RPN SAFETY ANALYSIS TO REDUCE THE RISK OF MALPRACTICES IN HIGH DOSE RATE BRACHYTHERAPY

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ABSTRACT
A new fuzzy rule-based assessment model is proposed to evaluate the risk priority number in the Failure Mode, Effects, and Criticality Analysis (FMECA) method to rank component failures and human errors from the medical staff, leading to potential radiological over-exposure of patients during high-dose-rate brachytherapy treatment. The obtained results are relevant for a range of causes that have a reasonable probability of producing significant adverse outcomes. Thus, recommendations are provided for procedures and safety devices to reduce the occurrence of radiological over-exposure accidents. This method can solve the problems in conventional FMECA applications and improve the safety and quality process of radiological treatments, or of other applications in healthcare field.

1. INTRODUCTION

Over the last decade, the International Commission on Radiological Protection (ICRP) has devoted research efforts to examining high-dose-rate (HDR) brachytherapy practices and has issued documents describing the safe delivery of these advanced treatments. Recent years have seen a large increase in the use of automated remote techniques involving large doses applied over a short period of time. In these cases mistakes can lead to under-or over-dosage that could result in adverse clinical effects. Several hundred undesirable events have been reported with varying degrees of severity (including death), and a review of the root causes confirms that accidents can occur by the combination of several problems associated with technical faults and weaknesses in radiological practices [1].
For this reason, high-quality maintenance and accurate risk analyses should be provided by using new computational tools, considering the complexity of both the equipment and the procedures.
This paper presents the results of the safety analyses of accidental events involving patient over-exposure during HDR brachytherapy treatment using a modified FMECA (Failure Mode, Effects, and Criticality Analysis) methodology. The FMECA technique is a powerful qualitative tool for the early identification of the initiating event and the root cause of unacceptable outcomes, although it can be difficult for this technique to identify accident sequences and dependencies between equipment and human actions. To identify the critical failure modes associated with the components or the process, the risk priority number (RPN) can be used as a tool to rank the importance of each potential fault.
In this study, to enhance the performance of the FMECA technique, a new approach based on a fuzzy rule assessment model is proposed to evaluate the RPN with the aim of prioritising an exhaustive list of component failures as well as human errors that can lead to radiological over-dosing during brachytherapy treatments. Moreover, the probability of errors by medical personnel or misjudgements during treatment has been evaluated using the fuzzy HEART methodology. This tool proved to be an easy and versatile method for the evaluation of human error in various safety studies [2-4].
These obtained results indicate the critical points of radioprotection systems and highlight the human errors that contribute to the occurrence frequency of high-dose-rate patient exposures. Finally, a set of suitable procedures to reduce the risk of over-dose is suggested.

2. FMECA METHODOLOGY

FMECA technique consists of two separate analyses, the FMEA and criticality analysis (CA), which ranks the significance of each potential failure of each component in the system according to the failure rate, the severity of this failure and the detection which defines the likelihood of the failure being detected by design control [5].

For each component or manufacturing processing step under evaluation, the function of the component, the potential failure mode and the effect of the failure mode should be recorded by compiling the appropriate tables. The structure, number and meaning of the columns of the resulting FMEA table may vary; however, the following column headings are commonly used: investigated component, failure mode, description of the failure mode, local effect of the failure mode, effect at the system level, failure detection mechanism, and mitigation mechanism.
FMECA uses three numerical values to describe each failure mode: occurrence (O), which describes the probability that a particular accidental event will occur; severity (S), which is a measure of the severity of the consequences resulting from the undetected failure mode; and detection (D), which describes the probability that the failure will be detected before the failure occurs. The product of these three numbers yields the RPN as follows:

$$RPN = O \times S \times D \qquad (1)$$

Generally, these parameters are estimated by expert judgement on a scale ranging from 1 to 10 based on commonly agreed upon evaluation criteria. The calculated RPN rank is between 1 and 1000, and users can define priorities in the FMECA procedure as:

- Acceptable if RPN<200,
- Undesirable if 200< RPN<500,
- Unacceptable if RPN>500.

However, this method has been criticised for a variety of reasons, including:

- Different combinations of O, S, and D may yield the exact same RPN value despite significant differences in their risk implications (for example, RPN=1x10x2 and RP =1x5x2 have the same value of 20),
- The relative importance among O, S, and D is not taken into account,
- It is difficult to precisely estimate these three factors,
- The human error is not treated.

These weaknesses in the FMECA analysis likely result in high-risk events going unnoticed.

3. FUZZY RPN METHOD

Significant efforts have been made in the literature to overcome some of the above mentioned drawbacks of the FMECA analysis, and fuzzy logic has been widely used to rank failure modes [6-11]. However, these fuzzy approaches require a vast amount of expert knowledge, and experts often have different or inconsistent judgements, making it very difficult to combine or complete the rules necessary for the fuzzy logic procedures. Moreover these method don't allow to deal with human error problems.
The proposed method can allow to generate if-then fuzzy rules for RPN evaluation in order to overcome the these weaknesses, including to detect accidental events due to human actions.

3.1. Fuzzy sets and fuzzy logic systems

The fuzzy logic model was introduced by Zadeh [12, 13] to address problems in which phenomena are imprecise and vague or to model experiences defined by linguistic expressions, for example, expert knowledge that can be expressed in natural language (low, medium, high, etc.). Traditional set theory is based on a bivalent logic, where a number or object is either a member of a set or not. In contrast, let X be a collection of numbers or objects (fuzzy set) called the universe, whose elements are denoted by x; a fuzzy subset A in X is characterised by a membership function $\mu_A(x)$ that associates each element x in X with a real number in the interval [0, 1]. The function $\mu_A(x)$ represents the degree of membership of x in the fuzzy set A.
A membership function for a fuzzy set is usually assumed to be a triangular or trapezoidal function, but other shapes may also be used. The expressions that define the membership functions of triangular and trapezoidal fuzzy numbers are:

$$\mu_A(x) = \begin{cases} \frac{x - x_1}{x_2 - x_1} & x_1 \le x \le x_2 \\ \frac{x - x_3}{x_2 - x_3} & x_2 \le x \le x_3 \\ 0 & \text{otherwise} \end{cases}$$ for the triangular membership function (1)

where $x_1 < x_2 < x_3$

$$\mu_A(x) = \begin{cases} \frac{x - x_1}{x_2 - x_1} & x_1 \le x \le x_2 \\ 1 & x_2 \le x \le x_3; \\ \frac{x - x_4}{x_3 - x_4} & x_3 \le x \le x_4 \\ 0 & \text{otherwise} \end{cases}$$ for the trapezoidal membership function (2)

with $x_1 < x_2 < x_3 < x_4$.
For triangular fuzzy numbers, x_2 yields the maximum value of $\mu_A(x)$, i.e., $\mu_A(x_2) = 1$, making this the most probable value, whereas x_1 and x_3 are the lower and upper bounds of the variable area of the evaluated data.
For trapezoidal fuzzy numbers, the most likely values of $\mu_A(x)$ fall in the interval $[x_2; x_3]$, whereas x_1 and x_4 are the lower and upper bounds of the variable area for the evaluated data.
For brevity, triangular and trapezoidal fuzzy numbers are often denoted as (x_1, x_2, x_3) and (x_1, x_2, x_3, x_4). Obviously, triangular fuzzy numbers are special cases of trapezoidal fuzzy numbers with $x_2 = x_3$.
In the fuzzy logic system, the fuzzy rule base consists of a collection of fuzzy if–then rules, and the fuzzy inference uses these fuzzy if–then rules to map from fuzzy sets in the input universe of discourse $X \subset R^n$ to fuzzy sets in the output universe of discourse $Y \subset R^m$ based on fuzzy logic principles.
The fuzzy if-then rules can be described as:

If x *is* A and y *is* B *then* z *is* C (w) (3)

where A and B are the linguist variables defined in X fuzzy sets and C is the linguist variable defined in Y fuzzy sets, where X and Y are the above quoted input and output universes of discourse. The *if* part of the rule "x *is* A" and "y *is* B" is called the antecedent, while the *then* part of the rule "z *is* C" is called the consequent.
The parameter w in Eq. (3) denotes the degree of importance of the rule in the range (0, 1), and often this factor is used to describe the uncertainty of an expert's assessment of the rules.
Matching the fuzzy concepts and rule sets, the degree of fulfilment of the antecedent of each rule is computed using fuzzy logic operators.
There are several ways to combine all the rules into a single fuzzy set, such as the min–max inference method. An example of min–max inference applications is reported in Fig. 1. This method starts with the selection of the minimum membership in both IF and THEN parts of each rule as C_1, C_2 and C_3 shown in the figure. This is followed by the determination of the maximum membership of the rules for each linguistic term category, represented as C.
The finally step is the defuzzification which maps the output from the fuzzy domain back into the crisp domain. This step consists of averaging the outputs from all of the individual fuzzy rules into a single output decision. The output decision is a precise, defuzzified, crisp value.
Many ranking methods have been proposed, and the centre of gravity (COG) method, also called the centroid method, is widely used because of its straightforward geometric meaning. The crisp value of the output variable is computed using the analytical calculation of the centre of "gravity" of the area produced by the combination of the membership functions in the fuzzy inference step. However, this method is not appropriate for distinguishing two fuzzy sets that may have the same centroid but differ greatly in their degrees of fuzziness. In this case, the weighted centre of gravity method (WCOG) is proposed as follows:

$$\mathrm{WCOG} = \frac{\int g(x)\mu(x)^q \ dx}{\int \mu(x)^q \ dx} \quad (4)$$

where g(x) is the horizontal component of the area under scrutiny and μ (x) is the membership function value. The value of q is a control parameter ranging.

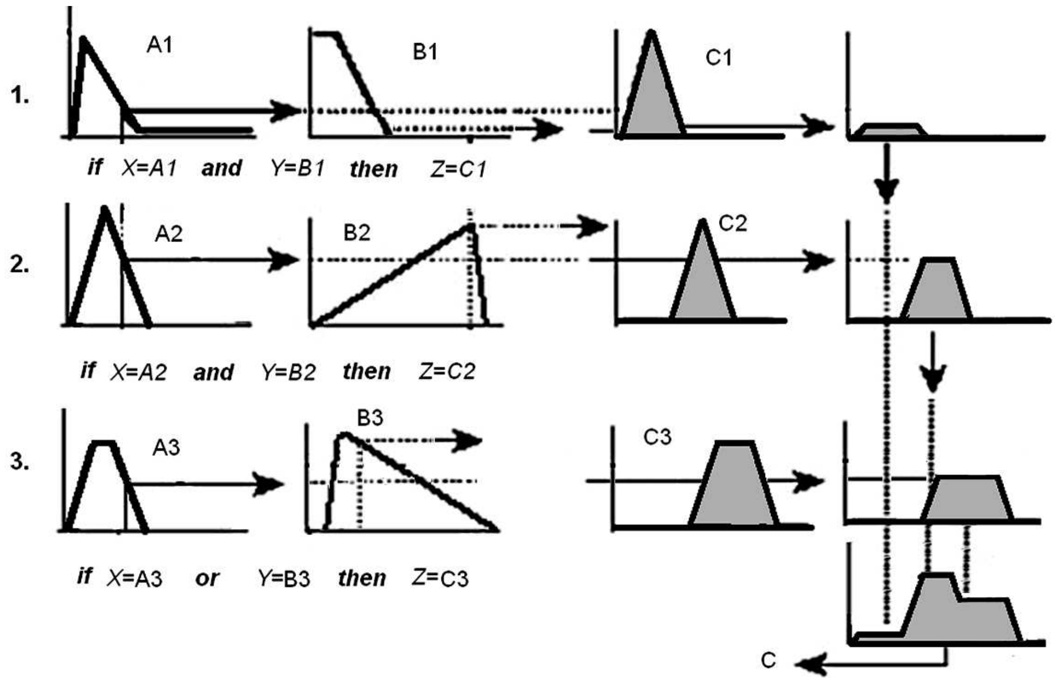

Fig. 1. A generic example of the min-max fuzzy inference process.

3.2. Fuzzy rule-based approach proposed to evaluate RPN

Using triangular and trapezoidal functions as linguistic data, the inputs O, S and D and the output RPN have been decomposed in fuzzy sets as shown in Figs. 2 and 3. The values are based on the ranking scales presented in Tables 1 through 4, which summarise some evaluation criteria used in hazardous industrial processes and inmedical practices management [15-17].
Note that Table 1 shows the occurrence rating scale for component failures, and for the sake of brevity, this table also reports the human error rating scale, given that the two rating scales have the same classification.
After the inputs and outputs have been decomposed into fuzzy sets, a set of fuzzy if-then-else inference rules is used to process the inputs and produce a fuzzy output.
In this study, the fuzzy inference rules are generated taking into account the relative importance of the input variables O, S, and D and assuming linear relationships for the weight of the linguistic terms in both inputs and RPN outputs.
The relative importance of the O, D, and S parameters is set as RO = 0.3, RD = 0.3, and RS = 0.4, respectively, to emphasise the severity of the consequences. The weights WO, WD, WS of the five linguistic terms describing the parameters O, S (VL, L, M, H, VH) (see Tables 1 and 2) and D (VH, H, M, R, VR) (see Table 3) are assumed to be 1/5=0.2, 2/5=0.4, 3/5=0.6, 4/5=0.8, and 5/5=1.
Based on similar assumptions, the weights w for the nine RPN output linguistic terms, described as VL, VL_L, L, L_M, M, M_H, H, H_VH, and VH (see Table 4), are assumed to be 1/5=0.2, 1.5/5=0.3, 2/5=0.4, 2.5/5=0.5, 3/5=0.6, 3.5/5=0.7, 4/5=0.8, 4.5/5=0.9, and 5/5=1, to respect the linear hypothesis.
The linguistic term of the RPN fuzzy output and the pertinent weight are determined using the summation of the product of the relative importance factor and weight for each fuzzy input term:

$$w = RO \times WO + RD \times WD + RS \times WS \quad (5)$$

The threshold value of w allows to identify the output of the RPN linguistic term.

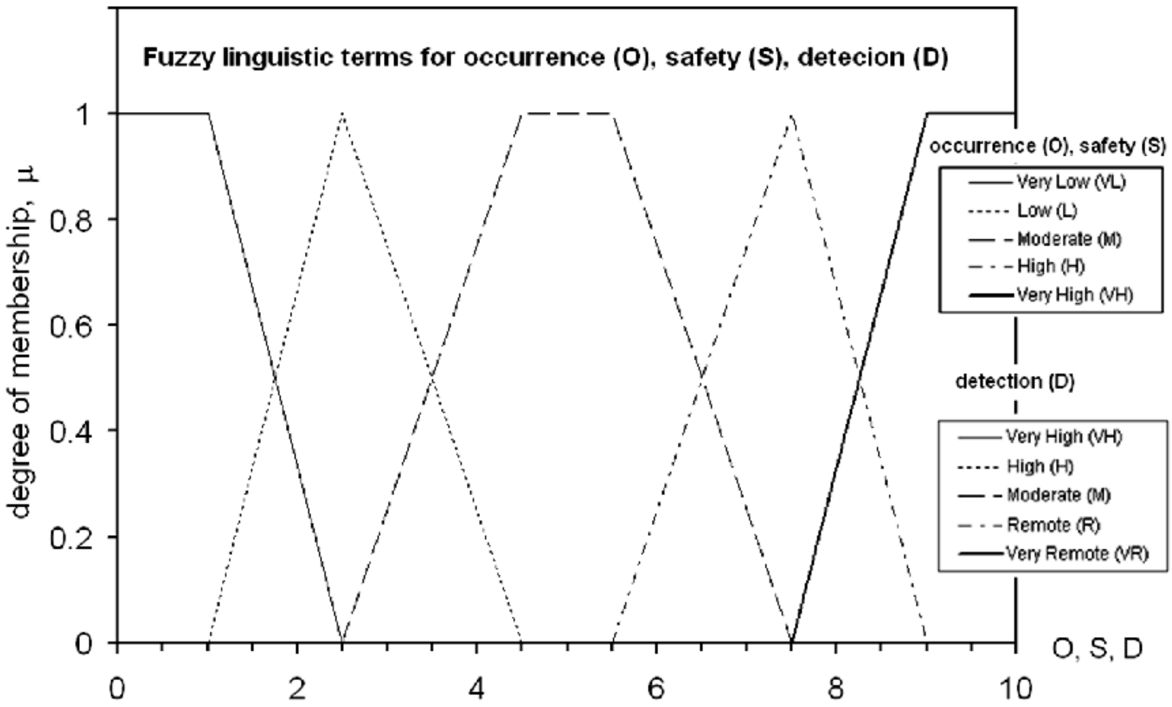

Fig. 2. Representation of fuzzy linguistic variables relevant to occurrence (O), severity (S), and detection (D) parameters.

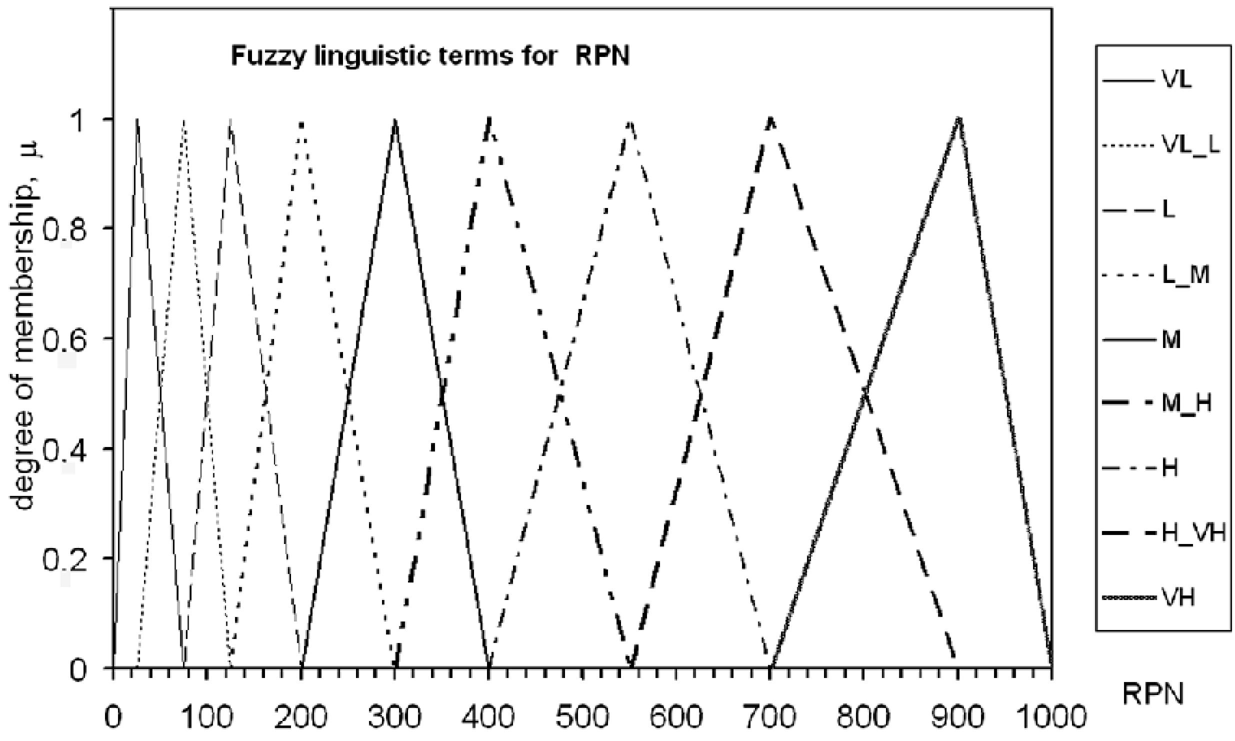

Fig. 3. Representation of fuzzy linguistic variables relevant to risk priority number (RPN).

Some examples of proposed fuzzy inference rules are as follows:

Rule 1: ***If*** the occurrence is "VL" (W_O = 0.2), ***and*** the detection is "R" (W_D = 0.8), ***and*** the severity is "M"

(W_S = 0.6), ***then*** the consequent part is the threshold value obtained by eq. (5) as summation 0.3x0.2+0.3x0.8+0.4x0.6=0.54, which corresponds to the fuzzy set of the RPN linguistic term "L_M"; w = 0.54 is the degree of importance of the rule;

Rule 2: ***If*** the occurrence is "VL" (W_O = 0.2), ***and*** the detection is "VR" (W_D = 1), ***and*** the severity is "H" (W_S = 0.8), ***then*** the consequent part is the threshold value obtained by eq. (5) as summation 0.3x0.2+0.3x1+0.4x0.8=0.68, corresponding to the fuzzy set of the RPN linguistic term "M"; w = 0.68 is the degree of importance of the rule.

The fuzzy rule base has 125 combinations (5O×5S×5D), based on the above assumptions. Table 5 shows the fuzzy inference rules obtained by setting the linguistic term of occurrence, O, as Very Low (VL) and varying the linguistic terms of severity, S, and detection, D. The importance factors, w, for each fuzzy rule are also reported.
The fuzzy inference process employed in this study is the above described min-max method, moreover Eq. (4) is used for the defuzzification step, where g(x) is the RPN fuzzy variables, x, and q is the importance factors of the linguistic terms of the consequent part of the activated rules, w.

Table 1. FMECA scale for the component failure and human error probabilities

Component failure occurrence probability (operating day)	Human error occurrence probability per year	Rank	Linguistic Value	Fuzzy linguistic number (x1, x2, x3, x4)
Failure unlikely, < 1:20,000	Less than one time per 10 years, < 0.1	1	Very Low (VL)	(0, 0, 1, 2.5)
Few failures, 1:20,000/1:10,000	Less than one time per 5 years, 0.1 ÷ 0.2	2, 3	Low (L)	(1, 2.5, 4.5)
Occasional failures, 1:2000/1:1000/1:200	Less than one time per 2 years, 0.2 ÷ 0.5	4, 5, 6	Moderate (M)	(2.5, 4.5, 5.5, 7.5)
Repeated failures, 1:1000/ 1:20	Less than one time per year, 0.5 ÷ 1	7, 8	High (H)	(5.5, 7.5, 9)
Inevitable failure, 1:10/ 1:2	Multiple times per year, $\geq$ 1	9, 10	Very High (VH)	(7.5, 9, 10, 10)

Table 2. FMECA scale for the severity

Severity of each effect of failure or error	Rank	Linguistic Value	Fuzzy linguistic number (x1, x2, x3, x4)
No reason to expect failure to have any effect on safety or health	1	Very Low (VL)	(0, 0, 1, 2.5)
Decreased effectiveness	2, 3	Low (L)	(1, 2.5, 4.5)
A failure that causes a high degree of operator dissatisfaction or that causes noticeable but slight deterioration in system performance or that leads to minor injuries	4, 5, 6	Moderate (M)	(2.5, 4.5, 5.5, 7.5)
A failure that causes significant deterioration in system performance and/or leads to injuries	7, 8	High (H)	(5.5, 7.5, 9)
A failure that would seriously affect the ability to complete the task or cause serious injury or death	9, 10	Very High (VH)	(7.5, 9, 10, 10)

Table 3. FMECA scale for detection

Likelihood of detection of failure or error	Probability of failure detection %	Rank	Linguistic Value	Fuzzy linguistic number (x1, x2, x3, x4)
Design control will almost certainly detect a potential failure mode/task error	0÷ 15	1	Very High (VH)	(0, 0, 1, 2.5)
High chance the design control will almost certainly detect a potential failure mode/task error	16 ÷ 35	2, 3	High (H)	(1, 2.5, 4.5)
Moderate chance that the design control will detect a potential failure mode/task error, or the defect will remain undetected until the system performance is affected	36 ÷ 65	4, 5, 6	Moderate (M)	(2.5, 4.5, 5.5, 7.5)
Remote chance that the design control will detect a potential failure mode/task error, or the defect will remain undetected until an inspection or test is carried out	66 ÷ 85	7, 8	Remote (R)	(5.5, 7.5, 9)
Defect remains undetected or the task will certainly be performed in the presence of the defect	86 ÷ 100	9, 10	Very Remote (VR)	(7.5, 9, 10, 10)

Table 4. FMECA risk evaluation criteria

Linguistic Value of the Risk	Rank	Fuzzy linguistic number (x1, x2, x3)
Very Low (VL)	1-50	(0, 25, 75)
Between Very Low and Low (VL_L)	50-100	(25, 75, 125)
Low (L)	100-150	(75, 125, 200)
Between Low and Moderate (L_M)	150-250	(125, 200, 300)
Moderate (M)	250-350	(200, 300, 400)
Between Moderate and High (M_H)	350-450	(300, 400, 550)
High (H)	450-600	(400, 550, 700)
Between High and Very High (H_VH)	600-800	(550, 700, 900)
Very High (VH)	800-1000	(700, 900, 1000)

Table 5. RPN fuzzy inference rules obtained for occurrence (O) defined as Very Low (VL) and for various detection (D) and severity (S) linguistic terms. The importance factors, w, for each fuzzy rule are also reported

Occurrence VL (Very Low)

		Severity				
		VL	L	M	H	VH
Detection	VH	VL; w=0.20	VL; w=0.28	VL-L; w=0.36	L; w=0.44	L_M; w=0.52
	H	VL; w=0.26	VL_L; w=0.34	L; w=0.42	L_M; w=0.50	L_M; w=0.58
	M	VL_L; w=0,32	L; w=0.40	L; w=0.48	L_M; w=0.56	M; w=0.64
	R	VL_L; w=0.38	L; w=0.46	L-M; w=0.54	M; w=0.62	M_H; w=0.70
	VR	L; w=0.44	L_M; w=0.52	M; w=0.60	M; w=0.68	M_H; w=0.76

RPN linguistic value
- Very Low (VL)
- Very Low_ Low (VL_L)
- Low (L)
- Low_Moderate (L_M)
- Moderate (M)
- Moderate_High (M_H)
- High (H)
- High_Very High (H_VH)
- Very High (VH)

4. DESCRIPTION OF HDR DEVICES AND BRACHYTHERAPY PROCEDURES

Recently, the possibility of producing high-specific-activity radioisotope sources, together with the development of the computer-controlled loading system, has increased the use of HDR technology. Further advantages of this process include dose optimisation capabilities and the short durations of the treatment procedures [14].
However, considering the relatively complicated treatment system and the dangers of using a high activity source, it is important to have appropriate planning procedures and trained medical staff.
The system examined here consists of a motor-driven source transport device that automatically transfers radioactive material between a shielded safe and the treatment applicator.
The device contains a small, sealed, stepping source that is mounted at the end of a stainless steel drive wire. The afterloader system is connected to the implanted applicator, catheter, or needle with flexible transfer tubes.
Typically, the dose is calculated at representative points with the treatment planning system (TPS), and the therapy is then performed with the treatment control system (TCS), which enables an operator to remotely insert a radionuclide source into the body. The TCS supports the following functions:

- Make a new plan,
- Add a plan (from the library),
- Import a plan (from a treatment planning system),
- Load a patient study (from the database),
- Edit, print and save plan information,
- Execute treatment,
- Start and monitor treatment,
- Print a treatment report.

For each computer system that produces isodose curves for remote afterloaders, it is imperative that the user understand the algorithm and the method used to compute the doses. The user may enter key parameters specific to a radionuclide and source model or select parameters from an existing menu. The treatment documentation should aim to be complete. All critical information, including applicator types, the relationship between the body target volume and applicators, dose description, and simulator localisation information, should be recorded on appropriate forms by the individual team member that is primarily responsible for each activity.
As shown in Fig. 4, the afterloader unit contains:

- A Geiger-Muller counter to check the source in the safe,
- A stepping motor (SM) to drive the source,
- A direct current (DC) motor that is available for source retraction in the case of SM failure, equipped by a backup battery in case of electrical blackouts,
- A control device to check if the backup battery is charged,
- A cable transfer tube that is identical in appearance to the source cable (but not radioactive) to check the treatment channel,
- An opto-pair to verify the position of the source,
- Several channels for source transport and the transfer tube connector,
- Primary and secondary timers for the measurement of the pre-programmed exposure times.

A “last resort” mechanical system for manually returning the source to the safe is included in the case of a fault in the electrical source for the return mechanism. The indexer guides the source into one of the 18 source channels, and a dummy source (check cable) is inserted into each of the channels to check for obstructions before the active source is used. The check cable is connected with a second stepper motor different from the motor used to drive the source. When the appropriate stepper motor rotates, the source or the check cable is advanced into the treatment channel and positioned with an accuracy of ± 1 mm.
The after-loader system mechanically drives the source to pre-programmed locations in the applicator (dwell positions) and holds it in place for certain pre-programmed periods of time (dwell time).
A primary timer measures the exposure time for each source dwell position, while a secondary timer measures the time between the source channel transit time and the dwell time for each pre-programmed location. The software system in the TCS checks the consistency between these time measurements. The data are also compared with the values specified in the treatment plan. If an error occurs, the source is withdrawn to the safe position. If both timers fail, the operator in the control room (CR) is alerted with a light alarm and a warning on the console display.

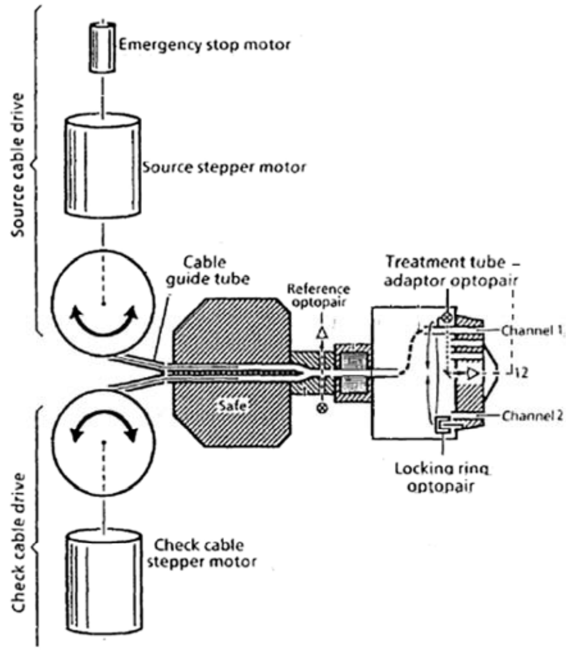

Fig. 4. Components of the after-loader unit used in brachytherapy treatments.

Prior to the initial use of a new (or replaced) applicator, it is necessary to verify that the source dwell positions correspond to the radiographic marker positions used in the simulation and treatment planning. The dose distribution can be optimised by adjusting the dwell time at each source position.

For each type of HDR treatment, the procedures and duties of each team member should be carefully defined. For example, the radiation therapist or the physicist who assists the physician should document the applicator placement, the surface marker, and the applicator geometry that are used to select the active dwell position. The physicist should review the proposed treatment delivery process, check the treatment unit program, monitor the treatment progress, and review emergency procedures.

The control console located inside the CR operates the after-loader, shows the source position and the treatment progress on the display, and prints a report of the treatment.

Emergency stop push-buttons located on the HDR unit, inside the treatment room (TR) and on the control console located in the CR allow for termination of the procedure at any time.

When the treatment is in progress, an electrical switch detects whether the TR door is closed. If the operator erroneously opens the door during the treatment, the irradiation process is interrupted by the DC safety motor, which moves the source into the safe.

4.1. Fuzzy FMECA analysis for HDR brachytherapy treatment

Human error assessment has been performed by using fuzzy HEART (Human Error Reduction and Assessment Technique) methodology, a simple and versatile tool to support safety studies in various industrial fields characterised by innovative and complex systems [18-20]. Obviously a different human reliability technique can be used on the basis of the analyst requirements.

The results obtained with this method are reported in Table 6 in terms of fuzzy triangular membership functions. These probabilities were evaluated by considering that the medical team is trained in operating practices associated with brachytherapy treatments, and the conditions that favour errors are “shortage of time for error detection or correction”, “information overload”, “a means of suppressing or overriding information”, “transfer knowledge from one task to another”, and “mismatch between perceived and actual risk”.

In the FMECA analysis, the upper bounds of the human error fuzzy intervals are used for conservative calculations of the RPN number. The analysis was summarised in FMECA data sheets, as reported in Tables 7 and 8 for component failures and human errors, respectively.

Fig. 5 and Table 9 show the comparisons between traditional and fuzzy RPN rankings for the various component failure modes.
The obtained results highlight that in most cases the failure modes and human errors define priorities in the FMECA procedure up 200 (undesirable events). Whereas the FMECA traditional method considers all events as acceptable.
The order obtained from the traditional RPN method is as follows: incorrect identification of the patient (ID12_1); data insertion errors during TPS (ID11_1); dose calculation errors during TPS (ID10_1); error in loading the patient information from the database (ID 13_1); error in data entry for the dwell time or in dwell position programming (ID 14_1); failure of the stop button to retract the wire source during treatment (ID 9_1); failure of the computerised security program due to incorrect calculations from incorrect data entry (ID 8_1); and backup battery failure (operator forgets to charge the battery) (ID 7_2).
The results obtained in terms of RPN fuzzy numbers are: data insertion errors during TPS (ID11_1); dose calculation errors during TPS (ID10_1); failure of the stop button to retract the wire source during treatment (ID 9_1); incorrect identification of the patient (ID12_1); error in loading the patient information from the database (ID 13_1); failure of the computerised security program due to incorrect calculations from incorrect data entry, (ID 8_1); backup battery failure (operator forgets to charge the battery) (ID 7_2); and error in data entry for the dwell time or in dwell position programming (ID 14_1).

Table 6. Triangular membership function of human error fuzzy probabilities

Human errors Identification number (ID)	Fuzzy probability, error per year (x_1, x_2, x_3)
ID7_2	(0.122, 0.2, 0.29)
ID10_1	(0.145, 0.266, 0.450)
ID11_1	(0.22, 0.48, 0.91)
ID12_1	(0.04, 0.48, 0.77)
ID13_1	(0.01, 0.35, 0.72)
ID14_1	(0.04, 0.30, 0.60)
ID15_1	(0.04, 0.1, 0.19)

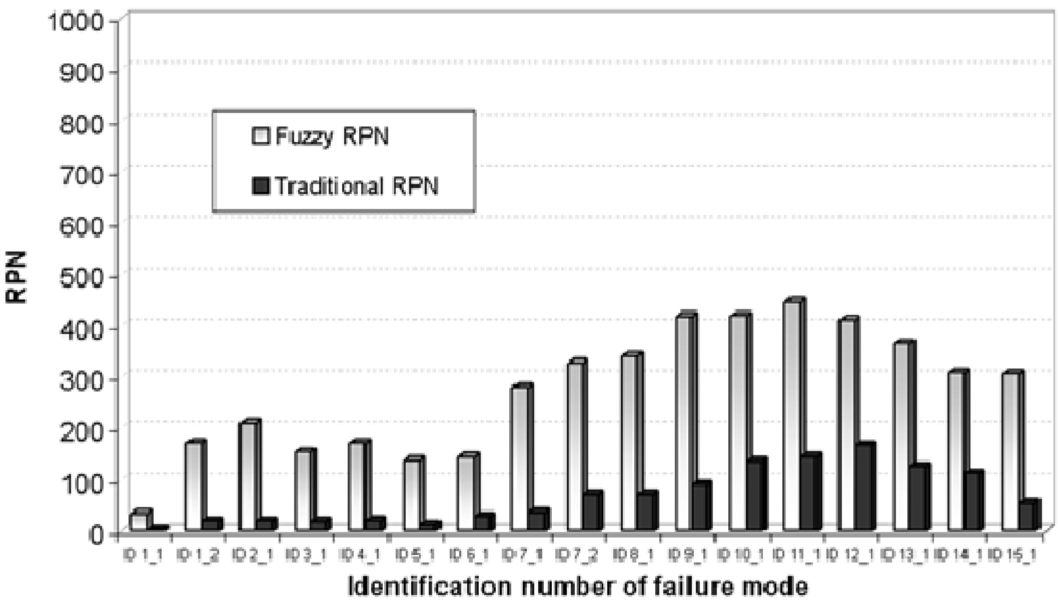

Fig. 5. Comparison between traditional and fuzzy RPN number relevant to accidental events leading to potential radiological over-exposure of patients during high-dose-rate brachytherapy treatment.

Table 9. RPN ranking comparison

Identification number (ID)	O	S	D	RPN	Traditional ranking value	Fuzzy RPN	Fuzzy ranking value
ID 1_1	1	1	2	2	15	35,76	17
ID 1_2	2	1	10	20	12	172,26	12
ID 2_1	1	10	2	20	12	210,10	11
ID 3_1	1	6	3	18	13	154,09	14
ID 4_1	1	7	3	21	11	171,90	13
ID 5_1	2	6	1	12	14	138,32	16
ID 6_1	2	7	2	28	10	143,79	15
ID 7_1	2	9	2	36	9	280,01	10
ID 7_2	4	9	2	72	7	327,30	7
ID 8_1	1	8	9	72	7	341,40	6
ID 9_1	1	10	9	90	6	418,12	3
ID 10_1	5	9	3	135	3	419,11	2
ID 11_1	8	9	2	144	2	446,73	1
ID 12_1	7	8	3	168	1	411,75	4
ID 13_1	7	9	2	126	4	366,30	5
ID 14_1	7	8	2	112	5	309,37	8
ID 15_1	3	9	2	54	8	307,08	9

The comparison shows that the critical events are assigned different rankings by traditional and fuzzy RPN methods; as expected fuzzy FMECA emphasises failures characterised by high severity conditions (i.e., events ID2_1 and ID9_1, with S = 10, in Table 9). In particular, for the event ID9_1, the traditional RPN ranking value is 6, whereas the fuzzy application assigns a ranking of 3. Moreover, the events ID7_2 (O=4, S=9, D=2) and ID8_1 (O=1, S=8, D=9) have the same RPN ranking values (7 in Table 9), whereas the detections are very different. In contrast, the fuzzy value prioritises the criticality of the event ID7_2, in which the failure is affected by human factors. The same reasoning can be applied for the events ID1_2 and ID2_1.

For the results described above, certain recommendations for safety equipment and procedures can be adopted to reduce the risk of radiological over-exposure.

For the tasks performed by the medical staff, the TPS and TCS treatment data can be checked by both the therapist and the physicist before beginning the treatment. A photo of the patient can be enclosed with the treatment plan card. Periodic maintenance of the backup battery can prevent faults, and an acoustic alarm can be provided to identify an uncharged battery. Periodic tests based on treatment simulations during accidental conditions can be planned to verify the control and safety systems or the procedures adopted by the medical staff.

When the treatment is in progress, an electrical switch detects whether the TR door is closed, as described in section 2. If the operator erroneously opens the door during the treatment, the irradiation process is interrupted by the DC safety motor, which returns the source to the safe. This safety device can be used as a further control system to stop the procedure if the stop button on the console fails.

Finally, workers should be certified before being allowed to operate control and safety systems. Certification should require that individuals achieve a passing score on an examination that tests the individuals' knowledge of the following topics:

- Instruction of the TPS and TCS procedure,
- Treatment parameters in the TPS and TCS process,
- Calibration,
- Maintenance or Repair.

Examinations consisting of multiple-choice questions and written problems that test the candidate's ability to apply the knowledge and skills required for each subject are recommended.

5. CONCLUSION

The paper presents the results obtained from the safety analyses of accidental events that can result in radiological over-exposure during HDR brachytherapy treatment. A modified FMECA technique with fuzzy set theory to evaluate the RPN was used to prioritise an exhaustive list of component failures as well as human errors that can lead to accidental events.

FMECA is a very important safety analysis tool that has widely used in many industrial areas; however, it is difficult to obtain a precise assessment of risks related to the probability of occurrence of a component failure, the severity of those failures, and their probability of detection.

Significant efforts have been undertaken in this field to use fuzzy logic to rank failure modes. However, this requires a large amount of expert knowledge, and these experts can often have different or inconsistent judgements, making it difficult to combine or complete the rules necessary for the fuzzy logic procedures.

To overcome this weakness and the difficulty in building a complete fuzzy if-then rule base, a new RPN fuzzy ranking model was proposed to evaluate the risk factors and their relative weights in a linguistic manner.

The fuzzy approach allowed for the identification of component faults and human errors that are necessary to achieve a better understanding of the radiotherapy treatment process so that it can be properly monitored and appropriately managed.

On the basis of these results, this methodology can solve some problems in conventional FMECA applications and improve the safety and quality process of radiological treatments, or of other applications in healthcare field.

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Table 7
FMECA of component faults

ID	Component	Failure mode	Failure effect (system)	Failure detection method	Failure rate (1/days)	Effect of failure on patients	O	S	D	Fuzzy RPN
1_1	SM stepper motor	Loss of power	HDR unit is stopped & DC motor withdraws the source to the safe	Light alarm & Warning on user control panel	$1.1x\ 10^{-5}$	No	1	1	2	33.78
1_2		Electrical blackout		no	$7\ x\ 10^{-5}$	No	2	1	10	172.26
2_1	DC safety motor	Loss of power	Operator goes into the TR to manually return the source to the safe	Light alarm & Warning on user control panel	$4.2x10^{-6}$	Patient over-exposure	1	10	2	210.10
3_1	Opto-pair sensors	Light sensor fault	Source position not verified	Software check & Warning on user control panel	$4.8x10^{-8}$	Treatment not completed correctly	1	6	3	154.09
4_1	Dwell position distance control device	Stepper motor failure	Source position not correct	Radiographic marker position not corresponding to the dwell position	$1.0x10^{-6}$	Erroneous treatment	1	7	3	171.90
5_1	Primary timer	Electronic fault	Source dwell time error	Inconsistency between the measurements of the two timers & Source is withdrawn into the safe position	$2.4x10^{-4}$	Treatment not completed correctly	2	6	1	138.32
6_1	Secondary timer	Electronic fault	Incorrect check of the primary timer	Software check & Source is withdrawn into the safe position	$2.4x10^{-4}$	Treatment not completed correctly	2	7	2	144.87
7_1	Backup battery	Power-off	DC motor fault	Control device to check if the backup battery is charged	$5.8x10^{-4}$	Patient over-exposure	2	9	2	280.01
7_2		Operator forgets to charge the battery			0.29		4	9	2	327.30
8_1	Software	Power-off	Safety and control system fault	No signal in the console system	$2.4x10^{-8}$	Patient over-exposure	1	8	9	341.40
9_1	Stop button on the console	Contact fault	During treatment, the stop button on the console did not retract the wire source	No	$5.47x10^{-6}$	Patient over-exposure	1	10	9	418.12

Table 8

FMECA of human errors

ID	Component	Failure mode	Failure effect (system)	Failure Detection method	Failure mode frequency (error per year)	Patient Failure effect	O	S	D	Fuzzy RPN
10_1	physicist	Dose calculation errors during TPS	Incorrect HDR treatment	The therapist detects the error	0.450	Patient over-exposure	5	9	3	419.11
11_1	therapist	Data insertion errors during TPS	Incorrect HDR treatment	Data do not correspond to the TPS planning & The physicist detects the error	0.91	Patient over-exposure	8	9	2	446.73
12_1	medical operator	Incorrect patient identification	Incorrect data are used during TCS	Therapist asks the patient name at the start of the treatment	0.77	Patient over-exposure	7	8	3	411.75
13_1	therapist	Error in loading patient information (from the database)	Incorrect data are used during TCS	Data do not correspond to the TPS planning & The physicist detects the error	0.72	Patient over-exposure	7	9	2	366.30
14_1	therapist	Error in the data entry for dwell time or dwell position programming	Incorrect data are used during TCS	Data do not correspond to the TPS planning & The physicist detects the error	0.60	Patient over-exposure	7	8	2	309,37
15_1	medical operator	Incorrect medical application of the catheter or applicator	Incorrect HDR treatment	Radiation therapist or physicist assisting the physician detects an error during applicator placement & Radiographic marker position not corresponding to the treatment plan	0.19	Patient over-exposure	3	9	2	307.08