FAILURE MODE AND EFFECT ANALYSIS - METHODOLOGY

Failure mode and effect analysis (FMEA) is a systematic way of assuring that every conceivable potential failure of a design/process has been considered with the objective of minimising the probability of failure.

1 INTRODUCTION

Definition

Failure mode and effect analysis (FMEA) is a systematic way of assuring that every conceivable potential failure of a design/process has been considered. The object of using FMEA is to minimise the probability of failure. More precisely, IEEE Std 352-1975: Guide for General Principles of Reliability Analysis of Nuclear Power Generating Station Protection Systems, one of the definitive works on FMEA, defines the purposes of an FMEA as being to:

- assist in selecting design alternatives with high reliability and high safety potential during early design phase
- ensure that all conceivable failure modes and their effects on operational success of the system have been considered
- list potential failures and identify the magnitude of their effects
- develop early criteria for test planning and the design of the test and check-out systems
- provide a basis for quantitative reliability and availability analyses
- provide historical documentation for future reference to aid in analysis of field failures and consideration of design changes
- provide input data for trade off studies
- provide basis for establishing corrective action priorities
- assist in the objective evaluation of design requirements related to redundancy, failure detection systems, fail-safe characteristics and automatic and manual override

.(IEEE Std 352-1975)

Timing

The FMEA should be an integral part of the early design evaluation and should be periodically updated to reflect changes in design or application.
An updated FMEA should be a major consideration in design reviews, inspections, or other major system review points in the program.
During the design phase, an FMEA should be performed or updated at the following program stages:

- Concept formulation or selection
- Preliminary design or layout
- Completion of detail part design
- Design improvement programs

The FMEA may also be performed with limited design information in which case the basic questions to be answered by an FMEA are as follows:

- How can each part conceivably fail?
- What mechanisms might produce these modes of failure?

- What could the effects be if these failures did occur?
- Is the failure in the safe or unsafe direction?
- How is the failure detected?
- What inherent provisions are provided in the design to compensate for the failure?

Preparation
Before undertaking an FMEA it is essential to undertake certain preparatory steps; the scope will depend on the complexity of the system/article being studied.

- Definition of the system/article to be analyzed and its mission.
- Description of the operation of the system.
- Identification of failure categories.
- Description of the environmental conditions.

Method
Data is entered into a table (see below) under the following headings:

- Part; each system component or part being analyzed is named (or referenced by other appropriate designator such as circuit reference
- Function; brief note as to function of part.
- Potential failure mode; this should cover ever way in which the part could fail and should include random and degradation failures. Ask 'How could it fail?' not 'Will it fail?'
- Potential effect of failure; brief description of the consequences of failure.
- Severity; see the section on severity below.
- Potential causes of failure; what caused this failure mode.
- Occurrence; see section on occurrence below for guidance.
- How will the potential failure be detected? Some failures are obvious to the person using the subject of the FMEA, but if this is not the case, the means by which the failures can be detected should be listed.
- Detection; see section on detection below for guidance.
- Risk Priority Number (RPN) = Severity * Occurrence * Detection
- Actions: Detail recommended actions

.Example failure mode and effect analysis table for ball-point pen

Part	Function	Potential Failure Mode	Potential effects of failure	SEVERITY	Potential causes of failure	OCCURRENCE	How will the potential failure be detected?	DETECTION	RPN	Actions
Outer tube	Provides grip for writer	Hole gets blocked	Vacuum on ink supply stops flow	7	Debris ingress into hole	3	Check clearance of hole	5	105	Make hole larger
Ink	Provide writing medium	Incorrect viscosity	High flow	4	Too much solvent	2	QC on ink supply	4	32	Introduce more rigid QC
Ink	Provide writing medium	Incorrect viscosity	Low flow	4	Too little solvent	2	QC on ink supply	3	24	No action required

2 OCCURRENCE

The Occurrence is the assessment of the probability that the specific cause of the Failure mode will occur. It is part subjective, but the wording should describe the probability. Failure history is helpful in increasing the truth of the probability. Questions of the following type are helpful:

- What statistical data is available from previous or similar process designs?
- Is the process a repeat of a previous design, or have there been some changes?
- Is the process design completely new?
- Has the environment in which the process is to operate changeable?
- Have mathematical or engineering studies been used to predict failure

The Ranking and suggested criteria are:

Notional probability of failure	Evaluated Failure Rates	Cpk	Rank
Remote: Failure is unlikely. No Failures ever associated with almost identical processes	1 in 1,500,000	>1.67	1
Very Low: Only Isolated Failures associated with almost identical processes	1 in 150,000	1.50	2
Low: Isolated Failures associated with similar processes	1 in 15,000	1.33	3
Moderate: Generally associated with processes similar to previous processes Failures, but not in 'major' proportions	1 in 2,000	1.17	4
	1 in 400	1.00	5
	1 in 80	0.83	6
High: Generally associated with processes similar to previous processes that have often failed	1 in 20	0.67	7
	1 in 8	0.51	8
Very High: Failure is almost inevitable	1 in 3	0.33	9
	1 in 2	<0.33	10

3 SEVERITY

Severity is an assessment of the seriousness of the Effect and refers directly to the potential failure mode being studied.
The Customer in process FMEA is both the internal and where appropriate, external Customer.
The severity ranking is also an estimate of how difficult it will be for the subsequent operations to be carried out to its specification in Performance, Cost, and Time

The Ranking and suggested criteria are:

Effect	Criteria	Severity of Effect	Rank
None		No Effect	1
Very Minor	Minor disruption to production line	A portion of the product may have to be reworked. Defect not noticed by average customers; cosmetic defects.	2
Minor	Minor disruption to production line.	A portion of the product may have to be reworked. Defect noticed by average customers; cosmetic defects.	3
Very Low	Minor disruption to production line.	The product may have to be sorted and reworked. Defect noticed by average customers; cosmetic defects.	4
Low	Some disruption to product line.	100% of product may have to be reworked. Customer has some dissatisfaction. Item is fit for purpose but may have reduced levels of performance.	5
Moderate	Some disruption to product line.	A portion of the product may have to be scrapped. Customer has some dissatisfaction. Item is fit for purpose but may have reduced levels of performance.	6
High	Some disruption to product line.	Product may have to be sorted and a portion scrapped. Customer dissatisfied. Item is useable but at reduced levels of performance.	7
Very High	Major disruption to production line.	100% of product may have to be scrapped. Loss of primary function. Item unusable. Customer very dissatisfied.	8
Hazard with warning	May endanger machine or operator.	Failure occurs with warning. The failure mode affects safe operation and involves noncompliance with regulations	9
Hazard without warning	May endanger machine or operator	Failure occurs without warning. The failure mode affects safe operation and involves noncompliance with regulations	10

4 DETECTION

This is an assessment of the probability that the proposed Process Controls will detect a potential cause of Failure or a Process weakness.
Assume the Failure has occurred and then assess the ability of the Controls to prevent shipment of the part with that defect.
Low Occurrence does not mean Low Detection - the Control should detect the Low Occurrence.
Statistical sampling is an acceptable Control.
Improving Product and/or Process design is the best strategy for reducing the Detection ranking - Improving means of Detection still requires improved designs with its subsequent improvement of the basic design.
Higher rankings should question the method of the Control.

The Ranking and suggested criteria are:

Detection	The likelihood the Controls will detect a Defect	Rank
Almost Certain	Current controls are almost certain to detect the Failure Mode. Reliable detection controls are known with similar processes.	1
Very High	Very High likelihood the current controls will detect the Failure Mode.	2
High	High likelihood that the current controls will detect the Failure Mode.	3
Moderately High	Moderately high likelihood that the current controls will detect the Failure Mode.	4
Moderate	Moderate likelihood that the current controls will detect the Failure Mode.	5
Low	Low likelihood that the current controls will detect the Failure Mode	6
Very Low	Very Low likelihood that the current controls will detect the Failure Mode	7
Remote	Remote likelihood that the current controls will detect the Failure Mode	8
Very Remote	Very Remote likelihood that the current controls will detect the Failure Mode	9
Almost Impossible	No known controls available to detect the Failure Mode.	10