INTEGRATION OF POKA YOKE INTO PROCESS FAILURE MODE AND EFFECT ANALYSIS: A CASE STUDY

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ABSTRACT
The Failure Mode and Effect Analysis (FMEA) is a one of the requirements which was required by the Automotive Industries Action Group (AIAG) to all the automotive suppliers and manufacturers worldwide through the TS16949 Quality System. There were a lot of discrepancies detected on implementing the FMEA which directly related to the user experiences and knowledge. The discrepancies cause the FMEA not meeting the objectives of it. Conceptually, Poka Yoke is able to fit into the Process FMEA. Failure Mode and Effect Analysis (FMEA) helps predict and prevent problems through proper control or detection methods. Mistake proofing emphasizes detection and correction of mistakes before they become defects. Poka Yoke helps people and processes work correctly the first time. It refers to techniques that make mistakes impossible to commit. These techniques eliminate defects from products and processes as well as substantially improve their quality and reliability. Poka Yoke can be considered an extension of FMEA. The use of simple Poka Yoke ideas and methods in product and process design eliminates both human and mechanical errors. Ultimately, both FMEA and Poka Yoke methodologies result in zero defects and benefit either the end or the next-in-line customer. The first concept of Poka Yoke emphasizes elimination of the cause or occurrence of the error that creates the defects by concentrating on the cause of the error in the process. The defect is prevented by stopping the line or the machine when the root cause of the defect is triggered or detected. The second concept of Poka Yoke focuses on the effectiveness of the detection system. The foolproof detection system eliminates the defect or detects the error that causes defects. The implementation of the Poka Yoke concept in a foolproof detection system eliminates the possibility that error or defects will slip through the process and reach the customer.

Keywords: Poka Yoke, Failure Modes and Effects Analysis (FMEA) and the Integration of the Poka Yoke into the PFME

1. INTRODUCTION
Quality is one of the most important aspects or requirements in the manufacturing industry today. Mistakes in processes or in products result in considerable damages or defects that greatly affect the organization, especially in terms of cost or expenses. Manufacturers may lose their credibility, customers and even their business itself. As such, they must always look for more robust processes that result in higher productivity, thus increasing the profitability of the company. This constant drive to improve processes is also the reason various manufacturing concepts are introduced and upgraded time to time.

Failure Mode and Effects Analysis (FMEA) is a technique of identifying potential problems in the design or process by examining the effects of lower-level failures. Recommended actions or compensatory provisions are made to reduce the likelihood of the occurrence of the problem and to mitigate its consequent risks should the problem occur.

In manufacturing industries, the human element, which is one of the contributors to defects and loss of productivity, cannot always be eliminated. Thus,
managers seek ways of reducing human intervention in manufacturing processes, such as conversion of processes into automatic processes and the use of automatons instead of humans. Humans are liable to commit mistakes, whereas machines are designed to fulfill expectations.

Mistakes are inevitable, especially in processes that involve human intervention. Defects, which are entirely avoidable, occur when a mistake is allowed to reach a customer. Poka Yoke aims to guide the process such that mistakes are prevented or immediately detected and corrected (Shingo, 1986).

FMEA identifies solutions to potential problems. However, a given solution does not guarantee zero-problem results unless the given solution is oriented toward error elimination (foolproof or Poka Yoke). As such, the integration of the concept of Poka yoke in FMEA promises to provide a very significant effect and result in a more robust problem analysis and solution processes.

In actual practice, several problems have been observed in the implementation of FMEA. Previous studies have also identified similar concerns or problems that were traced to a discrepancy in the implementation of FMEA. Many irregularities have been detected, which have caused much confusion and ineffectiveness, thereby defeating the purpose of FMEA, which is supposed to improve product and process quality, reliability and customer satisfaction (Teng and Ho, 1996). Based on the author’s experience, despite the implementation of FMEA, especially Process FMEA (PFMEA), the objectives cited above are not met because of the lack of understanding and knowledge of FMEA, especially on the part of fresh graduate engineers and beginners.

2. INTEGRATION ELEMENTS

2.1. FMEA Irregularities

FMEA focuses on prioritizing critical failures to improve the safety, reliability and quality of products and processes. It prioritizes the potential failure mode of determining a Risk Priority Number (RPN) to perform corrective actions. A numerical scale that ranges from 1 to 10 is used to rank the Severity (S) of the failure, the likelihood of the occurrence of the failure mode (O) and the probability of detecting a failure (D). Higher numerical values for S and O indicate more serious consequences associated with the failure and a higher probability of the failure occurring, respectively. A higher numerical value for D indicates the higher ineffectiveness in detecting the failure. Failure modes with higher RPN are given higher priority than those with lower RPN. RPN is calculated by multiplying S, O and D. This calculation method mathematically determines the risk level of a process.

The risk priority rank technique, which utilizes a ranking scale from 1 to 1000, was recently introduced to represent the increasing risk of various S, O and D combinations (Sankar and Prabhu, 2001). Evidential reasoning, which uses fuzzy rules and grey relation theory to rank the risks of different failure modes, was developed to overcome the disadvantages of the traditional FMEA approach (Pillay and Wang, 2003). A modified FMEA that employs a reliability and cost-based approach was also proposed to overcome the disadvantages of traditional FMEA (Arunachalam and Jegadheesan, 2006). Moreover, research conducted on the FMEA implementation of selected automotive manufacturers identified seven irregularities associated with the traditional approach: Knowledge, training, failure history, teamwork and synergy between supplier and manufacturer, time of method completion and control (Estorilio and Posso, 2010).

Sometimes, an action is taken based on RPN, but without consideration of the effectiveness of the action or the type of process control to eliminate the problem because of lack of understanding or improper guiding mechanism. This widely accepted FMEA approach has its own disadvantages. One disadvantage is the variety of different risk scenarios represented by various S, O and D values, which results in different RPN values. FMEA does not allow one to distinguish among different risk implications. Another disadvantage is the FMEA team’s use of the average S, O and D values despite or precisely because of a difference of opinions, which may generate an RPN that is identical to the others, but which does not consider or articulate risk implications.

Arffin (2012) has used in the early stage of analysis before the new framework of Reliability Centered Maintenance (RCM) is proposed. The purpose of FMEA the test is to measure which is the most appropriate maintenance strategy to be applied to the particular equipment. Based on the result gained, they established a guideline to select a proper score for the variables and classified the equipments into classes. The implemented RCM significantly helps to improve the preventive maintenance schedule in production line (Arffin, 2012).

In most cases, the corrective action is not oriented toward elimination of the reject and instead depends on
experience. No proper rule or guidelines exist in a proper and effective action plan. Although the traditional outline is clearly identified, the directive or correct direction always confuses the user. Such disadvantages have been observed in the actual implementation of PFMEA in various companies and organizations in Malaysia.

FMEA focuses on the occurrence and detection of problems and the controls and actions that were taken. The last part measures the effectiveness of the new Poka Yoke in helping PFMEEA eliminate or reduce rejects internally and at the customer’s end. This study explores the various aspects and applications of PFMEA and Poka Yoke and their approach to an effect on various organizational manufacturing performance measures, such as efficiency and productivity, with the aim of determining the possibilities of integrating the two concepts for enhanced quality performance.

The success of the implementation of PFMEA depends greatly on the experience of the implementer. The implementation of the FMEA is laborious, time consuming and expensive, especially when the results are unsatisfactory because of inconsistencies in descriptions of the functions and failures of the object being analyzed (Tumer et al., 2003). This study was conducted to seek ways to improve FMEA as an effective tool.

2.2. Philosophy and Steps of Mistake Proofing

Shingo (1986) from Japan introduced the idea of Poka Yoke. The term “Poka Yoke” comes from the Japanese words “poka” (inadvertent mistake) and “yoke” (prevent). The underlying philosophy of mistake proofing explicitly recognizes that people forget and make errors, that machines and processes fail and make errors and that the use of simple mistake proofing ideas and methods in product and process design can eliminate both human and mechanical errors. Grounded in common sense, mistake proofing is very easy to understand. Its essence is to design both the product and processes such that mistakes are either impossible to make or are at least easy to detect and correct. At the heart of mistake proofing is attentiveness to every activity in the process and the placing of appropriate checks and problem prevention facilitators at every step of the process. In this view, mistake proofing may be seen as simply a matter of constant data feedback, similar to that required in maintaining one’s balance when riding a bicycle.

In its simplest form, mistake proofing is achieved through three sequential steps (Oakland, 2000). The first philosophy, which is related to the likelihood of people to forget and make errors, is to identify all possible errors that may still occur despite preventive actions. At each step in the process, one must simply ask, “What possible human error or equipment malfunction might occur in this step?” The next philosophy, which is related to the likelihood of machines to fail and make errors, is to determine a way of detecting an error either when it is taking place or is about to take place. A guide pin may be added to prevent the incorrectly installed part sited when people forget as an action. Mistake proofing holds that one must not only rely on people to identify their own errors all the time. Last but not the least, the philosophy related to methods in product and process design is to identify and select the specific action to be taken when an error is detected to eliminate both human and mechanical errors. These steps are the three basic actions at the core of mistake proofing. In order of preference, they include control (i.e., an action that self-correction, the process error, such as a spellchecker/corrector), shutdown (i.e., a procedure that blocks or shuts down the process when an error occurs, such as lockout switches) and warning (i.e., a mechanism that alerts the person involved that something is going wrong, such as an aircraft pilot who issues a verbal warning to “PULL UP, PULL UP” in the event of altitude problems mid-flight). The primary weakness of warnings is that they are frequently ignored, especially if they occur too frequently.

Controls and shutdowns are generally preferred over simple warnings. Controls that use electronic devices are the best among all types of controls. Anything that does not involve human intervention is the best solution because the machine or equipment automatically functions according to what it was designed or programmed to do.

FMEA is a systematic approach of identifying all the potential risks or causes. It is commonly practiced and enforced in automotive industries and their suppliers. FMEA and Poka Yoke have the same orientations: To ensure good controls and prevent defects in processes, which are part of the Six Sigma program. Both approaches also prevent or eliminate errors. However, FMEA results in more irregularities in its implementation.

2.3. Prosperous of Integration

The successful of integration that evolve lean was carried out but the integration between poka yoke and process FMEA is a novelty approach (Hu et al., 2000) have done the integration between lean production and
group technology. They found out that the integration gives lots of benefits into production process, i.e.: Shorten production cycles, reduce particular checking process, lower inventory, improve product quality and cut product cost. They also mentioned that the integration must abide by several principles in order to get the whole benefit from his company.

The integration of FMEA was done by Arffin (2012) were they emphasize the Reliability Centered Maintenance (RCM) to improve the critical analysis in FMEA. The FMEA is used in order to identify the critical maintenance practice and yet measure which is the most appropriate maintenance strategy to be applied to the particular equipment. The RCM has been applied to study and perform a decision making process in which maintenance strategy needs to be selected depends on the criticality of the equipment to the governance. Then the RCM practice has been implemented directly in order to improve maintenance scheduling and maintenance strategy in their production line (Arffin, 2012). A significant benefits is gained when the number of checklists used is reduced which resulted in substantial reduction of operator’s workload and avoided maintenance personnel from committing fraud.

The integration evolves in lean tools been done by (Xinyu and Jian, 2009) where he tried to integrate the methods of value stream and material flow, simultaneously identifying and monitoring costs and pollution problems. The integration is possible and feasible and very conducive to reducing production costs and simultaneously achieving reduction of material and friendly-environment (Xinyu and Jian, 2009).

The integration of Poka Yoke into process FMEA is a novelty approach in order to guide the user in more effectively. The 2 concepts of Poka Yoke were able to be integrated conceptually into the Process FMEA which falls under Occurrence and Detection. The new model and guidelines of the Process FMEA which consists of Poka-Yoke concepts being developed is able to guide the user effectively. The new model had been implemented into the real working environment and validates the effectiveness. The results shown that it is effective to reduce the rejects as well as customer’s feedback.

3. PREIMPLEMENTING THE INTEGRATION CONCEPT

Lean process focuses on cost reduction by eliminating non-value added activities, which are labelled as waste in every organization that either produces products or provides services (Puvanasvaran et al., 2008). Given this purpose, several actions are taken to ensure that integration concepts were emphasized on poka yoke and FMEA are compatible with and can be adapted to the production lines. The efforts of the management in the recent times have been on enhancing productivity through efficient methods of production that emphasizes on the elimination of unnecessary procedures and processes that add to production costs (Puvanasvaran et al., 2011).

3.1. Performing the Walkthrough

The new FMEA spreadsheet was generated based on the Poka Yoke concept. The flow of FMEA implementation was conducted. All four main processes and their steps were recorded in the spreadsheet. Every process input for each process step was reviewed by identifying every potential failure and its effect on the process output and customers.

The severity of each potential effect was then categorized based on the severity category. The severity of each potential effect was categorized based on the impact or the seriousness of the problem to the user or customer and the manufacturer. The occurrence of the potential failures was recorded. The occurrence factors depended greatly on the history of the occurrences.

Based on the occurrence table, if the potential failure was prevented through the help of the Poka Yoke concept, then it was automatically ranked “1.” The rest followed the specified classification in the occurrence table. The detection ranking greatly depended on the effectiveness of the detection of the process input or output. The highest detection that clearly identified and segregated the defects or rejects was given the rank of “1.” In this definition, a foolproof detection process is correlated with a Poka Yoke capability. The detection ranking is referred to as the table of detection category. Based on the detection, classification, the detection ranking, filled the spreadsheet following the ranking.

For both occurrence and detection, the Poka Yoke concept was integrated such that the user was well guided whether the concepts were implemented or not. An additional column for the concepts was included in the spreadsheet. Each column of the spreadsheet clearly defined the items that had to be filled up for the convenience of the users, especially the new engineers.

3.2. Process Step Identification

The four major processes consisted of a tape unwinding process, which was initiated upon loading of the raw material and which detailed how the
materials were employed in the next process. All processes from the loading of the raw material up to the indexing of the raw material in the heater (the release of material) were captured. Similar activities were performed to identify all the steps in the heating, forming and punching processes. The flow was captured and reviewed by the FMEA team to ensure that no step was overlooked and that every single process or step of any of the processes was covered.

3.3. Brainstorming

The FMEA team conducted a brainstorming session to identify all the process input and output so that the potential failures of each process input could be clearly identified. The process input included all the ingredients that ensured that the process was running according to the required flow. The process output consisted of the expected outcome from the process input or the expected results of the process.

3.4. Involved Process

In the unwinding process, the material was loaded into the unwinding shaft and motor. Motor activation depended on the signal given by the top and bottom sensors. The top sensor activated the motor to turn and release the material. The bottom sensor activated the motor to stop, which prevented the material from being released. The process was repeated until the material was consumed. The whole process of releasing the raw material is called the unwinding process (releasing process), the output of which is the best material that was released. The team identified several problems in this process based on the process input. The failure of the process input was then recorded in the new format of the Poka Yoke FMEA.

The purpose of the heating process is to heat the material (plastic sheet) to soften it before it is indexed in the forming process, which is the next process. This process is very critical as it involves softening the material to ensure that it meets the required condition. Otherwise, it will impact the forming results such that they are either undersized or overheated. The heating process has only four steps: Heater block, heater block move (clamp), heating of the material (contact) and retraction of the heater block. The team members identified all the process input and the output were identified by examining the mechanism involved in the process. Each process input was logged in the new Poka Yoke FMEA to identify the possible failures and the controls needed for each failure.

A molding mechanism was used to facilitate the forming process. The bottom mold always moved up and down, while the top mold remained fixed (static). The softened material was moved into the mold and was then clamped by the bottom mold. Then, the air started to be released from the top mold. The air pressure forced the soft material to follow the shape of the mold. If the material was not soft enough, then the forming was affected (i.e., it could not form the required shape). The up-and-down motion of the bottom mold was controlled by the mold arm, which in turn was controlled by the cam. The displacement of the mold depended on the cam profile. The forming process consisted of only three stages: Mold clamp and hold, air blow (to form) and mold release (to retract). Based on this three-step process, all process input that covered all the mechanism involved a teach of the process step were identified. The mold clamp and the mold release had the same process input because both used the same mechanism to accomplish the process.

The punching mechanism consisted of top and bottom punch units. The punching pins were secured at the top punch, which was driven by the punch arm and the cam to move up and down through the main motor. The bottom punch consisted of a bottom die that had a hole through which the pin could penetrate.

When the tape was sheared through by the pin, the pocket and sprocket holes were created. The tape was then indexed into the next process. The punched-out residue dropped into the punch-out container. When the punch container was full after a certain period of time, it had to be removed and emptied. All these activities were manually performed by the operator. The process consisted of three steps: The top punch moving down, the shearing of the hole and the retraction of the top punch. Each step had process input and output.

3.5. Filling the New Poka Yoke PFMEA

Based on Fig. 1, the process step created by the process walkthrough, the PFMEA was generated through the new format of the Poka Yoke PFMEA. This time, with the use of the new spreadsheet, feedback was gathered to understand the responses of the FMEA team members to the implementation of the Poka Yoke FMEA. The following question was given: Did the new spreadsheet help and direct the engineers toward the proper control and action plan?

The values of the occurrence and the detection were automatically ranked as “1” when the prevention and detection met the Poka Yoke concept requirements. In the occurrence, the Poka Yoke Concept 1, which required that the line/machine should stop when the cause of the mistake was identified.
Focusing on the cause meant that the defect or the mistake did not occur. Given this capability, the occurrence was almost zero or below rank 1 of the occurrence.

The detection capability depended on how well the system detected the mistake or the defects and segregated the defects clearly without causing any leakage to the user or customer. If the system had such capability, then it was considered a foolproof detection system that fell below rank 1.

When either one of that met the requirements of Poka Yoke concept, no action was generally needed for the particular process. Such process is then considered foolproof. However, among the Poka Yoke concepts, the best priority or direction should be Poka Yoke Concept 1, because it totally eliminates the creation of defects by eliminating the root causes of the mistake. However, even though the detection is foolproof, continuous improvement of the Poka Yoke concept is still recommended.

4. ACHIEVED IMPROVEMENTS

The brainstorm session was performed to identify the necessary action for each potential cause that created the failures or defects. Based on the new format, the Poka Yoke solution was improvement to ensure the effectiveness of the action.

4.2. Internal Rejection Cost per Month from the Four Processes

Figure 2 shows the percentage of rejection in the four processes described earlier. Table 1 shows the scrap cost from the four main processes. As Table 1 shows, scrap cost was significantly reduced from the average, that is, from about RM200K to about RM100K, which is almost a 50% reduction. The number of reels is not a good reference to benchmark the improvement because it depends on the production output schedule or planning. However, the percentage of the rejection against the output indicated the level of improvement. Figure 2 show that the four main processes resulted in approximately 50% improvement in the reduction of rejects between March and October. This improvement can be seen only in terms of the cost of the rejected parts. However, other improvements are not reflected in the computation, including improvements in productivity, cost of attending to the rejects and resources and the cost that results from the rejects.

4.3. Internal Detection

The internal or in-process rejection rate was recorded starting in March 2012. The improvement program was
performed following the new FMEA format. Efforts were directed toward a foolproof solution that did not incur high cost. The action was conducted gradually according to the plan and timeline given by the team members. Based on the improvement of the action and the direction provided by the new FMEA, the rejects were reduced as recorded in the in-process line rejection, as shown in Fig. 2.

Figure 3-6 shows that the improvements were very significant even though they did not achieve 100% eliminations. The reason for this finding is that some of the actions were not foolproof and could not really eliminate the error or rejects. Figure 3 show that the heating process improvement provided very significant results. The rejects were reduced from 0.14 to 0.06%.

The data indicate an overall reduction in the rejects. The data for March 12 to April 12 may be used as a benchmark before the improvement was obtained. A slight improvement was observed beginning May 12, after which greater improvements were seen in the succeeding months. Based on the reject percentage versus the output, the total improvement was more than 50% from March 12 or April 12, which suggests that if the directions are correct, then the results are likely to be very encouraging.

**Fig. 2.** The percentage of rejection from the 4 processes

**Fig. 3.** The trend of rejection from unwind process start from Mar till Oct 2012
Figure 3 shows the trend of the rejects during the unwinding process. The rejects were reduced from 0.18% on March 12 to 0.08% on October 12. The improvement was more than 50% of the total unwinding rejects. The improvement was caused solely by the foolproof solution. However, given that the new FMEA was able to facilitate a foolproof process improvement, the results were very promising. The correct and foolproof solution always makes the results more significant and effective. A simple but effective action yields highly significant results.

Figure 4 shows that among all the processes, the heating process had the most significant improvement. The rejects were reduced to almost 70% based on the decrease in the percentage of rejects from 0.14 to 0.06%. A slight increase in the number of rejects occurred on August 12 because of improper setting of the detection system, which caused a slight over-rejection. Specifically, the over-rejection was the result of the wearing off of the heater Teflon coating, which increased the heater mark and the shining surface.
The problem was minimized after fine tuning and recoating the heater block surface. The observation and testing on the heating area showed many potential failures that can be controlled by foolproof concepts. The sensors and the machine detection system were built to ensure that the failures could be immediately stopped. This design led to a more reliable and robust process in terms of handling defects or mistakes.

Rejects during the forming process were reduced by about 50% based on the data recorded beginning March 12. The trend in Fig. 5 shows that the reduction gradually occurred for about five months. Generally, the improvement was especially related to the undersized/underformed/flat tape issue. As discussed earlier, this improvement was directly due to the elimination of the Teflon tape in the heater and its replacement with a Teflon-coated heater. This area improved very significantly when the detection was improved through effective segregation of defects by linking the defect to the auto cut, which focused more on the flat tape issue. The team still needs to work on the elimination of the cause of flat tape.

As Fig. 6 shows, the amount of rejects gradually decreased from 0.85 to 0.39% on October 12. The foolproof solution was not able to perform some actions because of cost constraints, among other reasons. Generally, further improvement can still be achieved, especially on the punch jamming issue. The foolproof solution to eliminating the cause of punch jamming resulted in a tremendous reduction from 152 cases on March 12 to 52 cases on October 12. This reduction is a very good example of the elimination of the cause of error of defects or is considered a foolproof preventive improvement action.

5. CONCLUSION

The current implementation of the FMEA reveals many discrepancies or variations in its implementation as a result of lack of training. The training records indicate that the majority of the engineers do not undergo proper training in the implementation of FMEA. Some have minimal experience and basic knowledge but do not have a thorough understanding of the implementation.
Improper guidance is another cause of the discrepancies. Around 60% of the engineers are fresh graduates who were not properly trained. The only form of guidance they obtain from senior engineers focuses more on the method rather than correct implementation. The objectives and goals of the FMEA are also not clearly communicated to new engineers. Discrepancies are also caused by the practice of simply implementing the FMEA for the sake of complying with requirements rather than improving the processes. For example, the company CP supplies semiconductors, which requires compliance with TS16949. As such, the PFMEA was implemented just for the sake of fulfilling customers’ request.

The integration of the Poka Yoke concept definitely helped to guide the action of engineers in the case of every potential failure that might be generated from the process input. It is become a barrier to fresh engineer to understand the FMEA concept because they tend to not to understand clearly. Futhermore the training process is required in order to them to optimize the PFMEA.

Proper implementation of Poka Yoke PFMEA was able to reduce line defects and customers’ complaints as well as improve productivity, which ultimately translated into cost savings. Every reject is a cost and every cost contains profit and affects the future of the company. Some of the improvements that were undertaken did not require high expenses.

Future studies should consider how the Poka Yoke FMEA can be integrated with the lean system so that all improvement activities will be included in the lean concept. This approach will greatly impact quality improvement and process optimization and ultimately help to reduce cost, because the lean system is ultimately oriented toward improvement. The issues of waste control, optimization, push-pull concepts, 5S and others must also be oriented toward elimination of rejects and optimization of the overall manufacturing cost. Given that the lean concept is directly linked with the Toyota Production System, it may also be said to have a direct link with the FMEA, which is implemented in the automotive industry. The possible failure mode may also help to identify the cause related to lean manufacturing, such as the cause of the disorder of the line (5S concept).

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7. REFERENCES


Science Publications

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