CHAPTER 8: FAILURE MODES AND EFFECTS ANALYSIS

Chapter outline

- Why do an FMEA?
- Creating an FMEA
- Using the results

8.1 WHY DO AN FMEA?

Periodically throughout the life of a project, it is important to assess the risks related to the product being designed. Some risks are project-focused and often have to do with schedules and budgets. These risks can be addressed through careful project planning and monitoring with tools such as Gantt and RAM charts and by creating contingency plans.

Other risks have to do with the product themselves. One useful tool for analyzing the product risks is called Failure Modes and Effects Analysis (FMEA).

The purpose of an FMEA is to identify every possible way in which the product could fail and to assess the potential effects of that failure on the product and any people interacting with it. Once all of the risks have been identified and understood, designers can determine how to change the product.

A table format is used to capture the information gathered during the FMEA. Different companies vary in their approach, but the basic function is the same. The table below shows a sample FMEA for a baby monitor. Baby monitors generally have two components: the baby unit and the parent unit. The baby unit is placed near the child to pick up sound, and possibly video, and transmit this information to the parent unit. The device allows a parent to be in a separate room and still know if the baby is awake, asleep, crying, etc.

Table 8.1: Baby monitor FMEA

Item	Failure Mode	Failure Cause	Failure Effect on Component	Failure Effect on System	Failure Detection Method	Severity*	Frequency**	Part Failure Score	Action
Plastic housing	break	mfg defect	component broken	internal elements exposed; may create sharp edges/small pieces	visual	3	1	3	inspect before packaging
	break	drops on floor	component broken	internal elements exposed; may create sharp edges/small pieces	visual	3	4	12	design plastic housing to withstand a drop test at 4 feet
	come open/ loose	missing screws	none	potential exposure to internal elements	visual	3	2	6	include some snap features in addition to screws
Power cord	cord housing cracks	stress at junction to unit	wires exposed, possibly broken	may prevent use of device	unit doesn't work	3	2	6	add strain relief
	becomes disconnected	child pulls on cord	none	child may play with cord: choking, strangulation	adult supervision	4	2	8	clear warnings in instruction and on base unit
Power button	non-functional	mfg defect	non-functional	system cannot be used	nothing happens when button is pressed	2	1	2	test unit before packaging
	pressed at wrong time	child presses button	none	caregivers cannot hear child	change in sound on parent unit	2	2	4	place button in inconspicuous location, have indicator on parent unit for no signal
Battery door	missing	door lost	none	batteries accessible by child	visual	3	2	6	consider hinged door or leash options
	missing	screws lost	none	batteries accessible by child	visual	3	2	6	consider slide or snap in design in addition to child-resistant screw
	alignment tabs break	stress concentration	can’t be assembled	batteries accessible by child	visual	3	3	9	more robust design needed
Microphone	non-functional	mfg defect	non-functional	caregivers cannot hear child	cannot hear child	3	1	3	test unit before packaging
	damaged	child sticks fingers in openings	non-functional	caregivers cannot hear child/ possible injuries to finger	cannot hear child/see injured finger	3	2	6	all openings should be smaller than child's finger

Item	Failure Mode	Failure Cause	Failure Effect on Component	Failure Effect on System	Failure Detection Method	Severity*	Frequency**	Part Failure Score	Action
LEDs	non-functional	mfg defect	non-functional	caregivers need to test unit to be sure it is working	LED not lit when power button pressed	1	2	2	test unit before packaging
	non-functional	burned out	non-functional	caregivers need to test unit to be sure it is working	LED not lit when power button pressed	1	1	1	select LED life to correspond with expected product life

*Severity Values (user/device)
1 = mild annoyance/visual but not functional defect
2 = really irritated/damaged part, still functional
3 = minor injury/part requires replacement
4 = serious injury/ device requires replacement

**Frequency Values
1 = 1 in 10,000 uses
2 = 1 in 1,000 uses
3 = 1 in 100 uses
4 = 1 in 10 uses

8.2 CREATING AN FMEA

To create the FMEA table, follow the steps listed below. (The title of the column in the table appears in parentheses after each step.)

1. List the parts of the product ("Item"). It is helpful to group these parts in their subassemblies if they exist.
2. List each way the part could fail ("Failure Mode"). Below are questions to consider to help you think of how a part might fail:
   - What are the potential manufacturing defects?
   - How might the product fail due to normal wear and tear?
   - What are the steps the user is supposed to take when using the product? What mistakes might a user make?
   - How would users with various limited abilities interact with the product? What problems might they encounter?
   - How might the product be misused or abused?

   For misuse/abuse modes, it is not necessary to consider every possible contingency. Instead, focus on likely misuses and abuses. A toddler playing with the power cord or randomly pressing buttons on the unit are both likely to occur, though clearly these are not intended uses for the product.
3. Explain the cause of each failure ("Failure Cause").
4. Describe the effect of the failure on the part itself ("Failure Effect on Component"). Does the part still function? Is it weakened? Will it need to be replaced?

5. Describe how that failure impacts the overall product ("Failure Effect on System"). What happens if the user continues to use the product?
6. Describe how that failure is detected ("Failure Detection Method"). Some failures might be immediately obvious, while others might not be noticed until they in turn cause greater damage.
7. Provide a severity rating for the failure ("Severity"). It is important to determine the relative values of the ratings in advance to maintain consistency. The severity ratings are at the bottom of the table.
8. Provide a frequency rating ("Failure"). How frequently do you expect this type of failure to occur? Your instructors can help you determine this rating. The frequency ratings are at the bottom of the table.
9. Determine the "Part Failure Score." Multiply the severity rating by the frequency rating.
10. Describe the action to be taken in response to this potential failure ("Action").

8.3 USING THE RESULTS

Based on the results of your analysis, determine what actions should be taken to improve your product. Low scoring items, such as something that is not likely to occur and does not cause much damage, may be able to be ignored, in which case the action is "none." However, you may still choose to address it if there is an easy fix.

Higher-scoring items must be addressed. Depending on the failure, you may be able to design it out. You do not need to describe the particular design changes at the time of the FMEA; that can be a follow-up activity. In the action column, you can list "design change." By understanding all of the failures that require design changes, you may be able to combine them to address as many failures as possible with the minimal number of changes.

Some items cannot be designed out, such as preventing a user from putting the baby monitor in a bathtub. You may have to resort to clear instructions in the manual and/or the use of labels. This should be a last resort due to limited effectiveness.

In the example of the baby monitor, only the components that were designed by the EDC team were included in the FMEA. If this monitor were being manufactured in industry, the entire assembly would be considered, down to the individual screws used to hold it together.