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Evaluation of the effectiveness of defense measures during radiological risk assessment in gynecological brachytherapy

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Abstract: The implementation of risk analysis to all those practices that work with ionizing radiation is of paramount importance. Thanks to the studies published on risk assessment in radiation medicine, a culture on this subject is being created, which has led to the systematization of different methods created for this purpose. Such is the case of the Failure Mode and Effects Analysis (FMEA), the basis on which this research has been developed. The American Association of Physicist in Medicine (AAMP) TG-100 report, which provides all the details on the use of this technique, is used as main reference. On the other hand, the recommendations recently published by AAMP TG-275 report are also used, applying the FMEA methodology to the high dose rate gynecological brachytherapy (B-HDR-GYN), among other practices. The novelty of this research is the implementation of an operational algorithm that improves the analytical capacity of the traditional FMEA approach by allowing the measurement of the effectiveness of defense measures within it. In this study, when the defense measures interact in the FMEA, a decrease of four RPN values of the failure modes (FM) occurs; compared to reference values. This algorithm is based on a synergy of the risk matrix (RM) approach and the information on FMEA available in the TG-100 and TG-275.

Keywords: risk, gynecologic brachytherapy, FMEA, defenses, effectiveness.

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Evaluación de la efectividad de las medidas de defensa durante el análisis del riesgo radiológico en braquiterapia ginecológica

Resumen: La implementación de un análisis de riesgos a todas aquellas prácticas que trabajan con radiaciones ionizantes es de primordial importancia. Gracias a los estudios publicados sobre evaluación de riesgos en medicina radiológica, se está creando una cultura sobre este tema, lo que ha propiciado la sistematización de diferentes métodos creados con este fin. Tal es el caso del Análisis de Modos de Fallo y Efectos (FMEA), base sobre la cual se ha desarrollado esta investigación. Se utiliza como principal referencia el informe de la Asociación Americana de Físicos Médicos (AAMP) TG-100, que proporciona todos los detalles sobre el uso de esta técnica. Por otro lado, también se utilizan las recomendaciones publicadas recientemente por el informe AAMP TG-275, el cual aplica la metodología FMEA a la braquiterapia ginecológica de alta tasa de dosis (B-HDR-GYN) y a otras prácticas médicas. La novedad de esta investigación es la implementación de un algoritmo operativo que mejora la capacidad analítica del enfoque FMEA tradicional al permitir medir la efectividad de las medidas de defensa dentro del mismo. En este estudio, cuando las medidas de defensa interactúan en el FMEA, ocurre una disminución de cuatro valores RPN de los modos de fallo (FM); en comparación con los valores de referencia. Este algoritmo se basa en una sinergia del enfoque de la matriz de riesgos (RM) y la información sobre el FMEA disponible en los TG-100 y TG-275.

Palabras chaves: riesgo, braquiterapia ginecológica, FMEA, defensas, efectividad.

1. INTRODUCTION

Cervical cancer ranks fourth among the most frequently diagnosed cancers and one of the most common causes of death in women. There are 36 countries that are most affected by this disease, most of them are in Sub-Saharan Africa, Melanesia, South America and Southeast Asia [1]. The most used treatment for this type of pathologies is radiotherapy (RT); especially the modality of internal radiotherapy or brachytherapy (BT) as it is commonly known.

The analysis and study of the High Dose Rate Brachytherapy (HDR-BT) process that works with high source activity is of special interest worldwide. This treatment is in high demand by female patients; in low- and middle-income countries, with 50% to 90% brachytherapy utilization rate [2]. Due to the high activity of the source used in this treatment, the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP) have addressed potential risk issues at centers using this resource [3, 4].

Among the methods most widely used in probabilistic risk studies in radiation medicine are the Risk Matrix (RM) and the Failure Mode and Effects Analysis (FMEA). The RM is a semi-quantitative risk assessment tool, which uses the postulation of accident sequences to describe the risks of each practice [5]. On the other hand, the FMEA is a quantitative method that represents the risk through failure modes (FM) and causes, which cause certain effects [6].

The approaches recommended by the American Association of Physicists in Medicine (AAPM) TG-100 and TG-275 Task Group (TG) reports were used in this work [6, 7]. The TG-100 uses FMEA to evaluate workflow and develop methods to minimize risk and improve treatment quality. That report does not resolve the measurement of the effectiveness of defense measures. The authors propose that the effectiveness study will be the result of an FMEA, after a period of time of implementation of the defense measures [6].

On the other hand, the TG-275 report, using TG-100 as a guide, conducts a study with FMEA of the plan and chart review process by medical physicists for three radiation therapy practices, including high-dose rate gynecologic brachytherapy (HDR-GYN-BT). That report has been used in the present investigation as the basis for obtaining the list of FM-causes, and the parameters resulting from the FMEA analysis. In addition, through TG-275, a checklist is obtained that corresponds to the defense measures proposed for the FM considered in this study.

Currently, the FMEA has been applied to a large variety of radiotherapy modalities [8-18]; however, there is a gap in the process of measuring the effectiveness of defenses. Considering the non-existence of a methodology to cover this deficiency, the objective of the present study is to achieve the measurement of effectiveness of the measures of defenses within the FMEA applied to the HDR-GYN-BT by using additional capabilities offered by the RM prospective approach.

From the methodological point of view and as useful informatics support, the SECURE-MR-FMEA code is used [19], developed by an interdisciplinary group of the Higher Institute of Applied Technologies and Sciences (InSTEC), Havana, Cuba. The system coherently combines prospective and reactive methods of analysis to perform risk assessments with an integral approach.

2. MATERIALS AND METHODS

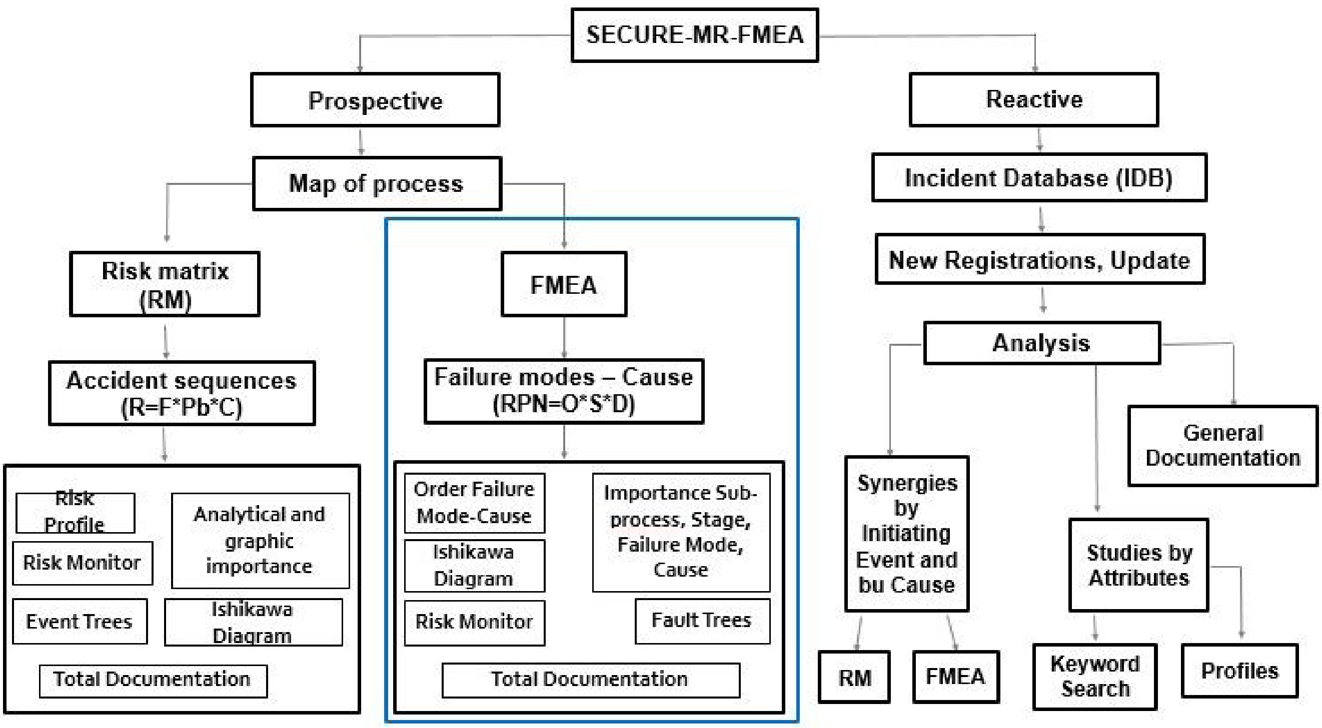
For the development of this research, the data provided by the TG-275 were used, among them: the list of FM-causes, the values of the severity (S), occurrence (O) and non-detectability

(D) indicators. In addition, a checklist was extracted from that report, that corresponds to the defense measures proposed for the FM-Causes to which they are associated.

It is important to note that TG-275 carried out its study based only on those phases of the radiotherapy process, related to patients´ Plan and Chart Review. In the case of HDR-GYN-BT, the steps linked to this process are: (1) applicator placement, (2) imaging, (3) planning, and (4) post-procedure; 53 FM-Causes and 16 defense measures were associated with these process steps [7].

The SECURE-MR-FMEA has been the computing tool used for the development of this research. This software is designed to provide an integral approach to risk assessment studies. The code allows interfacing between prospective methods (RM and FMEA) and its incident database (IDB) which has reactive learning capabilities. The Figure 1 illustrates the SECURE working algorithm, highlighting the FMEA algorithm [19].

Figure 1: Algorithm illustrating SECURE-MR-FMEA code capacities



Source: Risk management in medical practices with ionizing radiation[20]

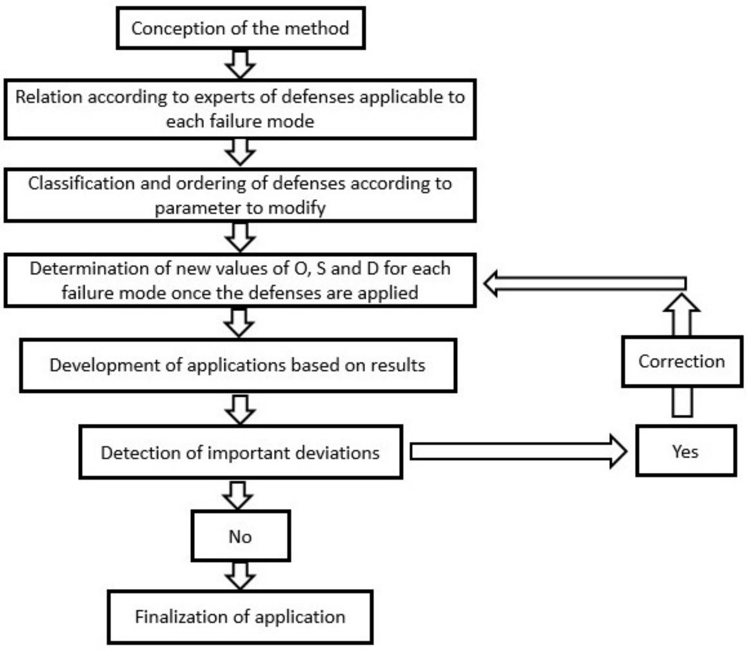
2.1 Algorithm for measuring the effectiveness of defense measures

The effectiveness of defense measures in the case of the FMEA can be evaluated directly or indirectly. In the case of indirect measurement, the capabilities of the SECURE-MR-FMEA code allow to convert the FMEA to RM. In RM, since the defenses are incorporated in the accidental sequences, it is possible to quantify their effect on the variation of risk.

In the direct method, the defenses are incorporated directly into the FMEA. To work with this method, it is necessary to follow an operational algorithm (Figure 2) for which it was necessary to introduce terms in the FMEA, that emulate their equivalents in the RM (see conceptualization of the method in Figure 2). In essence the terms are:

- Occurrence modifiers (OM), corresponding to frequency reducers (FR) in RM, are used to reduce the frequency of occurrences.
- Severity modifiers (SM), equivalent to consequence reducers (CR) in RM.
- Non-detectability modifiers (DM), analogous to barriers (B) in RM.

Figure 2: Algorithm for evaluating the effectiveness of defense measures within the FMEA



Source: A tool for automating the AAPM TG-275 approach in the physics chart and plan review during EBRT[21]

In the conception of the method also establishes the methodological aspects of the calculation of the effect of the modifiers on their respective parameters.

Since the defenses applicable to each MF are known from TG-275, it is possible to extract this relation from this reference (See the second block of Figure 2).

During the process of classifying the defenses (OM, SM, DM) and ordering them according to the parameter to be modified, the robustness that characterizes each one is also established. This step is based on knowledge of the characteristics of each defense (interlocks, alarms, redundant or non-redundant human procedures, etc.). This adaptation step can be considered one of the most complicated, since it requires skills and knowledge to identify the type of defense with respect to the parameter that it will modify (O, S, D) and its robustness.

The effect of the defenses on the corresponding parameters (O, S, D), which are used for the calculation of the Risk Priority Number (RPN), is included in the determination of new indicator values for each FM after applying the defenses in the FMEA. The modifiers of the quantitative factors of the FMEA work according to the robustness of the defenses and are multiplied to give a correction factor [21]. The results of the modifier multiplications use criteria equivalent to those of their corresponding originals in the RM method, to affect the RPN values. Once the modifications have been applied, the highest possible values are assigned to the factors of each RPN to ensure that the results are conservative. The particularities of each are shown in Table 1.

Table 1: Features of the correction factors for each parameter of the RPN

CORRECTION FACTOR FOR	FEATURES
Occurrence (O)	The contribution of the multiplication of the OM given in the correction factor affects the O indicator (there is a dependence on the initial value of O to determine the occurrence value to be assigned)
Non-detectability (D)	The contribution of the multiplication of the DM to calculate the correction factor affects the value of D (similarly there is a dependence on the initial value of D to determine the value of non-detectability to be assigned)
Severity (S)	The contribution of the SM multiplication given in the correction factor affects the value of S (again, there is a dependence on the initial value of S to determine the severity value to be assigned)

Source: A tool for automating the AAPM TG-275 approach in the physics chart and plan review during EBRT*[21]*

With the application of this algorithm, results are obtained that can have the following applications (see application development in Figure 2) [21]:

- Calculation of the impact of defense measures;
- Comparison (Sensitivity Analysis) between preliminary and improved values after applying modifiers, in order to know the safety improvement;
- Studies of the importance of defense measures, to determine those that contribute the most to risk control.

The representation of the risk profiles for this format is done in the form of tables and graphs through SECURE-MR-FMEA.

Once the applications have been performed, it will be possible to determine adjustments to be made to the resulting model (see Detection of important deviations in Figure 2). These correspond to the determination of the most vulnerable FM, incorporation of new defenses, etc.

3. RESULTS AND DISCUSSIONS

The results are based on the comparison of the FMEA, with input data provided by the TG-275, implemented in the SECURE-MR-FMEA as computing tool; resulting in a new FMEA that incorporates the defense measures.

The original FMEA study (extracted from TG-275) has 51 FMs; table 2 illustrates the distribution of FMs by each stage of the brachytherapy process.

Table 2: Distribution of the amount of FMs by stage

STAGES	AMOUNT OF FMS
Applicator placement	13
Imaging	9
Planning	26
Post-procedure	5

As a result of SECURE-MR-FMEA capabilities, it is possible to have a complete analysis and visualization of the risk profile associated with the practice. The software works with sliding values of the risk priority number (RPN) and severity (S). This option is significant, since the subsequent analyzes are executed from the limits. This is important, because the values reported in the TG-100 (RPN=100 and S=7) may not be applicable to the practice under study. For example, in the case of TG-275, RPN≥50 and S ≥5 were adopted as limit values, given the particularities of the practice.

In the case under study, the 16 defensive measures will be classified as modifiers of the non-detectability indicator (DM) because they act on the FM by affecting the parameter D.

Based on the classification of the defenses, the indicators per process that may be affected, once the defenses are implemented, are:

- The number of FM whose RPN value is higher than the limit (RPN≥50). This term depends on the multiplication of the O, S and D indicators;
- The Quality Indicator (QI) [22], because according to its formula (equation 1 and 2) it depends on the number of FM whose RPN is higher than the limit (RPN ≥ 50).

$$QI_i = (SevI)_i * N_{(NPR \geq NPR\mathrm{lim})_i} \quad (1)$$

QI_i- Quality Index for Subprocess.

$N_{(NPR \geq NPR\mathrm{lim})_i}$ - Number of FM in Subprocess i

$(SevI)_i$ – Severity Index for Subprocess l [22]. with $NPR \geq NPR\mathrm{lim}$

$$(SevI)_i = \sum_g^4 N_g P_g \quad (2)$$

N_g: Number of FM attributed to group G in the process l

P_g: Weight factor (epigraph 2.4.2 [23])

In the next step it will be possible to represent these indicators in stages, as well as to analyze the rearrangement of the FM, once the defense measures have been applied.

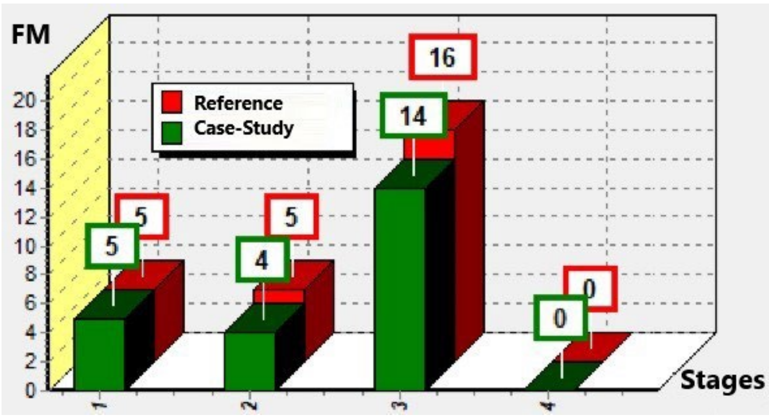
3.1 Results of the comparison between FMEA data with and without incorporating the defense measures; with respect to RPN and QI

To perform the sensitivity analyzes of this investigation, the average values provided by the TG-275 report were used as data. To obtain the data, this working group carried out an exhaustive study to identify the FM, in addition to consulting published literatures. The scoring of the different parameters was performed based on the TG-100 scoring system.[6,7]

A sensitivity analysis allows visualizing the number of FM exceeding the proposed S and RPN limits. The histogram in Figure 3 is a comparative study of the two risk profiles obtained (profile 1: original FMEA and profile 2: FMEA with defense measures). The decrease in the indicators studied occurs in the Imaging and Planning stages, which means that the risk of these FMs decreases and they move to a region of vigilance or where the risk may be acceptable, this happens when the RPN value is less than 50 (RPN <50).

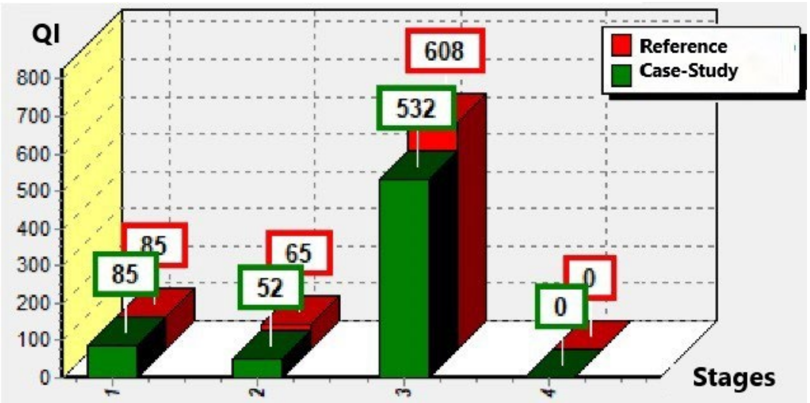
Another type of analysis that can be performed is related to the QI, which is calculated internally by the program (see equation 1). As expected, the parameter shows variation in the same stages as in the case of Figure 3. This is due to the decrease in these stages of the RPN. The result is illustrated in the histogram in Figure 4.

Figure 3: Comparative histogram for #FM with RPN ≥ 50 between risk profile 1 (original FMEA) illustrated in red and risk profile 2 (FMEA with defenses measures) illustrated in green



Source: SECURE-MR-FMEA

Figure 4: Comparative histogram between risk profile 1 (FMEA without defense measures) illustrated in red and risk profile 2 (FMEA with defense measures) illustrated in green, with respect to the QI value



Source: SECURE-MR-FMEA

3.2 Risk management criteria for both risk profiles. Comparison

Considering the decrease in the RPN of some FM, a new reorganization of the risk profile occurs. The SECURE-MR-FMEA has its own color code for prioritization and risk ranking, which facilitates the search for those FMs that are in a new position. Table 3 highlights the feature that a FM determined by a color in SECURE must have.

Table 3: Assignment of colors for risk levels according to importance in FMEA.

COLOR LEGEND	MEANING
	FM that are located at 20% of the practice's cumulative RPN
	FM whose RPN values ≥ RPN limit and S ≥ S limit (except the former)
	FM whose RPN assigned values ≥ RPN limit and S< S limit
	FM whose assigned RPN values < RPN limit and S ≥ S limit.

The new position in the risk priority list will depend not only on whether some FMs have decreased their RPN, but also on whether these FMs have lower RPN than other FMs not having any change in any of their parameters. Figure 5 shows those FM that have changed their position in the risk priority list.

Figure 5: Comparative table of the new position of some FMs between risk profile 1 (original FMEA) and risk profile 2(FMEA with measures of defenses)

No.	Stage	Failure Mode	D	RPN	Potencial Defenses	Failure Mode	Dmod	RPNmod
14	Imaging	(#14)Wrong dataset exported	5.8	91.6		(#14)Wrong dataset exporte	5.8	91.6
15	Imaging	(#15)Incorrect measurement a	4.3	95.3	MD2(N),MD5(N),MD9(N)	(#15)Incorrect measuremen	2	40
19	Imaging	(#19)Scan orientation labeled	4.6	49.3	MD11(N),MD12(N)	(#19)Scan orientation label	2	24
28	Planning	(#28)BED calculated using wr	5.8	80.9	MD2(N),MD14(N)	(#28)BED calculated using	2	32
32	Planning	(#32)Applicator model placed	4.3	68.0	MD11(N),MD12(N)	(#32)Applicator model plac	2	32

Source: SECURE-MR-FMEA

Figure 5 shows those FM that after the effect of the defenses, thanks to the DM, decrease their RPN. The changes achieved by the application of the working algorithm to measure the effectiveness of the defense measures are given by:

- Decrease of parameter D:
    - FM 15 (Incorrect measurement and/or documentation of channel lengths or number);
    - FM 19 (Scan orientation labeled incorrectly);
    - FM 28 (BED calculated using wrong formulation) and
    - FM 32 (Incorrect applicator selected from library [e.g. shielded cylinder vs non-shielded vs stump]).
- New position with respect to risk priority due to reorganization due to RPN variation in some FM, coinciding here FM 15, FM 28 and FM 32; in addition:
    - FM 14 (wrong dataset exported [e.g. 2nd scan performed after applicator adjustment but 1st scan sent for planning]);

Once the application of the algorithm is completed, there is a second risk profile (risk profile 2). It is possible to proceed to classify the risks with this (following a philosophy similar to the risks of RM), using a triangle that allows ordering and classifying the risks by levels [24].

This classification can be done by the contribution of the FM using the RPN and S parameters as shown on the left side of Figure 6 in the case of the FMEA. Three zones of the triangle can be seen:

- Very important risks: FM with RPN in the zone of 20% of the cumulative RPN in the whole practice or with RPN and S value higher than the RPN limit and S limit respectively;
- Surveillance region: FM whose RPN ≥ RPN limit or S ≥ S limit;
- Region of widely accepted risk: FM whose RPN value < RPN limit or S < S limit.

Figure 6: Acceptance criteria. Modifiable limits. RPNl (RPN limit) and Sl (S limit) [left side]. Representation by region of the FMs for the risk profile1 (original FMEA) illustrated in red and risk profile 2 (FMEA with measures of defenses) [right side].

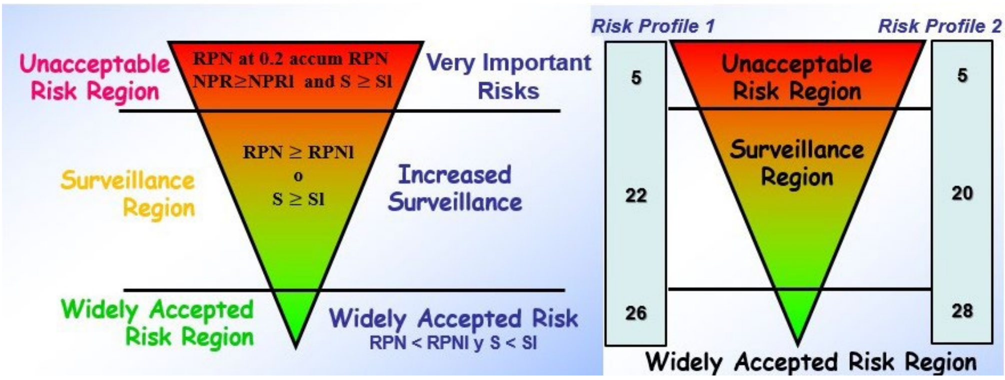


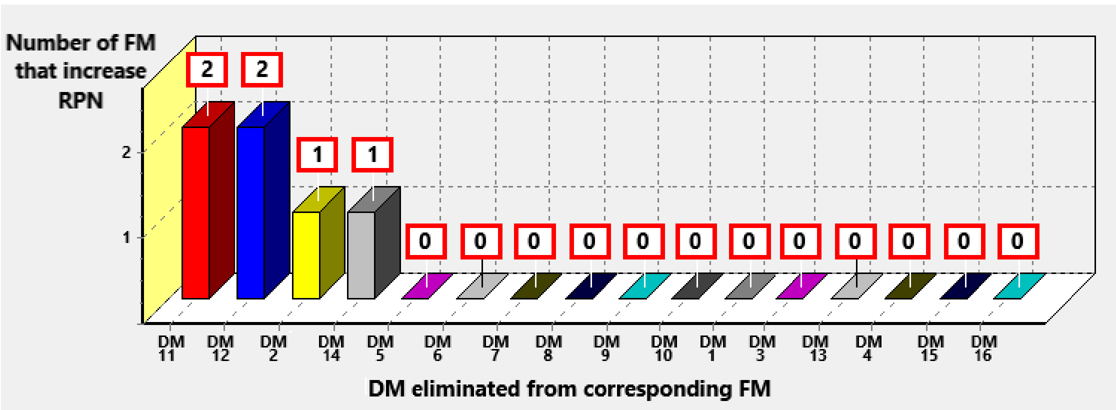
Figure 6 shows the change of region experienced by two FM after the introduction of DM. All of the above corroborates the ability of the algorithm to measure the effectiveness of the defense measures.

3.3 Comparison between the results of this research and those reported by TG-275

TG-275 displays explicit tables of failure modes (FM) sorted in descending order by RPN (Table S3.A.i.) [7]. As an important contribution, the report provides a detailed analysis of the defenses suggested by the experts, quantifying their level of participation by the number of FMs controlled, as well as identifying the highest risks of this group based on their RPN (Table S3.A.ii.) [7]. The ranking of the defenses according to their priority has been done only by the criterion of the highest RPN value among the FM controlled by the corresponding defense. The FMEA reassessment carried out by *SECURE-MR-FMEA* allows the realization of a new ranking, which will be based on the importance of each measure.

The importance of the measures is given according to their action on the FM, which is related to the effect that the elimination of the defense measure has on each failure mode to which it was assigned, but taking into account that the other defenses retain their effect. Figure 7 shows a histogram in which the bars represent the number of FM for which the RPN value increases when the corresponding defense is eliminated. In this case, only the first four measures, when eliminated, cause an increase in the RPN of any of the FM on which they act.

Figure 7: Importance of Defense Measures [Non-detectability modifiers (DM)]



Source: SECURE-MR-FMEA

Figure 7 refers in its DM numbering to the new priority order given to the defense measures by SECURE-MR-FMEA according to its action on the FMs. Table 5 shows the new position of the defense measures; highlighting in italics those that are most important according to this study.

Table 5: Order of priority of DM provided by SECURE.

Priority-SECURE [1]	**Priority TG-275 [2]**	**DESCRIPTION OF DEFENSES**	**# of FM that Increase RPN**
1 [DM11(N)]	11	*Verify that reference points are placed correctly and that plan is normalized properly*	2
2 [DM12(N)]	12	*Review integrated dose/kerma*	2
3 [DM2(N)]	2	*Verify catheter digitization/applicator modeling*	1
4 [DM14(N)]	14	*Review the quality of the treatment plan*	1
5 [DM5(N)]	5	Review the quality of the implant for discernable errors	0
6 [DM6(N)]	6	Verify OAR constraints have been met and that BED, if used, has been calculated correctly	0
7 [DM7(N)]	7	Review any special conditions	0
8 [DM8(N)]	8	Verify that the correct fiducials set was used and the fiducials were inserted fully	0
9 [DM9(N)]	9	Verify that the applicator matches the plan	0
10 [DM10(N)]	10	Verify plan transfer to treatment control station	0
11 [DM1(N)]	1	Review OAR and target contours for discernable errors	0
12 [DM3(N)]	3	Verify treatment length	0
13 [DM13(N)]	13	Verify that the plan matches the prescription	0
14 [DM4(N)]	4	Verify planning and secondary datasets	0
15 [DM15(N)]	15	Verify correct source, decay, and afterloader	0

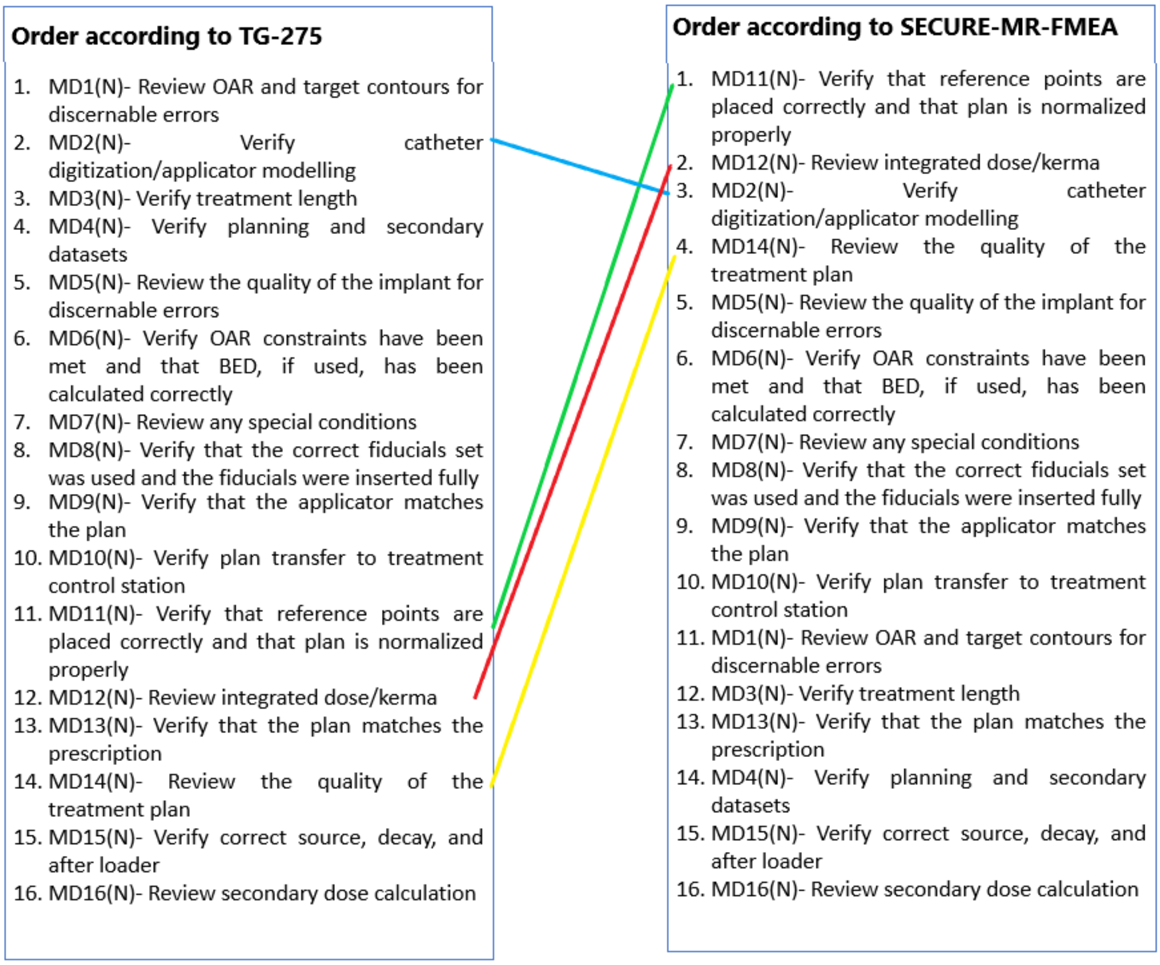
Priority-SECURE [1]	Priority TG-275 [2]	Description of defenses	# of FM that Increase RPN
16 [DM16(N)]	16	Review secondary dose calculation	0

[1] This order of priority is given by the SECURE-MR-FMEA in relation to the importance of each DM.

[2] This order of priority is extracted from the TG-275 report.

Figure 8 shows a comparison between two lists of priority order of defense measures. It can be seen that there is an important difference between the order obtained through *SECURE-MR-FMEA* given by the importance of each measure and the order provided by TG-275; with the colored lines, defense measures have been indicated that manage to reduce the initial RPN value.

Figure 8: Ordering comparison between TG-275 and SECURE-MR-FMEA.



The reasons for the difference shown can be listed in the following order:

- There is no methodology defined in the TG-275 that allows to appreciate the effect of the defense measures on the RPN of the FM. Apparently, their effect is considered homogeneous and is greater the higher the RPN of the controlled FM. This does not seem logical since the nature of the defense measures causes heterogeneous effects on the FM. This heterogeneity is recognized in the TG-100 itself, when it classifies the effectiveness of the defenses (Table III of TG-100) [6]. Another important and necessary aspect, recognized in the TG-100 itself, is the classification of defenses by the RPN parameter they modify (O, S, D). This detail is not fulfilled in TG-275, nor in TG-100 itself (see Step 5, Annex A of TG-100) [6].

- The TG-275 does not evaluate the existence of redundant or simultaneous defense measures on some FM. It should be considered that in those cases in which there are several defense measures affecting an FM, the disappearance of some of them can be compensated by the effect of the others.

- The novel working algorithm used in this report ranks the defense measures according to their importance, thus, it could be considered that the defenses will be more important for those cases in which the defense measures are less redundant in the same FM. However, this reasoning also depends on the effect on the FM considered for the defense measure. In general, the existence of conservative rules to re-quantify the RPN (taken from similarities with the effect of the defenses in the risk matrix) given the effect of the defenses associated with each FM, causes the redundancy and robustness of the defenses to be essential factors in this re-quantification. Therefore, some defense measures associated with FMs with low robustness and low redundancy have a negligible effect on the RPN of that FM. This means that their application on the FM does not cause changes in the RPN.

4. CONCLUSIONS

The main conclusion of this study is that it has been possible to implement the evaluation of the effectiveness of defense measures within the FMEA, which is demonstrated by a specific application to HDR-GYN-BT. The method of measuring the effectiveness of defenses, implemented within the FMEA, is self-sufficient and does not require recourse to complementary methods such as the FMEA to RM conversion, and the use of the latter to measure the effectiveness of defenses.

The comparison of the results obtained after considering the effect of the defense measures, with the average reference values (obtained from TG-275); demonstrate improvements in this practice. These improvements are observed when the defense measures are applied, since a variation occurs in the RPN values with respect to the originals. The FM in which the RPN varies are the following cases:

- FM 15: Incorrect measurement and/or documentation of channel lengths or number [new value of RPN=40];
- FM 19: Scan orientation labeled incorrectly [new value of RPN=24];
- FM 28: BED calculated using wrong formulation [new value of RPN=32] and
- FM 32: Incorrect applicator selected from library [new value of RPN=32].

This aspect does not have a great impact for the HDR-GYN-BT practice, since the defenses implemented are less numerous for this specific case. However, for external beam radiation therapy (EBRT) in TG-275 there are a greater number of defenses measures implemented, so it would be expected that, for this case, the approach developed in this report would have a more notable effect.

In particular, an in-depth study of a FMEA based risk assessment of a HDR-GYN-BT practice was achieved. The study through SECURE-MR-FMEA proved to be consistent with the overall RPN ordering results of the practice's FM, according to TG-275. The risk study through the software adds capabilities to the results, which are not shown in TG-275.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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