Product optimization by Design and Process FMEA

The automotive industry has done it for years, the wind industry has begun and a wide range of companies and sub-contractors have now also begun to use Design FMEA and Process FMEA to optimize the quality of the entire process from product conception to serial deliveries.

This article describes some of the practical challenges that are often seen in connection with the implementation and use of FMEA.

Constant change

Many companies have to realize that there is a need to make strategic choices to continue to assert themselves in a world where globalization and increased competition are everyday things.

Some companies go from one-off production to serial production and others from producing only in the home country to global production. In both situations, it requires a set of actions on quality and where FMEA can be one of the tools.

What is really FMEA?

FMEA (Fault-Possibility and Effect Analysis) is a tool for identifying potential risks, where Design FMEA focuses on design and development of a product and Process FMEA focuses on the manufacture and assembly of the product.

By applying FMEA on a specific design, a production process or a sub-assembly it can be identified what could go wrong on each sub function or subassemblies, what are the consequences of such a failure for the end customer and what precautions are in place, to catch such a failure possibility before delivery.

All findings should be documented in a spread sheet and the result is a series of RPN values (Risk Priority Numbers), which can then be used to prioritize areas for action. See Figure 1 where the individual steps in a Process FMEA is shown.

Why introduce FMEA

There are several good reasons to introduce respectively Design FMEA / Process FMEA:

1. Some customers require it
2. For competitive reasons - the others do it
3. Reduce risks in design and production

Both reasons # 1 and # 2 should preferably give the effect as mentioned in # 3 and thus become an advantage for both the company itself and its customers. If FMEA is not actively being used in the company to identify and reduce risks, the introduction and utilization of FMEA can easily be an extra burden, which costs time and money.
**Barriers to adoption**

Quality is as we all know about leadership. All change and improvement initiatives must necessarily be anchored at Management, from where results should be demanded. Introducing FMEA requires therefore the full support from the Management and that result from the planned FMEA’s are continually demanded.

FMEA relies heavily on teamwork between designers, manufacturing engineers, quality personnel, operators, and if possible, representatives from service and maintenance. An FMEA does not give the required benefits if it is produced by individuals. It is the creativity that occurs in a team that is the basis for a successful outcome of a FMEA.

One of the pitfalls in the use of FMEA is that Design FMEA and Process FMEA get mixed up. It is very important to separate the two things during the identification of failure possibilities. Design changes can however be obvious to reduce the RPN values for a Process FMEA.

FMEA is normally introduced most effectively by a brief introduction to the concepts, but the actual learning takes place when the process is performed and managed by an independent person who is experienced in FMEA and who is not directly involved in the product.

**Efficient Design FMEA**

A Design FMEA should be started up early in a product development phase in order to identify possible defects in a design as a basis to introduce optimizations in the product before it is released for production. In many cases the Design FMEA is started late in the development phase and the benefits are consequently reduced. Once a design is released to production the possibility of introducing even small changes may be difficult and costly.

It is also important that employees from production actively participate in Design FMEA, as they often have some very relevant input that designers do not always have in mind. If representatives from service and maintenance participate, it is an extra plus.

In some cases, manufacturing, service and maintenance are not included in the Design FMEA and the benefits are often not quite as good as it could have been.

In these cases, the feedback usually come when the product goes into mass production and must be serviced and maintained, but at that time, the ability to make design changes might be impossible.

**Effective Process FMEA**

A Process FMEA should be started up shortly after the first Design FMEA is completed. It is of great importance that design engineers, production workers and employees from service and maintenance are involved in a Process FMEA, as improvements or adjustments to design often can reduce the risk of errors in the production and subsequent at the end-customer.

If the design is released to production, it is in most cases difficult and costly to introduce changes in the product, though it might benefit the production and subsequent servicing and maintenance.

An alternative to introducing design changes to reduce risks are usually additional inspection and testing activities. Inspection and testing often increases the cost of production, whereas a design
change in many cases can be cost neutral or even save costs. Precisely for this reason it is important to conduct Process FMEA before the design is frozen for production.

Sub-contractors, which produces based on customer's design, has a special challenge in getting production experience led back to the customer's engineers in a timely manner.

In very many cases, the sub-contractor is not able to join the Design FMEA at the customer, which could be valuable for both parties.

A proactive approach from the sub-contractor often give the possibility to incorporate production experience in the customers design and thereby creating benefits for both parties and also a competitive advantage to the sub-contractor due to the added value in the design.

**Purpose of the FMEA is to**

- identify possible errors in design and production
- identify opportunities to reduce the risk of errors
- uncover optimizations opportunities in the design and production
- provide a basis for the preparation of work instructions

**Effective FMEA requires**

- regularly update of FMEA during the product’s lifetime
- use in development, manufacturing and maintenance
- implementation before design and production is determined

**Business benefits of FMEA**

- Better opportunity to be considered “Best in Class”
- Sub-contractors may have greater influence on design
- Reduced risk of subsequent serial failures in the product
- Better ability to optimize work and assembly operations
- Basis for global applicable manufacturing documentation

**Additional Information**

- Danish standard DS / INF 142:2005
- [http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis](http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis)
Figure 1. Steps for conducting FMEA

1: Identify operation steps
2: Determine individual operations
3: Identify potential error modes
4: Identify consequence of error
5: Determine consequence (1-10)
6: Identify possible causes to error
7: Determine probability (1-10)
8: Identify present detection
9: Determine detection level (1-10)
10: Calculate risks (RPN nr. 1 - 1000)
11: Assess results for RPN
12: Recommend actions to reduce RPN

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