

Failure Analysis of FMEA

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SUMMARY & CONCLUSIONS

Failure Mode and Effect Analysis (FMEA) is a proactive tool developed to identify, evaluate and prevent product and/or process failures. The conventional FMEA procedure suffers from inadequate definitions for some steps, high uncertainty, and even decision making failures throughout the procedure.

The effectiveness of an FMEA can be significantly improved by identifying potential pitfalls, and raising awareness of potential problems. Applying a strategy that utilizes controls and rules can efficiently mitigate, or even avoid, all known possible harmful effects.

This article proposes proven solutions that support the entire end-to-end FMEA sequence of activities (from the point of initiation of the analysis - Failure Modes identification – up to its culmination – evaluation of the effectiveness of the procedure), and the remedies proposed, in reducing risk.

1. INTRODUCTION

FMEA is a classic tool of what we refer to as "Disciplined Engineering" - a systematic framework considered as a tool to reduce potential errors, prevent common mistakes, and improve the consistency of the engineering work.

The purpose of FMEA is to examine possible failure modes and determine the impact of these failures on the product (Design FMEA - DFMEA) and process (Process FMEA - PFMEA):

- DFMEA is used to analyze product designs before they are released to production. It focuses on potential failure modes associated with the functions of the product and caused by design deficiencies;
- PFMEA is used to analyze the new or existing processes. It focuses on the potential failure modes associated with both the process safety /effectiveness/efficiency, and problems with the functions of a product caused by the problems in the process.

Traditionally, in order to assess risk the FMEA team ranks the Severity (S) of the failure, the probability of its Occurrence (O) and the probability of detecting the failure mode or its cause, i.e. Detectability (D). Risk assessment is determined via RPN (Risk Priority Number), which is calculated by multiplying the ranking values of Severity, Occurrence and Detectability and obtaining one categorization

number for each possible cause of each failure using the following equation:

$$RPN = S * O * D \quad (1)$$

Once all items under consideration have been analyzed and the estimated RPN values assigned, corrective actions can be planned for the RPN values in descending order.

The ultimate goal of a corrective action is to achieve an appropriate reduction in the severity, occurrence and/or detection rankings in order to obtain "acceptable" RPNs.

2. POSSIBLE FAILURES OF CONVENTIONAL FMEA STEPS AND PROPOSED REMEDIES

2.1. Step 1: Failure Modes Identification

Pitfall: Missing Failure Modes. The first step of the FMEA 'Step by Step' procedure is compiling a list of system functions or system equipment items and identifying the failure modes of each item.

One of the main problems besetting the FMEA process is the omission of Failure Modes because the brainstorming session is not sufficiently comprehensive.

One of the causes of this problem is inherent in the well-known classical definition of failure: "The inability of an item, product or service to perform required functions on demand due to one or more defects" [1]. We are of the opinion that this definition is too narrow and, therefore, does not cover all possible aspects of failure analysis.

Remedy. This paper proposes a checklist of 10 types of Failures Modes that can be utilized by the FMEA team as a basis for defining the customized list of failures associated with any given activity or item. This check list is based on the Key Question "What Can Go Wrong?":

1. The intended function (mission) is not performed.
2. The intended function (mission) is performed, but there is some safety problem or a problem in meeting a regulation (for example, ecological) associated with the intended function (mission) performance.
3. The intended function (mission) is performed, but at a wrong time (availability problems).
4. The intended function (mission) is performed, but at a wrong place.
5. The intended function (mission) is performed, but in a wrong way (efficiency problems).

6. The intended function (mission) is performed, but the performance level is lower than planned.
7. The intended function (mission) is performed, but its cost is higher than planned (unscheduled maintenance or repair, higher consumption of required resources, etc.).
8. An unintended (unplanned) and (or) undesirable function (mission) is performed.
9. Period of intended function (mission) performance (life time) is lower than planned (reliability problem).
10. Support for intended function (mission) performance is impossible or problematic (maintenance, repairability, serviceability problems).

2.2. Step 2: Ranking Procedure

Pitfall: Use of Irrelevant Statistics. After the failure effects have been identified, Severity (S), Occurrence (O) and Detectability (D) should be evaluated. One possible method is the use of the conventional ranking procedure to rank these risk components on a '1' (Best Case) to '10' (Worst Case) ordinal scale that appears on standard FMEA forms [2].

A comprehensive FMEA team discussion on a specific item can result in a wide spread of ranks raising the question of how to resolve this situation. Drop Outliers? Calculate average rank? Define as highest rank (Worst Case Approach)?

Conventional FMEA does not provide any guidelines for this eventuality. Typically, such problems are resolved by applying the arithmetic mean value. In some cases more sophisticated specialists calculate the standard deviation of the proposed values and then, using Normal distribution approximation, apply all kinds of statistical sensitivity analyses. This is a mistake!

The RPN components are evaluated on the Ordinal Scale. This scale uses so-called Non-Parametric Statistics! Such measures as mean, standard deviation, etc. are absolutely irrelevant to the Ordinal Scale because the distance between ranks is meaningless.

Remedy. The following is a short list of proven guidelines that could be useful for FMEA teams:

- Team members could decide not to participate in the ranking of a given item or given component due to lack of relevant knowledge or experience
- A wide rank spread indicates some problem (usually due to the heterogeneity of the team). Nonetheless, we always try to obtain consensus. On the other hand, zero difference of ranks could indicate total indifference by team members towards the item under discussion.
- Outliers should be considered. Maybe they represent true estimates proposed by "process experts"! Maybe these outliers are the result of some misunderstanding or irrelevant experience!
- Either the Median or Mode (certainly not the Mean!) should be used as the team's rank estimate!

Remark. Actually, even the RPN calculation obtained by multiplying the Ordinal Scale values (1) is a kind of pitfall, which is, unfortunately, regulated by the Automotive Industry Action Group (AIAG) Standards [2]! As a result, this case needs to be dealt as well. The situation can be improved by

using some alternative scales, considering RPN as an illustration of the Pareto Priority Index PPI [3]. For example, one could use 'Rational Scales' for RPN components evaluation, such as Failure Rate for Occurrence, probability of misdetection for Detectability and the Failure Cost for Severity.

2.3. Step 3: Total Risk Estimate

Pitfall: Undefined Risk Acceptance Criteria. Once all items have been analyzed and evaluated by a RPN value, it is common to plan corrective actions for the failure modes/causes - from the highest RPN value down.

While the goal of any corrective action is the reduction of the Severity, Occurrence and/or Detectability rankings, the question is whether corrective action is necessary. During the Risk Management process, based on the overall risk analysis results, important decisions are made to either modify or accept the tasks at hand. If a risk level does not exceed an acceptable risk level, set at the project start, the operation is permissible and no corrective action is required. Acceptance of 'Zero' risk level as an ultimate requirement is foolish in any business area. Firstly, it is impossible to achieve, and secondly, even if it was possible (theoretically), it is not profitable.

The only method of achieving zero risk is to go out of business! But then you are taking another risk...

Unfortunately, the conventional FMEA procedure does not set any Risk Acceptance Criteria, nor does it require any evaluation of the general necessity of corrective actions. Furthermore, in some cases the teams tinker with the process/product when it is unnecessary.

Remedy. This paper proposes the use of calculated RPN values in order to derive the Total Risk Estimate (TRE) characterizing the overall risk level for each given project, where RPN_i are RPN values for a given i-th cause and 'n' is the number of causes in the FMEA table:

$$TRE = \frac{\sum_{i=1}^n RPN_i}{n * 1000} * 100 \% \quad (2)$$

One can see that the TRE values will always fluctuate between 0.1% and 100%. Risk Acceptability Criteria could be established as 17%, i.e. with risky projects assigned higher TRE values. Boundary value 17% approximately corresponds to the multiplied Midpoint (5.5) values for three RPN components ranked on a '1' to '10' scale.

This does not mean that no corrective action is required for $TRE < 17\%$. Obviously, extremely high RPN values should be dealt with. Nevertheless, calculated TRE values could be used for comparative analysis of different processes or operations in order to focus efforts on the most critical operation, or as an indicator of design maturity when deciding when to claim a design freeze and transfer a design to production.

2.4. Step 4: Critical Items Identification

Pitfall: Wrongly Defined Criteria for High Priority Items.

From the risk values point of view, the items covered by the FMEA procedure are usually very different. Obviously, the most significant items, characterized by high RPN, should be separated from those characterized by a significantly lower RPN value. Selected 'High Priority' items represent issues for corrective action plan development.

Some FMEA instructions recommend the acceptance of failures with $RPN \leq 80$ [2, 4], and therefore, require corrective action for all failure causes with $RPN \geq 80$. This rule tends to mislead the team requiring a large number of corrective actions.

Another common practice resorted to by FMEA teams analyzing RPN values in Pareto fashion is to limit the list of recommended corrective actions to 'Top 'X' Issues'. In such cases, the X-value chosen could be 3 or 5 or 10, etc. In other words, the 'X' selected will be an absolutely random choice. Obviously, this kind of decision-making is very problematic.

Remedy. We recommend the usage of a very simple and quite effective graphical tool, so-called Scree Plot used in principal component analysis, for RPN value analysis [5]. Scree Plot settings require the preliminary ordering of the RPN values by size, from the smallest to the largest. These values are then plotted, by size, across the graph, and then typically appear, when observing from the right, like a cliff descending to base level of ground (see Fig. 1).

The lower long part of the plot is characterized by a gradual increase of the RPN values that can, usually, fit a straight line with a rather slight slope. The RPN values scattered around this line should be considered as a kind of 'Information Noise'. The issues characterized by these RPN values do not require immediate attention.

The short uppermost part of Scree Plot is characterized by a very steep increase of the RPN values (RPN jumps). A straight line with a very strong slope could fit it. The RPN values scattered around this line are related to the most critical issues of FMEA that need to be dealt with promptly.

2.5. Step 5: Corrective Action & Prevention Action (CAPA)

Pitfall: Lack of Guidelines for the Optimal Choice. There are, usually, several possible competitive corrective actions that, theoretically, are capable of reducing the RPN for any given failure mode. Since conventional FMEA does not provide any guidelines for selecting the optimal option between competitive corrective actions, the FMEA team faces a difficult task.

Remedy. We propose a simple procedure that provides the basis for the optimal corrective action choice. This procedure evaluates both the feasibility of a corrective action implementation and the expected RPN value after implementing this action.

Similar to the conventional FMEA's procedure, the feasibility rank (F) is estimated on a '1' (Best Case) to '10' (Worst Case) scale using the criteria proposed by the authors and presented in [5]. The final decision, i.e. the choice of the optimal corrective action, is based on the results of the comparative analysis of the differences between the RPN values before and after the implementation of given corrective

actions divided by the corresponding feasibility ranking factors:

$$\frac{RPN_{i\text{ Before}} - RPN_{i\text{ After}}}{F_i} = \frac{\Delta RPN}{F_i} \quad (3)$$

Where: $RPN_{i\text{ Before}}$ and $RPN_{i\text{ After}}$ are RPN values for a given item before and after implementation of the i -th corrective action, ΔRPN is the difference between these values; F_i is the feasibility rank of i -th corrective action.

Obviously, the most preferable corrective action is the one characterized by the largest ratio.

2.6. Step 6: FMEA Effectiveness Evaluation

Pitfall: Lack of Guidelines for FMEA Effectiveness Evaluation. Since FMEA performance is a rather time consuming activity, requiring the participation of highly experienced personnel (team members), its cost is rather high. Therefore the effectiveness of the procedure should be evaluated after completing the FMEA.

Remedy. We suggest performing the calculation of normalized improvement estimate for this evaluation:

$$\Delta RPN_{\text{Rel}} = \frac{\sum RPN_{i\text{ Before}} - \sum RPN_{i\text{ After}}}{\sum RPN_{i\text{ Before}}} * 100\% \quad (4)$$

Where: $\sum RPN_{i\text{ Before}}$ and $\sum RPN_{i\text{ After}}$ represent the sum of the RPN values before and after CAPA implementation, respectively.

In our experience, if the FMEA is performed correctly, the magnitude of the reduction in the risk level after FMEA completion is expected to be in the vicinity of at least 30%.

3. CASE STUDY

The proposed procedure was applied to the evaluation of a medical device (Design FMEA). After the identification of all failure effects and the application of root-cause analysis of failure modes in teamwork, 40 corresponding RPN values were calculated and used for TRE evaluation.

The calculated TRE value in the initial state was rather high, indicating serious risk-related problems:

$$TRE_{\text{Initial}} = \frac{11022}{40 * 1000} * 100\% = 27.6\% \quad (5)$$

The RPN values were sorted and plotted on a graph in ascending order (see Fig. 1). Eight critical issues appearing at the uppermost part of Scree Plot were identified and reviewed.

In planning corrective actions, 1 to 3 alternatives for every issue have been suggested by the FMEA team (see Table 1). Each corrective action was then evaluated, using the proposed 'standardized-improvement' criterion (3) calculated as RPN reduction divided by corresponding feasibility ranks ($\Delta RPN/F$) and the software package [6] supporting the proposed improved FMEA procedure [5].

Post-FMEA evaluation of CAPA effectiveness revealed significant risk reduction:

$$\Delta RPN_{\text{Rel}} = \frac{11022 - 5682}{11022} * 100\% = 48.4\% \quad (6)$$

$$TRE_{Final} = \frac{5682}{40 * 1000} * 100\% = 14.2\% \quad (7)$$

Item (Failure Mode & Cause)	Recommended Corrective Action	Current Vs. Expected									F	$\frac{\Delta RPN}{F}$	Corrective Action's Priority
		S		O		D		RPN					
		Current	Expected	Current	Expected	Current	Expected	Current	Expected	Difference			
Failed Measurement Due to Low Accuracy	Detector Change	10	10	7	2	6	6	420	120	300	6	50	2
	Change of Measurement Procedure	10	10	7	4	6	6	420	240	180	2	90	1
	Change of Calibration Procedure	10	10	7	5	6	6	420	300	120	4	30	3

Table 1. Example of Corrective Actions Prioritization

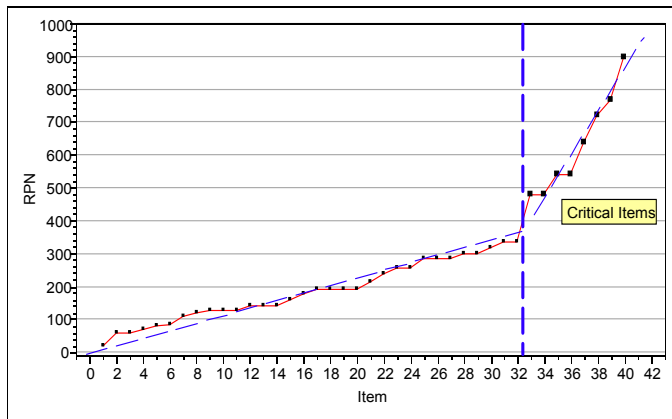


Figure 1. Scree Plot of Ordered RPN Values

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