FAILURE MODE EFFECTS AND ANALYSIS

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Introduction

In today's highly competitive, global environment, there's virtually no margin for error in manufacturing. So when introducing a new product - re-engineering a process - or undertaking any project - it makes good business sense to maximize the opportunities for success and minimize the risk of failure. Failure Mode and Effects Analysis (FMEA) is a systematic process for identifying the most critical potential design and process failure modes before they occur, in order to eliminate or mitigate their effects at early stages of product design and development. It incorporates specific opportunities for preventive action. The power of this technique is further enhanced by a numerical scheme for prioritizing the failure prevention activities.

Also known as Failure Mode, Effects and Criticality Analysis (FMECA) the technique was developed in response to military and commercial requirements for improved product reliability. The FMEA discipline was developed in the United States Military. Military Procedure MIL-P-1629, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis, is dated November 9, 1949. The intent of the MIL standard was to evaluate system reliability to determine the effect of system and equipment failures on mission critical components. Failure modes were classified according to their impact on mission success and safety. After WWII, some manufacturers of consumer products established a new set of business priorities, including customer satisfaction and safety. As a result, there remained a need for FMEA as a risk assessment tool.

In 1988, the International Organization for Standardization issued the ISO-9000 series of business management standards. The requirements of ISO-9000 pushed organizations to develop formalized Quality Management Systems that ideally are focused on the needs, wants, and expectations of customers. QS-9000 is the automotive analog to ISO-9000. A Task Force representing Chrysler Corporation, Ford Motor Company, and General Motors Corporation developed QS-9000 to standardize automotive supplier quality systems. In accordance with QS-9000, automotive suppliers shall use Advanced Product Quality Planning (APQP), including design and process FMEAs.

The Automotive Industry Action Group (AIAG) and the American Society for Quality Control (ASQC, now ASQ) copyrighted industry-wide FMEA standards in February of 1993, the technical equivalent of the Society of Automotive Engineers procedure SAE J-1739. These standards were published in an FMEA manual approved and supported by all three domestic automakers. The manual provides general guidelines for preparing an FMEA. (1)

While it was developed primarily to aid in product design, recently, there has been an increase in usage of this tool to aid in process design, including manufacturing and maintenance processes. The product design and process FMEA techniques can be applied to tape manufacture with effective results in a continual improvement environment. Up front benefits include:

- Identifying prioritized design improvements
- Documenting rationales for change
- Helping to develop product design verification and testing
- Documenting preventive measures for ISO-9000:2000
Helping to identify critical or significant product traits
Assisting in the evaluation of design alternatives
Helping identify and eliminate potential safety issues

Constructing an FMEA
FMEA is a systematic, team driven, process for looking at how a product or process design could fail and for examining impact of the results of a failure. Consistent with Concurrent Engineering precepts, FMEAs are conducted with cross-functional teams. Team members identify the potential failure modes, the effects of these failures, the possible causes of these failures, and the steps necessary to eliminate or minimize the possible causes of each potential failure before they occur. Instruction on how to execute an FMEA can be integrated with training in team techniques, quality improvement programs and other business improvement activities.

MIL-STD-1629 points out that “While the objective of an FMECA is to identify all modes of failure within a system design, its first purpose is the early identification of all catastrophic and critical failure possibilities so they can be eliminated or minimized through design correction at the earliest possible time. Therefore, the FMECA should be initiated as soon as preliminary design information is available ...” An early, important step in an FMEA is to clearly define the scope: the component, system, or process that is to be analyzed.

While the calculations are elementary, the FMEA is usually presented in a spreadsheet format. At each step of the FMEA development, critical information is specified and written into the FMEA document (2):

> Failure mode
> Cause of failure
> Effect on the application or system
> Preventive action

Furthermore, ratings are introduced at each step such that at the conclusion of the process, relative priorities have been identified for each area of potential action. Action results are recorded and recalculation of the action priorities may also be included so that the one document summarizes the entire team activity and their results. Thus, FMEAs are action tools, providing direction and priority for product and process improvement.

FMEA Elements are the building blocks of related information that comprise an analysis. The team approach is almost essential in identifying FMEA elements. Although actual document preparation is often the responsibility of an individual, FMEA input should come from a multi-disciplinary team. The team should consist of knowledgeable individuals with expertise in design, manufacturing, assembly, service, quality, and reliability. The responsible designer or engineer typically leads the FMEA team. Members and leadership may vary as the system, product, and process designs mature.

To begin the analysis, the product application criteria must be examined and the primary modes of product failure determined. For processes, begin with a block diagram of the system, subsystem or component that indicates the flow of information or operations. For products, Juran suggests that other tools, such as Fault Tree Analysis (FTA), can be used at this point (3). For each failure mode identified, the effect on the customer’s application must be estimated.
A failure mode is the result of a cause and its effect. The failure mode(s) determined by the team are written into the spreadsheet. With pressure sensitive tape products, failure modes may be due to premature application, loss or degraded adhesion, excess adhesion and/or inability to remove the product, dimensional constraints, visual defects and others. For each failure mode, the effects on the customer are recorded in the next column. When all such effects are listed, the team evaluates the severity of each of the effects.

The AIAG reference manual for automotive suppliers provides a specific scale for evaluating severity ratings that yields ratings from one to ten. Other rating scales may be used in other industrial applications (4). For example, the value of an automotive FMEA severity rating of seven indicates a moderately severe effect that would render the item “operable, but at reduced level of performance. Customer dissatisfied.” The severity ratings are entered in their column adjacent to the effect.

<table>
<thead>
<tr>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Effect(s) of potential failure</th>
<th>severity rating</th>
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**Figure 1.** Section of FMEA spreadsheet showing development of severity rating number for potential failure effects.

The next step in the analysis is to determine how often these identified failure modes are likely to occur. But to do this, the cause(s) of the failure must be established. For each mode of failure, the most likely causes are determined and recorded. As all possible causes do not necessarily result in the failure mode, this uncertainty is indicated through the use of the term “potential cause”. The frequency of occurrence of these potential causes is rated on a scale of one to ten with ten being the likeliest occurrence. For automotive applications, the AIAG reference manual indicates that a high frequency of one failure in three opportunities should receive a nine rating whereas a low frequency of 1 in 150,000 would be accorded a two rating.

<table>
<thead>
<tr>
<th>Potential cause(s) of failure</th>
<th>Occurrence rating</th>
<th>Existing controls to eliminate cause of failure</th>
<th>Detectability rating</th>
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**Figure 2.** Section of FMEA spreadsheet showing development of cause frequency and control method detectability rating numbers for calculation of the Risk Priority Number.

Once all the potential causes have been enumerated and evaluated, the existing design controls are reviewed. Insofar as some controls are not completely effective, the likelihood that a particular control technique will detect the stated cause must also be determined and rated. The AIAG reference
manual provides a specific one-to-ten scale for evaluating detectability ratings for automotive applications. As an example, a situation in which there is very remote chance that the design control will detect a potential cause would have an associated rating of nine. A rating of one is used when “the design control will almost certainly detect the potential cause”.

The Risk Priority Number (RPN) is calculated by taking the product of the severity, occurrence and detectability rating numbers. When using the scales recommended for automotive FMEAs, the RPN will fall between 1 (virtually no priority) and 1,000 (very high priority). It is the responsibility of the team to address preventive action for all of the higher priority items. In most cases, an RPN of 100 or more requires a formal action plan to address the potential failure mode.

The action plan and the completed actions can be tracked on the same master FMEA spreadsheet as was used for the RPN analysis. When the preventive action is complete, the three ratings are reassessed and the RPN recalculated. Continued high criticality ratings require that the control plans be revisited and further action taken.

<table>
<thead>
<tr>
<th>Recommended actions</th>
<th>Actions taken</th>
<th>New Sev.</th>
<th>New Occur.</th>
<th>New Detect</th>
<th>New RPN</th>
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Figure 3. Section of FMEA spreadsheet showing development of preventive actions and the re-evaluation of the Risk Priority Number.

The FMEA in the Tape Industry

In tape manufacture, the FMEA tool still fits well as a product design tool. In fact, many of our products can be considered as belonging to an application family where the failure modes for the product include many common faults. Thus, the model, once constructed, can be used as a basis for evaluating more than one product. This analytic process can become a catalyst for probing customer applications and developing even better products. The FMEA process becomes a platform for reviewing the customers’ applications and fine tuning new designs.

According to MIL-STD-1629A: “The failure mode, effects, and criticality analysis (FMECA) is an essential function in design from concept through development. To be effective, the FMECA must be iterative to correspond with the nature of the design process itself. The extent of effort and sophistication of approach used in the FMECA will be dependent upon the nature and requirements of the individual program. This makes it necessary to tailor the requirements for an FMECA to each individual program.”

This basic premise leads to both the benefits and drawbacks of using FMEA in pressure sensitive tape product development. The main drawback of this technique is that for packaging and protective tape applications, the number of traditional failure modes is limited and thus the technique may appear repetitive and non-productive with time.

On the beneficial side, this process causes the development engineering team to review the nuances of customer applications from new perspectives. It is a constructive opportunity for “out-of-
the-box” thinking and may lead to breakthrough concepts of product design. How you benefit from using FMEA: The use of FMEA can contribute significantly to the bottom line by helping to:

- Improve product performance,
- Focus design and manufacturing resources where they're needed most,
- Reduce warranty and product failure costs,
- Reduce product development costs,
- Condense the product development and launch cycle times,
- Document the history of potential failures,
- Analyze products systematically.

The FMEA process guides you toward better project management.

- Zero in on critical process or design elements that need immediate attention,
- Identify process or design elements that need ongoing analysis and attention,
- Optimize the roles and contributions of FMEA team members.

Conclusions
The Failure Mode and Effects Analysis technique provides a living tool that can be viable throughout the life of a product. As the culmination of a team activity to anticipate customers’ concerns at the time of product development, continual feedback from field experiences keeps the tool alive. And, with this ongoing input, the FMEA promotes preventive action and continual product/process improvement.

FMEA was a driving force in the early aerospace industry - helping to make safe, effective commercial air travel possible. And from the '70s, FMEA has helped the auto industry improve its track record by minimizing risks and improving automobile safety and performance. Today, FMEA continues to be a versatile, straightforward tool for analyzing and minimizing risk in new product development - a tool that is well suited to the needs of the pressure sensitive tape business in today’s competitive market.

References
2. JR Evans, WM Lindsay The Management and Control of Quality Fourth Ed. Cincinnati South-Western College Publishing 1999