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# FMEA Analysis for Reducing Breakdowns of a Sub System in the Life Care Product Manufacturing Industry

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***Abstract— This paper provides the use of Failure Mode and Effects Analysis (FMEA) for improving the reliability of sub systems in order to ensure the productivity which in turn improves the bottom line of a manufacturing industry. Thus the various possible causes of failure and their effects along with the prevention are discussed in this work. Severity values, Occurrence number, Detection and Risk Priority Number (RPN) are some parameters, which need to be determined. These are the steps taken during the design phase of the equipment life cycle to ensure that reliability requirements have been properly allocated and that a process for continuous improvement exists. The FMEA technique is applied on an automatic plastic welding machine used for the production of blood bags in a life care manufacturing company in south India. The preventions suggested in this paper can considerably decrease the loss of production hours in the industry due to the breakdown of the machine.***

*Index Terms* — **Detection Number, FMEA, Occurrence Number, RPN, Severity Value.**

## I. INTRODUCTION

Failure Mode and Effect Analysis (FMEA) was first developed as a formal design methodology in the 1960s by the aerospace industry with their obvious reliability and safety requirements. FMEA is a systematic method of identifying and preventing system, product and process problems before they occur. It is focused on preventing problems, enhancing safety and increasing customer satisfaction. Ideally FMEA's are conducted in the product design or process development stages, although conducting an FMEA on Existing products or processes may also yield benefits. FMEA is a tool that allows us to prevent System, Product and Process problems before they occur. It reduces costs by identifying system, product and process improvements early in the development cycle. It prioritizes actions that decrease risk of failure.

**FMEA analyses**

- Potential failure modes of product or machine,
- Potential effects of failure,
- Potential causes for failure (like Material defects, Design deficiencies, Processing and manufacturing deficiencies, and Service condition etc.)
- Assesses current process controls, and
- Determines a risk priority factor

One of the most powerful methods available for measuring the reliability of products or process is FMEA. Customers are placing increased demands on companies for high quality, reliable products. The increasing capabilities and functionality of many products are making it more difficult for manufacturers to maintain the quality and reliability.

## II. LITERATURE REVIEW

From the literature survey, it is evident that some researches on FMEA have been carried out by previous researchers but still a lot of applied research in the above field is required so as to explore the successful utilizations of the FMEA technique in the area of manufacturing and design. Some of the past research works are discussed as under. With the appearance of jet planes in 1950s, the U.S.-based Grumman Co. developed the FMEA method to address the reliability of main controlling system of the ever-complicated jet planes. In 1977, Ford Motors introduced FMEA to address the potential problems in the R&D and the early stage of production and published the Potential Failure Mode and Effects Analysis Handbook in 1984 to promote the method. Later on the automobile manufacturers in America also introduced the FMEA into the management of suppliers, and took it as a key check issue. Hughes et al. (1999) stated that traditional quantitative methods for modeling mechanical

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systems are in-appropriate for automated mechanical production. Rhee and Ishii (2003) demonstrated the systematic use of empirical data in performing Life Cost-Based FMEA and how it can improve the reliability and life cycle cost of complex systems such as a linear particle collider. Narayanagounder et al. (2009) addressed the drawbacks in traditional FMEA and proposed a new approach to overcome these shortcomings. The Risk Priority Code (RPC) was used to prioritize failure modes, when two or more failure modes have the same RPN. They proposed a new method to prioritize failure modes, when there is a disagreement in ranking scale for severity, occurrence and detection. An Analysis of Variance (ANOVA) was used to compare means of RPN values. SPSS (Statistical Package for the Social Sciences) statistical analysis package is used to analyse the data. The results presented by them are based on two case studies. It was found that the proposed new methodology/approach resolves the limitations of traditional FMEA approach. FMEA does not attempt to give comprehensive answers to the frequently answered questions (FAQs), which are addressed in the main document.

## III. FMEA

There are two types of FMEA: Design FMEA and Process FMEA. Design FMEA aids in the design process by identifying known and foreseeable failure modes, and then ranking failures according to relative impact on the product. Process FMEA is utilized to identify potential process failure modes by ranking failures and helping to establish priorities according to the relative impact on the internal or external customer. Implementing process FMEA will help to identify potential manufacturing or assembly causes in order to establish control for occurrence reduction and detection which enhances failure reduction .The FMEA attempts to detect the potential product related failure modes. The technique is used to anticipate causes of failure and prevent them from happening .FMEA uses occurrence and detection probability criteria in conjunction with severity criteria to develop risk priority numbers for prioritization of corrective action considerations.  This method is an important step in debugging and preventing problems that may occur in the manufacturing process. It should be noted that FMEA to be successful, it is extremely important to treat the FMEA as a living document, continually changing as new problems are found and being updated to ensure that the most critical problems are being dealt with. Ideally the analytical feedback of RPN should go back to the equipment manufacturer and corrective measures should be incorporated in the controls if necessary. The process for conducting an FMEA is straightforward. It is developed in three main phases, in which appropriate actions need to be defined. But before starting with a FMEA, it is important to complete some pre-work to confirm that robustness and past history are included in the analysis. The documentation and procedure for conducting FMEA study is given below.

### *A. Severity*

Severity is the assessment of the seriousness of the effect of the potential failure mode. In this we have to determine all failure modes based on the functional requirements and their effects. An example table of severity is given below.

**Table 1example Table of Severity**

| Code | Classification | Example |
|---|---|---|
| 10 | Dangerously High | Injury or Death |
| 9 | Extremely High | Regulatory non-compliance |
| 8 | Very High | In-effective service or treatment |
| 7 | High | High Customer Dissatisfaction |
| 6 | Moderate | Potential in-effectiveness |
| 5 | Low | Customer Complaints |
| 4 | Very Low | Lowered effectiveness |
| 3 | Minor | A nuisance to the customer |
| 2 | Very Minor | Not apparent; minor effect |
| 1 | None | Not apparent; no effect |

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### *B. Occurrence*

Occurrence is the chance that one of the specific cause/mechanism will occur. In this step, it is necessary to look at the cause of a failure and how many times it occurs. Looking at similar products or processes and the failures that have been documented for them can do this. A failure cause is looked upon as a design weakness. An example for occurrence rating is given in following table.

**Table 2 example Table of Occurrence**

| Code | Classification | Example |
|---|---|---|
| 10<br>9 | Very High | Inevitable Failure |
| 8<br>7 | High | Repeated Failures |
| 6<br>5 | Moderate | Occasional Failures |
| 3<br>2 | Low | Few Failures |
| 1 | Remote | Failure Unlikely |

### *C. Detection*

Detection is an assessment of the probability that the current process control will detect a potential weakness or subsequent failure mode before failure mode the part or component laves the manufacturing operation or assembly location. Assume the failure has occurred and then asses the capabilities of the current process control to prevent shipment of the part having this nonconformity (defect).in simple words it can said that detection ranking is done based on prevention failure modes from occurring or which detect the failure before it reaches to the customer An example for ranking of the detection table is shown below.

**Table 3 EXAMPLE TABLE OF DETECTION**

| Detection | Rank | Criteria |
|---|---|---|
| Extremely Likely | 1 | Can be corrected prior to prototype/ Controls will almost certainly detect |
| Very High Likelihood | 2 | Can be corrected prior to design release/Very High probability of detection |
| High Likelihood | 3 | Likely to be corrected/High probability of detection |
| Moderately High Likelihood | 4 | Design controls are moderately effective |
| Medium Likelihood | 5 | Design controls have an even chance of working |
| Moderately Low Likelihood | 6 | Design controls may miss the problem |
| Low Likelihood | 7 | Design controls are likely to miss the problem |
| Very Low Likelihood | 8 | Design controls have a poor chance of detection |
| Very Low Likelihood | 9 | Unproven, unreliable design/poor chance for detection |
| Extremely Unlikely | 10 | No design technique available/Controls will not detect |

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### *D. Risk Priority Numbers (RPN)*

RPN is the indicator for the determining proper corrective action on the failure modes. It is calculated by multiplying the severity, occurrence and detection ranking levels resulting in a scale from 1 to 1000.After deciding the severity, occurrence and detection numbers, the RPN can be easily calculated by multiplying these 3 numbers:

$$RPN = Severity \times Occurrence \times Detection$$

The small RPN is always better than the high RPN. The RPN can be computed for the entire process and/or for the design process only. Once it is calculated, it is easy to determine the areas of greatest concern. The engineering team generates the RPN and focused to the solution of failure modes.

### *E. FMEA Procedure*

The process for conducting FMEA is explained with the help of flow chart shown below. [7]

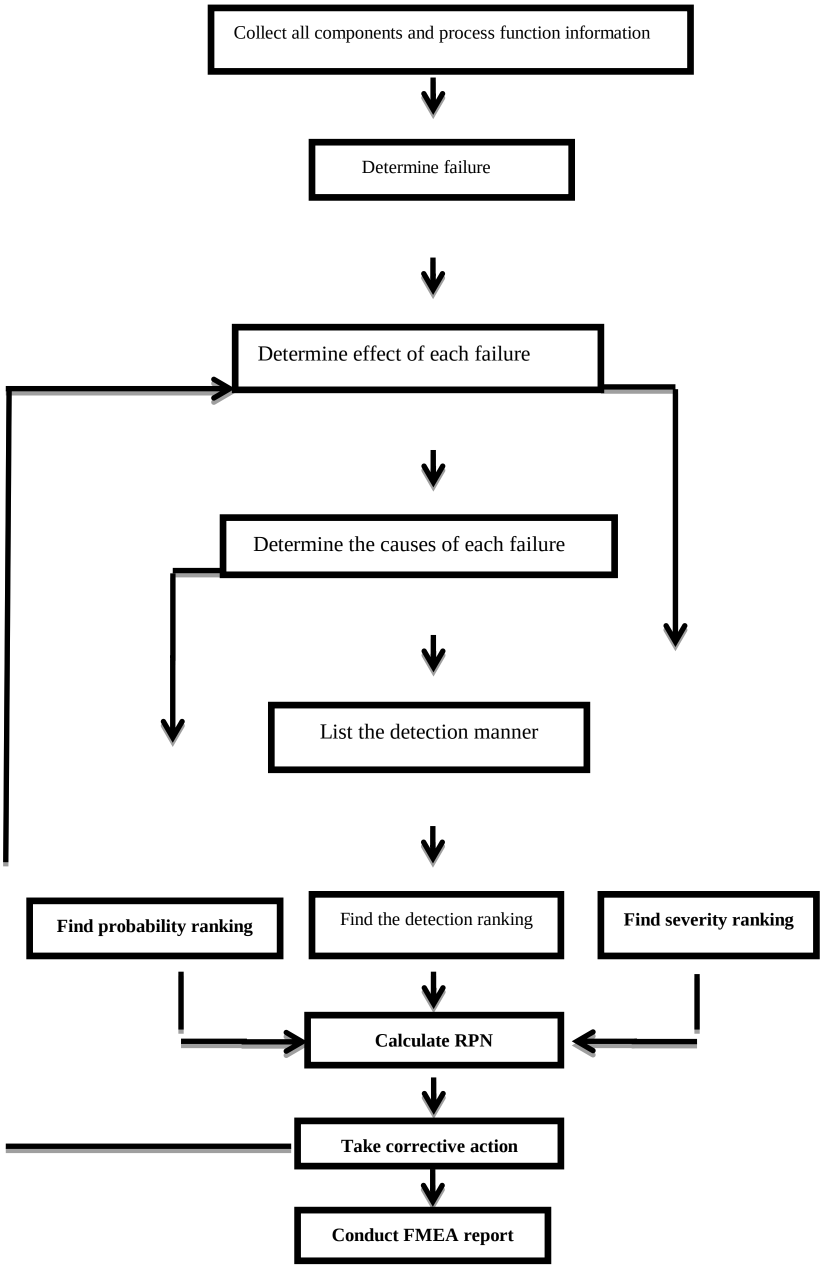


**Fig 1 FMEA Procedure**

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## III. CASE STUDY AND FMEA IMPLEMENTATION

Case study is conducted and FMEA technique is applied to the automatic plastic welding machine in a life care product industry. Automatic plastic welding machine is used for the production of blood bags. Automatic plastic welding machine is manufactured by Colpitt which is a ten station fully automatic machine consisting of two robotic arms. Capacity of the machine is 12000 bags per shift. For the analysis, the machine breakdown details for the past three years are taken. Criteria for ranking of severity occurrence and detection are selected suitably by analyzing the past failure records of the machine. Using values of severity occurrence and detection numbers risk priority number is calculated.

### *A. Sample Calculation*

Sample calculation for stripping process in automatic plastic welding machine is given below

**Step 1.** Potential failure mode of stripping process found.

**Step 2.** Potential effect of failure is found out. Failure affect company (Internal) because due to the failure of stripping unit company has to assign an additional worker for stripping job.

**Step 3.** From the table values of severity, occurrence and detection values are calculated and they were obtained as 4, 8 and 5 respectively.

**Step 4.** RPN value calculated as

R.P.N. = S × O × D

Considering S = 4, O = 8 and D = 5

The R.P.N. = 4 × 8 × 5 = 160

### *B. Ranking of Severity of Effect*

Ranking for severity of effect is shown in table.

**Table 4Severity of Effect**

| Effect | Criteria: Severity of effect | Ranking |
|---|---|---|
| Hazardous without warning | May endanger machine or assembly operator .failure mode affects safe operation and will occur with out warning | 10 |
| Hazardous with warning | May endanger machine or assembly operator. Very high severity ranking . failure will occur without warning | 9 |
| Very high | Major disruption to production line. 100% of product may have to be scrapped | 8 |
| High | Minor disruption to production line apportion of the product have to be scrapped. Item operable but reduced level | 7 |
| Moderate | Minor disruption to product line. A portion of product may have to be scrapped (no sorting) | 6 |
| Low | Minor disruption to product line .100% of product may have to be reworked . item operable | 5 |
| Very low | Minor disruption to production line. Product may have to be sorted and a portion reworked. Minor adjustment do not conform. Defect noticed by customer. | 4 |
| Minor | Minor disruption to production line. A portion of product may have to be reworked on-line, but out of station. Minor adjustments do not conform | 3 |

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| | | |
|---|---|---|
| Very minor | Minor disruption to production line. A portion of product may have to be reworked on-line, but out of station. Minor adjustments do not conform. Defect noticed by discriminating customer. | 2 |
| None | No effect | 1 |

### C. *Ranking For Possible Failure Rates (Occurrence)*

Ranking for occurrence is shown in the table.

**TABLE VRANKING FOR POSSIBLE FAILURE RATE**

| **Possibility of failure** | **Possible failure rate** | **Ranking** |
|---|---|---|
| Very high | >1 in 4<br>1 in 5 | 10<br>9 |
| Moderate | 1 in 7<br>1 in 8 | 8<br>7 |
| Low | 1 in 10<br>1 in 12 | 6<br>5 |
| Very low | 1 in 20<br>1 in 34 | 4<br>3 |
| Remote | 1 in 50<br><1 in 50 | 2<br>1 |

### D. *Ranking of Likelihood of Detection*

Ranking of likely hood of detection is shown in table.

**TABLE VILIKELIHOOD OF DETECTION**

| **Detection** | **Criteria** | **Ranking** |
|---|---|---|
| Absolutely impossible | No known controls available | 10 |
| Very remote | Very remote likelihood current controls will detect failure mode | 9 |
| Remote | Remote like hood current controls will detect failure mode | 8 |
| Very low | Very low likelihood current controls will detect failure mode | 7 |
| Low | Low likelihood current controls will detect failure mode | 6 |
| Moderate | Moderate likelihood current controls will detect failure mode | 5 |
| Moderately high | Moderately high likelihood current controls will detect failure mode | 4 |
| High | High likelihood current controls will detect failure mode | 3 |
| Very high | Very high likelihood current controls will detect failure mode | 2 |
| Almost certain | Current controls almost certain to detect failure mode | 1 |

### E. *FMEA Chart of Automatic plastic welding machine*

FMEA chart for the plastic welding machine is shown in the table VII.

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TABLE VIIFMEA CHART

| No | Process function requirements | Potential failure mode | Potential effect of failure | Recommended action | Actions taken | Severity | Occurrence | Detection | Risk priority number |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Electric supply- Electrical power supply for all sub systems and components.Requred for smooth and regular functioning of whole | Fail to meet the entire process requirement | Internal and external | Repairing and strengthening of electric supply system | Rectified and reinitiated electrical supply by internal source. | 8 | 4 | 1 | 32 |
| 2 | Stripping-stripping of welded blood bag from sheet | Fail to meet the subsequent operation | Internal | Replacement of vacuum cables | Damaged vacuum cable is replaced | 4 | 8 | 5 | 160 |
| 3 | port delivery - Delivering connection ports to the blood bag | fail to meet the subsequent operation | External | Correcting suction pressure of port delivering unit | Suction pressure is corrected | 8 | 5 | 1 | 40 |
| 4 | Current indication- regulating and monitoring of input current | Fail to meet the entire process requirement | Internal and external | Replacement or repair of ammeter | Ammeter replaced | 8 | 4 | 1 | 32 |
| 5 | Cooling water indication- regulation and monitoring of cooling water to sealing unit | Fail to meet the entire process requirement | Internal and external | Repair or replacement | Repaired | 8 | 4 | 1 | 32 |
| 6 | Software- controls and co-ordinates all operations to be performed | Fail to meet the entire process requirement | Internal and external | Ask for online support from the supplier | Error fixed by online support | 9 | 6 | 1 | 54 |
| 7 | Weld RF generator - To deliver high frequency power supply to machine | Fail to meet the entire process requirement | Internal and external | Repair or replacement | Repaired | 9 | 1 | 5 | 45 |
| 8 | Robotic axis out of sync- supply transfer ports to the sheet delivering station | Fail to meet the subsequent operation | Internal | Correcting the alignment | Alignment corrected by external source | 9 | 1 | 9 | 81 |
| 9 | Side seal - used for primary sealing of blood bag | Fail to meet the subsequent operation | Internal | Repair sealing unit | Sealing unit repaired | 8 | 4 | 1 | 32 |
| 10 | Sheet pic up unit -pic up and deliver pic sheets to the welding unit | Fail to meet the subsequent operation | Internal | Check the vacuum pic up pressure and sheet quality | Sheet pic up pressure is corrected | 8 | 4 | 1 | 32 |
| 11 | Sheet holding pin - supports feeded sheets to the machine | Fail to meet the subsequent operation | Internal | Repair | Repaired | 8 | 4 | 1 | 32 |
| 12 | Sensor indication - indicates pressure at each station | fail to meet the entire process requirement | Internal and external | Repair or replacement | Repaired | 8 | 1 | 2 | 16 |
| 13 | Sheet cutting head- system which separates sheet according to its required dimension | fail to meet the subsequent operation | Internal | Repair or replacement | Repaired | 8 | 1 | 2 | 16 |

## F. Risk Priority Numbers

The risk priority numbers of different processes are found out. The RPN of different process are shown in the following bar chart

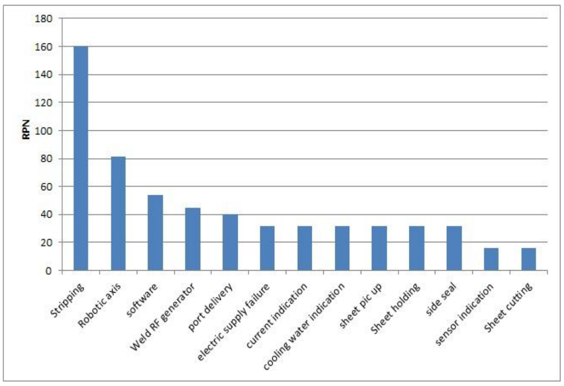


FIG 2- RPN CHART

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## IV. ANALYSIS OF THE RESULTS

Higher value of risk priority number is obtained for stripping process. Detailed component wise reliability analysis should be conducted on the unit to reduce its failure rates. Proper care and maintenance should be given to stripping unit while scheduling preventive maintenance. Training should be given to engineering personals to enable its detection easier. Misalignment of robotic axis has an effect on the sheet delivering process. This process has a Considerable RPN value because of its high severity due to hazardous nature of failure, and detection of the problem is very difficult. Proper training and awareness should be given to operating people and engineering personals which will reduce RPN value. Software errors have seen high RPN value, due to its number of occurrence and high severity. To minimize these, online support for software errors should ensure from its supplier.

## VI. CONCLUSION

The present work deals with the FMEA study of an Automatic plastic welding machine. The basic manufacturing process is studied and failure modes are identified. Potential effects of failures are evaluated with their severity value and then the causes and their prevention are calculated along with their occurrence value .The Detection value was assigned to the failure mode, and finally the R.P.N value is calculated. FMEA analysis helps in reducing down time of the machine by improving its reliability.

## REFERENCES

[1] SEGISMUNDO, A.; MIGUEL, PAC. Failure mode and effects analysis (FMEA) in the context of risk management in new product development: A case study in an automotive company. International Journal of Quality and Reliability Management.

[2] Narayanagounder, S. and Gurusami, K.2009, "A New Approach for Prioritization of Failure Modes in Design FMEA using ANOVA", Journal of World Academy of Science (Engineering and Technology), Vol. 49, 2009, pp. 524-531.

[3] B.G. Dale and P. Shaw, "Failure Mode and Effects Analysis in the U.K. Motor Industry: A State-of-Art Study," Quality and Reliability Engineering International, Vol. 6, 184, 1990.

[4] Rhee, S., and K. Ishii .2003, "Life Cost-Based FMEA Using Empirical Data", Proceedings of the ASME 2003 DETC/CIE Conference, Chicago, Illinois, pp. 48-50.

[5] Hughes, N., Chou, E., Price, C. J. and Lee, M. 1999, "Automating mechanical FMEA using functional models", Proceedings of the Twelfth International Florida AI Research Society Conference, (AAAI Press, Menlo, CA), pp. 394–398.

[6] A ArunChauhan,Raj Kamal Malik, Gaurav Sharma, MukeshVerma 2011"Performance Evaluation of Casting Industry by FMEA 'A Case Study'" International Journal of Mechanical Engineering Applications Research.

[7] Arvanitoyannis, I. S. and Varzakas, T. H. 2009. "Application of failure mode and effect analysis (FMEA) and cause and effect analysis for industrial processing of common octopus (Octopus vulgaris) – Part II", International Journal of Food Science and Technology, Volume 44, Issue 1, pp. 79-92.

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