ADVANCED TECHNIQUES FOR QUALITY MANAGEMENT:

THE FAILURE MODE AND EFFECTS ANALYSIS

(FMEA)

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1.1. Definition of Failure mode and effects analysis

FMEA is an analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development cycle. FMEA helps to:

- Discover the potential failures, their potential cause mechanisms and the risks designed into a product or process
- Develop actions that reduce the risk of failure
- Follow-up and evaluate the results of actions on the risks that were discovered

1.2. Origin

The FMEA discipline was developed in the United States Army. The Military Procedure MIL-P-1629, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis, is dated November 9, 1949. It was used as a reliability evaluation technique to determine the effect of system and equipment failures. Failures were classified according to their impact on mission success and personnel/equipment safety. It was later adopted in the Apollo space program of NASA to mitigate risk due to small sample sizes. The use of FMEA gained momentum during the 1960s, with the push to put a man on the moon and return him safely to earth. In the late 1970s the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair [1]. They also used it to improve production and design.

In 1971 NASA prepared a report for the U.S. Geological Survey recommending the use of FMEA in assessment of offshore petroleum exploration. Furthermore, in 1973 an U.S. Environmental Protection Agency report described the application of FMEA to wastewater treatment plants.

In the 1980s, the automotive industry began implementing FMEA by standardizing the structure and methods through the Automotive Industry Action Group. Although developed by the military, the FMEA method is now extensively used in a variety of industries including semiconductor processing, foodservice, plastics, software, aeronautics, automotive, and healthcare, etc.

1.3.   Design and structure

The FMEA is based on these three sections:

- Failures: identify how things can go wrong
- Effects of Failures: understand various impacts of failure. Failures with severe impact need to be resolved on priority.
- Causes of Failure: take action on these problems. Actions are most effective when they prevent causes of failure from occurring.

FMEA will become effective only if the correct relationship between Failure Modes, Effects, Causes, actions and other elements is understood. The FMEA structure needs to be understood in its correct perspective.
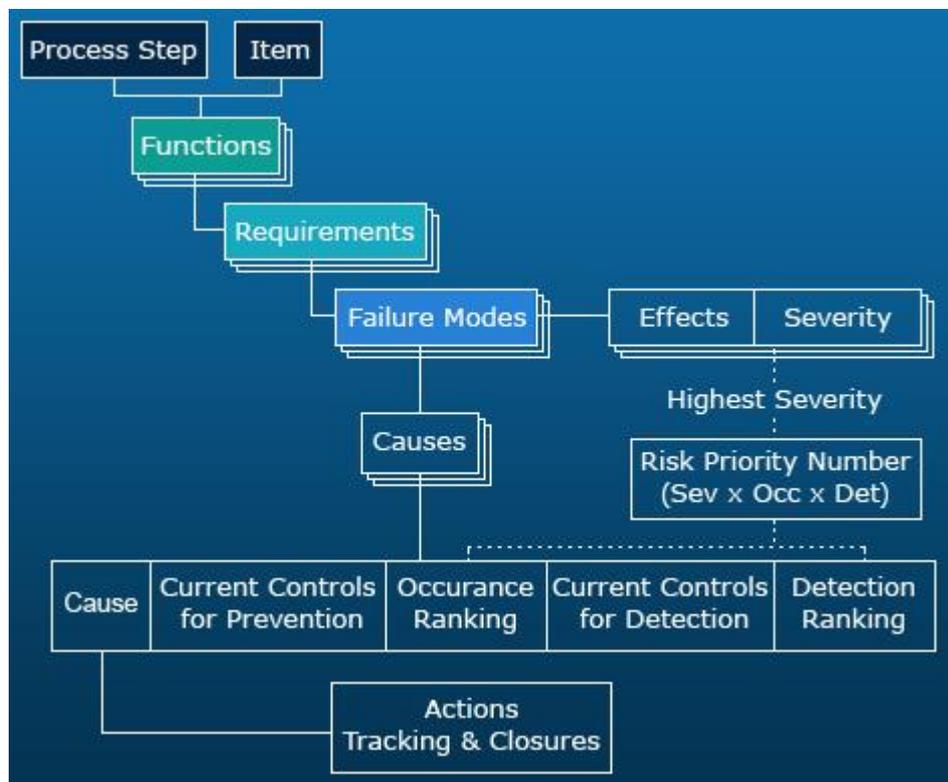
Figure 1.

Failure Modes, Effects, Causes, Actions are thus elements of FMEA. Let us now examine each element in the FMEA structure. There are two ways of looking at an element of FMEA.

The Designer's view: This describes how the designer would look at the FMEA element. For DFMEA the designer is the Product Designer, and for PFMEA the designer is the Process Designer. The Designer is the one responsible for a failure-free working of the system.

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Customer's View: This describes how the customer would look at the FMEA element. The term Customer refers to the user of the system. These can be end-users (ones who buy the products) or internal customers within the organization.

A very good way of correctly identifying and describing the element is to understand whether it is looked upon from the Customer's view or the Designer's view.

Examples of Customers and Designers:

1. For a DFMEA for a vehicle braking system the customer is the person who drives the car. The designer is the brake system designer.
2. For a PFMEA for an Ambulance operation in a hospital, the customer is the patient as well as the hospital staff availing of the ambulance service. The designer is the ambulance service provider.
3. For a PFMEA for a restaurant service, the customer is the one who visits the restaurant and would like to be served good quality food in a prompt manner. The designer is the restaurant manager who designs the logistics and work-flow of the ordering system and is responsible for the quick and accurate service of good food.

Having understood designers and customers, let us look at the elements of FMEA.

1. **Item or Process Step:** A DFMEA refers to an Item and a PFMEA to a Process Step as a starting point of the analysis. You perform the analysis on an Item or a Process Step.

   Examples of items are a Radiator in a truck, seat in an office or a probe in a patient heart-rate monitor. Items can refer to components, aggregates or entire products.

   Examples of Process Steps are receiving a phone call for Pizza delivery, Logging a customer complaint or Brazing Radiator tubes. An item should be described as visualized by the customer as well by the Designer.

2. **Function:** Function is the task the system should perform in order to satisfy the quality or performance expectations of the Customer.

   Examples of Functions are pumping water to the overhead tank for a water pump DFMEA, and delivery of metered fluids and drugs through an intravenous delivery in a patient safety PFMEA. The function should be described as viewed by the Customer. A function description is the answer to the question, 'What should the product or process do to satisfy the customer?'

Many times the analysts stop at the primary function description. Functions may go way beyond only the primary one. For example, a pump may have a primary function of delivering water to an overhead tank. However a noise-free and vibration-free operation is also an important function. The Automotive FMEA manual gives a listing of the following categories of functions that need to be considered:

- Primary Design intent
- Safety
- Government regulations
- Reliability (Life of the Function)
- Loading and Duty Cycles: Customer Product usage profiles
- Quiet Operations: Noise, Vibration and Harshness (NVH)
- Fluid Retention
- Ergonomics
- Appearance
- Packaging & Shipping
- Service
- Design for Assembly
- Design for Manufacturability

If functions from all the above categories are considered, the FMEA becomes a lot more comprehensive.

3. **Requirement:** A requirement is a technical specification or a numerical measure of the desired function. Being a technical measure, this needs to be described from the Designer's point of view.

Examples of requirements are:

- Flatness of 0.2 mm on a sealing surface for a Gate Valve DFMEA.
- Pizza Delivery within 30 minutes for a Pizza Chain Service PFMEA.
- Braking Distance of 6 meters when traveling at 40 Km/hr for a vehicle braking system DFMEA.

Identifying requirements help you in quantifying the expectations from a function. This leads to a more precise way of addressing failure.

4. **Failure Mode:** A Failure Mode is the negation of the requirement. It is a description of the way in which a requirement is not met with. A Failure Mode needs to be described from the Customer's as well as the Designer's point of view. It can be identified by both. Examples of failure Modes:

- An Ambulance reaching late for a Healthcare PFMEA.
- A seal not being able to sustain the peak fluid pressure required by the design in a valve DFMEA.
- A hotel check-out time exceeding the stipulated 3 minutes in a Service PFMEA.

5. **Effects and their respective Severities:** Once a failure mode is identified, the team takes it up for detailed analysis. A failure will lead to many effects. Some effects are more severe in consequences, other less.

   Each one of the effects identified with the failure mode must be noted along with its severity ranking. The severity ranking is a number on the 1- 9 scale that tells you about how serious that effect of failure is. Rank 1 is for the least severe failure and rank 9 is for the most severe one.

   Effects should always be written as perceived by the customer. One failure mode will lead to many effects. Thus potentially every effect identified can occur once the Failure occurs. This means that the most serious effect can also occur once the Failure occurs. The failure mode of vehicle braking distance excess can have the following two consequences:

   - Accident leading to fatality: Very serious
   - Driver discomfort: Less serious

   It must be understood that once the braking distance exceeds the stipulated value both, accident as well as driver discomfort will occur.

6. **Causes, Occurrence & Detection rankings and Current Controls:** Causes are mechanisms or events that lead to failure. These are identified by the analyst. The Cause descriptions should be written therefore as perceived by the designer. Along with the Cause narration, the following need to be identified:

   - Current controls of prevention of the cause from occurring.
   - Occurrence Ranking (scale 1- 9) that tells you how frequently a failure due to this cause can occur, in spite of the Current Control of Prevention being in place. Rank 9 is the most frequently.

- Current controls of detection that will detect that the cause or the Failure Mode has occurred.
- Detection ranking (scale 1- 9) that tells you how easy or difficult are to identify the cause or failure once it occurs, in spite of the Current Detection Control being in place. Rank 9 is the failure most difficult to detect.

7. **Risk Priority Number (RPN):** The Risk Priority Number for every Cause is the multiplication:

- Occurrence Ranking **X** Detection Ranking **X** Highest Severity Ranking associated with the Failure Mode

The RPN is one of the metrics that helps you prioritize causes with high risks on which actions need to be taken.

8. **Actions:** Actions need to be taken on causes. Several actions can be taken to address the potential risk associated with the cause. The actions, responsibility and schedule thus need to be logged for each cause. Results of actions completed also need to be logged with each cause.

Actions that have worked towards improvement provide an analyst with a model problem solving cycle in future risk analysis. Actions that have not yielded benefits also need to be logged to remind the future analysts of what has not worked in the past.

To conclude, can be seen from the discussion above, that a FMEA has a tree structure:

- An Item or Process Step can have several functions.
- A single function can have several requirements.
- A requirement can be negated by several failure modes.

Once a Failure Mode is identified, it can be seen that:

- Each Failure Mode can lead to several Effects. Each one of the effects can potentially happen once the Failure occurs.
- Each failure Mode can be caused by several Causes. Each one of the causes can potentially lead to the Failure. Either singly or multiply.
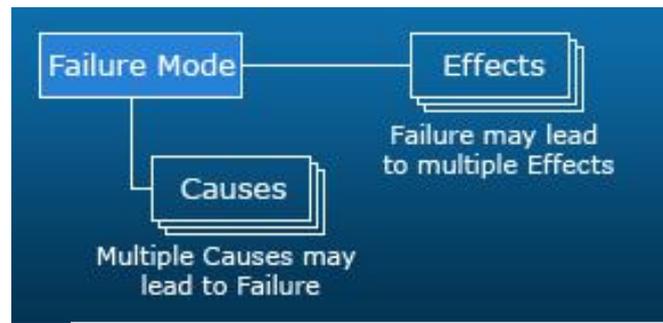
Figure 2. Relationship between failures, causes and effects

FMEA doesn't follow Cause-Effect relationships.

FMEA represented in a spreadsheet format can be misleading due to the Failure Modes, Causes and Effects written in a Row-Column format. It gives a notion that the Effect written in the first row is associated with the Cause written in the first row. Analysis resulting out of this confusion can lead one on the wrong path and may not prove to be an effective one.

For an effective implementation, FMEA has to be organized in a tree format. The spreadsheet-like format that you see is only a report document representation of the actual FMEA which is easy for printing.

2.1. Health care (PFMEA)

This point consists to design step by step an FMEA of prescribing and dispensing an analgesic, following the steps that I explained in the theoretical part of the FMEA's design and structure.

They have separated the main process to a few sub processes, what is very useful in PFMEA because each process has its different parts and steps and you can study them separately,because in the part of prescribing the analgesic, an expert who could design the FMEA would be a doctor, but in the part of dispensing, would be a pharmacist. It would be the same in factory process, because you would have different workers and experts in the different steps of the process.

The three subprocesses are the following:

- Prescribing
- Dispensing
- Monitoring

Once they had got the sub processes, they look for the functions that the sub processes have to accomplish. It's shown in the first column. Secondly, the table shows how they can fail in the objective to achieve the functions. Thirdly, the diagram shows the possible causes of that failure and in the next column the consequences of it.

After that, we can see the rankings of severity and probability of that failure and the multiplication of them, the RPN.

To conclude, in the last column we see the possible actions to prevent and detect each failure.

Figure 3.

Figure 4.

Function	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	RPN	Actions to Reduce Failure Mode
Prescribing							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen
	No order received	Unable to reach covering physician	Poor pain control	2	2	4	Proper physician coverage and communication channels

Function	Failure Modes	Causes	Effects	Severity	Probability	RPN	Actions to Reduce Failure Mode
Dispensing							
Send order to pharmacy	Order not received/processed in pharmacy	Unaware of order on unit; medication used from floor stock, so order not sent; order entered onto wrong form or screen; verbal orders not documented	Drug therapy omitted; Overdose; under-dose; ADR; allergic response if wrong drug used	3	3	9	Flagging system for new orders; policy to send all orders to pharmacy; physician review of new orders with unit staff; shift chart checks; standard verbal order receipt/ documentation process
	Delay in receiving/processing order	Order not flagged; inefficient process for sending orders to pharmacy; order not seen/misplaced after reaching pharmacy	Delay in dispensing drug; use of floor stock before pharmacy order screening; delay of drug therapy	3	4	12	As above; standard, efficient process for pharmacy order receipt; timely review and triaging of orders received in pharmacy
Enter order into computer	Order misunderstood	Illegible order; use of abbreviations, trailing zeroes, naked decimal doses; verbal orders; look-alike drug names; order copy unclear	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	4	12	CPOE; preprinted orders; prohibit dangerous abbreviations, dose expressions, non-urgent verbal orders; fax original order to pharmacy; seek clarification directly with prescriber
	Order entered incorrectly	Design of software; computer mnemonics; look-alike drugs; failure/absence of double check	Same as above	3	3	9	User-friendly order entry process; look-alike drug alerts; double check process for order entry
	Order entered into wrong patient profile/wrong encounter	Poor presentation of patient demographics (fax interference, light imprint, order copy unclear); look-alike names	Same as above	3	3	9	CPOE; vivid demographics on order forms/screens; high quality fax machines, routine maintenance; *view only* access to prior patient encounters; alerts for look-alike names
	Standard directions (concentration, mixing instructions) in computer wrong	Use of substitute drug due to shortage; overlook default directions in computer when changing processes	Overdose, under-dose; poor pain control	3	2	6	Checklist/testing to ensure revisions in electronic/print when changing processes/ drugs; quick access to information on substitute drugs

Function	Failure Modes	Causes	Effects	Severity	Probability	RPN	Actions to Reduce Failure Mode
Dispensing							
Produce label	Label inaccurate	Inaccurate order entry	Overdose, under-dose; wrong route; ADR	3	3	9	As above under "order entered into computer" section
	Label unclear	Ambiguous information; poor quality of printer	Same as above; delay in therapy; poor pain control	3	3	9	High quality laser printer; improve presentation of label information with nursing input
	Label not printed	Equipment malfunction; improper interface with pharmacy computer	Missed therapy; delay in therapy; poor pain control	2	1	2	Routine equipment maintenance and performance testing
	Label lost	Inefficient process for printing/retrieving labels; remote location of printer	Same as above	2	2	4	Reorganize workflow and placement of printers to improve efficiency
Prepare medication	Wrong drug	Look-alike products stored near each other; drug shortage; knowledge deficit	ADR; overdose; under-dose; allergic reaction; poor pain control	4	3	12	Separate look-alike products; PCA protocols; feedback mechanism on drug shortages with information on substitute drugs available; readily available mixing protocols; compounding log of ingredients with lot numbers; independent double check
	Wrong diluent	Same as above	ADR; toxicity from diluent	3	3	9	Same as above
	Wrong dilution/ concentration	Knowledge deficit; calculation error	Overdose; under-dose; poor pain control	4	3	12	PCA protocols; independent double check for all calculations
Check medication before distribution	Check not completed	Inadequate staffing patterns	Potential error not detected	3	3	9	Adequate staffing patterns
	Check inadequate	Same as above; environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors	Same as above	3	3	9	As above; environmental and workflow improvements; mental warm-ups before checking to increase task focus; use of verbal checks

Function	Failure Modes	Causes	Effects	Severity	Probability	RPN	Actions to Reduce Failure Mode
Dispensing							
Deliver medication to patient care unit	Delay in distribution	Inadequate staffing patterns/equipment used for delivery of drugs; inefficient drug delivery system; delivery equipment mechanical failure; shared delivery system	Delay in drug therapy; use of floor stock before pharmacy order screening	3	4	12	Establish dedicated delivery system under direct control of pharmacy; use dedicated staff/equipment for medication delivery; routine maintenance and update of equipment
	Delivered to wrong unit	Inadequate, untimely interface with admission/transfer information	Same as above; omitted doses; unneeded doses on wrong unit (possible administration to wrong patient)	3	3	9	Timely and seamless communication of admissions/transfers to pharmacy
Monitoring							
Monitor effects of medication	Insufficient monitoring of effects of PCA	Workload; knowledge deficit; monitoring parameters not ordered; ineffective communication between caregivers; cultural influences	Failure to recognize the consequences of an error before patient harm occurs; inability to evaluate pain management; poor pain control	3	3	9	Standard order sets with monitoring guidelines; standard scale to help assess pain; training on cultural influences; proper staffing patterns and safe workload; use flow sheet at bedside to document PCA and patient monitoring parameters

*Scoring Guidelines**

Key for Severity Rating:

Severity Score	Description
1	*Minor* patient outcome: No injury, nor increased length of stray, nor increased level of care
2	*Moderate* patient outcome: Increased length of stay or increased level of care for 1 to 2 patients
3	*Major* patient outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increase level of care for 3 or more patients
4	*Catastrophic* patient outcome: death or major permanent loss of function (sensory, motor, physiologic, intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong part of body, infant abduction or discharge to wrong family

Key for Probability Rating:

Probability Score	Description
1	*Remote*: Unlikely to occur (may happen sometime in 5 to 30 years)
2	*Uncommon*: Possible to occur (may happen sometime in 2 to 5 years)
3	*Occasional*: Probably will occur (may happen several times in 1 to 2 years)
4	*Frequent*: Likely to occur immediately or within a short period (may happen several times in one year)

Key for RPN:

Hazard score = Severity Score x Probability Score

Hazard Scoring Matrix:

Failure modes with scores that fall in the gray area (8 and greater) should be given highest priority

Probability	Severity of Effect			
	Catastrophic	*Major*	*Moderate*	*Minor*
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

*Scoring method adapted from: VA National Center for Patient Safety, Healthcare Failure Mode and Effect Analysis (HFMEA™)

2.2. Stedifoot design

This point consists to design step by step an FMEA of a stedifoot design, following the steps that I explained in the theoretical part of the FMEA's design and structure. First of all, I am going to explain what a stedifoot is. It is an innovative walking aid attachment for both indoor and outdoor use, providing additional contact with the ground, resulting in improved grip, stability and support for those with a variety of walking disabilities and designed specifically for people with moderate, but permanent walking disabilities, who need the use of, or assistance from, a stick, crutch or other device[2].

Secondly, it's time to study which are the functions that the stedifoot has to accomplish to satisfy the company and customer desires.

They have found six:

- Enhances stability to existing walking sticks that the ferrule cannot provide
- Easily attaches to / detaches from most walking sticks with ease
- Remains in correct position during use
- Aesthetics
- Recommendations to new customers
- Conforms to regulations

And to achieve these functions, some requirements have to be accomplished. They've separated it in function of the different parts of the stedifoot, which are the following:

- Body
    1. Remains inside a specified space envelope
    2. Allows handling without injury
    3. Provides sufficient flexibility when under load
    4. Resistant to the operating environment
- Sole
    5. Provides a durable non-slip foot print indoors and outdoors
    6. Does not transfer colour to surfaces
- Anti-slip Pad
    7. Provides a durable non-slip surface to retain the ferrule
    8. Retains colour throughout life time
- Stedigrip
    9. Secures the stedigrip to the walking stick shaft
    10. Clips and unclips with a specified range of shaft dimensions
    11. Allows handling without injury

Each function has its own requirements to be accomplished, but for the design is better to get all the requirements to achieve the functions and after separate it by the element parts of the stedifoot, to make clearer the FMEA diagram and its implementation.

Figure 5. Real stedifoot

The next table shows the complete FMEA of the stedifoot design. In the first column, there are the requirements that we have to achieve. In the second one, there are the potential failure modes, it means, how the requirements cannot be accomplished.

The third column show the possible consequences of don't accomplish the requirements. The fourth column shows the severity in a ranking 1-10 of each failure.
The next one describes the potential causes of each failure. The sixth column shows the actions that the company can do to prevent the fail.
In the seventh column we see the frequency of a failure due to this cause can occur in a ranking from 1 to 10.

The next column describes the possible actions to detect the fail and the ninth shows the possibility to detect the fail in a detection ranking from 1 to 10.
To conclude, the last one shows the RPN, which is the multiplication of the three previous rankings and shows the risk priority of each fail due to its cause.

Requirement	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	Preventive Actions	O	Detection actions	D	RPN
System element: Body									
Remains inside a specified space envelope	Body exceeds space envelope	Stedigrip becomes a tripping hazard	10	[Body dimensions] Foot print is too wide	CAD	3	Prototype testing	2	60
		Loss of customer confidence/ referrals	8						
		Infringement of regulations	10						
Allows handling without injury	Causes injury when handled (cut finger)	Loss of customer confidence / referrals	8	[Body dimensions] Surface finish not specified on drawing	Drawing specifies no sharp edges	1	Prototype testing	1	10
		Infringement of regulations	10						
Provdes sufficient flexibility when under load	Form impedes shock absorption / flexibility	Stedigrip does not increase stability sufficiently	9	[Body dimensions] Thickness impedes shock absorption/ flexibility	Design calculations; CAD; Stress Analysis	2	Destructive testing; Prototype testing	2	36
				[Metal] Metal specified is too rigid	Design calculations; Steel specified	3	Destructive testing; Prototype testing	2	54
	Deformation when exposed to loads	Loss of customer confidence / referrals	8	[Metal] Metal specified is too soft	Design calculations	3	Destructive testing	2	54
		Stedigrip does not increase stability sufficiently	9		Steel specified		Prototype testing		

Function	Failure mode	Effect	S	Cause	Recommended action	O	Detection	D	RPN
		Stedi-grip decreases walking stick stability	9						
Resistant to the operating environment	Corrosion of the body	Loss of customer confidence / referrals	8	[Body coating] Surface protection peels off	Anodised steel	1	Prototype testing	1	8
		Poor aesthetics	6						

System element: Sole

Function	Failure mode	Effect	S	Cause	Recommended action	O	Detection	D	RPN
Provides a durable non-slip foot print indoors and outdoors	Tread of the sole does not provide a firm grip on the ground	Loss of customer confidence / referrals	8	[Rubber] Incorrect rubber type	Industrial conveyor belt rubber specified	2	Destructive testing	3	60
		Stedi-grip does not increase stability sufficiently	9				Prototype testing		
		Infringement of regulations	10	[Adhesive] Insufficient adhesion properties throughout expected life time	Water proof silicon adhesive specified	4	Destructive testing	3	120
		Stedi-grip decreases walking stick stability	9				Prototype testing		
				[Rubber] Rubber is not resistant to specified temperature range	none	10	none	10	1000

Failure mode	Effect	Sev	Cause	Current controls	Occ	Detection	Det	RPN
			[Rubber dimensions] Sole is thinner than the body	Drawing specifies oversize by 2mm to prevent body from contacting objects CAD	1	Prototype testing	1	10
Excessive tread wear	Loss of customer confidence / referrals	8	[Rubber] Incorrect rubber type	Industrial conveyor belt rubber specified	2	Destructive testing	3	54
	Stedigrip does not increase stability sufficiently	9				Prototype testing		
	Stedigrip decreases walking stick stability	9	[Rubber dimensions] Insufficient thickness	Industrial conveyor belt rubber specified	2	Destructive testing	2	36
						Prototype testing		
Tread peels away from the body	Loss of customer confidence / referrals	8	[Adhesive] Insufficient adhesion properties throughout expected life time	Water proof silicon adhesive specified	4	Destructive testing	3	120
	Stedigrip becomes a tripping hazard	10				Prototype testing		
	Poor aesthetics	6						
	Stedigrip decreases walking stick stability	9						

Function	Failure mode	Effect	S	Cause	Current design	O	Controls	D	RPN
Does not transfer colour to surfaces	Black marks left on floor surfaces (e.g. lino)	Loss of customer confidence / referrals	8	[Rubber] Incorrect rubber type	Industrial conveyor belt rubber specified	2	Destructive testing / Prototype testing	3	48
System element: Anti-slip Pad									
Provides a durable non-slip surface to retain the ferrule	Does not retain the ferrule in correct place	Stedigrip decreases walking stick stability	9	[Pad Dimensions] insufficient size of pad specified	Over sized for aesthetics	1	Destructive testing	1	10
		Loss of customer confidence / referrals	8				Prototype testing		
		Infringement of regulations	10	[Rubber] Incorrect rubber type	ahdesive rubber pad used is similar to lino flooring	5	Prototype testing	6	300
Retains colour throughout life time	Colour loss / degradation of the anti-slip pad	Poor aesthetics	6	[Rubber] Rubber is not UV resistant	none	10	Prototype testing	7	630
		Stedigrip does not increase stability sufficiently	9						
System element: Stedigrip									
Secures the stedigrip to the walking stick shaft	Insufficient compression	Walking stick rotates during use	9	[Dimensions] incorrect form / type specified	CAD	8	Prototype testing	3	240
		Loss of customer confidence / referrals	8						

Function	Failure mode	Effect	S	Cause	Current controls (prevention)	O	Current controls (detection)	D	RPN
		Stedi-grip does not increase stability sufficiently	9	grip materials] Plastic specified is too soft	CAD	8	Destructive testing	3	240
		Infringement of regulations	10		Design calculations		Prototype testing		
	Stedifit works loose from the body	Loss of customer confidence / referrals	8	[Fasteners] Incorrect nut & bolt type specified (wrong thread / tightening torque)	Design calculations	4	Destructive testing	4	160
		Stedi-grip does not increase stability sufficiently	9				Prototype testing		
		Stedi-grip decreases walking stick stability	9	[Fasteners] Incorrect nut & bolt type specified (strength)	Design calculations	4	Destructive testing	2	80
		Infringement of regulations	10		M6 allen key bolt used		Prototype testing		
Clips and unclips with a specified range of shaft dimensions	Stedifit is difficult to remove from walking stick	Loss of customer confidence / referrals	8	grip materials] Plastic specified is too rigid	CAD	3	Destructive testing	3	72
		Cannot be used with large diameter walking sticks	7		Design calculations		Prototype testing		

Function	Failure Mode	Effect	S	Cause	Controls (Prevention)	O	Controls (Detection)	D	RPN
		Cannot be attached detached by uses with arthiritic fingers / poor grip strength	7	[Dimensions] incorrect form / type specified	CAD	8	Prototype testing	3	192
	Stedifit snaps off duing removal	Loss of customer confidence / referrals	8	grip materials] Plastic specified is too rigid	CAD	3	Destructive testing	3	72
		Cannot be used with large diameter walking sticks	7		Design calculations		Prototype testing		
				[Body dimensions] Thickness impedes shock absorption / flexibility	Design calculations	2	Destructive testing	2	32
					CAD / Stress Analysis		Prototype testing		
Allows handling without injury	Causes injury when handled (cut finger)	Loss of customer confidence / referrals	8	[Dimensions] Surface finish not specified on drawing (flashing)	Drawing specifies no sharp edges	1	Prototype testing	1	10
		Infringement of regulations	10						

3.1. Recycling WEEE industrial plant PFMEA

In this section, I am going to design a Process FMEA of a Recycling Waste of Electric and Electronic Equipment (WEEE) industrial plant. First of all, I explain what does the plant and how it works. Firstly, the plant receives the WEEE and they store it. Then, the waste goes to a disposal unit, which shred the trash. Secondly   , the workers separate the rubbish in 4 main groups: iron material, no iron material, plastic and glass. The breaking up could be done by a machine or manually.

Thirdly, they shred the waste again but in a smaller size than the first trituration, in a size of 30 mm. Finally, they compact the material per each group and they sell it to another plant which will melt the material to recycle it in a last step.

After the explanation of how works the plant, I'm going to enumerate the steps of the recycling process to make easy the search of the functions and the requirements of each step. They are the following:

- Transportation the waste to the plant
- Store the waste
- First trituration
- Breaking up per each material group
- Second trituration
- Compacting

Once I have the process steps, my goal is do the PFMEA table with the functions and requirements per each process, the failure modes, the causes of that fail, the four rankings of detection, occurrence, severity and RPN, and finally the possible actions to prevent and detect it.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Process Step: Transportation the waste to the plant									
The waste must be WEEE	The waste is not WEEE	We discover it before compacting. We lost time and energy. We don't detect it and we send it to the next plant. We lost prestige and reputation because we don't provide the correct materials.	The company which recollect the rubbish has mixed it with another type of rubbish	4	5	2	40	Have a work team with the mission of find and separate, once we have done the first trituration, the rubbish which is not WEEE. We have an agreement with the supplier company to bring it back.	Have a work team with the mission of find and separate, once we have done the first trituration, the rubbish which is not WEEE.
Transport of the waste within the estimated time.	The lorry which brings the waste has an accident.	Delay of the production.	Lorry too heavy to drive it with security. Driver was not in well conditions to drive. Fortuitous accident.	5	2	1	10	Contract a well-known company of transportation.	Make statistics about the accidents that our transporters have in the last few years.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Process Step: Store the waste									
The waste stored must be less than 30 Tn.	Waste stored is more than 30 Tn.	We don't have space to keep the waste which has brought the lorry. It goes to another recycling plant. We lose prestige.	Our logistic director didn't make his job and he hasn't anticipated the situation.	3	3	2	18	Have a good logistic schedule and department.	Pay the transport of the material by lorry to don't lose our reputation.
Process Step: First trituration									
The garbage disposal unit does its job well.	Breakdown in the trituration machine	Delay of the production. Spend money to repair it.	We haven't done the necessary technical inspections.	5	4	5	100	Do the required technical inspections to the machine.	Divert the rubbish to the other disposal unit. Have an expert worker who can repair it in the shortest time.
	Failure in the electric supply	Delay of the production. Plant could be stopped.	Failure in the electric public network or in our electric network.	7	2	7	98	Do the correct maintenance of the electric network. Have an electric generator.	Use the electric generator until we recover the electric supply. Be in contact with the local council to know which the problem is.
	The blades have been worn.	The big or strong waste has not cut.	We haven't done the necessary technical inspections.	3	6	2	36	Do the required inspections and the correct maintenance of them.	Have a few spare blades.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Process Step: Breaking up per each material group									
We separate the waste in the 4 material groups: iron material, no iron material, plastic and glass.	We mixed some of the 4 main groups between them.	We lost prestige and reputation because we don't provide the correct materials.	The separation machines don't work correctly. The workers haven't done their job correctly.	4	5	2	40	Have qualified workers who can detect it. Not only one worker checks the result of the breaking up.	We check it carefully and if the separation is not correct, we put it back and separate again.
	We don't detect other types of waste.	We lost prestige and reputation because we don't provide the correct materials.	The separation machines don't work correctly. The workers haven't done their job correctly.					Have qualified workers who can detect it. Not only one worker checks the result of the breaking up	We check it carefully and if the separation is not correct, we put it back and separate again.
The breaking up machine does its job well.	Breakdown in the separation machines.	The workers have to separate the materials by themselves. If they cannot do it, we have a production delay.	We haven't done the necessary technical inspections.	6	4	5	120	Do the required technical inspections to the machine.	Have an expert worker who can repair it in the shortest time, because is not very profitable to have two breaking up machines of the same material.
	Failure in the electric supply	The workers have to separate the materials by themselves. If they cannot do it, we have a production delay	Failure in the electric public network or in our electric network.	7	2	7	98	Do the correct maintenance of the electric network. Have an electric generator.	Use the electric generator until we recover the electric supply. Be in contact with the local council to know which the problem is.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Process Step: Second trituration									
The blades have to cut the material at 30 mm.	The machine is not well settled and don't provide the material with the correct size.	We have a material for compacting without the correct size that he following plant requires to us.	The blades come loose and they have to be fixed.	4	4	4	64	Do the required technical inspections to the machine.	Get samples of the material packs and measure them. Have an expert worker who can repair it in the shortest time.
The garbage disposal unit does its job well.	Breakdown in the trituration machine	Delay of the production. Spend money to repair it.	We haven't done the necessary technical inspections.	5	4	5	100	Do the required technical inspections to the machine.	Divert the rubbish to the other disposal unit. Have an expert worker who can repair it in the shortest time.
	Failure in the electric supply	Delay of the production. Plant could be stopped.	Failure in the electric public network or in our electric network.	7	2	7	98	Do the correct maintenance of the electric network. Have an electric generator.	Use the electric generator until we recover the electric supply.
	The blades have been worn.	The big or strong waste has not cut.	We haven't done the necessary technical inspections.	3	6	2	36	Do the required inspections and the correct maintenance of them.	Have a few spare blades.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Process Step: Compacting									
Compacted waste with the correct material and size and ready to be delivered.	More demand of material than offer of it we can produce.	The client could start to search another recycling plant.	Important construction project which needs a lot of material.	4	4	4	64	Updated market study to know the needs of the companies around us.	Get an agreement to deliver the material in a few instalments.
	Robbery of material already compacted.	Loss a lot of money and loss of reputation because we cannot deliver the orders.	No security in the plant or not enough.	7	2	5	70	Have the enough number of security guards and cameras.	Be in touch with the local police if something happens.
	Composition material in the waste packs is not correctly.	We lost prestige and reputation because we don't provide the correct materials.	We haven't done correctly the breaking up step.	4	5	2	40	Have qualified workers who can detect it. Not only one worker checks the result of the breaking up.	The next time we give for free a pack to the following plant to maintain our prestige and reputation.

3.2. Table lamp DFMEA

In this part, my objective is to design a DFMEA of the table lamp that we have in the Ingegneria Gestionale office in the University of Udine. This model is from the company PAN and it's the model TOM PFA980.

Firstly, I am going to enumerate the main functions that the lamp has to accomplish:
- Stability
- Flexibility
- Capacity to use bulbs until 20 V
- Allow a voltage of 230 V and a current of 50 Hz
- Weight less than 1.25 kgs
- Switch works correctly

Secondly, as I did in the Stedifoot DFMEA in section 2.2, I am going to separate the requirements to achieve these functions per each part of the lamp's body [3]. They are the next:

Base

- Base completely flat
- Volume of 1600cm3 +/- 200cm3
- Switch works correctly
- Weight of 850g +/- 100g

Stick

- Length of 20cm +/- 2cm
- Flexibility of 120º
- Wire works correctly

Head

- Flexibility of 220º from the stick
- Capacity to use bulbs until 20 V
- Allow a voltage of 230 V and a current of 50 Hz

Finally, the table of the next sheet shows the DFMEA diagram with the same pattern than the WEE plant PFMEA.

Function/ Requirement	Failure Mode	Effects of Failure	Causes	S	O	D	RPN	Preventive actions	Repairing/Detection actions
Part of the lamp: Base									
Base completely flat	Base is not flat	There is no stability	Error in the commands of the production machine	9	2	3	56	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.
Volume of 1600cm3 +/- 200	Volume bigger than required	The lamp take up too much space and is too heavy	Error in the commands of the production machine	4	2	3	24	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.
	Volume less than required	The base could not have enough space for the electronic systems or enough resistance.	Error in the commands of the production machine	3	2	3	18	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.
Switch works correctly	Switch doesn't work correctly	The lamp doesn't work; we have to find a spare. If we don't detect it, we get bad reputation.	Error in the commands of the production machine	3	3	5	45	Switch on and off every lamp that we have made. It's quickly and easy and we don't lose too much time.	Have a good and fluid system of repairing to be quick and don't lose clients.
Weight of 850g +/- 100	Base heavier than required	The lamp is too heavy and the consumers would choose another model.	Error in the commands of the production machine	4	2	3	24	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.

	Base less heavy than required	The base could not have enough space for the electronic systems or enough resistance.	Error in the commands of the production machine	3	2	3	18	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.
Part of the lamp: Stick									
Length of 20cm +/- 2cm	Stick is larger or shorter than the required length.	Lose of time changing the stick.	Error in the commands of the production machine	1	2	3	6	Analyse samples of the production to detect the mistakes.	Analyse samples of the production to detect the mistakes.
Flexibility of 120º	More flexibility than 120	The union between the stick and the base could be broken.	The pieces that subject the stick and permit it turn around are bad designed or built.	3	3	3	27	Check the union between the stick and the base once we have assembled them.	Analyse samples of the production to detect the mistakes.
	Less flexibility than 120	The lamp doesn't offer the ideal possibilities of illumination.	The pieces that subject the stick and permit it turn around are bad designed or built.	3	3	3	27	Check the union between the stick and the base once we have assembled them.	Analyse samples of the production to detect the mistakes.
Wire works correctly	Wire from the base to the head through the stick doesn't work	The lamp doesn't work	The wire works correctly but not the electronic system. The cable is not well connected or it has a short-circuit.	8	2	5	80	It's difficult to check the operation of the cable before we check the whole lamp. We should check it once we have all the components.	Check the lamp and if the lamp doesn't work, we should have a workshop where we can repair it before we will send it to the shop.

Part of the lamp: Head									
Flexibility of 220º from the stick	More flexibility than 220º	The union between the head and the stick could be broken.	The pieces that join the stick and the head which permit it turn around are bad designed or built.	4	3	3	36	Check the union between the stick and the head once we have assembled them.	Analyse samples of the production to detect the mistakes.
	Less flexibility than 220º	The lamp doesn't offer the ideal possibilities of illumination.	The pieces that join the stick and the head which permit it turn around are bad designed or built.	2	3	3	18	Check the union between the stick and the head once we have assembled them.	Analyse samples of the production to detect the mistakes.
Capacity to use bulbs until 20 V	The lamp has not capacity to use bulbs until 20V	The lamp doesn't offer the ideal possibilities of illumination.	The electronic circuit of the head has a problem. The bulb that we use to try is blown.	5	3	5	75	We should sell the lamps with a bulb of 20V inside, so it will be easy to check it.	Analyse each lamp that we produce. If doesn't work, send it to the workshop.
Allow a voltage of 230 V and a current of 50 Hz	The lamp doesn't allow the international type of electricity.	The lamp doesn't work.	The electronic circuit of the head or the base has a problem.	9	2	5	90	Check the functioning of each lamp that we produce.	If the lamp doesn't work, send to our workshop and hope that the problem is not in the electronic circuit.

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November, 1984).

ANNEX

[1]: Through the production run of the model, it became a focus of a major scandal when it was discovered that the car's design allowed its fuel tank to be easily damaged in the event of a rear end collision which often resulted in deadly fires and explosions.

Furthermore, it was alleged that Ford was aware of this design flaw, but they refused to pay the minimal expense of a redesign.

Instead, it was argued, Ford decided it would be cheaper to pay off possible lawsuits for resulting deaths. This discovery of Ford's apparent disregard for human lives in favour of profits led to major lawsuits, inconclusive criminal charges, and a costly recall of all affected Pintos.

[2]:

[3]:

HEAD

STICK

BASE