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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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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 it's 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.