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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)	

RATIONALE

Widespread use of design and process FMEA is a benefit to consumers and manufacturers. The application of FMEA has been in place in the automotive industry since the late 1960's with emphasis on standard ranking criteria and forms since the early 1990's. The FMEA methodology has proven itself useful in the prevention and mitigation of potential failure modes. However, a growing need developed for improved failure mode ranking criteria and a change in thinking about the use of the Risk Priority Number (RPN). This standard includes updated ranking charts and de-emphasizes the use of an RPN threshold as the primary factor in determining preventive or corrective action efforts. It also includes a Boundary Diagram and Process Flow Diagram example as use of these tools has increased. The section for Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA) is a form of Design FMEA and has been removed. Machinery FMEA is a type of Design FMEA for equipment. There are numerous books, reference manuals and training references on the subject of FMEA. This standard serves as a common starting point for the development of an effective DFMEA and PFMEA.

FOREWORD

The former Recommended Practice for Potential Failure Mode and Effects Analysis in Design (DFMEA) and Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (PFMEA) has been revised and approved as a Standard. As such, it contains requirements and recommendations for effective use of DFMEA and PFMEA as a potential failure analysis tool. This document was revised by a balanced committee and represents current thoughts and practices on the subject from the viewpoint of OEM (Original Equipment Manufacturers) and their suppliers.

1. SCOPE

This FMEA Standard describes Potential Failure Mode and Effects Analysis in Design (DFMEA) and Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (PFMEA). It assists users in the identification and mitigation of risk by providing appropriate terms, requirements, ranking charts, and worksheets. As a Standard, this document contains requirements "must" and recommendations "should" to guide the user through the FMEA process. The FMEA process and documentation must comply with this Standard as well as any corporate policy concerning this Standard. Documented rationale and agreement with the customer is necessary for deviations in order to justify new work or changed methods during customer or third-party audit reviews.

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2. REFERENCES

2.1 Related Information

The following referenced documents may be useful in connection with the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1.1 SAE Publication

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

ARP5880 Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications, Issued July 2001, (Replaces MIL-STD-1629a)

2.1.2 IEC Publication

Available from International Electrotechnical Commission, 3, rue de Verambe, P.O. Box 131, 1211 Geneva 20, Switzerland, Tel: +41-22-919-02-11, www.iec.ch.

IEC 60812 Analysis Techniques for System Reliability – Procedure for Failure Mode and Effects Analysis (FMEA), January 2006

2.1.3 AIAG Publication

Available from Automotive Industry Action Group, 26200 Lahser Road, Suite 200, Southfield, MI 48034-7100, Tel: 248-358-3570, www.aiag.org.

Potential Failure Mode and Effects Analysis (FMEA) Reference Manual, Chrysler LLC, Ford Motor Company, General Motors Corporation, Fourth Edition, June 2008

3. TERMS AND DEFINITIONS

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

3.1 Baseline FMEA

A baseline FMEA document contains enough similarities when compared to the new FMEA project, to promote its usefulness as a starting point for that new FMEA project. The baseline FMEA is not program specific and its use is optional. Common names for a baseline FMEA also include Generic, Best Practice, and Gold Standard.

3.2 Block Diagram

The Block or Boundary Diagram is a pictorial tool to facilitate analysis of system interfaces usually used in Design FMEAs. It defines the analysis scope and responsibility and it provides guidelines for structured brainstorming. The scope of analysis is defined by the boundaries of the system; however interfaces with external factors/systems are to be addressed. An example of a block diagram can be found in Appendix D. An example of a boundary diagram can be found in Appendix E.

3.3 Control Plan

Written descriptions of the system used for controlling parts and processes. It can be component or process specific, or family where multiple parts are produced using the same processing line. The control plan describes the actions that are required at each phase of the process including receiving, processing, material handling, and periodic requirements to assure that all process outputs will be in control. The control plan provides the process monitoring and control methods that will be used to control product or process characteristics. Typical types include Prototype, Pre-Launch and Production.

3.4 Customer

The customer includes all users of the product. Customers are end users (external), manufacturing and assembly operations (internal) and service operations (external). Internal customers can be interim users of the product such as the next higher-level assembly or users of the process such as subsequent manufacturing operations.

3.5 FMEA Team

A team consists of knowledgeable individuals who perform the FMEA analysis. This may include but is not limited to representatives from: Design, Manufacturing, Validation, Suppliers, Materials, Service, Quality, Reliability and Technical Experts.

3.6 FMEA Worksheet

The content of the FMEA worksheet is the output of a Design or Process FMEA. The worksheet provides a structure for conducting risk analysis. An example of a DFMEA worksheet can be found in Appendix F. An example of a PFMEA worksheet can be found in Appendix I. These worksheets can be modified to meet company requirements (e.g. add or move columns, but column headings are standardized and should not change so the logic of the analysis is not lost).

3.7 Hidden Factory

A hidden factory is a deviation from the planned process flow. A hidden factory occurs when the product is handled other than in accordance with the planned process flow (all operations included in a process flow such as rework/repair, scrap, material movement, etc. are planned). Examples such as ad hoc repairs in a storage facility, hand torque due to equipment being down for repair, handling of parts that have failed in-process tests, and extra parts at a station may be considered part of a hidden factory. Hidden factory processes may contribute to the realization of failure modes or defects in a manufacturing or assembly process because a hidden factory doesn't prevent reject parts from re-entering the line or parts being mixed.

3.8 Product Family DFMEA

A product family FMEA is a specialized baseline design FMEA that generally contains consistent product boundaries and related functions. These would not typically change from one application to another. Added to this product family FMEA would be the new project specific components and related functions to complete the new product FMEA.

3.9 Process Family PFMEA

A process family FMEA is a PFMEA covering a series of operations that produce multiple products or part numbers. Processes producing many similar products do not need unique FMEA's for each product. The family PFMEA is dictated by the manufacturing process that is used to make the product, not by the product's functional requirements or application. When the manufacturing process is the same as other parts in the family then a family PFMEA is appropriate.

3.10 Process Flow Diagram

A process flow diagram is a graphical representation of the movement of product or a service as they travel through the processing cycle. A process flow includes the primary process flow as well as secondary operations such as off-line inspection or off-line repair and material movement. It can be macro level listing all operation steps or micro level detailing each incremental step of work or processing being performed within an operation. A process flow diagram may also include potential sources of variation (some of which may be process characteristics) and necessary product or process requirements. An example of a process flow diagram can be found in Appendix H.

3.11 Risk Mitigation

The primary objective of the FMEA process is to identify potential high risks and try to keep those high risks from occurring in the end product or if that cannot be accomplished, then to minimize the risk effect(s) to the end product user. There are only three ways (factors) one can mitigate risk: change the design, prevent the risk from occurring or detect it so that a follow up action can take place to eliminate or reduce the risk effect(s).

4. OVERVIEW

4.1 Introduction

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 and causes 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.

The earlier the FMEAs are started during the development phase, the better the chances of optimizing the various activities/designs/processes in a cost and time effective manner. 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 should 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 that would create an even larger concern.

There are three basic cases for which FMEAs 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 an FMEA for the existing design or process). The scope of the revision efforts should focus on the modification to design or process, possible interactions due to the modification, and field performance. Modifications include removal or addition of new parts or processing operations. Modifications also include changes to existing product or process functions

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 revision 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 consulted (e.g., engineers with expertise in design, analysis/testing, manufacturing, assembly, service, recycling, quality, and reliability). The FMEA should be a catalyst to stimulate the interchange of ideas between the functions affected and thus promote a team approach.

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).

4.2 Purpose and Objectives

The intended purpose of the Design and Process FMEA is to support the processes used to design, manufacture, or assemble a product. The objectives can best be met by considering the following:

- a. Risk identification
- b. Risk prioritization
- c. Risk mitigation

The fundamental value of the FMEA process is to identify potential risks, rank those risks, and then mitigate as many of those risks over time as possible. There are at least three key categories of risks discussed during the FMEA process including **design risks** (i.e., requirements and specification errors, engineering calculation error or material selection error, etc.), **failure to warn risks** (i.e., inadequate or missing labels/information, etc.), and **process risks** (i.e., manufacturing errors, etc.).

5. FMEA GENERAL REQUIREMENTS

5.1 Ownership

Management must establish design and process FMEA ownership for the analysis. The owner of the FMEA will establish the FMEA team, as necessary, to suit the needs of the scope and ensure timely analysis.

Management must establish ownership for FMEA procedures and methodology.

5.2 Storage and retrieval

Management must ensure a system is in place for storage and retrieval of FMEA documents.

5.3 Confidentiality

Management or the FMEA team must determine when a FMEA is deemed Confidential.

NOTE: Proprietary, Confidential and Secret document handling is not prescribed by this document.

5.4 Usage

Management must establish a corporate policy regarding the application of FMEA as related to the corporation's product development program from concept design through validation, start of production and beyond.

6. DESIGN FMEA

6.1 Timing

The Design FMEA should typically be started after project initiation and completed prior to design release. Baseline FMEAs or product family FMEAs from similar products are the starting point for the risk management process when available. The baseline FMEA or product family FMEA should be edited to document those specific design and application differences between the baseline project and the current project. Changes to the Design FMEA can be made throughout product development and regular production.

6.2 Scope

The scope of a DFMEA depends on many factors including:

- a. design-responsibility
- b. interfaces/interactions
- c. system architecture

The scope of a Design FMEA can more easily be defined by using a block diagram, interface diagram, functional diagram, structure tree, schematic illustration or similar tool that represents elements being analyzed. This 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 be available upon request.

6.2.1 Design Responsibility

The scope should define the hardware for which the team is responsible for designing. This defines the elements that will be analyzed. This is the item for which the engineering team has design ownership and risk mitigation.

6.2.2 Interfaces and Interactions

The team should discuss and document the interfaces to other components, subsystems or systems. These are the physical interfaces that are required for securing the item, transmitting signals, fluids, or power. They also include non-physical interactions that could influence the products functionality such as High Intensity Radiated Frequencies. These interfaces and interactions may be analyzed using an interface FMEA or included in a component, subsystem or system analysis.

6.2.3 System Architecture

The team should discuss and document information about the item being analyzed by defining what role the item plays in the overall design (e.g. the item is a component in the AC compressor, or a sub-assembly to the instrument cluster). This also defines design architecture levied by the customer (e.g. the console will have four cup holders, two power points, two ashtrays, and a coin holder).

6.3 Inputs

The DFMEA team should review various inputs such as:

- a. Warranty
- b. Recalls
- c. Engineering requirements
- d. Drawings
- e. Lessons learned
- f. Preliminary design verification plan
- g. Best Practices
- h. Baseline/family or prior DFMEA
- i. Higher level FMEA (System FMEA or Design FMEA)
- j. Bill of Material
- k. Manufacturing feasibility study
- l. Diagrams such as a Block Diagram or Boundary Diagram

6.4 Outputs

The DFMEA team should produce various outputs such as:

- a. Failure mode risk assessment
- b. Failure mode risk mitigation (recommended actions)
- c. DFMEA document(s)

6.5 Assumptions

The DFMEA should address the design intent and assume the design will be manufactured /assembled to this intent. The PFMEA should address manufacturing and assembly risk. However, this does not prevent a team from considering design for assembly and design for manufacturing functions as part of the DFMEA (e.g. when known failures have occurred in the past).

The DFMEA should not rely on manufacturing 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 harden ability of steels
- e. Tolerances/process capability/performance
- f. Die capability and limitations

The DFMEA, as an analytical engineering tool, records the ideas and concerns of a design team; therefore it is understood that failures shown in the DFMEA are potential. As such, failures described in the DFMEA may or may not occur.

6.6 Procedure

6.6.1 Header Information

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

6.6.2 Item

The name or other pertinent information (e.g. the number, the part class, etc.) of the item being analyzed must be written in the DFMEA.

6.6.3 Function and Requirement

A design function is a description of the design intent for a system, subsystem, or component. The function(s) of each item being analyzed must be written in the DFMEA. A product may have more than one function.

The more precise the function, the easier it is to identify potential failure modes for preventive/corrective action. If the item has more than one function with different potential modes of failure, list all the functions separately in the DFMEA worksheet.

A product requirement defines how a product function should perform. A product function may have multiple requirements. Product requirements relate to the desired output of a function such as power or fluid flow. Requirements are measurable characteristics of a product function or its operation and may be documented in the DFMEA worksheet. Values for requirements should be included in the product specification to define the acceptance criteria for the validation test plan. Design features should be included in the product drawing.

Typical functions could be, but are not limited to:

Transforms (speed and torque)
Operates (quietly)
Contains (operating fluids)
Attaches to (mating part)

Typical requirements could be, but are not limited to:

Pressure (xx psi)
Flow rate (xx lpm)
Noise levels (at cold start)
Noise levels (during operation)
External leakage specification
Positive contact

6.6.4 Potential Failure Mode

The failure modes are the manner in which a component, subsystem, or system could potentially fail to meet or deliver the intended function(s) and its requirements. The failure mode(s) should be written in the DFMEA for each function identified. The team determines the priority in which to analyze functions. Each potential failure mode in an FMEA is considered independently of another failure mode. This enables the team to address the unique reasons (causes of failure) independently of other failure modes. Grouping multiple potential failure modes in one cell in a worksheet is not recommended.

There are at least five different types of potential failure modes discussed during the FMEA process including loss of function (i.e. inoperable, etc.), partial function (i.e. performance loss, etc.), intermittent function (i.e. operation starts/stops/starts often as a result of moisture, temperature, etc.), degradation (i.e. performance loss over time, etc.), and unintended function (i.e. operation at the wrong time, unintended direction, etc.). The team should describe component/system failure behavior in physical terms, different from the desired outcome or function.

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

Does not transmit torque	Slips (does not hold full torque)
No support (structural)	Inadequate support (structural)
No signal	Intermittent signal
Complete fluid loss	Leaking more than xx
Does not disengage	Disengages too fast

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

cracked	deformed
sticking	oxidized
fractured	loose

NOTE: A detailed component failure mode can be the cause of an integrated system failure mode in a higher-level subsystem.

6.6.5 Potential Effects

The effects are consequences or results of each failure mode. The effect(s) must be listed in the DFMEA for each failure mode in the Potential Effects column. The effects of the failure mode should be considered against the next level up assembly, the final product, and the end customer when known. End customer effects should state what the user might notice or experience. They should clearly state if the effect of a failure mode could impact safety or non-compliance to regulations, when applicable. The intent is to forecast the failure effects consistent with the team's level of knowledge.

Typical effects could be, but are not limited to:

1. No discernable effect
2. Noise e.g. misalignment/rub, squeak/rattle
3. Poor appearance e.g. unsightly close-out, color fade, cosmetic corrosion
4. Noise e.g. fluid-borne noise, squeak/rattle, chirp, squawk
5. Unpleasant odor, rough feel, increased efforts
6. Operation impaired, intermittent, unable to operate, electro-magnetic compatibility (EMC)
7. External leak resulting in performance loss, erratic operation, unstable
8. Unable to drive vehicle (walk home)
9. Loss of steering or braking with warning to driver, regulatory non-compliance with warning
10. Loss of steering or braking without warning to driver, regulatory non-compliance without warning

NOTE: In some cases, the team conducting the analysis may not know the end user effect (e.g. commodity parts such as screws and bolts). When this information is not known, the effects should be defined in terms of the part function and specification.

NOTE: Some failures may be considered failure modes, effects or causes (e.g. leaks) depending on the function and requirements of a system, subsystem or component.

6.6.6 Severity Ranking Number

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

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

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

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

One of the goals of the FMEA process is to mitigate risk or lessen the impact of a potential failure mode. The severity ranking itself can not be changed without eliminating the failure mode and its effects.

NOTE: Writing the individual severity numbers for each effect as part of the effects description is considered a best practice with the highest (worst case) effect used as the severity number.

6.6.7 Classification

The use of the classification column is optional in a DFMEA. This column may be used to highlight failure modes or causes for the purpose of identifying issues to be further discussed with the team as well as others outside the team including management and a Process FMEA team to determine if additional action is necessary. Certain letter codes or symbols may be used. Companies may use various criteria for including:

- High priority failure modes (based on Severity, Severity and Occurrence, Severity and Detection)
- Special characteristics (examples include safety, government, critical, and key characteristics which are directed by specific company policy and are not standardized in this document)

- Warranty campaigns and recalls
- Other criteria specified by the team

6.6.8 Potential Cause of Failure

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

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

- **Design for functional performance** (incorrect material specified, incorrect geometry, incorrect part selected for application, incorrect surface finish specified, inadequate travel specification, improper friction material specified, insufficient lubrication capability, inadequate design life assumption, incorrect algorithm, improper software specification, improper maintenance instructions, etc.)
- **System interactions** (mechanical interfaces, fluid flow, heat sources, controller feedback, etc.)
- **Changes over time** (yield, fatigue, material instability, creep, wear, corrosion, chemical oxidation, electro migration, over-stressing, etc.)
- **External environment** (heat, cold, moisture, vibration, road debris, road salt, etc.)
- **Customer use** (high speeds, towing, fuel types, service damage, etc.)
- **Piece to piece variation** (variation within tolerance)
- **Design for manufacturing** (part geometry allows part installation backwards or upside down, part lacks distinguishing design features, shipping container design causes parts to scratch or stick together, part handling causes damage, etc.)

NOTE: The above examples represent categories. Specific details need to be added to complete the cause description. Only specific failure causes (e.g. radius too small) should be listed; ambiguous phrases (e.g., poor design) should not be used.

NOTE: The Design FMEA team should include appropriate subject matter experts that can provide accurate information about how the proposed design can impact the vehicle driver, interfacing systems, manufacturing, etc. Similarly, the Process FMEA team should include appropriate subject matter experts that can provide accurate information about how the proposed manufacturing process and error proofing solutions can impact the vehicle driver, interfacing systems, and the functionality of the product.

6.6.9 Occurrence Ranking Number

Occurrence is a ranking number associated with each cause for a given failure mode being evaluated. The occurrence ranking considers the likelihood of occurrence during the design life of the product. The occurrence ranking number has a relative meaning rather than an absolute value and is determined without regard for severity or detection. The occurrence ranking takes into account the prevention-type design controls.

Occurrence should be estimated using the criteria in Appendix B – Suggested DFMEA Occurrence Evaluation Criteria. The table may be supplemented with warranty data. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The occurrence ranking itself can not be changed without changing the design to decrease the chance of the failure cause and subsequent failure mode from happening. In the case of a new design (new technology), the occurrence number can be reduced from a 10 (new design, no history) once test or field data/experience has been gained.

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

6.6.10 Current Design Controls – Prevention

Current design controls are controls that are being used with the same or similar designs. Prevention types of design controls should be considered when developing the DFMEA, as applicable. A prevention control may not be applicable for every cause and/or failure mode. When not applicable, the prevention controls column on the worksheet can be left blank.

Prevention type design controls describe how a cause, failure mode or effect is prevented. It is part of the basis for determining the rate of occurrence. It is an input to the occurrence ranking when integrated as part of the design intent. Prevention design controls are based on the application of standards, specifications, design rules, design guides, lessons learned, legal standards, design norms or best practices, etc. as a means prevent field failure.

Causes or failure modes that are managed by system detection, decisions and/or actions during normal operation can also be considered prevention design controls because detection controls in the typical DFMEA are limited to product development prior to customer usage. The intent of risk mitigating systems is to detect, by design, a condition or problem and once detected, either take appropriate actions to reduce or eliminate the risk effects or communicate to the end user to take action as failure could be inevitable. Some mitigating prevention controls may also influence the failure effects and severity.

The Design FMEA Example in Appendix G 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. If a one-column (for design controls) form is used, then the following prefix should be used. For prevention controls, place a 'P' before each prevention control listed.

Typical current design controls – prevention could be, but are not limited to:

- Published design standard for thread class
- Heat treat specification on drawing
- Redundant design includes sensor shield
- Corporate best practice standard design
- System detection and driver notification for service
- System detection and operational status displayed to driver

NOTE: Use of “carryover design” as a prevention control can only be applied when the application, duty cycle, etc. are the same (no change). Poor field history for a “carryover design” will mean “carryover quality”. The Design FMEA team should consider improvements to a carryover design as necessary.

6.6.11 Current Design Controls – Detection

Detection design controls should be considered when developing the DFMEA as applicable. The detection type of design control describes how a cause and/or failure mode is detected, either by analytical or physical methods, before the item is released to production and is used as an input to the detection ranking. A detection control may not be applicable for every cause and/or failure mode. When not known or not applicable, the detection controls column on the worksheet can be left blank and should be ranked according to the Detection ranking criteria (i.e. Detection 10).

The Design FMEA Example in Appendix G 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. If a one-column (for design controls) form is used, then the following prefix should be used. For detection controls, place a 'D' before each detection control listed.

Typical current design controls – detection could be, but are not limited to:

- Finite Element Analysis (FEA)
- CAE analytics
- Tolerance stack analysis
- Validation testing (fatigue, water intrusion, vibration, ride and handling, etc.)

NOTE: Manufacturing process controls are not valid design controls.

NOTE: Writing the individual detection numbers for each design control as part of the design control description is considered a best practice with the lowest (best case) detection method used as the detection number.

6.6.12 Detection Ranking Number

Detection is the rank associated with the best design control from the list of detection-type design controls. Detection is a relative ranking, within the scope of the individual FMEA and is determined without regard for severity or occurrence. Detection should be estimated using the criteria in Appendix C – Suggested DFMEA Detection Evaluation Criteria. This table may be augmented with examples of common detection methods used by the company. The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual process analysis.

One of the goals of the DFMEA process is to increase the ability to validate a design prior to start of production. The detection ranking itself can not be improved without changing the sensitivity to detect failure modes during validation and/or verification activities as well as the timing of such activities.

NOTE: Controls such as those that detect and react to faults during vehicle operation are considered mitigating controls. Mitigating controls (e.g. limp home mode) alter the effect of failures in order to protect vehicle occupants. Warning mechanisms (e.g. seat belt tone, anti-lock brake light, etc.) alert the driver to take action. Mitigating controls and warning mechanisms are important aspects of product design and should be considered as part of product functionality. The detection ranking criteria reflects those activities done before design release including the validation or verification of the functionality of mitigation controls.

6.6.13 Risk Priority Number (RPN) and Criticality Number (SO)

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

RPN = (S) * (O) * (D)

Example: Severity 7, Occurrence 3, Detection 5 is RPN 105

Risk priority number is one of many tools available to a team for evaluating potential risk. It provides an indicator of improvement (before and after actions taken) that reduces any one factor of Severity, Occurrence or Detection. The risk priority number is a tool available to allow review with others outside the team who need to share in the risk assessment process and contribute to risk mitigation.

Final RPN ratings are relative to a particular analysis and are subjective; therefore selecting an RPN threshold is not an acceptable practice. In other words, there is no value above which it is mandatory to take a recommended action or below which the team is automatically excused from an action.

Applying (RPN or SO) thresholds assumes that RPNs are a measure of relative risk (which they often are not) and that continuous improvement is not required (which it is). For example, if the customer applied an arbitrary threshold of 100 to the following, the supplier would be required to take action on Item B with the RPN of 112.

TABLE 1 - RPN COMPARISON

Item	Severity	Occurrence	Detection	RPN
A	9	2	5	90
B	7	4	4	112

In this example, the RPN is higher for Item B than Item A. However, the priority should be to work on Item A with the higher severity 9, although its RPN is 90 which is lower and below the threshold. Establishing such thresholds may promote the wrong behavior causing team members to spend time trying to justify a lower occurrence or detection ranking value to reduce the RPN. This type of behavior avoids addressing the real problem that underlies the cause of the failure mode and merely keeps the RPN below the threshold. It is important to recognize that determining reasonable risk is desirable, it should be based on an analysis of severity, occurrence and detection and not through the application of RPN thresholds.

The severity and occurrence risk priority number (SO) is the product of the severity (S) and occurrence (O) ranking. It is sometimes referred to as the Criticality Number. Within the scope of the individual FMEA, this value (between “1” and “100”). The use of SO is an alternative to RPN and is optional.

SO = (S) * (O)

Example: Severity 7, Occurrence 3, Detection 5 is SO 21

In using this index, the organization may focus on how to reduce SO by reducing the value of “O” through preventive actions. Furthermore, this may lead to subsequent detection improvements for those with the highest SO value.

TABLE 2 - CONTRAST AMONG RPN AND SO

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

6.6.14 Recommended Actions

The intent of a recommended action is to prevent or mitigate the risk of the failure (Severity). This is achieved by reducing the likelihood of failure (Occurrence) and/or improving the ability to detect failures prior to production release (Detection).

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 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 and normally occurs late in the design cycle. Emphasis should be placed on preventing failures (i.e., reducing the occurrence) rather than detecting them.

When the severity is a “9” or “10”, the potential risk must be reviewed 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).

The Recommended Action column should be left blank until the team has had the opportunity to assess the risk. If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering “None” in this column.

NOTE: It is recommended that Severity 9 or 10 issues be communicated to the process-responsible team for consideration in a Process FMEA and/or Control Plan. The method for communicating issues from the Design FMEA to the Process FMEA may vary by company.

It is acceptable to include the name of an organization or department with a recommended action; however a person's name is required for the Responsibility and Target Completion Date.

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

- Revised Design Geometry and/or tolerances,
- Revised Material Specification,
- Design of experiments (particularly when multiple or interactive causes are present)/or other problem solving techniques, and
- Revised Test Plan
- Confirmation/verification of information (test results, analytical studies, etc.)

- f. Communication of information (PFMEA team, Control Plan team, Customer, Supplier, etc.)
- g. Other as needed

6.6.15 Responsibility and target completion date

Enter the individual responsible for completing each recommended action by the due date. Additional information such as organization or department may be added to the recommended action statement or responsibility.

6.6.16 Action taken

After an action has been implemented, enter a brief description of the action taken and effective date.

6.6.17 Revised ratings

After the action been implemented, write the revised occurrence and detection rankings (the Severity ranking itself can not be changed without eliminating the failure mode and its effects). Calculate and record the resulting RPN (when used). If no actions were taken, leave the related ranking columns blank. If further action is considered necessary, repeat the analysis. The focus of the DFMEA should be on continual improvement.

NOTE: The DFMEA serves as a historical record for the design, therefore the original Severity, Occurrence, and Detection numbers are not modified once actions have been taken.

NOTE: Original ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

7. PROCESS FMEA

7.1 Timing

The Process FMEA should be started before or at the feasibility stage and prior to tooling for production. Basis, Baseline, Generic FMEAs or process family FMEAs from similar manufacturing processes are the starting point for the risk management process when available. The basis FMEA or process family FMEA should be edited to document those specific manufacturing and assembly differences between the basis project and the current project. Early review and analysis of new or revised processes allows the team to anticipate, resolve or monitor potential process concerns during the manufacturing planning stages of a new model or component program.

The FMEA should be "in principle" complete prior to tooling release. There may be more than one tooling release date for a complex project and if so, then each of those areas of risk connected with the specific tool can be completed "in principle" by the appropriate tooling date constraint. The tooling date can be considered as actual tooling die release or it can be more broadly understood as the software release date, integrated circuit mask release date, wire harness release date, manufacturing plant layout, specific machine design release date, etc. The tooling release date is the date at which further design changes to the actual tooling become difficult or impossible to incorporate beyond drawing or other supporting document changes.

7.2 Scope

The scope of a PFMEA depends on many factors including:

- a. process-responsibility
- b. process interfaces

The scope of a Process FMEA can more easily be defined by using a process flow diagram. The process flow diagram should take into account every possible process step a part is anticipated to take through the manufacturing or assembly process. A detailed process flow diagram provides a roadmap for analysis of each step in the process. The process flow diagram provides a format to consider how process characteristics (inputs) help control the effect on product characteristics (outputs) within a given operation. Copies of the diagrams used in FMEA preparation should be available upon request.

7.2.1 Process Responsibility

The scope defines the operations for which the team is responsible for designing. This defines the elements that will be analyzed. This is the item for which the engineering team has process design ownership and risk mitigation.

7.2.2 Process Interfaces

The scope defines the process boundary. At the process boundaries there are interfaces with other processes such as receiving, off-line repair, off-line inspection, dunnage and shipping. Process FMEA can be used to analyze these interfacing processes by their owners.

7.3 Inputs

The PFMEA team should review various inputs such as:

- a. Warranty
- b. Recalls
- c. Engineering requirements
- d. Drawings
- e. Lessons learned
- f. Preliminary process verification plan
- g. Family or product-specific DFMEA
- h. Family or prior PFMEA
- i. Bill of material
- j. Manufacturing feasibility study
- k. Process flow diagram
- l. Characteristic matrix
- m. other

7.4 Output

The PFMEA team should produce various outputs such as:

- a. High-severity failure modes
- b. High-risk failure modes
- c. Updated characteristic classification list
- d. Design features that may require additional controls
- e. Action plans for design, verification, manufacturing, supplier, etc.
- f. PFMEA worksheet
- g. A summary document comprised of some or all the above
- h. Preventive and detective controls which are detailed on the pre-launch or production control plans

7.5 Assumptions

The PFMEA should address manufacturing/assembly risk and assume the product, as designed, will meet the design intent. The Design FMEA should address the design intent and assume the design will be manufactured/assembled to this intent.

In preparation for the PFMEA, the assumption may be made that incoming part(s)/material(s) are correct. Exceptions can be made as experience dictates (e.g. known deficiencies in incoming part quality).

The PFMEA, as an analytical engineering tool, records the ideas and concerns of a process team; therefore, it is understood that failures shown in the PFMEA are potential. As such, failures described in the PFMEA may or may not occur.

7.6 Procedure

7.6.1 Header Information

The PFMEA worksheet contains important information about the analysis. The header must include a project name, latest revision date, and organization, department, and group or individual who is process responsible. Additional information such as PFMEA number, model year, program number, key date analysis completion target date, core and support team member names, and team facilitator, etc. may be documented in the header to provide useful information for tracking or storage and retrieval purposes. A separate team member list including names and departments is optional.

7.6.2 Process Step

The process step is an identification of the operation or steps in an operation being analyzed and must be written in the PFMEA. The process step identification (e.g. department number, operation number, work element number, etc.) should be consistent with other process documents including the process flow diagram and control plans.

7.6.3 Function and Requirement

A process function describes what is happening to the part within a detailed step of a given operation. The function(s) of each operation being analyzed must be written in the PFMEA. A process may have more than one operation.

Wording of the operation description should consider the operation (Do this), the part (To this) and tooling (With this). Operations include, but are not limited to, fabrication, move, store, get, inspect, rework, scrap, changeover, quality audits and other planned process activities. The more precise the description of the process functions, the easier it is to identify potential failure modes for preventive/corrective controls and actions. If the operation has more than one step with different potential modes of failure, list each of the steps separately in the PFMEA worksheet.

A process requirement defines the desired outcome of the process or operation. A process function may have multiple requirements. Requirements are measurable characteristics of a product or process and may be documented in the PFMEA worksheet. Values for requirements should be included in the product specification to define the acceptance criteria for the control plan.

NOTE: If the operations within the Process Flow Diagram (PFD) are well defined, the operation description in the PFD should be identical to the process function in the PFMEA. The process function within the PFMEA should become the operation description within the Process Control Plan (PCP). This provides a clear linkage between the PFD, PFMEA and PCP. It is recommended to link operation number between PFD, PFMEA and PCP as well.

Typical process functions could be, but are not limited to:

Load
Unload
Induction Harden
Grind
Wash
Inspect
Repair

Typical requirements could be, but are not limited to:

Correct part number loaded
Hardness
Outside Diameter
Inside Diameter
Length
Concentricity
Cleanliness
Reject bad parts

7.6.4 Potential Failure Mode

A potential failure mode is the manner in which the manufacturing and assembly process could potentially fail to meet the product and process requirements. It is a description of the product or process failure mode at that specific operation. Each potential failure mode (product defect or process non-conformance) should be considered independently of other potential failure modes. This enables the team to address the unique reasons (causes of failure) independently of other failure modes. Grouping multiple potential failure modes in one cell in a worksheet is not recommended.

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

- Hole too shallow
- Hole too deep
- Hole missing
- Hole off-location
- Dirty
- Deformed
- Surface finish too smooth
- Burred
- Open circuited
- Short circuited
- Bent
- Cracked
- Misaligned
- Missing label

7.6.5 Potential Effects

The effects of the failure mode on the customer in terms of what the customer might notice or experience. The effects can be the effect at the operation, subsequent operations, customer operations as well as the end customer. It should clearly state if the effect of a failure mode could impact safety or non-compliance to regulations, when applicable.

NOTE: In some cases, the team conducting the analysis may not know the end user effect. For example, the application for the hinge may not be known (emergency exit door, dumpster lid, gate, etc.) or it may not be known how this hinge affects the next level system. When this information is not known, the effects should be defined in terms of the operation. Manufacturing/assembly customers are those that require the feature not necessarily the next step in the operation.

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

For the End User, the effects should be stated in terms of product or system performance (refer to the Design FMEA when applicable) such as:

- End User: Vehicle control impaired, inoperative, erratic operation, intermittent operation, operation impaired, unstable, rough, external leaks, noise, poor appearance, unpleasant odor, draft
- Government: Non-compliance with regulations

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

- Operator: Ergonomics, operator safety
- Operation: Cannot fasten, cannot mount, does not fit, does not match, cannot bore/tap
Does not connect, can not face, excessive tool wear, equipment damage, scrap, rework

7.6.6 Severity Ranking Number

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

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

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

One of the goals of the FMEA process is to mitigate risk or lessen the impact of a potential failure mode. The severity ranking itself can not be changed without eliminating the failure mode and its effects.

NOTE: Writing the individual severity numbers for each effect as part of the effects description is considered a best practice with the highest (worst case) effect used as the severity number.

7.6.7 Classification

The use of the classification column is optional in a PFMEA. This column may be used to highlight failure modes or causes for the purpose of identifying issues to be further discussed with the team as well as others outside the team including management and a Design FMEA team to determine if additional action is necessary. Certain letter codes or symbols may be used. Companies may use various criteria for including:

- High priority failure modes (based on Severity, Severity and Occurrence, Severity and Detection)
- Special characteristics (examples include safety, government, critical, and key characteristics which are directed by specific company policy and are not standardized in this document)
- Warranty campaigns and recalls
- Other criteria specified by the team

7.6.8 Potential Cause of Failure

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

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

- **Machine/Equipment** (machine capability, initial setup adjustment, machine wear over time, inadequate gating/venting, inadequate or no lubrication, tool wear over time, tool breakage, tool-to-tool differences, fixture tolerance, fixture adjustment, fixture wear over time, chip on locator, worn locator, weld current too high or low, weld pressure, heat treat temperature too high or low, equipment maintenance including repair, replacement, reassembly, and adjustment, inspection gauging failures including inaccuracies, and ineffectiveness, etc.)
- **Methods/Systems** (sequence, procedures, layout, off-line rework/repair, off-line inspection, material flow, process control programming, etc.)
- **Material/Components** (part missing, part mis-located, incoming raw material, purchased parts, previous operations)
- **Manpower/Operator** (manual over torque, manual under torque, operator skill, ergonomic factors, time, visual aids, etc.)
- **Environment** (plant temperature, humidity, dust, noise, etc.)

NOTE: The above examples represent categories. Specific details need to be added to complete the cause description. Only specific errors or malfunctions (e.g. part installed upside down) should be listed; ambiguous phrases (e.g., operator error, machine malfunction) should not be used.

NOTE: Refer to assumptions for failure causes that may, or may not be included in the analysis.

7.6.9 Occurrence Ranking Number

Occurrence is a ranking number associated with each cause for a given failure mode being evaluated. The occurrence ranking considers the likelihood of occurrence during production. The occurrence ranking number has a relative meaning rather than an absolute value and is determined without regard for severity or detection. The occurrence ranking takes into account the prevention-type process controls.

Occurrence should be estimated using the criteria in Appendix B – Suggested PFMEA Occurrence Evaluation Criteria. The table may be supplemented with volumes and quality levels such as parts per million or statistical measures such as capability and performance indices. In other cases, a subjective assessment can be made by using the word descriptions from the left column of the table. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The occurrence ranking itself can not be changed without changing the design or process to decrease the chance of the failure cause and subsequent failure mode from happening.

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

7.6.10 Current Process Controls – Prevention

Prevention process controls should be considered when developing the PFMEA as applicable. The prevention controls describe how a cause and/or failure mode is prevented or how the rate of occurrence is reduced and is used as input to the occurrence ranking when integrated as part of the process. A prevention control may not be applicable for every cause and/or failure mode. When not applicable, the prevention controls column on the worksheet can be left blank.

The Process FMEA Example in Appendix J 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. If a one-column (for process controls) form is used, then the following prefix should be used. For prevention controls, place a 'P' before each prevention control listed.

Product and process error proofing features and devices and automated process controls are examples of prevention controls.

Prevention Process Controls

Error proofing
Equipment maintenance (e.g. skilled trades performed)
Operator maintenance (e.g. blow chips out of nest)
Work instructions / Visual aids
Machine controls (e.g. machine monitoring of fluid levels)

7.6.11 Current Process Controls – Detection

Detection process controls should be considered when developing the PFMEA as applicable. The detection control assumes a failure has occurred and describes how a cause and/or failure mode is detected. The process control may occur at the subject operation or at subsequent operations. Detection controls are used as an input to the detection ranking. When not known or not applicable, the detection controls column on the worksheet can be left blank and should be ranked according to the Detection ranking criteria (i.e. Detection 10).

The Process FMEA Example in Appendix J 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. If a one-column (for process controls) form is used, then the following prefix should be used. For detection controls, place a "D" before each detection control listed.

Detection Process Controls

Gauging
End of line test
Visual inspection

7.6.12 Detection Ranking Number

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

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

NOTE: Writing the individual detection numbers for each design control as part of the design control description is considered a best practice with the lowest (best case) detection method used as the detection number.

7.6.13 Risk Priority Number (RPN) and Criticality Number (SO)

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

RPN = (S) * (O) * (D)

Example: Severity 7, Occurrence 3, Detection 5 is RPN 105

Risk priority number is one of many tools available to a team for evaluating potential risk. It provides an indicator of improvement (before and after actions taken) that reduces any one factor of Severity, Occurrence or Detection. The risk priority number is a tool available to allow review with others outside the team who need to share in the risk assessment process and contribute to risk mitigation.

Final RPN ratings are relative to a particular analysis and are subjective, therefore selecting an RPN threshold is not an acceptable practice. In other words, there is no value above which it is mandatory to take a recommended action or below which the team is automatically excused from an action.

Applying (RPN or SO) thresholds assumes that RPNs are a measure of relative risk (which they often are not) and that continuous improvement is not required (which it is). For example if the customer applied an arbitrary threshold of 100 to the following, the supplier would be required to take action on the characteristic B with the RPN of 112.

TABLE 3 - RPN COMPARISON

Item	Severity	Occurrence	Detection	RPN
A	9	2	5	90
B	7	4	4	112

In this example, the RPN is higher for Item B than Item A. However, the priority should be to work on Item A with the higher severity 9, although its RPN is 90 which is lower and below the threshold. Establishing such thresholds may promote the wrong behavior causing team members to spend time trying to justify a lower occurrence or detection ranking value to reduce the RPN. This type of behavior avoids addressing the real problem that underlies the cause of the failure mode and merely keeps the RPN below the threshold. It is important to recognize that determining reasonable risk is desirable, it should be based on an analysis of severity, occurrence and detection and not through the application of RPN thresholds.

The severity and occurrence risk priority number (SO) is the product of the severity (S) and occurrence (O) ranking. It is sometimes referred to as the Criticality Number. Within the scope of the individual FMEA, this value (between "1" and "100"). The use of SO is an alternative to RPN and is optional.

SO = (S) * (O)

Example: Severity 7, Occurrence 3, Detection 5 is SO 21

In using this index, the organization may focus on how to reduce SO by reducing the value of "O" through preventive actions. Furthermore, this may lead to subsequent detection improvements for those with the highest SO value.

TABLE 4 - CONTRAST AMONG RPN AND SO

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

7.6.14 Recommended Actions

The intent of a recommended action is to prevent or mitigate the risk of the failure (Severity). This is achieved by reducing the likelihood of failure (Occurrence) and/or improving the ability to detect failures prior to production release (Detection).

The primary objective of recommended actions is to reduce risks and increase customer satisfaction by improving the design. Only a design or process 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 of the failure mode through a design or process revision. An increase in process detection actions will result in a reduction in the detection ranking only.

When the severity is a "9" or "10", the potential risk must be reviewed 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).

The Recommended Action column should be left blank until the team has had the opportunity to assess the risk. If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering "None" in this column.

NOTE: It is recommended that Severity 9 or 10 issues be communicated to the design-responsible team for consideration in a Design FMEA. The method for communicating issues from the Process FMEA to the Design FMEA may vary by company.

NOTE: It is acceptable to include the name of an organization or department with a recommended action; however a person's name is required for the Responsibility and Target Completion Date.

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

Manufacturing system design changes (e.g. sequence of stations, material flow, etc.)
Process changes (e.g. tool design, equipment usage, etc.)
Product design changes (e.g. geometry, surface finish, etc.)
Process and/or product monitoring actions (e.g. monitor temperature, measure finished part, etc.)

Emphasis should 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.

7.6.15 Responsibility and Target Completion date

Enter the individual responsible for completing each recommended action by the due date. Additional information such as organization or department may be added to the recommended action statement or responsibility.

7.6.16 Action Taken

After an action has been implemented, enter a brief description of the action taken and effective date.

7.6.17 Revised Ratings

After the action been implemented, write the revised occurrence and detection rankings (the Severity ranking itself can not be changed without eliminating the failure mode and its effects). Calculate and record the resulting RPN (when used). If no actions were taken, leave the related ranking columns blank. If further action is considered necessary, repeat the analysis. The focus of the PFMEA should be on continual improvement.

NOTE: The PFMEA serves as a historical record for the process, therefore the original Severity, Occurrence, and Detection numbers are not modified once actions have been taken.

NOTE: Original ratings may be modified for basis, family or generic PFMEAs because the information is used as a starting point for an application-specific analysis.

8. NOTES

8.1 Marginal Indicia

A change bar (I) located in the left margin is for the convenience of the user in locating areas where technical revisions, not editorial changes, have been made to the previous issue of this document. An (R) symbol to the left of the document title indicates a complete revision of the document, including technical revisions. Change bars and (R) are not used in original publications, nor in documents that contain editorial changes only.

APPENDIX A - SUGGESTED DESIGN AND PROCESS FMEA SEVERITY EVALUATION CRITERIA

Category (Product)	Criteria: Severity of Effect (Effect on Product) – DFMEA & PFMEA	Rank	Category (Process)	Criteria: Severity of Effect (Effect on Process) - PFMEA
Safety and/or Regulatory Compliance	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	Safety and/or Regulatory Compliance	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation)	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
Essential	Degradation of primary function (vehicle operable, but at reduced level of performance)	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process; decreased line speed or added manpower.
Secondary Function	Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable)	6	Rework out-of-station	100% of production run may have to be reworked off line and accepted.
Convenient	Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance)	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by most customers (> 75%)	4	Rework in-station	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by many customers (50%)	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by discriminating customers (< 25%)	2	Minor Disruption	Slight inconvenience to process, operation, or operator
No effect	No discernible effect.	1	No effect	No discernible effect

APPENDIX B - SUGGESTED DESIGN AND PROCESS FMEA OCCURRENCE EVALUATION CRITERIA

Likelihood of Failure	Criteria: Occurrence of Cause – DFMEA (Design life/reliability of item/vehicle)	Rank	Criteria: Occurrence of Cause – PFMEA (Incidents per 1000 items/vehicles)
Very High	New technology/new design with no history.	10	≥ 100 per thousand pieces >/= 1 in 10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	9	50 per thousand pieces 1 in 20
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	8	20 per thousand pieces 1 in 50
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	7	10 per thousand pieces 1 in 100
	Frequent failures associated with similar designs or in design simulation and testing.	6	2 per thousand pieces 1 in 500
Moderate	Occasional failures associated with similar designs or in design simulation and testing.	5	.5 per thousand pieces 1 in 2,000
	Isolated failures associated with similar design or in design simulation and testing.	4	.1 per thousand pieces 1 in 10,000
	Only isolated failures associated with almost identical design or in design simulation and testing.	3	.01 per thousand pieces 1 in 100,000
Low	No observed failures associated with almost identical design or in design simulation and testing.	2	≤.001 per thousand pieces 1 in 1,000,000
Very Low	Failure is eliminated through preventative control.	1	Failure is eliminated through preventative control.

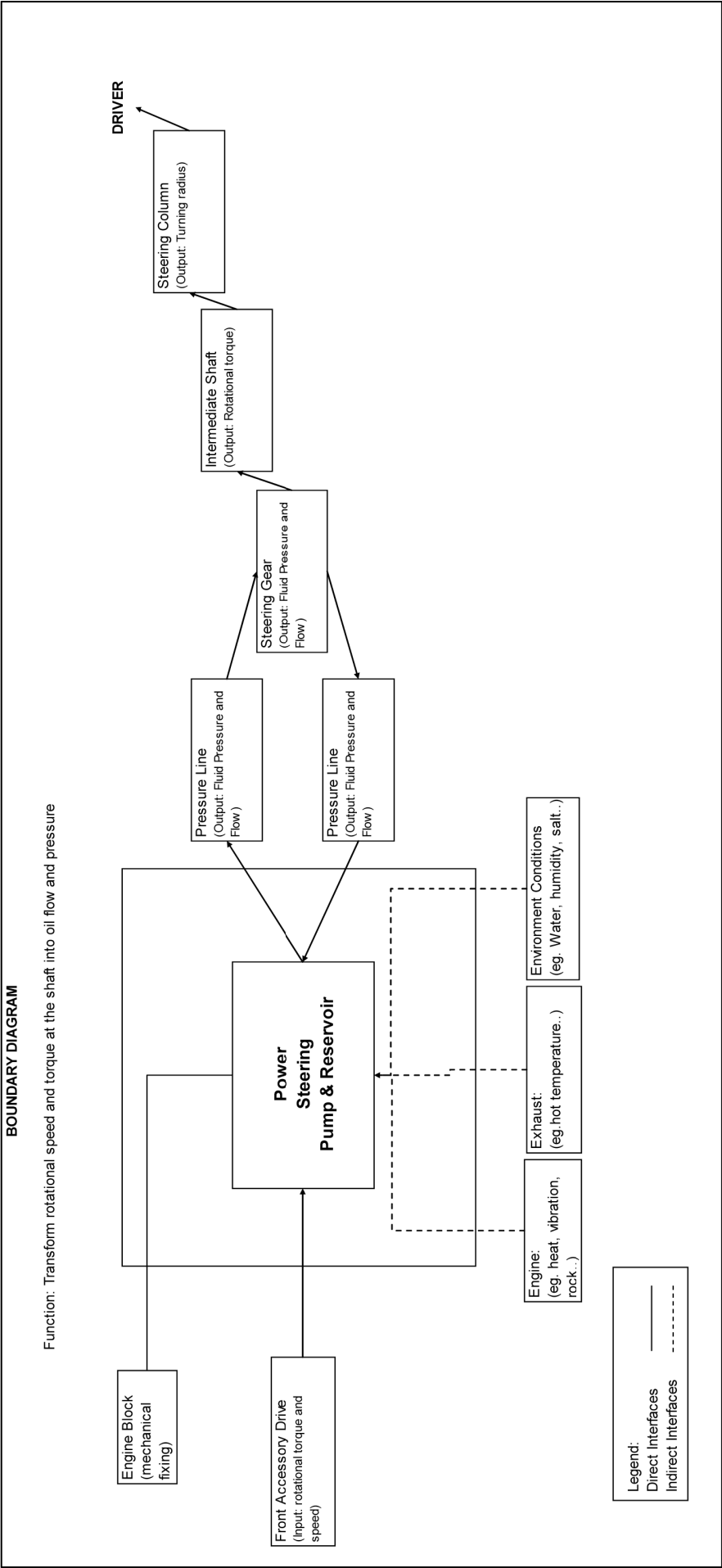
APPENDIX C - SUGGESTED DESIGN AND PROCESS FMEA DETECTION EVALUATION CRITERIA

Category (Product)	DFMEA Criteria: Likelihood of Detection by Design Control	Rank	Category (Process)	PFMEA Criteria: Likelihood of Detection by Process Control
Absolute Uncertainty	No current design control; Cannot detect or is not analyzed	10	Absolute Uncertainty	No current process control; Cannot detect or is not analyzed
Difficult to Detect	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g. CAE, FEA, etc.) is not correlated to expected actual operating conditions.	9	Difficult to Detect	Defect (Failure Mode) and/or Error (Cause) is not easily detected (e.g. Random audits)
Post Design Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with pass/fail testing (Sub-system or system testing with acceptance criteria e.g. Ride & handling, shipping evaluation, etc.)	8	Defect Detection Post Processing	Defect (Failure Mode) detection post-processing by operator through visual/tactile/audible means.
	Product verification/validation after design freeze and prior to launch with test to failure testing (Sub-system or system testing until failure occurs, testing of system interactions, etc.)	7	Defect Detection at Source	Defect (Failure Mode) detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)
	Product verification/validation after design freeze and prior to launch with degradation testing (Sub-system or system testing after durability test e.g. Function check)	6	Defect Detection Post Processing	Defect (Failure Mode) detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using pass/fail testing (e.g. acceptance criteria for performance, function checks, etc.)	5	Defect Detection at Source	Defect (Failure Mode) or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only)
	Product validation (reliability testing, development or validation tests) prior to design freeze using test to failure (e.g. until leaks, yields, cracks, etc.)	4	Defect Detection Post Processing	Defect (Failure Mode) detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.
	Product validation (reliability testing, development or validation tests) prior to design freeze using degradation testing (e.g. data trends, before/after values, etc.)	3	Defect Detection at Source	Defect (Failure Mode) detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.
Virtual Analysis - Correlated	Design analysis/detection controls have a strong detection capability. Virtual Analysis (e.g. CAE, FEA, etc.) is highly correlated with actual and/or expected operating conditions prior to design freeze.	2	Error Detection and/or Defect Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made
Detection not applicable; Failure Prevention	Failure cause or failure mode can not occur because it is fully prevented through design solutions (e.g. Proven design standard/best practice or common material, etc.)	1	Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design.

APPENDIX D - BLOCK DIAGRAM EXAMPLE - DFMEA

FAILURE MODE AND EFFECTS ANALYSIS (FMEA) BLOCK DIAGRAM/ENVIRONMENTAL EXTREMES			
SYSTEM NAME:	FLASHLIGHT		
YEAR VEHICLE PLATFORM:	1994 NEW PRODUCT		
FMEA I.D. NUMBER:	XXX110D001		
<u>OPERATIONAL ENVIRONMENTAL EXTREMES</u>			
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			
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. <pre> graph TD C[SWITCH ON/OFF C] --- 2 --- A[HOUSING A] D[BULB ASSEMBLY D] --- 3 --- A A --- 1 --- B[BATTERIES B] A --- 4 --- F[SPRING F -] E[PLATE E +] --- 5 --- B B --- 5 --- F </pre> COMPONENTS A. HOUSING B. BATTERIES (2 D Cell) C. ON/OFF SWITCH D. BULB ASSEMBLY E. PLATE F. SPRING ATTACHING METHOD 1. SLIP FIT 2. RIVETS 3. THREAD 4. SNAP FIT 5. COMPRESSIVE FIT			

APPENDIX E - BOUNDARY DIAGRAM EXAMPLE - DFMEA



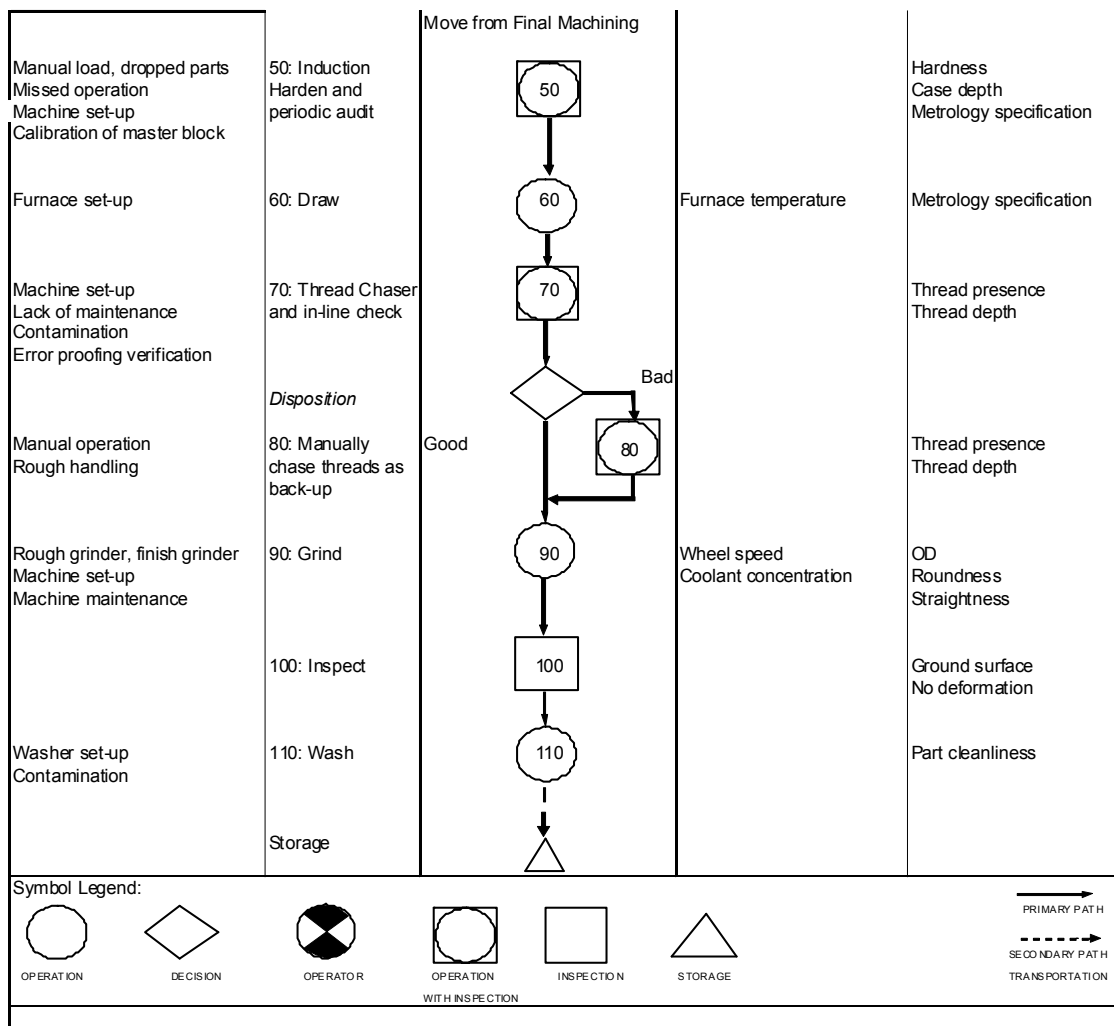
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APPENDIX G - DESIGN FMEA EXAMPLE

DESIGN FAILURE MODES AND EFFECTS ANALYSIS (DFMEA)														
System / Subsystem / Component Name: Steering System / Pump Subsystem / Driveshaft Component Examples Model Year / Program(s): Starting 2012 / New Power Pump Family DFMEA Owner (Design Resp.): Patrick Schreiner (DE), Paul Baird (DE), John Paris (DE) Core Team / Facilitator: Mike Down (VE), Bill Haughey (PE) / Rhonda Brender (Facilitator) Support Team: Bernd von Regius (Customer DE), Hisham Younis (SE), Glen Vallance (ME), John Feghali (OE) Design Eng (DE), Validation Eng (VE), Systems Eng (SE), Manuf Eng (ME), Process Eng (PE), Quality Eng (QE)														
DFMEA Number: D453301021 Revision Date: 17JIN2008 Key Date: 08JIN2008 Original Completion Date: 14FE2008														
Item / Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Classification	Potential Cause(s) of Failure	O C C	Current Design Controls Prevention	Current Design Controls Detection	D E T	R P N	Recommended Action	Responsibility & Target Completion Date	Actions Taken & Effective Date	S O D E V C T	R P N
System (Vehicle level excerpts for example purposes, not all requirements are shown or analyzed here.)														
Steering System / Direct front vehicle wheels based on driver steering input / turning degrees, turning efforts	Steering effort too low (light steering feel)	End user: Minor driver actions cause excessive wheel movement Steering System: No effect	7	Power steering pump has excessive flow	7	Steering system design guideline	Vehicle testing and validation (8) Supplier bench rig test (5)	5	245	Conduct virtual analysis for steering system flow rates	Von Regius, Bernd	Virtual analysis completed; confirmed flow rates within operating parameters is acceptable, ref. file no. VA2380, Jan. 2007	7 2 2	28
Steering System / Direct front vehicle wheels based on driver steering input / turning degrees, turning efforts	Steering efforts too high (periods of difficult steering or pump catch)	End user: Driver has difficulty turning or parking Steering System: No effect	7	Power steering pump inadequate flow	7	Steering system design guideline	Vehicle testing and validation (8) Supplier bench rig test (5)	5	245	Conduct virtual analysis for steering system minimum flow capability	Von Regius, Bernd	Virtual analysis completed; confirmed flow rates within operating parameters is acceptable, ref. file no. VA2380, Jan. 2007	7 2 2	28
Sub-system (Assembly level excerpts for example purposes, not all requirements are shown or analyzed here.)														
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	Excessive pressure (more than xx psi)	End user: Steering efforts drop (less effort at higher tie rod end loads), loss of hydraulic assist Steering System: Excess pressure to gear and hoses Pump: Fluid leakage, fractured housing, pump inoperable	8	Pressure relief valve design guidelines	7	Pressure relief valve design guidelines	Bench rig test for function (5)	5	280	Review results of function test to confirm successful pressure and flow rates achieved	Down, Mike	Pump passed function test, ref. test plan no. V13741 Nov. 2007	8 3 5	120
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	Inadequate flow (less than xx lpm)	End user: Increased steering effort when turning quickly Steering system: Steering gear piston unable to travel at required minimum speed Pump: Pump catch	5	Fluid incorrectly specified (viscosity too low resulting in limited internal leakage)	5	Design guidelines for fluid	Vehicle durability testing (6)	6	150	Obtain and evaluate results of OEM durability testing	Younis, Hisham	Vehicle testing and validation completed; confirmed fluid performance, ref. test no. P039, April 2008	5 2 6	60
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	Inadequate flow (less than xx lpm)	Pump: Pump catch Steering system: Steering gear piston unable to travel at required minimum speed Vehicle: Increased steering effort when turning quickly	5	Clearances between components incorrectly called out on drawing (gaps too large resulting in large internal leakage)	3	Design standards for clearances	Engineering calculations (2), validation function test (5)	2	30	Characterize development sample unit for performance (tolerance analysis and stacks)	Haughey, Bill	Completed tolerance and stack analysis; confirmed design tolerance within required parameters, ref. study no. 753, April 2008	5 2 2	20
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	No flow	End user: Loss of hydraulic assist (manual steer only) Steering system: Loss of oil flow and pressure Pump: Inoperable	8	Fractured shaft	7	Standard shaft design	Pump pressure shock test, cold start durability test, broken drive shaft test	5	280	1. Conduct DRBTR tear down review after test 2. Update drive shaft component DFMEA	Schreiner, Pat	Validation completed and passed, DRBTR showed no evidence (buds) of problems exist on shaft, ref. test plan V13741, August 2008	8 2 5	80
Component (Part level excerpts for example purposes, not all requirements are shown or analyzed here.)														
Shaft / Withstand rotational forces / forces of xx	Shaft fractured	End user: Loss of hydraulic assist (manual steer only) Pump: No flow output (does not transform energy)	8	Shaft not strong enough due to material heat treat incorrectly specified	1	Heat treat specification	Pump pressure shock test, cold start durability test, broken drive shaft test	1	8	None				
Shaft / Withstand rotational forces / forces of xx	Shaft fractured	End user: Loss of hydraulic assist (manual steer only) Pump: No flow output (does not transform energy)	8	Shaft stressed due to new step design feature	7		Engineering calculations (2), pressure shock test, broken drive shaft test, high ambient heavy belt load test (5), durability vehicle test (6)	2	112	1. Conduct Finite Element Analysis 2. Convert to constant diameter drive shaft if necessary	Schreiner, Pat	FEA completed; confirmed shaft strength is adequate, ref. file no. FEA1950 step design approved, March 2007	8 2 2	32

Classification: DR (Documentation Required Special Characteristic) to verify parts meet specification.

APPENDIX H - PROCESS FLOW DIAGRAM EXAMPLE



Note: Process flow diagram formats are based on company procedures. Symbol usage and definitions vary.

[illegible]

APPENDIX J - PROCESS FMEA EXAMPLE

PROCESS FAILURE MODES AND EFFECTS ANALYSIS (PFMEA)

Item: Driveshaft Induction Hardening Example		PFMEA Number: P453301022
Model Year / Program(s): Starting 2012 / New Power Pump Family		Revision Date: 12-Sep-2008
PFMEA Owner (Process Resp.): Glen Vallance (ME)		Key Date: 2-Sep-2008
Core Team / Facilitator: Bill Haughey (PE), Pat Schreiner (DE), Paul Baird (DE) / Rhonda Brender (Facilitator)		Original Completion Date: 30-Aug-08
Support Team: John Feghali (QE), Jill Gjysta (IE)		

Menu Eng (ME), Process Eng (PE), Quality Eng (QE), Industrial Eng (IE), Design Eng (DE)															
Process Step / Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	S E V	Classification	Potential Cause(s) of Failure	O C C	Current Process Controls Prevention	Current Process Controls Detection	D E T	Recommended Action	Responsibility & Target Completion Date	Action Results			
												Actions Taken & Effective Date	S O D	E C E	N V C T
Operation (Steps shown for example purposes, not all steps and requirements are shown or analyzed here.)															
50 INDUCTION HARDEN AND PERIODIC AUDIT															
50.1 Load shafts to machine from basket manually / shafts cannot be dropped	Shafts dropped	End user: Power steering pump function degraded (7) Pump: Damage to ring groove (7) In Plant: Fail in-line check, fail final inspection (5) Vehicle asm: not noticeable during assembly (1)	7		Dropped parts continued to be processed	6	Drop part policy, work instructions	Visual	8	Investigate the use of soft/padded flooring to reduce risk of damage	Bill Haughey	Load station floor covered with soft pad flooring Aug 25, 2008	7	4	8 224
50.2 Induction harden shafts using induction hardening machines (2) / hardness to specification, case depth	Shaft hardness too soft	End user: Power steering pump function degraded (7) Pump: Shaft wear (7) In Plant: 100% scrap (6) Asm Plant: not noticeable during assembly (1)	7	D	Machine temperature set too high for part number	3	Set up instructions	Test lab audit	9	Investigate use of lot containment unit released by test lab results	Bill Haughey	Run ahead authorized for 1 shift's requirements for shafts. All shift production will be held until OK'd for release by test lab.	7	3	2 42
	Shaft case depth too shallow	End user: Loss of hydraulic assist (manual steering only) (8) Pump: Shaft fracture leading to no flow output; does not transport energy (8) In Plant: 100% scrap (6) Asm Plant: not noticeable during assembly (1)	8	D	Machine temperature set too low for part number	3	Set up instructions	Test lab audit	9	Investigate use of lot containment unit released by test lab results	Bill Haughey	Same as above	8	3	2 48
	Shaft case depth too shallow	End user: Loss of hydraulic assist (manual steering only) (8) Pump: Shaft fracture leading to no flow output; does not transport energy (8) In Plant: 100% scrap (6) Asm Plant: not noticeable during assembly (1)	8	D	Machine cycle time too short	3	Set up instructions	Test lab audit	9	Add to notify operator of over/under cycle time	Pat Schreiner	Alarm added to machine and work instructions updated. Sept. 12, 2008	8	3	2 48
	Shaft crack during hardening	End user: not applicable In Plant: Cannot test pump assembly, 100% reject and repair Asm Plant: not applicable	6		Too much heat due to machine adjustment after set-up	3	Operator work instructions	In-line gage at operation 70	6	Investigate use of lot containment unit released by test lab results	Pat Schreiner	Same as above	6	3	2 36
50.2.1 Inspect sample shafts from each steel coil using Rockwell tester / case depth	Bad part passed inspection	End user: Power steering function could be degraded or reduced to manual steer (8) Pump: Shaft wear, fracture In Plant: 100% scrap Asm Plant: not noticeable during assembly	8		Wrong master block	2	Dedicated tester with master attached	Set-up verification	5	None					
	Bad part passed inspection	End user: Power steering function could be degraded or reduced to manual steer (8) Pump: Shaft wear, fracture In Plant: 100% scrap Asm Plant: not noticeable during assembly	8		Tester worn	3	Preventive maintenance, Gage R&R schedule	Set-up verification	5	None					
	Good part failed inspection	Pump: no effect Vehicle: not applicable In Plant: Scrap rate increases Asm Plant: not applicable	2		Wrong master block	2	Dedicated tester with master attached	Set-up verification	5	None					
50.3 Unload shafts from induction hardener machine to basket automatically / parts unloaded without damage	No further analysis required based on risk assessment results														

Classification: DR (Documentation Required Special Characteristic)