FMECA Analyses of radiological over-exposure accident to patients in brachytherapy

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Abstract. This paper presents safety analyses of accidental events which can involve patient during High Dose Rate brachytherapy treatment in over-exposures. The study has been performed by using the well-known techniques FMECA modified by Fuzzy logic theory. Moreover, fuzzy HEART methodology was employed in order to evaluate human error probabilities for each treatment stage. The obtained results, aimed to obtain a list of the deviations with a reasonable probability to produce significant adverse outcomes, provided some recommendations for procedures and safety equipments to reduce the occurrence of radiological over-exposure accidents.

Keyword: High Dose Rate, radiation therapy, radiological risk, FMECA, fuzzy RPN.

1. Introduction

In 2001, Committee 3 (protection in medicine) of the International Commission on Radiological Protection (ICRP) formed a Working Party to study problems associated with the widespread introduction of High Dose Rate (HDR) brachytherapy, which concluded that a full report addressing such problems was desirable. Subsequently, a Task Group on Prevention of HDRate Brachytherapy Accidents performed studies to identify reported accidents and incidents by category (transport, handling, procedures, dosimetry, etc..); to identify potential events; and to analyze the geographic distribution of machines and trends.

It is estimated that about 500,000 procedures (administrations of treatment) are performed by HDR units annually. This technique delivers a very high dose, of the order of 1.6–5.0 Gy/min, so mistakes can lead to under- or over-dosage with the potential for clinical adverse effects. More than 500 HDR accidents (including some deaths) have been reported along the entire chain of procedures from source packing to delivery of dose, and the revision of their root causes confirms that the accidents rarely occur due to a single failure or human error [1]. They are instead caused by the combination of different events that denote weaknesses in the radiological practice.

So the prevention of radiological exposure accidents requires design of proper radioprotection systems with more quality assurance and highly qualified maintenance, together with accurate risk analyses which should allow to highlight the causes of the possible shortages and, if necessary, to predispose the safety devices against those events with high occurrence frequency, especially in case of radiotherapy procedure where the over-dosage accidents have devastating and sometimes fatal consequences.

In order to achieve this aim, the paper presents the results obtained in the safety analyses of some representative accidental events involving patient during HDR brachytherapy treatment in over-exposures, carried out by using modified FMECA (Failure Mode, Effects, and Criticality Analysis) methodology, for obtaining an exhaustive list of the deviations with a reasonable probability to occur. FMEA (Failure Mode and Effect Analysis)is a powerful qualitative tool for systematically identifying the initiating event and the root causes of unacceptable outcomes, though this tool has difficulties to identify accident sequences and dependences between equipment or human actions. In FMECA analysis, to classify each critical failure the calculation of Risk Probability Number (RPN) is used. In the present paper RPN fuzzy rule-based assessment model based on fuzzy logic theory [2] is proposed to systematically review of system or component failures as well as human errors in Brachytherapy treatment. Moreover to evaluate the error probability of human actions the fuzzy HEART methodology has been employed, as proposed in [3, 4].

The obtained results have allowed to characterize the critical points of the radioprotection systems, highlighting the human errors which principally contribute in occurrence frequency of high dose rate patient exposures. Moreover, it has been possible to suggest the introduction of suitable operating procedures that reduce the over-dose risk.

2. Safety analyses of the patient exposure in HDR brachytherapy

Brachytherapy treats cancer by placing radioactive sources directly into or next to the area requiring treatment, enabling clinicians to deliver a high dose with minimal impact on surrounding healthy tissues. Among the devices for the medical applications, the use of remote afterloading of radioactive sources is becoming increasingly popular in much countries because these units offer both the potential for superior dose distributions and the practical advantages of better radiation protection.

In this field, the safety assessment in high dose-rate HDR treatment delivery practices at the Oncological Unit of Paolo Giaccone Policlinic of Palermo (Italy) has been performed.

The examined system consists of a motor-driven source transport device for automatically transferring radioactive material between a shielded safe and the treatment applicator (MicroSelectron HDR manual)[5].

The device contains a small, sealed, 450 GBq ^{192}Ir stepping source, mounted at the end of a stainless steel drive wire. The afterloader is connected to the implanted applicator, catheter or needle using flexible transfer tubes.

Typically, the dose is calculated at representative points by the Treatment Planning System (TPS) and then the therapy is performed by Treatment Control System (TCS) which enables an operator to apply, by remote control, a radionuclide source into the body. The TCS supports amongst others 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 any computer system that produces isodose curves for remote afterloaders, it is imperative that the user understand the algorithm and exactly how the doses are computed. The user may choose to enter key parameters specific to a radionuclide and source model, or select parameters from an existing menu.

The after-loader unit contains (Fig. 1):

- Geiger-Muller counter to check the source in safe;
- Stepping Motor (SM) to drive the source
- Direct Current (DC) motor available for source retraction in case of SM failure, supplied by backup battery in case of electrical blackout;
- check cable, identical in appearance to the source cable (but not radioactive) to check the treatment channel, transferring tube and the distance of the pre-programmed source positions;
- opto-pair to verify source position;
- several channels for source transport and transfer tube connector;
- primary and secondary timers for measurement the pre-programmed exposure times.

A “last resort” mechanical system for manually returning the source to the safe, in the event of other electrical source return mechanisms fail, is included.

The check cable is connected with a second stepper motor. When the appropriate stepper motor rotates the source or the check cable is advanced in the treatment channel and positioned with an accuracy of $\pm$ 1 mm.

The afterloader system drives the source mechanically 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, whereas a secondary timer measures the time between the source channel transit time and the dwell time for each pre-programmed locations. The software system in TCS checks the consistence between the measurements performed by the timers, and the data are also compared with those reported in the treatment plan. If error occurs, the source is withdrawn into the safe position. In case of failure of both timer, the operator in the (Control Room) CR is

alerted by light alarm and warning in the consol display.
Prior to the initial use of a new (or replacement) applicator, it is necessary to verify that the source dwell positions correspond to the radiographic marker positions used in simulation and treatment planning. The dose distribution can be optimized by adjusting the dwell time at each source position.
Moreover, for each type of HDR treatment, the procedures and duties of each team member should be carefully defined. A radiation therapist or physicist assisting the physician during the applicator placement should document: the applicators type used, body anatomy, surface markers.

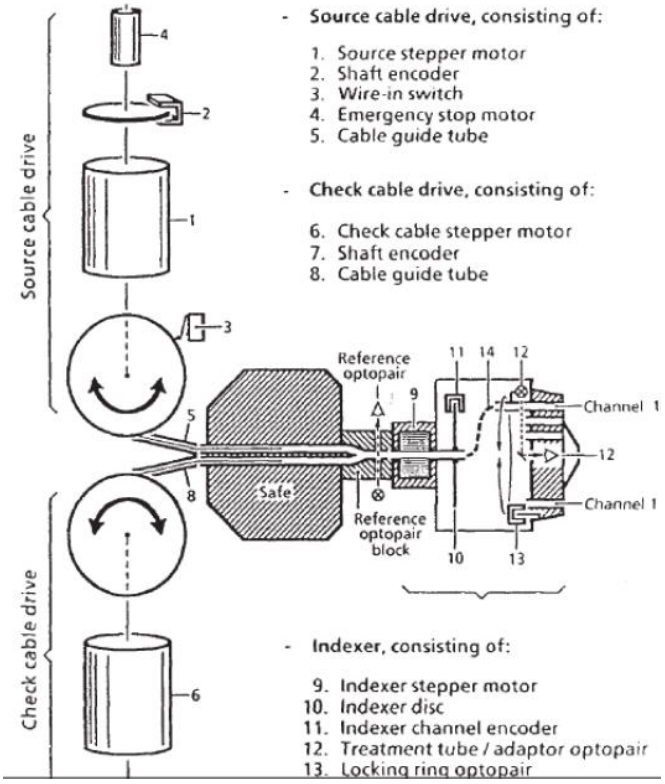

Fig. 1 Components of the after-loader unit.

The indexer guides the source into one of the 18 source channels. Before the active source is inserted into any of the channels, a dummy source is inserted to check for obstructions.
The control console, located inside the CR operates the after-loader, shows the source position on the display, the treatment progress, and prints out a report of the treatment.
Tree emergency stop push-buttons, located on the HDR unit, inside the Treatment Room (TR) and on the control console located in the CR, respectively, allow interruption of the procedure at any time.
When the treatment is in progress, an electrical switch detects if 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 withdraws the source in safe.

3.1 FMECA Analysis

FMEA may be performed to identify failure scenarios in the examined facility, i.e. potential accident initiators by systematically reviewing the failure of each system or component in terms of its potential consequences.
The FMECA analysis is a procedure that is performed after a FMEA analysis to classify each potential failure effect according to its severity and probability of occurrence (Pillay and Wang, 2003). In particular,

three numerical values can be used to describe each failure mode: Occurrence (O) which describes to the probability that a particular accidental event occurs ; severity (S) which is a measure of the severity of the consequences resulting from the failure mode if it is not detected and corrected; Detectability (D) which describes the probability that the failure will be detected before the treatment commences or the failure is effective. Multiplying these three numbers together yields a Risk Probability Number (RPN) which can be used for prioritizing quality control tests and activities.
In general, these three parameters are estimated by experts in accordance with a scale from "1" to "10" based on commonly agreed evaluation criteria. Higher value points to critical situation. Tables 1 through 3 summarize the evaluation criteria for occurrence, severity, and detect ratings, respectively, which is used practically in high-risk medical applications.
The calculated RPN rank will be between 1 and 1000, and some users define priorities in their FMECA procedure as:

- acceptable if RPN < 200
- undesirable 200 < RPN <500
- unacceptable if RPN > 500

In this paper to evaluation of RPN number, a fuzzy rule-based assessment models, similarly to one suggested by Guimarees et al. [6, 7], is used to identify the critical events relevant both human errors and potential failures.
As well known, a fuzzy rule can be created by combining various fuzzy sets, to form the premise (input fuzzy sets) and the consequence (output fuzzy sets) of the rule. The fuzzy inference sequence are performed by the following steps: fuzzy input composition, rule evaluation, fuzzy output composition, defuzzification. The fuzzy input and output composition is the process of decomposing input and outputs variables into one or more fuzzy sets. For example, the first step to perform a risk study based on fuzzy logic is to define the linguistic terms connotations and the relation with the factors used on risk estimation.
After the inputs and outputs have been decomposed into fuzzy sets, a set of fuzzy if-then-else rules is used to process the inputs and produce a fuzzy output. Each rule consists of a condition and an action where the condition is interpreted from the input fuzzy set and the output is determined on the output fuzzy set. In other words fuzzy inference is a method that interprets the values in the input vector and, based on some set of rules, assigns values to the output vector.
In this research, the parameters O, S, and D (used as input fuzzy sets) are combined as linguistic data. The fuzzyfication process is based on five fuzzy triangular and trapezoidal membership functions that show the degree of potential attribute as follows: Very High, High, Moderate, Low, and Very Low, denoted as VH, H, M, L, and VL. The graphical representation of fuzzy membership function to Occurrence, Severity and Detection are identical and only one, Occurrence is shown in Fig. 2.
The fuzzy output RPN was scaled in the range 0 through 1000 in order to be compatible with the classic results (Fig. 3) and the corresponding five membership functions are: Acceptable (A), Almost Acceptable (AA), Undesirable (U), Almost Unacceptable (AU), and Unacceptable (U).These RPN linguistic representations taken into account the classification above described.
Concerning the fuzzy IF-THEN rules, it assumes the form:

If x *is* A *then* y *is* B (1)

where A and B are the linguist variable defined by fuzzy sets on the ranges (universe of discourse) X and Y, respectively.
In the present study, the fuzzy rule base has 125 (5 O×5 S×5 D). A simple example follows:

If Occurrence *is* L *and* Detection is VL *and* Severity *is* VH *then* RPN *is* VH (2)

Table 4 presents a sample of the inference rules adopted for fuzzy RPN evaluation.
The finally step is the defuzzification to obtain a crisp value.

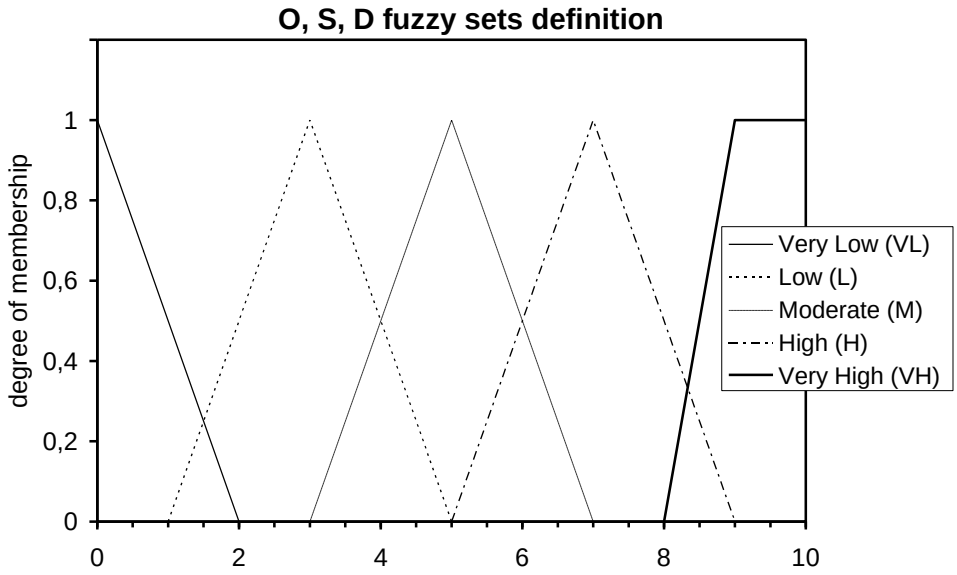

Fig. 2- Occurrence fuzzy sets definition.

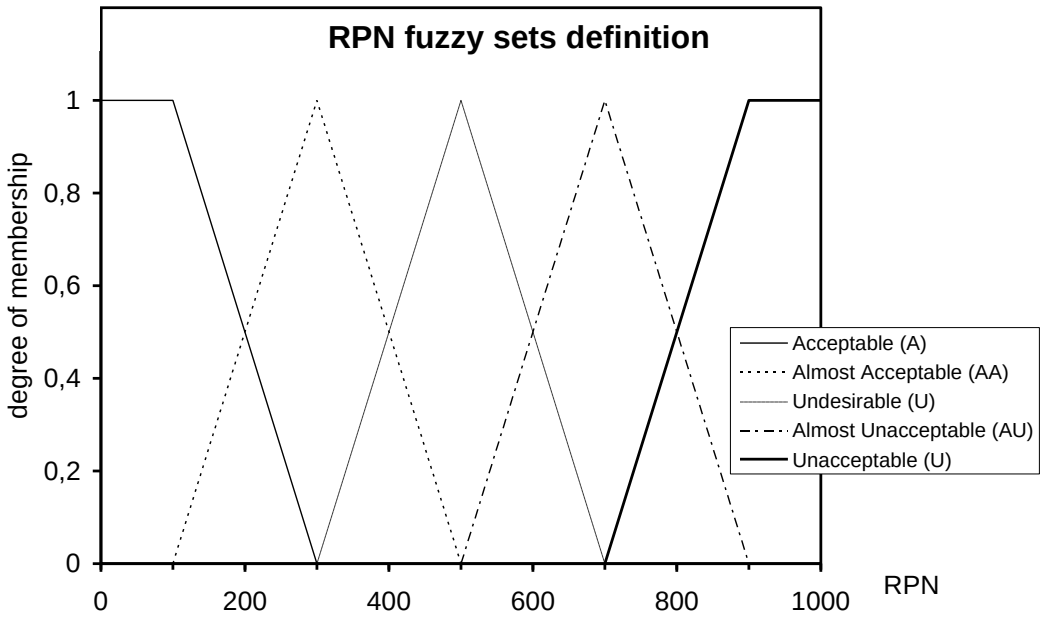

Fig. 3- RPN fuzzy sets definition.

Table 1 - Occurrence rating.

Probability of occurrence	Human error occurrence probability	Component failure occurrence probability	Rank	Linguistic value
Failure unlikely	One time per 10 year	$< 5\ 10^{-6}$	1	VL
Few Failures	Some time per 5 year	$5\ 10^{-6} \div 10^{-4}$	2, 3	L
Occasional failures	Some time per 2 year	$10^{-4} \div 5\ 10^{-3}$	4, 5, 6	M
Repeated failures	One time per year	$510^{-3} \div 5\ 10^{-2}$	7, 8	H
High Inevitabile failure	More time per year	< 0.5	9, 10	VH

Table 2 Severity rating.

Severity ranking		Rank	Linguistic value
Very minor	No effect	1	VL
Very Low	Minor effect	2, 3	L
Moderate	Potential ineffectiveness	4, 5, 6	M
High	Regulatory non-compliance	7, 8	H
Very High	Injury or death	9, 10	VH

Table 3 - Detection rating.

Likelihood of detection ranking	Rank	Linguistic value
Almost Certain	1	VH
High	2, 3	H
Moderate	4, 5, 6	M
Remote	7, 8	L
Absolute uncertainty	9, 10	VL

Table 4 - Inference rules adopted for fuzzy RPN evaluation in case of Occurrence Very Low.

Occurrence VL						
		Severity				
		VL	**L**	**M**	**H**	**VH**
Detection	**VH**	**VL**	**VL**	**VL**	**L**	**M**
	H	**VL**	**VL**	**L**	**M**	**M**
	M	**VL**	**L**	**M**	**M**	**H**
	L	**L**	**M**	**M**	**H**	**H**
	VL	**M**	**M**	**H**	**H**	**VH**

3.1. FMECA analyses in HDR Brachytherapy

By applying fuzzy FMECA technique, a systematically review of system or component failures as well as human errors in Brachytherapy treatment have been studied.

To evaluate human errors probability the fuzzy HEART methodology has been employed. The obtained results are reported in Table 5 in terms of triangular fuzzy error probability sets and crisp value of the probability expressed as error per years, obtained by using the center area defuzzification method. The number of patient per years is considered equal to 100.

The probabilities have been evaluated by taking into account that the operating medical team is trained in operating practices, whereas the conditions that can favour the error are assessed to be “Shortage of time for error detection or correction”, “Noisy signal”, “A means of suppressing or overriding information”, and “Mismatch between perceived and actual risk”.

The obtained results in classic FMECA approach are reported in Tables 6 and 7 for components failures and human errors, respectively.

As shown in Figure 3, the more critical events are rated in the following order: data insertion errors in TPS (ID 11), error in data entry of dwell time or dwell position programming (ID 14), backup battery failure (ID 7), dose calculation errors in TPS (ID 10), incorrect identification of the patient (ID 12).

In Figure 4 the results obtained in terms of fuzzy RPN numbers are shown. In this case the rating is: backup battery failure (ID 7), data insertion errors in TPS (ID 11), error in data entry of dwell time or dwell position programming (ID 14), dose calculation errors in TPS (ID 10), during treatment, the stop button in the console did not retract the wire source (ID 9), failure of the computerized security program with incorrect calculation after wrong data entry or incorrect use of source strength, or step size, tip length (ID 8), incorrect identification of the patient (ID 12).

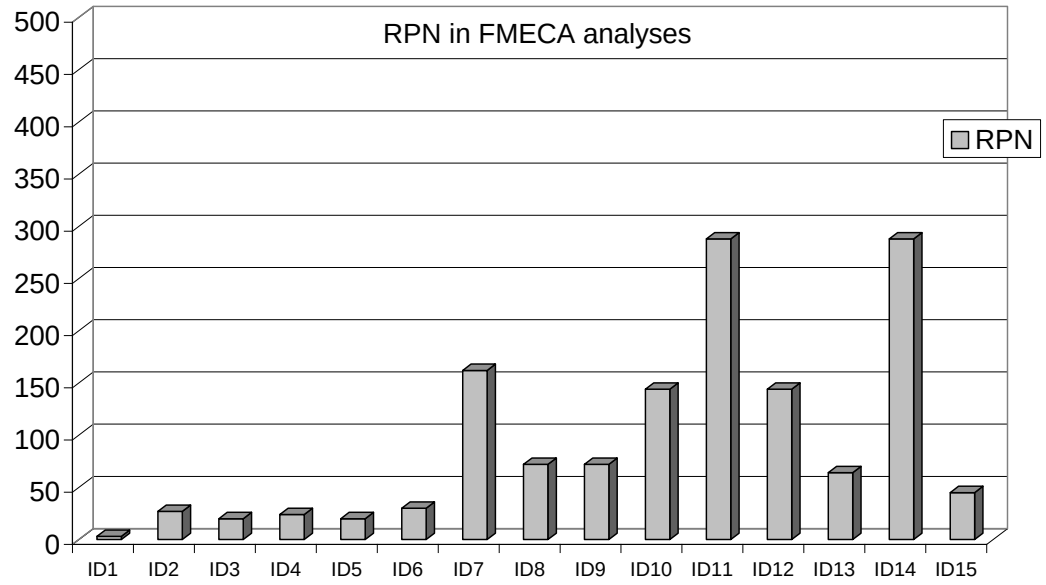

Figure 3. RPN indexes classic FMECA analyses.

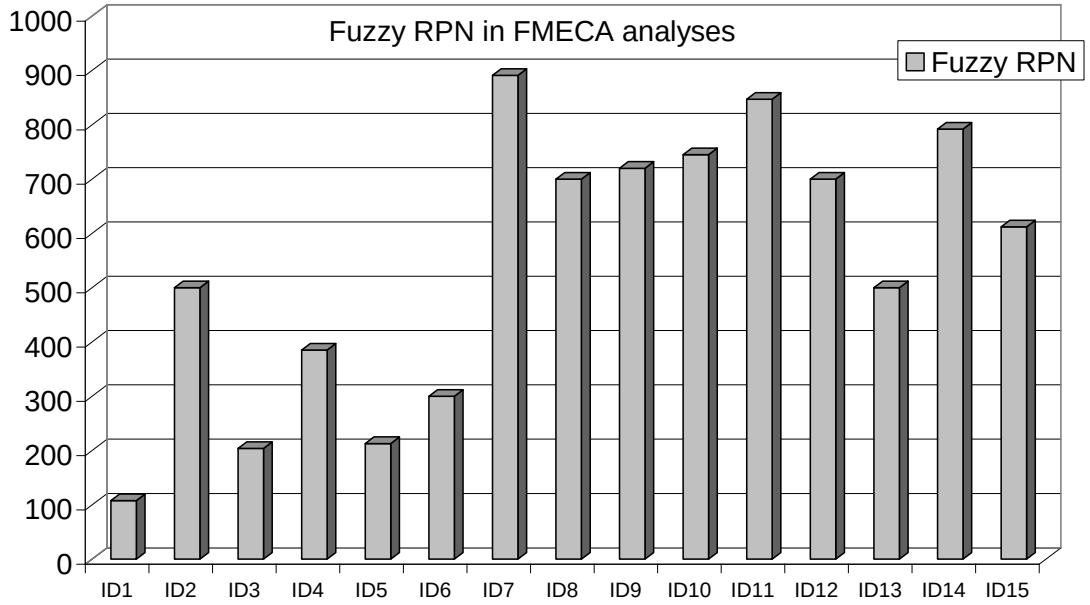

Figure 4. Fuzzy RPN indexes.

Table 5. – Triangular membership function of human error probabilities and relevant crisp number

Human errors	Probabilità fuzzy			probability expressed in error per year
	x_1	x_2	x_3	
Dose calculation error in TPS	1.98E-3	2.84E-3	3.84E-3	0.2
Data entry error in TPS	4.22E-3	6.24E-3	8.64E-3	0.4
Incorrect identification of the patient	1.08E-2	2.50E-2	4.98E-2	1.0
Error in load a patient study (from database)	4.22E-3	6.24E-3	8.64E-3	0.4
Error in data entry of dwell time or dwell position programming	4.22E-3	6.24E-3	8.64E-3	0.4
Incorrect medical application of catheter, or applicator	1.54E-3	2.16E-3	2.88E-3	0.6

On the basis of the results described above, some recommendations on safety equipment and procedures can be adopted to reduce the risk of radiological over-exposure. For example, periodic maintenance of the backup battery can prevent component faults, whereas an acoustic alarm can be provided to signal the condition of uncharged battery. When the treatment is in progress, an electrical switch detects if 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 returns the source to the safe. This safety device allows also to dispose a redundant system in case of stop button in the console failure to withdraw the source in safe, if necessary.
For the medical staff tasks, TPS and TCS treatment data can be checked and compared both by Therapist and Physicist. Moreover passport type photo of the patient can be enclosed in treatment plan. It is worth to highlight that the fuzzy approach procedure allows a more accurate ranking classification of the critical events.

4. Conclusion

The paper presents the results obtained by safety analyses of accidental events which can involve patient during HDR brachytherapy treatment in over-exposures, performed by using modified FMECA techniques. In particular, the calculation of the Risk Probability Number (RPN) is performed by using fuzzy rule-based assessment model based on fuzzy logic theory. Moreover, the fuzzy HEART methodology is also employed in order to evaluate human errors for each treatment stage.
As expected, the obtained results suggest that the events related to human error are very significant and important in the accidental scenarios.
On the basis of the obtained results in terms of fuzzy RPN, it is worth to highlight that the fuzzy approach to RPN evaluation produces a more accurate ranking about the critical events importance, so it is more immediate to provide some recommendations for procedures and safety equipment to reduce the occurrence of radiological over-exposure accidents.

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Table 6 - FMECA of components faults

ID	Component	Failure mode	Failure effect (system)	Failure Detection method	Failure mode frequency (1/h)	Patient Failure effect	O	S	D	RPN
1	SM stepper motor	Loss of power	HDR unit stopped its operation & DC motor withdraws the source in safe	Light alarm & Warning in user control panel	4.57E-7	No	1	1	3	3
2	DC safety motor	Loss of power	HDR unit stopped its operation & Operator goes in TR to manual-ly return the source in safe	Light alarm & Warning in user control panel	1.67E-7	Patient over-exposure	1	9	3	27
3	Opto-pair sensors	light sensor fault	Source position not verified	Warning in user control panel	2.0E-9	Treatment not completed correctly	1	5	4	20
4	Dwell Position Distance control device	Stepper motor failure	Source position not correct	Radiographic marker position not corresponding to dwell position	2.0E-7	Erroneous treatment	1	7	3	21
5	Primary Timer	Electronic fault	Source dwell time error	Inconsistence between the two timers measurements & source is withdrawn into the safe position	1.0E-5	Treatment not completed correctly	2	5	2	20
6	Secondary Timer	Electronic fault	Not correct check of primary timer	Source is withdrawn into the safe position	1.0E-5	Treatment not completed correctly	2	5	3	30
7	Backup battery	Power-off	DC motor fault in case of electrical blackout	No	2.41E-5	Patient over-exposure	3	9	9	243
8	Software	Power-off	Failure of the computerized security program with incorrect calculation after wrong data entry OR *i*ncorrect use of source strength, or step size, tip length	No	1.0E-9	Patient over-exposure	1	7	9	63
9	Stop button in the console	Contact fault	During treatment, the stop button in the console did not retract the wire source	No	2.28E-7	Patient over-exposure	3	7	9	189

Tale 7 – 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	RPN
10	physicist	dose calculation errors in TPS	Incorrect HDR treatment	no	0.2	Patient over-exposure	2	8	9	144
11	therapist	data insertion errors in TPS	Incorrect HDR treatment	no	0.4	Patient over-exposure	4	8	9	288
12	medical operator	Incorrect identification of the patient	incorrect data are used in TCS	Therapist asks the patient name first of beginning treatment	1.0	Patient over-exposure	8	9	2	144
13	therapist	Error in load a patient study (from database)	incorrect data are used in TCS	Data are not corresponding to TPS	0.4	Patient over-exposure	4	8	2	64
14	therapist	Error in data entry of dwell time or dwell position programming	incorrect data are used in TCS	no	0.4	Patient over-exposure	4	8	9	288
15	medical operator	Incorrect medical application of catheter, or applicator	Incorrect HDR treatment	A radiation therapist, or physicist assisting the physician during the applicator placement & Radiographic marker position not corresponding to treatment plan	0.6	Patient over-exposure	5	9	1	45