode. The cause/mechanism should be listed as concisely and completely as possible so that remedial efforts can be aimed at pertinent causes.

Typical failure causes may include, but are not limited to:

- | | |
|---------------------------------------|-------------------------------------|
| Tool Drift | Contamination |
| Incorrect Material Specified | Inadequate Design Life Assumption |
| Over-stressing | Insufficient Lubrication Capability |
| Inadequate Maintenance Instructions | Incorrect Algorithm |
| Improper Maintenance Instructions | Improper Software Specification |
| Improper Surface Finish Specification | Inadequate Travel Specification |
| Improper Friction Material Specified | Excessive Heat |
| Improper Tolerance Specified | Worn Locator |
| | Chip on Locator |

Typical failure mechanisms may include, but are not limited to:

- | | |
|----------------------|--------------------|
| Yield | Chemical Oxidation |
| Fatigue | Electromigration |
| Material Instability | Wear |
| Creep | Corrosion |

5.2.15 (15) OCCURRENCE (O)—Occurrence is the likelihood that a potential cause/mechanism of failure will occur within a specific time period. Preventing or controlling the cause/mechanism of failure through a design change is the preferred way to reduce the occurrence ranking.

A consistent occurrence ranking system should be used to ensure continuity. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence.

5.2.15.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for an individual system. (See Table 8). The following suggested criteria allows for the use of standard operating time or reliability as a means for determining the occurrence rankings.

- a. Reliability is the probability that manufacturing machinery/equipment can perform continuously, without failure, for a specified interval of User's time when operating under stated conditions.
- b. User's time is the span of time the machinery is required to run without failure (time, cycles, etc.). The User's time frame should be defined in terms of an operating pattern that is important to the user.

NOTE—The ranking value of 1 is reserved for “Failure occurs once in 25 000 hours of operation”.

TABLE 8—SUGGESTED OCCURRENCE EVALUATION CRITERIA

Criteria: Possible Number of Failures within Hours of Operation	or	Criteria: Possible Number of Failures within Cycles of Operation	or	Criteria: The Reliability based on the Users Required Time	Ranking
1 in 1		1 in 90		R(t) <1%: MTBF is about 10% of the User's required time.	10
1 in 8		1 in 900		R(t) = 5%: MTBF is about 30% of User's required time	9
1 in 24		1 in 36000		R(t) = 19%: MTBF is about 60% of the User's required time.	8
1 in 80		1 in 90000		R(t) = 37%: MTBF is equal to the User's required time.	7
1 in 350		1 in 180000		R(t) = 61%: MTBF is 2 times greater than the User's required time.	6
1 in 1000		1 in 270000		R(t) = 78%: MTBF is 4 times greater than the User's required time.	5
1 in 2500		1 in 360000		R(t) = 85%: MTBF is 6 times greater than the User's required time.	4
1 in 5000		1 in 540000		R(t) = 90%: MTBF is 10 times greater than the User's required time.	3
1 in 10 000		1 in 900000		R(t) = 95%: MTBF is 20 times greater than the User's required time.	2
1 in 25 000		1 in more than 900000 cycles		R(t) = 98%: MTBF is 50 times greater than the User's required time.	1

NOTE—The reliability values listed previously assume the machines have a constant failure rate and are repairable. See Appendix J for sample calculations for the occurrence table.

5.2.16 CURRENT MACHINERY CONTROLS—List the prevention, detection, design validation/verification (DV), or other activities that have been completed or committed to and that will assure the design adequacy for the failure mode and/or cause/mechanism under consideration. Current controls (e.g., design reviews, mathematical studies, feasibility review, prototype tests) are those that have been or are being used with the same or similar designs. The team should always be focused on improving design controls; for example, creating new system tests, or creating new system modeling algorithms, etc. There are two types of design controls to consider:

- a. Prevention: Prevent the cause/mechanism of failure or the failure mode from occurring, or reduce their rate of occurrence.
- b. Detection: Detect the cause/mechanism of failure or the failure mode, either by analytical or physical methods.

The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the design intent. The initial rankings for detection will be based on design controls that either detect the cause/mechanism of failure, or detect the failure mode.

For example, consider a failure mode of “belt breaks”. A detection control could be a sensor that detects the breakage and notifies through the use of an alarm or light that the belt has broken. A prevention control could be a sensor with a feedback system to an automatically adjustable pulley system that continuously adjusts the tension to prevent the belt from breaking, and thus, reduces the rate of occurrence of the belt breaking due to improper tension.

The Machinery FMEA form in this manual has two columns for the machinery controls (i.e., separate columns for Prevention Controls and Detection Controls) to assist the team in clearly distinguishing between these two types of machinery controls. This allows for a quick visual determination that both types of machinery controls have been considered. Use of this two-column form is the preferred approach. (See Figure 5A.)

If a one-column (for machinery controls) form is used, then the following prefixes should be used. For prevention controls, place a ‘P’ before each prevention control listed. For detection controls, place a ‘D’ before each detection control listed. Once the machinery controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised. (See Figure 5B.)

5.2.17 DETECTION—Detection is the rank associated with the best detection control listed in the machinery controls. Detection is a relative ranking, within the scope of the individual FMEA. In order to achieve a lower ranking, generally the planned machinery control has to be improved. (See Table 9.)

5.2.17.1 *Suggested Evaluation Criteria*—The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for an individual system.

NOTE—The ranking value of 1 is reserved for “Almost Certain.”

TABLE 9—SUGGESTED DETECTION EVALUATION CRITERIA

Detection	Criteria: Likelihood of Detection by Design and/or Machinery Control	Ranking
Almost Impossible	Design and/or Machinery Controls cannot detect a potential cause and subsequent failure, or there are no design or machinery controls.	10
Very Remote	Very remote chance that design and/or machinery controls will detect a potential cause and subsequent failure mode.	9
Remote	Remote chance that design and/or machinery controls will detect a potential cause and subsequent failure mode. Machinery control will provide indication of failure.	8
Very Low	Design and/or Machinery controls do not prevent the failure from occurring. Machinery controls will isolate the cause and subsequent failure mode after the failure has occurred.	7
Low	Low chance that design and/or machinery controls will detect a potential cause and subsequent failure mode. Machinery controls will provide an indicator of imminent failure.	6
Medium	Medium chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent imminent failure.	5
Moderately High	Moderately high chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent imminent failure.	4
High	High chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent an imminent failure and isolate the cause.	3
Very High	Very high chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls may not be required.	2
Almost Certain	Design controls almost certain to detect a potential cause and subsequent failure mode, machinery controls not required.	1

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- 5.2.18 **RISK PRIORITY NUMBER**—The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. (See Figure 5A or 5B).

$$\text{RPN} = (\text{S}) \times (\text{O}) \times (\text{D}) \quad (\text{Eq. 3})$$

Within the scope of the individual FMEA, this value (between “1” and “1000”) can be used to rank order the concerns in the design (e.g., in Pareto fashion).

- 5.2.19 (19) **RECOMMENDED ACTION(S)**—Engineering assessment for corrective action should be first directed at high severity, high RPN, and other items designated by the team. The intent of any recommended action is to reduce rankings, in the following preference order: severity, occurrence, and detection rankings. (See Figure 5A or 5B.)

In general practice when the severity is a “9” or “10”, special attention must be given to assure that the risk is addressed through existing design and/or machinery controls or preventative/corrective action(s), regardless of the RPN. In all cases where the effect of an identified potential failure mode could be a hazard to manufacturing/ assembly personnel, preventive/corrective actions should be taken to avoid the failure mode by eliminating or controlling the cause(s), or appropriate operator protection should be specified.

After special attention has been given to Severity(s) of 9 or 10, the team then addresses other Failure Modes, with the intent of reducing Severity, then Occurrence, and then Detection. The primary objective of recommended actions is to reduce risks, increase customer satisfaction, and improve the reliability, maintainability, and durability of the machine.

Only a design revision can bring about a reduction in the severity ranking. A reduction in the occurrence ranking can be effected only by removing or controlling one or more of the causes/mechanisms of the failure mode through a design revision. An increase in design validation/verification actions, machine controls, inspection, and/or preventive/predictive maintenance will result in a reduction in the detection ranking only. Increasing the design validation/verification actions is a less desirable engineering action since it does not address the severity or occurrence of the failure mode.

If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering a “NONE” in this column.

- 5.2.20 **RESPONSIBILITY (FOR THE RECOMMENDED ACTION)**—Enter the organization and individual responsible for the recommended action and its target completion date. (See Figure 5A or 5B.)
- 5.2.21 **ACTIONS TAKEN**—After an action has been implemented, enter a brief description of the actual action taken and its effective date. (See Figure 5A or 5B.)
- 5.2.22 **REVISED RATINGS**—After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the related ranking columns blank. (See Figure 5A or 5B.)

All revised ratings should be reviewed and if further action is considered necessary, repeat the analysis. The focus should always be on continuous improvement.

- 5.2.23 **FOLLOW-UP ACTIONS**—See 1.5.

6. **Notes**

- 6.1 **Marginal Indicia**—The change bar (I) located in the left margin is for the convenience of the user in locating areas where technical revisions have been made to the previous issue of the report. An (R) symbol to the left of the document title indicates a complete revision of the report.

PREPARED BY THE SAE AUTOMOTIVE QUALITY AND PROCESS IMPROVEMENT GROUP

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APPENDIX A

DESIGN FMEA QUALITY OBJECTIVES

NOTE: SPECIFIC PROGRAM REQUIREMENTS TAKE PRECEDENCE

1. DESIGN IMPROVEMENTS
The FMEA drives Design Improvements as the primary objective.
2. HIGH RISK FAILURE MODES
The FMEA address all high risk Failure Modes, as identified by the FMEA team, with executable Action Plans. All other failure modes are considered.
3. A/D/V OR DVP&R PLANS
The Analysis/Development/Validation (A/D/V), and/or Design Verification Plan and Report (DVD&R) considers the failure modes from the Design FMEA.
4. INTERFACES
The FMEA scope includes integration and interface failure modes in both block diagram and analysis.
5. LESSONS LEARNED
The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification.
6. SPECIAL OR KEY CHARACTERISTICS
The FMEA identifies appropriate Key Characteristics candidates, as input to the Key Characteristics selection process, if applicable due to company policy.
7. TIMING
The FMEA is completed during the "Window of Opportunity" where it could most efficiently impact the product design.
8. TEAM
The right people participate as part of the FMEA team throughout the analysis, and are adequately trained in FMEA methods. As appropriate, a facilitator should be used.
9. DOCUMENTATION
The FMEA document is completely filled out "by the book", including "Action Taken" and new RPN values.
10. TIME USAGE
Time spent by the FMEA team, as early as possible, is an effective and efficient use of time, with a value-added result. This assumes Recommended Actions are identified as required and the actions are implemented.

APPENDIX B

PROCESS FMEA QUALITY OBJECTIVES

NOTE: SPECIFIC PROGRAM REQUIREMENTS TAKE PRECEDENCE

1. PROCESS IMPROVEMENTS
The FMEA drives Process Improvements as the primary objective, with an emphasis on Error/Mistake Proofing solutions.
2. HIGH RISK FAILURE MODES
The FMEA addresses all high risk Failure Modes, as identified by the FMEA team, with executable Action Plans. All other failure modes are considered.
3. CONTROL PLANS
The Pre-launch and Production Control Plans consider the failure modes from the Process FMEA.
4. INTEGRATION
The Process FMEA is integrated and consistent with the Process Flow Diagram and the Process Control Plan. The Process FMEA considers the Design FMEA as part of its analysis.
5. LESSONS LEARNED
The FMEA considers all major "lessons learned" (such as high warranty, campaigns, non-conforming product, customer complaints, etc.) as input to failure mode identification.
6. SPECIAL OR KEY CHARACTERISTICS
The FMEA identifies appropriate Key Characteristics candidates, as input to the Key Characteristics selection process, if applicable due to company policy.
7. TIMING
The FMEA is completed during the "Window of Opportunity" where it could most efficiently impact the design of product or process.
8. TEAM
The right people participate as part of the FMEA team throughout the analysis, and are adequately trained in FMEA methods. As appropriate, a facilitator should be utilized
9. DOCUMENTATION
The FMEA document is completely filled out "by the book", including "Action Taken" and new RPN values.
10. TIME USAGE
Time spent by the FMEA team, as early as possible, is an effective & efficient use of time, with a value-added result. This assumes Recommended Actions are identified as required and the actions are implemented.

APPENDIX C

DESIGN FMEA BLOCK DIAGRAM EXAMPLE

FAILURE MODE AND EFFECTS ANALYSIS (FMEA)
BLOCK DIAGRAM/ENVIRONMENTAL EXTREMES

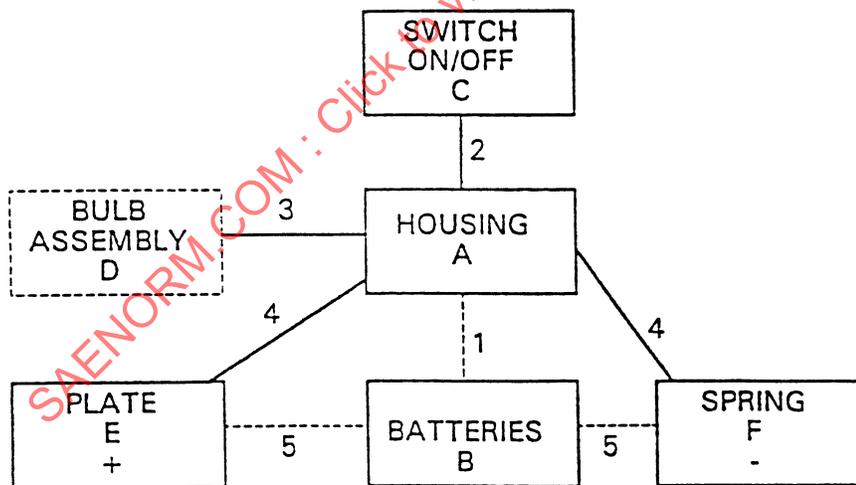
SYSTEM NAME: FLASHLIGHT
YEAR VEHICLE PLATFORM: 1994 NEW PRODUCT
FMEA I.D. NUMBER: XXXI10D001

OPERATIONAL ENVIRONMENTAL EXTREMES

TEMPERATURE: -20 to 160 °F CORROSIVE: TEST SCHEDULE B VIBRATION: NOT APPLICABLE
SHOCK: 6 FOOT DROP FOREIGN MATERIAL: DUST HUMIDITY: 0 - 100% RH
FLAMMABILITY: (WHAT COMPONENT(S) ARE NEAR HEAT SOURCE(S)? _____
OTHER: _____

LETTERS = COMPONENTS _____ = ATTACHED/JOINED - - - - = INTERFACING, NOT JOINED = NOT INCLUDED IN THIS FMEA
NUMBERS = ATTACHING METHODS

The example below is a relational block diagram. Other types of block diagrams may be used by the FMEA Team to clarify the item(s) being considered in their analysis.



- | COMPONENTS | ATTACHING METHOD |
|-------------------------|--------------------|
| A. HOUSING | 1. SLIP FIT |
| B. BATTERIES (2 D Cell) | 2. RIVETS |
| C. ON/OFF SWITCH | 3. THREAD |
| D. BULB ASSEMBLY | 4. SNAP FIT |
| E. PLATE | 5. COMPRESSIVE FIT |
| F. SPRING | |

FIGURE C1—DESIGN FMEA BLOCK DIAGRAM EXAMPLE

**POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)**

System _____ FMEA Number _____
 Subsystem _____ Page _____ of _____
 Component _____ Prepared By _____
 Model Year(s)/Program(s) _____ Design Responsibility _____ FMEA Date (Orig.) _____ (Rev.) _____
 Key Date _____
 Core Team _____

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C I S S I S	P o t e n t i a l C a u s e (s) M e c h a n i s m (s) o f F a i l u r e	O c c u r r e n c e	C u r r e n t D e s i g n C o n t r o l s - P r e v e n t i o n - D e t e c t i o n	D e t e r m i n e d R e s p o n s i b i l i t y	R e c o m m e n d e d A c t i o n (s)	R e s p o n s i b i l i t y & T a r g e t C o m p l e t i o n D a t e	A c t i o n s T a k e n	A c t i o n R e s u l t s				
											S e v e r i t y	O c c u r r e n c e	D e t e c t i o n	R e p a r a b i l i t y	

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FIGURE D2—STANDARD FORM FOR DESIGN FMEA
 – ONE COLUMN, CURRENT DESIGN CONTROLS –

APPENDIX F
SYSTEM FMEA

F.1 Section 3.2.2 discusses the scope of System, Subsystem, and Component FMEA's. To help illustrate the meaning of these FMEA's, two examples have been constructed in Figure F1 (for Interfaces and Interactions) and in Figure F2 (for Item, Function, and Failure Modes).

EXAMPLE 1: Interfaces and Interactions

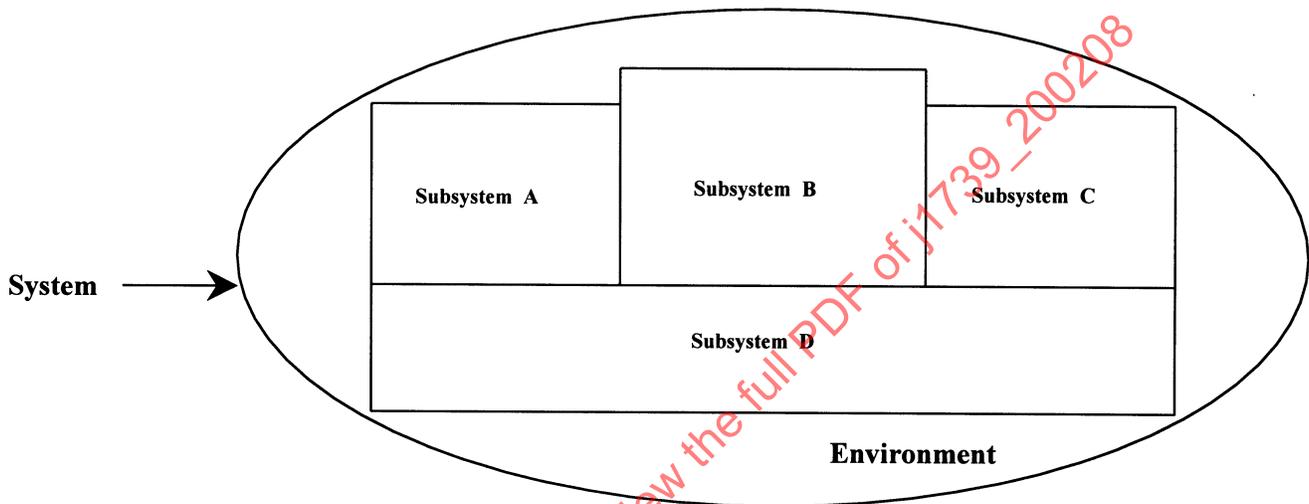


FIGURE F1—INTERFACES AND INTERACTIONS

It is the responsibility of the FMEA Team to specify the scope of their respective FMEA's. The example in Figure F1 shows that the Team has specified Subsystems A, B, C, and D along with the surrounding environment as comprising the System that must be considered while completing the System FMEA.

INTERFACES: SUBSYSTEMS ARE DIRECTLY CONNECTED VIA INTERFACES.

In Figure F1, interfaces between subsystems are shown where Subsystem A touches (connects with) Subsystem B, B touches C, C touches D, A touches D, and B touches D. It should be noted that the Environment also touches each of the subsystems listed in Figure F1, which requires that the 'Environmental Interfaces' be considered when completing the FMEA.

NOTE—Each Subsystem FMEA should have its Interfaces included in its respective Subsystem FMEA.

INTERACTIONS: A CHANGE IN ONE SUBSYSTEM MIGHT CAUSE A CHANGE IN ANOTHER SUBSYSTEM.

In Figure F1, interactions between subsystems can occur between any of the interfacing systems (e.g., Subsystem A heats up resulting in Subsystem D and Subsystem B also gaining heat through the respective interfaces, as well as the Subsystem A giving off heat to the environment). Interactions might also occur between 'non-contacting' systems via transfer through the 'environment' (e.g., if the environment is composed of high humidity and Subsystems A and C are dissimilar metals separated by a non-metal composing Subsystem B, Subsystems A and C can still have an electrolytic reaction due to the moisture from the environment). Thus, interactions between non-contacting subsystems can be relatively difficult to predict, but are important and should be considered.

EXAMPLE 2: Items, Functions, and Failure Modes

Figure F2 (see next page) describes a method of showing the Items, Functions, and Failure Modes in a 'tree arrangement' that can assist the team in visualizing the System, Subsystems, and Components. At the System Level, the descriptions will tend to be much more general than for the Subsystems and Components (Components will usually have the most specific descriptions).

The 'tree arrangement' is arranged as follows for the System, Subsystem, and Components:

ITEM

Design Objectives (a statement of design objectives is often helpful)

--FUNCTION 1

FAILURE MODE A
FAILURE MODE B
etc.....

--FUNCTION 2

FAILURE MODE A
FAILURE MODE B
etc.....

-- etc.....

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