**ABSTRACT**

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.

**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.

**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 ranked 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).

- 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.

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