N. 2358226

13th INTERNATIONAL CONGRESSOF THE INTERNATIONAL RADIATION PROTECTION ASSOCIATION
13 - 18 MAY 2012, GLASGOW, SCOTLAND

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

M. Casamirra, F. Castiglia, M. Giardina, E. Tomarchio
University of Palermo, V.le delle Scienze, 90128, Palermo, Italy

ABSTRCT

This paper presents safety analyses of accidental events which can involve patient during High Dose Rate brachytherapy treatment in over-exposures. In particular 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 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 equipment to reduce the occurrence of radiological over-exposure accidents

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.

• This paper presents safety analyses of accidental events which can involve patient during High Dose Rate brachytherapy treatment in over-exposures. In particular 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 192Ir 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. The afterloading device is shown in Figure 1

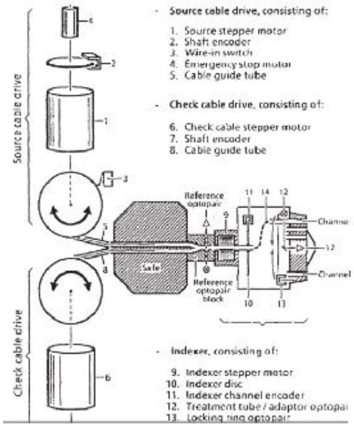

Fig. 1

FUZZY FMECA ANALYSES

• FMEA may be performed to identify failure scenarios in 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.
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.

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 Inevitable 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

• In this paper to evaluation of RPN number, a fuzzy rule-based assessment models, similarly to one suggested by Guimarees et al., is used to identify the critical events relevant both human errors and potential failures.

• 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.

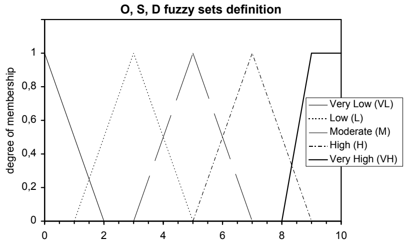

Fig. 2

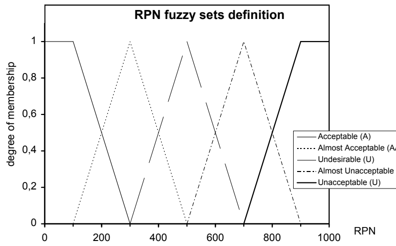

Fig. 3

• An example of FMECA analyses of components failures is reported in the following.

ID	Component	Failure mode	Failure effect (system)	Failure Detection method	Failure mode frequency (1/h)	Patient Failure effect
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
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
3	Opto-pair sensors	light sensor fault	Source position not verified	Warning in user control panel	2.0E-9	Treatment not completed correctly
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
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
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
7	Backup battery	Power-off	DC motor fault in case of electrical blackout	No	2.41E-5	Patient over-exposure
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
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

RESULTS and CONCLUSIONS

• Figures 4 and 5 reports the obtained results in terms of classic and fuzzy RPN indexes, respectively. As shown in Figure 4, 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 5 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).

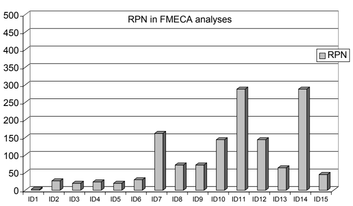

Fig. 4

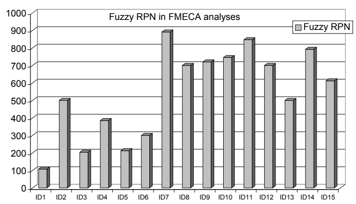

Fig. 5

• On the basis of the results described above, 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. 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.

The authors tanks Nuclital for furnishing the figure showing the MicroSelectron afterloading unit.