

Failure Mode and Effect Analysis (FMEA)

Description and Definition:

While Root Cause analyses are usually involved in the investigation of sentinel and near miss events, failure mode and effect analyses are used before an event occurs. FMEA is a systematic method of identifying and preventing process problems before they occur. FMEAs are focused on preventing defects, enhancing safety, and increasing customer satisfaction.

Ways in which a process can fail are called failure modes. Each failure mode has a potential effect, and some effects are more likely to occur than others. In addition, each potential effect has a relative risk associated with it. The FMEA process is a way to identify the failures, effects, and risks within a process and then eliminate or reduce them.

The relative risk of a failure and its effects is determined by three factors (See Tables, 1, 2, 3):

- Severity – the consequence of the failure should it occur.
- Occurrence – the probability or frequency of the failure occurring.
- Detection – the probability of the failure being detected before the impact of the effect is realized.

Procedure:

A failure mode and effect analysis includes the following steps.

1. Select a high-risk process.
2. Define the process/procedure as designed and actual implementation of the process/procedure by completion of a flowchart.
3. Identify discrepancies between designed and actual processes
 - . For each process step in the flowchart determine:
 - Failure Mode: What can go wrong with this step? (All possible failure modes.)
 - Cause of Failure: Why would this failure mode occur? (Reason for variation.)
 - Effects of Failure: What could happen if this failure mode occurred? (Effect on patient.)
5. Assess the Risk Priority Number (RPN) for each failure mode
Using data and knowledge of the process, each potential failure mode and effect is rated in each of these three factors on a scale ranging from 1 to 10, low to high. By multiplying the rating for the three factors (severity x occurrence x detection), a risk priority number or RPN is determined for each potential failure mode and effect.

Occurrence (Occ):

What is the likelihood that this failure would occur?
(0 = never, 10 = could easily happen)

Severity (SV):

If this failure occurred, how severe is the effect?
(0 = no harm, 10 = possible death)

Delectability (DT):

If this failure occurs, how likely is it that it would go through undetected?
(0 = certain detection, 10 = it would never be noticed)

6. Identify why variation occurred leading to the effect (root cause analysis).
7. Redesign the process to minimize the failure mode (Solutions for Improvement).
8. Test and implement redesigned processes.
9. Measure effectiveness of the process change and implement strategies to maintain over time i.e. if effective the Risk Priority Number should be reduced.

Table 1. Severity Rating Scale*

| Rating | Description | Definition |
|----------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10 | Extremely dangerous | Failure could cause death of a patient (visitor, employee, staff member, business partner) and/or total system breakdown, without any prior warning. |
| 9 8 | Very dangerous | Failure could cause major or permanent injury and/or serious system disruption with interruption in service, with prior warning. |
| 7 | Dangerous | Failure causes minor to moderate injury with a high degree of customer dissatisfaction and/or major system problems requiring major repairs or significant re-work. |
| 6 5 | Moderate danger | Failure causes minor injury with some customer dissatisfaction and/or major system problems. |
| 4 3 | Low to Moderate danger | Failure causes very minor or no injury but annoys customers and/or results in minor system problems that can be overcome with minor modifications to system or process. |
| 2 | Slight danger | Failure causes no injury and customer is unaware of problem however the potential for minor injury exists; little or no effect on system. |
| 1 | No danger | Failure causes no injury and has no impact on system. |

- **Should be modified to fit the specific product or process.**
- **Patient – Could also be patient and family, employee**

FMEA Rating Scales (McDermott, R. Mikulak, R., Beuregard, M. (1996). *The Basics of FMEA*. Portland, OR: Productivity Inc.

Adapted from: *The Basics of FMEA*, Productivity, Inc. Copyright 1996 Resource Engineering, Inc.; Goodman, S. I., *Design for Manufacturability at Midwest Industries*, Harvard Business School, *February 2, 1996 Lecture*; Wheelwright, S. C.; Clark, K. B., *Revolutionizing Product Development: Quantum Leaps in Speed, Efficiency, and Quality*, The Free Press; *Potential Failure Modes and Effects Analysis*, Automotive Industry Action Group, 1993.

Table 2. Occurrence Rating Scale*

| Rating | Description | Definition |
|----------------|--------------------------------------------------|----------------------------------------------------------------------------------|
| 10 | Certain probability of occurrence | Failure occurs at least once a day; or, failure occurs almost every time. |
| 9 | Failure is almost inevitable | Failure occurs predictably; or, failure occurs every 3 or 4 days. |
| 8 7 | Very high probability of occurrence | Failure occurs frequently; or failure occurs about once per week. |
| 6 5 | Moderately high probability of occurrence | Failure occurs about once per month. |
| 4 3 | Moderate probability of occurrence | Failure occurs occasionally; or, failure once every 3 months. |
| 2 | Low probability of occurrence | Failure occurs rarely; or, failure occurs about once per year. |
| 1 | Remote probability of occurrence | Failure almost never occurs; no one remembers last failure. |

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Table 3. Detection Rating Scale*

| Rating | Description | Definition |
|----------------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| 10 | No chance of detection | There is no known mechanism for detecting the failure. |
| 9 8 | Very Remote/Unreliable | The failure can be detected only with thorough inspection and this is not feasible or cannot be readily done. |
| 7 6 | Remote | The error can be detected with manual inspection but no process is in place so that detection left to chance. |
| 5 | Moderate chance of detection | There is a process for double-checks or inspection but it not automated and/or is applied only to a sample and/or relies on vigilance. |
| 4 3 | High | There is 100% inspection or review of the process but it is not automated. |
| 2 | Very High | There is 100% inspection of the process and it is automated. |
| 1 | Almost certain | There are automatic “shut-offs” or constraints that prevent failure. |

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