Application of Risk Management in Condom Manufacturing

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Abstract: A Failure Mode & Effects Analysis is a step-by-step approach for evaluate a system, design and services for identifying all possible ways in which failures can occur. The main purpose of this project is to identify and map the internal disturbances of a contraceptive industry. The central objective will be to identify the most critical risks within supply and production processes and then find strategies of how control and manage disturbances when, or preferably before, they occur. In recent years, contraceptive companies have gained significant market share in the markets of both developed and developing countries. But defects in contraceptives are crucial in the case of human healthcare, where it retards to achieve industrial benchmarking as well. Because of this, manufacturers try to improve and increase both quality and productivity continuously. By this project, major risks in the condom manufacturing are identified and proposed a new approach for prioritize failure modes and overcome the limitations of the FMEA technique.

Keywords: FMEA = Failure Mode and Effects Analysis, RPN = Risk priority number

1. Introduction

FMEA is a analysis tool allowing engineers to define, identify and evaluate known or potential failure, problems, errors and so on from the system. FMEA was first used in 1960s for the Apollo Missions by NASA to record and assess design related risks. Since then, FMEA has extensively used as a powerful tool for safety and reliability of products, industries particularly, nuclear, aerospace, automotive, chemical, mechanical, medical technologies and electronics.

It is a structured approach to
• Identify the way in which a design / process can fail to meet critical customer requirements.
• Estimating the risk of specific causes with regard to the failures.
• Evaluating the Current control plan for preventing the failures from occurring. Prioritizing the actions that should be taken to improve the design/process.

By FMEA implementation we can track product failure modes. Their causes and effects which provides valuable knowledge about future process design. By this methodology we can eliminate the failure modes in the order of quantitatively RPN. FMEA has been a well-accepted Risk analysis method than alternatives. But it suffers drawbacks in the risk prioritization. The most critical disadvantage of the FMEA is that various sets of S, O and D may produce an identical value. However, the risk implication may be totally different. This project propose a modified prioritization methodology for risk analysis for overcoming these shortcomings. By this project, the major risks in the firm can be identified, and find most critical failure modes (need more attention) leads major defects.

2. Method and Procedure

In this paper FMEA method has been applied to evaluate various in the condom manufacturing industry. Most critical risk of the company are evaluated and defined. For calculating the risk Prioritization in FMEA method.

Risks have been evaluated by set of Questionnaire respond from SME. This phase involves creating the questionnaire for each risk factor, the main aim of our problem is risk Prioritization and various risk factors. After creating the questionnaire, the next step is measuring and collecting the data, the risk factors (RF) are identified through literature review and in consultation with expert opinions.

Risks have been evaluated in three components which are multiplied to produce a Risk Priority Number (RPN): 1) Severity (S): Severity is described on a 10-point scale where 10 is highest. 2) Occurrence (O): Occurrence is described on a 10-point scale where 10 is highest. 3) Detection (D): Detection is described on a 10-point scale where 10 is highest. RPN = S × O × D.

Examples for the Risk Analysis

Failure mode - Variation of dipping tank latex temperature
Cause - Breakdown of mould cooling fan
Severity, S = 3 (High)
Occurrence, O = 2 (Average likelihood of occurrence)
Detection = 1 (Absolute uncertainty)

Risk Priority Number
RPN = S × O × D
= 4 × 3 × 2
= 24

Failure Mode – Contamination on dipping tank latex temperature
Cause – Failure in hot water pump
Severity, S = 5
Occurrence, O = 4
Detection = 2
RPN = 5 × 4 × 2 = 40
corresponding to the failure mode 'ai', where
Let 'Lij' denote the ranks of 'S', 'O' and 'D' respectively
with the same RPN
A general method with 'n' failure mode is discussed below
used to prioritize failure modes
identical value of RPN. The Risk Priority Code (RPC) is
possibility of considering different failure modes with
The proposed failure mode prioritization method provides
it's ability to prioritize failure modes by

Methodology
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possibility of considering different failure modes with
identical value of RPN. The Risk Priority Code (RPC) is
used to prioritize failure modes.

A general method with ‘n’ failure mode is discussed below
with the same RPN.

Let ‘Lij’ denote the ranks of ‘S’, ‘O’ and ‘D’ respectively

corresponding to the failure mode ‘ai’, where i = 1, 2, 3 … n
and j = 1, 2, 3. Where, 1 ≤ Lij ≤ 10 for all i, j.

### Table 1: Risk Evaluations on the basis of SME (Subject
Matter Expert) Inputs

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Risk</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN = (SxOxD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mould collision in okomoto Machines</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>Low level of anti sticker tank</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>3</td>
<td>Low sufficient silica content in slurry</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>45</td>
</tr>
<tr>
<td>4</td>
<td>Improper slurry jet</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>Variation in compounded latex test results</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>Variation of leeching tank temperature</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>90</td>
</tr>
<tr>
<td>7</td>
<td>Low % of ammonia in the leaching tank</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>30</td>
</tr>
<tr>
<td>8</td>
<td>Improper functioning of de humidifier</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>9</td>
<td>Biological contamination is on</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>120</td>
</tr>
<tr>
<td>10</td>
<td>Variation of dipping tank latex</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>11</td>
<td>Contamination of dipping tank latex</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>120</td>
</tr>
<tr>
<td>12</td>
<td>Latex accumulation of heater chamber in RRT machines</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>90</td>
</tr>
<tr>
<td>13</td>
<td>Variation hot air blower speed</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>14</td>
<td>Clogging of condoms in dehydrator</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>120</td>
</tr>
<tr>
<td>15</td>
<td>Glass mould falling from chain in dipping area</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>48</td>
</tr>
<tr>
<td>16</td>
<td>Presence of coagulum in dipping tank</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>17</td>
<td>Overflow of slurry from slurry pit</td>
<td>6</td>
<td>2</td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>18</td>
<td>Variation in speed of dehydrator</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>45</td>
</tr>
<tr>
<td>19</td>
<td>Variation in soap tank solution temperature</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>32</td>
</tr>
<tr>
<td>20</td>
<td>Variation in dipping tank level</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>21</td>
<td>Hole in 25 mm from bead</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>120</td>
</tr>
<tr>
<td>22</td>
<td>Improper edge rolling setting</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>23</td>
<td>Level of ammonia in leaching tank falling below bead</td>
<td>4</td>
<td>2</td>
<td>6</td>
<td>48</td>
</tr>
<tr>
<td>24</td>
<td>Blockage in a condom carry pipe between stripping to Dehydrator</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>25</td>
<td>Sharp deposit in dehydrator</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>90</td>
</tr>
<tr>
<td>26</td>
<td>Low air pressure from carry fan</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>27</td>
<td>Variation of speed of vulcanizing mesh barrel</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>28</td>
<td>Vulcanizing barrel getting stuck</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>29</td>
<td>Variation in vulcanizing temperature</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>30</td>
<td>Variation in quenching time</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>31</td>
<td>Foam or bubbles in dipping latex of RRT machines</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>32</td>
<td>Quality variations in latex from different suppliers(a2)</td>
<td>2</td>
<td>5</td>
<td>6</td>
<td>60</td>
</tr>
</tbody>
</table>

Prioritization method is a three step procedure

- Critical Failure Mode (CFM) Index
CFM index I(a) = min {max (L11, L12… Lni), max (L12,L22…Ln2), max (L13, L23… Ln3)}

- Risk Priority Code (RPC)
RPC (ai) = N (ai)
Where, N(ai) be the number of places, in the row corresponding to ‘ai’ for which Lij> I(a).

- Critical Failure Mode (CFM)
CFM (a) = failure mode corresponding to max {N (ai)} If there is a tie situation, consider the set of all ai’s for which N (ai) are equal, for such ai’s we define;
T (ai) = max { Li1 – Lk1, Li2 – Lk2 , Li3– Lk3 }

- Critical Failure Mode (CFM)
CFM (a) = failure mode corresponding to max {T (ai)}

Examples

Case 1
Consider two failure modes with RPN is 60

Table 2 case 1
Critical Failure Mode (CFM) Index,
I(a) = min{max(5,2),max(4,5),max(3,6)}= min {5, 5, 6} = 5

Calculate RPC (ai) from each failure mode
N(a1) = 0       N(a2) = 1

In this case most critical failure mode is a2 and the next level is a1

Case 2
Three failure modes a1, a2, a3, has same RPN

### Table 2: Case 2

<table>
<thead>
<tr>
<th>Risk</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN</th>
</tr>
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<tbody>
<tr>
<td>Contamination of dipping tank latex</td>
<td>6</td>
<td>5</td>
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3. Modified risk prioritization method

The most critical disadvantage of the FMEA is that various
sets of S, O and D may produce an identical value. However, the
risk implication may be totally different.

The proposed failure mode prioritization method provides
possibility of considering different failure modes with
identical value of RPN. The Risk Priority Code (RPC) is
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A general method with ‘n’ failure mode is discussed below
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Let ‘Lij’ denote the ranks of ‘S’, ‘O’ and ‘D’ respectively
corresponding to the failure mode ‘ai’, where i = 1, 2, 3 … n
and j = 1, 2, 3. Where, 1 ≤ Lij ≤ 10 for all i, j.
4. Findings and Recommendations

Plant study is conducted and major risks occurred in condom manufacturing are identified by questionnaire to workers and severity of each failure mode according to the respective effect on the process and likelihood of each failure occurred are found out and listed approach to detect the failures and evaluated the ability of the system to detect failures founded out the Risk Priority Number by assign the rating of severity, occurrence and detection.

The unacceptable risks occurred in the plant are

- Quality variation in different suppliers
  Suggestive actions – Blending of latex from different suppliers
  To establish argument for blending latex from different suppliers by recent months.
  Regular checking and clarification of dipping tank latex twice or thrice in a month.
- Variation in vulcanization temperature
  Suggestive actions - Cross checked inlet steam pressure
  Ensure proper functioning hot air blower and verified blower rpm
- Hole in 25 mm from bead is produced due to improper mould cleaning
  Suggestive action – Ensure sufficient level in soap tank during acid cleaning of mould
  To introduce air jet cleaning in the cooling chamber
- Human interference in highly precision works
  Suggestive actions – The complex actions are done by using sensors like arduino, plc or timer for the restriction of human interventions
- Biological Contamination on
  Suggestive actions – Ensuring the workers wored mask, caps etc during working.

By using these above risk management techniques we can reduce defects and improve the process performance and profit of the firm.

5. Conclusion

Defects in contraceptives are crucial in the case of human healthcare, where it retards to achieve industrial benchmarking as well. Risk assessment and risk analysis of technical systems can be defined as a set of systematic methods to Identify hazards or Quantify risks tools. By applying risk management techniques in the plant many kinds of risks and its effects are identified. Found out the risk priority number and Prioritized major failure modes occurred in the plant. Prioritized the major risk in condom manufacturing. The possible effects produced by these defects are also investigated. By using risk management techniques major defects in condom manufacturing can be reduced and profit of the firm can be increased. 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. According to the proposed actions in this project to prevent or reduce failure, expect this is an area for future research in analysis, examination and finally future development. Using such methods can result saving money and time. The high efficiency will not be possible except through the prioritization of defects, based on reliable scientific data, so that corrective actions are taken to be as competent and efficient planning.

This paper shows the new method to prioritize failure modes and how it can improve the evaluation of risk priority number. The case study presented in this paper resolves the limitations of traditional FMEA technique. If two or more failure modes have the same RPN, it is possible to prioritize the failure modes with the help of Risk Priority Code (RPC).

References