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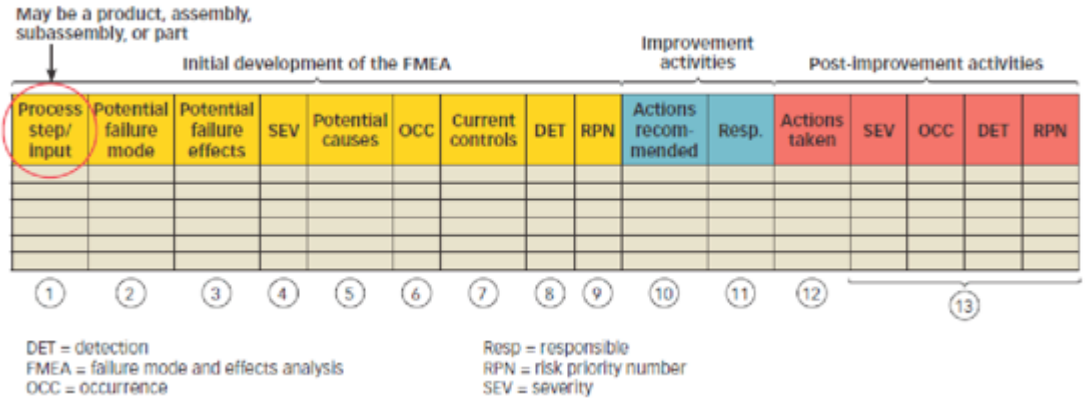
FAILURE MODE & EFFECTS ANALYSIS (FMEA)

Quality Glossary Definition: FMEA (/quality-resources/quality-glossary/f)

Also called: potential failure modes and effects analysis; failure modes, effects and criticality analysis (FMECA).



Begun in the 1940s by the U.S. military, failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. It is a common process analysis tool (/quality-resources/process-analysis-tools).

- **"Failure modes"** means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual.

- **“Effects analysis”** refers to studying the consequences of those failures.

Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected. The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones.

Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is used during design to prevent failures. Later it’s used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

WHEN TO USE FMEA

- When a process, product or service is being designed or redesigned, after quality function deployment (QFD) (/quality-resources/qfd-quality-function-deployment).
- When an existing process, product or service is being applied in a new way.
- Before developing control plans for a new or modified process.
- When improvement goals are planned for an existing process, product or service.
- When analyzing failures of an existing process, product or service.
- Periodically throughout the life of the process, product or service

FMEA PROCEDURE

Note: This is a general procedure. Specific details may vary with standards of your organization or industry. Before undertaking an FMEA process, learn more about standards and specific methods in your organization and industry through other references and training.

1. Assemble a cross-functional team of people with diverse knowledge about the process, product or service and customer needs. Functions often included are: design, manufacturing, quality, testing, reliability, maintenance, purchasing (and suppliers), sales, marketing (and customers) and customer service.
2. Identify the scope of the FMEA. Is it for concept, system, design, process or service? What are the boundaries? How detailed should we be? Use flowcharts (/quality-resources/flowchart) to identify the scope and to make sure every team member understands it in detail.
3. Fill in the identifying information at the top of your FMEA form. (Figure 1 shows a typical format.) The remaining steps ask for information that will go into the columns of the form.

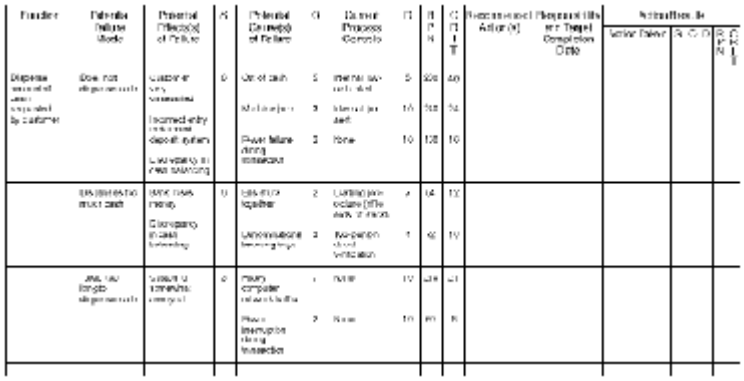


Figure 1: FMEA Example

4. Identify the functions of your scope. Ask, “What is the purpose of this system, design, process or service? What do our customers expect it to do?” Name it with a verb followed by a noun. Usually one will break the scope into separate subsystems, items, parts, assemblies or process steps and identify the function of each.
5. For each function, identify all the ways failure could happen. These are potential failure modes. If necessary, go back and rewrite the function with more detail to be sure the failure modes show a loss of that function.
6. For each failure mode, identify all the consequences on the system, related systems, process, related processes, product, service, customer or regulations. These are potential effects of failure. Ask, “What does the customer experience because of this failure? What happens when this failure occurs?”
7. Determine how serious each effect is. This is the severity rating, or S. Severity is usually rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic. If a failure mode has more than one effect, write on the FMEA table only the highest severity rating for that failure mode.
8. For each failure mode, determine all the potential root causes. Use tools classified as cause analysis tool (/quality-resources/root-cause-analysis/tools), as well as the best knowledge and experience of the team. List all possible causes for each failure mode on the FMEA form.
9. For each cause, determine the occurrence rating, or O. This rating estimates the probability of failure occurring for that reason during the lifetime of your scope. Occurrence is usually rated on a scale from 1 to 10, where 1 is extremely unlikely and 10 is inevitable. On the FMEA table, list the occurrence rating for each cause.
10. For each cause, identify current process controls. These are tests, procedures or mechanisms that you now have in place to keep failures from reaching the customer. These controls might prevent the cause from happening, reduce the likelihood that it will happen or detect failure *after* the cause has already happened but *before* the customer is affected.
11. For each control, determine the detection rating, or D. This rating estimates how well the controls can detect either the cause or its failure mode after they have happened but before the customer is affected. Detection is usually rated on a scale from 1 to 10, where 1 means the control is absolutely certain to detect the problem and 10 means the control is certain not to detect the problem (or no control exists). On the FMEA table, list the detection rating for each cause.
12. *Optional for most industries:* Ask, "Is this failure mode associated with a critical characteristic?" (Critical characteristics are measurements or indicators that reflect safety or compliance with government

regulations and need special controls.) If so, a column labeled “Classification” receives a Y or N to show whether special controls are needed. Usually, critical characteristics have a severity of 9 or 10 and occurrence and detection ratings above 3.

13. Calculate the risk priority number, or RPN, which equals S × O × D. Also calculate Criticality by multiplying severity by occurrence, S × O. These numbers provide guidance for ranking potential failures in the order they should be addressed.
14. Identify recommended actions. These actions may be design or process changes to lower severity or occurrence. They may be additional controls to improve detection. Also note who is responsible for the actions and target completion dates.
15. As actions are completed, note results and the date on the FMEA form. Also, note new S, O or D ratings and new RPNs.

FMEA EXAMPLE

A bank performed a process FMEA on their ATM system. Figure 1 shows part of it: the function “dispense cash” and a few of the failure modes for that function. The optional “Classification” column was not used. Only the headings are shown for the rightmost (action) columns.

Notice that RPN and criticality prioritize causes differently. According to the RPN, “machine jams” and “heavy computer network traffic” are the first and second highest risks.

One high value for severity or occurrence times a detection rating of 10 generates a high RPN. Criticality does not include the detection rating, so it rates highest the only cause with medium to high values for both severity and occurrence: “out of cash.” The team should use their experience and judgment to determine appropriate priorities for action.

Adapted from *The Quality Toolbox, Second Edition* (http://asq.org/quality-press/display-item?item=H1224), ASQ Quality Press.