FIELD Perspectives On Quality

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FMEA and You

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To properly evaluate a process or product for strengths, weaknesses, potential problem areas or failure modes, and to prevent problems before they occur, it may be necessary to use a Failure Modes and Effects Analysis (FMEA). An FMEA provides a systematic method of resolving the questions: "How can a process or product fail? What will be the effect on the rest of the system if such failure occurs? What action is necessary to prevent the failure?"

You may have noticed the omission of, "Will it fail?" This will be determined a little later in the probability statement on likelihood of occurrence.

One difficulty with FMEAs is that, to properly perform the activity, it is necessary to objectively question a design for adequacy. And people who design a process or product are reluctant to admit that potential weaknesses exist. Therefore, the FMEA should be a team action that consists not only of the designers, but also other personnel that are qualified to critique designs constructively and offer potential solutions.

While a Process FMEA and a Design FMEA differ in the areas being analyzed, the thought process is similar. The FMEA should generally be performed during the design-and-development stage. The earlier a change is found to be necessary, the lower the cost of making that change. Steps in performing an FMEA are not difficult, but do require that a logical sequence of events be followed and that actions be documented. The steps in performing a Process FMEA follow:

1. Do not try to use memory or the written routing alone to review the flow of a process-use a flow chart indicating the activities taking place at each operation. Criticality of the dimension or process output should also be documented.

Depending upon the end user of the FMEA (customer), specific headings, model years, drawing release dates or other characteristics may be required. If your company is a supplier to Chrysler, Ford or General Motors, they will make FMEA guidelines available to you.

2. Develop a written description of each operation in the process. This serves a twofold purpose. First, it requires that the process be investigated in enough detail to provide a description, and it assists in getting consensus understanding of what is actually taking place. "Grind O.D." is generally not enough. Is it a rough grind, a finish grind, a form grind? A little extra effort up front in this step can save considerable backtracking later.

3. What is the potential failure mode(s)? This is a description of the way(s) a processed part could fail to meet requirements. Put another way, against how many criteria could a given part be rejected at each operation, and why? Doing this may uncover past rejectable conditions that actually may not be legitimate reasons for scrapping the part.

Although type of failure will be specific to a given process, here are just a few potential failure modes: axial play; bad threads; binding; burrs; out of round; heat-treatment; out of alignment; surface finish, etc.

4. Potential effect of any given failure can be traced to the failure mode. The effect could be a minor annoyance at the next operation in the cycle; it could prevent further processing from taking place due to a missing locating hole; it could result in the end product not functioning; or it could be a safety issue.

To determine the effects, view the failure from the eyes of the next, or end, user. How might the next party experience the results of the failure? Here are a few effects that might be encountered.

Customer effect: noisy; premature failure; intermittent contact; slow operation; unacceptable appearance; will not maintain setting.

Manufacturing effect: cannot ream hole; cannot load in fixture; crash at next operation; tap breakage; insufficient stock; nonadhering paint.

Now that the modes of failure and the effects have been determined, it will be necessary to decide which of these to focus upon for resolution. It would be inefficient to work on every failure mode and its potential effect, so a method of prioritization will include: (1) severity of the effect; (2) probability of the failure mode occurring; and (3) probability of failure detection.

Severity of Effect

There is more than one rating scale available for severity of effect. Some use a I-to-5 scale, while others use a I-to-l0 scale. The latter is somewhat more appealing, as it allows for a smoother transition between levels. The following abbreviated table describes levels of effect severity and assigns a ranking from I to 10. Once the effect of the failure is determined, which often surprises some personnel, the probability of occurrence (failure) should be estimated. This is not very difficult to do if the processes have been studied statistically, are in a state of

statistical control and capability has been determined. In the example shown in the following table, normal distribution has

Severity of Effect	Ranking
Insignificant: Defect may not be noticed at all. Will not result in downstream processing problems or impair usability.	1
Low: Some downstream effect may occur in processing. May affect end user or cause less-than-optimal performance.	2,3
Moderate: Will likely cause processing problems down-stream or result in degraded performance of end product if part reaches the customer. Customer dissatisfaction is probable.	4, 5, 6
Significant: Serious downstream proceeding problems may occur. If product reaches customer, equipment failure is likely.	7, 8
Very High: Potential failure affects safety issues in operation or processing.	9, 10

been assumed.

At this point, both severity of effect and likelihood of failure have been determined. What is needed now is the Probability of Detection of the existence of a defect. If the defect is not easily prevented (relative term), a high probability of detection is needed to counterbalance future problems in processing or in the field. A table outlining the Probability of Detection and

Probability of Failure	Rank-ing	Failure Rate	Process Capability
Unlikely	**1**	**<1 in 10,000,000**	**± 5 Sigma**
Very Low	**2**	**1 in 16,000**	**± 4 Sigma**
Low	**3**	**1 in 2000**	**± 3.5 Sigma**
Moderate	**4**	**1 in 1000**	**± 3.3 Sigma**
	5	**1 in 500**	**±2.65 Sigma***
	6	**1 in 100**	**± 2.5**
High	**7**	**1 in 50**	
	8	**1 in 25**	
Very High	**9**	**1 in 10**	
	10	**1 in 50**	

***Process not capable at minimal levels.**

assigning a ranking follows:

Now it is time to put these three items in place to develop one usable index for action. This index, called the Risk Priority Number (RPN), prioritizes our actions for problem resolution (though safety issues should always receive attention, even with low RPN values). Here is an example: The severity of effect of a grinding operation on a connector, if oversize, is determined to be moderate, and is given a ranking of 5. The process is in statistical control with ±3.5 sigma capability, thus the probability of failure rating is 3. The likelihood of detection of an oversize part is high, for a rating of 4. Therefore, the RPN is the product of the numbers 5, 3 and 4, or 60.

Probability of Detection of Existing Defect	Ranking
Very High: The detection of the existince of a defect is almost a certainty. This may be a result of foolproof fixturing.	1, 2
High: There are controls to detect defects, but there is a small chance of defects not being detected.	3, 4
Low: There is only a small chance of detecting an existing defect.	7, 8
Very Low: Controls in place will not generally detect the existance of a defect.	9
None: A defect will almost certainly escape detection.	10

At this point there is no indication as to whether or not this is a high-priority item. If all other RPN values are lower than 60, this is a high-priority item for resolution. If all other RPN values are higher, and some are safety-related issues, this will be a low-priority item for resolution.

How do we resolve these issues? Look at the makeup of the RPN calculation. If the RPN value is high as a result of the severity of effect, it will likely require a product redesign. If the RPN value is high due to probability of occurrence, then it will be necessary to investigate the process for control and capability to reduce this value. If the RPN value is high due to the inability to detect defects, it may be beneficial to foolproof the fixturing downstream so it won't accept a defective part. It also may be necessary to redesign the part to reduce, or eliminate, the probability of this defect recurring. One-hundred percent inspection may be considered as a stop-gap measure. Process FMEA requires that we take an analytical view of our procedures.