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APPLICATION OF FUZZY FMEA TO THE INTENSIVE CARE CORONARY UNIT ELECTRIC BED DESIGN

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Abstract: According to *Medical Device Good Manufacturing Practices Regulation*, FMEA technique is devoted to determining design reliability by considering potential causes of failure and their effects on the medical equipment. Intensive care unit (ICU) and intensive care coronary unit (ICCU) electric bed is a development of manual bed type in which the motion system had used electric power and gas-spring. There is a difference significant of RPN rating results between a traditional and fuzzy FMEA. Consider 88 failure modes that resulted from failure analysis, only 15.9% (14 failure modes) have the same RPN rating position.

1. INTRODUCTION

Failure Mode and Effect Analysis (FMEA) deals with the identification of its failure modes, failure causes and frequencies and the effect that might result if any specific failure occurs during the process operation. Traditionally, FMEA has been a design tool, used extensively in the recognition and understanding of inherent design weaknesses. Based on the information provided by FMEA, design and management personnel are better informed about the way to determine what can be done in order to avoid or mitigate failure modes. This information also provides basic input to reliability models that can be used to predict and measure product reliability performance against specified targets and requirement.

In a traditional FMEA, the criticality assessment is performed by developing a risk priority number (RPN). RPN is the product of the severity, occurrence, and detection ratings. These parameter are assumed to be equal importance, but this may not be the case in practice. Failure modes having a higher RPN are assumed to be more important and given a higher priority for corrective action than those having a lower RPN. It has been pointed out that the same RPN can be obtained from a number of different score combinations of severity, occurrence and detection. The same value of RPN may imply difference risk representations. According Xu et al. (2002) FMEA team usually suffers from several difficulties when conducting FMEA in real industrial situation. In conducting FMEA, the diversity and ability of the FMEA team members are the most important considerations. It is difficult to share the team members' experience.

Fuzzy system is a knowledge-based system which is constructed from expertise and experience in the form of fuzzy IF-THEN rules. Through building knowledge-based model, expert knowledge and judgment could be utilized to make the FMEA assessment method more reasonable and convenient.

In this paper, we focus on the use and applicant of fuzzy inference technique as an alternative to overcome the weakness associated with the traditional FMEA system. Comparing with traditional FMEA, the fuzzy approach allows failure risk evaluation and prioritization to be conducted based on experts' knowledge.

1.1 The Traditional FMEA

Considered as the last point in failure investigation, FMEA is devoted to determining design reliability by considering potential causes of failure and their effects on the system under study. Briefly, FMEA is concerned with listing each potential failure mode of a (global) system and its effects on the listed subsystems (Braglia, 2000). This bottom-up approach can be utilized at any level, from complete systems to components.

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The main advantages of FMEA are: it is a visibility tool that can easily be understood and used, a systematic procedure which is arranged in a computer program based on a data base, it identifies weakness in the system design, focusing attention on a few components rather than on many and useful in design comparison.
The traditional FMEA procedure is explained as follows. First, listing the subsystem and parts of the system (functional analysis). Second, listing and description of all failure modes for the part under consideration. Third, assign the severity rating of each failure mode according to the respective effects on the system, assign the occurrence rating of each failure mode according to its likelihood of occurrence, assign the detection rating of each failure mode. Fourth, calculate RPN and establish the priorities for attention. Fifth, take recommended action to enhance and correct the performance of system.

1.2 Fuzzy FMEA

In fuzzy FMEA, the three input factors of the RPN function, i.e. severity, occurrence and detect, are assumed to be the input factors of the fuzzy RPN function as well. According Yeh and Hsieh (2007), this approach is similar to the fuzzy expert system and control system, the inference process of fuzzy FMEA includes:

1. Fuzzification:
   Through defining the membership functions of input fuzzy sets which are determined by expertise, the three parameters, (S), (O), and (D) ratings, can be transformed into fuzzy input.
2. Rule evaluation:
   By using the IF-THEN rules gathered from experts and engineers and integrating them into fuzzy rule, the fuzzy IF-THEN rules in fuzzy rule base can be combined into a mapping from fuzzy inputs to fuzzy conclusion.
3. Defuzzification:
   Through defining the membership functions of output fuzzy sets and defuzzifier, fuzzy conclusion can be converted into a real-valued risk representation.

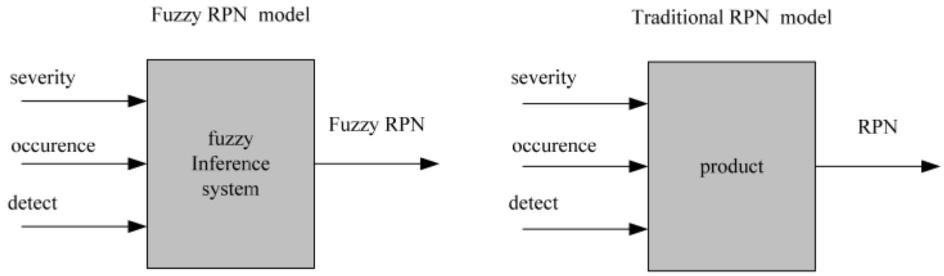

Figure 1. Comparison between the traditional and fuzzy RPN function
(Tay and Lim, 2006)

2. METHODOLOGY

2.1 Fuzzy Membership Function

The variables are used in the case studies consists of input variable and output variable. Input variable consists of severity (S), occurrence (O), and detection (D) value, is varied from 1 to 10. Similar to the traditional RPN system, the fuzzy RPN output is assumed to be varying from 1 to 1000.

In this paper, input variable is divided into five linguistic terms equal partitions namely: remote (R), low (L), moderate (M), high (H), and very high (VH). Risk, the output variable, is used to represent the priority for corrective action with five linguistic terms: low (L), low medium (LM), medium (M), high (H), and medium high (MH). In the proposed fuzzy FMEA approach, several experts are required to develop the membership functions of the input and output variables.

The triangular membership function *(a, b, c)* is used to represent each linguistic terms. Abscissa (x), represents the specified rating and ordinate ($\mu(x)$) represents the value of its membership function, i.e. the degree of membership. The input membership functions of five linguistic terms for occurrence in this example can be presented in Equation 1 and illustrated in Figure 2.

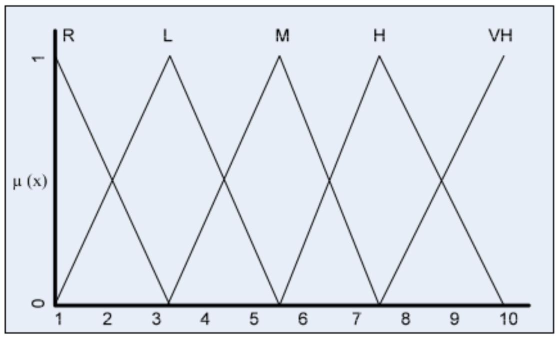

Figure 2. Membership Function for Occurrence

2.2 Fuzzy Rule Base

In a fuzzy inference system, experts' knowledge is represented with a rule base comprising fuzzy production rules (Jang et al., 1997). Each fuzzy production rule consists of two parts: an antecedent (input) and consequent (output). Generally, a fuzzy production rule has the form (Tay and Lim, 2006):

If X_1 is F_1 and … X_n is F_n, ***then*** Y is G
where X_i and Y are the inputs and output of the fuzzy inference system, F_i and G are input and output linguistic variables, respectively.

Considering the input and the linguistic terms describing each inputs as exemplified in this case studies, the fuzzy rule base has 125 (5 x 5 x 5) rules in total using the grid partition approach. All the combinations should be grouped to generate the fuzzy rule base. The example of some rules presented in Table 1.

Table 1. An Example of Fuzzy Rules

Rule #	***IF***			***THEN***
	Severity	Occurrance	Detection	Risk
R1	R	R	VH	L
R27	L	R	H	LM
R40	L	M	R	H
R56	M	L	VH	L

R65	M	M	R	H
R96	H	V	VH	L
R97	H	V	H	LM
R108	VH	L	M	M
R125	VH	V	R	H

In this studies, minimum inference engine is used to combine the fuzzy IF-THEN rules in fuzzy rule base and implicate the fuzzy conclusion. The minimum inference engine uses: 1) *min* operator for and in the IF-part of rules and *max* operator for or in the IF-part of rules, 2) the *union* combination (*max* operator) to aggregate the consequence of individual rules.

2.3 Defuzzification

In this paper, the product-sum composition inference was used in the fuzzy inference system while the weighted average method was used as the defuzzification approach.

3. RESULTS

The actual case study here proposed deals with a medical equipment, i.e. intensive care unit (ICU) and intensive care coronary unit (ICCU) electric bed. According to its functions, ICU-ICCU electric bed can be classified into five subsystem function level 1: place the uses, defense load, arrange mattress position, move the bed, place the bed, and arrange the slope. In order to mathematical express each failure mode, let F_{ijkl} represent the *k*-th potential effect failure mode in the *i*-th subsystem function level 1 and *j*-th subsystem function level 2. Subscript *l* used to represent potential cause failure mode.

Consider 88 failure modes that resulted from failure analysis. The failure mode F_{611e}, F_{611c}, F_{311d} have the same RPN of 140 and the same priority of 7. However, the different ratings combinations can infer different fuzzy risk. Thus, they have the fuzzy rankings of 2, 4, and 11, respectively. By using the fuzzy FMEA, it is convenient for user to differentiate the risk representations in the failure having the same RPN.

Consider that the failure modes F_{211a} and F_{341g} where the RPN is 16. The value of (S), (O), (D) ratings are 8, 2, 1 and 4, 4, 1, respectively. Although the RPN for both failure modes are the same, the risk level may be different. The fuzzy ranks of 27 and 28. The failure mode F_{211a} has a higher priority than F_{341g}. Thus, the traditional FMEA may result in a different action.

In addition, the ranking produced by the proposed method doesn't differentiate the failure modes which have the adjacent ratings. Failure modes F_{331i} and F_{421d}, where (S), (O), (D) ratings are 5, 2, 1 and 5, 6, 4. The fuzzy ranking is 24 for both failure modes. This entails these two failure modes should be given the same priority. However, the traditional FMEA method procedures the resulting RPN of 10 and 120, respectively.

Table 2. The Part of Priority RPN and Fuzzy RPN Results

Failure mode	Input Variable			RPN	RPN RANKING	FUZZY RPN	FRPN RANKING
	(S)	**(O)**	**(D)**				
6.1.1.g	10	3	7	210	4	665	1
6.1.1.e	10	2	7	140	7	610	2
2.5.1.b	10	2	7	140	7	610	2
6.1.1.a	10	4	7	280	3	583	3
6.1.1.c	10	2	7	140	7	565	4
3.1.1.d	5	4	7	140	7	472	11
4.1.1.c	5	4	7	140	7	472	11
4.2.2.b	6	3	6	108	10	463	12
3.3.1.i	5	2	1	10	30	305	24
4.2.1.d	5	6	4	120	9	305	24
2.1.1.a	8	2	1	16	27	113	27
2.1.1.b	8	2	1	16	27	113	27
3.4.1.d	4	2	1	8	32	113	27
3.4.1.g	4	4	1	16	27	85	28

4. CONCLUSION

The analysis of the results produced by the traditional FMEA and the fuzzy FMEA methods shows that a more accurate, reasonable ranking can be achieved by applying fuzzy FMEA. The most critical disadvantage of the traditional FMEA is that various combinations of the three parameter ratings may procedure an identical value of RPN. However, the risk representations may be thoroughly different.

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