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Original Article

An overview of the use of risk analysis methodologies in radiotherapy facilities in Brazil

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Abstract: The increasing incidence of cancer and rapid advancements in radiotherapy technology have significantly heightened the complexity of treatment processes, necessitating robust infrastructure and safety protocols. This study assessed the implementation of risk analysis methodologies in Brazilian radiotherapy facilities through a nationwide survey of 196 centers, with 111 responses (57%). Results show that the Radiotherapy Risk Assessment System (SEVRRA) is the predominant tool, applied in 86.5% of facilities, while Failure Mode and Effects Analysis (FMEA) remains limited (7.2%), with only a small fraction using both. Adoption has been uneven across regions, with the South and Southeast concentrating the majority of facilities, technological resources, and advanced treatment techniques such as IMRT, VMAT, and SRS, while the North and Central-West report fewer centers and less diversity in methodologies. The peak in implementation occurred between 2017 and 2021, particularly in 2019, influenced by regulatory standards and international recommendations. Medical physicists (69.4%) and Radiation Protection Supervisors (27.9%) are the primary professionals responsible for applying risk analysis, though regulatory compliance issues persist. Despite barriers such as workload constraints and limited training, the integration of risk analysis practices has strengthened safety protocols and quality management, underscoring their importance in minimizing risks and safeguarding patient well-being throughout radiotherapy treatment in Brazil.

Keywords: radiotherapy, patient protection, risk analysis methodologies, SEVRRA, FMEA.

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Uma visão geral do uso de metodologias de análise de risco em instalações de radioterapia no Brasil

Resumo: O aumento da incidência de câncer e os rápidos avanços na tecnologia usada em radioterapia elevaram significativamente a complexidade dos processos de tratamento, tornando necessária uma infraestrutura robusta e protocolos de segurança. Este estudo avaliou a implementação de metodologias de análise de risco em instalações de radioterapia no Brasil por meio de uma pesquisa nacional envolvendo 196 centros, com 111 respostas (57%). Os resultados mostram que o Sistema de Avaliação de Risco em Radioterapia (SEVRRA) é a ferramenta predominante, aplicada em 86,5% das instalações, enquanto a Análise de Modos de Falha e Efeitos (FMEA) permanece limitada (7,2%), com apenas uma pequena fração utilizando ambas. A adoção tem sido desigual entre as regiões, com o Sul e o Sudeste concentrando a maioria das instalações, recursos tecnológicos e técnicas avançadas de tratamento, como IMRT, VMAT e SRS, enquanto o Norte e o Centro-Oeste apresentam menos centros e menor diversidade de metodologias. O pico de implementação ocorreu entre 2017 e 2021, especialmente em 2019, influenciado por normas regulatórias e recomendações internacionais. Os físicos médicos (69,4%) e os Supervisores de Proteção Radiológica (27,9%) são os principais profissionais responsáveis pela aplicação da análise de risco, embora persistam questões relacionadas ao cumprimento regulatório. Apesar de barreiras como limitações de carga de trabalho e treinamento insuficiente, a integração das práticas de análise de risco fortaleceu os protocolos de segurança e a gestão da qualidade, ressaltando sua importância na minimização de riscos e na proteção do bem-estar dos pacientes ao longo do tratamento radioterápico no Brasil.

Palavras-chave: radioterapia, proteção do paciente, metodologias de análise de risco, SEVRRA, FMEA.

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1. INTRODUCTION

High-energy radiation has become one of the most widely used approaches in modern oncology, allowing clinicians to target tumors while limiting damage to surrounding tissues [1, 2]. However, radiation therapy is inherently complex, involving sophisticated technologies, intricate treatment planning, and high doses of radiation that, if mismanaged, can lead to severe consequences for patient safety. Therefore, the use of risk analysis methodologies may ensure the safety and effectiveness of radiation therapy [3-7]. In this context, it is important to distinguish between risk assessment and risk analysis. Risk assessment refers to the overall process of identifying, analyzing, and evaluating risks in order to prioritize and mitigate them. Risk analysis is a specific step within this process, focusing on the detailed examination of individual risks, their likelihood, and potential consequences.

Risk assessment techniques in radiation therapy focus on identifying, evaluating, and mitigating potential hazards throughout the treatment process. These methodologies aim to reduce errors, improve process reliability, and ensure patient safety [3, 5]. The complexity of radiation therapy workflows - encompassing imaging, treatment planning, machine calibration, and patient setup - necessitates a systematic approach to uncover vulnerabilities and implement safeguards.

Risk assessment involves multiple steps, including risk analysis methods such as Probabilistic Risk Assessment (PRA), Failure Mode and Effects Analysis (FMEA), and Root Cause Analysis (RCA), which have been adapted for use in radiation therapy [8-10]. Additionally, the incorporation of human factors, engineering and data-driven approaches, such as machine learning, has further enhanced the ability to predict and mitigate risks [11, 12]. Even with new technologies, radiotherapy accidents still occur, making the use of risk assessment techniques crucial to protect the patient and to guarantee the treatment quality [13, 14].

The inclusion of safety criteria and compliance with the standards of national regulatory bodies such as the Brazilian Comissão Nacional de Energia Nuclear (CNEN)[1] and international bodies such as the International Atomic Energy Agency (IAEA), as well as reports on safety policies provided by the American Society for Radiation Oncology (ASTRO), serve as important safety policy [15-18]. Risk analysis comes into play in this context with the purpose of preventing accidents in radiotherapy. TG 100 is an official document prepared by a group of professionals from the American Association of Physicists in Medicine (AAPM) with the aim of carrying out a prospective risk approach using risk analysis tools in radiotherapy, and developing process maps by a clinical team in order to identify potential failure modes [3]. Another tool made available is the Radiotherapy Risk Assessment System (SEVRRA), which is a prospective risk analysis tool based on a risk matrix [7, 14, 19].

In this work we investigated how the application of risk analysis methodologies has been applied in radiotherapy facilities in Brazil. We aim to gain insight into the current scenario of these facilities regarding risk analysis tools and to highlight the importance of using them in the treatment processes, through research and studies of the literature that officially addresses this topic. The survey covers questions related to the composition of the multidisciplinary team in the radiotherapy facilities, as well as treatment complexity offered.

2. MATERIALS AND METHODS

In this work, we conduct a study on the application of risk analysis methodologies in radiotherapy facilities in Brazil. The theoretical basis for this work was developed based on a literature review, with searches in sources such as Google Scholar, PubMed, Scielo, among others, as well as regulatory standards from official bodies on risk analysis methodologies,

[1] From September 2025 on, the Autoridade Nacional de Segurança Nuclear (ANSN) became the regulatory and supervisory authority for nuclear and radiological facilities and activities in Brazil.

such as TG 100, related to quality control and safety in radiotherapy services. Subsequently, an online consultation was conducted with the CNEN website, verifying the number of authorized radiotherapy facilities in Brazil [20]. Then, we discussed the development of the questions for the form, defining 10 questions about the use of risk analysis techniques in exposures in Brazilian radiotherapy facilities, addressing risk analysis tools, staffing, technologies employed, among other aspects. The literature consulted reinforces the need to discuss different approaches adopted in the practice of risk analysis, aiming to mitigate and prevent errors that could result in accidents during medical exposures. Based on most studies related to risk analysis in radiotherapy in Brazil, the FMEA and risk matrix methodologies are widely used. FMEA is a prospective approach that acts preventively on the process maps of radiotherapy treatment units, being used as a quantitative tool within the quality control program [9]. On the other hand, SEVRRA is a proactive and qualitative risk analysis tool based on the risk matrix methodology, as described in reference [7]. These two tools can be applied together, as they complement each other. FMEA identifies failure modes and risk effects, while SEVRRA focuses on risk analysis and determining which radiotherapy techniques should be evaluated. Therefore, the combined use of these methodologies allows for a more comprehensive and effective risk analysis in radiotherapy.

The questionnaire was created and organized on docs.google.com, containing 10 questions. The data provided by the facilities were organized according to their geographical area, taking into account a nomenclature to distinguish one region from another. The questions were:

1. What is the name of the radiotherapy facility and in which city is it located?
2. Regarding professionals (doctors, medical physicists, technicians, etc.) how many are part of the institution's multidisciplinary team?
3. Who is the professional responsible for implementing/analyzing/maintaining the risk analysis tool in the institution?

a) medical physicist, b) doctor, c) technician, d) radiation protection supervisor, e) other

4. What is the description/list of the institution's equipment (Linear accelerators (Linacs), cobalt units, high dose rate (HDR), etc.)?
5. How many patients are treated annually and how complex are the treatments?
6. Does the radiotherapy facility perform risk analysis using any methodology aimed at patient protection? If so, since when?
7. What is the risk analysis methodology used?
8. How often is the risk analysis methodology used and reviewed/updated?
9. Why might a radiotherapy facility not perform patient-centered risk analysis at least twice a year?

    a) lack of time, b) lack of management incentive, c) lack of knowledge of risk analysis methodologies, d) need for training, e) other

Do you have any suggestions or criticisms regarding the use of risk analysis methodologies within the radiotherapy facility?

The survey was conducted between January–June 2024. A list of 196 authorized radiotherapy centers was obtained from the CNEN registry, and each center was contacted via email with a unique link to the online questionnaire. Instructions requested that a single representative (preferably a Medical Physicist or Radiation Protection Supervisor (SPR)) complete the survey to ensure one response per center. Partially completed questionnaires were included in the analysis when they provided sufficient information to address most of the survey questions; responses with minimal data were excluded. Participation was voluntary, and informed consent was obtained electronically at the start of the questionnaire. As the study did not involve patient-level data and focused exclusively on institutional practices, ethical approval was not required and was formally waived.

The open-ended responses to Question 10 were analyzed using a thematic content analysis approach. Two researchers independently reviewed all responses, identified recurring themes, and coded them accordingly. The codes were then consolidated into four broader categories that represented the main perspectives expressed by respondents. Discrepancies in coding were discussed and resolved through consensus, ensuring consistency and reliability in the interpretation of qualitative data.

3. RESULTS AND DISCUSSIONS

The analysis of the results of this work is related to the importance of radiotherapy facilities in Brazil to use hazard evaluation methods as part of the quality assurance and safety program in the treatment processes, as established by the regulatory authority in its rules [17, 18]. The answers presented in this work aim to provide an overview of the scenario of radiotherapy facilities in Brazil in relation to the use of risk analysis techniques for medical exposures. For this purpose, questions were considered about number of professionals, equipment, number of patients treated, complexities of treatments, which risk analysis tools are used and how often these tools are applied. The form was sent to 196 radiotherapy facilities but only 111 answered the questions, which corresponds to 57% of the total. Data analysis was performed by region and state. In what follows we perform an analysis of the answer for each question.

QUESTION 1. Results indicate that among the facilities that responded to the survey, the majority are located in the Southeast region, in contrast to the North region, which has the fewest. The number of facilities by region is as follows: Central-West - 8 (7.2%), North - 5 (4.5%), Northeast - 15 (13.5%), South - 27 (24.3%), and Southeast - 56 (50.5%).

QUESTION 2. In Table 1 is summarized the quantity of professionals per region of Brazil.

Table 1: Number of professionals per regions.

REGION	MEDICAL PHYSICIST	DOCTOR	DOSIMETRIST	TECHNICIAN	NURSE/ OTHER	TOTAL
Central-West	24	7	8	84	Data not provided	123
North	9	9	Data not provided	23	10	51
Northeast	44	59	19	230	26	378
South	44	77	17	231	66	435
Southeast	130	197	39	425	208	999

Based on the results of this survey, the Southeast region shows the highest number of multidisciplinary profiles, which may be related to the larger number of facilities and the greater availability of technological resources for cancer treatment in this region. We can see that, in all regions, the number of professionals such as medical physicists, doctors, and technicians, for example, varies from region to region. This is directly related to the number of equipment units, patients treated annually, and treatment complexity offered by the service. It will be also observed later in the compilation of data for questions 4 and 5 of this survey, which collected data on the equipment most used by radiotherapy facilities, the number of patients treated annually, and treatment complexity.

Considering this fact, we can infer that the use of hazard evaluation methods in radiotherapy, as part of a quality control program, may take advantage of these professionals in a multidisciplinary manner. To achieve this, it is important to consider all the activities performed in the routine of the work teams, such as equipment maintenance, the quality of the resources and accessories applied, the equipment used, the patients treated, and the treatment complexity.

Therefore, risk analysis aims to identify potential problems or complications before treatment begins, assisting these healthcare professionals in making decisions about the treatment plan. This risk analysis, as part of quality control, may include considerations of radiation dose, toxicity to surrounding tissues, the accuracy of patient positioning, and other relevant factors. It is essential that the risk analysis be performed by a multidisciplinary team

composed of radiation therapists, medical physicists, oncologists, and other specialized healthcare professionals, ensuring a comprehensive and safe approach for the patient.

In this survey, among the professionals mentioned as members of the radiation therapy work team, medical physicists, physicians, and technicians were the most frequently mentioned. It was possible to note that dosimetrists and nurses were less significant in these results. For the facilities that responded only with the total number of members, without specifying each one's specialty, we were unable to identify exactly how many there are in each position. However, this represents a very small sample compared to the others.

Table 2: Professionals responsible for implementing the risk analysis in the facility per region. Values in parentheses indicate the percentage distribution of each professional category within the respective region.

PROFESSIONAL	REGION	QUANTITY PER REGION	PERCENTAGE [%]
MEDICAL PHYSICIST	Central-West	4 (3.6)	69.4
	North	4 (3.6)	
	Northeast	11 (9.9)	
	South	22 (19.8)	
	Southeast	36 (32.5)	
RADIATION PROTECTION SUPERVISOR	Central-West	3 (2.7)	27.9
	North	1 (0.9)	
	Northeast	4 (3.6)	
	South	5 (4.5)	
	Southeast	18 (16.2)	
OTHER	All regions	3 (2.7)	2.7
TOTAL		111 (100)	100

QUESTION 3. This question refers to the professional profiles designated as responsible for implementing risk analysis in the radiotherapy facility and the results are shown in Table 2. Considering the whole country, results indicated that 77 of 111 facilities (69.4%) reported that Medical Physicists are responsible for implementing risk analysis methodologies, while 31 of 111 (27.9%) indicated Radiation Protection Supervisors, and 2.7% belong to other categories, such as technician, doctor, and other data not provided by the facility. This last group contradicts CNEN NN 6.10 [17], which establishes that risk analysis must be carried

out by the SPR, a role that can be accumulated by the Medical Physicist only in services treating fewer than 600 patients per year, provided that the physicist is certified by CNEN. Thus, it is necessary to discuss regulatory compliance and emphasize that the presence of professionals not qualified for this function represents a weakness in the safety system.

We can observe the numerical variation between the different regions in Table 2. The Southeast and South regions have the largest numbers of professionals involved in the application of hazard evaluation methods. It is important to emphasize that the Medical Physicist also performs the SPR function, but this depends on the circumstances, as specified in CNEN NN 6.10 [17] regarding the number of physicists and patients treated annually. An additional aspect that deserves attention is the presence of residency programs in radiotherapy. In these institutions, residents learn by practicing, which may increase the likelihood of incidents if additional safety barriers are not in place. Therefore, risk analysis should also consider whether the service has a residency program, as this directly impacts on professional training and the need for more robust safety protocols.

QUESTION 4 AND 5. Questions 4 and 5 were analyzed jointly, as they require relevant information about the treatment equipment used in radiotherapy facilities, the number of patients treated, and the complexity of the treatments. These questions are very important because it represents the variety of techniques in line with the use of linac for cancer treatments in modern radiotherapy. Risk analysis in radiotherapy is performed using hazard evaluation methods that can be customized and directed to the application of different types of radiotherapy processes (simulation, planning, quality control, and treatment). For synthesis purposes, the data regarding equipment, number of patients, and techniques used were grouped by region, as shown in Table 3. Although the questionnaire originally requested information on the number of patients treated annually, the data provided by the facilities were converted into weekly patient numbers to allow for a more standardized comparison across regions. Specifically, the reported annual number of unique patients treated per facility was divided by 52 (weeks per year), assuming an even distribution of treatments across the

year. The weekly estimates for each facility were then aggregated to obtain cumulative regional totals. Thus, the values presented in Table 3 under "patients treated weekly" represent the sum of unique patients estimated to be under treatment per week across all facilities in a given region. These figures do not correspond to treatment fractions or fields, but rather to standardized estimates of patient workload based on institution-reported annual volumes. The values presented in Table 3 correspond to the cumulative weekly totals of patients treated by all facilities in each region, rather than averages per facility. This approach ensures consistency in the dataset and facilitates regional comparisons. This consolidation enables a more objective view of the national landscape, highlighting the predominance of advanced techniques in the South and Southeast regions, which concentrate the highest technological infrastructure. It is important to emphasize that, based on the answers to these questions, the 3D Conformal Radiation Therapy technique (3D-CRT is a modern radiotherapy technique that uses advanced imaging to shape radiation beams to match the three-dimensional shape of a tumor) and modulated treatment techniques, such as Intensity Modulated Radiotherapy (IMRT is an advanced form of external beam radiotherapy that delivers precise radiation doses to a tumor by modulating the intensity of each radiation beam), Volumetric Arc Therapy (VMAT, is an advanced form of intensity-modulated radiation therapy that delivers radiation by rotating the linear accelerator around the patient in one or more arcs) and Stereotactic Radiosurgery (SRS, is a highly precise form of radiation therapy mainly used to treat small tumors or abnormalities in the brain, and despite the name, it is a non-surgical procedure that delivers a high dose of radiation in one or a few sessions, using advanced imaging and targeting systems), and SBRT (Stereotactic Body Radiation Therapy) are the most used in radiotherapy treatment in Brazil, as can be seen in Table 3. Although the 3D technique is the most frequently cited in this survey as one of the main alternatives, we can see that modulated techniques have gained considerable ground due to factors such as technological innovation, the complexity of treatments, the qualifications of professionals, and the increase in the number of new cancer cases in Brazil and over the world [21]. Electron beam therapy was cited only once, indicating its limited application

among surveyed facilities, possibly due to its niche use in treating superficial tumors or specific anatomical sites. 2D radiotherapy (Two-Dimensional Radiation Therapy, is a conventional form of radiotherapy that uses flat, two-dimensional X-ray images to plan and deliver radiation. It lacks the precision of modern techniques like 3D conformal radiotherapy or intensity-modulated radiation therapy) is still used in some facilities but tends to be phased out in favor of more advanced techniques. TBI (Total Body Irradiation) and 4D-RT (is an advanced technique that incorporates time as the fourth dimension in treatment planning. In addition to the three spatial dimensions, it accounts for tumor motion over time - typically due to breathing) are also cited.

Table 3: Number of facilities, treatment equipment, and cumulative weekly patient totals per region, along with cited treatment techniques. Patient numbers represent the sum of weekly workloads reported by all facilities in each region, not averages per facility.

REGION	NUMBER OF FACILITIES	LINACs	HDRs	PATIENTS TREATED WEEKLY	CITED TREATMENT TECHNIQUES
CENTRAL-WEST	8	18	5	9,730	3D (4 times), IMRT (3 times), VMAT (2), Radiosurgery (1), not informed (4)
NORTH	5	6	2	2,160	IMRT (2), 3D (1), VMAT (1), Radiosurgery (1), not informed (3)
NORTHEAST	15	39	10	20,170	3D (11), IMRT (8), VMAT (4), SRS/Radiosurgery (3), SBRT (2), TBI (1), 2D (1), not informed (4)
SOUTH	27	46	9	23,420	3D (18), IMRT (15), SRS/Radiosurgery (11), VMAT (8), 2D (8), SBRT (6), 4D (1), not informed (6)
SOUTHEAST	56	97	18	41,919	3D (35), IMRT (26), VMAT (20), 2D (14), SRS/Radiosurgery (12), SBRT (10), TBI (3), electron beam (1), not informed (11)

It can be observed that the South and Southeast regions report the largest use of modulated techniques for cancer treatment. This may be interpreted as reflecting a higher concentration of facilities and technological innovation, which could be associated with greater investment in research, training, and infrastructure in hospital networks aimed at combating malignant neoplasms. This distribution may suggest that regions with greater

investment in radiotherapy services are more likely to implement innovative techniques, deliver complex treatments, assemble multidisciplinary teams, and achieve effective outcomes - ensuring patient improvement or cure, as well as enabling more appointments within shorter time intervals. In this context, soon even more advanced techniques such as IGRT (Image-Guided Radiation Therapy) will begin to play a significant role.

QUESTION 6. This question allows us to know in which years risk analysis methodologies began to be used in the responding facilities, as shown in Table 4. All the data presented in this work aims to evaluate the importance of implementing risk analysis in a quality control program at radiotherapy facilities in Brazil, in order to identify flaws, analyze them, and prevent potential accidents during treatment processes, ensuring that patients are well cared for and avoiding any harm from ionizing radiation.

Table 4: An overview of the year when risk analysis methodologies began to be used in radiotherapy facilities in Brazil.

STARTING YEAR	CENTRAL-WEST	NORTH	NORTHEAST	SOUTH	SOUTHEAST	TOTAL
2005					2	**2**
2013					1	**1**
2015			1		4	**5**
2016			1	2	5	**8**
2017	1		3	1	5	**10**
2018	2			4	10	**16**
2019	2		4	8	9	**23**
2020	2	1	3	7	7	**20**
2021	1	1	1	1	8	**12**
2022		2	2	2	2	**8**
2023		1			2	**3**
Data not apply				2	1	**3**
TOTAL	**8**	**5**	**15**	**27**	**56**	**111**

According to results shown in Table 4, between 2017 and 2021 were the years with the highest number of implementations of risk analysis in radiotherapy facilities in Brazil, with emphasis on 2019, when the highest number of facilities began risk analysis in radiotherapy. Furthermore, as expected, due to the highest number of facilities, the Southeast region leads this scenario. The increased use of risk analysis in radiotherapy appears to have been influenced by the need to prevent accidents and by the promotion of official literature such as CNEN standards (from 2013 onwards), which included recommendations to implement risk analysis methodologies, in addition to the contributions of international reports such as those of the IAEA, which in 2016 launched FMEA as a risk analysis methodology for the quality control program in radiotherapy. Therefore, in this regard, we noticed that in 2019 there was a great adoption of these tools when compared to previous years. This was the result of the data presented on previous accidents in radiotherapy and the influence of competent international and national bodies, a direct relationship in the implementation of risk analysis in radiotherapy.

QUESTION 7. This question reveals which hazard evaluation methods are most applied in radiotherapy facilities in Brazil. SEVRRA leads the scenario (used in 100 facilities), as shown in Table 5. This tool is based on a risk matrix and acts prospectively, which is when it acts in advance to identify errors and prevent the occurrence of accidents in radiotherapy treatment processes. Its analysis is qualitative, naming risks according to their level (low, medium and high). FMEA is in second place in the application of risk analysis in radiotherapy. It also acts prospectively in preventing accidents. This tool is guided by TG 100 as an option to be applied in quality control management of radiotherapy risk analysis. Its analysis is quantitative, when potentially identified risks need to be prioritized based on a number, considering a scale of 1 to 10. Therefore, the emphasis in the application of risk analysis methodologies is between SEVRRA and FMEA. Some facilities even responded that they use both tools. Also according to the data shown in Table 5, 86.5% of facilities use only SEVRRA as a risk analysis tool, 7.2% use only FMEA, 3.6% use both tools, and 2.7% do not apply risk analysis methodologies. In the Northeast, nearly all facilities (14 of 15; 93%)

reported exclusive use of SEVRRA, whereas in the Central-West region, a more diverse pattern emerged, with 25% (2 of 8) applying FMEA. The Southeast, which hosts the largest number of centers (56), reported the highest absolute number of SEVRRA users (50 facilities), while the South showed a similarly high proportional adoption (24 of 27; 89%). These comparisons illustrate that while SEVRRA is the predominant tool nationwide, regional variation exists in the extent to which FMEA is incorporated. Such differences provide important context for understanding workload and treatment complexity. Regions with higher adoption of structured methodologies may reflect greater institutional capacity, more advanced technology, and stronger multidisciplinary engagement, whereas regions with limited methodological diversity may face constraints in training or resources.

Table 5: Regions versus used risk analysis methodologies. Numbers in parentheses indicate the percentage distribution of each tool within the respective region.

REGION	NUMBER OF FACILITIES	RISK ANALYSIS TOOL			
		FMEA	SEVRRA	FMEA/SEVRRA	DOES NOT APPLY
CENTRAL-WEST	8	2 (25)	5 (62.5)	1 (12.5)	-
NORTH	5	2 (40)	3 (60)	-	-
NORTHEAST	15	-	14 (93.3)	1 (6.7)	-
SOUTH	27	1 (3.7)	24 (88.9)	-	2 (7.4)
SOUTHEAST	56	3 (5.3)	50 (89.3)	2 (3.6)	1 (1.8)
TOTAL	**111**	**8**	**96**	**4**	**3**

It is important to highlight that, within the Brazilian regulatory framework, the implementation of risk analysis in radiotherapy services is a mandatory requirement established by the national authority. However, the regulations do not prescribe the use of specific tools such as SEVRRA or FMEA. The choice of methodology is left to the discretion of each institution, depending on factors such as available resources, staff training, and complexity treatment. In practice, SEVRRA has been widely adopted due to its accessibility and national promotion, while FMEA and other methodologies are applied in accordance with international recommendations and institutional preferences.

It is also important to note that although SEVRRA and FMEA were the methodologies most frequently cited by the participating services, it is important to highlight that other risk analysis approaches are applicable to radiotherapy, such as Probabilistic Risk Assessment (PRA), Root Cause Analysis (RCA), and emerging methodologies based on human factors and machine learning. Recent academic work has explored these alternatives, which may complement or even surpass traditional methodologies in certain contexts.

QUESTION 8. The analysis of Question 8 reveals important aspects of how Brazilian radiotherapy facilities apply and update risk analysis methodologies, highlighting both strengths and weaknesses in current practices. When examining the frequency of use, the data show that the majority of facilities adopt an annual cycle, with 47 centers (42.3%) reporting annual application of risk analysis tools. This aligns with regulatory expectations and reflects a structured approach to patient safety. However, a significant portion of facilities (29 centers, 26.1%) reported biennial use, which suggests that updates are being delayed and may reduce the effectiveness of risk management in a rapidly evolving technological environment. Smaller groups reported biannual use (16 centers, 14.4%), while only a handful integrate risk analysis into routine operations more frequently, such as daily, weekly, or monthly. These latter cases, although rare, represent best practice by embedding risk analysis into the daily workflow and ensuring continuous monitoring of potential hazards. On the other end of the spectrum, five facilities apply risk analysis only when deemed necessary, and three facilities do not apply it at all, which points to gaps in safety culture and compliance.

The responsibility for reviewing and updating these methodologies further illustrates the diversity of practices. Annual reviews dominate, with 41 facilities reporting this frequency, and an additional 14 explicitly stating that the SPR is responsible for annual updates. This is consistent with CNEN NN 6.10, which requires SPR oversight, although medical physicists often overlap in this role due to staffing realities. Biennial reviews are also common, with 25 facilities reporting this frequency and 11 specifying SPR

responsibility. While this demonstrates that SPRs are actively engaged in risk management, the reliance on biennial cycles raises concerns about whether safety protocols remain sufficiently current. Smaller numbers of facilities reported biannual reviews, again with SPR involvement in some cases, and three facilities indicated that "other" professionals were responsible for annual updates, which may represent a compliance gap. Finally, three facilities reported no application of review or update processes, reinforcing the need for stronger regulatory enforcement.

Taken together, the data suggest a dual culture among Brazilian radiotherapy facilities. On one side, proactive centers conduct annual or more frequent reviews, often under the supervision of SPRs, thereby fostering a strong safety culture and compliance with regulatory standards. On the other side, reactive centers rely on biennial or ad hoc reviews, sometimes with unclear responsibility, which increases vulnerability to incidents and undermines patient protection. The uneven distribution of practices indicates that while many facilities are aligned with best practices, a substantial portion still operates with weaker safety protocols. This highlights the importance of regulatory bodies such as ANSN in reinforcing minimum standards, particularly the need for annual reviews with SPR oversight, to ensure consistency across the country. By standardizing review cycles and clarifying professional responsibilities, Brazil can strengthen its radiotherapy safety framework, minimize risks, and safeguard patient well-being in an increasingly complex treatment environment.

QUESTION 9. According to the responses, the reasons for not applying risk analysis methodologies in radiotherapy facilities at least biannually include lack of time (9.1%), lack of administrative encouragement (4.5%), unfamiliarity with such methodologies (2.3%), need for training (6.8%), and other reasons (77.3%). The most striking finding is that 77.3% of respondents selected "other", indicating that the majority of non-application cases lack a clearly defined reason. This suggests a potential gap in awareness, documentation, or prioritization of risk analysis practices.

The remaining reasons, though smaller in percentage, reflect systemic and operational challenges: time constraints may stem from understaffing or inefficient workflows; lack of administrative support points to organizational culture and leadership gaps, and limited familiarity and training needs highlight the importance of continuous professional development.

These findings underscore that a well-prepared multidisciplinary team - equipped with training, institutional support, and time allocation - is a hallmark of effective management and quality control in radiotherapy settings.

QUESTION 10. Only 78 facilities answered this question. Considering that the answers to this question are based on knowledge and use of risk analysis methodologies, the results obtained present a diversity of opinions, with opinions ranging from practical to theoretical point of view. Certainly, there are suggestions, compliments, and criticisms about these tools used by professionals working in radiotherapy facilities. The open-ended responses to Question 10 were categorized into four groups based on a thematic content analysis. Two researchers independently coded the responses and reached consensus on the final grouping, ensuring consistency in interpretation. The categories are presented below as representative of the main perspectives expressed by the facilities.

The responses from **Group 1** have some points in common in their contexts about the CNEN as:

a) Respondents believe CNEN makes mandatory the application of risk analysis.

b) Suggestion that CNEN provides training to the professional community on the use of SEVRRA [7].

c) They emphasize the need for annual training to update and standardize risk analysis, stating that these trainings should also be organized by CNEN.

d) The SEVRRA tool serves the process well, but they suggest that it be expanded to include new technologies.

e) Including an entire multidisciplinary team is seen as a major challenge, along with the lack of interest on the part of professionals due to their lack of knowledge of the tools and their objectives.

f) There is a lack of complete and comprehensive tools within the reality of radiotherapy facilities in Brazil.

When analyzing these positions, it is important to emphasize that, although CNEN encourages the use of the SEVRRA tool in radiotherapy facilities and makes it available [7], it does not require its use. Regarding the difficulties related to the lack of knowledge of risk analysis tools and the preparation of teams to work with the tool, we are reminded of the fact that there are bibliographies available for the minimum knowledge required for training purposes. For example, there is the TG 100 AAPM report that addresses the application of the FMEA tool for quality control in treatments using IMRT and HDR.

In the case of training, it would be important for there to be a commitment from interested societies, such as the Brazilian Association of Medical Physics and the Brazilian Society of Radiotherapy to implement not only to comply with a standard requirement, but to improve the quality and safety of patients, since ANSN, as a regulatory body, does not have the scope of responsibility to provide training and therefore does not require services to use specific tools, but to perform risk analysis. The Ibero-American Forum of regulatory and nuclear bodies has in the SEVRRA development project, specifically, Medical Physicists of Brazil and CNEN acts in Brazil as a provider of the platform for the use of this tool.

Group 2 mentions the use of such risk analysis tools in radiotherapy in Brazil and makes some comments, including:

a) SEVRRA, FMEA, and Failure Mode, Effects and Criticality Analysis (FMECA), stating that SEVRRA is the most used and commented tool in the current scenario by radiotherapy facilities in Brazil.

b) SEVRRA is the tool that has frequency and consequence mitigation factors that, in many examples, do not seem sufficient or adequate.

c) They suggest a review of SEVRRA, considering the possibility of editing and the need for updating to more recent technologies, especially for IMRT, cranial (SRS) and extracranial (SBRT) radiosurgery, as it is observed that SEVRRA can identify weak points in the clinical workflow, but there are criticisms about its intuitiveness and lack of updating.

d) There are items in SEVRRA that do not match the Brazilian reality, there is confusion for Brazilian users, a lack of clarity in the questions and answers, and a poor translation.

e) The portal used for SEVRRA is experiencing problems, which sometimes makes periodic updates difficult.

f) It is suggested that the use of tools such as FMEA and FMECA can address the institution's specific flow more efficiently compared to SEVRRA.

The meaning in the context of the responses for **Group 2** is that risk analysis methodologies play a crucial role in radiotherapy processes. However, in terms of comparisons between SEVRRA and FMEA, they attribute some criticisms to the SEVRRA tool. Regarding risk analysis with FMEA, they suggest that its application in institutional processes is simpler and more efficient in improving safety.

Group 3 assigns some of the responsibilities for applying risk analysis methodologies in radiotherapy to the administration of the facility:

a) It would be more common if it had greater support from the administration and was more widespread in radiotherapy departments, since it is considered an excellent practice for minimizing errors in treatment processes.

b) Although there is no objection to the methods used, it is mentioned that it would be interesting if there was a standard method for all institutions.

c) A more dynamic and agile filling method would facilitate the daily routine, which is intense by nature, allowing for revisions in shorter periods"

d) The importance of implementing risk analysis becomes fundamental for taking safety actions in radiotherapy, but unfortunately, it is sometimes left aside due to the intense routine.

e) Some administrative sectors do not seem to understand the importance of applying hazard evaluation methods, as well as some factors such as time and incentive for responsible professionals to be able to use and constantly review the evaluation criteria.

f) Resistance from employees in implementing the risk management program, which also reflects the need for greater interest from institutions (hospitals and clinics) so that a tool can truly be implemented for the purposes for which it is intended.

g) Furthermore, these methodologies are very efficient predictive tools that can demonstrate the fragility of security systems and processes, in addition to encouraging a culture of security when the entire team is involved in applying the tool.

This group conveys an idea of how important it is to use hazard evaluation methods in a radiotherapy service. On the other hand, the effective involvement of management in this process reflects the most bureaucratic aspect, in addition to other factors, such as the issue of time, task assignments and routines that overload professionals who could participate in the risk analysis process, such as physicists, doctors, etc.

Group 4 emphasized in its statements the importance of risk analysis in radiotherapy. It is an essential tool and helps determine which are the most vulnerable points that deserve

more attention, resulting in a reduction in the risk of process failures and consequently increasing the quality and safety of treatments. Among their opinions:

a) Some questions or suggestions about frequency mitigation factors, such as the following statement: There is a weak correlation between some events and the frequency mitigation factors available in the original model.

b) In several events, frequency mitigation factors are suggested that are not actually effective and at the same time there is a lack of important barrier/reducer options.

c) If in vivo dosimetry is so important, why is it not mandatory, while some mandatory tests have little impact on safety?

d) Physicists should be trained or guided in a more academic and professional way on the idea of risk analysis, showing statistics, cases, etc.

e) Some professionals stated that risk analysis is necessary and important because it allows for the identification of flaws in the process and the creation of barriers to prevent accidents. They consider it a valuable tool, find it interesting, and believe it is essential for ensuring patient safety, especially when treating homonymous patients.

f) They suggest a more dynamic and quick-to-answer form, as the process is very slow and repetitive in the tool they work with (SEVRRA). It would be good to have more education/training on the subject for professionals.

g) Risk analysis in Brazil may be being neglected due to a lack of data on accidents. Unfortunately, the rate of underreporting of accidents in Brazil is very high.

h) The lack of error notifications creates the false impression that accidents are rare, which is not true.

i) Since it is considered a necessary methodology, the use of the risk analysis tools could take into account the participation of different professionals involved in the stages of radiotherapy. In addition, the risk analysis could be done for more specific processes,

implementing different barriers for different types of treatment (3D-RT, IMRT, TBI, SRS).

j) Although high demand in the radiotherapy sector is often a major obstacle to implementing or enhancing quality programs, one suggestion for improving such analyses is to hire professionals dedicated to this practice.

Some points highlighted by the opinions here are that they believe that quality control of the designs (target and organs at risk) are essential and have never been seen in any risk analysis, in addition to the fact that it is extremely difficult to perform the analysis in a multidisciplinary manner due to the lack of time to gather the team for long processes in this way. And finally, among their considerations regarding risk analysis methodologies, they suggest that there should be a more realistic and less complex methodology, that there should be more questions about emergency procedures and, since it is a necessary tool, there should be more incentives for implementing risk analysis in radiotherapy.

This study has several limitations that should be acknowledged. First, the questionnaire-based design relies on self-reported institutional data, which may introduce reporting bias. Second, partially completed responses were included when they contained sufficient information, which may reduce completeness and comparability across facilities. Third, the response rate of 57% raises the possibility of non-response bias, as facilities that did not participate may differ systematically from those that did. Finally, the descriptive nature of the analysis precludes inferential statistical conclusions, and the findings should be interpreted as a cross-sectional overview rather than causal associations. Despite these limitations, the study provides valuable insights into the current use of risk analysis methodologies in Brazilian radiotherapy facilities.

4. CONCLUSIONS

This study demonstrated that, despite significant technological and structural advancements in radiotherapy across Brazil, key challenges remain regarding patient safety and risk management. The survey results revealed that most facilities rely on SEVRRA as their primary risk analysis tool, while the use of FMEA is still limited. The predominance of these methodologies in the South and Southeast regions correlates with higher concentrations of technological infrastructure and qualified multidisciplinary teams. Although barriers such as workload, lack of institutional support, and the need for professional training were identified, the adoption of risk analysis practices has contributed to improvements in safety protocols. Medical physicists and radiation protection supervisors emerged as the main professionals responsible for implementing these tools, highlighting the importance of specialized technical expertise. Therefore, strengthening a culture of safety in radiotherapy depends not only on the adoption of effective tools but also on institutional commitment, continuous professional development, and the integration of multidisciplinary teams. Reinforcing these practices is essential to ensure safer, more effective treatments that comply with both national and international regulatory standards.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The authors declare that the data supporting the results of this study are available in the article. Derived data supporting the conclusions of this study are available upon request from the corresponding author.

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