

Guidelines for
**Failure Mode and
Effects Analysis,**

For Automotive, Aerospace
and General Manufacturing
Industries.



FMEA



**Also available as a printed book
see title verso for ISBN details**

Guidelines for Failure Mode and Effects Analysis for Automotive, Aerospace and General Manufacturing Industries

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Guidelines for Failure Mode and Effects Analysis for Automotive, Aerospace and General Manufacturing Industries

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ISBN 0849319080

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CRC PRESS

Boca Raton London New York Washington, D.C.

This edition published in the Taylor & Francis e-Library, 2005.
“To purchase your own copy of this or any of Taylor & Francis or
Routledge’s collection of thousands of eBooks please go to
[http://www.ebookstore.tandf.co.uk/.](http://www.ebookstore.tandf.co.uk/)”

Library of Congress Cataloging-in-Publication Data

Catalog record is available from the Library of Congress

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ISBN 0-203-00968-1 Master e-book ISBN

International Standard Book Number 0-8493-1908-0 (Print Edition)

About Dyadem Engineering Corporation

Dyadem Engineering Corporation focuses on controlling the risks associated with major hazards in the automotive, aerospace, process, medical device and general manufacturing industries, delivering a wide spectrum of services in the fields of process design, risk management, incident investigation and risk study facilitation.

We offer professional training services for Failure Mode and Effects Analysis, Process Hazards Analysis, Job Safety Analysis and Ergonomics. Dyadem has also become a respected publisher of engineering manuals. Our successful *Guidelines* series also includes *Guidelines for Failure Mode and Effects Analysis for Medical Devices* and the popular *Guidelines for Process Hazards Analysis, Hazards Identification & Risk Analysis*.

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Glossary

- Acceptable Quality Level (AQL):** For the purposes of sampling inspection, AQL is the maximum percent defective that can be considered satisfactory as a process average.
- Average Outgoing Quality Limit (AOQL):** For a given sampling plan, it is the maximum average quality of outgoing product after 100% screening of rejected lots.
- Characteristics:** Distinguishing features of a process or its output on which variables or attributes data can be collected.
- Control Plans:** A description of the system for controlling parts and processes. It is written by suppliers to address the important characteristics and engineering requirements of the product.
- Cpk (process capability per thousand):** An index that considers both the process spread and the proximity of the process spread to specifications limits.
- Design Defect:** An imperfection that causes a product to inadequately protect against risks of injury, fail to perform intended functions safely, inadequately safeguard against a specific danger, create unreasonably dangerous side effects, or fail to minimize avoidable consequences in the event of an accident.
- Design for Manufacturability (DFM)/Design for Assembly (DFA):** A simultaneous engineering process designed to optimize the relationship between design function, manufacturability, and ease of assembly.
- Design of Experiment (DOE):** An experimental technique used to manipulate process inputs in order to better understand their effects on process outputs.
- Detection:** The probability of the failure being detected before the impact of the effect is realized.
- Facilitator:** An expert who ideally has no vested interest in the process under investigation, but who has the knowledge and ability to guide the project leader and the team through the various process improvement steps. The facilitator will work with the client to identify the opportunity, develop a structure for the project, and contract for the boundaries of the project and timing issues. He or she should be aware of sources for information, expert advice and practical assistance.
- Failure Mode:** A symptom, condition or fashion in which hardware fails. A failure mode might be identified as loss of function, premature function (function without demand), an out-of-tolerance condition, or a simple physical characteristic such as a leak observed during inspection.
- Failure Modes and Effects Analysis (FMEA):** A systematic, tabular method for evaluating and documenting the causes and effects of known types of component failures.
- Failure Modes, Effects and Criticality Analysis (FMECA):** A variation of FMEA that includes a quantitative estimate of the significance of the consequences of a failure mode.

Fault Tree: A logic model that graphically portrays the combinations of failures that can lead to specific main failure or accident.

Hazard: Any situation with the potential for causing damage to life, property or the environment.

Human Error: Any human action (or lack thereof) that exceeds some limit of acceptability (i.e., an out-of-tolerance action) where the limits of human performance are defined by the system. Human errors include actions by designers, operators or managers that may contribute to or result in accidents.

Likelihood: A measure of the expected probability or frequency of an event's occurrence.

Manufacturing Defect: An imperfection that causes a product to fail to meet the manufacturer's own specifications. Manufacturing defects occur when the raw materials or components used in making the product contain unacceptable flaws, or there are assembly mistakes.

Original Equipment Manufacturer (OEM): Entity holding design rights to any product. The OEM is not necessarily the manufacturer, designer or distributor of the product.

Occurrence: The probability or frequency of the failure occurring.

Process Capability Index (CpK): A measure of both process dispersion and its centering about the average.

Quality Function Deployment (QFD): A structured method in which customer requirements are translated into appropriate technical requirements for each stage of product, development and production.

Quality System: The organization, structure, responsibilities, procedures, processes and resources for implementing quality management. It is a method of maintaining consistent quality for producing products or providing services that consistently meet or exceed the customer's implied or stated needs.

Quantitative Risk Analysis: The systematic development of numerical estimates of the expected frequency and/or consequence of potential accidents associated with a facility or operation based on engineering evaluation and mathematical techniques.

Repeatability: Variation in measurements obtained with one gage when used several times by one appraiser while measuring a characteristic on one part.

Reproducibility: Variation in the average of the measurements made by different appraisers using the same gage when measuring a characteristic on one part.

Residual Risk: Risk remaining after protective measures have been taken.

Risk: A measure of the consequence of a hazard and the frequency with which it is likely to occur.

Risk Analysis: Systematic use of available information to identify hazards and to estimate the risk.

Risk Assessment: Overall process of risk analysis and risk evaluation.

Risk Evaluation: Judgment based on the risk analysis to determine whether the risk is acceptable given the context and the current values of society.

Risk Management: The systematic application of management policies, procedures and practices to the tasks of analyzing, assessing and controlling risk in order to protect employees, the general public, the environment and company assets.

Safety: A judgment of the acceptability of risk. An activity is deemed as “safe” if its risks are judged to be acceptable when compared with other common daily activities. No activity is totally free from risk. Provided the activity is undertaken, risk can never be totally eliminated. However, it can usually be reduced to acceptable levels with the use of adequate safeguarding.

Statistical Process Control (SPC): Use of statistical techniques to analyze a process or its output in order to take appropriate actions to achieve and maintain a state of statistical control and to improve the capability of the process.

Value Engineering (VE): A planned, clean sheet approach to problem solving, focusing on specific product design and process characteristics. Value engineering is employed to maximize value prior to expenditures of facilities and tooling money.

CHAPTER 1

Introduction

Product quality planning and assessment are critical to assure that a product meets the requirements of the customer and that it satisfies all safety and regulatory requirements. One of the key elements to success is to manage and reduce risk effectively throughout the product's life cycle. This requires a delicate balance between risk, cost and performance. Risk management provides the required decision framework centered on understanding risks and evaluating their acceptability by weighting technical and economic practicability against risk/benefits. It manages the residue risk, as risk cannot be completely eliminated.

To reduce risk, it is essential to identify hazards, evaluate the associated potential consequences and their likelihood, and then estimate the risk. A number of analysis techniques, including top-down and bottom-up approaches, can be used. These techniques include Failure Mode and Effects Analysis (FMEA), Hazard and Operability Analysis (HAZOP) and Fault Tree Analysis (FTA).

These Guidelines focus on FMEA and its application throughout the product's life cycle. Other topics include regulatory requirements relating quality system analysis in the automotive, aerospace and general manufacturing industries, risk management, Failure Mode, Effects and Criticality Analysis (FMECA), Control Plans and Advanced Product Quality Planning.

The following list describes the organization of the manual:

Chapter 2—Automotive, Aerospace and General Manufacturing Quality System Standards

Quality system regulations and specifications associated with the automotive, aerospace and general manufacturing industries are reviewed in this chapter for the purpose of identifying the requirements for Failure Mode and Effects Analysis and Control Plans in the Product Quality Cycle. The intent of this chapter is to provide the readers with a general overview of the regulatory requirements related to the above-mentioned industries in the United States and in Europe.

Chapter 3—Industry Specific Standards for Failure Mode and Effects Analysis

This chapter reviews the current industry-specific standards and technical specifications that provide guidelines for performing FMEA.

Chapter 4—Risk Management Planning

This chapter briefly describes the essence of risk management planning.

Chapter 5—Risk Analysis Methodologies

This chapter gives an overview of Hazard and Operability Analysis (HAZOP) and Fault Tree Analysis (FTA), which are risk analysis techniques commonly used in the automotive, aerospace and general manufacturing industries as alternatives to Failure Mode and Effects Analysis.

Chapter 6—Overview of FMEA

This chapter is an introduction to Failure Mode and Effects Analysis (FMEA). It outlines the objectives of FMEA, reasons and benefits of performing FMEA and the limitations of the technique.

Chapter 7—FMEA Procedures

This chapter describes the basic terminology and process used in FMEA. In addition, the procedures for setting up, conducting and following up FMEA are described.

Chapter 8—FMEA Team

This chapter describes the responsibilities of FMEA team members and the facilitator/team leader.

Chapter 9—Common Tools Used with FMEA

This chapter gives an overview of tools commonly used with FMEA, including process flowcharts, block diagrams and Pareto charts.

Chapter 10—Pitfalls with FMEA

This chapter describes some major pitfalls that can arise while conducting FMEA studies.

Chapter 11—Product Life Cycle & FMEA

This chapter outlines the application of FMEA at various stages in a product's life cycle. It also introduces the use of Control Plans as a tool to document the design and process characteristics required for the manufacturing of an item/component or system.

Chapter 12—Product/Design FMEA

This chapter describes the objectives of Product/Design FMEA (D-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection.

Chapter 13—Process FMEA

This chapter describes the objectives of Process FMEA (P-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection.

Chapter 14—Machinery FMEA

This chapter describes the objectives of Machinery FMEA (M-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection.

Chapter 15—Application FMEA

This chapter describes the objectives of Application FMEA (A-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection.

Chapter 16—Service FMEA

This chapter describes the objectives of Service FMEA (S-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection.

Chapter 17—Hardware and Software FMEA

This chapter provides an overview of Hardware and Software FMEA.

Chapter 18—Analysis of FMEA Results

This chapter provides a brief overview of Failure Mode Ratios, Failure Equivalence Numbers and process variation indices.

Chapter 19—Overview of Failure Mode, Effects and Criticality Analysis (FMECA)

This chapter provides an overview of Failure Mode, Effects and Criticality Analysis (FMECA), including the terminology and the worksheets used in the analysis for both quantitative and qualitative approaches.

Chapter 20—Post FMEA Study

This chapter describes the required steps to be taken after the completion of the FMEA.

Chapter 21—FMEA in Advanced Quality Planning/Advanced Product Quality Planning

This chapter provides a brief overview of Advanced Quality Planning (AQP) and Advanced Product Quality Planning (APQP) and the use of FMEA in quality planning.

Chapter 22—Product Quality Control Plans and Dynamic Control Plans

This chapter provides an overview of Control Plans and Dynamic Control Plans and their elements.

CHAPTER 2

General Manufacturing, Automotive and Aerospace Quality System Standards

Quality system standards and specifications associated with the automotive, aerospace and general manufacturing industries are reviewed in this chapter for the purpose of identifying the requirements for Failure Mode and Effects Analysis and Control Plans in the Product Quality Cycle. This chapter provides only a brief overview of each document, and anyone who wants to fulfill the regulatory and industrial requirements should obtain a copy of the respective documents from the International Organization for Standardization (ISO), Society of Automotive Engineers (SAE) or other publishing organizations in order to ensure that all documentation required for registration is completed. As regulations and standards are periodically updated, it is the reader's responsibility to ensure the applicability of these documents.

General Manufacturing Industry

ISO 9000 Series

The ISO 9000 family of international quality management standards and guidelines has earned a global reputation as the basis for establishing quality management systems. The familiar three standards—ISO 9001, ISO 9002 and ISO 9003—have been integrated into the new ISO 9001:2000. This new standard specifies requirements for a quality management system for any organization that needs to demonstrate its ability to consistently provide products that meet customer and applicable regulatory requirements and aims to enhance customer satisfaction. The standard is used for certification/registration and contractual purposes by organizations seeking recognition of their quality management system.

The greatest value is obtained when the entire family of standards is used in an integrated manner. In order to achieve a first level of performance, it is suggested that ISO 9001:2000 be adopted, beginning with ISO 9000:2000. The practices described in ISO 9004:2000 may then be implemented to make the quality management system increasingly effective in achieving the business goals.

ISO 9001:2000 and ISO 9004:2000 have been formatted as a consistent pair of standards to facilitate their use. Using the standards in this way will allow them to be

related to other management systems (e.g. environmental) and many sector-specific requirements (such as ISO/TS/16949 in the automotive industry), and it will help to gain recognition through national awards programs.

The following table presents all the standards listed in the ISO 9000 series:

Table 2.1: List of standards in the ISO 9000 series

Standard Title	Description
ISO 9000:2000, Quality management systems—Fundamentals and vocabulary	Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family so you avoid misunderstandings in their use.
ISO 9001:2000, Quality management systems—Requirements	This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried.
ISO 9004:2000, Quality management systems—Guidelines for performance improvements	This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.
ISO 19011, Guidelines on Quality and/or Environmental Management Systems Auditing (currently under development)	Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.
ISO 10005:1995, Quality management Guidelines for quality plans	Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.
ISO 10006:1997, Quality management Guidelines to quality in project management	Guidelines to help you ensure the quality of both the project processes and the project products.
Standard Title	Description
ISO 10007:1995, Quality management—Guidelines for configuration management	Gives you guidelines to ensure that a complex product continues to function when components are changed individually.
ISO/DIS 10012, Quality assurance requirements for measuring equipment—Part 1: Metrological confirmation system for measuring equipment	Give you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.
ISO 10012-2:1997, Quality assurance for measuring equipment—Part 2: Guidelines for control of measurement of processes	Provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.
ISO 10013:1995. Guidelines for developing	Provides guidelines for the development and

quality manuals	maintenance of quality manuals tailored to your specific needs.
ISO/TR 10014:1998, Guidelines for managing the economics of quality	Provides guidance on how to achieve economic benefits from the application of quality management.
ISO 10015:1999, Quality management Guidelines for training	Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.
ISO/TS 16949:1999, Quality systems—Automotive Suppliers—Particular requirements for the Application of ISO 9001:1994	Sector-specific guidance to the application of ISO 9001 in the automotive industry.

Automotive Industry

a. Quality System Requirements—QS 9000:1998

Quality System Requirements, QS-9000 was developed by the Chrysler/Ford/General Motors Supplier Quality Requirements Task Force. This system was developed to standardize the reporting formats, technical nomenclature and reference manuals. QS-9000 is a harmonization of Chrysler's Supplier Quality Assurance Manual, Ford's Q-101 Quality System Standard and General Motors' NAO targets for Excellence.

QS-9000 is structured according to ISO 9001:1994 Section 4 and includes automotive specific requirements to the general ISO requirements for a supplier's quality system.

QS-9000 applies to the following:

Internal and external supplier sites of—

- a. Production materials;
- b. Production or service parts;
- c. Heat treating, painting, plating or other finishing services directly to OEM customers subscribing to QS-9000.

Providers of—

- a. Semiconductors in conjunction with the Semiconductor Supplement issued by Chrysler, Ford and Delco Electronics;
- b. Tooling and equipment in conjunction with the Tooling and Equipment (TE) Supplement issued by the Big Three (Chrysler/Ford/General Motors).

Proof of conformance to QS-9000 is certification/registration by an accredited third party, such as Underwriter's Laboratories (UL) or the American Bureau of Shipping (ABS). Companies that become registered under QS-9000 will be considered to have higher standards and better-quality products.

QS-9000 has the following two sections:

Section 1: contains ISO-based Requirements (section 4 of ISO 9000:1994).

Section 2: contains customer-specific requirements (Ford, Chrysler, GM and OEM specific requirements).

QS-9000 is sometimes seen as being identical to ISO 9000, but this is not true. Even though each element of ISO 9000 is an element of QS-9000, QS-9000 adds clauses to the majority of the ISO 9000 elements. For example, QS-9000 adds requirements for a business plan, tracking customer satisfaction and bench marking to element 4.1 of ISO 9000, Management Responsibility. QS-9000 also uses sector-specific requirements.

The following requirements are not based on ISO 9000:

- Production part approval process;
- The requirements for gaining approval from the customer to run a new or altered part or process;
- Continuous improvement;
- Automotive suppliers are required to have systems in place to ensure that organized, measurable improvement activities take place for a variety for business aspects;
- Ensure sufficient manufacturing capabilities;
- Requirements for planning and effectiveness for equipment, facilities and processes;
- Requirements for mistake proofing and tooling management.

Section I—ISO 9000-based requirements include the following elements as per ISO 9000:1994 section 4

4.1 Management Responsibility

- This element and its sub-elements require the company to define and document the objectives for quality and its commitment to quality;
- A clear structure of responsibility and authority levels should be established to meet the quality requirements;
- A management review should be conducted to ensure that the quality system requirements are met continuously;
- The supplier should maintain a well-documented business plan, although this document is not subject to third party audit;
- The supplier should document trends in quality, productivity, efficiency, effectiveness, and cost of poor quality and periodically compare with those of competitors;
- A well-documented process should be maintained to determine customer satisfaction.

4.2 Quality System

- A quality system should be established and maintained to ensure the conformity of the product to specified requirements. Quality planning is key to the establishment of a good quality system. Preparation of quality plans, as per 4.2.3, include the following:
 - ✓ Identification and acquisition of controls, processes, equipment, fixtures, resources and skills for the required quality;
 - ✓ Ensuring the capability of the design, the production process, installation, servicing, inspection and test procedures;

- ✓ Updating of quality control, inspection and testing techniques as required;
 - ✓ Identification of measurement requirements for the needed capability;
 - ✓ Identification of suitable verification at appropriate stages;
 - ✓ Clarification of standards of acceptability;
 - ✓ Identification and preparation of quality records.
- Advanced Product Quality Planning (APQP) should be established and implemented. The APQP should include these elements:
 - ✓ Development/finalization of special characteristics (this could be identified from the dimensional, material, appearance, performance product characteristic categories);
 - ✓ Feasibility reviews to ensure the capability of producing the proposed products;
 - ✓ Product Safety should be considered in the design control/process control policies;
 - ✓ Development and review of FMEAs:
 - Process FMEA should consider all special characteristics. Methods for defect prevention should be encouraged instead of defect detection;
 - Establishment of actions to reduce the potential failure modes with high risk priority numbers.
 - ✓ Mistake-proofing methods should be established;
 - ✓ Development/review of Control Plans:
 - Control Plans should be developed at the system, subsystem and component or material level;
 - Control Plans should be established for the Prototype, Pre-launch and Production phases of the product. The output of APQP is the Control Plan.

Control Plans are reviewed and updated when any of the following happens:

- Change in product;
 - Change in process;
 - Increased variance in the process (highly unstable);
 - Processes become non-capable;
 - Inspection, method, frequency, etc. is revised.
- ✓ Product Part Approval should be established as required by the Product Part Approval Process (PPAP) documentation released by the Automotive industry;
 - ✓ Efforts should be taken/established/defined for the continuous improvement of product quality;
 - ✓ The following techniques could be used for the continuous improvement of the product:
 - Control charts;
 - Design of experiments;
 - Theory of constraints;
 - Overall equipment effectiveness;
 - Parts-per-million analysis;
 - Value analysis;
 - Benchmarking;

- Analysis of motion/ergonomics;
 - Mistake proofing.
- ✓ Documentation should be established to ensure the effectiveness of facilities, equipment, tooling and process planning.

4.3 Contract Review

Procedures should be established and documented for the selection of suppliers, award of contracts, etc.

4.4 Design Control

This element applies to suppliers who are responsible for the design of a new product or who have the authority to change/modify an existing product design.

A plan for each design and development activity should be established.

Design Input requirements relating to the product, including applicable statutory and regulatory requirements, should be identified and documented.

Design Output should be verified, validated and documented. As per the Design Output—Supplemental—4.4.5.1 of this document, the supplier's design output shall be the result of a process that includes:

- Efforts to simplify, optimize, innovate, and reduce waste (e.g. QFD, DFM/DFX, VE, DOE, Tolerance studies, response methodology, or appropriate alternatives);
- Utilization of geometric dimensioning and tolerancing, as applicable;
- Analysis of cost/performance/risk trade-offs;
- Use of feedback from testing, production and field;
- Use of design FMEAs.

Reviews of design results should be conducted and documented at appropriate stages.

Design changes should be documented and approved before implementation.

4.5 Document and Data Control

As per Document and Data Control Element 4.5.1, the Supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of ISO 9000 including, to the extent applicable, documents of external origin such as standards and customer drawings.

Examples of appropriate documents include:

- Engineering drawings;
- Engineering standards;
- Math (CAD) data;
- Inspection instructions;
- Test procedures;
- Work instructions;
- Operation sheets;
- Quality manual;

- Operational procedures;
- Quality assurance procedures;
- Material specifications.

Engineering Specifications—4.5.2.1 requires the supplier to establish a procedure to assure timely review (e.g. business “days” not weeks or months), distribution and implementation of all customer engineering standards/specifications and changes.

The supplier shall maintain a record of the date on which each change is implemented in production. A change in the engineering specification should require updated Production Part Approval Process (PPAP) documents i.e. FMEAs, Control Plans, etc., when these specifications are referenced on the design record.

4.6 Purchasing

The supplier should establish and maintain documented procedures to ensure that the purchased product for ongoing production conforms to specified requirements, including Government, Safety and Environmental regulations (4.6.1.1 & 4.6.1.2).

Requirements for the selection of contractors and subcontractors should be defined and documented.

The supplier shall perform subcontractor quality system development with the goal of subcontractor compliance to QS-9000 using Section I of QS-9000 as their fundamental quality system requirement.

Required product identification information for the purchased products and the verification methods should be defined and documented.

4.7 Control of Customer Supplied Product

Procedures for the control of verification, storage and maintenance of a customer supplied product should be established and documented.

4.8 Product Identification and Traceability

Procedures should be established to identify the product from production, delivery, installation and storage stages.

4.9 Process Control

Production, installation and servicing processes that would adversely affect the quality of the product should be identified, planned and carried out under the following controlled conditions:

- Stepwise documentation for production, installation and servicing and the impact of these procedures on product quality;
- Use of suitable equipment and working environment;
- Identification and documentation of contingency plans in case of emergency;
- Compliance with reference, standards/codes and quality plans;

- Process parameters and product characteristics, especially defined special characteristics, which would affect the product's safety, compliance with government regulations, fit, function, appearance or quality of subsequent operations should be monitored;
- Routine for approval of processes and equipment;
- Documented criteria for workmanship;
- Documentation for suitable maintenance/preventive maintenance for equipment.

Each employee responsible for the operation and monitoring of the process should have documented operator instructions. The instructions can be included in any of the following documents:

- Process sheets;
- Inspection and laboratory test instructions;
- Test procedures;
- Standard operation sheets.

Process control should be maintained by ensuring process capability or performance as approved via PPAP. When product data indicate a high degree of capability, the Control Plan should be revised. Process changes should be documented and maintained.

4.10 Inspection and Testing

Procedures for inspection and testing activities to verify that the requirements for the product are met should be established, documented and maintained.

Procedures should be established to ensure that the incoming product is inspected and tested before it is used in the production. Procedures should be established as required by the quality plan i.e. Control Plans and/or other documented procedures to inspect the manufactured product, and the test results should be recorded and maintained.

4.11 Control of Inspection, Measuring and Test Equipment

Procedures should be established for the calibration, inspection and control of the test equipment used to demonstrate the conformance of the product to the specified requirements, and the records should be maintained. Appropriate Statistical Analysis tools should be used to evaluate the variation in the measurement analysis.

4.12 Inspection and Test Status

Based on the inspection and test status, the conformance/nonconformance of the product should be documented. This should be conducted as defined in the Quality Plan (Control Plan) throughout production, installation and servicing of the product to ensure that products that meet the conformance are released to the customer.

4.13 Control of Nonconforming Product

Procedures should be established and maintained for the identification, documentation, evaluation, segregation and disposition of products that do not conform to specified requirements.

4.14 Corrective and Preventive Action

Required procedures for corrective action implementation (as per 4.14.2):

- Effective handling of customer complaints and product nonconformities reports;
- Investigation and recording of the cause of nonconformities;
- Required corrective action and the application of controls to eliminate the cause of nonconformities.

Required procedures for preventive action implementation (as per 4.14.3):

- Appropriate sources of information (processes/operations that affect product quality, concessions, audit results, quality records, service reports and customer complaints) to detect, analyze and eliminate potential causes of nonconformities;
- Identification of problems requiring preventive action;
- Initiation of preventive action and application of controls. This is to ensure the preventive action is effective;
- Information on actions taken is submitted for management review.

4.15 Handling, Storage, Packaging, Preservation and Delivery

Procedures should be established for the handling, storage, packaging, preservation and delivery of products. These procedures should include:

- Methods of handling the product;
- Storage conditions;
- Packaging standards;
- Labeling systems;
- Delivery performance monitoring;
- Electronic communication and shipment notification system.

4.16 Control of Quality Records

Procedures should be established and documented for the identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality performance records—i.e., control charts, inspection and test results—should be retained for a minimum of one calendar year after the year in which they were created.

Records of internal quality system audits and management review should be retained for a minimum of three years.

4.17 Internal Quality Audits

Procedures should be established for the implementation of quality audits to verify the effectiveness of the quality system.

4.18 Training

Procedures should be established for conducting the training of all personnel. Training records should be maintained and the effectiveness of the training program should be reviewed periodically.

4.19 Servicing

When servicing of the product is a requirement, procedures should be established defining the specifications for servicing and verifying that specified requirements are met.

4.20 Statistical Techniques

Statistical tools should be identified during product quality planning and must be included in the Control Plan.

Section II—Customer-Specific Requirements

Chrysler-Specific Requirements

- Production and part suppliers to Chrysler should be QS-9000 registered;
- Products should be developed based on Product Assurance Planning (PAP) method or APQP and Control Plan;
- Significant characteristics should be identified and Special Characteristics should be identified by the symbols specified by Chrysler;
- An annual layout inspection to ensure continuous conformance to all Chrysler requirements should be conducted;
- Product Verification/Design Validation should be performed based on Chrysler's specification;
- Internal Quality Audits should be conducted at least once per year.

The Corrective Action Plan should include the following:

- Description of the nonconformance;
- Definition/root cause;
- Interim action and effective date;
- Permanent action and effective date;
- Verification;
- Control;
- Prevention;

- Approval of appearance masters, process approval, packaging, shipping and labeling should be performed according to Chrysler specifications.

Ford-Specific Requirements

- Suppliers to Ford are not required to have third party registration, except for Ford Australia's unique suppliers, who should have third party registration;
- Control Item parts that have critical characteristics that may affect the safe operation of the vehicle and/or compliance with government regulations are required to have Control Plans and FMEAs approved by Ford's design and quality engineers;
- All product characteristics are required to be measured annually to demonstrate conformance to specified requirements;
- Setup verification is required for all critical and significant characteristics;
- Lot traceability and Material Analysis for heat-treated and non-heat-treated parts should be included in the Control Plan for control items. And those who provide heat treating should comply with Ford's requirements (W-HTX, WSS-M99A3-A);
- Process changes and design changes for supplier-responsible designs require Ford's approval if specified in the design record;
- Corrective action should be taken if engineering specification does not confirm design intent;
- Ford's Quality Operating System methodology should be implemented;
- APQP guidelines should be used.

GM-Specific Requirements

QS-9000 applies to all contracted GM suppliers. GM suppliers should refer to the forms noted in QS-9000 to address the requirements that are applicable to them.

Other OEM-Specific Requirements

Suppliers to Mack Trucks Inc., Navistar International Transportation Corp., PACCAR Inc., Volvo Truck North America, Mitsubishi Motors—Australia and Toyota Australia require QS-9000 registration and additional supplier quality requirements.

b. ISO/TS 16949:1999—Quality Systems—Automotive Suppliers— Particular Requirements for the Application of ISO 9001:1994

TS 16949 is a new sector-specific automotive standard for the application of ISO 9001:1994. TS 16949 is a standard that has support from automotive groups from around the world. The concept is to have a single standard that all automotive suppliers can implement, and it is recognized in the U.S., Europe, Asia, Mexico, etc. Currently, a company doing business in different parts of the world with different auto manufacturers has to get certified to the local standard.

This technical specification is applicable to production and service part supplier and subcontractor "sites" providing:

- a. Parts or materials, or
- b. Heat treating, painting, plating or other finishing services, or
- c. Other customer-specified products.

The International Automotive Task Force (IATF) has been working with the ISO community on updating ISO/TS 16949 to align it with ISO 9001:2000. The expectation is that, sometime in 2002, the new ISO/TS 16949 will be released for use by automotive suppliers around the world. How APQP, PPAP and the other AIAG reference manuals will figure into the new ISO/TS 16949 is still not clear, although Ford has just announced in its new Q1–2002 program that its suppliers must be registered to either QS-9000 or ISO/TS 16949 and to ISO 14001 (Environmental management system—specification with guidance for use)

c. QS 9000 vs. ISO/TS 16949

ISO/TS 16949 harmonizes the supplier quality requirements of the U.S. Big Three (QS-9000, Third Edition) and French, German and Italian automakers. Of the European requirements, perhaps the most familiar in the United States is the German VDA 6.1, to which Volkswagen has required North American suppliers to its Mexican operations to be registered. The goal was to create a single document and a single third-party registration that the European automakers and the U.S. Big Three would accept.

Each company considering registration to ISO/TS 16949 should obtain the document as quickly as possible, because a close reading of ISO/TS 16949 will be necessary to determine the extent of needed revisions. However, the following element-by-element summary explains the direction and extent of the changes.

4.1—Management responsibility:

- A number of additions to this element are clearly intended to focus suppliers' attention on continuous quality improvement;
- Suppliers must establish goals, objectives and measurements to develop their quality policies;
- Continuous improvement in quality, service, cost and technology must be covered in the quality policy;
- Quality-responsible personnel's authority to stop production is no longer a "note" or suggestion, as in QS-9000, but a requirement;
- All production shifts must be staffed with personnel responsible for quality;
- The management review requirement is expanded to include the "performance (of the QMS) over time as an essential part of the continuous improvement process;"
- Evaluation of the cost of poor quality was a parenthetical note in QS-9000, but is a specific requirement of ISO/TS 16949;
- Suppliers must develop a process for motivating employees to achieve quality objectives and providing employees at all levels with "quality awareness;"
- Customer experience with the supplier's product must be communicated in a timely manner;

- Finally, the “due care for product safety” requirement from QS-9000 has been expanded to minimize risks to employees, customers and the environment.

4.2—Quality system:

- The term “product realization” is introduced to cover the entire process of designing, planning and delivering products that meet customer requirements;
- A requirement for a project manager and a project team is introduced;
- The modifying phrase “If a project management approach is used” suggests that this approach is preferred, if not actually required. Continuing to expand the project management concept, ISO/TS 16949 requires that a method be established for measuring the product-realization process against appropriate milestones, with appropriate analysis and management review;
- The factors to be measured include quality, risks, costs and lead times. Process capability studies must be conducted on all new processes;
- Results for the capability studies must be used to establish requirements for production equipment where applicable. Inclusion of all special characteristics on Control Plans, although always implicit, is now explicitly required;
- ISO/TS 16949 also has a requirement for procedures on developing and verifying the product-realization process;
- Detailed procedural requirements for process design inputs and outputs have been added, including a verification of the inputs vs. the outputs;
- The use of the “customer-recognized product approval process” (e.g., production part approval process [PPAP]) is mandated rather than recommended as in QS-9000, although General Motors has had a customer-specific requirement for subsupplier PPAP for some time;
- Additionally, when the customer so requires, special verification methods for new products must be implemented.

4.3—Contract review:

Suppliers must have a formal process for identifying cost elements and employ this process in the preparation of price quotations for new products.

4.4—Design control:

- The requirement for skill qualifications of the supplier’s design team is now a “shall” rather than a “should”;
- Suppliers must have access to research and development to support product innovation. Analysis of competitive products is identified as one alternative source of input for the design process;
- For design changes, the impact on the customer’s assembly operations is added to the factors that the supplier must consider for each change.

4.5—Document and data control:

There are no significant changes in this section.

4.6—Purchasing:

Suppliers must encourage their subsuppliers to comply with ISO/TS 16949. However, there's no target date for compliance, nor is there an expectation of third-party registration for subsuppliers.

4.7—Control of customer-supplied products:

There are no significant changes in this section.

4.8—Product identification and traceability:

There are no significant changes in this section.

4.9—Process control:

- The term “process monitoring and operator instructions” has been replaced with the simpler “job instructions,” which “shall” rather than “should” be accessible at the job station without disruption;
- These job instructions shall be derived from “appropriate sources,” including the Control Plan and the entire product-realization process;
- Significant process events shall be noted on control charts.

4.10—Inspection and testing:

- The incoming material requirements now allow the customer to waive the required control methods;
- Following the precedent of the Third Edition of QS-9000, requirements for internal laboratories are further strengthened. These laboratories, which include precision metrology and calibration as well as traditional laboratory functions, must now comply with ISO/IEC 17025 (General requirement for the competence of testing & calibration laboratories), although third-party accreditation to that document is not required.

4.11—Control of inspection, measuring and test equipment:

Methods and criteria for measurement system analysis shall conform to customer reference manuals (e.g., the Big Three Measurement Systems Analysis manual).

4.12—Inspection and test status:

There are no significant changes in this section.

4.13—Control of nonconforming product:

Progress on corrective action plans shall be regularly reviewed. A requirement has been added for customer notification when nonconforming material has been shipped.

4.14—Corrective and preventive action:

There are no significant changes in this section.

4.15—Handling, storage, packaging, preservation and delivery:

- The controls implemented for nonconforming products must also be used for obsolete products;
- If delivery will not happen according to schedule, the supplier must notify the carrier as well as the customer of the anticipated delivery problem.

4.16—Control of quality records:

- The requirements for scheduling the supplier's production process have been defined in greater detail;
- There must be a scheduling process based on meeting the customers' requirements, such as just-in-time;
- The information technology must support access to production data at key production checkpoints.

4.17—Internal quality auditing:

- Internal audits must be performed on all shifts and must include all activities affected by ISO/TS 16949 and all relevant customer requirements. Specifically, the internal audit must include an evaluation of the effectiveness of the product-realization and production process;
- A product audit has been included in 4.17 that includes the "final product" audit required in QS-9000 and expands it to include all specified requirements at appropriate points in the production and delivery process;
- Internal auditors must meet customer-established criteria.

4.18—Training:

Additions include requirements for on-the-job training for new or modified jobs affecting quality and for training on customer-specific requirements.

4.19—Servicing:

If the supplier provides post-sale servicing, the effectiveness of service centers' special equipment and personnel training must be re-evaluated.

4.20—Statistical techniques:

Appropriate statistical methods shall be determined during the planning process, and these methods shall be understood throughout the organization.

The sheer number and broad implications of these additions clearly indicate that a great deal of effort will be required to migrate from a QS-9000-based Quality Management System (QMS) to one that can be registered to ISO/TS 16949. However, there's no need to drop everything for ISO/TS16949 now; it will exist as an alternative to QS-9000 for a substantial period, perhaps 12 to 24 months. ISO/TS 16949 will be revised to mesh with the new ISO 9001. At that time, the countdown will begin for the possible replacement of QS-9000 with ISO/TS 16949. Nevertheless, automotive suppliers will want to prepare for ISO/TS 16949 with greater urgency than this scenario might suggest: Early evaluation of ISO/TS 16949 will allow suppliers to develop the most cost-effective ways to meet these new and revised requirements.

d. VDA 6.1

VDA 6.1 is the German Quality Management System for the automotive industry. Verband der Automobilindustrie e. V. (VDA) issued the 4th edition in December 1998 and it became mandatory for all German car manufacturers on April 1, 1999. Based on ISO 9001:1994, it includes all elements of QS-9000, with an additional four requirements specific to VDA 6.1 as follows:

- Element 06.3 Recognition of product risks—These are the risks of the product fulfilling its own function and its effect on the whole assembly;
- Element Z1.5 Employee satisfaction—The perception of the employees of the company, as well as the needs and expectations of the employees that will be met through the company's quality approach;
- Element 07.3 Quotation structure—A customer or market is offered products for purchase or made available to own or to use;
- Element 12.4 Quality history—The system describes the quality history of customer supplied product and gives an overview of the situation during a particular period.

The VDA standard is broken into two parts, with the first classed as management and the second focusing on products and processes. Any company that goes through an audit must achieve at least 90 percent correct on all questions to obtain registration.

Aerospace Industry

a. AS9000—Aerospace Basic Quality System

AS9000, Aerospace Basic Quality System, is the aerospace version of ISO 9000 and was published in 1997. AS9000 contains ISO 9001 in its entirety with the addition of 27 clarifications or qualifiers and eight notes to the existing 20 elements of ISO 9001. A consortium of aerospace prime contractors, operating as a subcommittee (Americas Aerospace Quality Group, AAQG) under the Aerospace and Defense Division of the American Society for Quality Control, developed the document. Companies that contributed to the development of AS9000 include the following:

- AlliedSignal;
- Allison Engine Company;
- Boeing;
- General Electric Engines;
- Lockheed Martin;
- McDonnell Douglas;
- Northrop Grumman;
- Pratt & Whitney;
- Rockwell—Collins;
- Sikorsky Aircraft;
- Sundstrand.

Aerospace is significantly more safety and quality sensitive than most other industries. Procurement Quality Assurance at prime contractors believes ISO alone is not sufficient to define supplier quality system requirements. Primes currently require purchase order adders for ISO 9000 registered suppliers with each prime having their own unique adders. The Federal Aviation Administration (FAA) believes ISO alone is not adequate to meet regulatory requirements and FAA expectations. FAA has indicated that it will accept AS9000 under defined circumstances including:

- Primes maintain liability and responsibility;
- Primes must demonstrate oversight of all third-party audits;
- Criteria for acceptance of demonstrated compliance must be defined.

The Department of Defense (DOD) accepts ISO 9000, however, DOD expects more than ISO 9000 at primes. The DOD has expectations of advanced quality systems from prime contractors, and many DOD requirements (i.e., configuration management) are added by other required specifications. In addition to contractual requirements, DOD primes have a significant financial exposure with regard to supplier quality.

AS9000 represents a dramatic streamlining of current aerospace quality standards. From the DOD through the FAA, to each prime contractor and subcontractor, there is a multiplicity of unique requirements imposed on the aerospace suppliers, creating a huge burden with little added value. AS9000 represents a significant step towards standardizing and consolidating the aerospace quality processes.

b. AS9100—Quality Systems Aerospace—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing

The Society of Automotive Engineers (SAE International) published AS9100 Quality Systems—Aerospace—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing, in March 2000, the first international aerospace quality systems standard. AS9100 is technically equivalent to the European version, published by The European Association of Aerospace Industries (AECMA) as prEN9100.

In North America, AS9100 replaces AS9000 as the registration standard for suppliers to the aerospace industry. AS9000 will become obsolete when revisions to AS9100 based on ISO 9001:2000 revisions are incorporated. The existing version of ISO 9100 and AS9100 is expected to remain available for use until November 2003. This will allow users to transition to the new version.

The ISO Aerospace Technical Committee 20, Working Group 11, in association with the American Aerospace Quality Group (AAQG) in the U.S. and the European Association of Aerospace Industries, AECMA in Europe, and other countries such as Japan, China, Mexico and Brazil, developed the quality systems standard for use by aerospace companies worldwide. AS9100 was developed using ISO9001, AS9000 and EN9000–1, and it builds upon their requirements to produce a globally harmonized standard that meets the requirements of aerospace companies worldwide. The first standard available for use across the global aerospace community, AS9100, adds the additional requirements necessary to address both civil and military aviation and aerospace needs.

Based on industry need, major changes to the AS9000 document have been made to accommodate the changes in the industry and worldwide focus on quality and safety. Significant changes and/or additions have been made in the following areas: configuration management; reliability, maintainability, and safety; process control; purchasing; design verification and validation testing; first article inspection; corrective action; inspection and test status; servicing, delivery, investigation, and control of technical documentation and expansion of the internal audit requirement. With major industry manufacturers on board, companies at all levels in the aerospace supply chain will need this document to keep up with the worldwide changes in standardization and stay competitive in the industry.

AS9100 is based on ISO 9001. AS9100 adds the additional requirements necessary to address both civil and military aviation and aerospace needs. AS9100 provides additional requirements to all but one of the 20 elements of ISO 9001. (The exception is element 4.7, Control of Customer Supplied Product.)

The major areas of emphasis that supplement the elements of ISO 9001 are:

- Key product/process characteristics;
- Design and development management planning;
- Customer and regulatory requirements;
- Verification and validation documentation and testing;
- Documentation and data changes;

- Supplier (the AS9100 organization) purchasing and subcontractor evaluation, data and product verification;
- Product identification and traceability;
- Process control documentation and process changes;
- Qualification and control of special processes;
- First article inspection;
- Inclusion of all inspection, measuring and test equipment devices;
- Nonconforming material review authority and disposition;
- Flow down of corrective action to the appropriate subcontractor(s);
- Flow down of requirements from the Quality Manual to work instructions for use on Internal Quality Audits;
- Where servicing is a requirement, the procedure(s) will address specifics on data, technical documentation, repair schemes and controls;
- In the event statistical techniques are required, some specific areas and techniques offered for consideration include the following:
 - Design verification;
 - Process control;
 - Inspection;
 - Quality management;
 - Failure Mode and Effects Analysis.

CHAPTER 3

Industry Specific Standards for Failure Mode & Effects Analysis

Aerospace Industry

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

This document provides guidance to perform Failure Mode and Effects Analysis for the non-automotive industry, utilizing the information published in MIL-Std 1629A and SAE recommended Practice J1739. It is intended for use by organizations whose product development processes use FMEA as a tool for assessing the safety and reliability of system elements. It provides an overview of the FMEA process with details on the overall enhanced methodology. It also introduces the following types of FMEA:

- Functional FMEA
- Interface FMEA
- Detailed FMEA

Different Types of FMEAs in APR 5580

Functional FMEA

This type of Failure Mode and Effects Analysis is initiated during the conceptual or preliminary design phase. Functional FMEA is performed on the conceptual design to support the architectural definition and verify necessary design compensation and failure recovery requirements derived by the Functional Requirements Analysis. Functional FMEA can be performed on control systems, processes, software and complex devices whose functionality is more readily understood than the details of their operation. Functional FMEA focuses on the functions that an item, group of items or process performs rather than on the characteristics of the specific implementation.

Interface FMEA

This type of FMEA is initiated during the preliminary or detailed design phase. Similar to Functional FMEA, Interface FMEA is performed to verify compliance to design, safety and regulatory requirements. Unlike Functional FMEA, Interface FMEA is the process of determining and recording characteristics of failures in the interconnections between interfacing system elements. Interface FMEA is done to evaluate interconnections between hardware elements (i.e. wires, cables, fiber optic lines, etc.) and software elements. While conducting an Interface FMEA, failure modes specific to the interfaces are defined and their characteristics (effects and fault signatures) are determined.

Detailed FMEA

This type of analysis is initiated during the detailed design phase, but in some cases the functional analysis may be updated during the detailed design phase rather than doing a Detailed FMEA. Detailed FMEA is performed to verify that the design complies with requirements for failures that can cause loss of end item functions, single point failures, fault detection and fault isolation. In Hardware Detailed FMEA, the components comprise the physical system design. In Software Detailed FMEA, the components are from the source code. The characteristics of the failure of each and every component is determined and documented in this process. The Detailed FMEA is initiated as the design of each element matures and the detailed design schematics, part lists, and detailed software design documents and source code become available.

FMEA Verification

This process is initiated during the design verification and validation phase. Verification of FMEA ensures that adequate actions are taken to control, prevent and reduce the end effects of the identified potential failure modes.

Documentation

This document suggests that the documentation set should include the following:

- ✓ Description of the system or subsystem analyzed;
- ✓ Worksheets for the types of FMEA conducted;
- ✓ Summary of the analysis results.

FMEA Applications

Applications of FMEA can be categorized into Product Design Hardware and Software FMEA, and Process Design FMEA. Functional, Interface and Detailed analysis could be done for both product design hardware and software FMEA.

The following guidelines are provided in SAE ARP 5580.

Product Design Hardware FMEA

Product design hardware FMEAs are applied to the physical design of the product, i.e., electrical, mechanical and hydraulic subsystems and the interfaces between those subsystems.

Hardware Functional FMEA

Hardware Functional FMEA is first applied early in the design cycle after the major system functional components and their interactions have been defined.

Typical functional failure modes pertain to a particular function not being performed or being performed incorrectly. Failure effects associated with the different modes of operation should be evaluated and recorded.

Hardware Functional FMEA is also used later in the design cycle for complex subsystems or components, such as integrated circuits and control systems, whose functionality is more readily described than the operation of individual components.

Hardware Interface FMEA

Hardware Interface FMEA is performed on the physical interfaces between major functional system elements, i.e., LRUs (Line Replaceable Units), which include mechanical linkages, hydraulic lines or electrical cabling.

Typical failure modes include low pressure in hydraulic lines, improper grounding of an electric cable, etc.

Hardware Detailed FMEA

Hardware Detailed FMEA is the most common type of FMEA. This is done at the lowest piece/part level of design and generally involves individual system components. Standard lists of potential failure modes are available for many of the widely used components.

Product Design Software FMEA

Software includes programs, their related data elements, their execution as tasks that implement various system functions and also includes program interfaces with hardware and the interfaces between different programs or tasks.

Software Functional FMEA

Software Functional FMEA is applied to the Computer Software Configuration Item (CSCI) during top-level software design.

Failure modes associated to the individual functions, which have been assigned to Computer Software Components and to individual modules, are developed and applied to the software design to determine the effect on the system performance and safety of incorrect performance of the software element.

The primary outputs of the Software Functional FMEA are used to identify software architectural changes to reduce failure exposure. They are also used to identify

requirements to ensure that incorrect software behavior can be detected and that appropriate system corrective actions are instituted.

Software Interface FMEA

Software Interface FMEA is similar to a Functional FMEA for software but focuses on the interfaces between disparate software and hardware elements. Failure modes specific to the message and/or data type being passed are postulated and the system level effects are identified.

Software Detailed FMEA

Software Detailed FMEA is generally done for systems that do not include robust hardware protection of memory elements, processing results and data transfers. The intent of the Detailed FMEA is to supplement the Functional and Interface FMEAs with a detailed assessment of the response of the as-developed software to plausible faults and failures. Both the Functional and Interface FMEAs will have to be updated at the time the Software Detailed FMEA is performed to reflect the ultimate software architecture.

Process Design FMEA

Process FMEA evaluates the failure modes associated with the manufacturing and assembly process deficiencies. Process FMEA assumes that the product as designed will meet the design intent provided the product is manufactured properly. Process FMEAs are conducted for new parts and processes, changed parts and processes, and new applications and environments for product manufacturing and assembly.

SAE ARP 5580 also provides guidance on FMEA planning, functional requirement analysis, FMEA task analysis (including failure analysis, failure ratios, process capability indices and risk criteria), documentation and reporting requirements.

The following table from SAE ARP5580 summarizes the application of various types of FMEA and related tasks during the design phase.

Table 3–1

FMEA Task	Value/Use	Timing	Recommendations
Functional Requirements Analysis	Defines the design requirements for fault compensation, mitigation and monitoring provisions.	Initiated during conceptual design phase.	Should always be performed.
Functional Failure Mode and Effects Analysis	Supports functional assessment of system architecture. Supports early verification of the conceptual baseline: <ul style="list-style-type: none"> • Completeness of fault compensation 	Initiated during conceptual or preliminary design phase.	Should always be performed.

	<p>requirements</p> <ul style="list-style-type: none"> • Requirements for FD/FI provisions. <p>Identifies critical functions for more detailed analysis.</p>		
Interface Failure Mode and Effects Analysis	<p>Supports system level assessment of downstream failure effects (e.g. cascading faults).</p> <p>Provides a system view to the response of the FD/FI provisions.</p> <p>Provides an assessment of the</p>	Initiated during preliminary or detailed design phase.	Performed when analyzing a system or subsystem or when required by the system integrator.
FMEA Task	Value/Use	Timing	Recommendations
	overall system architecture.		
Hardware Detailed Failure Mode and Effects Analysis	<p>Provides a higher fidelity assessment for critical and safety related functions.</p> <p>Provides a detailed assessment of LRU and SRU failure conditions.</p>	Initiated during detailed design phase.	Should be limited to safety or mission critical functions identified during the Functional Failure Mode and Effects Analysis.
Software Detailed Failure Mode and Effects Analysis	Provides evaluation of single variable or instruction failures in software.	Initiated in detailed software design phase.	Should be limited to systems without hardware protection of memory, processing results or data transfers.
Latency Assessment	Accounts for multiple simultaneous failure modes.	Performed as part of each analysis type.	Performed when there are safety concerns.
FMEA Verification	<p>Verifies accuracy of analysis results.</p> <p>Validates analysis ground rules.</p>	Initiated in verification and validation phase.	Done in conjunction with system verification testing, especially when the analyst is uncertain of the failure consequences, or when required by contract or there is concern about ground rules.

Automotive Industry

SAE.J1739—Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), and Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA)

This document provides guidance in the application of Failure Mode and Effects Analysis. It's a recommended practice that gives the freedom to each team to use it in the most effective way for a given situation.

The document states the following three basic cases for which FMEAs are generated, each with a different scope:

Case	Scope
New design, technology or process	Focus on complete design, technology or process
Modifications to existing design or process (assumes there is a FMEA for the existing design or process)	Focus on modification to design or process, possible interactions due to the modification, and field history
Use of existing design or process in a new environment, location or application (assumes there is a FMEA for the existing design or process)	Focus on the impact of the new environment or location on the existing design or process

Guidelines for the following three types of FMEAs are provided in this document:

- **Design FMEA (D-FMEA)**—Design FMEA evaluates the initial design for manufacturing, assembly, service and recycling requirements, including functional requirements and design alternatives. Design FMEA should be initiated before or at design concept finalization and be continually updated as changes occur or additional information is obtained throughout the phases of product development. Design FMEA should be completed before the production drawings are released for tooling. Suggested criteria for the evaluation of severity, occurrence and detection for D-FMEA are provided in Tables 1, 2 and 3 of SAE J1739.
- **Process FMEA (P-FMEA)**—Process FMEA is utilized to accomplish the following:
 - Identify the process functions and requirements;
 - Identify potential product- and process-related failure modes;
 - Assess the potential customer effects of the failures;
 - Identify the potential manufacturing/assembly process causes and identify process variables on which to focus controls for occurrence reduction or detection of the failure conditions;
 - Identify process variables on which to focus process controls;
 - Develop a ranked list of potential failure modes, thus establishing a priority system for preventive/corrective action considerations;

- Document the results of the manufacturing/assembly process.

Process FMEA should be initiated before or at the feasibility stage and prior to tooling for production. It should take into account all manufacturing operations from individual components to assemblies.

Suggested criteria for the evaluation of severity, occurrence and detection for P-FMEA are provided in Tables 4, 5 and 6 of SAE J1739.

- **Machinery FMEA (M-FMEA)**—The Machinery FMEA supports the design process in reducing the risk of failures by:
 - Aiding in the objective evaluation of equipment functions, design requirements and design alternatives;
 - Increasing the probability that potential failure modes and their effects on the machinery have been considered in the design and development process;
 - Providing additional information to aid in the planning of thorough and efficient design, validation and development programs;
 - Developing a ranked list of potential failure modes ranked according to their effect on the “customer,” thus establishing a priority system for design improvements, development and validation testing analysis.

Machinery FMEA should be initiated during design concept development and should be continually updated as changes occur or additional information is obtained throughout the phases of machinery development. The analysis should be completed before engineering release for construction. Suggested criteria for the evaluation of severity, occurrence and detection for Machinery FMEA are provided in Tables 7, 8 and 9 of SAE J1739.

CHAPTER 4

Risk Management Planning

Risk Management

The focus of risk management is to identify the hazards associated with functional units and their accessories, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

The foundation of effective risk management is a clear commitment from corporate management. There are three key commitments that must be made in order to build the necessary infrastructure for a cost-effective risk management program:

- Organize and maintain the knowledge and information on the design, development and manufacturing of the product and ensure this data is up-to-date and accurate. This process is essential as the quality of the risk management program depends directly on this information.
- Provide knowledgeable and competent personnel throughout the organization to manage the risk management process and to participate in risk assessment and other work activities.
- Create a system that not only documents and maintains risk management files, but also records management's response to these studies and enforces an audit system to ensure that all approved risk reduction actions are implemented in a timely manner.

The risk management process in general includes the following elements:

- Risk Management Plan;
- Risk Assessment—covering both Risk Analysis and Risk Evaluation;
- Risk Control;
- Post-Production Information.

Risk Management Plan

Management must clearly define the objectives and scope of the project, which are dependent on a number of factors:

- The part of the product/process/system on which the project focuses;
- The phase of the product's life cycle in which the project takes place;
- The amount of information available.

Responsibility and resources should be allocated to ensure that no responsibility is omitted.

Decisions concerning risk acceptability may be based on operational, technical, financial, legal, social, humanitarian or other criteria. The decisions can be justified by doing the following:

- Using product-specific standards. If standards are properly implemented and the product is tested, an acceptable level of risk should result.
- Comparing with levels of risk evident from other similar products/systems on the market, which should consider similarities and differences in:
 - Functionality/intended use;
 - Hazards;
 - Risk;
 - Safety features;
 - Historical data;
- Following appropriate guidance documents.

Risk Assessment (Risk Analysis & Risk Evaluation)

Risk analysis addresses three specific questions:

- What can go wrong?
- How likely is it?
- What are the impacts?

In order to answer the above questions, it is essential to understand the intended use or purpose of the product, including any foreseeable misuse, and to identify the product characteristics that could impact on safety.

The next step is to identify hazards associated with the product and determine the related causes and consequences, and ultimately estimate the risk.

Some potential hazards (if applicable) that should be evaluated include these factors:

- Toxicity, flammability and reactivity of raw materials and wastes;
- Sensitivity to environmental factors such as temperature and humidity;
- Mechanical or electronic hazards;
- Human factors associated with the operator-equipment interface.

The risk analysis is not restricted to only the design of the product but should also be done for the manufacturing process (e.g. assembly process, packaging) and the process of delivering the product to its intended location. For products that involve materials that are sensitive to the environment (e.g., heat, humidity, cold or light), storage and transportation methods need to be reviewed. If problems are identified, appropriate changes should be made in packaging or warnings on storage or packaging containers.

The software used in the functioning of a product to control or monitor systems also needs to be reviewed. The consequences of software errors can be unpredictable, particularly those that involve data corruption or false alarms. In such cases, the product should have a means of detecting software errors or the consequences. For example,

consider installing separate redundant alarms or interlocks on critical aspects of the system/product.

Depending on the complexity of the system/product, one or a combination of risk analysis techniques can be used to identify hazards. Some common techniques include Failure Mode and Effects Analysis (FMEA), Hazard and Operability Analysis (HAZOP) and Fault Tree Analysis (FTA). The FMEA methodology and its application throughout the entire life cycle of the system/product are addressed later in this manual. The other two techniques are described in the next chapter.

Once the risk estimation for all hazards is completed, the acceptability of risk is determined based on the company's risk-acceptability criteria (based on what was established in the risk management plan) and, if it is too high, the risk needs to be mitigated.

Risk Control

Risk reduction should focus on reducing the hazard severity, the probability of occurrence, or both. The following are examples of risk control:

- Inherent safety by design;
- Use of consensus standards;
- Protective design measures (e.g. incorporating alarms and interlocks into the design to mitigate risks that cannot be eliminated);
- Protective manufacturing measures, with improved process or test capabilities;
- Safety information (labeling, instructions for use, training, etc.).

The technical and economic practicality of implementing the options should be evaluated. Once the risk reduction decisions are made, the associated risk reduction actions should be implemented and monitored throughout the product's life cycle.

Post-Production Information

Throughout the product's lifetime, new information obtained during postmarketing vigilance regarding a new hazard or risk must be assessed and recorded in the risk management file. Hence, risk analysis and management is an ongoing process throughout a product's lifetime and it is the continuous responsibility of the manufacturer to ensure the product/system safety.

Risk management should start at the early design stage to establish the highest level of inherent safety. This can significantly offset the cost of implementing risk-mitigating measures.

CHAPTER 5

Risk Analysis Methodologies

This chapter gives an overview of Hazard and Operability Analysis (HAZOP) and Fault Tree Analysis (FTA), which are risk analysis techniques commonly used in the industry as alternatives to Failure Mode and Effects Analysis (FMEA).

Hazard and Operability Analysis (HAZOP)

This technique was originally developed for use in the chemical process industry for identifying hazards and operability problems.

HAZOP is a highly structured bottom-up methodology. It uses the combination of design parameter and guide word to help identify deviation from design intent. The following are examples of guide words and design parameters:

Guide Words

- **More** or **High** or **Higher** or **Greater** (words that imply an *excess*), when compared to the design intent;
- **No**, **None**, **Less** or **Low** or **Lower** or **Reduced** (words that imply *insufficiency*), when compared to the design intent;
- **Part of** or **Not all of** or **Partially** (words that imply *incompleteness*), when compared to the design intent.

Design Parameters

Applicable **parameters** typically include:

- Pressure;
- Temperature;
- Flow;
- Composition;
- Level;
- Reaction Rate;
- Viscosity;
- pH.

Applicable **operations** typically include:

- Filling;
- Transferring;
- Purging;
- Emptying;
- Draining;
- Venting;
- Maintenance;
- Start-up;
- Shut-down.

Deviations

Guide Word + Property = Deviation

For example:

■ **When Property=Parameter:**

High	+	Flow	=	High Flow
Low	+	Pressure	=	Low Pressure
More	+	Reaction	=	Greater Reactivity

■ **When Property=Operation:**

No	+	Transfer	=	No Transfer
Less	+	Empty	=	Residue Remaining

■ **When Property=Material:**

No	+	Steam	=	No Steam
More	+	Diluent	=	More Diluent

Fault Tree Analysis (FTA)

Fault Tree Analysis is a top-down methodology. The analysis starts with the undesired consequence or top event and identifies the various combinations of faulty and normal possible events occurring in the system. This procedure deduces the root cause(s) of the top event. The events and logical relationships between events are represented graphically in a tree structure using both logic and event symbols, as shown in Tables 5-1 and 5-2, respectively. An example of a fault tree is shown in Figure 5-1.

FTA can be used to identify multiple failure conditions where two or more events must occur for the top-level event to occur. If estimates of failure rates are available for individual events, the probability of the top event can be predicted.

Table 5–1: Logic Gate Symbols







Gate Symbol	Gate Name	Causal Relation
	AND	Output event occurs if all input events occur simultaneously
	OR	Output event occurs if any one of the input events occurs

Table 5–2: Event Symbols

Event Symbol	Event Name	Meaning
	CIRCLE	Basic event with sufficient data
	DIAMOND	Undeveloped event
	RECTANGLE	Event represented by a gate
	TRIANGLE	Transfer symbol

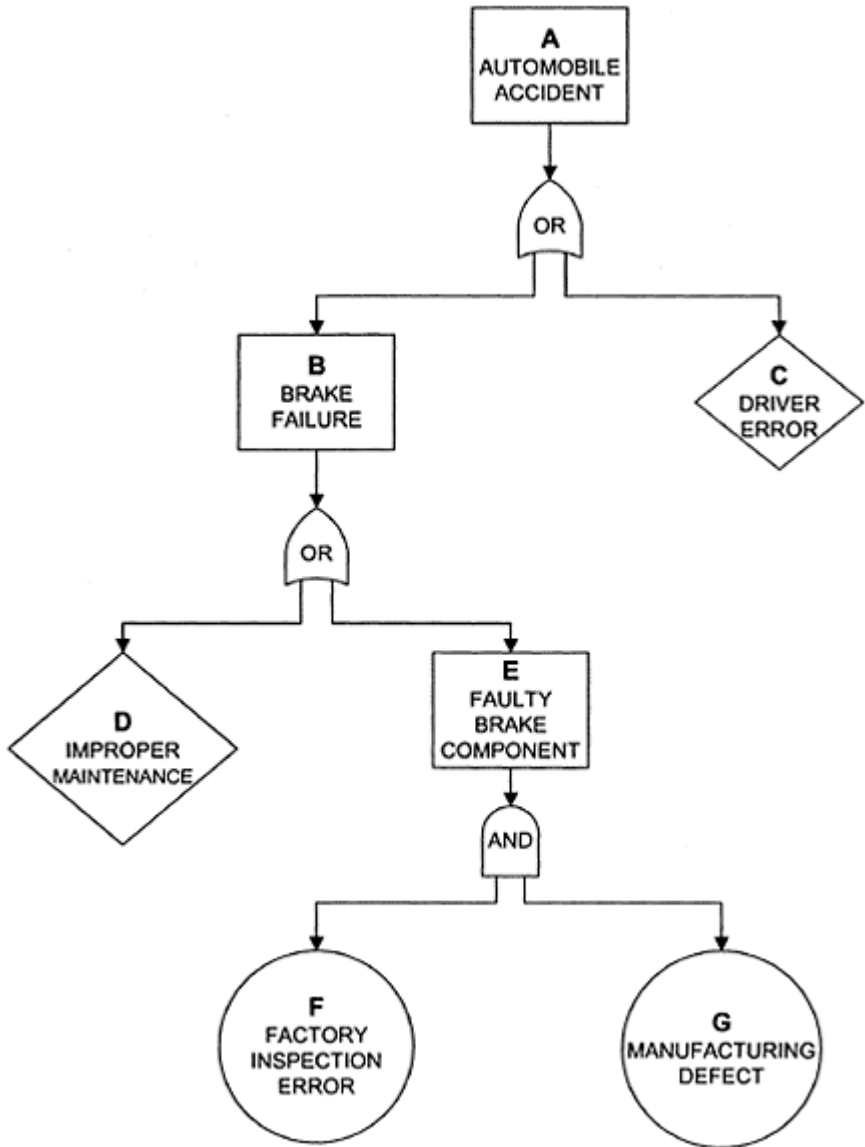


Figure 5-1: Fault Tree Analysis Example

CHAPTER 6

Overview of FMEA

This chapter is an introduction to Failure Mode and Effects Analysis (FMEA). It outlines the objectives of FMEA, reasons and benefits of performing FMEA and the limitations of the technique.

Overview

The need for continuous improvement of product quality, reliability and safety arises from product recalls (see Table 6–1), government regulatory requirements, agency recommendations, legal implications and above all a company's desire to improve its market position and customer satisfaction. These issues require product manufacturers to perform risk analyses that identify and minimize part/system failures throughout the product's life cycle.

The FMEA methodology is one of the risk analysis techniques recommended by international standards. It is a systematic process to identify potential failures to fulfill the intended function, to identify possible failure causes so the causes can be eliminated, and to locate the failure impacts so the impacts can be reduced. The process of FMEA has three main focuses:

- The recognition and evaluation of potential failures and their effects;
- The identification and prioritization of actions that could eliminate the potential failures, reduce their chances of occurring or reduce their risks;
- The documentation of these identification, evaluation and corrective activities so that product quality improves over time.

FMEA is primarily adapted for material and equipment failures, but in a broad sense, human error, performance and software errors can also be included.

By applying the FMEA methodology during the various phases of a product's life cycle, the methodology provides a systematic and disciplined strategy for examining all the ways in which a product can fail. The results of FMEA in turn affect the product design, process development, sourcing and suppliers' quality, downstream (referring to downstream of a process or user of the product) application, and field service.

The following are some of the benefits of conducting a FMEA study:

- Ensures that the potential failures and their effects on the system have been identified and evaluated, consequently helping to identify errors and define corrective actions;
- Provides a means for reviewing product and process design;
- Helps to identify critical characteristics of the products and processes;

- Improves productivity, quality, safety and cost efficiency;
- Helps to determine the need for selecting alternative materials, parts, devices, components and tasks;
- Assists in documenting the reasons for changes;
- Provides a means of communication between different departments;
- Helps increase customer satisfaction;
- Improves a company's image and competitiveness.

Table 6–1: List of Product Recalls

Model/Type of Product	Quantity Recalled	Problem	Failure Effect
<i>Automotive</i>			
2001 Nissan Sentra	130,000 passenger cars	One or more of the attachment bolts for the front-suspension, lower control arms may break.	Unusual noise or vibration felt through the steering wheel when hitting bumps.
2000 and 2001 Chrysler Neon	515,000 from USA, Canada, Mexico and foreign markets	Brake booster vacuum hose may loosen.	Harder for drivers to stop the vehicle. Greater pedal pressure may be required to stop the vehicle.
1997-2000 Chevrolet Venture, Pontiac Trans Sport/Montana and Oldsmobile Silhouette	54,700 minivans	Passenger side power sliding doors may close but not latch.	Door could open while the car is in motion.
Pontiac Grand Am, Buick Skylark and Oldsmobile Achieva	778,000 cars	High current flows and heat in the ignition switch when key held in the start position for an extended period of time.	Fires could occur in the steering system. Reports of three injuries from electrical fires.
GM light trucks and sports utilities	1.38 million vehicles	Brake pedal will be lower than normal and stopping distances will be longer.	Crash could occur when stopping distance is smaller.
Model/Type of Product	Quantity Recalled	Problem	Failure Effect
<i>Home Products</i>			
Take 2, Travel Solutions, Pioneer, Travelite, Pro Sport 4-in-1 strollers	650,000 strollers	Strollers can unexpectedly collapse or the car seat/carrier adapter can unexpectedly detach.	Infants can suffer serious injuries. 681 incidents including 250 injuries reported.
Star Cruiser and Rock Rider swings (backyard gym sets)	190,000 sets	Screws that hold the swing together can fall out, causing the seat to fall to	291 incidents of seats separating and 19 injuries reported.

		the ground.	
Ariens Scotts and Husqvarna walk-behind lawnmowers	40,000 lawnmowers	Piece attaching the blade to the mower can crack and break off.	Possible injury to the operator or bystander.
Zep commercial cleaner	1.4 million 32 oz. bottles	Leaking occurs through the cap when bottles are turned on their side.	Cleaner causes irritation and burns to the skin and eyes. 10 bottle leaks and three injuries reported.
AquaStar natural gas water heaters	320 units	Produces dangerous levels of carbon monoxide in exhaust gas.	Serious injuries and death possible.
Model/Type of Product	Quantity Recalled	Problem	Failure Effect
<i>Children's Toys and Consumer Goods</i>			
Princess Ariel costumes	54,000 costumes	Fabric ignites easily.	A burn injury to a four-year-old girl and one case of ignition reported.
Accessory to a video game—baseball bats	140,000 baseball video games to replace the bats	Bats can separate during swinging.	A split lip, facial lacerations, a bump on the head and bruising reported.
Nike Trunner LX and Jordan Trunner 2000 cross trainers	225,000 pairs	Thin metal strip on the outside of the heel can protrude from the shoe.	Forms a sharp edge that can cut. 16 reports of cuts to the lower legs. Some stitches to close.
Scuba buoyancy compensator devices (BCDs) by Sheico PKS Inc.	10,000 units	Overpressure valve can stick in the open position.	Risk of drowning to divers.
<i>Medical Devices and Pharmaceuticals</i>			
Inter-Op shells by Sulzer Orthopedics	Approximately 17,500 patients worldwide have received the recalled Inter-Op shells.	Lubricant residue may cause the shells to come loose and may prevent implant from bonding with the bone, causing the shells to loosen.	129 cases of loosening reported. All presented symptoms of aseptic loosening within six months of implantation.
Migraine drug Sandomigran DS (pizotifen, double strength) by Novartis Pharmaceuticals Canada	941 large bottles sent out to pharmacists still need to be located	Muscle relaxant tablets were found in some bottles.	These foreign tablets could lead to drops in blood pressure.

Model/Type of Product	Quantity Recalled	Problem	Failure Effect
<i>Consumer Electronics</i>			
Electric drills	58,000 units	Switches on these power tools can stick.	Drills can continue to operate after the trigger is released. Risk of injury to user.
Nightlights by Dura Kleen Inc.	459,000 nightlights	Electrical connections are loose; made of flammable plastic, and power switch does not work.	Poses shock and fire hazards to consumers.
Black & Decker miter saws	118,400 units	Bolts can loosen.	Risk of lacerations to the user.
Batteries in Dell Inspiron 5000 and 5000e notebook computers	284,000 batteries	Can overcharge and become very hot.	Possible smoke and fire.

Limitations of FMEA

Using Failure Mode and Effects Analysis can potentially be disadvantageous for the following reasons:

- Analysis of complex systems that have multiple functions consisting of a number of components can be tedious and difficult;
- Compound failure effects cannot be analyzed;
- Incorporating all possible factors influencing the product/process, such as human errors and environmental impacts, can make the analysis lengthy and require a thorough knowledge of the characteristics and performance of the different components of the system;
- Successful completion requires expertise, experience and good team skills;
- Dealing with data redundancies can be difficult;
- Can be costly and time consuming.

CHAPTER 7

FMEA Procedures

This chapter describes the basic terminology and process used in FMEA. In addition, the procedures for setting up, conducting and following up FMEA are described.

Introduction

Similar to a HAZOP, the FMEA is a bottom-up approach starting with components and using a single-point failure approach to progressively work up to the top level. During the FMEA study, risk is estimated by rating the severity of failure effects, the likelihood of causes, and the likelihood of detecting the cause of a failure or the failure mode. Table 7–1 shows a sample FMEA worksheet for documenting the results of the analysis. The terminology used on the worksheet and the FMEA procedures are described below.

FMEA Terminology

Item Function

Item function specifies the function of the part or item under review.

Potential Failure Mode

A potential failure mode is the manner in which a failure can occur i.e. the ways in which the reviewed item can fail to perform its intended design function, or perform the function but fail to meet the objective. The potential failure mode may also be the cause of another potential failure mode in a higher-level subsystem or system, or be the effect of one in a lower-level component.

Typical potential failure modes include the following:

- Fail to open/close;
- Brittle;
- Cracked;
- Warped;
- Underfilled;
- Undersized/Oversized.

Potential Failure Causes

Potential failure causes identify the *root cause* of the potential failure mode, not the symptoms, and provide an indication of a design weakness that leads to the failure mode. The prompt identification of the root cause is important for the implementation of preventive or corrective measures. Failure causes often include these types of problems:

- Overstressing;
- Incorrect material specified;
- Improper wall thickness;
- Improper tolerance.

Potential Failure Effects

Potential failure effects refer to the potential outcome of the failure on the system, design, process or service. The potential failure effects need to be analyzed based on the local and global impacts. A local effect is an outcome with only an isolated impact that does not affect other functions. A global effect, on the other hand, affects other functions/components and has a domino effect on the system.

For a design, three types of potential failure effects need to be considered:

- The effect on the end user of the product (end effect);
- The effect on the local/reviewed area (local effect);
- The effect on aspects situated between the above two (next high level effect).

For a manufacturing process, two types of potential failure effects need to be considered:

- The effect on the product;
- The effect on local and downstream processes.

The severity of a particular failure is determined based on the failure effect. The more serious the effect is, the higher the severity.

Potential failure effects might include these examples:

- Erratic operation;
- Failure to operate;
- Noise;
- Loss of life.

Current Controls

Current controls are the safeguarding measures in place at the time of review that are intended to do the following:

- Eliminate causes of failure;
- Identify or detect failure;
- Reduce impacts/consequences of failure.

This list includes common examples of current controls:

- Statistical Process Control (SPC) analysis;
- Product capability studies;
- Function tests;
- Gauge repeatability and reproducibility (R&R) studies;
- Durability tests;
- Design reviews and design guidelines;
- Operator training.

Severity (S)

Severity is the seriousness of the effects of the failure. Severity is an assessment of the failure effects on the end user, local area and in-between (next higher) areas. The severity rating applies only to the effects.

The severity can be reduced only through a change in the design. If such a design change is attainable, the failure can possibly be eliminated.

Occurrence (O)

Occurrence is the frequency of the failure—that is, how often the failure can be expected to take place.

Detection (D)

Detection is the ability to identify the failure before it reaches the end user/customer.

Risk Priority Number (RPN)

An RPN is a measurement of relative risk. It is calculated by multiplying together the severity, occurrence and detection ratings. The RPN is determined before implementing recommended corrective actions, and it is used to prioritize the actions. The value, by itself, does not have any other significance.

RPN = SEVERITY × OCCURRENCE × DETECTION
--

Recommended Corrective Action

The recommended corrective action is intended to reduce the RPN by reducing the severity, occurrence or detection ranking, or all three together.

Corrective Actions Taken

It is a brief description of the actual actions taken, after identifying recommended corrective actions.

Resulting Severity

After a corrective action has been chosen/identified, “estimate” and record the resulting severity rating.

Resulting Occurrence

After a corrective action has been chosen/identified, “estimate” and record the resulting occurrence rating.

Resulting Detection

After a corrective action has been chosen/identified, “estimate” and record the resulting detection rating.

Resulting RPN

The resulting RPN is determined based on the resulting severity, occurrence and detection.

Critical Characteristics

Critical characteristics are characteristics that can affect compliance with government regulations or product safety. Critical characteristics are defined by:

- The courts—through product liability;
- Regulatory agencies—through formal laws and/or regulations;
- Industrial standards—through generally accepted practices in the industry;
- Customer requisitions—through their wants, needs and expectations;
- Internal engineering requirements—through historical data, or leading edge technology, or experiences with products or services.

Such characteristics require specific producer, assembly, shipping or monitoring actions and inclusion on Control Plans. Examples of critical characteristics include part or process requirements, such as dimensions, specifications, tests, processes, assembly sequences, tooling, torque, welds, attachments and component usages.

Significant Characteristics

Significant characteristics are characteristics of products, processes and tests where a reduction in variation within a specified tolerance around a proper target will improve customer satisfaction. Significant characteristics must be supported with Control Plans.

Control Items

Control items are parts that can affect either compliance with government regulations or safe product/process operation. They are identified by the customer's product engineering on drawings and specifications with a specific and unique symbol.

FMEA Steps

During an FMEA study, the product/process/service/system being reviewed is broken down into smaller items/subsystems. For each item, the following steps are performed:

1. Define the item being analyzed.
2. Define the functions of the item being analyzed.
3. Identify all potential failure modes for the item.
4. Determine the causes of each potential failure mode.
5. Identify the effects of each potential failure mode without consideration of current control.
6. Identify and list the current controls for each potential failure mode.
7. Determine the most appropriate corrective/preventive actions and recommendations based on the analysis of risk.

After going through all the items for each failure, assign a rating (from 1 to 10, low to high) for severity, occurrence and detection. Determine the RPN and use it to prioritize the recommendations. The severity rating should be based on the worst effect of the potential failure mode.

When the severity is very high (8 to 10), special attention must be given to ensure that the risk is addressed through existing design controls or corrective/preventive actions, regardless of the RPN.

If there are no recommended actions for a specific potential failure mode, failure cause or existing control, enter "None".

If this is a follow-up of an existing FMEA, note any action taken to eliminate or reduce the risk of failure modes. Determine the resulting RPN as the risk of the potential failure modes are reduced or eliminated.

Once corrective action has been taken, the resulting RPN is determined by reevaluating the severity, occurrence and detection ratings. Improvement and corrective action must continue until the resulting RPN is at an acceptable level for all potential failure modes.

When it comes to planning the meeting, the following is a suggested list of considerations:

- *People*—People involved in all meetings may differ in values, attitudes, experiences, gender, age and education. All these differences must be accounted for in the planning of the meeting.
- *Purpose*—As mentioned before, the scope of the study—the purpose, objective and the goal—must be understood by all, both management and participants.
- *Atmosphere or climate*—The atmosphere contributes to the effectiveness of the meeting. It is imperative that whoever plans the meeting takes into consideration the climate and atmosphere.
- *Place and space*—All meetings are held in a place and a space. Therefore, planners must consider the following:
 - Access to the space, available parking;
 - Size of the space;
 - Acoustics, lighting, temperature control;
 - Cost;
 - Equipment requirements.
- *Costs*—The FMEA budget should take into consideration the required preparation time, as it can be lengthy. The required preparation work is discussed further in the next section. As the system, design, process or service personnel assigned to do the FMEA may be in different places, one should consider the travel expenses of participants.
- *Time dimensions*—When estimating the time required for conducting the FMEA, one should consider the conditions, objectives and complexity of the project. The time constraints should be fully evaluated. If the meeting is going to be prolonged, the agenda items and objects should be adjusted accordingly.
- *Prework and “after the official meeting work”*—The quality of the FMEA study depends on good preparation work, which is discussed further in the next section.
- *Plans, program and agenda*—All meetings have an agenda, for without an agenda, there cannot be a meeting. A detailed planned program or agenda, which can be shared (no surprises) by all participants, is a valuable addition to a meeting. When planning the agenda, make sure all the objectives of the meeting are covered.
- *Follow-up*—After the meetings have ended, there is a need for some follow-up in these areas:
 - Implementing action items;
 - Communicating information to all appropriate personnel;
 - Publishing the documented study and writing the report.

Preparation Before FMEA Sessions

Before conducting a FMEA, preparation work should be done to ensure that the FMEA study is carried out smoothly. The following are the recommended procedures for doing so:

1. Define scope

After considering the questions outlined in the previous section, the study scope should be defined and documented. This would help prevent the FMEA team from focusing on the wrong aspect of the product, process or service during the FMEA. It would also assist the process of data collection (next step).

2. Collect data

On the basis of the scope defined in step 1, assemble as much information as possible. The following are some examples:

- Product prototype;
- Design specification;
- Design drawings;
- Process flow diagram;
- Operating manual;
- Maintenance log.

3. Break down the system

During the process of breaking down the product/process/service into smaller items, consider the following:

- If items are too small, you can lose your sense of analysis and incur excessive repetition;
- If items are too large, they can become confusing and hard to handle. The best way to size an item is based on item function.

4. Prepare list of potential failure modes

The list of potential failure modes prepared at this stage acts as a starting point for the FMEA section. It is not intended to replace the effort of identifying the potential failure modes during the FMEA section. The list can be established based on this information:

- Failure history of products with similar design;
- Product recalls;
- Failure records of the product/process/system;
- Review of the product/process/system.

5. Assemble FMEA team

A FMEA study requires efforts of experts from different areas. It cannot be done on an individual basis. Hence, the team should be cross-functional and multi-disciplined. It is important to ensure that the appropriate individuals are going to participate.

6. Choose the right tool for transcribing FMEA

Choosing the right tool for transcribing the FMEA ensures efficiency of conducting the analysis. There are three different methods (non-computer and computer based):

- Manual transcription;
- Spreadsheet-type software;
- Risk analysis software (Windows based).

Table 7–2 compares the features of the above methods. Each feature is ranked from 10 to 1, with 10 being the best performance. It is concluded that using risk analysis software is the best and most efficient method.

Table 7–2: Comparison of features of different methods of transcribing risk analysis

Feature	Manual Transcription	Spreadsheets	Risk analysis software (Windows based)
Learning Curve Required	None (10)	Little (7)	Some (4)
User Friendliness	Maximum (10)	Good (7)	Good (7)
Productivity	Poor (1)	Fair (4)	Very Good (10)
Customization Features	Very Good (10)	Good (7)	Very Good (10)
Copying Capabilities	None (1)	Some (4)	Very Good (10)
Team Participation	No (1)	Some (4)	Very Good (10)
Quality Assurance	None (1)	Little (4)	Very Good (10)
Assists Auditing of FMEA	No (1)	Little (4)	Very Good (10)
Good Documentation	No (1)	Fair (4)	Very Good (10)
“Power” Features	None (1)	Some (4)	Very Good (10)
Overall Assessment	Poor (37)	Fair (49)	Very Good (91)

Conducting FMEA Sessions

The FMEA team is led by the team leader or the facilitator. The team leader/facilitator provides assistance and guidance to the team to ensure that the FMEA session is conducted effectively on a timely basis. A typical FMEA session would follow the steps outlined below:

1. Facilitator or team leader explains

The facilitator or one of the team members explains the purpose and scope of the FMEA and sets the rules for the study.

2. Review the system being studied

The system is reviewed to ensure everyone on the FMEA team has the same understanding of the system.

3. Perform the analysis

The FMEA process described earlier is applied to the product/process/system. When FMEA is performed on commodity items, it would be efficient to perform group FMEAs on similar or identical items and then address the out-of-the-ordinary conditions as separate items.

4. Review FMEA

At the end of the FMEA, the team should ensure that the function, purpose and objective have been met. Some helpful hints include the following questions:

- Is the problem identification specific?
- Was a root cause, effect or symptom identified?
- Is the corrective action measurable?
- Is the corrective action proactive?
- Is the use of terminology current and consistent?

Follow-Up of FMEA

- The facilitator/team leader would issue a preliminary FMEA report including the following:
 - Attendance;
 - Study Outline;
 - Detail Report;
 - Action Register.

- The FMEA is a living document and should always reflect the latest level of the system being analyzed, as well as the latest relevant actions, including those occurring after the start of production.
- The distribution is a controlled document and should be treated as such.
- Each recommendation must be assigned to the appropriate personnel to ensure it has been implemented or adequately addressed.
- A person should be assigned to oversee the progress of implementing all recommendations and to ensure all actions are carried out properly.

CHAPTER 8

FMEA Team

This chapter describes the responsibilities of FMEA team members and the facilitator/team leader.

Introduction

Failure Mode and Effects Analysis (FMEA) is a team function and cannot be done on an individual basis. The makeup of the FMEA team is cross-functional and multi-disciplined for each study. The knowledge that is required for a specific problem is often unique to that problem and may require personnel from other specialized departments as well.

Team Size

- The best size for the team is usually four to six people;
- The minimum number of people can be dictated by the number of areas that are affected by the FMEA;
- When appropriate, consider offering team membership to the customer, whether internal or external to the organization.

Team Membership

The responsibilities of team members are as follows:

- Participate;
- Contribute knowledge and experience;
- Be open-minded for discussion, negotiation and compromise;
- Share adequate information with colleagues.

Team Leader (Facilitator)

The team leader is responsible for coordinating the FMEA process:

- Setting up and facilitating meetings;
- Ensuring that the team has the necessary resources available;
- Making sure the team is progressing toward the completion of the FMEA.

The team leader should not dominate the team and does not normally have the final word on team decisions. The team leader's role is more like that of a facilitator than a decision-maker.

Arrangements should be made for a scribe to be responsible for documenting the study during the FMEA sessions. The scribe's role is often rotated among all team members, except the team leader. This spreads the burden equally among all participants.

CHAPTER 9






Common Tools Used with FMEA


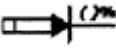
This chapter gives an overview of tools commonly used with FMEA, including process flowcharts, block diagrams and Pareto charts.

Process Mapping/Process Flowcharts

The concept of process mapping is to capture knowledge and sequence of flow of operations about processes and then represent that knowledge using boxes and arrows. Process mapping provides a clear picture of the process and allows easy identification of the main sequence of activities, and it clarifies critical connections across individual operations and departments. Table 9–1 shows some commonly used symbols in process mapping. An example process map is given in Figure 9–1.

Table 9–1: Common Symbols Used in Process Mapping

Symbol	Meaning	Examples
	Decision	<ul style="list-style-type: none"> • Is the part to customer spec? • Is the supplier the correct one?
	Control/Inspection	<ul style="list-style-type: none"> • Inspect part. • Is it the correct quality/quantity?
	Operation	<ul style="list-style-type: none"> • An action or process. • Is it manual or automatic?
	Movement/Transfer	<ul style="list-style-type: none"> • Material handling. • Movement of people. • Data transfer.
Symbol	Meaning	Examples
	Delay	<ul style="list-style-type: none"> • Down time or setup time. • Items in queue. • Waiting for additional information.

	Storage/Inventory	<ul style="list-style-type: none"> • Inventory materials, finished products.
	Reject	<ul style="list-style-type: none"> • Items rejected. • What happens to rejected part and subsequent parts?
<p>Here are just a few of the typical symbols used in process mapping. By using symbols and words, a picture of a company's manufacturing process can be drawn.</p>		

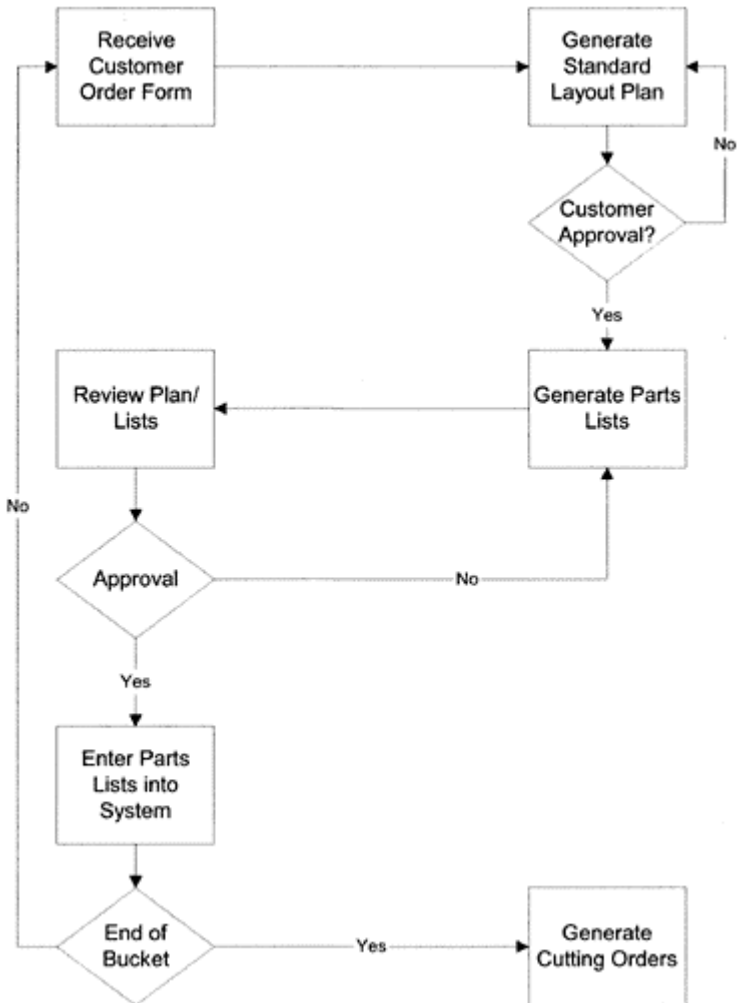


Figure 9–1: Sample Process Map for Order Entry

Block Diagrams/Functional Flow Diagrams

Block diagrams illustrate the operation, interrelationships and interdependencies of the functions of a system, which are required to show the sequence and the series dependence or independence of functions and operations. Block diagrams may be constructed in conjunction with, or after, defining the system and shall present the system breakdown of its major functions. More than one block diagram is sometimes required to represent alternative modes of operation, depending upon the definition established for the system.

Two types of block diagrams are used in FMEA:

- **Functional block diagrams**—Functional block diagrams illustrate the operation and interrelationships between functional entities of a system as defined in engineering data and schematics. An example is given in Figure 9–2.
- **Reliability block diagrams**—This type is useful for identifying the series dependence or independence of major components, subsystems or detail parts in achieving required functions. An example is given in Figure 9–3.

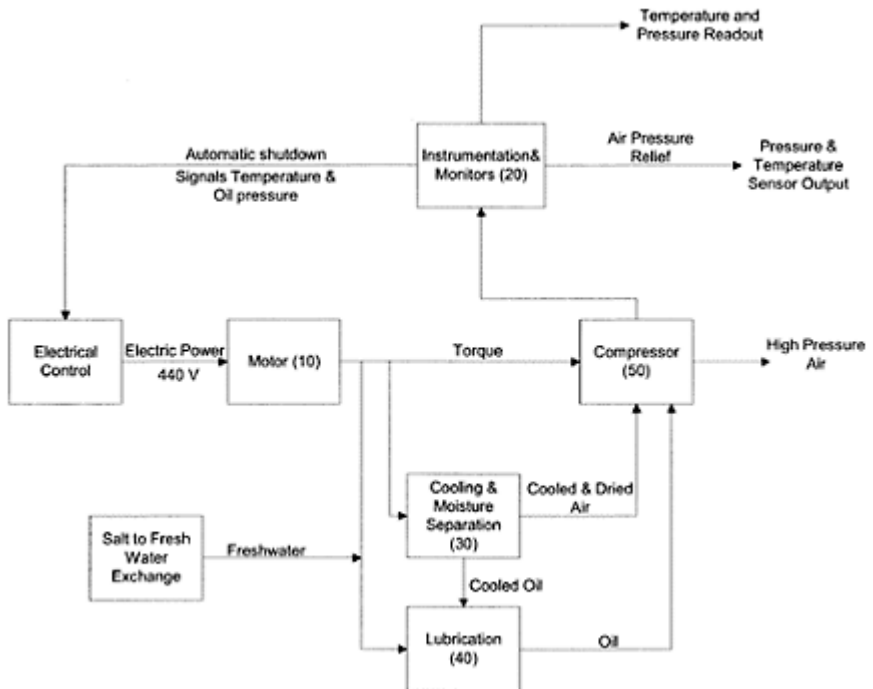


Figure 9–2: Functional Block Diagram

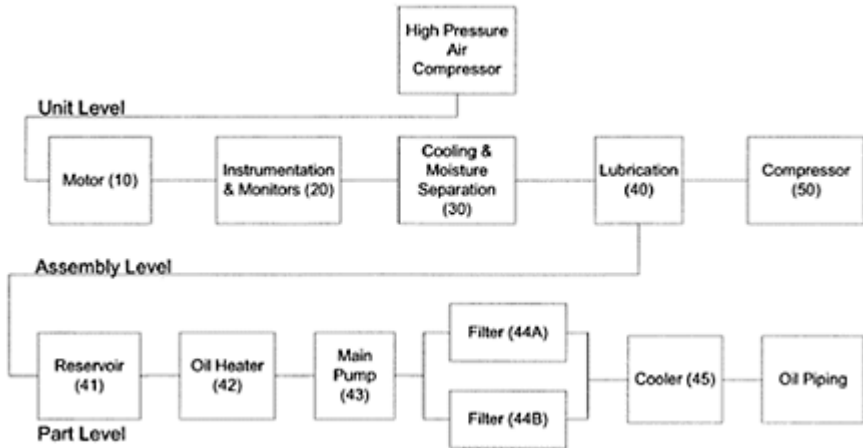


Figure 9–3: Reliability Block Diagram

Pareto Charts

The Pareto Chart combines a bar graph with a cumulative line graph. The bars are placed from left to right in descending order. The cumulative line graph shows the percent contribution of all preceding bars. The Pareto Chart shows where effort can be focused for maximum benefit. It may take two or more Pareto Charts to focus the problem to a level that can be successfully analyzed.

In FMEA, Pareto Charts are usually used for the following:

- Comparison of RPNs between different failure modes of the item analyzed and identification of high RPN failure modes.
- Comparison of total RPNs between items and identification of high RPN items. The total RPN of each item is the summation of RPNs of all failure modes of the item.

In either case, the team must set a cut-off RPN, where any failure modes or items with an RPN above that point require further attention. An example Pareto Chart for comparison of RPNs between different failure modes is given in Figure 9–4.

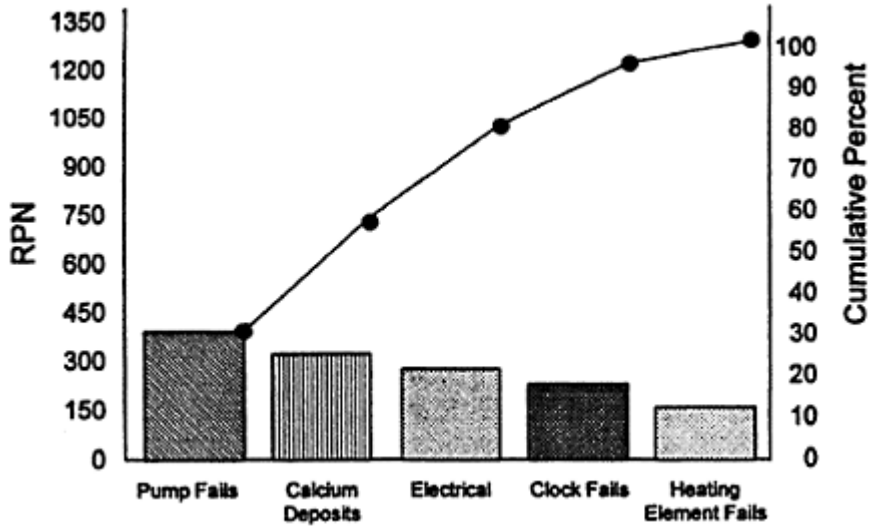


Figure 9-4: Pareto Chart for comparison of RPNs between different failure modes

CHAPTER 10

Pitfalls with FMEA

This chapter describes some major pitfalls that can arise while conducting FMEA studies.

Prepare FMEA Team

Inadequate preparation may:

- Slow down the team;
- Result in excessive study times.

Do Not Assume Everyone Understands FMEA

Prepare the team. This objective can be achieved through the services of risk management consultants.

Choose Team Members Carefully

The wrong team players can negatively impact the FMEA. See Chapters 12 to 16 for a suggested list of team members for different types of FMEA.

Avoid Getting Sidetracked

- Avoid getting off topic;
- Avoid “hobby horses;”
- Avoid redesigning during the FMEA. Identify Action Items for further study.

Do Not Run Excessively Long Sessions

FMEA sessions should not exceed six to seven hours since the team will become very exhausted and will be ineffective.

Use the Right Type of FMEA Methodology

Selecting the right type of FMEA methodology depends on which stage the product cycle is at. For example, during the preliminary design stage, Product/Design FMEA should be used to review the design of the product, while Process FMEA should be used in the process planning stage.

Address Group Participation

- Avoid team sessions being dominated totally by one or two people;
- Ensure everyone is encouraged to input by using “round table” techniques and sharing the responsibility of the FMEA.

List Action Items Effectively

- Record the Action Item so that it can be acted upon by the responsible person designated to execute it. Avoid indecisive instructions such as “Consider studying...”
- Do not propose Actions that are just “wish lists.” Excessive numbers of Actions tend to devalue their worth. Be critical, but not over or under zealous.

CHAPTER 11

Product Life Cycle & FMEA

This chapter outlines the application of FMEA at various stages in a product's life cycle. It also introduces the use of Control Plans as a tool to document the design and process characteristics for the manufacturing of a product.

Introduction

During the process of design, development and manufacture, the following issues affect the reliability (safety, durability and robustness) of components:

- Design of process and product;
- Verification of product design;
- Quality of parts purchased from suppliers;
- Validation of processes for production;
- Amount of process variation;
- Clarity of the device instruction.

Applying FMEA at different stages in the product's life cycle helps in the identification of not only design and manufacturing defects but also the product and process characteristics that need to be controlled, monitored and tested. Such information, together with the methods of monitoring and testing, are documented in the Control Plan.

A Control Plan is a written summary of the producer's quality planning actions for a specific process, product and/or service. The Control Plan lists all process parameters and design characteristics considered important to customer satisfaction and which require specific quality planning actions. It also describes the actions and reactions required to ensure that the process is maintained in a state of statistical control, as agreed upon between the design team, customer and supplier. It supports verification and validation of the product and the process. It also helps minimize process variation.

Figure 11–1 is an illustration of how various types of FMEAs and Control Plans can be integrated into the product's life cycle. The various types of FMEAs in Figure 11–1, their application in the product's life cycle and the use of Control Plans are described in the following sections. The various FMEA methodologies are discussed in Chapters 12 to 16.

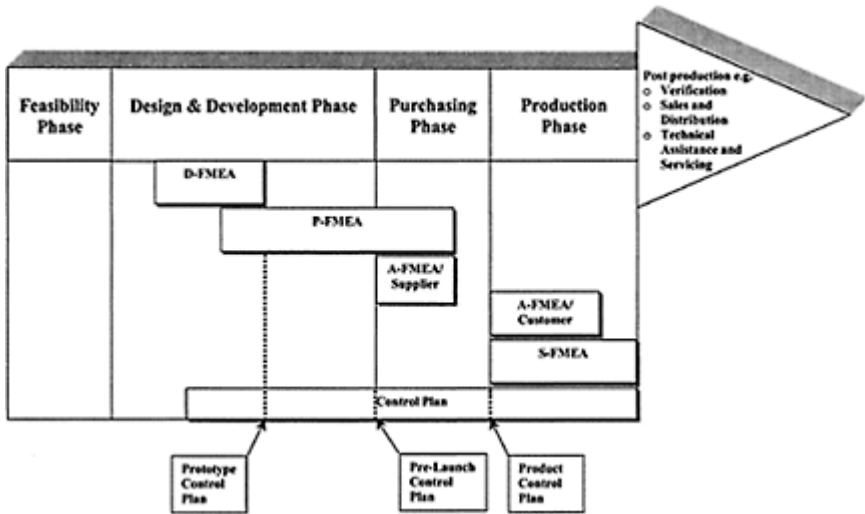


Figure 11–1: Relationship between FMEA, Control Plan and product cycle.

Different Types of FMEAs

Table 11–1 summarizes the focuses of the various types of FMEAs. Each type of FMEA is briefly described below:

Product/Design FMEA (D-FMEA)

The primary focus of D-FMEA is on the product. This includes the components/parts, raw materials used and the features/characteristics of the product. The D-FMEA is important in a product’s life cycle as approximately 76 percent of all engineering changes are due to the correction of bad designs, and the rest are the result of other improvements. Therefore, identifying all potential failures in the design stage is crucial.

Process FMEA (P-FMEA)

Process FMEA focuses on the manufacturing process, including the process steps, process equipment, process conditions, tooling/fixtures, operator errors, materials quality and so on. This methodology identifies potential or known failure modes and provides follow-up and corrective actions before the first or subsequent production runs.

Application FMEA (A-FMEA)

Application FMEA focuses on the design application. There are two types of A-FMEA: supplier-side A-FMEA and downstream customer-side A-FMEA. The purpose of the supplier-side A-FMEA is to detect any potential failures of the product relating to the application, design and manufacturing processes of parts and materials acquired from an outside supplier. The downstream customer-side A-FMEA investigates the effects of the customer’s application of the product on the product itself and on the customer. It is used to eliminate confusion and customer complaints.

Service FMEA (S-FMEA)

Service FMEA focuses on field service after sales—for example, serviceability, spare parts availability and service manpower availability. The objectives of the FMEA are to define, demonstrate and maximize solutions in response to quality, reliability, maintainability, cost and productivity as defined by the design specifications and the customer. These goals are achieved through the active participation of personnel in the departments of customer service, product development, research, quality assurance, marketing and operations. Thus, the focus of the Service FMEA is to minimize failure effects on the service, regardless of what level of FMEA is performed, and to maximize customer satisfaction.

Table 11–1: Focuses of various types of FMEAs

Type of FMEA	Product /Design FMEA	Process FMEA	Application FMEA/ Supplier Side	Appl ication FMEA/Down stream Customer Side	Service FMEA
Review Item	Design of the product	Process (manufacturing and assembly processes)	Your product & the application process	Your product customer’s process	Product
Focus	Determine what could go wrong with the product in both manufacturing operations and in services as a result of weaknesses in the design	Concentrate on potential failures during manufacturing and in service resulting from non-compliance to specification and/or design intent	Focus on failures of your product relating to parts and components from outside suppliers	Focus on failures of your product, which affect downstream customer’s process	Minimize service failures on the total organization
Failure	On product e.g.	On	On the product	On the product	On the

Modes	components, sub-systems, sub-assemblies	manufacturing & process, e.g. equipment, machines, tooling, process steps			product/service
Causes	From engineering efforts, e.g. <ul style="list-style-type: none"> • Improper tolerance • Incorrect stress calculations • Wrong assumptions 	From manufacturing and process, e.g. <ul style="list-style-type: none"> • Missing parts • Adjustment error • Equipment not set up properly • Hardware failure 	From the supplier, e.g. <ul style="list-style-type: none"> • Ambiguous instruction • Insufficient information in user manual 	From the customer, e.g. <ul style="list-style-type: none"> • Wrong interpretation of instruction 	From the service provider, e.g. <ul style="list-style-type: none"> • Human error • Failure to enforce process and quality controls • Improper selection of component parts
Effects	<ul style="list-style-type: none"> • Impacts to the item being reviewed (Local effects) • Impacts on the end user (End effects) • Impacts between local and end user (Next higher level effects) 	<ul style="list-style-type: none"> • Impacts on the operation itself (Local process effects) • Impacts to downstream operations (Downstream process effects) • The end user of the produced product (End Product Effects) 	<ul style="list-style-type: none"> • Impacts on the significant characteristics of the product (Local effects) • Impacts on the end user (End effects) 	<ul style="list-style-type: none"> • Impacts on the significant characteristics of the product (Local effects) • Impacts on the end user (End effects) 	<ul style="list-style-type: none"> • Impacts on the product/service (Local effects) • Impacts on the end user (End effects)

Integration of FMEA and Control Plan to Product Cycle

Based on Figure 11–1, the following discusses the integration of the FMEAs and Control Plan to the product’s life cycle.

Feasibility Phase

At this stage, financial and technological feasibility studies are established. The feasibility phase is concluded with the product design target specifications.

Product Design and Development Phase

At the beginning of the design phase, several candidate concepts are usually developed based on the product design target specifications established in the feasibility phase. Design FMEA (D-FMEA) can be used in the selection of the most promising concept by

providing a means of locating respective weaknesses. Although there is often little information made available at this stage, the failure modes can either be established through design analysis or recalls of products with similar design. The causes of failure modes would be mainly engineering related.

Once a design is selected, the associated critical characteristics identified in D-FMEA are recorded in the Control Plan. The primary purpose of the Control Plan at this stage is to document and communicate the initial plan for process control. At the end of the design phase, preliminary design and mechanical drawings are available, and the basic process operations (manufacturing and assembly) have been defined.

During the development phase, before building the prototype, a more detailed D-FMEA can be performed to minimize design defects, eliminate all high-severity hazards and reduce as many medium- and low-severity hazards as possible. As there is considerable flexibility at this early design stage, the cost of major changes to make the device inherently safer would be minimal. The critical design characteristics identified in the FMEA are recorded in the Control Plan (prototype Control Plan).

Process Design and Development Phase

Based on the product criteria, features and mission requirements, conceptual process designs are established. A preliminary Process FMEA (P-FMEA) can be used in the selection of the most promising concept by providing a means of locating respective weaknesses. The preliminary P-FMEA is also used to solidify product design characteristics and manufacturing processes. When the process design is selected, the P-FMEA is expanded by incorporating product characteristics that are identified in the Control Plan. The failure modes in the D-FMEA identify their own causes in the system. These failure modes, which affect the production processes, will also be used for the P-FMEA.

At the end of the development phase, the P-FMEA reflects the final design of both the product and process and provides risk control/mitigation activities for personnel in production, product support and quality control. The critical process characteristics identified in the FMEA are recorded in the Control Plan (pre-launch Control Plan).

Purchasing Phase

At this stage, production and tooling planning take place with the P-FMEA focusing on the key characteristics of the processes in production.

A-FMEA (supplier side) can be used to evaluate the potential process failures resulting from application of parts, components and materials from outside suppliers. The causes are due to suppliers' manufacturing processes or designs, but the effects would be on the respective product manufacturing process. The failure modes in the A-FMEA identify their own causes in the system. These failure modes, which affect the manufacturing process, will also be used for the P-FMEA. The key characteristics identified in the FMEA would be recorded in the Control Plan (production Control Plan).

Production Phase

The production Control Plan is executed in the production phase. Prior to post-production activities (e.g. product verification, packaging, distribution and servicing), A-FMEA (customer side) can be used for evaluating the application of the product by the customer (if the product is involved in the customer's downstream manufacturing process) or the end user (if it is the end product, e.g. reviewing the user instruction manual).

In the S-FMEA, the end product is the focus. It is very difficult to evaluate the entire service, especially in the early stage or initiation of the services. In most cases, the service evaluation develops over time and as such the S-FMEA becomes a living document to reflect the changes of the services. The failure causes in the D-FMEA and P-FMEA, if not corrected, would have an effect on the end product, which in turn would result in failure modes in the Service FMEA and would lead to product recalls.

Table 11–2 shows how each type of FMEA interacts with the Control Plan at various stages of the product cycle.

**Table 11–2: Relationship between FMEA,
product cycle and Control Plan**

Stages in Product Cycle	Function	Type of FMEA	FMEA Focuses	Control Plan Status
Product Design	Engineering	Product FMEA	Balanced Design	Started
Process Planning	Processing	Process FMEA	Process Seq. & Flow Study	Continued
Sourcing & Suppliers, Quality Planning	Purchasing	Supplier-Side Application FMEA	Key Characteristics of Parts Identified	Continued
Production, Tooling Planning	Manufacturing	Process FMEA	Key Characteristics of Process Identified	Executed
Product Usage & Application	Services	Customer-Side Application FMEA & Service FMEA	Key Characteristics of Product Identified	Monitored

CHAPTER 12

Product/Design FMEA

This chapter describes the objectives of Product/Design FMEA (D-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection. Based on the company's needs and requirements, additional information can be included in the worksheet. The rating guidelines provided in this chapter are not universal, and each company can modify them to reflect the needs of its organization and the product, as well as the concerns of customers.

Objectives

- Focus on failure modes caused by design deficiencies;
- Maximize design quality, reliability and maintainability while optimizing expenses;
- Aim to identify, eliminate or minimize the impact of potential risks to the product and user to an acceptable level with the current state of technology;
- Identify critical and/or significant characteristics of the product;
- Prioritize the engineering efforts and resources based on the assessment of potential failure impacts to the product or user;
- Establish links between design engineering efforts and production, quality and service, together with marketing efforts.

Recommended Team Members

The following is a list of recommended team members for Product/Design FMEA:

- Product and Development/Manufacturing Engineering;
- Quality Assurance;
- Research and Development;
- Test Engineering;
- Reliability Engineering;
- Purchasing/Marketing/Customer Service/Complaints Group;
- Legal team for product liability purposes for new product development.

Recommended Information in the Product/Design FMEA Worksheet

A recommended worksheet for documenting a D-FMEA is given in Figure 12–1. The worksheet is divided into two main sections: general information inserted above the columns and the actual worksheet columns. Each item in the worksheet is described below.

General Information

- | | |
|---|--|
| 1. System, Subsystem, or Component name and number | Indicate the level of analysis and enter the system, subsystem or component name and number |
| 2. Prepared By | Indicate the name, telephone number and company of the engineer responsible of preparing the FMEA |
| 3. Design Responsibility | Record the salable number studied or reviewed. |
| 4. FMEA Number | Enter the D-FMEA number used for tracking the document. |
| 5. Page __ of __ | Indicate the number of pages of the FMEA worksheet. |
| 6. Key Date | Indicate the initial FMEA due date, this date should not exceed the schedule production design release date. |
| 7. FMEA Date (Orig.) | Specify the date on which the original FMEA study was conducted, and the latest revision date. |
| 8. FMEA Date (Rev.) | Specify the latest revision date. |
| 9. Core Team | Enter the names of individuals and departments that have authority to identify and/or perform tasks. |

Columns On the D-FMEA Worksheet

- | | |
|---|--|
| 10. Item | Enter the reviewed item's name and part number. |
| 11. Item Function | Define the function of the item being studied: the purpose, goal or objective of the design.
Note: The reviewed item may have more than one function, and each of these functions may have different potential failure modes. In this case, list the functions separately |
| 12. Potential Failure Mode | List the potential failure modes based on failure of the component, subsystem or system under review to perform or deliver the intended function. A good starting point is a review of past things-gone-wrong, concerns, reports and group brainstorming.
Examples: leaking, cracked, loosened, inadequate support. |
| 13. Potential Effect(s) of Failure | The potential effects of failure are the impacts and consequences to the affected area. State clearly if the failure mode could impact safety or non-compliance to regulations.
Examples of failure effects:
Noise, erratic operation, inoperative, regulatory non-compliance. |

- 14. Severity(S)** Severity is an assessment of the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. A suggested severity ranking is given in Table 12–1.
Note: The severity can be reduced only through a change in the design. If such a design modification is attainable, the failure can possibly be eliminated.
- 15. Class** Use this column to classify any special characteristic, i.e. control, critical, major, key, and significant. This label is not the function. Control items may be controlled by government regulations because failure might affect the general public. Critical items may be safety-related items. Significant items are those, which the designer/engineer has identified as having particular importance to the product.
- 16. Potential Cause(s)/ Mechanism(s) of Failure** List all potential causes and or failure mechanism for each failure mode. These causes of failure are an indication of design weakness. Typical failure causes may include, but are not limited to:
- Incorrect material specified;
 - Over-stressing;
 - Improper friction material specified;
 - Excessive heat;
 - Corrosion.
- 17. Occurrence (O)** Occurrence is the likelihood that a specific failure mode, which is the result of a specific cause under current design control, will happen. Occurrence is a relative ranking within the scope of the individual FMEA. A suggested occurrence ranking is given in Table 12–2.
- 18. Current Design Controls Prevention** Indicate all controls intended to prevent the causes or mechanism of failure from occurring, or reduce their rates of occurrence. Current controls include those used with the same or similar designs. The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent.
- 19. Current Design Controls Detection** Indicate all controls (analytical or physical methods) intended to detect the causes or mechanism before the item is released to production. Current controls include those used with the same or similar designs. The initial rankings for detection will be based on design controls that either detects the cause of failure or the failure mode.
- 20. Detection(D)** Detection is an assessment of the ability of current design controls to identify any potential failure mode if it does occur. Detection is a relative ranking within the scope of the individual FMEA. A suggested detection ranking is given in Table 12–3.
- 21. Risk Priority Number (RPN)** The Risk Priority Number represents the multi-effects of severity, occurrence and detection. The RPN is calculated by multiplying together these three ratings:
 $RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$
Severity, occurrence and detection must have a value greater than zero.
- 22. Recommended Actions** List your study group’s recommendations for preventing the failure mode or limiting its consequences. The following are examples of corrective actions:

- Revised design geometry and/or tolerances;
- Revised material specification;
- Design of experiments;
- Revised test plan.

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 causes.

- 23. Responsibility** State the name(s) of the team member(s) responsible for ensuring that the recommendations are implemented or properly addressed.
- 24. Target Completion Date** Specify the target date for completing the necessary actions.

Action Results

After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence and detection rankings. Calculate the resulting RPN. If no actions are taken, leave the related ranking columns blank.

- 25. Actions Taken** List all corrective measures that have been implemented.
- 26. Severity** The severity rating in this section should indicate the seriousness of the effects of the potential design failure mode after the corrective measures have been implemented.
- 27. Occurrence** Indicate the occurrence rating after the corrective measures in the “Existing Product Conditions” section have been implemented.
- 28. Detection** Record the resulting detection rating after the corrective actions have been identified.
- 29. Risk Priority Number (RPN)** Recalculate the Risk Priority Number after the actions have been taken:
 $RPN = Severity \times Occurrence \times Detection$

Suggested Risk Guidelines for Product/Design FMEA (D-FMEA)

The suggested risk guidelines for severity, occurrence and detection of D-FMEA are given in Tables 12–1, 12–2 and 12–3, respectively.

Table 12–1: Suggested Severity Ranking for D-FMEA (1–10 qualitative scale)

Effect	Rank	Criteria
None	1	No effect.
Very Slight	2	Negligible effect on product performance. User not affected.
Slight	3	Slight effect on product performance. Non-vital faults will be noticed most of the time.

Minor	4	Minor effect on product performance. User slightly dissatisfied.
Moderate	5	Reduced performance with gradual performance degradation. User dissatisfied.
Severe	6	Product operable and safe but performance degraded. User dissatisfied.
High Severity	7	Product performance severely affected. User very dissatisfied.
Very High Severity	8	Product inoperable but safe. User very dissatisfied.
Extreme Severity	9	Product failure resulting in hazardous effects highly probable. Compliance with government regulations in jeopardy.
Maximum Severity	10	Product failure resulting in hazardous effects almost certain. Non-compliance with government regulations.

Table 12–2: Suggested Occurrence Ranking for D-FMEA (1–10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.
Extremely Likely	10	Failure almost certain.

Table 12–3: Suggested Detection Ranking for D-FMEA (1–10 qualitative scale)

Detection	Rank	Criteria
Extremely Likely	1	Can be corrected prior to engineering prototype.
Very High Likelihood	2	Can be detected and corrected prior to engineering design release.
High Likelihood	3	Has high effectiveness.
Moderately High Likelihood	4	Has moderately high effectiveness.
Medium Likelihood	5	Has medium effectiveness.

CHAPTER 13

Process FMEA

This chapter describes the objectives of Process FMEA (P-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection. Based on the company's needs and requirements, additional information can be included in the worksheet. The rating guidelines provided in this chapter are not universal, and each company can modify them to reflect the needs of its organization and product, as well as the concerns of customers.

Objectives

- Focus on failure modes caused by process or assembly deficiencies;
- Maximize the total process quality, reliability, maintainability and productivity while optimizing expenses;
- Aim to identify, eliminate or minimize the impact of potential risks to the process and product, as well as to the end user to an acceptable level with the current state of technology;
- Identify critical and/or significant characteristics, which help in developing Control Plans;
- Prioritize the manufacturing engineering efforts and resources;
- Establish links between manufacturing effort, design engineering, quality and service together with marketing efforts.

Recommended Team Members

The following is a list of recommended team members for Process FMEA:

- Manufacturing Engineering;
- Product Development;
- Quality Assurance;
- Reliability Engineering;
- Purchasing/Marketing/Customer Service/Complaints Group;
- Production Control;

- Testing Engineering.

Recommended Information in the Process FMEA Worksheet

A recommended worksheet for documenting a P-FMEA is given in Figure 13–1. The worksheet is divided into two main sections: general information inserted above the columns and the actual worksheet columns. Each item in the worksheet is described below.

General Information

- | | |
|---|--|
| 1. System, Subsystem, or Component name and number | Indicate the level of analysis and enter the system, subsystem or component name and number |
| 2. Prepared By | Indicate the name, telephone number and company of the engineer responsible of preparing the FMEA |
| 3. Process Responsibility | Record the salable number studied or reviewed. |
| 4. FMEA Number | Enter the P-FMEA number used for tracking the document. |
| 5. Page __ of __ | Indicate the number of pages of the FMEA worksheet. |
| 6. Key Date | Indicate the initial FMEA due date, this date should not exceed the schedule production design release date. |
| 7. FMEA Date (Orig.) | Specify the date on which the original FMEA study was conducted, and the latest revision date. |
| 8. FMEA Date (Rev.) | Specify the latest revision date. |
| 9. Core Team | Enter the names of individuals and departments that have authority to identify and/or perform tasks. |

Columns On the P-FMEA Worksheet

- | | |
|-----------------------------------|--|
| 10. Item | Enter the reviewed item's name and part number. |
| 11. Item Function | Define the function of the item being studied: the purpose, goal or objective of the design.
Note: The reviewed item may have more than one function, and each of these functions may have different potential failure modes. In this case, list the functions separately |
| 12. Potential Failure Mode | List the potential failure modes based on failure of the component, subsystem or system under review to perform or deliver the intended function. A good starting point is a review of past things-gone-wrong, concerns, reports and group brainstorming.
Examples: leaking, cracked, loosened, inadequate support. |
| 13. Potential | The potential effects of failure are the impacts and consequences to the affected |

- Effect(s) of Failure** area. State clearly if the failure mode could impact safety or non-compliance to regulations.
 Examples of failure effects:
 Noise, erratic operation, inoperative, regulatory non-compliance.
- 14. Severity (S)** Severity is an assessment of the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. A suggested severity ranking is given in Table 13–1.
Note: The severity can be reduced only through a change in the design. If such a design modification is attainable, the failure can possibly be eliminated.
- 15. Class** Use this column to classify any special characteristic, i.e. control, critical, major, key, significant. This label is not the function. Control items may be controlled by government regulations because failure might affect the general public. Critical items may be safety-related items. Significant items are those which the designer/engineer has identified as having particular importance to the product.
- 16. Potential Cause(s)/ Mechanism(s) of Failure** List all potential causes and or failure mechanism for each failure mode. These causes of failure are an indication of design weakness. Typical failure causes may include, but are not limited to:
 a. Incorrect material specified;
 b. Over-stressing;
 c. Improper friction material specified;
 d. Excessive heat;
 e. Corrosion.
- 17. Occurrence (O)** Occurrence is the likelihood that a specific failure mode, which is the result of a specific cause under current design control, will happen. Occurrence is a relative ranking within the scope of the individual FMEA. A suggested occurrence ranking is given in Table 13–2.
- 18. Current Process Controls Prevention** Indicate all controls intended to prevent the causes or mechanism of failure from occurring, or reduce their rates of occurrence. Current controls include those used with the same or similar designs.
 The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent.
- 19. Current Process Controls Detection** Indicate all controls (analytical or physical methods) intended to detect the causes or mechanism before the item is released to production. Current controls include those used with the same or similar designs. The initial rankings for detection will be based on design controls that either detects the cause of failure or the failure mode.
- 20. Detection(D)** Detection is an assessment of the ability of current design controls to identify any potential failure mode if it does occur. Detection is a relative ranking within the scope of the individual FMEA. A suggested detection ranking is given in Table 13–3.
- 21. Risk Priority Number (RPN)** The Risk Priority Number represents the multi-effects of severity, occurrence and detection. The RPN is calculated by multiplying together these three ratings:
RPN = Severity × Occurrence × Detection
 Severity, occurrence and detection must have a value greater than zero.

- 22. Recommended Actions** List your study group's recommendations for preventing the failure mode or limiting its consequences.
The following are examples of corrective actions:
- Revised design geometry and/or tolerances;
 - Revised material specification;
 - Design of experiments;
 - Revised test plan.
- 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 causes.
- 23. Responsibility** State the name(s) of the team member(s) responsible for ensuring that the recommendations are implemented or properly addressed.
- 24. Target Completion Date** Specify the target date for completing the necessary actions.

Action Results

After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence and detection rankings. Calculate the resulting RPN. If no actions are taken, leave the related ranking columns blank.

- 25. Actions Taken** List all corrective measures that have been implemented.
- 26. Severity** The severity rating in this section should indicate the seriousness of the effects of the potential design failure mode after the corrective measures have been implemented.
- 27. Occurrence** Indicate the occurrence rating after the corrective measures in the "Existing Product Conditions" section have been implemented.
- 28. Detection** Record the resulting detection rating after the corrective actions have been identified.
- 29. Risk Priority Number (RPN)** Recalculate the Risk Priority Number after the actions have been taken:
 $RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$

Suggested Risk Guidelines for Process FMEA (P-FMEA)

The suggested risk guidelines for severity, occurrence and detection of P-FMEA are given in Tables 13-1, 13-2 and 13-3, respectively.

Table 13–1: Suggested Severity Ranking for P-FMEA (1–10 qualitative scale)

Effect	Rank	Criteria
None	1	Might be noticeable by the operator (Process). Improbable/not noticeable by the user (Product).
Very slight	2	No downstream effect (Process). Insignificant/negligible effect (Product).
Slight	3	User will probably notice the effect but the effect is slight (Process and Product).
Minor	4	Local and/or downstream processes might be affected (Process). User will experience minor negative impact on the product (Product).
Moderate	5	Impacts will be noticeable throughout operations (Process). Reduced performance with gradual performance degradation. User dissatisfied (Product).
Severe	6	Disruption to downstream process (Process). Product operable and safe but performance degraded. User dissatisfied (Product).
High Severity	7	Significant downtime (Process). Product performance severely affected. User very dissatisfied (Product).
Very High Severity	8	Significant downtime and major financial impacts (Process). Product inoperable but safe. User very dissatisfied (Product).
Extreme Severity	9	Failure resulting in hazardous effects highly probable. Safety and regulatory concerns (Process and Product).
Maximum Severity	10	Failure resulting in hazardous effects almost certain. Non- Injury or harm to operating personnel (Process). compliance with government regulations (Product).

Table 13–2: Suggested Occurrence Ranking for P-FMEA (1–10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.

CHAPTER 14

Machinery FMEA

This chapter describes the objectives of Machinery FMEA (M-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection. Based on the company's needs and requirements, additional information can be included in the worksheet. The rating guidelines provided in this chapter are not universal, and each company can modify them to reflect the needs of its organization and the product, as well as the concerns of customers.

Objectives

- Ensure that potential failure modes and their effects on the machinery were identified during the design and development process;
- Reduce life cycle costs by improving the reliability and durability of the machinery;
- Provide information for the development of an efficient preventive maintenance plan;
- Aim to identify, eliminate or minimize the impact of potential risks to the product and user to an acceptable level with the current state of technology;
- Identify critical and/or significant characteristics of the product;
- Prioritize the engineering efforts and resources based on the assessment of potential failure impacts to the product or user;
- Establish links between design engineering efforts and production, quality and service, together with marketing efforts.

Recommended Team Members

The following is a list of recommended team members for Machinery FMEA:

- Machinery-responsible Engineer;
- Quality Engineer;
- Safety Engineer;
- Production Engineer;
- Reliability Engineering;
- Product and Development/Manufacturing Engineering;

- Purchasing/Marketing/Customer Service/Complaints Group;
- Legal team for product liability purposes for new product development.

Recommended Information in the Machinery FMEA Worksheet

A recommended worksheet for documenting an M-FMEA is given in Figure 14–1. The worksheet is divided into two main sections: general information inserted above the columns and the actual worksheet columns. Each item in the worksheet is described below.

General Information

- | | |
|---|--|
| 1. Machinery/System, Subsystem, or Component name and number | Indicate the level of analysis and enter the system, subsystem or component name and number |
| 2. Prepared By | Indicate the name, telephone number and company of the engineer responsible of preparing the FMEA |
| 3. Design Responsibility | Indicate the OEM, department or supplier name if applicable. |
| 4. FMEA Number | Enter the M-FMEA number used for tracking the document. |
| 5. Page__ of__ | Indicate the number of pages of the FMEA worksheet. |
| 6. Key Date | Indicate the initial FMEA due date, this date should not exceed the schedule production design release date. |
| 7. FMEA Date (Orig.) | Specify the date on which the original FMEA study was conducted, and the latest revision date. |
| 8. FMEA Date (Rev.) | Specify the latest revision date. |
| 9. Core Team | Enter the names of individuals and departments that have authority to identify and/or perform tasks. |

Columns On the M-FMEA Worksheet

- | | |
|-----------------------------------|---|
| 10. Item | Enter the reviewed item's name and part number. |
| 11. Item Function | Define the function of the item being studied: the purpose, goal or objective of the design.
Note: The reviewed item may have more than one function, and each of these functions may have different potential failure modes. In this case, list the functions separately |
| 12. Potential Failure Mode | List the potential failure modes based on failure of the component, subsystem or system under review to perform or deliver the intended function. A good starting point is a review of past things-gone-wrong. |

concerns, reports and group brainstorming.
Examples: leaking, cracked, loosened, inadequate support.

- 13. Potential Effect(s) of Failure** The potential effects of failure are the impacts and consequences to the affected area. State clearly if the failure mode could impact safety or non-compliance to regulations.
Examples of failure effects:
Noise, erratic operation, inoperative, regulatory non-compliance.
- 14. Severity(S)** Severity is an assessment of the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. A suggested severity ranking is given in Table 14-1.
Note: The severity can be reduced only through a change in the design. If such a design modification is attainable, the failure can possibly be eliminated.
- 15. Class** Use this column to classify any special characteristic, i.e. control, critical, major, key, significant. This label is not the function. Control items may be controlled by government regulations because failure might affect the general public. Critical items may be safety-related items. Significant items are those which the designer/engineer has identified as having particular importance to the product.
- 16. Potential Cause(s)/ Mechanism(s) of Failure** List all potential causes and or failure mechanism for each failure mode. These causes of failure are an indication of design weakness. Typical failure causes may include, but are not limited to:
- Incorrect material specified;
 - Over-stressing;
 - Improper friction material specified;
 - Excessive heat;
 - Corrosion.
- 17. Occurrence (O)** Occurrence is the likelihood that a specific failure mode, which is the result of a specific cause under current design control, will happen. Occurrence is a relative ranking within the scope of the individual FMEA. A suggested occurrence ranking is given in Table 14-2.
- 18. Current Machinery Controls Prevention** Indicate all controls intended to prevent the causes or mechanism of failure from occurring, or reduce their rates of occurrence. Current controls include those used with the same or similar designs. The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent.
- 19. Current Machinery Controls Detection** Indicate all controls (analytical or physical methods) intended to detect the causes or mechanism before the item is released to production. Current controls include those used with the same or similar designs. The initial rankings for detection will be based on design controls that either detects the cause of failure or the failure mode.
- 20. Detection(D)** Detection is an assessment of the ability of current design controls to identify any potential failure mode if it does occur. Detection is a relative ranking within the scope of the individual FMEA. A suggested detection ranking is given in Table 14-3.
- 21. Risk Priority** The Risk Priority Number represents the multi-effects of severity.

- Number (RPN)** occurrence and detection. The RPN is calculated by multiplying together these three ratings:
 $RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$
 Severity, occurrence and detection must have a value greater than zero.
- 22. Recommended Actions** List your study group's recommendations for preventing the failure mode or limiting its consequences.
 The following are examples of corrective actions:
 ○ Revised design geometry and/or tolerances;
 ○ Revised material specification;
 ○ Design of experiments;
 ○ Revised test plan.
 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 causes.
- 23. Responsibility** State the name(s) of the team member(s) responsible for ensuring that the recommendations are implemented or properly addressed.
- 24. Target Completion Date** Specify the target date for completing the necessary **actions** actions.

Action Results

After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence and detection rankings. Calculate the resulting RPN. If no actions are taken, leave the related ranking columns blank.

- 25. Actions Taken** List all corrective measures that have been implemented.
- 26. Severity** The severity rating in this section should indicate the seriousness of the effects of the potential design failure mode after the corrective measures have been implemented.
- 27. Occurrence** Indicate the occurrence rating after the corrective measures in the "Existing Product Conditions" section have been implemented.
- 28. Detection** Record the resulting detection rating after the corrective actions have been identified.
- 29. Risk Priority Number (RPN)** Recalculate the Risk Priority Number after the actions have been taken:
 $RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$

Suggested Risk Guidelines for Machinery FMEA (M-FMEA)

The following risk guidelines for severity, occurrence and detection for M-FMEA shown in Tables 14–1, 14–2 and 14–3 respectively are extracted from SAE J1739 Section 5.

Table 14–1: Suggested Severity Ranking for M-FMEA (1–10 qualitative scale)

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

Table 14–2: Suggested Occurrence Ranking for M-FMEA (1–10 qualitative scale)

Rank	Occurrence	Criteria: Possible Number of Failures within Hours of Operation	Criteria: The Reliability Based on the User's Required Time
Failure Occurs every 5 Years	1	1 in 25,000	$R(t)=98\%$: MTBF is 50 times greater than the User's required time.
Failure Occurs every 2 Years	2	1 in 10,000	$R(t)=95\%$: MTBF is 20 times greater than the User's required time.
Failure Occurs every Year	3	1 in 5,000	$R(t)=90\%$: MTBF is 10 times greater than the User's required time.

Failure Occurs every 6 Months	4	1 in 2,500	R(t)=85 %: MTBF is 6 times greater than the User's required time.
Failure Occurs every 3 Months	5	1 in 1,000	R(t)=78 %: MTBF is 4 times greater than the User's required time.
Failure Occurs every Month	6	1 in 350	R(t)=60 %: MTBF is 2 times greater than the User's required time.
Failure Occurs every Week	7	1 in 80	R(t)=37 %: MTBF is equal to the User's required time.
Failure Occurs every Day	8	1 in 24	R(t)=20 %: MTBF is about 60% of the User's required time.
Failure Occurs every Shift	9	1 in 8	R(t)=5 %: MTBF is about 30% of the User's required time.
Failure Occurs every Hour	10	1 in 1	R(t)<1 %: MTBF is about 10% of the User's required time.

Table 14-3: Suggested Detection Ranking for M-FMEA (1-10 qualitative scale)

Detection	Rank	Criteria
Almost Certain	1	Design controls almost certain to detect a potential cause and subsequent failure mode. Machinery controls not required.
Very High	2	Very high chance that designs controls will detect a potential cause and subsequent failure mode. Machinery controls may not be required.
High	3	High chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent an imminent failure and isolate the cause.
Moderately High Likelihood	4	Moderately high chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent imminent failure.
Medium Likelihood	5	Medium chance that design controls will detect a potential cause and subsequent failure mode. Machinery controls will prevent imminent failure.
Moderately Low Likelihood	6	Low chance that design or machinery controls will detect a potential cause and subsequent failure mode. Machinery controls will provide an indicator of imminent failure.
Low Likelihood	7	Design or machinery controls do not prevent the failure from occurring. Machinery controls will isolate the cause and subsequent failure mode after the failure has occurred.

CHAPTER 15

Application FMEA

This chapter describes the objectives of Application FMEA (A-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection. Based on the company's needs and requirements, additional information can be included in the worksheet. The rating guidelines provided in this chapter are not universal, and each company can modify them to reflect the needs of its organization and product as well as the concerns of customers.

Objectives

- Focus on failure modes caused by the design application;
- Aim to identify, eliminate or minimize the impact of potential risks associated with the user or customer interface to an acceptable level with the current state of technology;
- Identify the product's significant characteristics in terms of form, fit, function and appearance;
- Identify the downstream customer's or upstream supplier's key characteristics that may affect the product's significant characteristics;
- Prioritize the engineering efforts and resources by assessing any potential failure impacts to the product or user;
- Establish link between design engineering efforts and customer interface to ensure field complaints are eliminated or minimized.

Recommended Team Members

The following is a list of recommended team members for Application FMEA:

- Product and Development/Manufacturing Engineering;
- Quality Assurance;
- Research & Development;
- Test Engineering;
- Reliability Engineering;
- Purchasing/Marketing/Customer Service/Complaints Group;

- Legal Counseling.

Recommended Information in the Application FMEA Worksheet

A recommended worksheet for documenting an A-FMEA is given in Figure 15–1. The worksheet is divided into two main sections: general information inserted above the columns and the actual worksheet columns. Each item in the worksheet is described below.

General Information

- 1. Product Description** Enter the name of the product.
- 2. Product Code/Model Number** Indicate the product code and/or model number, if applicable.
- 3. Catalog Number** Record the salable number of the product studied or reviewed.
- 4. Primary Product Responsibility** Record the name of the project leader.
- 5. FMEA Date** Record the date on which the FMEA study is conducted.
- 6. FMEA Revision Number** Enter the revision number, if applicable.
- 7. Product Development (PD) Engineer** State the name of the product development engineer.
- 8. Independent Reviewer** Enter the name of the independent reviewer, who is a team member taking part in the product FMEA but who does not have direct responsibility for the design.
- 9. Other Information** Record any information not already covered in steps 1 to 8 that is important.
- 10. Team Members** Enter the names of the individuals who participated in the study.

Columns On the Application FMEA Worksheet

- 11. User Application Step** Enter the name and/or sequence ID number of the customer's process being studied.
- 12. Reviewed Step Application Function** Describe the function of the process being studied. The reviewed step may have more than one function, and each of these functions may have different potential failure modes. In this case, list the functions separately.
- 13. Potential Function Failure Modes** This is not your customer's or supplier's product/process failure, but rather the failure of your product.
- 14. Potential Causes of Failure** For each potential failure mode of the product, list all conceivable failure causes with respect to the customer/end user and supplier. The listed

causes should pertain to your supplier's or customer's significant product/process characteristic so that the corrective actions can be aimed effectively and timely.

- 15. Potential Effects of Failure** The potential effects of failure are the impacts and consequences to the affected area. State clearly if the failure mode could impact safety or non-compliance to regulations.
This section is divided into three subsections:
End effects: impacts on the end product user;
Local effects: immediate impacts to the item being reviewed;
Next high-level effects: impacts between the local and end user.
- 16. Control/Critical/Significant Steps** Designate each item as being a "Control," "Critical" or "Significant" step/item. This designation is not the function. Control steps/items may be controlled by government regulations because failure might affect the general public. Critical steps/items may be safety-related items. Significant steps/items are those of significant importance to the product.

Existing Conditions

- 17. Current Controls** List all the controls in place intended to assist the customer/supplier to prevent the causes of failure from occurring, detect the causes of failure modes earlier should they occur, or reduce the impacts of failure.
The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent. The initial rankings for detection will be based on design controls that either detect the cause of failure or the failure mode.
- 18. Severity** Severity is an assessment of the failure effects on the end user, local area and the next high-level effects—that is, the intermediate effects that occur between these other two categories of effects. The severity rating applies only to the effects, but you must be able to specify the effects clearly enough. Severity is a relative ranking within the scope of the individual FMEA. A suggested severity ranking is given in Table 15–1.
Note: The severity can be reduced only through a change in the design. If your company is able to carry out such design modifications, it may be possible to eliminate the failure.
- 19. Occurrence** Occurrence is the likelihood that a specific failure mode, which is the result of a specific cause under current control, will happen. Occurrence is a relative ranking within the scope of the individual FMEA. A suggested occurrence ranking is given in Table 15–2.
- 20. Detection** Detection is an assessment of the ability of current design controls to identify any potential failure mode if it does occur. Detection is a relative ranking within the scope of the individual FMEA. A suggested detection ranking is given in Table 15–3.
- 21. Risk Priority Number (RPN)** The Risk Priority Number is a measure of the multi-effects of severity, occurrence and detection. The RPN is calculated by multiplying together these three values, and not through the use of a Risk Matrix:

RPN = Severity × Occurrence × Detection

Severity, occurrence and detection must have a value greater than zero.

- 22. Recommended Corrective Actions** List all of your team's recommendations for preventing the failure mode or limiting its consequences. 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 causes.
- 23. Responsibility** State the name of the team member who is responsible for implementing each recommendation.
- 24. Target Completion Date** Indicate the target date for completing the necessary actions for implementing each recommendation.

Action Results

After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence and detection rankings. Calculate the resulting RPN. If no actions are taken, leave the related ranking columns blank.

- 25. Actions Taken** Specify the corrective measures that have been implemented.
- 26. Severity** The severity rating in this section should indicate the seriousness of the effect of the potential design failure mode after the corrective measures have been identified.
- 27. Occurrence** Estimate and record the occurrence rating after the corrective action has been taken.
- 28. Detection** Estimate the detection rating after the corrective actions have been identified.
- 29. Risk Priority Number (RPN)** Recalculate the Risk Priority Number after the actions have been taken:
RPN = Severity × Occurrence × Detection
- 30. Comments (Optional)** Enter any supplementary comments that you want to incorporate in the study.

Suggested Risk Guidelines for Application FMEA (A-FMEA)

The suggested risk guidelines for severity, occurrence and detection of A-FMEA are given in Tables 15–1, 15–2 and 15–3, respectively.

Table 15–1: Suggested Severity Ranking for A-FMEA (1–10 qualitative scale)

Effect	Rank	Criteria
None	1	Improbable/not noticeable by the user.
Very Slight	2	Insignificant/negligible effect.
Slight	3	User will probably notice the effect but the effect is only slight.
Minor	4	User will experience minor negative impact on the product.
Moderate	5	Reduced performance with gradual performance degradation. User dissatisfied (Product).
Severe	6	Product operable and safe but performance degraded. User dissatisfied.
High Severity	7	Product performance severely affected. User very dissatisfied.
Very High Severity	8	Product inoperable but safe. User very dissatisfied.
Extreme Severity	9	Failure resulting in hazardous effects highly probable. Safety and regulatory concerns.
Maximum Severity	10	Failure resulting in hazardous effects almost certain.

Table 15–2: Suggested Occurrence Ranking for A-FMEA (1–10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.
Extremely Likely	10	Failure almost certain.

Table 15–3: Suggested Detection Ranking for A-FMEA (1–10 qualitative scale)

Detection	Rank	Criteria
Extremely Likely	1	Controls will almost certainly detect the existence of the defect. Supply chain detects.
Very High Likelihood	2	Controls have a very high probability of detecting the existence of failure. User will detect prior to purchasing.
High Likelihood	3	User will be able to detect when package is open.
Moderately High Likelihood	4	Defect is detectable prior to using the product.
Medium Likelihood	5	Has medium effectiveness for detection.
Moderately Low Likelihood	6	Defect is detectable during use. User will be able to correct it.
Low Likelihood	7	Defect is detectable after use. User will be able to correct the defect/situation.
Very Low Likelihood	8	Defect is detectable after use. User will be able to correct the defect/situation with certain limitations.
Remote Likelihood	9	Defect is detectable after use. User won't be able to correct it.
Extremely Unlikely	10	Controls will almost certainly not detect the existence of a defect. Undetectable until failure occurs.

Figure 15–1: Sample A-FMEA Worksheet

Product Description: ← 1										FMEA Date: ← 5									
Product Code: ← 2					Catalog Number: ← 3					FMEA Revision Number: ← 6					Product Development Engineer: ← 7				
Primary Product Responsibility: ← 4										Independent Reviewer: ← 8									
Team Members: ← 10										Other Information: ← 9									
User Application Step	Step Application Function	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	Control / Critical / Significant Steps	Current Controls	Existing Product Conditions			Recommended Corrective Actions	Responsibility	Target Date	Actions Taken	Action Results				Comments	
							S	O	D					SPN	S	O	D		SPN
11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30

CHAPTER 16

Service FMEA

This chapter describes the objectives of Service FMEA (S-FMEA), recommended team members and recommended information to be included in the FMEA worksheet. It also provides rating guidelines for severity, occurrence and detection. Based on the company's needs and requirements, additional information can be included in the worksheet. The rating guidelines provided in this chapter are not universal, and each company can modify them to reflect the needs of its organization and product, as well as the concerns of customers.

Objectives

- Focus on failure modes caused by deficiencies of field service after sales;
- Maximize the customer satisfaction through quality reliability and service;
- Aim to identify, eliminate or minimize the impact of potential risks to the process, operation, product, user or customer to an acceptable level with the current state of technology;
- Identify critical and/or significant tasks or processes;
- Establish a priority for improvement actions.

Recommended Team Members

The following is a list of recommended team members for Service FMEA:

- Department Head;
- Department Supervisor;
- Personnel involved with the service;
- Marketing Representatives;
- Material Manager;
- Field Service Manger.

Recommended Information in the Service FMEA Worksheet

A recommended worksheet for documenting an S-FMEA is given in Figure 16–1. The worksheet is divided into two main sections: general information inserted above the columns and the actual worksheet columns. Each item in the worksheet is described below.

General Information

- | | |
|-------------------------------------|--|
| 1. Product Description | Enter the name of the product. |
| 2. Product Code/Model Number | Indicate the product code and/or model number, if applicable. |
| 3. Catalog Number | Record the salable number studied or reviewed. |
| 4. Service Date | Identify the date (month/day/year) that the service/complaint was recorded. |
| 5. Product Release Date | Record the date the product was marketed/shipped from the manufacturing site. |
| 6. Involvement of Suppliers | State the names of contact people and the names of the companies. |
| 7. FMEA Date | Record the date on which the FMEA study is conducted. |
| 8. FMEA Revision Number | Enter the revision number, if applicable. |
| 9. Quality Assurance Manager | Enter the name of the quality assurance manager. |
| 10. Independent Reviewer | State the name of the independent reviewer, who is a team member taking part in the product FMEA but who is not directly responsible for the design. |
| 11. Other Information | Enter any other information not covered in the above items that you want to include. |
| 12. Team Members | Enter the names of individuals who participated in the study. |

Columns On the Service FMEA Worksheet

- | | |
|-----------------------------------|--|
| 13. Service Identification | Identify the service name, reference number or service code, as appropriate. |
| 14. Function | Describe the function of the service being studied: purpose, goal or objective of the service. The reviewed item may have more than one function and each of these functions may have different potential failure modes, in which case you must list the functions separately. |

- 15. Potential Failure Modes** Service failures occur when a service does not adequately protect against risks of injury, fails to perform intended functions safely, fails to minimize avoidable consequences in the event of an accident, or fails to deliver the expected service.
Examples of failure modes:
- Bad service;
 - Poor communication;
 - Poor customer service;
 - Cashier not knowledgeable about returns.
- 16. Potential Causes of Failure** The cause of a service failure mode is the service deficiency that results in the failure mode. The basic questions to ask are:
- In what ways can this service fail to perform its intended function and why?
 - What circumstances could cause the failure?
 - How or why can the service fail to meet its customer specifications?
- Examples of potential causes of failure:
- Improper selection of component parts;
 - Inadequate control procedures;
 - Failure to enforce process and quality controls;
 - Human error;
 - Improper training.
- 17. Potential Effects of Failure** The potential effects of failure are the impacts and consequences to the affected area. State clearly if the failure mode could impact safety or non-compliance to regulations.
The questions usually asked are:
- What does the customer experience as a result of the failure mode described?
 - What happens or what are the ramifications of this problem or failure?
- Often, the failure effect is evaluated from a customer's perspective or experience. Examples of potential effects of failure may be:
- Task function incomplete;
 - Poor service performance;
 - Customer completely dissatisfied;
 - May not comply with government regulations.
- 18. Control/Critical/Significant Items** Designate each item as being a "Control," "Critical" or Significant item. This label is not the function. Control items may be controlled by government regulations because failure might affect the general public. Critical items may be safety-related items. Significant items are those which the designer/engineer has identified as being of significant importance to the product.

Existing Conditions

- 19. Current Controls** List all controls intended to prevent the causes of failure from occurring, detect the causes of failure modes earlier should they occur, or reduce the impacts of failure.
The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls, provided they are integrated as part of the design intent. The initial rankings for detection will be

based on design controls that either detect the cause of failure or the failure mode. Typical controls may include:

- Checklists for completeness of the documentation;
- Trail testing;
- Design of experiments;
- Process verification testing.

- 20. Severity** Severity is an assessment of the failure effects on the end user, the local area and the next high level effects—that is, the intermediate effects that occur between these other two categories of effects. The next higher severity rating applies only to the effects, but the effects must be specified clearly enough. Severity is a relative ranking within the scope of the individual FMEA. A suggested severity ranking is given in Table 16–1. **Note:** The severity can be reduced only through a change in the design. If such a design change is attainable, the failure can possibly be eliminated.
- 21. Occurrence** Occurrence is the likelihood that a specific failure mode, which results from a specific cause under current control, will happen. Occurrence is a relative ranking within the scope of the individual FMEA. A suggested occurrence ranking is given in Table 16–2.
- 22. Detection** Detection is an assessment of the ability of current design controls to identify any potential failure mode if it does occur. Detection is a relative ranking within the scope of the individual FMEA. A suggested detection ranking is given in Table 16–3.
- 23. Risk Priority Number (RPN)** A Risk Priority Number is a quantitative measure of the multi-effects of severity, occurrence and detection. No Risk Matrix is used. Instead, you must multiply these three values together:
 $RPN = Severity \times Occurrence \times Detection$
 Severity, occurrence and detection must all have a value greater than zero.
- 24. Recommended Corrective Actions** List the recommended actions to remedy the situation. 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 causes. Typical recommendations may be:
 ○ Add built-in detection devices;
 ○ Provide alternatives to the design/service;
 ○ Add redundant subsystems.
- 25. Responsibility** State the name of the team member who is responsible for implementing each recommendation.
- 26. Target Completion Date** Indicate the target date for completing the necessary actions for implementing each recommendation.

Action Results

After the preventive/corrective action has been identified, estimate and record the resulting severity, occurrence and detection rankings. Calculate the resulting RPN. If no actions are taken, leave the related ranking columns blank.

- 27. Actions Taken** List the corrective measures that have been implemented.
- 28. Severity** The severity rating in this section should indicate the seriousness of the effect of the potential design failure mode after the corrective measures have been implemented.
- 29. Occurrence** Indicate the occurrence rating after the corrective action has been identified in the “Existing Product Conditions” section.
- 30. Detection** Record the resulting detection rating after the corrective actions have been identified.
- 31. Risk Priority Number (RPN)** Recalculate the Risk Priority Number after the actions have been taken:
RPN = Severity × Occurrence × Detection
- 32. Comments (Optional)** Record any further comments that you want to include in the study.

Suggested Risk Guidelines for Service FMEA (S-FMEA)

The suggested risk guidelines for severity, occurrence and detection of S-FMEA are given in Tables 16–1, 16–2 and 16–3, respectively.

Table 16–1: Suggested Severity Ranking for S-FMEA (1-10 qualitative scale)

Effect	Rank	Criteria
None	1	Improbable/not noticeable by the user (Product). Might be noticeable by the operator (Process).
Very Slight	2	Insignificant/negligible effect (Product). No downstream effect (Process).
Slight	3	User will probably notice the effect but the effect is slight (Product and Process).
Minor	4	User will experience minor negative impact on the product (Product). Local and/or downstream processes might be affected (Process).
Moderate	5	Reduced performance with gradual performance degradation. User dissatisfied (Product). Impacts will be noticeable throughout operations (Process).
Severe	6	Product operable and safe but performance degraded. User dissatisfied (Product). Disruption to downstream process (Process).

High Severity	7	Product performance severely affected. User very dissatisfied (Product). Significant downtime (Process).
Very High Severity	8	Product inoperable but safe. User very dissatisfied (Product). Significant downtime and major financial impacts (Process).
Extreme Severity	9	Failure resulting in hazardous effects highly probable. Safety and regulatory concerns (Product and Process).
Maximum Severity	10	Hazardous effects with injury or harm to operating personnel almost certain. Non-compliance with government regulations (Process).

Table 16–2: Suggested Occurrence Ranking for S-FMEA (1–10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.
Extremely Likely	10	Failure almost certain.

Table 16–3: Suggested Detection Ranking for S-FMEA (1–10 qualitative scale)

Detection	Rank	Criteria
Extremely Likely	1	Controls will almost certainly detect the existence of the defect.
Very High Likelihood	2	Controls have a very high probability of detecting the existence of failure.
High Likelihood	3	Has high effectiveness for detection.
Moderately High Likelihood	4	Has moderately high effectiveness for detection.
Medium Likelihood	5	Has medium effectiveness for detection.
Moderately Low Likelihood	6	Has moderately low effectiveness for detection.
Low Likelihood	7	Has low effectiveness for detection.

CHAPTER 17

Hardware and Software FMEA

Failure Mode and Effects Analysis is applied to a wide variety of products, from single-component systems to complex multi-component systems. As discussed in the preceding chapters, recent applications of FMEA have extended the analysis to the processes by which a product is built as well as to the software that contains the instructions for the functionality of the system

Hardware FMEA

Hardware FMEAs are applied to electrical, mechanical and hydraulic subsystems and the interfaces between these subsystems. The technique is first applied early in the design cycle after the major functional components and their interfaces have been defined.

Three types of analysis can be performed in a Hardware FMEA:

- Functional analysis;
- Interface analysis;
- Detail analysis.

In functional analysis, failure modes appropriate to each functional component are evaluated. Typical functional failure modes are that a particular function is not performed or it is performed incorrectly. When performing functional failure analysis, the team must be aware of the environment in which the system/equipment operates and the different operating modes. This knowledge would enable the team to effectively identify the failure consequences for different operating modes, as opposed to a general list of failure consequences.

Hardware interface failure analysis is performed on the physical interfaces between major functional system elements, which are usually called Line Replaceable Units or LRUs. Typical failure modes considered in the interface failure analysis are low pressure in a hydraulic line, no grounding of an electric cable, etc.

Hardware detailed failure analysis is done at the smallest/lowest component level of design and involves individual system components. The Reliability Analysis Center (<http://rac.iitri.org/>) contains failure modes associated with most of the components. Typical failure modes are:

- Stuck high;

- Stuck low;
- Open;
- Closed;
- Short;
- Binding or sticking;
- Excessive play;
- Contaminated.

Software FMEA

Software FMEA is done on programs, related data elements, execution of tasks that implement various system functions, program interfaces with hardware and interfaces between different programs or tasks.

Software FMEAs are quite labor intensive and costly. Therefore, it is crucial that the scope of the FMEA and the limit are defined clearly prior to the analysis. Software FMEA costs can be minimized if the software system has been designed with effective partitioning between critical and non-critical software elements.

The Software FMEA team assumes that the design—as represented in design documents, pseudo code and later high-level language code—is an accurate representation of the system that will be implemented.

Software FMEA too can be analyzed based on functional, interface or detailed analysis.

Software Functional FMEA is applied to the Computer Software Configuration Item (CSCI) during top-level software design. The primary outputs of the Software Functional FMEA are used to identify software architectural changes to reduce failure exposure and to identify requirements to ensure that incorrect software behavior can be detected and appropriate system corrective actions are implemented. In most cases, the following four failure modes are of particular interest when applied to the software elements within the architecture:

- Failure to execute;
- Incomplete execution;
- Execution at an incorrect time;
- Errors in the software element's assigned functioning.

Software Interface FMEA focuses on the interface/linkage between two or more separate software or hardware elements. For example, this could be between the systems for messaging and data transfer. The failure modes, such as incorrect data transfer, etc., could be postulated to evaluate the effects on the system. The following four failure modes are applied to each software interface:

- Failure of the interface to update a value;
- Incomplete update of the interface value;
- Updates to interface values occur at an incorrect time;
- Errors in the values or messages provided at the software interface.

Software Detailed FMEA is used to evaluate the impact of single variable or instruction failure. The analysis is generally conducted on systems that do not include adequate hardware protection of memory elements, processing results (e.g. arithmetic residue codes, etc.) and data transfers. The intent of the Detailed FMEA is to supplement the Functional and Interface FMEAs with a detailed assessment of the response of the as-developed software to potential faults and failures. If the language used is not limited to well-defined elements, the results of a Software Detailed FMEA may be incomplete or inaccurate.

CHAPTER 18

Analysis of FMEA Results

The following are used to analyze and evaluate the state of the system for which the FMEA has been conducted.

Failure Mode Ratios

Failure Mode Ratio is the fraction of item failures that are in the given failure mode. Item failure modes are considered to be mutually exclusive and the set of failure modes complete. Therefore, the sum of the failure mode ratios over all the item failure modes is considered to be 1.

Failure Mode Equivalence

The failure modes that exhibit identical consequences are termed “Fault Equivalence Failure Modes” and they are grouped by the same fault equivalence number. Identification of fault equivalence groups permits the analyst to manage failure consequences instead of individual failure modes.

The use of fault equivalence numbers for group failure modes with identical consequences facilitates integrating the Functional FMEA with subsequent Interface and Detailed FMEAs. It also supports timely feedback to the designer/person responsible for corrections/changes, etc.

Process Variation

The probability that an item parameter will be out of specification due to variations in the manufacturing process is given by the Process Capability Index (C_{pk}). It considers both the process spread and the proximity of the process spread to specification limits.

Process capability analysis examines:

- The variability in process characteristics relative to product specifications;
- Whether the process is capable of producing a product that conforms to specifications.

Record the Process Capability Index (C_{pk}), which is a measure of both process dispersion

$$\frac{USL - \bar{X}}{3\sigma}$$

and its centering about the average. C_{pk} is calculated to be the minimum of $\frac{USL - \bar{X}}{3\sigma}$ and

$$\left(\frac{\bar{X} - LSL}{3\sigma} \right)$$

Where:

USL=Upper Specification Limit

LSL=Lower Specification Limit

\bar{X} =Process Mean

σ =Standard Deviation

As a general rule in most production operations, a C_{pk} of 1.33 is the minimum acceptable level. Once the process drops below this level, containment actions are expected. A typical expectation is that 100% inspection and sorting process improvements are to be made. With a C_{pk} above 1.33, containment action is not expected. An action plan is needed to continually improve process potential through reduction of variation.

The Process Capability Index is a more direct indicator of the ability of the process to meet the specifications. It can be calculated for the product's Key Characteristics, which are identified during the FMEA study. Key characteristics are measurement indicators that provide rapid feedback to the process and thus provide the opportunity to immediately correct quality issues.

CHAPTER 19

Overview of Failure Mode, Effects and Criticality Analysis (FMECA)

Chapter 19 provides an overview of Failure Mode, Effects and Criticality Analysis (FMECA), including the terminology and the worksheets used in the analysis for both quantitative and qualitative approaches. This chapter also recommends the information to be included in the worksheets.

Overview of Criticality Analysis

Criticality describes the severity of the consequences of a failure. Criticality is designated by categories, or levels, that are functions of the dangers and losses of system capabilities and, sometimes, of the probabilities of their occurrence. MIL-STD-1629A defines the categories, and FMECA team members can either use these categories or define their own categories. Probability is best identified separately.

A logical extension of Failure Mode and Effects Analysis (FMEA) is to consider the criticality and probability of occurrence of the identified potential failure modes. This criticality analysis is widely known as Failure Mode, Effects and Criticality Analysis (FMECA).

Depending on the availability of part failure data, criticality analysis can be performed qualitatively or quantitatively. The qualitative approach is suitable when specific failure rate data are not available, and the quantitative approach is used when data are available. In the qualitative approach, failure modes are assessed in terms of probability of occurrence. In the quantitative approach, the criticality numbers for each failure mode reviewed and also for the item under consideration are calculated using failure rate data.

The criticality concept in Failure Mode, Effects and Criticality Analysis adds greatly to the benefits of the FMEA process by considering the following:

- Items to be given more intensive study to eliminate a particular hazard, increase the probability of a fail-safe outcome, or reduce the failure rate or extent and risk of resultant damage;
- Items requiring special attention during manufacturing, as well as stringent quality assurance or special handling controls;

- Special requirements in purchasing specifications concerning design, performance, reliability, safety or quality assurance;
- Acceptance standards for subcontractors' products, including parameters that should be stringently tested;
- Any special procedures, safeguards, protective equipment, monitoring devices or warning systems;
- The most cost-effective application of accident prevention resources.

Criticality Analysis Terminology

▪ Failure Modes

List each potential failure mode for an item.

▪ Failure Causes

Identify all the potential causes for each failure mode.

▪ Severity Classification

Evaluate each failure mode in terms of worst potential effect, and assign a severity classification.

▪ Failure Probability of Occurrence Level (for qualitative analysis only)

Assess failure modes in terms of probability of occurrence in the qualitative approach of the criticality analysis. The following failure probability of occurrence levels are based on MIL-STD-1629A:

Level A—Frequent

The single failure mode probability of occurrence is greater than 0.20 of the overall probability of failure during the item operating time interval.

Level B—Reasonably Probable

The single failure mode probability of occurrence is more than 0.10 but less than 0.20 of the overall probability of failure during the item operating time interval.

Level C—Occasional

The single failure mode probability of occurrence is more than 0.01 but less than 0.10 of the overall probability of failure during the item operating time interval.

Level D—Remote

The single failure mode probability of occurrence is more than 0.001 but less than 0.01 of the overall probability of failure during the item operating time interval.

Level E—Extremely Unlikely

The single failure mode probability of occurrence is less than 0.001 of the overall probability of failure during the item operating time interval.

▪ Failure Rate Data Source (for quantitative analysis only)

The data source used to obtain the failure rate data, such as Mil-Hdbk-217, must be listed in the worksheet for approval purposes. This information is necessary only for the quantitative analysis worksheet since failure rate data are not used in qualitative analysis.

▪ **Failure Effect Probability (β)**

The failure effect probability value is the conditional probability that the failure effect will result in the identified criticality classification, provided that the failure mode occurs.

The following table presents failure effect probability values, as listed in MIL-STD-1629A. This list can be customized if a study team wants to use values obtained from other resources.

Failure Effect	β Value
Actual loss	1.00
Probable loss	$0.10 < \beta < 1.00$
Possible loss	$0 < \beta \leq 0.10$
No effect	0

▪ **Failure Mode Ratio (α)**

The failure mode ratio is the probability—expressed as a decimal fraction—that the part or item will fail in the identified mode.

If all potential failure modes of a particular part or item are listed, the sum of the failure mode ratios for that part or item will be equal to 1.0.

The failure mode ratio is the fraction of the part failure rate (λ_p) that is related to the particular failure mode under consideration.

▪ **Part Failure Rate (λ_p)**

The part failure rate is derived from the appropriate reliability prediction, or is calculated by using the procedure described in Mil-Hdbk-217. The part failure rate is usually defined in terms of failures per million hours (for example, failures $\times 10^{-6}$ hours⁻¹).

▪ **Operating Time (t)**

Operating time is the number of hours or the number of operating cycles per operation.

▪ **Failure Mode Criticality Number (C_m)**

The failure mode criticality number is the portion of the criticality number for the item corresponding to one of its failure modes under a particular severity classification.

The C_m is calculated using the following formula:

$$C_m = \beta \alpha \lambda_p t$$

Where:

C_m = Criticality number for failure mode

β =Conditional probability of mission loss

α =Failure mode ratio

λ_p =Part failure rate

t =Duration of applicable operation time (hours or number of operating cycles)

▪ **Item Criticality Number (Cr)**

The item criticality number for an item is the number of system failures of a specific type that are expected due to the failure modes. For a particular severity classification for the item’s failure modes, the Cr for an item is the sum of the failure mode criticality numbers calculated using the following formula:

$$Cr = \sum_{n=1}^j f_{n-1} (\beta \alpha \lambda_p t)^n \quad n = 1, 2, 3, \dots, j$$

Where:

Cr=Criticality number for the item

n=The failure modes in the items that fall under a particular criticality classification

j=Last failure mode in the item under the criticality classification

▪ **Criticality Matrix**

The criticality matrix provides a means of identifying and comparing each failure mode to all other failure modes with respect to severity. The criticality matrix is constructed by inserting the item or failure mode identification numbers in matrix locations representing the severity categories, and then inserting either the probability of occurrence level or the criticality number (Cr) for the item’s failure modes.

Criticality Worksheet/Report Format

Recommended Product Information to be Included in Both the Quantitative and Qualitative Criticality Analysis Worksheet

Figures 19–1 and 19–2 show the worksheet format for qualitative and quantitative criticality analysis, respectively. Figure 19–3 shows the criticality matrix report format for qualitative criticality analysis. The report format for quantitative criticality analysis is given in Figure 19–4.

1. Product Name and Description

Enter the name and description of the product.

2. Catalog Number

Record the salable number studied or reviewed.

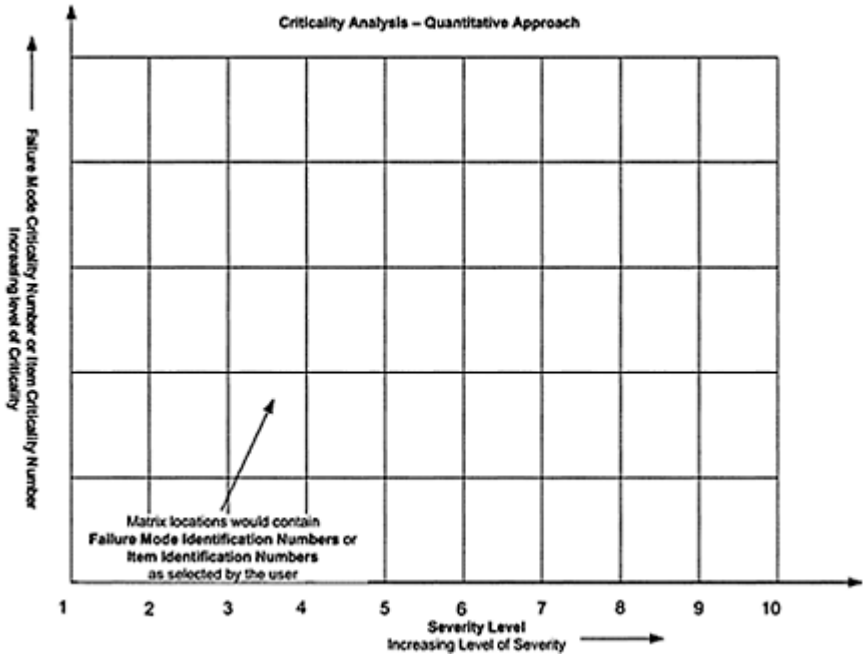
3. Product Code/Model Number

Specify the product code and/or model number, if applicable.

4. Item Description/Function

Describe the item being evaluated and its function.

**Figure 19-4: Criticality Matrix—
Report Format for FMECA**



CHAPTER 20

Post FMEA Study

This chapter describes the required steps to be taken after the completion of the FMEA.

1. Highlight the high-risk areas

High-risk areas need to be identified by reviewing the critical/control/safety related characteristics, as well as the severity and Risk Priority Number (RPN) columns. An RPN greater than or equal to 100 (when severity, occurrence and detection are ranked from 1 to 10) indicates that there might be a high-risk item. Severity greater than 5 (when severity is ranked from 1 to 10) would require design changes. These values may vary from company to company, so the FMEA team needs to be aware of the internal and regulatory requirements.

2. Ensure that a Control Plan exists and is being followed

All major characteristics require a documented plan—that is, a Control Plan for controlling, improving and/or handling changes. Control Plans provide guidance to manufacturing on how to control the product, improve product quality and meet customer/design requirements.

3. Conduct capability studies

Product capability needs to be studied once the Control Plan and SPC (Statistical Process Control) have been established.

4. Work on processes that have a CpK less than or equal to 1.33

Generally, a Process Capability Index (CpK) equal to 1.33 is considered to be acceptable as the minimum goal, but the acceptable CpK might vary, based on individual company quality requirements. For example, Ford Motor Company requires a CpK of 1.67, and Motorola requires a CpK of 2.00. The goal is to improve product and process quality by reducing variation in product characteristics and produce products on target. Companies should try to reach or exceed a CpK of 2.00 and should continuously try to improve product quality by exceeding minimum product quality requirements.

CHAPTER 21

FMEA in Advanced Quality Planning/Advanced Product Quality Planning

This chapter discusses Advanced Quality Planning, how to use this methodology and what the main benefits are. Quality planning takes place every day in every organization. To obtain the most when applying this methodology to develop products or services that satisfy customers needs, the organization has to be viewed as a system where every person and department is interrelated.

For a more detailed description of how to apply and implement AQP, refer to the Advanced Product Quality Planning and Control Plan reference manual issued by Ford, Chrysler and General Motors in July 1994.

What is AQP/APQP?

AQP (Advanced Quality Planning) is the generic methodology for all quality planning activities in all industries. APQP (Advanced Product Quality Planning) is AQP; however it emphasizes the product orientation of quality. APQP is a structured process to determine customer's needs and expectations.

APQP is used specifically in the automotive industry. AQP is a methodology that yields a quality plan for the creation of a process, product or service consistent with customer requirements. AQP offers the customer and the supplier a systematic approach to quality planning, defect prevention and continuous improvement. The Big Three (Ford, GM and Chrysler) have developed a standardized approach to AQP and it is a requirement for the QS-9000 certification.

AQP is used in the following situations:

- During the development of new products and processes;
- Prior to changes in processes and products;
- When reacting to processes or products with reported quality concerns;
- Before tooling is transferred to new producers or new plants;
- Prior to process or product changes affecting product safety or compliance regulations.

The basic requirements for an effective AQP include these items:

- Team approach;
- Systematic development of products, services and processes;
- Reduction in variation (should be able to reduce variation in product characteristics even before it reaches the customer);
- Development of a Control Plan.

AQP allows the supplier to effectively identify the following:

- Where the bottlenecks are (if any);
- What kinds of problems will be encountered;
- How problems will be overcome for successful delivery.

The process of APQP is broad and involves many individuals. The success of a good APQP depends on the team and the precise goals of the team. A typical APQP team consists of core and extended team members. Core team members could include the following:

- Manufacturing engineer;
- Industrial engineer;
- Production personnel;
- Quality assurance;
- Project engineer;
- Material engineer.

Extended team members could include the following:

- Packaging engineer;
- Facilities engineer;
- Tooling engineer;
- Supplier engineer;
- Purchasing engineer;
- Customer quality;
- Customer design;
- Maintenance.

The requirements for quality planning may vary from one organization to another. The following is an example of a typical quality planning check-off list, and Table 21–1 lists the requirements of Ford, Chrysler and General Motors.

Checklist 21–1: Typical Quality Planning Check-Off List (Stamatis, D.H. 1998)

Quality Systems

- Is the system approved by the customer?
- Prints/specifications
- Design FMEA/failure product analysis (FPA)

Key Characteristics

- Are design actions identified?
- Can product be manufactured, assembled, and tested?
- Are preventive process actions identified?
- Field/plant concerns
- Are engineering changes required?

Feasibility Analysis

- Have customer requirements been identified and taken into consideration?
- Process/inspection flow chart
- Process FMEA
- Equipment
- Previous statistical studies (surrogate data may be used)
- Design of experiments
- Cause and effect diagram
- Have characteristics for sensitive processes been identified for SPC?
- Can control charts be used on all key characteristics?
- Can causes of field/plant concerns be monitored?

Manufacturing Analysis

- Quality systems/procedures
- Key product/process characteristics
- Sample size/frequency
- Inspection methods
- Reaction plan
- Statistical methods
- Problem-solving discipline
- Are operating and SPC procedures sufficient to make control plan work?
- Is 100% inspection required?
- Does control plan have customer concurrence?

Process Potential Study

- Statistical training
- Implementation
- Results
 - Is the process ready for sign-off?
 - Are process changes needed to improve feasibility?

Process Sign-Off

- Process sheets

- Inspection instructions
 - Test equipment/gage
 - Initial samples
 - Packaging
- Was the process FMEA used to develop process sheets?
 - Was the process FMEA used to develop a dynamic control plan?
 - Does customer feedback suggest control plan changes?
 - Does the process conform to control plan requirements?

Table 21–1: AQP Requirements of Ford, Chrysler and GM (Stamatis, D.H. 1998)

Chrysler's AQP Schedule	Ford's AQP Status Reporting	GM's AQP Status Reporting
Feasibility sign-off	Sourcing decisions (Alternative suppliers, Customer awareness)	D-FMEA
Major characteristics	Customer input requirements	Design reviews
Field failure mode analysis	D-FMEA	Design verification plan
Consuming plant concerns	Design reviews	Facilities, tools and gages
D-FMEA (tooling)	Design verification plan	Prototype build Control Plan
Gage design	Subcontractor AQP status	Prototype builds
Previous statistical studies	Facilities, tools and gages	Drawing and specifications
P-FMEA	Prototype build Control Plan	Team feasibility commitment
Prototype parts	Prototype builds	Manufacturing Process Flow chart
PFD	Drawing and specifications	P-FMEA
Factory Floor Plan	Team feasibility commitment	Measurement systems evaluation
New equipment list	Manufacturing Process flow chart	Pre-launch Control Plan
Manufacturing Control Plan	P-FMEA	Operator Process instructions
Process Potential studies	Measurements systems evaluation	Packaging specifications
Process Sign-off	Pre-launch Control Plan	Production trial run
Process Sheet	Operator process instructions	Production Control Plan

Initial samples	Packaging specifications	Preliminary process capability study
Packaging design	Production trial run	Production validation testing
	Production Control Plan	Production part approval
	Preliminary process capability study	
	Production validation testing	
	Production Part Approval	
	Part submission warrant part delivery at material required date	

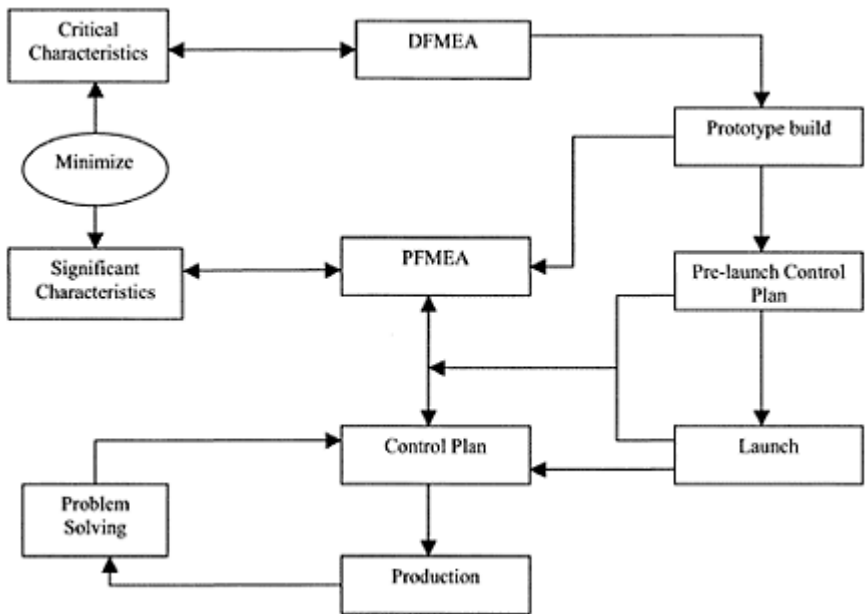


Figure 21–1: Flow Chart showing the relationship of the FMEA in the AQP/APQP process (Stamatis, D.H. 1998)

The Use of FMEA in Advanced Quality Planning

The above listed schedules (Figure 21–1) indicate that both Design and Process FMEAs are part of the AQP. Design FMEA (D-FMEA) is a method used for identifying potential problems and is a key component to determine design feasibility. D-FMEA is also a

problem-solving tool to identify design failures prior to release of the print without the identification of probable problems and an early capability assessment of high risk priority items, product/process control is unlikely. Failure to perform D-FMEA results in existing problems reappearing in future products and an increased likelihood that customer needs and various regulatory requirements from government agencies will not be met. During the D-FMEA/P-FMEA portion of AQP, the selection of significant and control or key characteristics is accomplished.

Control Items are parts that can affect either compliance with government regulations or safe product/process operation. These items are identified by the customer's product engineering on drawings and specifications with a specific and unique symbol. Significant and Critical characteristics are those product, process and test characteristics for which quality-planning actions must be summarized on Control Plans. These are identified by the team based on product knowledge and can be critical or significant to the quality, reliability, durability, fit or function of the product/process.

Process FMEA is a problem-solving tool used to eliminate problems from production systems prior to the official process design date for the product/process. All P-FMEA results should be incorporated into Control Plans and process/instruction sheets.

Control Plans are considered as the result or major output of the AQP process, and they become the basis for process control methodology. Through a Control Plan, one can identify if the control system strategy is prevention or detection oriented, as well as identify all the points at which special characteristics are affected by the process. Control Plans are addressed in more detail in the following chapter.

Implementation and control of the manufacturing product/process is crucial. Scrutinizing and confirming manufacturing capability always remains the assignment of the AQP team.

CHAPTER 22

Product Quality Control Plans and Dynamic Control Plans

This chapter outlines the benefits of creating a Control Plan and what information should be included. This discussion is accompanied by a sample template (Figure 22–1).

Introduction

The purpose of the Control Plan methodology is to aid in the manufacture of quality products according to customer requirements. It does this by providing a structured approach for the design, selection and implementation of value-added control methods for the total system.

A Control Plan focuses on the Product/Process and inspection requirements for a particular product.

The key items that need to be controlled and maintained to ensure product quality are as follows:

- Control of supplier products;
- Manufacturing process capability;
- SPC;
- Inspection and laboratory test inspection instructions;
- Measuring and testing equipment;
- Engineering performance testing;
- Product qualification and lot sampling;
- Control of non-conforming products;
- Layout inspection;
- Drawing and change control;
- Quality system and product performance records.

Although there are different formats for Control Plans, the automotive industry requires a standard form as included in the APQP manual.

A Control Plan is basically a written summary that describes the methods and tools that the process is using so that variation is minimized. This should not be replaced with the information contained in detailed operator instructions. Instead, the Control Plan supplements it, especially in the area of quality activities such as the following:

- When to use sampling;
- How much sampling is required;
- Frequency of inspection;
- Specified usage of SPC.

Control Plans are used in conjunction with other quality-related tools and are used throughout the product's life cycle:

Initial stage—documents and communicates the initial plan for process control;

Next stage—guides manufacturing in how to control process to ensure maximum product quality;

Later stage—continues to be a living document that contains current/up-to-date control methods. Since processes are updated and improved, the Control Plan is a continuous improvement tool as well as a control document.

Control Plans can be categorized into the following three types:

Prototype—A description of the dimensional measurements, materials and performance tests occurring during Prototype build.

Pre-launch—A description of the dimensional measurements, materials and performance tests that will occur after Prototype and before normal production.

Production—A comprehensive documentation of Product/Process characteristics, Process controls, tests and measurement systems occurring during normal production.

Control Plans include the following sections:

- A list of critical and significant characteristics;
- Sample sizes and frequency of evaluation;
- Method of evaluation;
- Correction and prevention plans/reaction plans.

A single Control Plan may apply to a group or family of products that are produced by the same Process at the same source. A Control Plan is a living document that should be updated to reflect the current methods of control and used throughout the product's life cycle.

Benefits of Developing and Implementing Control Plans

- Improve quality of products during design, manufacturing and assembly;
- Help to identify process characteristics and their sources of variation, which cause variation in product characteristics;

- Help to focus resources on processes and products related to characteristics that are important to the customer, which consequently increases customer satisfaction;
- Provide proper channel for communicating changes in the product/process characteristics, control method and characteristic measurement.

Information Used to Develop Control Plans

The following is a suggested list of information used to develop a Control Plan:

- Process flow diagram;
- Design/Process Failure Mode and Effects Analysis;
- Special Characteristics;
- Lessons learned from similar parts;
- Team's knowledge of the process;
- Design reviews.

Control Plan Terminology and Recommended Information to Include

Figure 22–1 is a recommended Control Plan template. The following is a list of items in the template. These items are not mandatory.

1. Control Plan Type

Identify whether the Control Plan is for a prototype, pre-launch item or for a product under production.

2. Control Plan Number

Enter the Control Plan document number used for tracking, if applicable.

3. Supplier/Plant

Specify the name of the supplier/plant.

4. Supplier Code

Provide the identification number (Duns, Z-code and so on), as requested by the procuring organization.

5. Engineering Drawing Number/ID

Enter the Engineering Drawing Number of the part or process being controlled.

6. Key Contact Name

Enter the name of the primary contact responsible for the Control Plan.

7. Key Contact Phone Number

Enter the phone number of the primary contact responsible for the Control Plan.

8. Engineering Approval Date

Record the engineering approval date for the process/product Control Plan.

9. Supplier/Plant Approval Date

Specify the approval date obtained by the responsible manufacturing plant.

10. Other Approval/Date (if applicable):

Record any other approval necessary

11. Control Plan Date (Original Release Date)

Record the date on which the original Control Plan was compiled.

12. Control Plan Revision Date

Specify the date of the latest Control Plan updates.

13. Customer/Engineering Approval Date (Specifications Approval Date)

If applicable, enter the customer approval date for the process/product Control Plan.

14. Customer Quality Approval Date

Specify the date of approval by the responsible supplier quality representative.

15. Part/Process Number/Latest Change Level

Enter the number of the system, subsystem or component being controlled. When applicable, enter the latest engineering change level and/or issue date from the drawing specification.

16. Process Name/Operation Description

All steps in the manufacturing of a system, subsystem or component should be described in a process flow diagram. From this diagram, identify the process/operation name that best describes the activity being addressed.

17. Core Team List

Record the names and telephone numbers of the individuals responsible for preparing the latest revision of the Control Plan. All of the team members' names, phone numbers and locations should be included on an attached distribution list.

18. Part/Process Number

Record the number of the process or part being controlled.

19. Process/Part Description

Describe the process and/or part being controlled.

20. Machine, Device, Jig, Tools for Manufacturing

For each operation that is described, identify the processing equipment, such as machine device, or other tools for manufacturing, as appropriate.

21. Characteristics

A distinguishing feature, dimension or property of a process or product on which variable or attribute data can be collected.

a. Characteristics Number

Enter the characteristics number from all applicable documents, such as but not limited to, process flow diagram, numbered blue print, FMEA and so on, if required or applicable.

b. Product Characteristics

Record the product characteristics, which are features or properties of parts or a group of components (assembly) that are described on drawings or other primary engineering information. Examples of product characteristics include appearance, wall thickness, part O.D., part I.D. and so forth.

c. Process Characteristics/Variables

Enter the process variables, which are factors that have a cause and effect relationship with the identified product characteristic. There could be one or more process characteristics listed for each product characteristic. In some processes, one process characteristic may affect several product characteristics. Examples of process variables include raw material mixing ratio, process temperature, process pressure and so on.

d. Special Characteristics Classification

Indicate the special characteristics classification, which includes critical, key and significant characteristics.

22. Methods**a. Product/Process Specification Tolerance**

Enter the product specification tolerance obtained from engineering resources. Specification tolerance should be based on design requirements.

b. Evaluation Measurement Technique

Identify the technique used to measure the product/process characteristics.

c. Gages Repeatability and Reproducibility (GR&R)

Record the total repeatability and reproducibility of the measuring device used for evaluation of product characteristics. Repeatability is the error due to the gage (precision), and reproducibility is the error due to differences in conditions in each repetition.

d. Confidence Level**d1. Sample Size**

Specify the number of samples to be used in the evaluation.

d2. Sample Frequency

Indicate how often the samples should be tested/evaluated for further quality control purposes.

d3. AQL/AOQL

This is a target-setting column to decide in-house production vs. outsourcing. Enter the Acceptable Quality Level (AQL) or the Acceptable Outgoing Quality Level (AOQL). The following Military standards can be used as references to determine the values for internal target setting: Mil-Std-105E for AQL and Mil-Std-1235 for AOQL.

d4. CpK Index (Process Capability Index)

Process capability analysis examines:

- The variability in process characteristics relative to product specifications;
- Whether the process is capable of producing a product that conforms to specifications.

Record the Process Capability Index (CpK), which is a measure of both process dispersion and its centering about the average. CpK is calculated to be the minimum of

$$\frac{USL - \bar{X}}{3\sigma} \text{ and } \left(\frac{\bar{X} - LSL}{3\sigma} \right)$$

Where:

USL=Upper Specification Limit

LSL=Lower Specification Limit

\bar{X} =Process Mean

σ =Standard Deviation

- e. Control Method** Enter a brief description of how the operation will be controlled. Control methods are unique to the process and should reflect the planning and strategy being implemented in the manufacturing process. If control procedures exist, the identification numbers of each of these procedures should also be included.

23. Reaction Plan/Corrective Action/Preventive Plan Record the reaction plan, which specifies the corrective actions necessary to avoid producing nonconforming products or operating out of control. The reaction plan should also include the person responsible for the corrective/preventive action.

The form is a detailed control plan template. It includes fields for:

- Control Plan Type (1)
- Control Plan No. (2)
- Supplier/Plant (3)
- Supplier Code (4)
- Engineering Drawing No. (5)
- Part/Process Number (15)
- Process Name/Operation Description (16)
- Core Team (17)
- Key Contact Name (6)
- Key Contact Phone No. (7)
- Engineering Approval Date (8)
- Supplier/Plant Approval Date (9)
- Other Approval Date (if applicable) (10)
- Date (Original) (11)
- Date (Revision) (12)
- Customer/Engineering Approval Date (13)
- Customer Quality Approval Date (if applicable) (14)

 Below these fields is a table with columns: Part/Process Number, Process Name/Operation Description, Machine, Device, Jig, Tools for Mfg, Characteristics (No., Product, Process, Special Char. Class), Product/Process Specifications/Tolerance, Evaluation/Measurement Technique, Control Methods (Gage R & R, Size, Freq., AQL/AOQL, Cpk Index), Control Method, and Reaction Plan. Numbered callouts 18-23 point to specific cells in this table.

Figure 22–1: Sample Control Plan Template

Dynamic Control Plans (DCP)

A Dynamic Control Plan is a combination of FMEA and Control Plan. A DCP ensures that the customer expectations/requirements, in the form of product design requirements,

Dynamic Control Plan Elements

As illustrated in Figure 22–2, a Dynamic Control Plan contains the following elements:

1. Company/Plant Name

Name and identification of the company.

2. Department

Name of the department using the control plan

3. Process Description/Name

Name and description of the process for which the DCP is carried out.

4. Operation #

Number of the operation

5. Machine

Machine description or identification if applicable.

6. Part Name

Product or part name for which the Dynamic Control Plan is carried out.

7. Part Number

Product or Part identification number, usually referenced from the process flow chart.

8. Control Plan Revision Date

Revision date of the corresponding Control Plan, if one exists.

9. Process Sheet Revision Date

Revision date of the corresponding Process sheet.

10. Issue Date

Dynamic Control Plan issue date.

11. Characteristic #

Cross-reference number from all applicable documents, if required.

12. Characteristic Description

Description of whether it is a product or process characteristic. Product characteristics are the features or properties of a part, component or assembly that are described on drawings or other primary engineering information. Process characteristics are the process variables that have a cause and effect relationship with the identified product characteristic.

13. Specification

Product/Process specification from various engineering documents, including tolerance.

14. Failure Mode

Failure modes associated with the product/process characteristic under review.

15. Failure Effects

Effects of the failure corresponding to the failure modes.

16. Severity

Severity of the effects of failure should be identified and ranked.

17. Causes of Failure

Appropriate causes for the failure modes should be listed.

18. Occurrence

The probability of occurrence of the causes for the failure mode should be documented.

19. Current Controls

The methods, systems, routines, etc. in place to prevent/mitigate the causes of failure should be identified and documented.

20. Detection

The effectiveness of the current controls in terms of detectability of causes of failure should be evaluated and documented.

21. RPN

The Risk Priority Number, as discussed previously, is a multiplication of severity, occurrence and detection. The RPN is used to risk rank the failure modes associated with each product/process characteristic.

22. Recommended Actions

Based on the risk analysis, the actions required or recommended to improve the safety of the system.

23. Area Responsible & Date

The department responsible to carry out the recommended actions and the suggested target date.

24. Actions Taken

Based on the recommended actions, the actions that were taken/implemented and comments if any.

25. Control Factor

Control factors could be the following:

- a. Fixture/Pallet dominant (F)—the fixtures or pallets holding the parts are the greatest source of inconsistency;
- b. Machine dominant (M)—the machine producing the characteristic is the greatest source of inconsistency;
- c. Component dominant (C)—incoming component nonconformity is the primary source of product variability;
- d. Setup dominant (S)—the characteristic is highly reproducible once the setup has occurred;
- e. Tool dominant (T)—the characteristic is uniform but drifts over time from tool wear;
- f. Operator dominant (O)—uniformity of the characteristic is highly dependent on operator skill;
- g. Preventive Maintenance dominant (P)—process consistency is dependent upon scheduled maintenance activities;
- h. Environment dominant (E)—the characteristic is susceptible to environmental conditions.

26. Classification

Characteristic classification is the process of categorizing characteristics for the purposes of control planning. The following are standard classifications:

Critical Characteristics (CC)—Part or process requirements that affect government regulatory compliance for safe product function and require specific supplier, manufacturing, assembly, shipping, monitoring and/or inspections.

Significant Characteristics (SC)—Categorized characteristics of products, processes and tests where a reduction in variation within a specified tolerance around a proper target will improve customer satisfaction.

High Impact Characteristics (HIC)—Product or process characteristics that, when outside the specification tolerance, can severely affect subsequent manufacturing operations or customer satisfaction. However, the product will not be unsafe.

27. Control Method

Control methods such as control charts, X-bar and R charts should be documented if implemented.

28. Tool

Identify the tools required for the manufacturing operation.

29. Gage Description, Master, Detail

Description of the specific gage as a means of measuring or testing and its respective master.

30. GR & R and Date

Record the total repeatability and reproducibility of the measuring device used for evaluation of product characteristics. Repeatability is the error due to the gage (precision), and reproducibility is the error due to differences in conditions in each repetition.

31. Cp/Cpk (target) & Date

Process capability analysis examines:

- The variability in process characteristics relative to product specifications;
- Whether the process is capable of producing a product that conforms to specifications.

Record the Process Capability Index (CpK), which is a measure of both process dispersion and its centering about the average. CpK is calculated to be the minimum or

$$\frac{USL - \bar{X}}{3\sigma} \quad \text{and} \quad \left(\frac{\bar{X} - LSL}{3\sigma} \right)$$

Where:

USL=Upper Specification Limit

LSL=Lower Specification Limit

\bar{X} =Process Mean

σ =Standard Deviation

32. Reaction Plans

Record the reaction plan, which specifies the corrective actions necessary to avoid producing nonconforming products or operating out of control. The reaction plan should also include the person responsible for the corrective/preventive action.

Dynamic Control Plan Question Log

A question log is used in conjunction with Dynamic Control Plans to track open issues and maintain a history of knowledge gained. It is specifically used to:

- Coordinate team activities;
- Record open questions, issues and concerns;
- Capture ideas for future consideration;
- Track progress and record knowledge gained.

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