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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 eliminate 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 10is 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 10is 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 $= S\times O\times D$
$= 4\times 3\times 2$
$= 24$
Failure Mode – Contamination on dipping tank latex temperature
Cause – Failure in hot water pump
Severity, S= 5
Occurrence, O= 4
Detection = 2
RPN $= 5\times 4\times 2 = 40$

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

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

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.

Methodology

The proposed failure mode prioritization method provides 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.

Prioritization method is a three step procedure

- Critical Failure Mode (CFM) Index
  CFM index I(a) = min {max (L11, L21… Ln1), 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).

- CriticalFailure 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 }
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

Risk	S	O	D	RPN
Contamination of dipping tank latex	6	5	3	90
Latex accumulation of heater chamber RRT machines	5	6	3	90
Sharp deposit in dehydrator	6	3	5	90

- Critical Failure Mode (CFM) Index ,
  I(a) = min{max(6,5,6),max(5,6,3),max (3,3,5)}
  = min {6,6,5} = 5

- Calculate RPC (ai) from each failure mode
  N (a1)= 1 N(a2) = 1 N(a3) = 1
  T (ai) = max { Li1 – Lk1, Li2 – Lk2 , Li3– Lk3 }
  T(a1) = Max {| 6-5|,| 6-5|,|3-3| }
  = Max{1,1,0 }= 1
  T(a2) = Max {| 6-5|,| 6-3|,|3-5| }
  = Max{1,3,2 }
  = 3
  T(a3) = Max {| 6-6|,| 5-3|,|3-5| }
  = Max{1,2,2 } = 2

From the above analysis , most critical risk amoung these three failure mode is a2. Next level of failuremodes are a3 and a1

Risk	S	O	D	RPN
Variation in vulcanizing temperature (a1)	5	4	3	60
Quality variations in latex from different suppliers (a2)	2	5	6	60

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 weared 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. Founded 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 twoaor more failure modes have the same RPN, it is possible to prioritize the failure modes with the help of Risk Priority Code (RPC).

References

[1] Gunjan Joshi Senior Engineer, Honeywell Aerospace, Hyderabad, India 'FMEA and Alternatives v/s Enhanced Risk Assessment Mechanism', International Journal of Computer Applications (0975 – 8887) Volume 93 – No 14, May 2014.

[2] Martin James, Cijo Mathew, Reji Mathew ' Process Improvement for Reducing Critical Defects in Contraceptives' International Journal of Engineering and Innovative Technology (IJEIT) Volume 2, Issue 8, February 2013.

[3] Carbone, T.A.andTippett,D.D. (2004),'Project risk management using the project risk FMEA', Engineering Management Journal, Vol. 16 No. 4, pp. 28-35.

[4] Sankar, N.R. and Prabhu, B.S. (2001), 'Modified approach for prioritization of failure in a system failure mode and effects analysis,International Journal of Quality & Reliability Management, Vol. 18, pp. 324-35.

[5] Overlay panel Huai-WeiLo[a]JamesJ.H.Liou[b]'A novel multiple-criteria decision-making-based FMEA model for risk assessment' volume 73, December 2018, Pages 684-696

[6] Agung Sutrisnoa, IndraGunawanb, Stenly Tangkumanca, c Department of Mechanical Engineering Sam Ratulangi University 'Modified failure mode and effect analysis (FMEA) model for accessing the risk of maintenance waste', Indonesia Industrial Engineering and Service Science 2015, IESS 2015.

[7] Mahdi Bahrami a, DanialHadizadehBazzazb , S. MojtabaSajjadic, 'Innovation and Improvements In Project Implementation and Management; Using FMEA Technique' International Conference on Leadership, Technology and Innovation Management.

[8] Lefayet Sultan Lipol (M.Sc in Textile Technology &M.Sc in Applied Textile Management, University of Boras, Sweden) 'Risk Analysis Method: FMEA/FMECA in the Organizations' International Journal of Basic & Applied Sciences IJBAS-IJENS Vol: 11 No: 05

[9] K. H. (2009), 'Evaluate the orderings of risk for failure problems using a more general RPN methodology'. Microelectronics Reliability, 49, 1586–1596.

[10] Franceschini F, Galetto M (2001) 'A new approach for evaluation of risk priorities of failure modes in FMEA' Int J Prod Res 39(13):2991–3002

[11] Murphy, James S. 'The Condom Industry in the United States.' McFarland and Company, Inc. 1990.

[12] Ian S.Sulton, 'failure Mode effect analysis' Southern Book Publication' volume-1 year 2002

[13] Chang, D. S., & Sun, K. L. P. (2009). 'Applying DEA to enhance assessment capability of FMEA' International Journal of Quality & Reliability Management, 26, 629–643

[14] Chang, D. S., & Sun, K. L. P. (2009). 'Applying DEA to enhance assessment capability of FMEA.' International Journal of Quality & Reliability Management, 26, 629–643RohitRavasahebShinde* Ramakant Shrivastava* Rupesh B. Morey Mechanical Engineering Department Government College of engineering Aurangabad 'Failure Mode Effect Analysis-Case Study for Bush Manufacturing process' Rohit Ravasaheb Shinde* RamakantShrivastava* Rupesh B. Morey Mechanical Engineering Department Government College of engineering Aurangabad – IJSEAS Volume-1, Issue-4, July 2015

[15] Pinnarat Nuchpho, SantiratNansaarng, Adisak Pongpullponsak King Mongkut's University of Technology Thonburi, Thailand 'Risk Assessment in the Organization by using FMEA Innovation' Proceedings of the 7th International Conference on Educational Reform (ICER 2014),