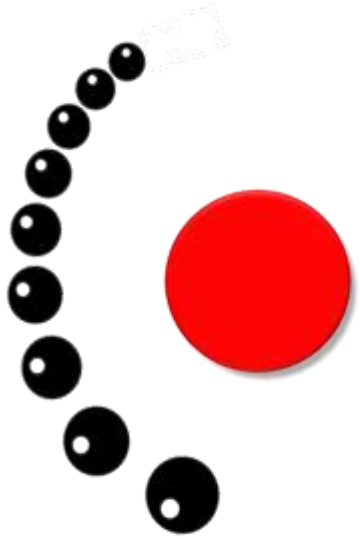

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Enabling Improved Performance.

PFMEA

Process Failure Mode and Effect Analysis

18 and 20 July 2020

Failure

Failure is the state or condition
of not meeting
a desirable or intended objective,
and may be viewed as
opposite of success.

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Defining an Engineering Product

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If there are two or more ways to do something and one of those results in a catastrophe, then someone will do it that way.

(Edward A. Murphy)

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FMEA

- FMEA is risk analysis analytical tool.
- It estimates the risk associated with customer and the organization. It predicts the risk levels and it's prioritization for all failure modes.
- A FMEA is a Systematic, Qualitative, disciplined analytical procedure
- It allows engineers to **anticipate** failures and **prevent** their occurrence in manufacturing by collective knowledge of CFTs.
- It identify ways the product or process can fail. Then plan to prevent those failures.

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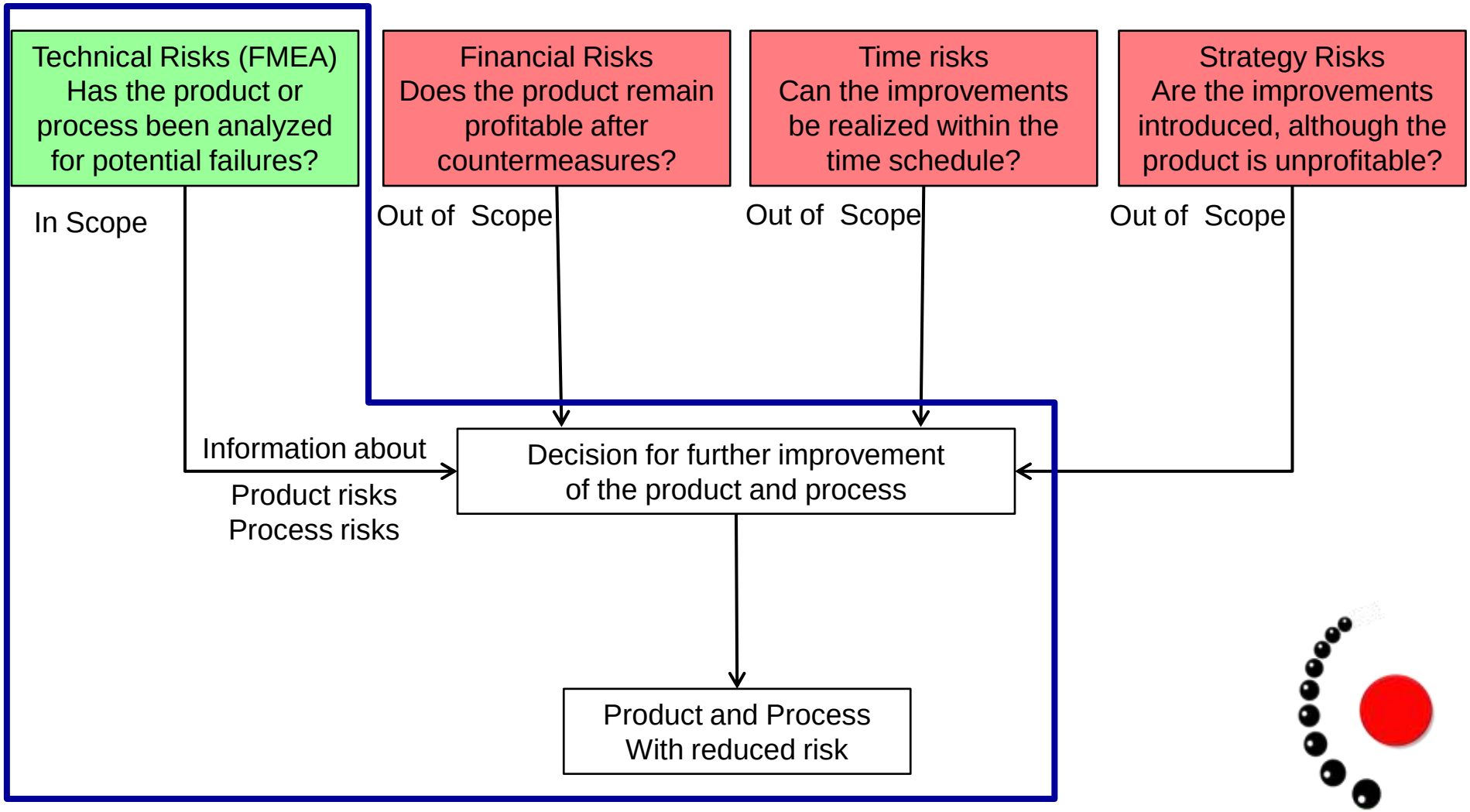
The industry is challenged by increasing quality demands of the customer, the necessary cost optimization of the products and processes, and higher complexity, as well as the product liability of the designer and the manufacturer required by the legislation.



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Business Objective Supported by FMEA

- Increasing the quality, reliability, manufacturability, safety and serviceability of automotive products.
- Reducing warranty and goodwill costs
- Increasing customer satisfaction in highly competitive market.
- Reducing late changes in development – *ECN, Deviations*.
- Maintaining defect-free product launches at reduced time and cost.
- Targeting communication in internal and external customer and supplier relationships.
- Building up a knowledge base in the company, i.e., document lessons-learned – *Training and development.*

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Transition Strategy

Existing FMEAs developed using the previous AIAG 4th Edition FMEA "Product and Process FMEA" of VDA Edition, may remain in their original form for subsequent revisions.

When practical, existing FMEAs used as a starting point for new programs should be converted to reflect the new rating scales, and format. However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave FMEA in existing format.

New projects should follow the FMEA method presented in this Handbook unless company leadership and Customer Specific Requirements (CSR) mandate a different approach. The transition date and project milestone after which new projects follow this method should be defined by the company taking into consideration CSRs.

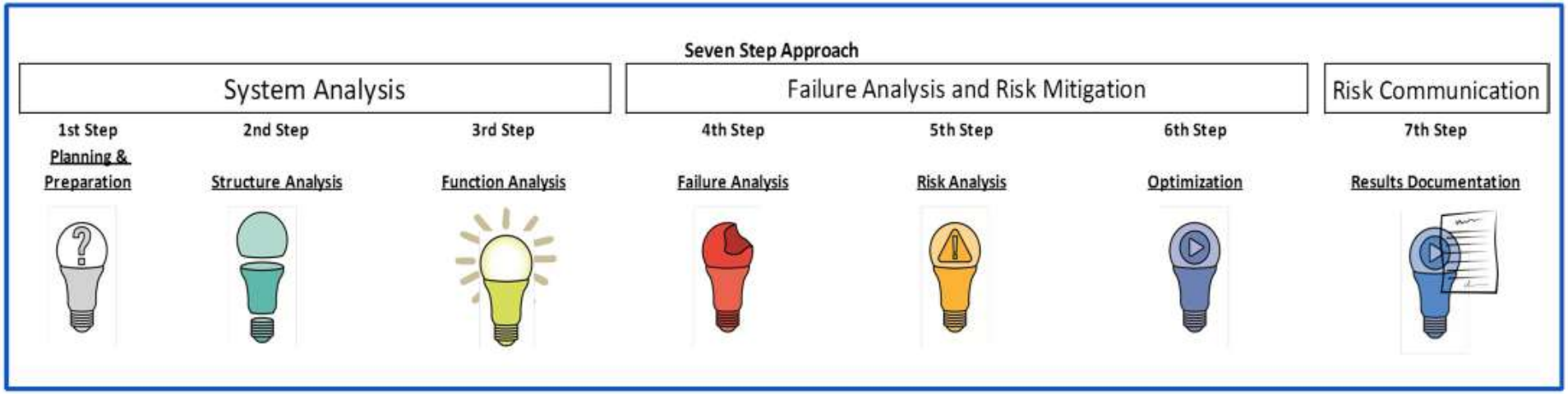
Foundation and Family FMEAs

Foundation and family FMEAs are recommended to be created and used a basis for new analysis. These optional practices provide the greatest opportunity to leverage past experience and knowledge.

Foundation FMEAs (also known as generic, baseline, template, core, master, or best practice) are FMEAs that contain knowledge of the organization form prior developments which make them useful as a starting point for new FMEAs. The foundation FMEA is not program specific, therefore the generalization of requirements, functions, and measures is allowed.

Family FMEAs are specialized foundation FMEAs. It is common to develop products that generally contain common or consistent product boundaries and related functions (a product family) or processes which contain a series of operations that produce multiple products or part numbers.

PFMEA Process



1st Step: Planning and Preparation

2nd Step: Structure Analysis

3rd Step: Function Analysis

4th Step: Failure Analysis

5th Step: Risk Analysis

6th Step: Optimization

7th Step: Results Documentation

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PFMEA Project Identification and Boundaries

PFMEA project identification includes a clear understanding of what needs to be evaluated. What to exclude can be just as important as what to include in the analysis.

- What is the customer buying from us?
- Are there new requirements?
- What specific process/elements cause a risk in imparting the requirement?
- Do we make the product and have design control?
- Do we buy the product and do not have the design control?
- Do we need a system, subsystem, component or other level of analysis?

Answers to these questions and others defined by the company help create the list of DFMEA projects needed.

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1st Step: Planning and Preparation
PFMEA Project Identification and Boundaries

The following may assist the team in defining PFMEA boundaries:

- Legal Requirements, Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Diagrams (Block/Boundary/System)
- Schematics, Drawings, and/or 3D models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products
- Error proofing requirements, Design for Manufacturability and Assembly (DFM/A), Quality Function Deployment (QFD).

Processes within the plant that can impact the product quality can be considered for PFMEA analysis including receiving processes, part and material storage, delivery, manufacturing, assembly, packaging, labeling, completed product transportation, storage, maintenance, detection processes , rework and repair processes.

Process Failure Mode and Effects Analysis (Process FMEA)

Planning and Preparation (Step 1)

Company Name:	Name of Company Responsible for PFMEA	**Subject:**	Name of PFMEA Project	**PFMEA ID Number:**	Determined by Company
Manufacturing Location:	Geographical Location	**PFMEA Start Date:**	Start Date	**Process Responsibility:**	Name of PFMEA Owner
Customer Name:	Name of Customer(s) or Product Family	**PFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross Functional Team:**	Team Roster needed		

Example: Process Failure Mode and Effects Analysis (Process FMEA)

Planning and Preparation (Step 1)

Company Name:	Acme Automotive	**Subject:**	PX123 Manual Column Assembly		
Manufacturing Location:	Plant 6, Saginaw, Michigan	**PFMEA Start Date:**	19-Mar-2018	**PFMEA ID Number:**	654321
Customer Name:	Jackson Industry	**PFMEA Revision Date:**	25-Sep-2018	**Process Responsibility:**	B. Black
Model Year(s) / Program(s):	2020 PX123	**Cross Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure 3.1-2 Example of Completed PFMEA Header Preparation (Step 1)

2nd Step: Structure Analysis

The Purpose of the process structure analysis is to identify and breakdown the manufacturing system into process items, process steps and process work elements,

The main objectives of a process structure analysis are:

- Visualization of the analysis scope
- Structure Tree (tree diagram) or equivalent process flow diagram
- Identification of process steps and sub-steps
- Collaboration between customer and supplier engineering teams (Interface responsibilities)

A process FMEA is intended to represent the process flow as it physically exists when "walking the process," describing the flow of product through the process.

Function Analysis (step3) should not begin until structure analysis (step 2) is complete.

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A Process Flow Diagram is a tool that can be used as an input to the Structure Analysis.

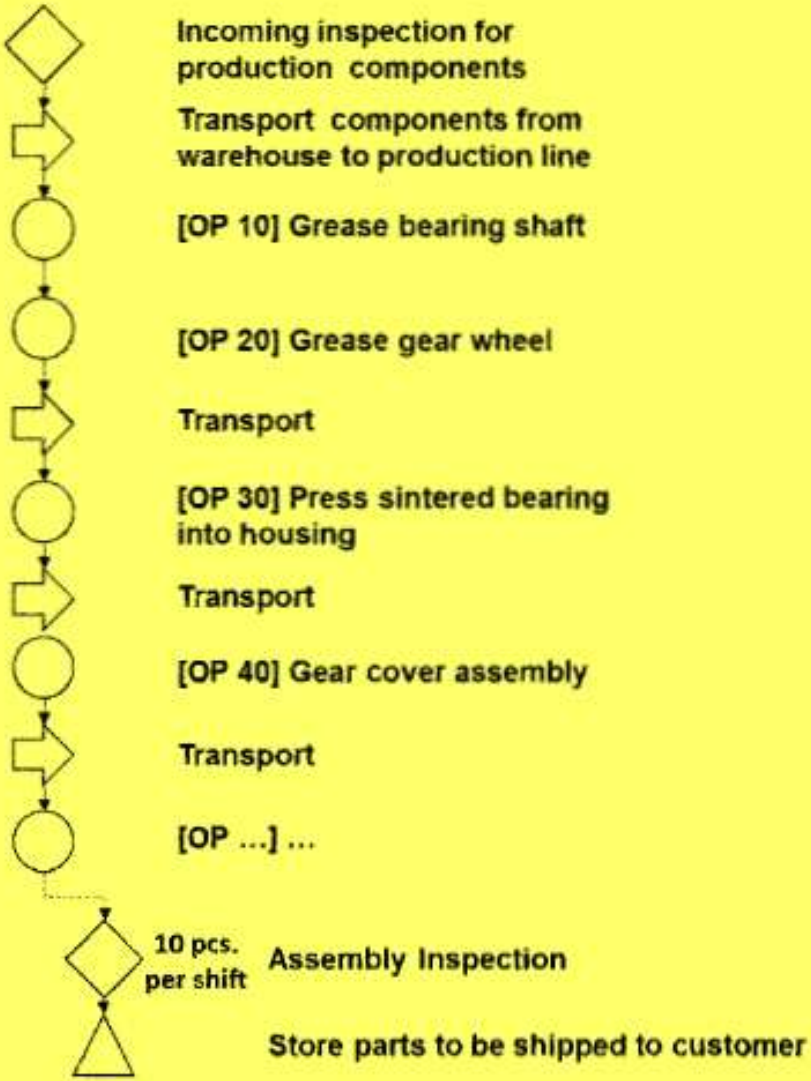

Figure 3.2-1 Process Flow Diagram

Structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections. Each of these is a building block that will later have functions and failures added.

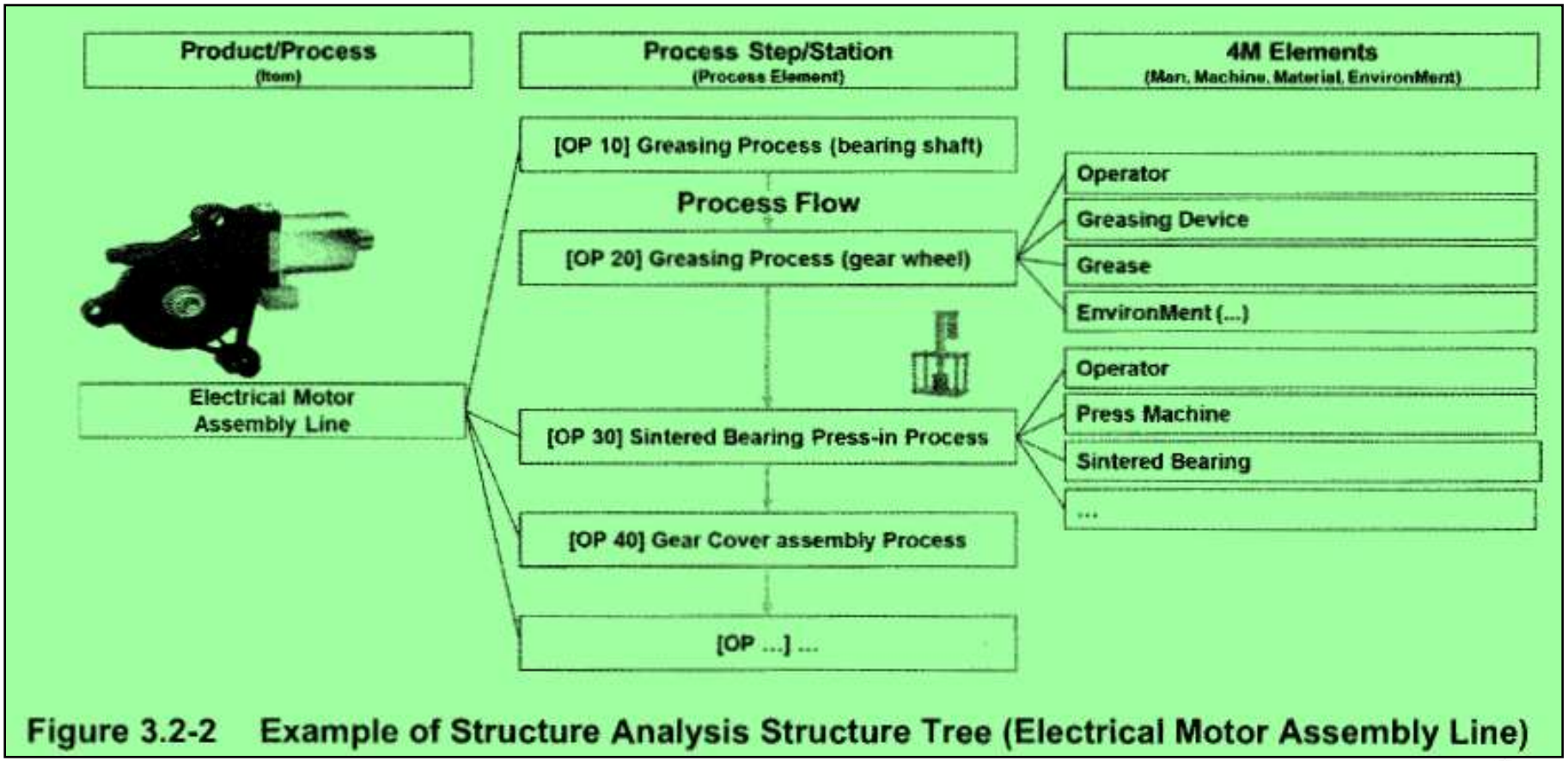

Figure 3.2-2 Example of Structure Analysis Structure Tree (Electrical Motor Assembly Line)

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STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Press Machine

Process item is the highest level of structure tree or PFD. This can also be considered the end result of all of the successfully completed process steps within the scope of analysis.

Process step is the focus of the analysis. Process step is a manufacturing operation or station (topic of consideration of failure)

Process work element is the lowest level of the process flow or structure tree. Each work element is the name of a main category of potential causes that could impact the process step. The number of categories may vary (4M, 5M, 6M).

3rd Step: Function Analysis

A function describes what the process item or process step is intended to do. There may be more than one functions for each process item or process step.

The main objectives of a Process Function Analysis are;

- Visualization of product or process functions
- Function tree or equivalent process flow diagram
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety and components)
- Basis for Failure Analysis step.

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3rd Step: Function Analysis

Characteristics:

A characteristic is a distinguishing feature (or quantifiable attribute) of a product. For example, a diameter or surface finishes.

For PFMEA, requirements are described in terms of Product Characteristics and Process Characteristics.

A product characteristic (requirement) is related to the performance of a process function and can be judged or measured. A product ***characteristic*** *is shown on a product drawing or specification document e.g. Geometry, Material, Surface finish, Coatings etc. Process functions create product characteristics. The design documents comprehend* ***legal requirements*** *(e.g. lead-free material),* ***industry requirements*** *(e.g. thread class),* ***customer requirements*** *(e.g. quantity), and* ***internal requirements*** *(e.g. part cleanliness).*

Product characteristics can be measured after the product has been made e.g. gap. Product Characteristics can come from performance or requirements e.g. performance of windshield wipers.

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3rd Step: Function Analysis

For the logical linking of a function and structure, questions are asked as:

“what does it do?”

How to achieve the product/process requirements – from right to left

(Process Item ⟶ Process Step ⟶ Process Work Element)

“How?”

Why implement the product/process requirements – from left to right

(Process Work Element ⟶ Process Step ⟶ Process Item)

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3rd Step: Function Analysis

The recommended phrase format is to use and action verb followed by a noun to describe the measureable process function

“DO THIS TO THIS”

A function should be in the PRESENT TENSE

Examples: drill hole, apply glue, insert pin, weld bracket

Note:

*Negative of functions of **process item** will be **Failure Effects***

*Negative of functions of **process step** will be **Failure Modes***

*Negative of functions of **process work element** will be **failure causes***

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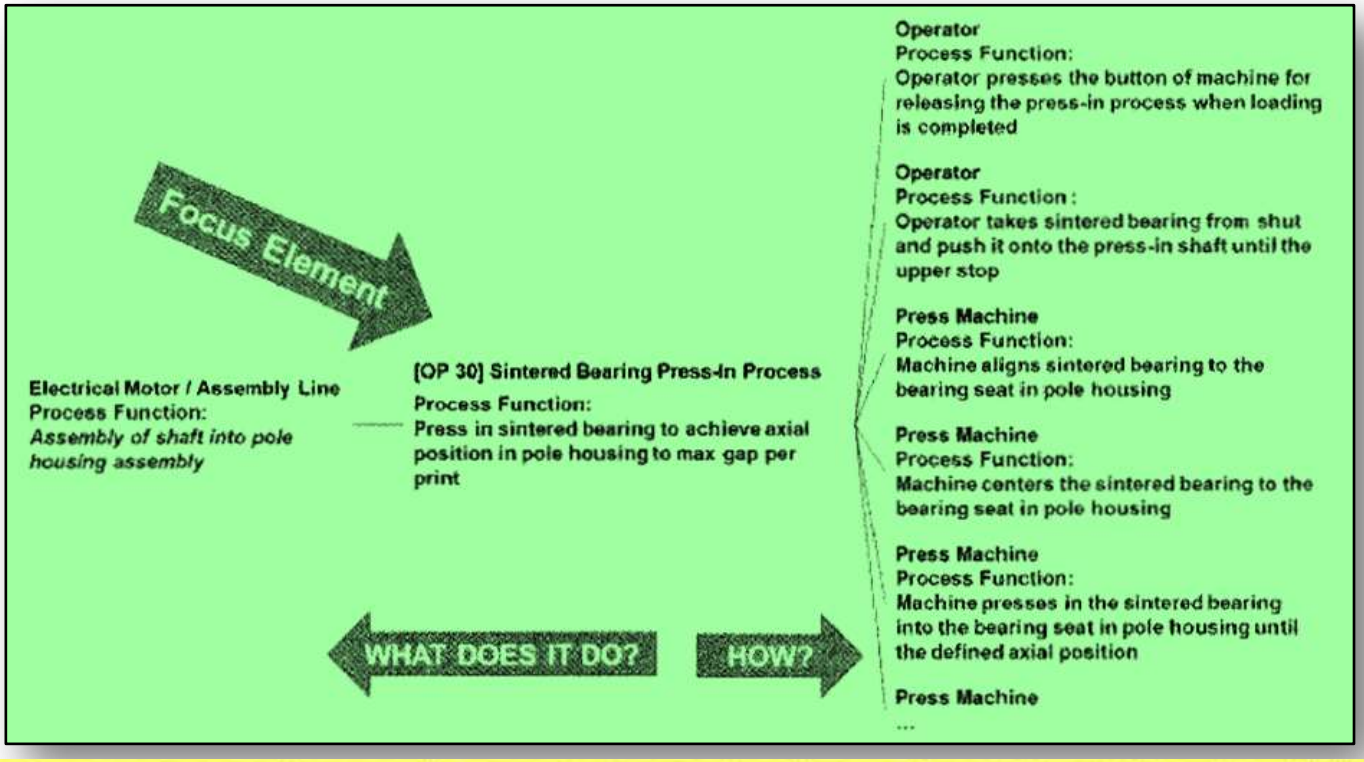


1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine presses sintered bearing into the pole housing seat until the defined axial position

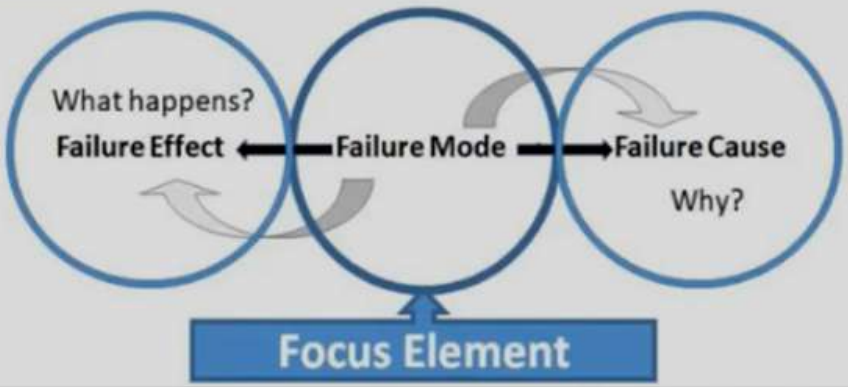
4th Step: Failure Analysis

The purpose of the Process Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The failure chain:
for a specific failure there are three aspects to be considered:

- **Failure Effect (FE)** – the consequences of a failure mode
- **Failure Mode (FM)** – manner in which an item could fail to meet or deliver the intended function
- **Failure Cause (FC)** – indication of why the failure mode could occur

Note: these are all failure modes at different levels



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4th Step: Failure Analysis

Failure Effects:

Failure effects are described in terms of what the customer might notice or experience. Failures that could impact safety or cause noncompliance to regulations should be clearly identified in PFMEA.

Customers could be:

- Internal customer (next operation/subsequent operation)
- External customer (Next Tier Level/OEM/dealer)
- Legislative bodies
- Product end user/operator

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4th Step: Failure Analysis

Effect: of the failure must be studied on following aspects:

- **Your Plant:** the effect of the failure mode assuming the defect is detected in the plant (what action will the plant take, e.g. scrap)
- **Ship-to-plant:** the effect of the failure mode assuming the defect is not detected before shipping to the next plant (what action will the next plant take, e.g. sort)
- **End user:** the effect of the process item effect (what will the end user notice, feel, hear, smell, etc. e.g. window raises too slow)

4th Step: Failure Analysis

Failure Mode: Process Failure Mode is defined as the manner in which the process could cause the product not to deliver or provide the intended function.

The team should assume that the basic design of the product is correct; however, if there are design issues which result in process concerns, those issues should be communicated to the design team.

Assume that the failure mode could occur but may not necessarily occur.

There are several categories of potential failure modes including:

- Loss of process function /operation not performed
- Partial function – incomplete operation
- Degradation of process function
- Overachieving process function – Too much too high
- Intermittent process function – operation not consistent
- Unstable operation
- Delayed process function – operation too late
- Wrong part installed

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4th Step: Failure Analysis

Failure Cause:

A failure cause is an indication of why a failure mode could occur. The consequence of a cause is the failure mode.

Typical failure causes may include the classic Ishikawa's 4M, but not limited to:

- Man
- Machine
- Material
- Environment (Milieu)

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4th Step: Failure Analysis

To link failure cause(s) to a failure mode, the question should be "why is the failure mode occurring?"
To link failure effects to a failure mode, the question should be "what happens in the event of a failure mode?"

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.	Axial position of sintered bearing is not reached	Machine stops before reaching final position

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1. Process Item System, Subsystem, Part Element or Name of Process	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	1. Failure Effects (FE) to the Next Higher Level Element and/or End User
Electrical Motor Assy Line	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.

2. Process Step Station No. and Name of Focus Element	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	2. Failure Mode (FM) of the Process Step
[OP 30] Sintered Bearing Press-In Process	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached

3. Process Work Element 4M Type	3. Function of the Process Work Element and Process Characteristic	3. Failure Cause (FC) of the Work Element
Press Machine	Machine presses sintered bearing into the pole housing seat until the defined axial position	Machine stops before reaching final position

Process Flow Diagram

Opn No.	OPERATION DESCRIPTION	TYPE OF MACHINE/ FACILITY	ADJUSTABLE PROCESS PARAMETERS	INCOMING SOURCES OF VARIATION	STORAGE	MOVE	PROCESS	INSPECTION	IN STATION INSPECTION	KEY PRODUCT CHARACTERISTIC	KEY CONTROL CHARACTERISTIC
					▽	⇨	○	▭	◎		

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FMEA Definitions

- **Failure Mode:** The manner in which a part /process/ service can fail to meet or deliver the intended function and associated requirements.

This is usually associated with a defect or non-conformance.

1) ***Omission (Did Not)***
2) ***Excessive Action (More)***
3) ***Incomplete Action (Less)***
4) ***Erratic Action (Unpredictable)***
5) ***Uneven Action (Focused into finite area)***
6) ***Too Much Time (Too Slowly)***
7) ***Too Little Time (Too Quickly)***

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FMEA Definition - Severity

“Severity” is an assessment of how significant is the Effect to any of the customers (internal or external.

It is denoted by a ranking number associated with the impact of the consequence if failure is not prevented.

Scale 1 to 10.

10 means ‘most severe’

1 means least significant

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FMEA Definition - Causes

- **Cause:** A deficiency that results in a Failure Mode. Causes are sources of variability. Causes are described in terms of something that can be corrected or controlled.

A “cause” is the specific reason for the failure, preferably found by asking “why”.

- **Causes:** Causes must be analyzed related to following:
  - Man
  - Machine
  - Material
  - Method
  - Measurement
  - Environment

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FMEA Definition - Occurrence

“Occurrence” is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analyzed.

Rating scale: 1 to 10

1 means remote chances

10 means very frequent

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FMEA Definition

Current Controls: The methods or actions currently in place, that prevent or detect the Failure or cause before it reaches your customer.

Typical Current Controls

Statistical Process Control - SPC

Inspections, Monitoring, Training

Preventive Maintenance

Road Test, Rig / Lab Test

Prototype test, Fleet test

Design Review / Feasibility review

There can be many controls for each cause / failure mode.

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5th Step: Risk Analysis

The purpose of the Process Risk Analysis is to estimate risk by evaluating Severity, Occurrence and detection, in order to prioritize the need for actions.

There are two different Control Groups:

Current Prevention Controls, and Current Detection Controls.

Prevention Controls:

- two handed operation of machines,
- Subsequent part cannot be attached (poka-yoke)
- Form dependent position (Fool-proof by design)
- Equipment maintenance
- Wok instruction /Visual aids, setup procedures
- Machine controls, calibration process
- First Part release, error-proofing verification

Failure causes are rated for occurrence, taking into account the effectiveness of the current prevention control.

5th Step: Risk Analysis

Current Detection Controls detect the existence of a failure cause or failure modes, either by automated or manual methods, before the items leaves the process or is shipped to the customer.

- Visual inspection
- Optical inspection with camera system
- Dimensional check with a caliper gauge
- Visual inspection with sample checklist
- Attribute test with mandrel
- Random inspection
- Torque monitoring
- Press load monitoring
- End of line function check

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FMEA Definition - Detection

It is an assessment of the ability of the current process controls to detect a Failure or Cause in the system.

Scale 1 to 10
1 means Certain Detection
10 means cannot Detect

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Rating Scale

- **Severity (SEV):** How significant is the impact of the Effect to the customer (internal or external)?
- **Occurrence (OCC):** How likely is the Cause of the Failure Mode to occur?
- **Detection (DET):** How Likely will the current system detect the Cause or Failure Mode if it occurs?

The rating can be anything between 1 and 10.

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5th Step: Risk Analysis

Risk Priority Numbers are the product of S X O X D and range from 1 to 1000. The RPN distribution can provide some information about the range of ratings, but RPN alone is not an adequate method to determine the need for more actions since RPN gives equal weight to S, O, and D.

The use of a Risk Priority Number (RPN) threshold is not a recommended practice for determining the need for actions. The RPN and S X O methods are not included in this publication.

Note: Action Priority rating tables are same for DFMEA and PFMEA.

- Priority High (H)
- Priority Medium (M)
- Priority Low (L)

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Action Priority (AP) for DFMEA and PFMEA

Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very high	1	H
		High	6-7	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very high	1	H
		Moderate	4-5	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very high	1	M
		Low	2-3	Low - Very low	7-10	H
				Moderate	5-6	M
				High	2-4	L
				Very high	1	L
		Very low	1	Very high - Very low	1-10	L
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very high	1	H
		High	6-7	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very high	1	M
		Moderate	4-5	Low - Very low	7-10	H
				Moderate	5-6	M
				High	2-4	M
				Very high	1	M
		Low	2-3	Low - Very low	7-10	M
				Moderate	5-6	M
				High	2-4	L
				Very high	1	L
		Very low	1	Very high - Very low	1-10	L
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H
				Moderate	5-6	H
				High	2-4	M
				Very high	1	M
		High	6-7	Low - Very low	7-10	M
				Moderate	5-6	M
				High	2-4	M
				Very high	1	L
		Moderate	4-5	Low - Very low	7-10	M
				Moderate	5-6	L
				High	2-4	L
				Very high	1	L
		Low	2-3	Low - Very low	7-10	L
				Moderate	5-6	L
				High	2-4	L
				Very high	1	L
		Very low	1	Very high - Very low	1-10	L
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M
				Moderate	5-6	M
				High	2-4	L
				Very high	1	L
		High	6-7	Low - Very low	7-10	L
				Moderate	5-6	L
				High	2-4	L
				Very high	1	L
		Moderate	4-5	Low - Very low	7-10	L
				Moderate	5-6	L
				High	2-4	L
				Very high	1	L
		Low	2-3	Low - Very low	7-10	L
				Moderate	5-6	L
				High	2-4	L
				Very high	1	L
		Very low	1	Very high - Very low	1-10	L
No discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L

Action Priority (AP)	Action Expectation
High	The team must either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.
Medium	The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.
Low	The team could identify actions to improve prevention or detection controls.
It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any actions that were taken.	

6th Step: Optimization

The purpose of the Process Optimization Step is to determine actions to mitigate risk and assess the effectiveness of those actions.
The primary objective of optimization is to develop actions that reduce risk by improving the process.

Actions represent a commitment to take a specific, measureable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls.

If the team decides that no further actions are necessary, “No further action is needed” is written in the Remarks field to show the risk analysis was completed.

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PFMEA RISK ANALYSIS (STEP 5)							PFMEA OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks
Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038..	2	M			Selected press with position control sensor	Selected press with force monitoring	Process Engineer Mr. Paul Duncan	dd. mm. yyyy	open			8	3	2		L	

7th Step: Documentation

The purpose of the results documentation step is to summarize and communicate the results of the Failure Mode and Effects Analysis Activity.

Communication of results and conclusions of the analysis
Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken.

Communication of actions taken to reduce risks, including within the organization, and with customers and/or suppliers as appropriate.
Record of risk analysis and risk reduction to acceptable levels.

The layout of the document may be company specific.

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A. A statement of final status compared to original goals established in 1.5 Project Plan
    a. FMEA Intent – Purpose of this FMEA?
    b. FMEA Timing – FMEA due date?
    c. FMEA Team – List of participants?
    d. FMEA Task - Scope of this FMEA?
    e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.
C. A summary of how the functions were developed.
D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (i.e., Action Priority table).
E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.
F. A plan and commitment of timing for ongoing FMEA improvement actions.
    a. Commitment and timing to close open actions.
    b. Commitment to review and revise the PFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)
    c. Commitment to capture "things gone wrong" in foundation PFMEAs for the benefit of future analysis reuse, when applicable. (Refer to section 1.3.6 Foundation and Family FMEAs)

Special Characteristics

All characteristics that are important and need to be controlled. However, some characteristics (called Special Characteristics) require extra attention/efforts to minimize the risk of adverse consequences.

Special Characteristics are those product or process characteristics that affect vehicle or process safety, compliance with government regulations, or customer satisfaction. Special Characteristics are identified during the DFMEA/PFMEA process, and are include on the control plan.

Special Characteristics

This column is used to classify any special characteristics (e.g. Critical or Significant) for components, subsystems or systems that may require additional process controls

Identified in the DFMEA form with the appropriate character or symbol and addressed in the Recommended Actions .
e.g. ‘YC’ : Severity Rating 9 or 10
‘YS’ : Severity Rating 5 to 8

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Special Characteristics

Critical Characteristic (CC):

- Process characteristics with a severity ranking of 9 or 10, an occurrence ranking greater than 2, and which results from a ‘Final’ process step that determines product characteristic that reaches the end customer.

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Special Characteristics

Operator Safety Characteristic (OS):

- Process characteristics that impact operator safety with a with a severity ranking of 9 or 10, and, are not related to product characteristics that reach the end customer.

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Special Characteristics

Significant Characteristic (SC):

- Process characteristics with a severity ranking of 5 to 8, an occurrence ranking of 4 to 10, and which results from a ‘Final’ process step that determines product characteristic that reaches the end customer.

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Special Characteristics

High Impact Characteristic (HI):

- Process characteristics with a severity ranking of 5 to 8, an occurrence ranking of 4 to 10, and which 'do not' result from a 'Final' process step that determines product characteristic that reaches the end customer.

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When is FMEA updated?

FMEA analysis should not be considered a single event, but a long-term commitment. One key aspect of continual improvement is the retention of the knowledge from past learning which often is captured in FMEAs.

- Whenever a change is being considered to a product's design, application, environment, material or its manufacturing process.
- Geographical changes (relocation of facilities)
- Material supplier change
- Major Breakdown of equipment
- Major rejection
- Any customer complaint
- Increased warranty failures
- Periodic revision

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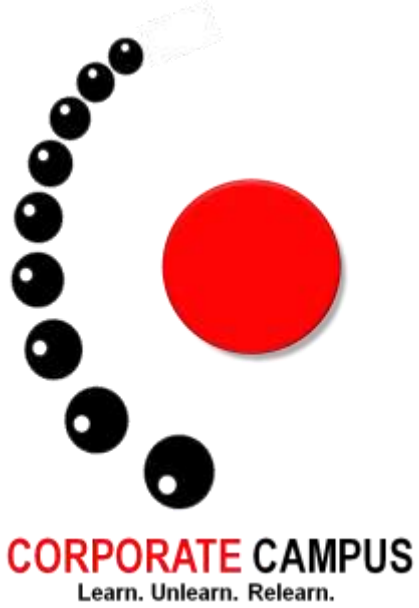
Inputs Required for Conducting FMEA

- DFMEA to understand functional requirements
- Potential critical and significant characteristics
- Customer communication for fitment requirement
- Cause wise history of in-house rejection/ rework data
- Documentation of the history of improvements
- Documentation of current controls
- Process Flow Diagram
- Quality Indices / Records
- AIAG Reference Manual
- CFT members



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