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# Radiological risk analysis of image-guided interventional procedures

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## ABSTRACT

**Image-guided interventional procedures have become one of the medical applications that produces the highest doses of radiation for both the patient and the personnel involved in it. Safety assessment was applied to a generic service where image-guided interventional procedures was carried, using the semi-quantitative method of risk matrix, implemented in the Cuban SECURE-MR-FMEA code. The process map was prepared, identifying 6 stages with 76 accidental sequences. Values showed that the first screening for the developed model reports 45 % of high risks, 42% and 13 % of moderate and low risks, and once the number of controllers increased, high risks decrease to 11 % and there is an increase in moderate and low risks of 54 % and 35 % respectively. These results stress the importance of using all necessary measures for the protection of the public, patients and occupationally exposed workers.**

*Keywords:* **Image-guided interventional procedures, radiological risk analysis, risk matrix, probabilistic safety analysis.**

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# 1. INTRODUCTION

Minimally invasive image-guided interventional procedures have expanded the scope of medical practice across numerous domains of medicine, owing to the demonstrated benefit to patients [1]. The use of this technique has multiplied vertiginously in recent times, also turning into one of the medical applications that produces the highest doses of radiation for both the patient and the personnel involved in the procedure [2], as well as the possible occurrence of deterministic effects. One way to reduce the occurrence of these incidents is through prospective risk analysis, which is focused on the prevention and mitigation of their consequences. For this reason, the goal of this work is to analyze the radiological risk in a generic service for image-guided interventional procedures.

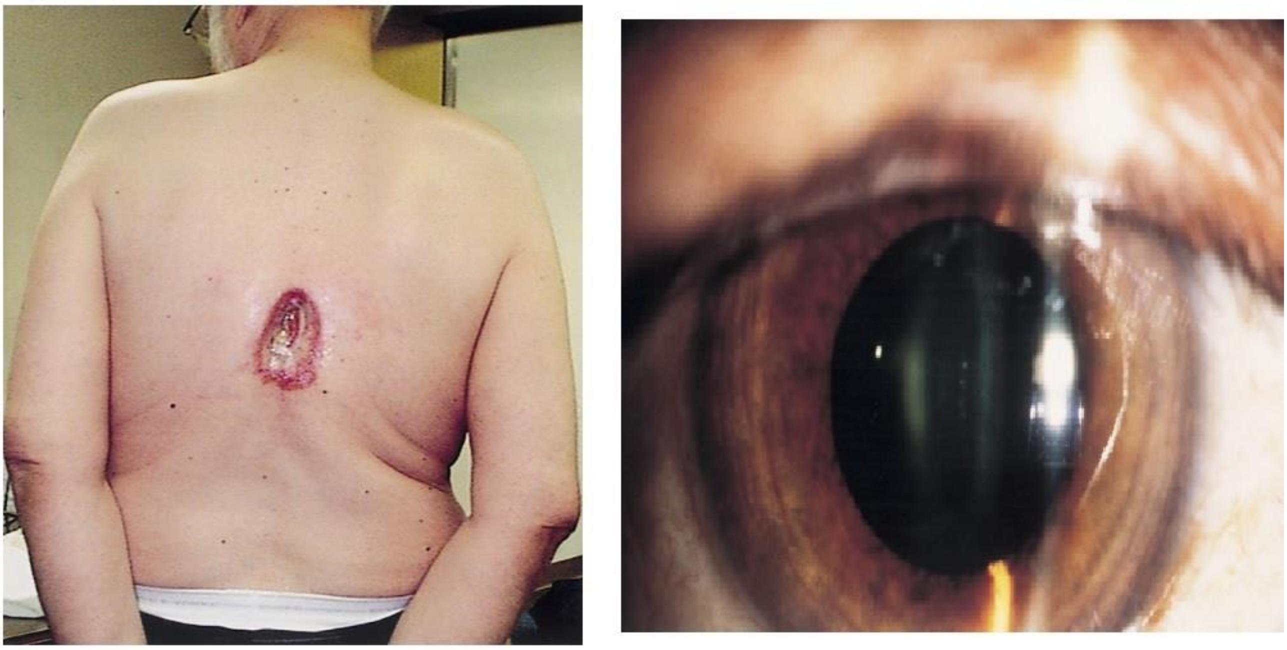
There is a potential danger in believing that modern equipment and new technologies require less quality control and highly skilled maintenance. Therefore, to avoid the occurrence of adverse situations, there must be adequately trained personnel, sufficient material resources, an implemented quality assurance program and ongoing training [3].

The results of using of the risk matrix for image-guided interventional procedures applying the Cuban SECURE-MR-FMEA code [4-6] are presented. In addition to identifying the causes and consequences that can trigger unwanted events; both for patients (C-PAC), occupationally exposed workers (C-OEW) or the public (C-PUB). This method has been applied in some medical practices (Radiotherapy [7-15] and Nuclear Medicine [16-20]) and industrial [21], there is no evidence of this type of analysis to image-guided interventional procedures.

# 2. MATERIALS AND METHODS

This research was focused in a generic service where image-guided interventional procedures are performed. To obtain the accidental sequences, reports on radiological incidents and accidents that occurred during interventional procedures were taken into account (Figure 1), as mentioned in the following bibliographic references [1, 2, 22-29], publications where the risk matrix methodology has been applied, and through consultation with experts. The methodology used for this process is illustrated in the algorithm of Figure 2.

**Figure 1:** *A - Photograph of the patient's back 21 months after a coronary angiography and two angioplasty procedures within a three-day period; assessed cumulative dose 15,000 to 20,000 mGy. The patient has consistently refused skin grafting after excision of necrotic tissue. B - Cataract in the eye of an interventionist after repeated use of old x-ray systems and improper working conditions related to high levels of scattered radiation.*

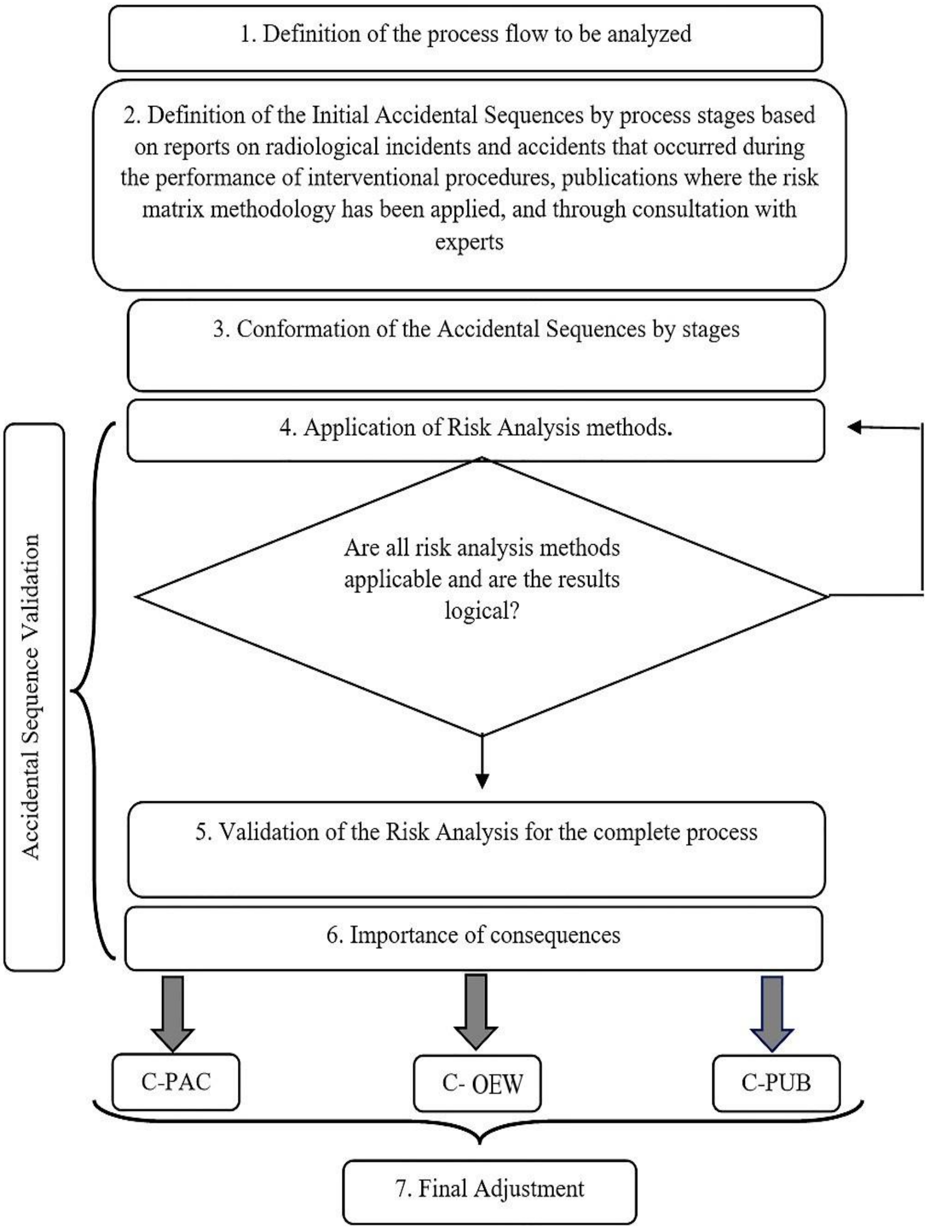


A B

Source: ICRP 85 "Avoidance of radiation injuries from medical interventional procedures "

Since a generic algorithm was created for obtaining and validating accidental sequences (Figure 2), which will be applicable to any process in which image-guided interventional procedures are performed, the first step was to define the process to identify its stages. The initial accidental sequences were elaborated where the initiators to be included in each stage are identified, as well as their barriers (B), consequences (C), frequency (FR) and consequence (CR) reducers. To form the final sequences, a validation process was conducted, during which the analysis methods specified in SECURE-MR-FMEA were consistently applied. The process involves multiple actors (PAC, PUB, OEW), which can result in different consequences for the initiators.

**Figure 2:** *Algorithm for obtaining and validating accidental sequences.*




Accidental sequences form a chain of initiating events that possibly end in undesirable consequences, including accidental exposure [10]; being useful for these cases to apply the risk matrix approach, which is an effective tool in the risk management of a facility from the combined analysis of the frequency of an adverse event (f), the probability of failure of the existing barriers (P) and their consequences (C) [7]. Although this methodology does not allow risk to be numerically quantified, it facilitates it possible to classify risk into levels, which is accurate to establish priorities, without the need for more precise risk analysis [4].

Safety measures or barriers detect, prevent, avoid and stop an accidental sequence or mitigate its consequences. Security measures can be technological, such as alarms, or of an organizational nature, such as procedures or double checks to avoid or detect an error. These are all part of the principle of defense in depth [16]. Procedures that reduce the probability of occurrence of the initiating event or the severity of the consequences are called frequency (FR) or consequence (CR) reducers, respectively. The robustness of barriers, frequency and consequence reducers was obtained from the criteria established in basic bibliographies [7,10,13,15].

To determine the types of consequences [7], cases that could affect the public, patients or OEW were analyzed.

- Very serious consequences (VS): They are of a catastrophic type, causing severe deterministic effects for several patients or OEW, they can be fatal, or lead to permanent damage.
- Serious Consequences (S): Those that cause deterministic effects on a patient or OEW by exceeding the thresholds for deterministic effects, can be fatal or lead to permanent damage.
- Moderate consequences (M): Those that provoke to exposures below the thresholds of deterministic effects for patients, public or OEW. They only represent an increase in the probability of occurrence of stochastic effects.
- Low Consequences (L): No effects on patients, public, or OEW, but decreased defense in depth.

The risk analysis was carried out with the SECURE-MR-FMEA code [4-6], this is a code developed in Cuba with the objective of carrying out comprehensive risk studies of practices involving ionizing radiation. This code interconnects prospective methods (risk matrix and FMEA) and an own database with reactive capabilities for incident learning. For this occasion, the risk matrix, which is one of the methods implemented in the software, was employed.

## 3. RESULTS AND DISCUSSION

For the radiological risk in image-guided interventional procedures (RRF), 6 stages are identified (Table 1), in which everything from the design of the premises and installation of equipment, to the post-treatment follow-up of the patient, are considered. 76 Initiating Events (IE), 26 Barriers (B), 24

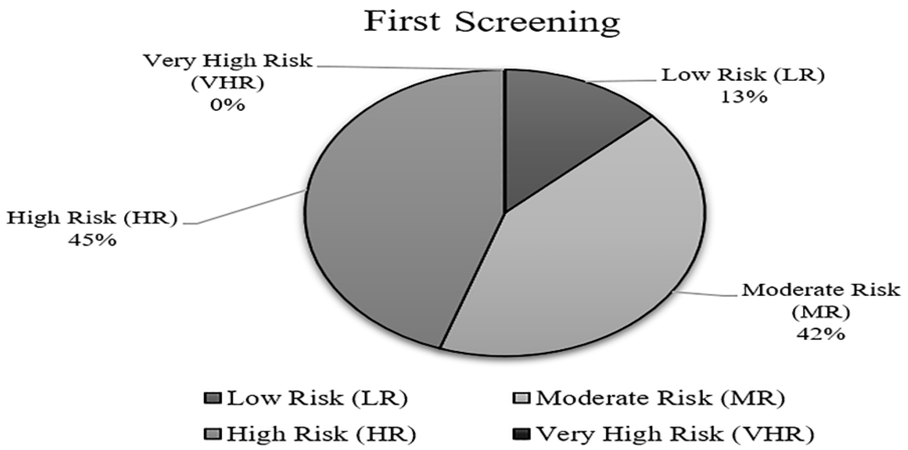
Frequency Reducers (FR) and 8 Consequence Reducers (CR) are postulated. Two screenings are applied to obtain risk, in the former, redundancies of the barriers present in each sequence are only considered, while in the latter, redundancy and robustness of the barriers and reducers were considered. (Figure 3).

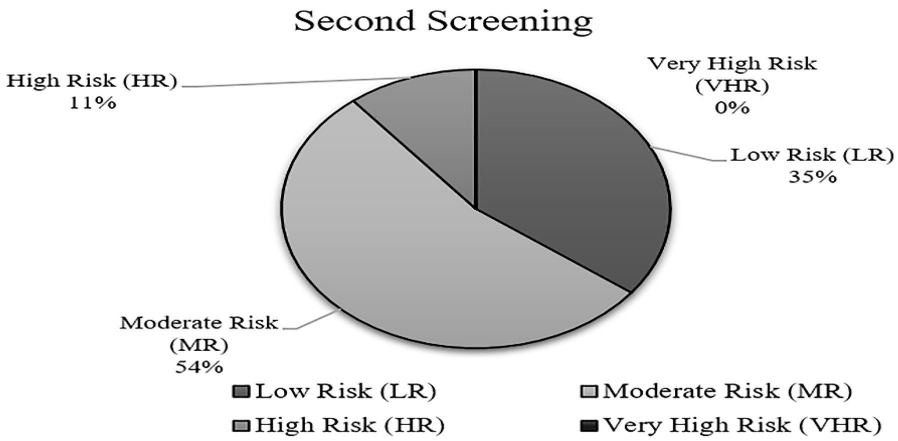
**Table 1:** *General distribution risk of radiological risk*

| Stage | Very High Risk (VHR) | High Risk (HR) | Moderate Risk (MR) | Low Risk (LR) | Total per stage |
|---|---|---|---|---|---|
| Design of the premises and installation of equipment (DPE) | 0 | 0 | 2 | 6 | 8 |
| Acceptance and commissioning (AAC) | 0 | 0 | 20 | 1 | 21 |
| Equipment maintenance (EQM) | 0 | 2 | 2 | 2 | 6 |
| Indication and prior stage of performing Image-Guided Interventional Procedures (IPF) | 0 | 0 | 3 | 0 | 3 |
| Performance of Image-Guided Interventional Procedures (PFP) | 0 | 5 | 14 | 17 | 36 |
| Post-treatment follow-up (SPT) | 0 | 1 | 1 | 0 | 2 |
| Process | 0 | 8 | 42 | 26 | 76 |

Applying the second screening, the risk level profile is obtained for each stage of the radiological risk in image-guided interventional procedures (Table 1), the main initiating events, the barriers, the most important reducers and consequences are analyzed.

**Figure 3:** *Percentage distribution of the level of radiological risk in image-guided interventional procedures at first screening (upper) and second screening (lower).*




The difference in the results of the aforementioned risk profiles are observed in the pie charts (Figure 3). For the first profile (higher), the existence of 45% high risks (HR), 42% moderate risks (MR) and 13% low risks (LR) of the total number of evaluated sequences was identified, by applying a greater number of risk drivers in a second screening, gradually decreased to 11% high risk (HR), and there is a rise in moderate (MR) and low (LR) risks of 54% and 35% respectively. The latest information mentioned shows that for high risk (HR), 8% corresponds to PAC and 3% to OEW, for moderate risk (MR), 38% is for PAC, 14% for OEW, and 1% for PUB, and for low risk (LR), 11% is for PAC, 17% for OEW, and 8% for PUB.

Table 2 shows the main initiating events that affect PAC, OEW, and PUB, as well as their corresponding risk level and type of consequence. High risks (HR) correspond to three stages EQM, PFP, and PTF.

**Table 2:** *Most important initiating events ordered by levels of radiological risk and severity of the consequences for PAC, OEW and PUB.*

| No | Risk Level | Consequences[1] | Stage | Description of the initiating events |
|---|---|---|---|---|
| | | | | PAC |
| 1 | HR | C-PAC(VS) | EQM | Not performing corrective actions when quality controls indicate that essential parameters are outside the established tolerances. |
| 2 | HR | C-PAC(VS) | PTF | Do not follow-up patients who received doses higher than the threshold skin doses during the intervention procedures. |
| 3 | HR | C-PAC(S) | PFP | Perform procedures on patients subjected to other exposures with ionizing radiation, in a short time between one and the other. |
| | | | | OEW |
| 4 | HR | C-OEW(S) | EQM | Not performing corrective actions when quality controls indicate that essential parameters are outside the established tolerances. |
| 5 | HR | C-OEW(S) | PFP | Performance of the interventional procedure by personnel without the necessary skills for the activity. |
| 6 | HR | C-OEW(S) | PFP | Collation of the interventional physician's hand on the beam. |
| | | | | PUB |
| 7 | MR | C-PUB(M) | PFP | The procedures were carried out with the access doors open. |
| 8 | LR | C-PUB(M) | PFP | Presence or incorporation of unauthorized personnel in the room during a procedure. |
| 9 | LR | C-PUB(L) | DLE | Failure to delimit areas or to carry out an incorrect delimitation during the design of the facility. |

[1]C-PAC (Consequences on patients), C-OEW (Consequences on OEW), C-PUB (Consequences on public).

Figure 4 and Table 3 shows the percentage participation of the frequency (upper graph) and consequences (lower graph) reducers. It can be seen that the frequency reducers that stand out are FR-16 (Sf). Systematic training of personnel involved in the procedure was found in 33% of the sequences; FR-17 (Sf) Prior training of personnel in matters of radiological protection in 33% of the sequences and FR-21 (R) Maintaining moderate workload in 32%. While the most important consequence reducers are CR-3(Sf) Annual quality control tests. with 48 %, CR-2 (N) Periodic radiometric survey, which is 39% and CR-1 (Sf) External annual audit of the entity with different equipment 39%.

**Figure 4:** *Total fraction of accidental sequences in which the frequency (upper) and consequence (lower) reducers participate that contribute to the level of radiological risk in image-guided interventional procedures (y-axis). Number and robustness of each reducer on the x-axis and the legend of the graph. Soft (Sf), Normal (N) and Robust (R) robustness.*

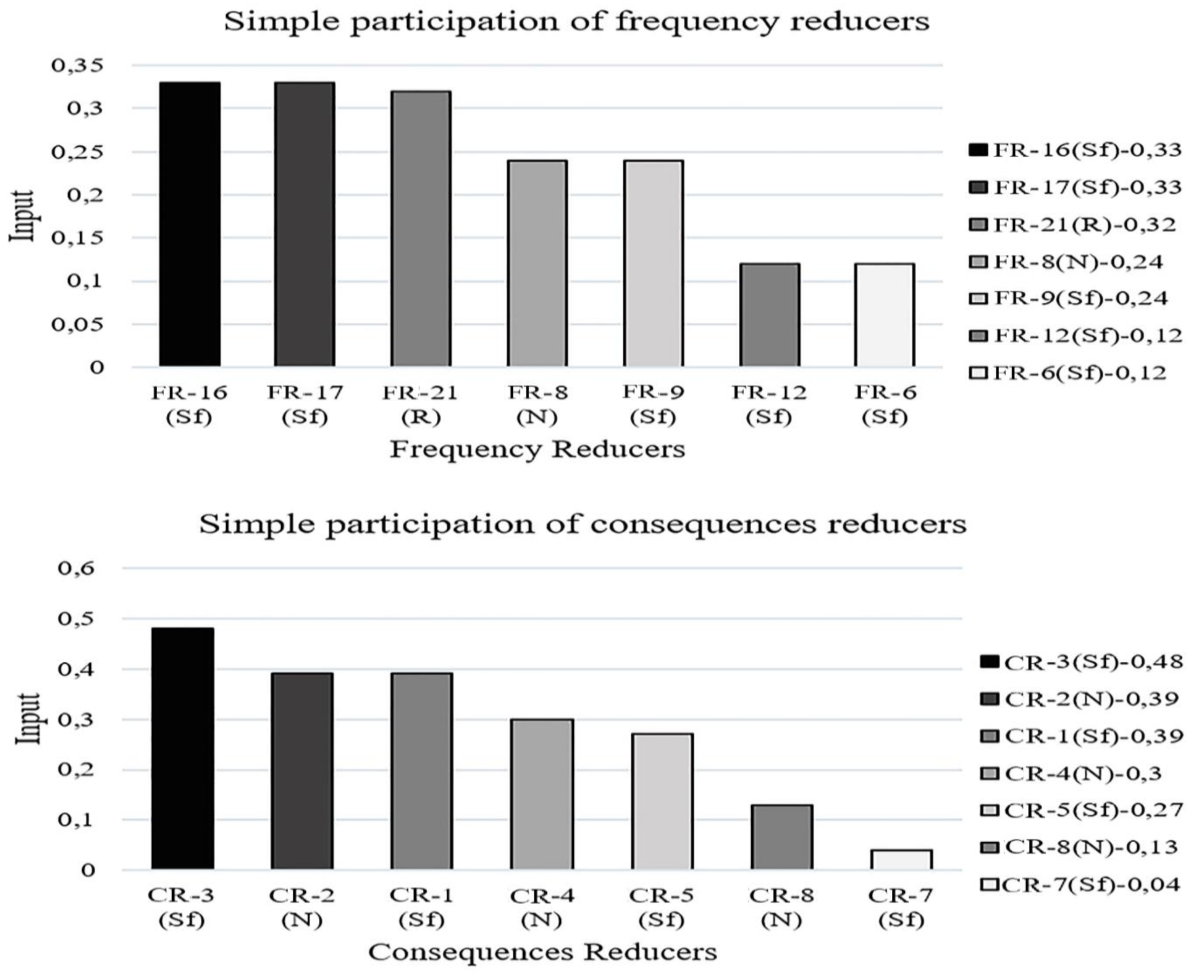


**Table 3:** *Frequency and consequence reducers participation percentage that contribute to the level of radiological risk in image-guided interventional procedures.*

| Frequency reducers | | | |
|---|---|---|---|
| **Code** | **Description** | **%** | **Classification** |
| FR-16 | Systematic training of personnel involved in the procedure. | 33 | Soft (Sf) |
| FR-17 | Prior training of personnel in matters of radiological protection. | 33 | Soft (Sf) |
| FR-21 | Maintaining moderate workload. | 32 | Robust (R) |
| FR- 8 | Correct application of the acceptance and commissioning procedures. | 24 | Normal (N) |
| FR-9 | Medical Physicist training. | 24 | Soft (Sf) |
| FR-12 | Maintenance personnel training. | 12 | Soft (Sf) |
| FR-6 | Radiation protection officer training. | 12 | Soft (Sf) |

| Consequences reducers | | | |
|---|---|---|---|
| **Code** | **Description** | **%** | **Classification** |
| CR-3 | Annual quality control tests. | 48 | Soft (Sf) |
| CR-2 | Periodic radiometric survey. | 39 | Normal (N) |
| CR-1 | External annual audit of the entity with different equipment. | 39 | Soft (Sf) |
| CR-4 | Reports of patients with skin lesions. | 30 | Normal (N) |
| CR-5 | Monthly individual radiological surveillance. | 27 | Soft (Sf) |
| CR-8 | Procedure for deciding on the follow-up of patients in whom the dose thresholds for deterministic effects may have been exceeded. | 13 | Normal (N) |
| CR-7 | External and internal audits during interventional procedures. | 4 | Soft (Sf) |

On the other hand, Figure 5 was obtained, which shows how the risk increases when the following barriers disappear B-21 (N). Presence in the room of at least one certified interventional radiologist to supervise the procedure and B-18 (R). Fluoroscopy use time control and shot counter with visual and acoustic alarms that allow increasing the risk if they disappear in 11 sequences, while B-5 (N). Institution procedure indicating that the equipment cannot operate without the appropriate clinical-use certification and B-6 (N). Redundant verification by another medical physicist with different dosimetric equipment and image quality during acceptance and commissioning does so in 10 and 9 sequences, respectively. Table 4 shows the aforementioned barriers in more detail.

**Table 4:** *Barriers that, when removed, result in an increased risk of accidental sequences during image-guided interventional procedures.*

| Barriers | | | |
|---|---|---|---|
| **Code** | **Description** | **Number of affected sequences** | **Classification** |
| B-21 | Presence in the room of at least one certified interventional radiologist to supervise the procedure. | 11 | Normal (N) |
| B-18 | Fluoroscopy use time control and shot counter with visual and acoustic alarms. | 11 | Robust (R) |
| B-5 | Institutional procedure indicating that the equipment cannot operate without the appropriate clinical-use certification. | 10 | Normal (N) |
| B-6 | Redundant verification by another medical physicist with different dosimetric equipment and image quality during acceptance and commissioning. | 9 | Normal (N) |
| B-3 | Acceptance testing and commissioning. | 4 | Normal (N) |
| B-15 | Procedures for minimizing the patient's received dose. | 4 | Normal (N) |
| B-9 | Work procedures that regulate access to controlled areas. | 3 | Normal (N) |

The percentage analysis of the level of severity of the consequences can be seen in Figure 6, where the moderate consequences (M) in the OEW are 26%, the very serious consequences (VS) and serious (S) in patients with the 19% and 18% in that order. This highlights the importance of applying optimization for this type of study. The increased variety, frequency, and complexity of these procedures, sometimes with relatively high radiation doses, and the involvement of personnel with insufficient training in radiation protection, pose challenges for managing patient dose and ensuring occupational safety. Patients may be at risk of tissue reactions (temporary and permanent erythema, temporary and permanent epilation, etc.), and both patients and staff are at increased risk of stochastic effects. In addition, OEWs who do not comply with all security measures are at risk of temporary epilation, hand injuries and cataracts caused by radiation.

**Figure 5:** *Total number of accidental sequences whose level of risk increases when the action of the barrier ceases in radiological risk in image-guided interventional procedures (y-axis). Number and robustness of each barrier on the x-axis and the legend of the graph. Normal (N) and Robust (R) robustness.*

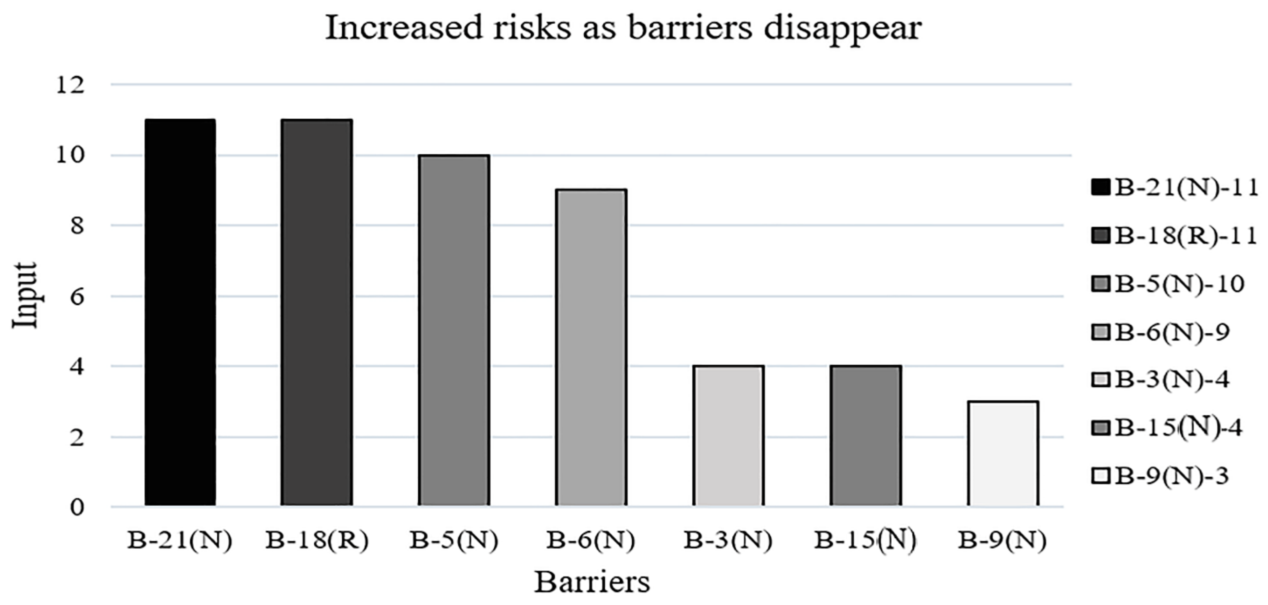
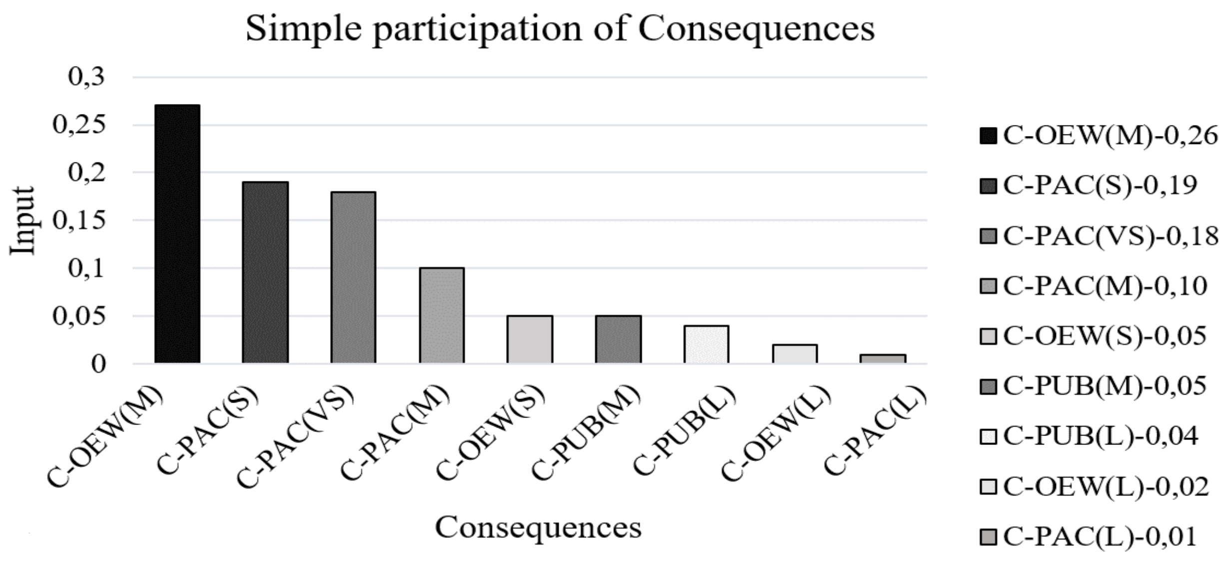



**Figure 6:** *Total fraction of accidental sequences in which the consequences participate that contribute to the level of radiological risk in image-guided interventional procedures (y-axis). Number and robustness of each consequence on the x-axis and the legend of the graph.*



## 4. CONCLUSION

The importance and benefits of applying image-guided interventional procedures are unquestionable, but this should bring rooted properly apply the ALARA (As Low as Reasonably Achievable) principle by the OEW, since this procedure not only protects patients, but also workers from the associated risks with employment of ionizing radiation. For this hence, applying radiological risk analysis with prospective methods to this type of practice allows time detection of unwanted events.

The use of the risk matrix methodology for practices including image-guided interventional procedures will boost better performance of institutional internal evaluations and will allow greater management of security measures.

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