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An introduction to risk analysis

By Steve Murphy and Marc Schaeffers

An introduction to risk analysis

Risk analysis is a very natural human activity. Imagine yourself as a hunter gatherer charged with organizing the evening meal. Together with your team you organize a hunting party and part of that plan will be some intuitive risk analysis. What are the dangers? You may consider predators, thirst, and injury during the chase. All being well the precautions you take result in a successful hunt, everybody returns home in one piece and the tribe eats their evening meal. Risk analysis remains an essential part of our business activity. We routinely analyze situations and take actions to minimize business risks and safety concerns. FMEA (Failure Modes and Effects Analysis) is an effective risk analysis method for design and manufacturing. It examines your design and manufacturing processes and identifies the opportunities for marginalities and defects which can result in customer dissatisfaction. Before we go into the detail why not carry out a simple trial. Walk down your production line and think to yourself “What can happen to the product here that will impact the customer? What are we doing about it ?” Ask the production staff what routinely goes wrong with the process and think “How can that affect the product”.
The FMEA will capture all this knowledge and experience in a structured way and will allow you to take actions which will minimize the risk of a disappointed customer.

A brief history of FMEA

FMEA was developed by the American military at the end of the 1940’s. I understand their frustrations with munitions malfunctioning led them to develop a methodology that would eliminate all the potential root causes. A detailed method was documented: MIL-P-1629. It worked and so it was adopted by the nuclear and aerospace industry. NASA credited the success of the moon landings to its use. NASA were also so concerned about contaminated food on space missions that they developed a very similar technique called HACCP(Hazard Analysis and Critical Control Points) specifically for the food industry. In the 1970’s slow speed shunts involving the Ford Pinto were resulting in fatal fires if the petrol tank split. As you can imagine this was a public relations disaster. To eliminate a reoccurrence for this and other serious problems the Ford Motor Company implemented FMEA in their design process. More organizations were using FMEA as a risk analysis tool and in 1993 the AIAG (Automotive Industry Action Group) incorporated it into the QS9000 standard for automotive production and its suppliers. QS9000 has become TS16949. While

FMEA was specifically aimed at automotive other industries which demand the highest levels of reliability, for example semiconductors and oil and gas, have implemented it. These reliability standards are now extending to white goods and everyday electronic products. Strictly the current format is FMECA (Failure Modes and Effects and Criticality Analysis), the Criticality of the defect for the end user is incorporated into the method. For practical purposes it is a risk analysis and defect reduction technique that takes into account three things; the SEVERITY of the defect for the end user, the OCCURRENCE of the potential root cause and our effective DETECTION or ELIMINATION of this root cause.

Getting started with risk analysis

An important part of any risk analysis is the scope of the process. This may sound trivial but it is essential to know if your analysis should include, for instance, the incoming materials store. Then we need to make a complete process flow. This is a crucial task and should include every step in the process including rework steps. At each of the process steps we need to identify the possible sources of variation and potential problems. We need to document defects that may occur on the product. We also need to list equipment and process problems that may cause defects on the product. In a risk analysis process the creation of a complete process flow and a complete list of potential problems can take 50% of your time.

Where do the ideas come from?

Traditionally a Brainstorming technique has been used to generate a list of possible problems at each process or design step. While this is useful it is often more useful to incorporate all your current sources of variation into your initial FMEA.
These include:

- Inputs from scrap incidents
- Inputs from customer returns
- Inputs from near misses
- Inputs from the next process
- Ideas from the designers
- Ideas from machine operators
- Ideas from the maintenance team
- If you have SPC then consider out of control points

- Incidents on similar equipment
- Advice from industry experts
- Advice from your material and equipment suppliers.

Using these sources will capture a lot of problems and marginalities that already exist and make your FMEA practical and useful from day one.

The TS16949 FMEA layout

When assessing potential risks in a process it is useful to document the information in a structured FMEA format. The TS16949 format is widely used and an example is shown in figure 1

In the first 4 columns you document the process steps, the process requirements, potential failure modes and the effects of the failures. In the next step you identify the process problems which can cause the failure and the controls you have in place to prevent or detect the problems. The final columns contain the corrective actions taken and the results of these actions.

Product No: DataLyzer Example FMEA TS16949

File New Edit Delete

Process Step / Function	Requirement	Potential Failure Mode	Potential Effects of Failure	SEV	CLASS	Potential Causes of Failure	Current Process: Controls Prevention	OCC	Current Process: Controls Detection	DET	RPN	Recommended Action	Responsibility / Target Completion Date	Action Results: Action Taken / Completion Date	SEV	OCC	DET	RPN
Op. 70 / Manual application of wax inside door panel	Cover inner door lower surfaces with wax to specification thickness	Insufficient wax coverage over specified surface	Allows integrity breach of inner door panel Corroded interior lower door panels Deteriorated life of door leading to: · unsatisfactory appearance due to rust through paint over time · Impaired function of interior door hardware	7		Manually inserted spray head not inserted far enough	None	8	Variables check for film thickness Visual check for coverage	5	280	Add positive depth stop to sprayer	Marc Schaeffers 8/ 10/ 2011	Stop added, sprayer checked online 7/ 29/ 2011	7	2	5	70
												Automate spraying	Marc Schaeffers 8/ 29/ 2011	Rejected due to complexity of different doors on the same line 7/ 29/ 2011				
						Spray head clogged · Viscosity too high · Temperature too low · Pressure too low	Test spray at start-up ad after idle periods and preventative maintenance program to clean heads	5	Variables check for film thickness Visual check for coverage	5	175	Use DOE on viscosity vs temperature vs pressure	Marc Schaeffers 8/ 29/ 2011	Temp and press limits were determined and control limits have been installed. Charts show process is in control with ppk = 1.85 7/ 29/ 2011	7	1	5	35
						Spray head deformed due to impact	Preventative maintenance program to maintain heads	2	Variables check for film thickness Visual check for coverage	5	70	None						
						Spray time sufficient	None	5	Operator instructions Lot sampling (visual) check coverage of critical areas	7	245	Install spray timer	Marc Schaeffers 8/ 29/ 2011	Automatic spray timer installed operator starts spray, timer controls shut off, charts show process is in control Ppk = 2.05 7/ 29/ 2011	7	1	7	49
		Excessive wax coverage over specified surface																

Figure 1: Example FMEA format

The Severity, Occurrence and Detection are all scaled on a 1 to 10 basis. 1 is the best rating and 10 is the worst. Multiplying them together gives the Risk Priority Number (RPN). Our goal is for our actions to lower the RPN, particularly the highest. All this information is stored in the FMEA. When a cycle of learning is completed the FMEA will be released. The FMEA is a living document and it will be reviewed and updated regularly. New causes, failure modes and actions will be added as you learn more about your process.

About the white paper:

This White Paper "An Introduction to Risk Analysis" is the first of a series of White Papers on the subject of risk analysis and especially FMEA.
Look at http://www.datalyzer.com/white-papers/ for all the available white papers.

About the authors

Steve Murphy has 30 years of experience within high tech manufacturing including senior roles within the semiconductor, aerospace and oil and gas sectors.

Marc Schaeffers has 25 years of experience with the implementation of quality systems in industry and is the designer of the DataLyzer FMEA software system.

Both are working with DataLyzer International, a software and consultancy company specialized in the implementation of FMEA, SPC, MSA and OEE.