Failure Mode Effect Analysis (F.M.E.A.) Overview

1. Identify the steps and the things done within that step

Options include the following…

a. …have the owner/person who does the work tell you what is done. This method is best used when in conjunction with another method but it is a good start to get a general picture. The strength of this method is that it is simple to do and does not require sophisticated training. The weakness is that this method can be deceiving because if used exclusively participants may often skip steps when talking about a job that they do often.

b. …read the work instruction or standard operating procedure. Read and study training material given to new associates. This could include any video or pictorial training material. A strength of this method is that the reviewer can take all of the time required to review the material to make sure the process is understood. What has been written is valuable particularly if it is current and correct. Do not over look memos written or posted to give more details about what is to be done. The weakness of this method is that the documents are often out of date, not intentionally but minor changes may not have been recorded.

c. …watch a video tape of the process to see and identify all steps. Because you are watching the steps on tape you can stop to study or go back to study in detail. This like reading or watching the S.O.P. training video is strength. A weakness is that you may need to video tape the process multiple times to get the complete picture. All processes have some variation and watching one "take" may not show all of the variation

d. …make pictorial diagram analysis like a value stream map or process map. This is an advantage over the previous methods because you will have a written record of the steps in the process for future reference. Many times written procedures do not have diagrams included. Do not do this without first physically seeing the process or the diagram will not be worth much. If you do not involve a significant proportion of the people who do the steps you may not include all of them or have them in the correct order.

e. …do a "job task analysis" to break down the job into steps. This is related to the TWI (training within industry) initiative. Here the job is broken down into simple steps making it easy to identify what is being done. The underlying strength of this method is that it not only includes the actual steps but also supporting things like skill level required, critical or non critical jobs and may even include why a step is preformed. Be prepared for this to take time and that may be considered a weakness if the F.M.E.A. is to be done in a hurry.

f. …develop computer simulations of the process and the steps. This is best if the process has never been done before and you are concerned with physical harm. Contemporary computer simulations can be very realistic and even interactive. If designed properly you can change parameters and redo the simulation to see different results. The best models may be difficult to program requiring a specialist to be employed.

2. Identify the possible failure in that step or action taken

FAILURE GUIDE WORDS TO HELP LEAD TO COMPLETE IDENTIFICATION[1]

DO: The intended activity, input material, out put results, machine activity, measurement methods, environment control and support activities i.e. training or procedures.

DON'T: Something from the above list doesn't work as designed, or the design doesn't achieve the desired end; something stops when it should not or someone doesn't do what they should. Equipment or supplies are not available to treat a patient. A pipe is not big enough to allow desired flow. Procedures are not followed.

MORE THAN: Something does more than the intended, higher pressure, more machine movement than designed or further action by operator is not necessary and can lead to failure. Tools have worn more than acceptable amount. More output over loading a down stream process. Waiting more time than is required for paperwork to be completed.

LESS THAN: Something does less than intended or coming short of the target. For example, an activity makes less than required, training is less than adequate, an environment is less than desirable or a device fails sooner than anticipated. Medication is only partially given to a patient. Waiting lees time than is required. A part of training is left out. Giving customers less than complete bid is another example.

AS WELL AS: Something additional that is not expected, a side product to a chemical reaction, a machine moves differently than designed or measure something unneeded. Patient is given medication to treat a symptom but has a side reaction. Something is moved but also warps the conveying device. After completion of the task and asset is changed and becomes unavailable for use.

DO PART OF: Something only works part of the way it is designed, missing a raw material so a part is not complete, a procedure is partially followed or only part of the training was completed. This could also be leaking (part of is not held). Orders for a patient are partially written down so only part of the treatment is completed. An interruption in continuity of flow or part of the paperwork is completed.

DO IN REVERSE: Something works in reverse, a pump moves material backward, temperature goes up instead of down at a point in a process or the operator turns a dial in the wrong direction than instructed. A component is installed in reverse. Patient instructions followed in an incorrect sequence. Accounting documents closed before all entries are made.

DO OTHER THAN: Something works to do a totally different thing instead of what it is suppose to do, instead of stacking pallets the machine throws then to the wall. Instead of curing in an oven the part cures in the environment. Instead of reading and following procedures to make a product the operators change the procedure and make a different product. A prescription is incorrectly read delivering medication other than required. There is a secondary defect from the process.

[1] These "guide words" have been used for hazardous operations analysis for years I am just applying them to failure mode effect analysis.

3. Determine the root cause of the failure (may do after step #8)

Options include the following…

a. …ask why 5 times. This is a classic old and simple process and can be easily used with tolls like brainstorming and nominal group technique. The weakness of this option is that it can be deceiving. Make sure you ask meaningful whys and not follow blind leads. This method tends to led to one root cause. Do not assume that the one root cause is the only root cause. For complex problems no one may know why something happens.

b. …draw some type of systematic diagram (like fault tree analysis or cause & effect diagram) can be useful if you are not sure where to go and you feel that there may be more than one cause for failure. The weakness of this option is that is may rely on heuristic assessments that at times can be incorrect. Systemic diagrams are of little use if the team or person compiling the diagram has little direct knowledge of the process.

c. …use relational analysis for example Kepner-Tregoe method, affinity diagrams or "Helpful/Unhelpful diagram". This is best used when at one time the process was performing as desired and you need a non-data based approach. Remember that this may be based on perceptions and not data which may have a greater degree of inaccuracies. This latter weakness is particularly true if you are doing a root cause analysis for a new process in the design stage.

d. …use semi-statistical based tools, like Pareto diagram or histograms tools are good to use when data is qualitative or attribute. Although relative easy to use the data may be force fit into the only tool with which the user feels comfortable. Another concern is the source of data. Make sure that the data is accurate and from a repeatable and reproducible source. If not the data may be a helpful starting point but accurate date should be obtained to insure accurate analysis.

e. …make a matrix to compare possible causes and effects, like using a quality functional development (QFD) tool or the various L, T, C, Y matrices that are available. This is best used when there is excessive amount of information, for example 60 possible causes and 50 possible outcomes. This option could be used like the relational analysis in that the interactions may be perceptions. If data is used then it would be like the semi-statistical option where the source of the data must be accurate. Because matrix analysis usually involves looking at multiple interactions this option cold be more time consuming than desired and the temptation would be to "cut corners" which would negate the effectiveness of the tool.

f. …apply statistical based tools like regression analysis, analysis of variation (ANOVA) or designed experiments (D.O.E.) are good when you have quantitative data. Although this is the most technical of all of the options there are computer programs that can help with the complicated mathematics. A common weakness is that using the wrong tool can lead to the wrong conclusions. This can easily happen if the user is untrained

Failure Mode Effect Analysis (F.M.E.A.) Overview

4. Assign a probability of occurrence ranking

1 Remote possibility of happening. Where similar actions have happened or parts have been used where failures have been non-existent DPMO[2] < 3.4

2-3 Low failure rate, failures are rare 6 > DPMO > 3.4

4-6 Moderate failure rate, general failure has occurred occasionally in the past but not in major proportions 300 > DPMO >6

7-9 Frequent failure rate, enough to be remembered 300,000 > DPMO > 300

10 High probability of failure; it is expected DPMO > 300,000

5. Assign a severity ranking

1 Failure of such a minor nature as to be undetectable by the customer.

2-3 Failure of a minor nature but detectable by the customer, in subsystem

4-5 Failure with prior warning causes customer dissatisfaction and discomfort or is in a minor system

6-7 Failure without prior warning, which causes *customer dissatisfaction and discomfort* or is annoying, in major system

8 Failure with prior warning, which causes major customer dissatisfaction and discomfort or inoperable systems

9 Failure without prior warning, which causes *major customer dissatisfaction* and discomfort or inoperable systems, or of a regulatory requirement

10 Failure without prior warning, which involves potential safety problems

6. Assign a detection possibility ranking

1-2 Almost certainly will be detected upon normal inspection, "functionally obvious"; a chair with no back (automatic 100% inspection);
Gage R&R negligible compared to tolerance.

3-4 Good probability of detection with normal inspection, "obvious characteristic"; door handle is too high. Gage R&R is less than 20% of tolerance

5-6 Possibility of detection with normal inspection, easy to see but not obvious; wrong color paint is easy to see but you must have a standard.
30% > Gage R&R > 20% of tolerance

7-8 Probability of not detect with normal inspection, subtle change; dimensional change of under 10% and not measured. 50% > Gage R&R > 30% of tolerance

9 Probably will not detect with extra inspection, inspectors do not know what to look for on the item or in the process. 100% > Gage R&R > 50% of tolerance

10 No possibility of detection with any amount of inspection.
Gage R&R > 100% of tolerance

7. Calculate a Risk Priority Number (R.P.N.); multiply the Occurrence ranking times the Severity Ranking times the Detection Ranking

8. Determine action to be taken on all failures above the acceptable R.P.N.
Options include the following…

a. …protection of the person, equipment, process or product to minimize or eliminate the severity risks. An often used plan for this is to install safety

[2] DPMO is Defects Per Million Opportunity

equipment or personal protective equipment. This could also require physical modification of the process

b. …notification alarms indicating when failure has occurred to minimize or eliminate the detection risk. This could be audio, visual or any other sensory (like a physical shock) mechanism. An often used plan is to use statistical quality control charts that measure the key property and give indication of out of control conditions.

c. …elimination of the root causes to minimize or eliminate the occurrence risk.

9. Take action using a plan on each failure above an acceptable R.P.N.

Good plans include not only what is done but who does each part, when each is done, where is part is done and how it is to be done. Options include the following…

a. …change or write operation procedures, which may include video taping as an effective way to communicate when you want people to change actions. For this to be effective you need to be very detailed and a good communicator. The challenge here is to make sure everything is being followed and the instructions are easy to understand. The weaker the communication the poorer the performance.

b. …complete a corrective action request (CAR) form. Many organizations have a form that prompts the user to identify the root cause, the action taken, date and any action taken to prevent recurrence. This fits well into an ISO based system. Often best when there is one cause to the problem and correction can be done at one point in time which does not need to be repeated. If there are multiple steps then the corrective action will need to be clear regarding what is to be done when and when the feedback is required.

c. …develop a checklist or check-sheet for the person doing the correction to complete and return indicating action has been taken. The checklist approach can be applied to things as diverse as go-no go gauges and shadow boards, anything where the person using it has an immediate assessment of what to do. This is particularly good for actions that need to be done regularly and the same every time. Always have some review of the checklist or sheet to make sure all deviations are addressed. The weakness of this method is that it is not as effective for implementing changes that require detailed instructions or evaluations to be made during the process. This assumes that the person completing the process has sufficient skills to accomplish the task.

d. …execute a Plan, Do, Check, Act (P.D.C.A.) cycle. This is a classic approach and covers both actions taken and follow-up to measure success. The plan and do steps do not dictate the specific actions to take just that planning and actions are required. This may be too general for some people who prefer clear instruction regarding how to fix a problem (i.e. write a procedure). It may be too complicated if the fix is simple and there are limited resources. It may be too time consuming if the "check" step is significantly after the "do" step.

e. …fill out an A3 report indicating root cause, current state, desired state and actions taken to achieve the desired state. This may be more technical than the P.D.C.A. cycle but it is also more prescriptive. The challenge is to fit a concise statement or picture for each step into a limited space, which also is the main attraction of this method. A common language or symbology is required. Most A3

reports have follow-up actions Make sure that some objective evaluation is done if this is used for follow-up too.

f. …follow a network plan like PERT (Program Evaluation and Review Technique), critical path method (CPM) or AON (Activity on Node) diagrams to completion. This is definitely a tool to be used when much planning is required; particularly if multiple independent people or organizations need to coordinate efforts. This is also a good option when the actions require multiple steps be taken over time and must be coordinated or the results will not be achieved. Because of the need to do planning it is the most time consuming of all of the implementation tools both is planning and monitoring.

10. Complete action and see what is the result

Options include the following…

a. …get a report of completion and acceptance. The most straight forward and simplest to do, which allows for reviewer to evaluate feedback anytime. This is particularly effective if the approach to corrections was to use a C.A.R. form, checklist or check-sheet. It could be time consuming if a complete feedback report is required

b. …audit the process to see if what was planed to get done was done. This can be done for any process using process audits or output audits. A tried and true method as long as the auditor is objective and knows for what to look. It is particularly useful to see if a procedure has been written. The weakness is that people can do the right thing while watched but what happens everyday may be different.

c. …identify critical parts of the process or output. Do a generic assessment feedback comparing conditions or results before the change to after the change, (hotter, less complaints, faster reports). Attribute listing or morphological analyses are two examples of the tools used for this option. It is best used when you have technical data or non-technical data sourced without the need for specific technical training. Since results may not be data driven the results may be misleading in that minor changes may not be seen or over emphasized.

d. …do survey of customers to see if the changes have been implemented. This is best used when the corrective action effects the finished product; not very effective for internal only, unless you consider internal customers. For internal customers posting the A3 and asking for feedback may be affective but also may not get any feedback if the culture does not support risk free feedback. If the customer is slow in responding feedback may come too late to correct any problems it uncovers.

e. …use a control chart to monitor completion and holding of that gain. This method is best used when the root cause and corrective action can be described in statistical terms and D.O.E. has been done. Those who maintain the chart may require training on how to develop of maintain a control chart.

f. …implement mistake proofing (Poka-Yoke) in the process so that it can not fail. It is often the surest way to insure change has taken place and will remain in place. What needs to be remembered is there are times that mistake proofing is too complicated to adequately implement simply and may require expert help.

11. **Reassess the occurrence, severity and detection rankings**

Failure Mode Effect Analysis (F.M.E.A.) Overview

WHAT OTHERS HAVE OFFERED RECENTLY

"A reverse FMEA (RFMEA) and service FMEA (SFMEA) can be initiated as soon as the manufacturing team has production intent parts in the production phase. This will help address human factors and process risks by reducing defect opportunities."
Stansbury, Wayne; Beenken, Kristine, "One good Idea: Failure is an Option"*, Quality Progress*, June 2011

The use of a cause and effect matrix helps to prioritize but does not help in determining if all possible failures have been identified.
Rodriguez-Perez, Jose and Pene-Rodriguez Manuel E., Fail-safe FMEA, "Combination of quality tools keeps risk in check"*, Quality Progress*, January 2012

John Casey on page #7 says that "the problem is, the possibilities for failure are infinite… this is a hugely wasteful, frustrating and limiting in terms of the return on th hours invested."
#5 of his book says that "there is no way to reduce the impact to the customer. The severity factor is relatively fixed, and engineers can do little to change it."
Casey, John J. Strategic error Proofing: Achieving Success Every Time with Smarter FMEAs, Psychology Press, Mortimer House, 37-41 Mortimer Street, London, W1T 3JH, 2008