Business Guidebook

FMEA

Failure Mode Effect Analysis

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This book is a guidebook on the analysis of Failure Modes and their effects.

Registered with Nielsen Pubeasy where you can order this book or, alternatively, you can contact the author herself at marthabegleybooks@gmail.com.

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About the Authors

z\With over 30 years of experience in the fields of Quality Management, Business Training and Quality System Auditing, Martha has a degree in Physics & Maths as well as an MBA. She is a certified auditor as well as a qualified Business Trainer and Coach.

Originally from Co Limerick in Ireland, her path has included two years in Connemara, 2 years in Berlin before the wall came down, 7 years in Stuttgart and twelve years in Munich.

In 2008, she returned to Ireland and to Galway, where she has been running an Online Training business. During this time, she also became an accomplished author of educational books on social issues for children.

Her passion lies in helping others to learn and live a better life.

. Co-author

Consulting and lecturing in sustainable solutions, lecturing at private institutions and tutoring of private MSc students in Environmental engineering, environmental impacts and QHSE Management systems. Author of Quality booklets on 8D, FMEA, valuating audit, SPC and continuous improvement, and teaching problem solving technics

Based on the experience obtained through 25 years engage in the ISO standardization, 20 years as international lead auditor, 15 years as Lean Six Sigma Black Belt and work experience from 16 different countries around the world, I have seen, developed, implemented products and systems which came out of basically nothing. From China over the Middle East to USA there is one thing which is the same, “if people want to do it, they can do it”.

Brian have proved that if you controlling the constrains and your processes; you minimize waste, simply optimize your output under the circumstance you are working under it can happen.

Aims of this Book

To explain the basics of FMEAs and to highlight how you can expand this to great use within your workplace.

FMEA stands for ....

Failure Mode and Effect Analysis

Objectives of this Book

After this book you will:

- Understand the purpose of FMEAs
- Know the different types of FMEAs
- Understand the process of doing FMEAs
- Feel at ease carrying out an FMEA
- Understand that FMEA is a tool use in all industries

Definition of Risk

RISK:

THE POSSIBILITY OF SUFFERING SOME

FORM OF

LOSS OR DAMAGE

Oxford Dictionary of Business

Definition of FMEA

An FMEA is a systematic approach to assessing risks and managing mitigating actions.

Synopsis

Preventing a problem is easier and cheaper than clearing them up afterwards.

In carrying out a Failure Mode and Effect Analysis, a team of experts look at the steps in a process, the components of a system or the elements of a design for possible failures or defects; they rate how likely they will occur, how severe the issues will be to the customer and whether there is a possibility of detecting the issue; The resulting Risk Priority Rating will give the team clear priorities according to which they can list corrective or preventive actions with the aim of risk-proofing the work under analysis.

FMEA's Are About Reducing / Avoiding Risk and look at:

What can happen?

How severe are the consequences?

Can it occur again?

Can we detect it before it happens?

How can we prevent it?

Think about this:

What went wrong? What caused the incidents? What control system could be implemented to prevent this from happening again?

Or in FMEA language:

What can happen? How severe are the consequences? Can it occur again? Can we detect it before it happens? How can we prevent it?



Doc. 804 finance rev 04/23

Balance sheet bell shop

Shop identification				
Fund: 6778___ 804___ other:		Local depository:		
Date	Description	Received (debit)	Disbursed (Credit)	Balance (DR – CR)
01/04	Transferred			750,200.00
02/04	100 Décor Kringle		5,200	757,700.00
02/04	10 door bells for Great building	75.00		757,625.00
03/04	2 luxury ship bells, marina shop	80.00		757.545.00



The key in the FEMA is to think ahead; what can go wrong, identify the proactive, preventive approach.

Understanding What an FMEA is

History of FMEA

Originally developed in the 1960's by the aerospace industry and used during the Apollo missions.

In 1974, the Navy developed MIL-STD-1629 which defined how to use an FMEA.

In the late 1970's, the automotive industry integrated FMEA in their drive to reduce liability costs.

Thereafter, the automotive industry saw the advantages of using this tool to reduce risks due to poor quality.

What is an FMEA?

It is a method we use:

- to help identify and fully understand potential failure modes, their causes and the effects these failure modes on a process.
- help us assess the risk
- help us prioritize issues for corrective action
- help us identify and carry out correction actions to address the most serious concerns.

An FMEA is a technique for analysing how systems, processes or designs may fail and what the consequences of that failure might be.

An FMEA identifies all the ways in which it is possible for each component to fail and then follows through the consequence of each type of failure.

Objectives of an FMEA

The primary objective is to improve:

- the design of the system,
- the design of the subsystem or component,
- the design of the manufacturing process,
- the processes you have in all management systems you have in your organization.
- to prevent your most critical failures happening or to mitigate the effects if they do happen.

Targets of an FMEA

- Identify and prevent safety hazards
- Minimize loss of product performance
- Improve test and verification plans
- Improve process control plans
- Consider changes to the product design / processes
- Identify significant product / process characteristics
- Develop preventive maintenance plans
- Develop diagnostic techniques

Why perform an FMEA?

- To define corrective actions
- To identify causes and effects, before problems occur
- To reduce product development times and costs
- To prevent failures and defects
- To minimise risks in processes
- To improve quality and reliability
- To increase customer satisfaction.

Benefits of FMEAs

Used effectively, it will result in significant improvements in:

- Reliability.
- Safety.
- Quality.
- Delivery.
- Cost.

From an FMEA it is possible to develop

- preventive maintenance and contingency plans.
- systematic approaches.
- precise data for control plans.
- a source of knowledge.
- measures used to minimize risk in systems, processes and designs.

Application Types of FMEA

You apply FMEA with:

- New designs, new technology, new processes.
- Modifications to existing designs or processes.
- Use of an existing design or process in a new location, new environment, application or profile of usage (including regulatory requirements, customer specs, etc.)

Process (P-FMEA)

This analysis is at the manufacturing / assembly process level.

Applies to processes; it identifies potential failure in terms of the process purpose or goal.

Failure Mode example: scrapped part

Design (D-FMEA)

This analysis at the subsystem level or component level.

Applies to component design and could be called 'Component FMEA'. It considers potential component failures in terms of component functions.

Failure mode example - not understood by customer

System/Concept (S-FMEA)

This analysis at the highest level of an entire system, made up of various subsystems.

Applies to systems; it considers failures within the system and at the interface to other systems.

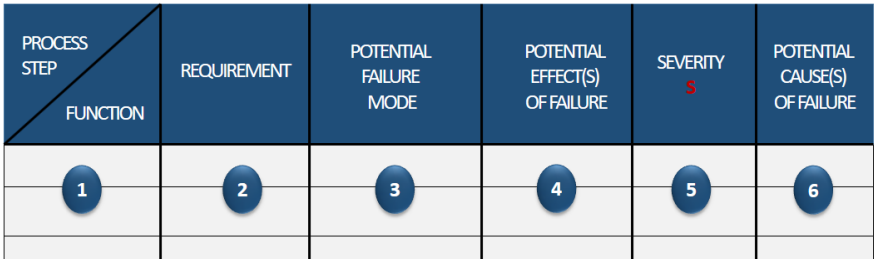
Failure Mode example: failure to meet regulatory standard. This can be all non-producing processes i.e., IT, HR, Finance, Education, etc.

The FMEA Process

Doing an FMEA has 3 major sections and this is reflected in the form you use.

Section 1:

Here is the listing of components, process steps or elements of a design, then the potential failure modes each could have, the possible causes of those failures, the probability that these causes will occur and the severity when they do.



First Section of an FMEA

1. What is the process step, system component or function under investigation?
2. What are the requirements? What aspect of the quality of the product could be affected?
3. What can go wrong in the process or work done?
4. What defects could occur if something goes wrong? What is the impact on the requirements of the customer?
5. How severe is the effect on the customer? What is the risk for the lifetime of the product?
6. What cause (s) could have lead to the failure?

Section Two:

In this part you document the evaluation done by the team of experts what the prevention method is or could be, how likely this particular problem will occur, how well it can be detected and the probablility of detecting the failure if it happens.

Using the ratings of the severity from the first part, the occurance and the detection, you calculate the Risk Priority Number, the RPN. This measures the risk and enables the team to prioritise action items.

You also document the action items that the team find necessary, who is reponsible for them and by when the action item should be completed.

Current Process			Detection D	RPN S x O x D	Actions Recommended	Responsibility & Target Date
Process Controls Prevention	Occurrence O	Process Controls Detection				
1	2	3	4	5	6	7

Second Section of an FMEA

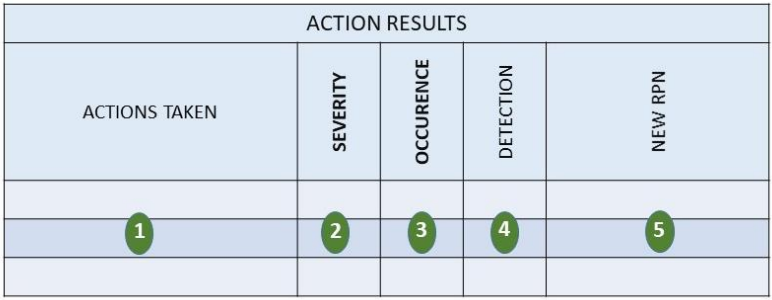
1. List the current process controls that are to be carried out according to the standard operating instructions or working instructions.
2. Determine how often the cause or the failure mode (the defect) occurs.
3. What are the methods of control that will detect these defects if they occur?
4. Here you rate the detectability according to a scale.

5. The evaluation of the Risk Priority Number is derived from multiplying the severity rating by the occurence rating and the detectability. The higher the RPN rating, the riskier a defect is. This will help the team to prioritise any action items to be taken.
6. What are the actions necessary to reduce the occurance, eliminate the cause or the failure mode or improve the detection.
7. Determine and document who is responsible and by when the action item should be carried out.

Section Three:

The re-evaluation of the failure modes after the corrective or precentive actions have been undertaken. The 3rd section is where the team lists the actions they decide to take to limit the risk of failure. This is then rated to measure the degree of improvement achieved.

This section is a source of knowledge for other systems processes and designs and can also be understood as legal documentation.



Third Section of an FMEA

1. Descriptions of the actions taken are listed
2. The Severity of the issue is now re-evaluated in the light of improvements made
3. The Occurrence is re-evaluated after actions have been taken
4. The Detectability is re-evaluated after the actions taken.
5. A new RPN is calculated as a result of the changes made. SxOxD

The 4 Key Words of FMEA

SEVERITY – S

Severity assesses how serious the effects would be should the potential risk occur.

Does it matter if this happens or are the effects of failure so small that we or the customer would hardly notice them?

Probability or OCCURRENCE – O

Occurrence is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analysed. Should we worry about this happening or is it so unlikely that we could use our resources on other things?

DETECTABILITY – D

Detection is a ranking number associated with the best control from the list of detection-type controls, based on the criteria from the detection scale.

If this happens, can we identify it or is it completely hidden until much later?

CRITICALITY OR RISK PRIORITY – RPN

The Risk Priority Number, RPN or "Criticality" quantifies the likelihood of occurrence **O**, likelihood of detection **D**, and severity of impact **S** of a problem.

It is calculated according to the formula

S x O x D

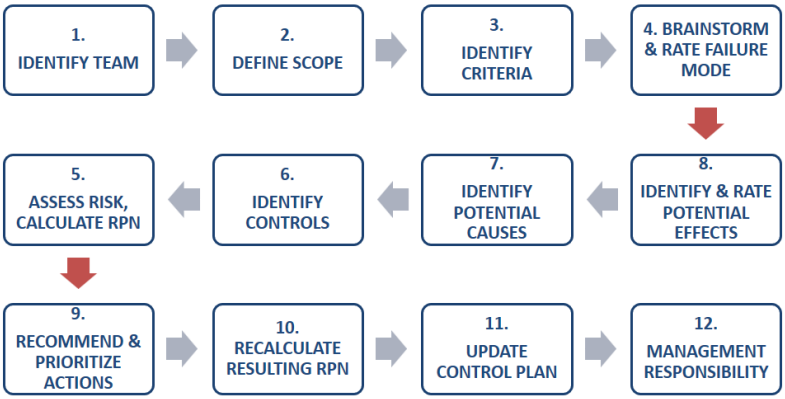
This also gives us a ranking of the risk of the Failure Mode and we know which items need the most immediate attention to prevent risk.

Your Complete FMEA Document

Item No	Process Step / Function	Require ment	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Process Controls Prevention	Occurrence	Process Controls Detection	Detection	RPN	Actions Recommended	Responsibility & Target date	Actions Taken	Severity	Occurrence	Detection	New RPN

Carrying Out FMEA's

A Process of 12-Steps



1. Identify Your Team

FMEA Output is only as good as the Input. A team approach benefits the FMEA development process and ensures input and collaboration from all affected function areas. Note that the "internal customers" of any process are critical stakeholders in an FMEA. They are the people who receive the results from the process.

The quality of the FMEA results will depend on the quality of the team put together to carry it out. So here are some guidelines:

- Ensure all affected areas are represented.
- Ensure all different levels and types of knowledge are also on the team.
- The best size for an FMEA team is 4 to 6 people, carefully selected, based on the contribution they can make to the specific FMEA.
- Your team should be cross functional or multi-disciplinary.
- A Subject Matter Expert must be included.
- The Team Leader should have the necessary facilitation expertise.
- At least one member must have knowledge of the FMEA Process.
- Consider having Suppliers or customers in the team.

- Consider team members from:
    - Manufacturing
    - Engineering
    - Materials/Purchasing
    - Research & Development
    - Maintenance
    - Quality
    - Technical Services
    - Customers
    - Suppliers
    - Finance

2. Defining the Scope

To achieve clarity and define **WHAT** is to be analysed by the team, the team defines the scope of the FMEA.
The scope establishes the boundaries and is essential because it sets limits on a given FMEA and makes it finite.
It defines what is to be included and excluded.
Usually, you will break the scope into separate subsystems, items, parts, assemblies or process steps and identify the function of each.
The scope is defined at the very start of the FMEA to assure consistent direction and focus.
How? Use methods such as Functional Flows, Block diagrams, Interface diagrams, Process flows, Interrelationships models, etc.

	Is Included	Is Not Included
Part		
Item		
Location		
Time		
Supplier		
Customer		

Setting boundaries to any problem description.

3. Identify Criteria

Give precise definitions of functions, requirements and specifications.
This assists in the determination of the potential failure mode for each attribute or aspect of the function.
Also, this clear definition has the aim of avoiding misunderstandings or addressing the issues incorrectly.

4. Brainstorm and Rate Failure Mode

Failure Mode is defined as the different ways or way a product or process could fail to meet design intent or process requirements. Determining what the failure modes are is where the expertise in the team comes into play. It will take experience and research. One great source of finding failure modes is looking at failures that have occurred in the past. Documents such as quality and reliability reports, test results and warranty reports are good places to start.
What is a Failure Mode?

'Failure Mode' = is the way in which something might fail.

For example:
A car's brakes might fail in several ways. Each way would be a different failure mode.

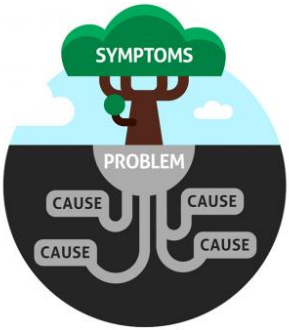
- Loss of brake fluid pressure
- Hydraulic pressure
- Air Pressure
- Brake line

- ABS modulator
- Power Brake Booster
- Water in the brake fluid

A plug's wiring may be faulty and there are different failure modes.

- Incorrectly wired
- Wiring is broken or frayed
- Internal short circuit
- Internal wire might be broken.

5. Identify Potential Causes



Aim of Determining the Causes.

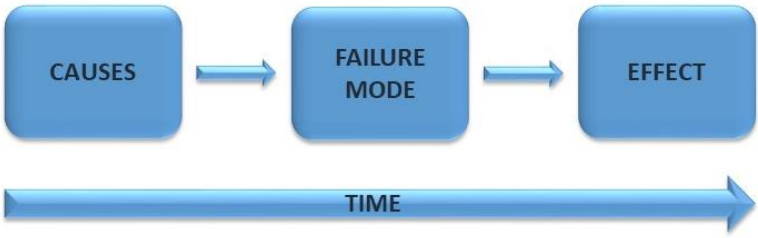
Identifying the cause and its resulting failure mode will enable the identification of appropriate controls and action plans.

Note: A separate potential cause analysis is performed for each cause if there are multiple causes.

Often failure is the result of poor design. Deficiencies in design will lead to manufacturing, assembly or field failures. To identify the causes, the team may need to experiment or carry out detailed analysis.

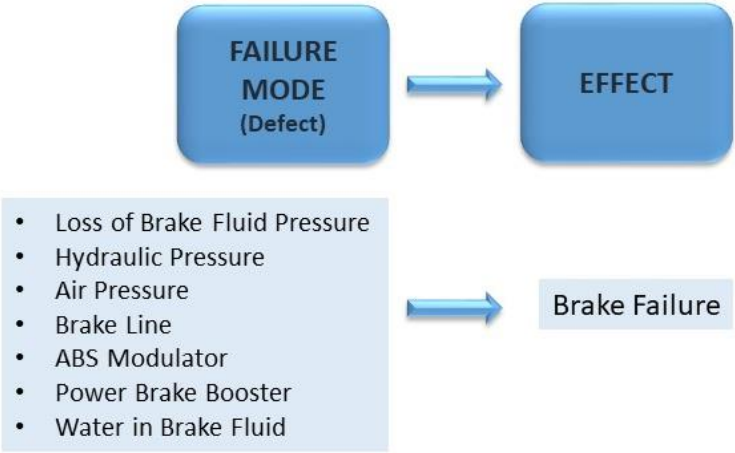
It is recommended to use “5 Whys” or “Cause & Effect tools” to identify the cause.

6. Linking Failure Mode: Cause and Effect



Linking Failure Mode, the causes and the effects.

A “Failure Mode” may have several causes. With Process FMEAs, we are talking about the “Effect” or severity of the failure mode on the customer of the process.



Note:

Your ranking scales should be standardized for all FMEA types so that all analyses can be comparable. A customised ranking scale needs to be developed before the first FMEA is conducted. The organisation decides what is relevant for their business.

Please note though that System failures can have different severity ratings than production failures.

Severity Rating **S**

Severity S is a ranking number associated with the most serious effect for a given failure mode. It should be measured on a scale of 1 to 10. Where "1" represents a failure so minor, a customer probably would not notice it. "10" would then represent the case where a customer (or employee) might be endangered.

It is determined without regard to the likelihood of occurrence or detection.

Note: The rating wordings are different for the purpose of the FMEA. e.g., working with finance is will be based on economic risks.

	Rating	Criteria: A Failure could.....
BAD	10	Injure a customer or employee
	9	Be illegal
	8	Render the product or service unfit for use
	7	Cause extreme customer dissatisfaction
	6	Result in partial malfunction
	5	Cause a loss of performance likely to result in a complaint
	4	Cause minor performance loss
	3	Cause a minor nuisance; can be overcome with no loss
	2	Be unnoticed; minor effect on performance
GOOD	1	Be unnoticed and not affect the performance

Example of a Scales to Rate Severity

Occurrence **O**

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

Process FMEAs looks at the likelihood of occurrence during production.

It is based on criteria from the corresponding Occurrence Rating Scale.

The frequency of occurrence is based on field performance or service history. It provides an indication of how significant the failure is.

	Rating	Time Period	Probability
BAD	10	More than once per day	> 30%
	9	Once ever 3 – 4 days	< 30%
	8	Once per week	< 5%
	7	Once per month	< 1%
	6	Once every 3 months	< 0.3%
	5	Once every 6 months	< 1 per 10,000
	4	Once per year	< 6 per 100,000
	3	Once every 1 – 3 years	< 6 per million
	2	Once every 3 – 6 years	< 3 per 10 million
GOOD	1	Once every 6 – 100 years	< 2 per billion

Example of a Scales to rate Occurence

Detection **D**

Detection is a ranking number associated with the best control from the list of detection type controls based on the criteria from the Detection Rating Scale.

It considers the likelihood of detection of the failure mode / according to defined criteria.

If this happens, can we identify it or is it completely hidden until much later?

Note: The rating wordings are different for the purpose of the FMEA. e.g., working with environment is can be based on Environmental & Social Impact Assessment (ESIA).

	Rating	Definition
BAD	10	Defect caused by failure is not detectable
	9	Occasional units are checked for defects
	8	Units are systematically sampled and inspected
	7	All units are manually inspected
	6	Manual inspection with mistake-proofing modifications
	5	Process is monitored via statistical process control (SPC) and manually inspected.
	4	SPC used, with an immediate reaction to out-of-control conditions
	3	SPC as above with 100% inspection surrounding out-of-control conditions
	2	All units are automatically inspected
GOOD	1	Defect is obvious and can be kept from affecting the customer.

Example of a Scales to Rate Detectability

7. Identify Controls

Controls are those activities that prevent or detect the cause of the failure or failure mode.

In developing controls, it is important to identify

- **what** is going wrong,
- **why** and
- **how** to prevent or detect it.

Controls that are focused on **prevention** will provide the greatest return.

These controls might include design changes, “mistake proofing”, better operating procedures, better user instructions, updated management responsibilities and should include target completion dates.

8. Assess Risk, Calculate RPN

How to calculate RPN - The Risk Priority Number

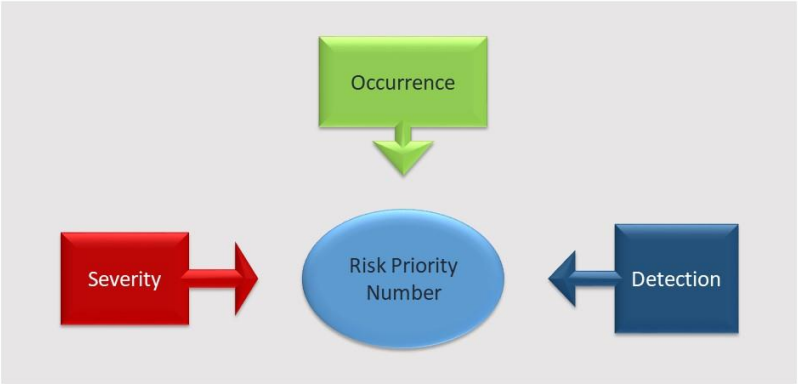
Risk Priority Number (RPN)

If the RPN is between 25 – 100, additional checks must be added to the inspection list or control plans. With updates of production documentation, the R&D and Quality departments are notified to

evaluate if changes are needed in the system or product documentation. If the RPN is below 25, no action is needed.

Note: The last FMEA version should always be available for audit by internal and 3th party auditors.

CRITICALITY OR RISK PRIORITY NUMBER – RPN



Risk Priority Number (RPN) = Severity X Occurrence X Detection

As the RPN, is a calculation of how severe the issue is, how likely it is to occur and how easily the problem can be detected, the higher the RPN, the higher the priority.

As Severity is the assessment of how the failure will impact the "customer", whether this may be the internal or external customer.

Should you have high severity rating, regardless of the Occurrence or Detection rates, you should give this a High Risk Priority. It is a high risk issue.

9. Recommend and Prioritise Actions

The real work starts when the FMEA Analysis is complete. An FMEA is a tool to identify and prioritize the risks associated with potential failures and effects of those failures. With that information, the team (or others in the organization) can work to mitigate the most serious risks. As improvements are made, the failures and effects addressed need to be reassessed to make sure the level of risk has been lowered to an acceptable level.

Develop an Action Plan to reduce risks with unacceptably high RPNs**.**

The aim of recommending actions is to reduce the overall risk and likelihood that the failure mode will occur. You reduce the severity, occurrence and detection.

Appropriate actions would include:

- Ensuring design requirements including reliability are achieved.
- Reviewing engineering drawings and specifications.
- Integrating tests into assembly or manufacturing processes.

- Reviewing related FMEAs, control plans and operations instructions.

Responsibility and timing to complete these actions must be recorded.

10. Recalculate Resulting RPN

Once actions are completed and results have been determined, you update the ratings for occurrence and deviation. Note the severity of the failure will not change; it will still be dangerous to cross when traffic lights are red even if you set up speed bumps, camera or other preventive / control actions.

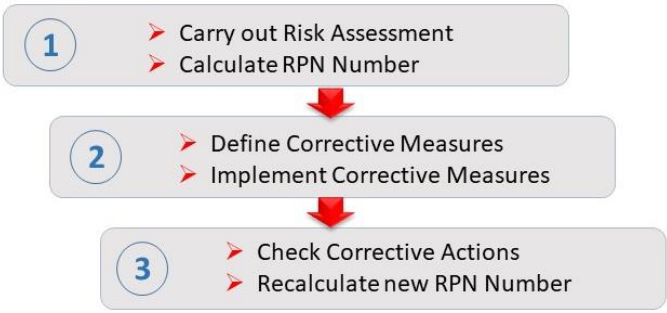


Diagram of the steps taken using the RPN number.

11. Update Control Plan

Make your FMEA a living document by adding to it and updating it whenever new information about the design or process develops. FMEAs should be updated when:

- Product or process improvements are made.

- New failure modes are identified.
- New data regarding effects are obtained.
- Root causes are determined.

The team should link the FMEAs to the corresponding Control Plans.

Control Plans

FMEAs can also serve as the basis of a Control Plan. A Control Plan provides specific instructions on how each component is to measured and monitored.

The intent of Control Plans is to create a structured approach for control of process and product characteristics while focusing on characteristics important to the customer.

A Control Plan provides a central focal point for documentation and communication of control methods.

Special attention is typically given to potential failures with high RPNs and those characteristics that are critical to the customer.

A Control Plan deals with the same information explored in a FMEA plus more.

The major additions to the FMEA needed to develop a Control Plan are:

- Identification of the control factors.
- The specifications and tolerances.
- The measurement system.

- Sample size.
- Sample frequency.
- The control method.
- The reaction plan.

CONTROL FACTOR	SPEC OR TOLERANCE	MEASURE-MENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQUENCY	CONTROL METHOD	REACTION PLAN

An Example of a Control Plan

12. Management Responsibility

Management owns the FMEA process and have the responsibility of selecting and approving resources and ensuring an effective risk management process.

Their responsibility is to provide direct support to the team through on-going reviews, elimination of roadblocks and incorporation of lessons learned.

Final Tips

Just doing an FMEA to tick off a checklist, only to file it away, never to be seen again, is a waste of time and adds no value.

Done well, FMEAs will

- Improve product functionality
- Improve product safety
- Reduce external failure costs
- Decrease manufacturing and service delivery problems
- On time FMEAs can save costs and reduce cycle times
- Provide a knowledge base to improve subsequent design efforts
- FMEAs can be used to identify hazardous conditions for workers
- FMEAs may identify operational problems that could disrupt a production process and result in scrap, downtime or unnecessary non-value-added costs.

Remember use the tool, as a tool.

A tool to improve your business.