Safety analyses of potential exposure in medical irradiation plants by Fuzzy Fault Tree

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Abstract. The results of Fuzzy Fault Tree (FFT) analyses of various accidental scenarios, which involve the operators in potential exposures inside an High Dose Rate (HDR) remote after-loading systems for use in brachytherapy, are reported. To carry out fault tree analyses by means of fuzzy probabilities, the TREEZZY2 computer code is used. Moreover, the HEART (Human Error Assessment and Reduction Technique) model, properly modified on the basis of the fuzzy approach, has been employed to assess the impact of performanceshaping and error-promoting factors in the context of the accidental events. The assessment of potential dose values for some identified accidental scenarios allows to consider, for a particular event, a fuzzy uncertainty range in potential dose estimate. The availability of lower and upper limits allows evaluating the possibility of optimization of the installation from the point of view of radiation protection. The adequacy of the training and information program for staff and patients (and their family members) and the effectiveness of behavioural rules and safety procedures were tested. Some recommendations on procedures and equipment to reduce the risk of radiological exposure are also provided.

KEYWORDS: Potential exposure; Fuzzy Analysis; Radiotherapy; irradiation plants.

1. Introduction

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The International Commission on Radiological Protection (ICRP) has issued many reports providing advice on radiological protection and safety in irradiation plants employed, for example, in industrial and agricultural applications, radiotherapy, and particle physics research [1-4].

Even though great care is given in planning safety systems to prevent the potential radiological exposure accidents, its effectiveness is conditional upon the work performance of the operator, which may act making mistakes during a well-designed task sequence. This is also confirmed by experience which has shown, up till now, that the human factor results one of the most important causes of accidental events in hazard industrial plants and that the underlying reasons of such events are very complex because of their difficult interpretation. Unfortunately, the human errors are also among the most difficult to quantify, because they are strongly dependent on the circumstances and on the socalled performance shaping factors (layout of the workplace, amount of noise and distraction, level of stress, and so on).

The lack of accurate quantitative human reliability data is to be seen as a serious limitation and a major source of uncertainty in the risk assessment. So, in the last years, various Authors have suggested to resort to fuzzy sets models which, indeed, prove to be well suited when uncertainty is present and little is known about it [5-8].

To further deepen studies relevant the risk in the above mentioned industrial fields, at the same time dealing with the uncertainties related to human errors, we carried out analyses by using Fuzzy Fault Tree (FFT) techniques. In particular, we are interested to the hypothesised accidental events which lead to the potential radiological exposure of the medical team operating in a center equipped with High Dose Rate (HDR) remote after-loading system for use in brachytherapy.

To evaluate the probabilities of the accidental events related to human error, it seemed appropriate to us to take into account the impact of situational characteristics and error-promoting factors, and to employ all these in the HEART (Human Error Assessment and Reduction Technique) methodology [9], a first generation HRA (Human Reliability Analysis) method, modified by us on the basis of fuzzy sets concept [10].

The analyses have been carried out by using a computer program named TREEZZY2 (TREE fuZZY) [11, 12] developed at the Department of Nuclear Engineering, of Palermo University. The code allows the use of fuzzy or classic methodologies in Fault Trees (FT) and Event Trees (ET) reliability analyses

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and to deepen the analyses by determining the tree's minimal cut sets and the importance indexes for the basic events.

As shown in the following, these studies have also allowed to provide procedural recommendations and suggestions on additional safety equipments to reduce the risk of radiological exposure.

2. Uncertainty analysis by fuzzy probabilities

The failure probabilities for components or systems can be affected with some uncertainties, either because of insufficient amount of available data or related to their imprecision as regards those connected with human errors. For this reason, the evaluation of the uncertainty affecting the overall system failure probability is, in many cases, mandatory, and entails complicated calculations to propagate the uncertainties up to the final probability.

The difficulties concerning insufficient amount of failure data, uncertainties, complexity of the propagation calculations, have been recently get over by resorting to the Fuzzy Set Theory (FST).

The Fuzzy logic model was introduced by Zadeh [10], to deal with the problem in which the phenomena are imprecise and vague. As it is known, the traditional set theory is based on a bivalent logic where a number or object is either a member of a set or it is not. Contrary to that, let X be a collection of number or objects (fuzzy set), called the universe, whose elements are denoted by x, a fuzzy subset A in X is characterized by a membership function $\mu_{\alpha}(X)$ which associates a real number in the interval [0, 1] with each element x in X. The function value $\mu_A(X)$ 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 (see Fig. 1), even if other shapes are used too.

Figure 1: Membership functions of triangular (a) and trapezoidal (b) fuzzy sets.

Let x, $x_1, x_2, x_3 \in R$ (Real line), a triangular fuzzy number is a fuzzy number A in R, if its membership function $\mu_A: R \rightarrow [0, 1]$ is:

$$
\mu_A(x) = \left[\frac{x - x_1}{x_2 - x_1} \text{ for } x_1 \le x \le x_2; \quad \frac{x - x_3}{x_2 - x_3} \text{ for } x_2 \le x \le x_3; \quad 0 \text{ otherwise} \right] \tag{1}
$$

with $x_1 < x_2 < x_3$. The triangular fuzzy number can be denoted by $A = [x_1; x_2; x_3]$ where x_2 gives the maximum grade of $\mu_A(x)$, i.e. $\mu_A(x_2) = 1$, the most probable value of the evaluation data, whereas x_1 and x_3 are the lower and the upper bound of the variable area for the evaluation data.

Further, a fuzzy number is trapezoidal fuzzy number if its membership function $\mu_A: \mathbb{R} \to [0, 1]$ is:

$$
\mu_A(x) = \left[\frac{x - x_1}{x_2 - x_1} \text{ for } x_1 \le x \le x_2; \quad \text{1 for } x_2 \le x \le x_3; \quad \frac{x - x_4}{x_3 - x_4} \text{ for } x_3 \le x \le x_4; \quad \text{0 otherwise} \right] \text{ (2)}
$$

with $x_1 < x_2 < x_3 < x_4$. The trapezoidal fuzzy number can be denoted by $A = [x_1; x_2; x_3; x_4]$. The interval $[x_2; x_3]$ are the most likely values of $\mu_A(x)$, x_1 and x_4 are the lower and the upper bound of the variable area for the evaluation data.

These two kinds of fuzzy numbers are used because these specific membership functions are intuitively easy for evaluation, under some weak assumptions [13].

3. Fuzzy approach to HEART

The HEART technique, derived from a wide range of findings in the ergonomics literature, assumes that any predicted reliability of task performance may be modified according to the presence and strength of the identified *Error Promoting Conditions* (EPCs). The method identifies nine generic task types and proposes nominal human unreliability values and their suggested bounding values, together with seventeen EPCs whose influence on performance task is considered of maximum effect [9]. In the HEART methodology the failure rate is estimated by using the following empirical expression:

$$
P = P_0 \left\{ \prod_i \left[(EPC_i - 1)Ap_i + 1 \right] \right\}
$$
 (3)

where P is the probability of human error, P_0 is the nominal human unreliability, EPC_i is the *i*-th Error-Promoting Condition and Ap_i is the engineer's assessment of the proportion effect (from 0 to 1) for each *i*-th EPC, so called *proportion assessment factor*. As above said, the method provides a very useful list of nominal human unreliability and error-promoting conditions, with suggested values for each P_0 (Table 1) and EPC_i (Table 2).

Table 1: Value of the probability of human error, P_0 .

Table 2: Value of the error-promoting condition EPC.

The use of HEART technique is favourable for its simplicity and easy application, but presents several problems. For example, the EPCs are not independent of each other and the use of the method is extremely subjective and heavily relied on the experience of the analyst. Moreover, they are an useful list of factors to qualitative guide safety managers, however the numerical values are context-sensitive and the predictive equation is empirical.

In order to take into consideration the above mentioned weaknesses, in this paper it is proposed to modify such technique by using the concept of the fuzzy linguistic expressions in the representation of the proportion assessment factors, Api. This approach to define the Api factor has been made because in the HEART model, among others, this parameter is the one mostly characterized by subjective and imprecise connotations.

As it is known, the concept of the linguistic variable, defined as a variable the values of which are words, phrases, or sentences in a natural or artificial language, is very useful when ones deals with situations too complex or too ill-defined to be reasonably described in conventional quantitative expressions. These Linguistic Values (LV) can be represented by the approximate reasoning of fuzzy number. For example, for Very Low (VL), Low (L), Medium (M), High (H), Very High (VH) the fuzzy number of these linguistic values can be described as in Fig. 2, whereas the relevant membership functions can be represented as Eq.s 4 trough 8.

Figure 2: Fuzzy linguistic variables representation.

The linguistic variables so represented can be suitable employed to estimate the Ap_i in Eq. (3) , which can be expressed as:

where AP_{LV} is for each ith EPC the triangular membership function variable represented by Eqs. 4 through 8. In the reported fuzzy fault tree analyses we have evaluated the fuzzy probabilities of basic events related to human error by using the HEART methodology modified as above said.

4. FFT analyses of the medical operator potential exposure in HDR brachytherapy

HDR brachytherapy is an advanced cancer treatment which involves remote-controlled after-loading of a high-activity sealed source (usually, ¹⁹²Ir) directly within the tumour of the patient. Over the last few years, HDR brachytherapy is a rapidly growing technique that has been replacing Low Dose Rate (LDR) procedures which often requires that the patients remain as still as possible for days at a time.

The remote-controlled after-loading eliminates the hazards of radiological exposure, allowing complete radiation protection for all hospital staff, regardless of whether LDR or HDR brachytherapy is used. However the use of HDR brachytherapy has the advantage that the treatments can be performed, as above said, in just a few minutes and to reduce the radiation exposure in the surrounding healthy tissues. An adequately shielded room, (Treatment Room, TR) for the remote afterloading device, a necessary imaging equipment, and a separate room for the operators (Control Room, CR) are required to avoid direct exposure of the operators. This allows all components of the treatment to take place without moving the patient.

The afterloader system here examined consists of a motor-driven source transport system for automatically transferring 192Ir source between a shielded source container and the treatment applicator. Parts of the system are: a Stepping Motor (SM) to move the source; a backup battery and Direct Current (DC) safety motor to withdraw the source into the safe; a control device to check if the backup battery is charged; a source transferring and positioning system; several channels for source transport and a built-in Geiger-Muller counter inside the HDR to check that the source has returned to the safe[14].

The control console, located inside the CR, operates the afterloader, shows the source position on the display as the treatment progresses, and prints out a report of the treatment. The monitoring of ambient dose level of the TR by using gamma detector, and the warning lights and acoustic alarms are also an integral part of safety devices. Tree emergency stop push-buttons located, respectively, on the HDR unit, inside TR and on the control console inside the CR allow to interrupt the procedure in 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 into the safe.

4.1 Description of the accidental scenario analysed by using FFT

The hypothesized accidental scenarios which lead to the potential exposure of the medical team during an HDR treatment procedure, are schematized by the following main circumstances:

- A. The operator, erroneously, tries to enter the treatment room when the irradiation is in progress. The failures of the following safety systems also occur: gamma detector, DC safety motor; electrical switch; warning lights and acoustic alarms. For these last systems, it is also considered that the signals can be ignored by the operator.
- B. The operator goes into the treatment room to manually withdraw the source into the shielded container when the electrical blackout occurs and the source safety transferring systems (DC motor and backup battery) fail.
- C. At the end of the treatment process, the operator must go into the treatment room to manually withdraw the source into the shielded container because the following components failure occurs: stepper motor; DC motor; all tree of the emergency stop push-buttons.
- D. The operator begins the irradiation and fails to notice that another operator is in the treatment room. This can occur if the operator is distracted and doesn't perform the visual inspection by television camera located inside the control room. The failure of the emergency stop pushbutton in the treatment room also occurs.

The above depicted scenarios are resumed in the fault trees reported in Figs. 3 through 7. The failure data used for the analysis are shown in Tables 3 and 4 as fuzzy probability.

Figure 3: Level of the fault tree.

Figure 4: Operator tries to enter in TR when the irradiation is in progress subfault tree.

Figure 6: Failure of the source transferring system at the end of the treatment process sub-fault tree.

Figure 5: Electrical blackout Sub - fault tree.

Figure 7: Operator fails to notice another operator in TR sub-fault tree.

We point out that the method described in a previous section has been adopted for fuzzy probability evaluation of the components and safety system, whereas the human error probability have been evaluated taking into account that the operating medical team is trained in operating practices.

The analysis carried out with the TREEZZY code, shows for the operator exposure the Top Event (TE) fuzzy probability:

$$
P(TE) = [x1, x2, x3] = [1.9 10-5; 2.56 10-5; 3.32 10-5] /year.
$$
 (10)

In Figs. 8 and 9 the obtained results in terms of the fuzzy FIM (Fuzzy Importance Measure) and FUIM (Fuzzy Uncertainty Importance Measure) indexes exhibiting the higher values are also reported.

Table 3: Occurrence Probability relevant to technical faults.

Table 4 : Occurrence Probability relevant to human errors.

Figure 8: FIM and FUIM indexes.

As it can see in Fig. 8, the more critical events are in correspondence of the accidental circumstances connected to the electrical blackout and the failure of the source safety transferring systems in safe container. It is to be noted that an important contribution to the uncertainty in the TE failure probability is related to the SM and DC motors. For the events connected to human error, high FIM and FUIM values are obtained for the operator which fails to notice that another operator is in TR and begins the irradiation procedure, and, the operator in the TR which disregards the acoustic alarm.

On the basis of these results, to reduce the risk of radiological potential exposure, besides what was provided with the plant (switches, push-buttons, dose alarms and so on), some recommendations on safety equipments and procedures can be adopted. For example, it can to think add in the HDR unit a passive safety system to allow the fast return of the source in safe container (however, with loss of device compactness), whereas to avoid the presence of an operator inside the TR when the irradiation process starts, it can also plan a procedure based on the acoustic and/or visual inspection of TR (for example with a motion detector camera). Moreover, periodic maintenance of the backup battery can prevent nearly all component faults.

4.2. Fuzzy potential dose evaluation

For some of the accidental scenarios characterised by higher probabilities, the fuzzy potential dose was evaluated. In particular, the more critical accidental event involves emergency entry of the operator into the TR, at the end of the treatment process, to manually withdraw the source into the shielded container (GATE3 in Fig. 3). The fuzzy probability for this event is:

$$
P (GATE3) = [1.2*10-5; 1.46*10-5; 1.87*10-5] /year
$$
 (11)

It was hypothesized a model which foresees for an operator the following procedures:

- entry in the TR, drawing near the patient and source removing from the anatomic district;
- going out with the patient out of the TR, in security.

whereas, for the second operator (physicist) it was supposed:

entry in the TR, after the going out of the patient and source manual recovering by a crank.

Since during the movement described above, the operator moves towards the source still into the treatment site, the relation between the dose rate and the distance, supposed variable with the operator moving velocity, was arranged on the hypothesis of point-like source as

$$
\frac{dD}{dx} = \frac{\Gamma \times A}{\nu \times (h^2 + x^2)}\tag{12}
$$

where Γ is the Specific Gamma Constant, *v* is velocity of operator, *x* the distance of the source at the time *t*, *h* the source height with reference to a landmark (gonads, if not else).

The solution of (12), with *v* and *h* no zero, with the operator moving between an initial position ($x_{initial}$) and a final one (x*final*), results:

$$
D = \Gamma \times A \times \frac{1}{h \times v} \times (arctg \frac{x_{final}}{h} - arctg \frac{x_{initial}}{h})
$$
 (13)

For the dose evaluation it was assumed the maximum value of 450 GBq (12 Ci) for source activity [14], a value Γ of 1.599×10^{-4} mSv h⁻¹ per MBq at 1 meter [15], while between patient and control room a distance of about 5 m, for *h* a distance of 10 cm. For the velocity parameter, the following values have been assumed:

- For radiotherapist, a drawing near velocity of 1 m/s;
- For radiotherapist and the patient going out of the TR, a velocity of 0.5 m/s;
- For physicist/second operator a drawing near velocity of 1 m/s.

For the intervals of permanence near the source, ∆t between 30 and 90 s have been cautelatively assumed. As regards the distance r of the first operator near the patient from the source, values between 30 cm and 90 cm have been assumed. For second operator, who have the possibility to operate more distant from the source (with suitable telemanipulators), a distance between 50 and 90 cm has been hypothesized. As these parameters can be expressed only by numerical intervals, it was believed right to attribute triangular fuzzy membership function to these, such as:

$$
\mu_{\Delta t}(t) = \begin{cases}\n\frac{t - 30}{60 - 30} & \text{per } 30 \le t \le 60 \text{ s} \\
\frac{t - 90}{60 - 90} & \text{per } 60 \le t \le 90 \text{ s} \\
0 & \text{otherwise}\n\end{cases}
$$
\n
$$
\mu_{\Delta t}(t) = \begin{cases}\n\frac{t - 30}{60 - 90} & \text{per } 90 \le t \le 60 \text{ cm} \\
\frac{t - 30}{60 - 30} & \text{per } 60 \le t \le 30 \text{ cm} \\
0 & \text{otherwise}\n\end{cases}
$$
\n
$$
\mu_{\Delta t}(t) = \begin{cases}\n\frac{t - 90}{70 - 90} & \text{per } 90 \le t \le 70 \text{ cm} \\
\frac{t - 30}{70 - 50} & \text{per } 70 \le t \le 50 \text{ cm} \\
0 & \text{otherwise}\n\end{cases}
$$

Finally, the times for radiotherapist together with the patient to way out of the TR were supposed non higher than 20 s. On the basis of these hypotheses, taking into consideration patient attenuation that, in accordance with that reported in [16] has to result equal to $2\div 2.5$, the fuzzy dose for every single event results

$$
D_{\text{Radiotherapist}} = [0.8; 2.1; 10.4] \text{ mSv/event}
$$

$$
D_{\text{physicist/second operator}} = [1; 2.6; 7.3] \text{ mSv/event}
$$

included the bringing near the source and the going away with patient phases or the source moving towards the HDR device one, that however don't contribute in significant way.

As one sees, especially in case of radiotherapist, the range of effective dose interval brings to suggest to responsible of such kind of plants the opportunity to set out intervention procedures that could allow remote and as fast as possible operations, that is quick, effective, easily acquirable by operators. The need to act quickly lies in the contemporary potential dose value to the patient that, for ∆t between 30 and 90 s ranges between 40 and 120 mSv (effective dose equivalent), considering that a 192 Ir source with an activity of 450 GBq stays in the coronary artery [17]. An increase in processing time of 90s (1.5 min) is, for some therapeutic applications, nearly doubling the therapy time.

Taking into account the maximum values of effective dose for radiotherapist and probabilities reported in (10), the following very small values for the risk R results:

$$
R = [9.6E-9; 3.1E-8; 1.95E-7] mSv/year.
$$

5. Conclusion

Irradiation plants are more and more used in a wide spectrum of applications. In this field, as a potential exposure could cause severe injuries or even be lethal for the patient. Many studies are been carried out about this issue, resulting that the human error is one of the most important causes of exposition.

Taking into account that the lack of accurate quantitative human reliability data is a serious limitation and a source of uncertainty in risk assessments, in this paper we try to deal with the uncertainties related to the human error using a fuzzy based methodology. As expected, the obtained results suggest that the events related human error are very significant and important in the hypothesized accidental scenarios, moreover the uncertainty related to them is the greatest cause of uncertainty in the whole analysis. The dose per event values may be high unless the security procedures osservance and stretch the operative timing. While safety devices of the system and the entire plant result in very small risk values, potential dose could be reduced by ensuring timely intervention of operators, with procedures tested and treated during regular exercises.

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