Viewpoint on Manufacturing:

Use of the FMEA Methodology for Risk Analysis and Mitigation

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The history of the FMEA methodology

FMEA is an acronym for Failure Mode and Effect Analysis. This methodology was first developed as a United States Military Procedure, MIL-P-1629, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis, dated November 9, 1949. It was used as a reliability evaluation technique to determine the effect of system and equipment failures. In the decades since 1949 the methodology has been embraced first by the automotive industry as part of its QS9000, but also by the FDA in its cGMP, and ISO in ISO 9001/2 and ISO 14000 as well as numerous other companies as part of their own activities.

What is a FMEA

It is a technique that provides a systematic approach to evaluating the risks associated with a product design, a process, a machine or a system. The level of risk is determined by evaluating the severity of the impact of a failure, the likelihood of occurrence of that failure and the likelihood of detection of an occurrence of the failure.

The value of performing an FMEA analysis is to thoughtfully evaluate all the potential failure possibilities to establish a number symbolic of the risk associated with each possibility called a Risk Priority Number, RPN. The RPN is then used provide an indicator of the potential failure modes that pose the most serious risks so that action can be taken to mitigate the exposure of these risks.

A FMEA analysis is preferably prepared by a cross-functional team under the leadership of an experienced facilitator. The FMEA then benefits from the diverse viewpoints and experience of all those concerned with the potential risks and their mitigation.

Each effect for a failure mode is evaluated for the severity of its impact and assigned a severity number with the larger the number indicating the more severe impact. Typically both the severity of the impact on the end user as well as downstream company processes are identified and evaluated. Likewise each cause is evaluated for its likelihood of occurrence; again, the larger the number indicates a higher likelihood of occurrence. Finally, the method of detection is evaluated for its effectiveness with the smaller number indicating a greater effectiveness. The RPN is determined by multiplying together these three numbers.

Figure 1 provides a fictitious example of a FMEA for the process of washing dishes. After the heading there is a line for each combination of Potential Failure Mode, Effect, Cause and Detection method. In the second column, each step of the process, part of a machine or

Figure 1: FMEA Example

FMEA Type: Process	Project Name/Description: Dish Washing			Date (Orig):	08/27/08
Responsible Function: Family Chores Office	Prepared by: Donald W. Havas (Applied Technology and Science, Inc.)			Date (Rev):	09/12/08
Team: Husband (drier), Wife (washer) and D. Havas				Rev No.:	01

Item No.	Design FMEA (Item/Function) Process FMEA (Function/Requirements)	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Cause/Mechanism of Failure	Occurance	Detection Method	Detection	RPN	Action	Respons-ibility	Target	Action Taken	Revised Severity	Revised Occurance	Revised Detection	Revised RPN
001	Dish Stacking	Bulk food remains not removed	Dish washing bath life is shortened	4	Dish not scraped properly by dish stacker	7	Visual inspection by dish stacker and dish washer	4	**112**								
001	Dish Stacking	Disk or glass cracked or chipped	Washer receives cut	10	Dish or glass dropped or jumbled by dish stacker	7	Observation of clash by dish stacker	4	**280**	1) Stacking rack made with nests for each piece 2) Inspection by washer prior to picking up	Husband Wife	Next Week Immediately	In progress Complete	10	3	2	60
001	Dish Stacking	Disk or glass cracked or chipped	Dish or glass must be disposed of and/or replaced.	8	Dish or glass dropped or jumbled by dish stacker	7	Observation of clash by dish stacker	4	**224**					8	3	2	48
002	Dish Washing	Disk or glass cracked or chipped	Washer receives cut	10	Dish or glass dropped or jumbled in wash water	6	Dish washer hears piece drop or crash in water	8	**480**	1) Wash tub replaced with plastic wash tub 2) Pieces to be washed one at a time	Husband Wife	Saturday Immediately	Complete Complete	10	1	8	80
002	Dish Washing	Disk or glass cracked or chipped	Dish or glass must be disposed of and/or replaced.	8	Dish or glass dropped or jumbled in wash water	5	Visual inspection by dish washer and dish drier	4	**160**								
002	Dish Washing	Dish not clean after washing	Water not hot enough	3	Water not hot enough when was tub filled	6	Washer tests water by hand when filling tub	3	**54**								
002	Dish Washing	Dish not clean after washing	Water not hot enough	3	Water used too long and cools off	7	Washer monitors water temperature during washing dishes.	4	**84**								
002	Dish Washing	Dish not clean after washing	Insufficient detergent used	3	Dish washer does not dispense enough detergent into wash tub	6	Washer estimates amount to dispense by eye and watches for sufficient foam formation	4	**72**								
002	Dish Washing	Dish not clean after washing	Insufficient cleaning action	3	Detergent used up by cleaning excessive number of pieces	7	Washer watches level of foam while washing	5	**105**								
002	Dish Washing	Dish not clean after washing	Insufficient cleaning action	3	Poor scrubbing/washing technique	2	Visual inspection by dish washer and dish drier	4	**24**								
003	Dish Drying	Disk or glass cracked or chipped	Drier or end user receives cut	10	Dish or glass dropped or jumbled when placed in drying rack	5	Visual inspection by dish washer and dish drier	4	**200**	Storage rack made with nests for each piece	Husband	Next Week	In progress	10	2	3	60
003	Dish Drying	Disk or glass cracked or chipped	Drier or end user receives cut	10	Dish or glass dropped or jumbled when put away	2	Observation by user	8	**160**	Inspection of pieces when placed in use.	Table setter	Immediately	Complete	10	2	3	60
003	Dish Drying	Dish or glass has water spots	User will not use piece	7	Piece incompletely dried by drier	6	Visual inspection by drier	4	**168**								

Adapted from: Potential Failure Mode and Effects Analysis (FMEA Third Edition), Version 03.00, 7/01, AIAG, Southfield, MI, www.aiag.org

system or design function is identified. As shown there may be multiple failure modes each item in the second column, multiple effects for each failure mode, multiple causes foe each failure mode and multiple methods of detection. Each effect for a failure mode is evaluated for the severity of its impact and assigned a severity number with the larger the number indicating the more severe impact. Typically both the severity of the impact on the end user as well as downstream company processes are identified and evaluated. Likewise each cause is evaluated for its likelihood of occurrence; again, the larger the number indicates a higher likelihood of occurrence. Finally, the method of detection is evaluated for its effectiveness with the smaller number indicating a greater effectiveness. The RPN is determined by multiplying together these three numbers.

In practice, a threshold is often established such that for any line having an RPN equal to or higher than that threshold an action is required to mitigate that risk. In the example of Figure 1, that threshold was chosen to be 200. Sometimes, if the severity associated with a failure mode is such that it is totally unacceptable, an action may be required to mitigate any risk for that failure mode. In the example of Figure 1, a severity of 10 was also identified as requiring mitigation.

The columns to the right of the RPN are used to identify the planned actions, responsible parties, targeted completion dates and the projected RPN based upon those actions.

Finally, at is best, a FMEA is a living document. The process or design for which the FMEA was prepared is seldom static and unchanging in the course of time. Therefore, a regular review of the FMEA against the current process or design will prevent new risks from evolving with out proper attention to mitigate them.

The Benefits of performing a FMEA analysis

As recognizable from the example, a thoughtfully prepared FMEA can provide benefits to a company in a number of ways. A FMEA prepared during the design process can reduce the number of potential failure modes by suitable changes to the design of the product; thereby making the product more reliable and easier to produce. A FMEA prepared with respect to the manufacturing processes can reduce the occurrence and escape of defects and potential failures to the customer; thereby reducing production costs and increasing customer satisfaction. A FEMA prepared with respect to equipment or systems can reduce the personnel risks and improve availability; thereby reducing internal dissatisfaction and operating costs. No matter where applied, a well done FMEA has the potential to save the company money and increase the level of customer satisfaction.

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