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A holistic approach for risk analysis in therapeutic nuclear medicine in Cuba

Zayda Haydeé Amador Balbona[1], Antonio Torres Valle[2], and Teresa Alejandra Fundora Sarraf[3], *

[1]*Centre of Isotopes, Ave. Monumental y carretera La Rada Km 31/2, Mayabeque, Cuba*
[2]*Higher Institute of Applied Technologies and Sciences, Ave. Salvador Allende Quinta de Los Molinos, Havana, Cuba*
[3]*Institute of Hematology and Immunology, Calle 8, Vedado, Havana, Cuba*
*Corresponding author's e-mail: zabalbona@centis.edu.cu

Abstract. The most useful prospective methods to risk analysis in medical practices with ionizing radiation are the risk matrix (RM) and the failure mode and effect analysis (FMEA). In another hand, at the world level developed various systems for reactive risk analysis (ILS), for example ARIR, ROSIS and SAFRON. In the state of the art, RM, FMEA and ILS are not matching. This study aims to identify the most contributors to the radiological risk for radionuclide therapy (RT) applying a holistic approach useful for decision makers and as a training tool for staff for strengthening safety culture.
Developed generic models for RT were adapted to six cases in nuclear medicine services in Cuba. This includes the radiosynoviorthesis and the myelosupressor treatment with Phosphorous 32 of Polycythaemia Vera. The TG-100 of AAPM was taken as reference for RT. For safety assessment are used a new combined methodology and a Cuban code SECURE-MR-FMEA version 3.0, which increases the efficacy and efficiency in this study.
The application of generic models shows a selection of 52% of the total accidental sequences, 61% of barriers, 56% of frequency reducers and 50% of consequence reducers, as minimum. For personalized treatment, these were higher than 91%. Most important identified process stages, control elements and root causes for the risk showed as integrators of the improvement quality and safety plan.
In addition, there are an informative compendium made with Dreamweaver version 8.0 and an international incident database (IDB) with around 30 years of published events, which includes near misses for this practice, and a wide standard list of root causes and adapted severity scale. This research allows identifying priority measures to keep exposure optimization for patients, workers, and public. The developed tools could applied to the rest of medical practices and for continuous learning in these organizations.

KEYWORDS: risk matrix, failure mode and effect analysis, incident learning system, radiological risk, radionuclide therapy, personalized treatment.

1 INTRODUCTION

For the management of quality and safety in nuclear medicine and the continuous improvement of the processes, the performance of the risk analysis is required in the safety assessment of practices in Cuba. The state-of-the-art of prospective methods such as risk matrix (RM) and analysis of failure modes and effects (FMEA) and reactive such as the incident learning system (ILS), shows that their combined use is limited and uncommon and without application in therapeutic nuclear medicine. The goal of this work is to evaluate the radiological risks in radionuclide therapy by establishing synergy between these methods in six Cuban nuclear medicine services for patients, workers and public.

2 MATERIALS AND METHODS

To undertake this research, as an answer of the Bon Call for action, the following procedure was followed:

a) Review and adaptation the developed risk matrix generic models [1, 2] and taking into account the publication TG-100 of AAPM [3] for each case of study (the first five case for conventional therapy and the six case for personalised treatment);
b) Selection of initiating events (IE) and defences (frequency reducers (FR), barriers (B) and consequences reducers (CR)), applicable to practices that were carried out in Cuba at the moment of this study. These practices are radiosynoviorthesis (RSV) and the myelosupressor treatment of Polycythaemia Vera (PV) with Phosphorous 32, the treatment of cancer and benign thyroid diseases and personalized treatment of thyroid illness [4] belonging of Cuban five nuclear services;

[1]zabalbona@centis.edu.cu

c) Determination by case in study of the inherent risk and the residual risk;
d) Identification of the main stages of process and defences to risk due to their participation percentage and their impact on the risk level when they are eliminated;
e) Determination of consequences of incidents behaviour for patients, workers and public.
f) Main sub-processes and root causes from FMEA are in correspondence with the risk priority number (RPN) and severity (S), but on the basis of equivalence between RM and FMEA with the previously adaptation of FMEA scale for patients, workers and public. [3] Also is a conversion of each defence in a root cause by expert´s criteria and a deployment of these. The used selection criterions are RPN≥100, Severity Index (ISev)≥7 and the 20% of highest value of RPN.
g) Creation of an ILS with information from articles and published reports, mainly from Australia (ARIR [5]) and the United States of America [6]. The adopted structure for the database of incidents (IDB) is similar to SAFRON [7]. This includes around 30 years of published events and near misses (for the last case it was used an adapted Nyflot´s five level scale [8]), a standard list of root causes and adapted SAFRON´s severity scale. [7] Obtaining information take into account some experiences from ROSIS [9];
h) Creation of a wide standardized list of root causes [10].
i) Realization of the FMEA-ILS synergies, to determine the most important sub-processes by FMEA and the predominant basic causes.
j) Validation of the risk matrix generic model with RM-ILS synergy and analysis of the matching between initiating events and records;
k) Determination of the most reported root causes in the ILS;
l) Use of the Cuban code SECURE MR-FMEA version 3.0, developed in the Higher Institute of Advanced Technologies and Sciences (INSTEC) [1] and
m) Creation of an informative compendium made with Macromedia Dreamweaver 8.
n) Formulation of recommendations for strengthening safety culture in an organization.
o) Formulation of recommendations to the Cuban regulatory bodies taking into account the ACCIRAD project ENER/D4/160-2011 for radiotherapy [11] and adapting to nuclear medicine.

3 RESULTS AND DISCUSION

The application of developed risk matrix generic models to the first five studied cases can be seen in Figs. 1-2. This is satisfactory due to obtained percentages like 50% as minimum and around 104% as the maximum. Sixth studied case belonging personalized treatment has better behaviour (Fig.2).

Figure 1: Minimum and maximum percentage of application of risk matrix reference model components for conventional radionuclide therapy applied in five Cuban nuclear medicine services

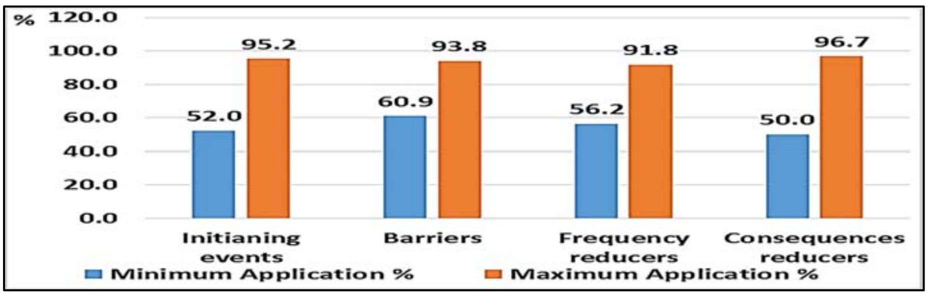
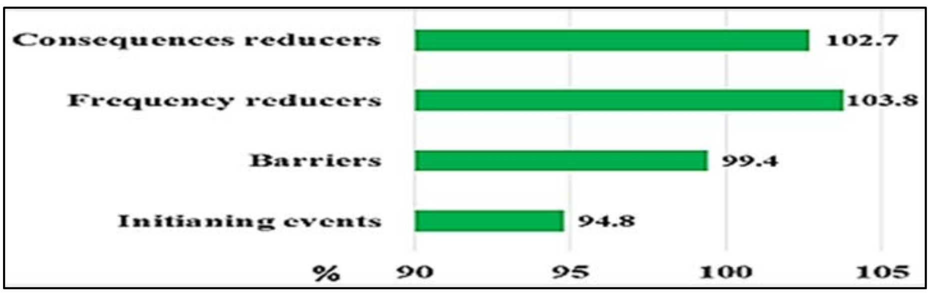


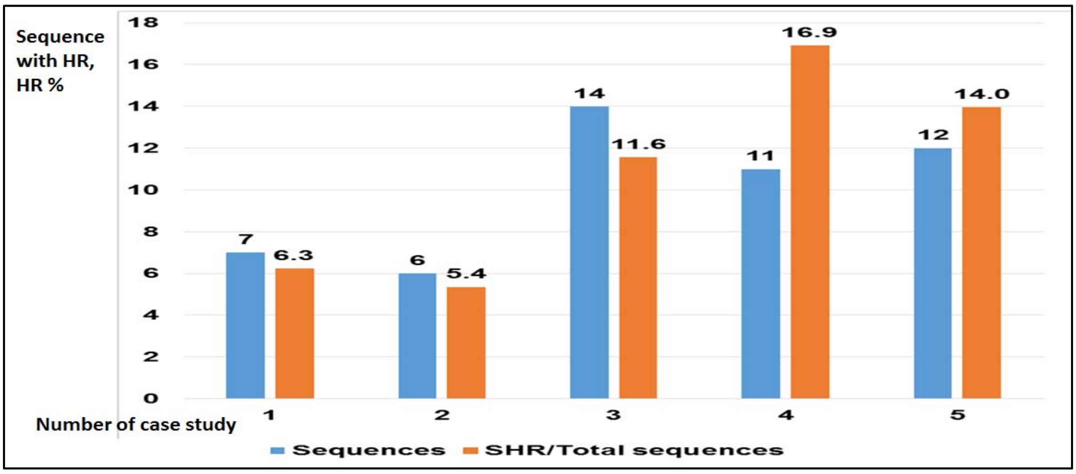
Figure 2: Percentage of application of risk matrix reference model of personalized treatment for the studied case No. 6



1zabalbona@centis.edu.cu

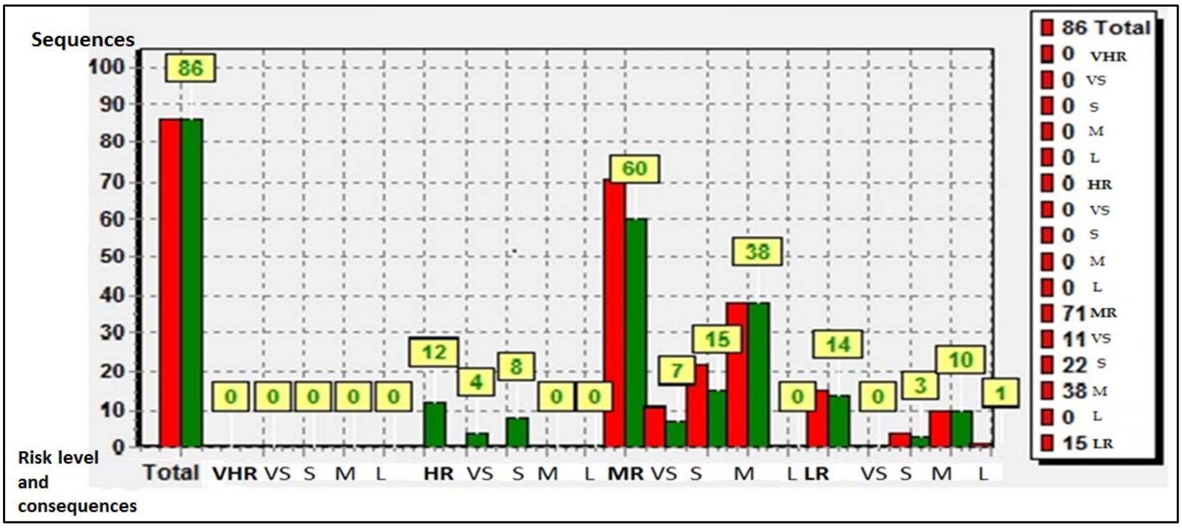
Fig. 3 shows studied cases No. 4 and 5 have the highest incidence of high risk in their accidental sequences. The different results among all services indicate non-uniform development of safety culture and the necessity to adopt more defences for worst cases in view of obtaining the residual risk.

Figure 3: Number of sequences by studied case with high risk (SHR) and high risk percentage (HR%) for radionuclide therapy in five services of nuclear medicine in Cuba



Radionuclide therapy for the selected studied case No. 5, since the worst behaviour against particularities of the RSV and the treatment of PV (case No. 4), have presented inherent risk and residual risk showed in Fig. 4.
The barriers with most contribution for risk of this case are shown in Fig. 5. It is important highlight the use of the impact from their elimination in the risk of accidental sequences as a meaningful complement of the participation analysis.

Figure 4: Comparative histogram of the inherent risk (green color) and residual risk (red color) for studied case No. 5. Total accidental sequences by each risk level (very high risk (VHR), high risk (HR), medium risk (MR) and low risk (LR)) and its consequences level (very severe (VS), severe (S), medium (M) and low (L)) in the x-axis

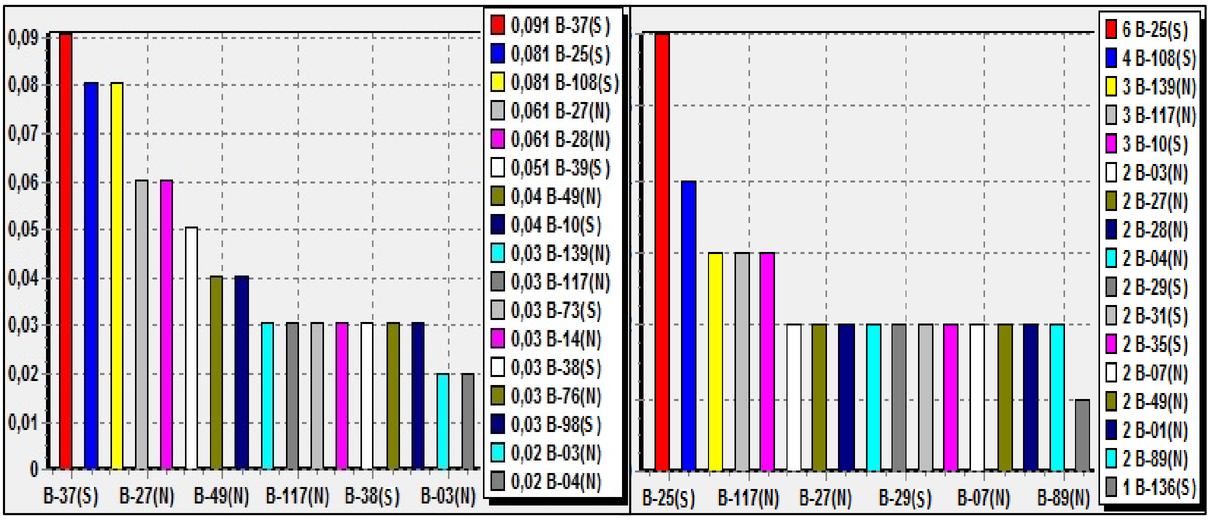


The personalized treatment (studied case No. 6) have more accidental sequences and its inherent risk and residual risk can be seen in Fig. 6. In the same way is analyzing the importance of their barriers and the results are in Fig. 7.
For radionuclide therapy the clinical prescription of treatment, preparation and administration of radiopharmaceutical are the process stages with the most important contribution to risk because they

[1]zabalbona@centis.edu.cu

have highest number of accidental sequences with high risk. This can be observed in Fig. 8 from risk matrix (left side) and FMEA (right side).

Figure 5: Fraction of the total accidental sequences in which there are barriers (B) contributing to risk level (left side) and number of total accidental sequences in which lack barriers contributing to increase of risk level (right side) for studied case No. 5. Number and robustness of each barrier are in x-axis and legend (normal (N), robust (R) and soft (S))



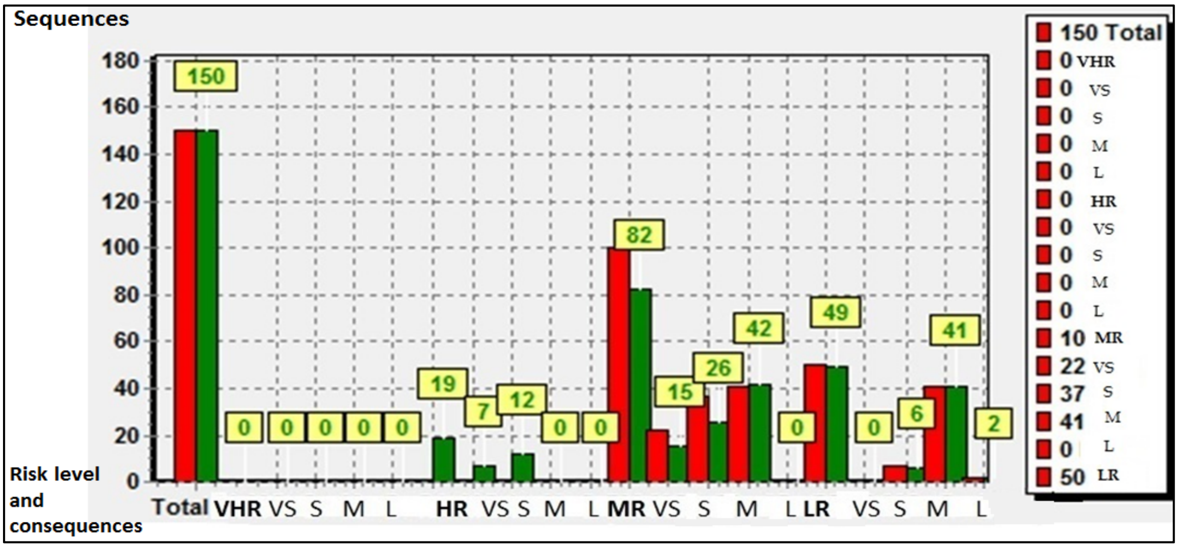
B-37(S): Use of individual protection means against radioactive surface contamination during execution of operations

B-25(S): During the prescription of the dose in which the Nuclear Physician evaluates the results of the clinical analyzes and the diagnosis of the images of the patient referred by the attending physician and determines the treatment that must be executed

B-108(S): Internal procedure that establishes the obligation to verify the data of the prescription of the treatment with respect to the dose that will be administered, before performing the administration.

B-139(N): Review of patients' medical histories by the Physician, Radiopharmaceutical and Medical Physician of the NM service before their treatment.

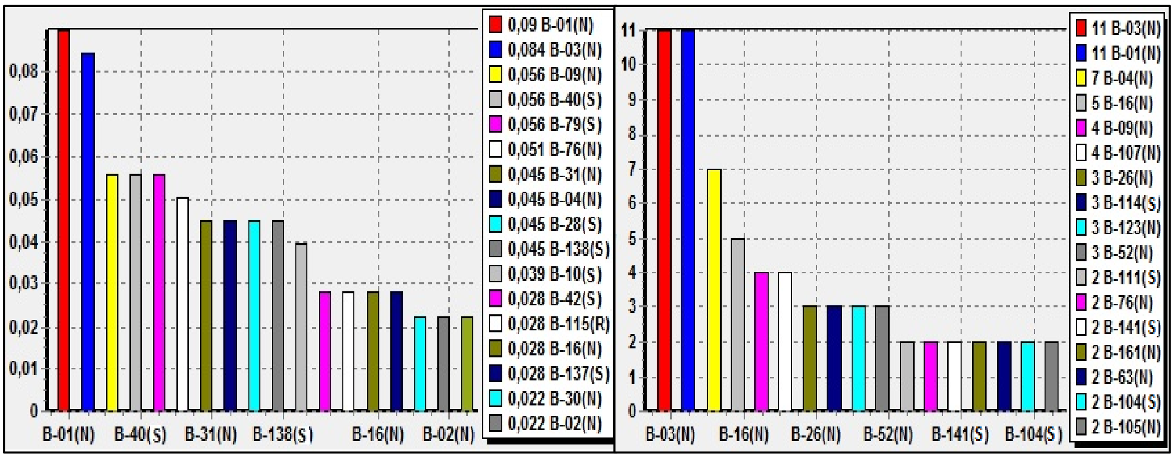
Figure 6: Comparative histogram of the inherent risk (green color) and residual risk (red color) for studied case No. 6 (personalized treatment). Total accidental sequences by each risk level (very high risk (VHR), high risk (HR), medium risk (MR) and low risk (LR)) and its consequences level (very severe (VS), severe (S), medium (M) and low (L)) in the x-axis



On the other hand, personalized treatment (studied case No. 6) has the acquisition of images for planning specific patient treatment and the maintenance and repair of equipment and systems, in addition to the three mentioned previously, as the main process stages (Fig. 9).

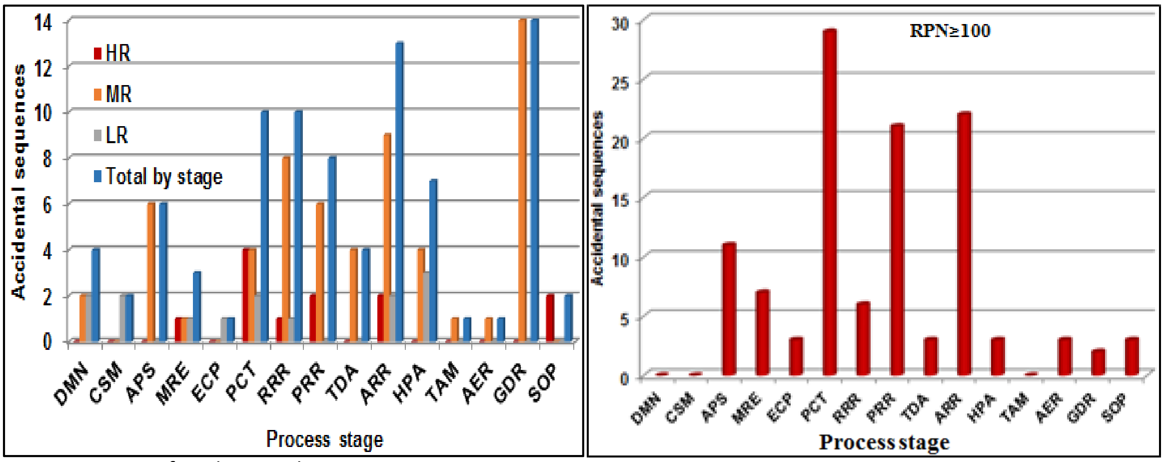
[1]zabalbona@centis.edu.cu

Figure 7: Fraction of the total accidental sequences in which there are barriers (B) contributing to risk level (left side) and number of total accidental sequences in which lack barriers contributing to increase of risk level (right side) for studied case No. 6 (personalized treatment). Number and robustness of each barrier are in x-axis and legend (normal (N), robust (R) and soft (S))



B-01(N): Project revision taking into account the applicable safety regulations
B-03(N): Initial radiological area monitoring of the nuclear medicine service
B-09(N): Internal procedure for measurement of the radiopharmaceutical activity in a redundant and independent way (by a second person and another equipment)
B-40(S): Use of individual protection means against radioactive surface contamination during execution of operations
B-04(N): Inspection of civil construction and equipment assembly before initial labors in nuclear medicine service

Figure 8: Number of sequences by process stage with high risk (HR), medium risk (MR), low risk (LR) and total by stage from risk matrix (left side) and accidental sequences from FMEA with RPN≥100 (right side), for studied case No. 5



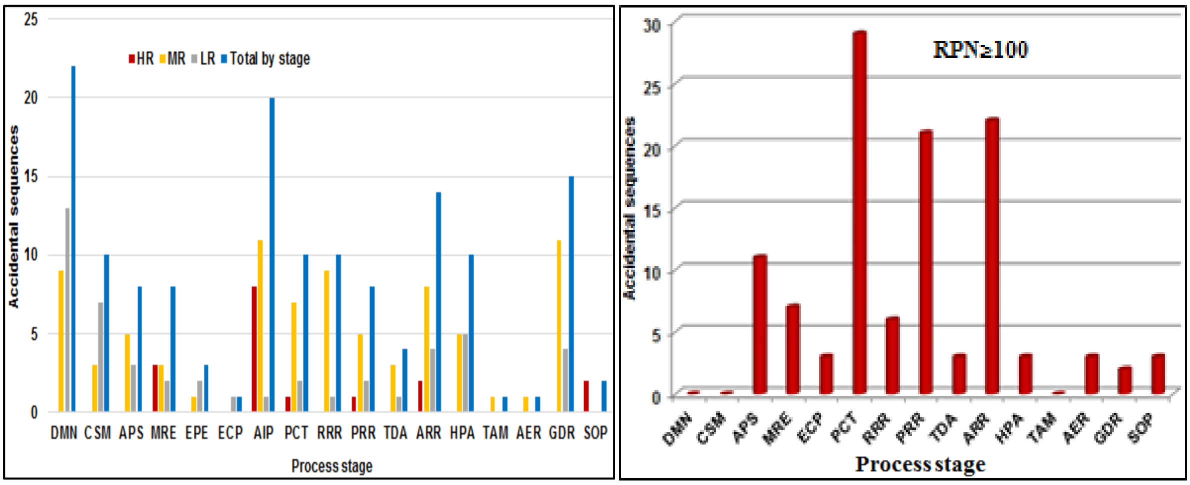
DMN	Design of nuclear medicine service
CSM	Construction of nuclear medicine service
APS	Acceptance and commissioning of the equipment used in the practice of Nuclear
MRE	Maintenance and repair of equipment and systems
ECP	Clinical evaluation of the patient
PCT	Clinical prescription of the treatment
RRR	Reception of the radiopharmaceutical
PRR	Preparation of the radiopharmaceutical
TDA	Transfer of the dose to the place of administration
ARR	Radiopharmaceutical administration
HPA	Hospitalization of the patient
TAM	Release of patients
AER	File and delivery of the results of Nuclear Medicine treatments
GDR	Radioactive waste management
SOP	Patient follow-up

From risk matrix in all cases the consequences of incidents are very severe and severe for patients with 11.1% and 23.2%, respectively for radionuclide therapy (studied case No. 5). Besides, workers have highest percentage of medium consequences and the public is in the third place (Fig. 10).
Table 1 is presenting main root causes for six Cuban services of nuclear medicine from their FMEA. There is prevalence of no fulfilment of practices, procedures or standards in all cases which denotes a

[1]zabalbona@centis.edu.cu

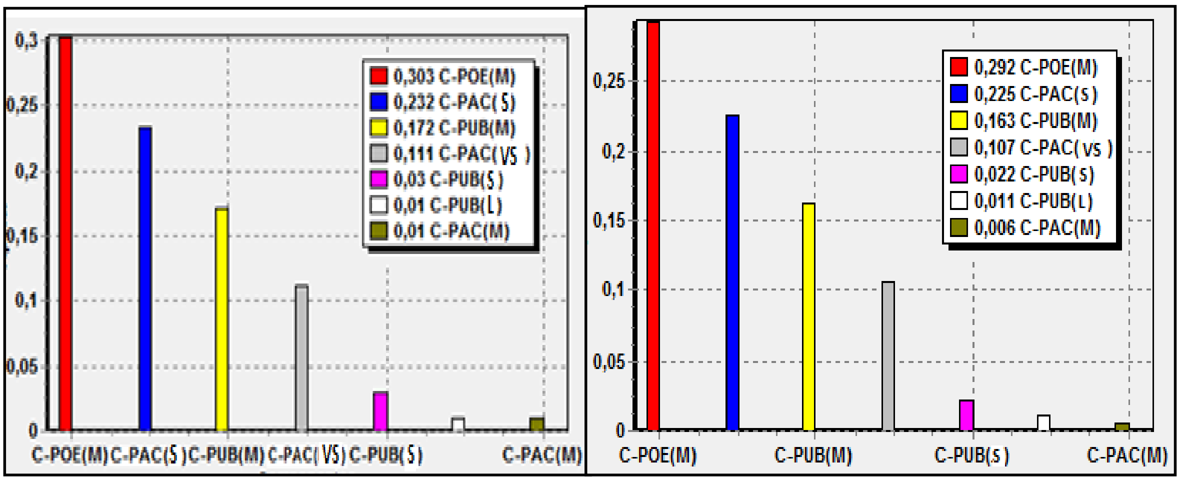
weakness in safety culture of these organizations. The adding new corrective or preventive actions for eliminating identified root causes together with defences incorporated from obtaining residual risk is a complement for this analysis and represent a meaningful tool for decision makers.

Figure 9: Number of sequences by process stage with high risk (HR), medium risk (MR), low risk (LR) and total by stage from risk matrix (left side) and accidental sequences from FMEA with RPN≥100 (right side), for studied case No. 6 (personalized treatment)



DMN	Design of nuclear medicine service
CSM	Construction of nuclear medicine service
APS	Acceptance and commissioning of the equipment used in the practice of Nuclear
MRE	Maintenance and repair of equipment and systems
EPE	Preparation of the treatment protocol for clinical trial
ECP	Clinical evaluation of the patient
AIP	Acquisition of images for planning specific patient treatment
PCT	Clinical prescription of the treatment
RRR	Reception of the radiopharmaceutical
PRR	Preparation of the radiopharmaceutical
TDA	Transfer of the dose to the place of administration
ARR	Radiopharmaceutical administration
HPA	Hospitalization of the patient
TAM	Release of patients
AER	File and delivery of the results of Nuclear Medicine treatments
GDR	Radioactive waste management
SOP	Patient follow-up

Figure 10: Fraction of the total consequences (x-axis) by each consequence level (medium (M), severe (S), very severe (VS) and low (L)) belonging to workers (POE), patients (PAC) and public (PUB) for radionuclide therapy (left side) and personalized treatment (right side) in y-axis and legend.



The created informative compendium on risk management in medicine with ionizing radiations contains 427 components like publications, User´s Manuals of SEVRRA and SECURE-MR-FMEA, database of incidents, IAEA´s documents, and process sheets for nuclear medicine practices. Its home web page is presented in Fig. 10.

[1]zabalbona@centis.edu.cu

Table 1: Order of importance of the main root causes from FMEA for studied case of the conventional radionuclide therapy (1-5) and personalized treatment (6)

Root causes	Studied case number					
	1	2	3	4	5	6
	Order of importance					
1.3 Practices/Procedures/Standards- non-compliance	1	1	1	1	1	1
6.1 Development of abilities and knowledge-inadequate training/orientation (lack or inadequacy)	3	2	3	2	2	2
8.4 Worker´s perception- Fatigue of staff	2	3	2	3	3	3

The created international data base incident (IDB) for radionuclide therapy has a total of 125 records until November 2019 from 13 countries. Obtained 21% of initiating events (IE) with better matching with records, from synergy RM-ILS, can be seen in Fig. 11. This indicates the necessity of expert´s work improvement. The synergy FMEA-ILS focused in root causes delivers the main contributors displayed in Fig.12. It highlights that the lacking or inadequate development skills and knowledge is the most important root cause.

Figure 11: View of home page web for the informative compendium on risk management

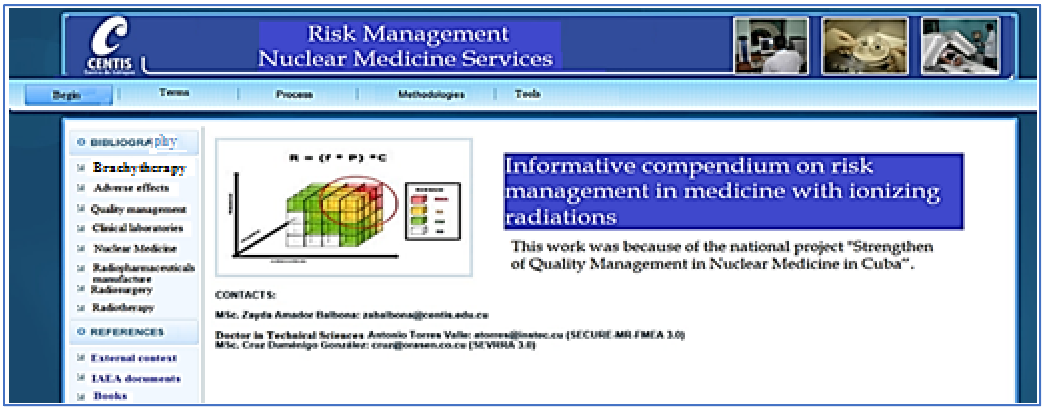
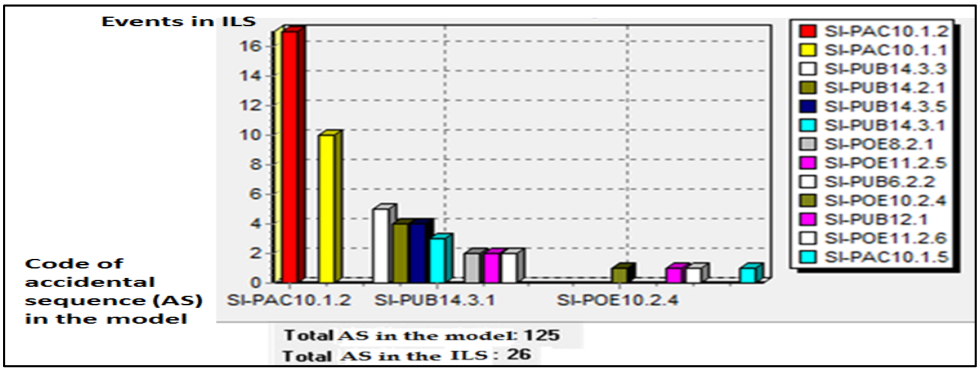


Figure 12: Histogram of the initiating events (IE) with better matching from synergy RM-ILS

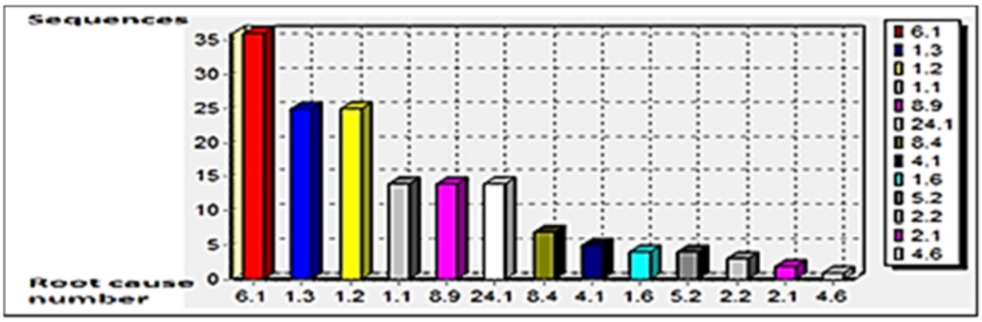


- SI-PAC10.1.2: Error when trying to administer to a patient a total dose higher than that considered in the prescription of the treatment of a radiopharmaceutical
- SI-PAC10.1.1: Error when trying to administer to a patient a total dose lower than that considered in the prescription of the treatment of a radiopharmaceutical
- SI-PUB14.3.3: Evacuation as common waste of packages containing radioactive waste

Main recommended components are increasing report culture in organizations for all nuclear medicine services. Besides, for Cuban regulators these are updating legislation, this methodology for quality and risk management, dissemination of information on risk management, training in risk management and safety culture, informing patients and public to increase trust in the health care system, clinical audits and regulatory inspections. This is an adaptation of European project for radiotherapy [11].

[1]zabalbona@centis.edu.cu

Figure 13: Histogram of root causes recorded in ILS for radionuclide therapy



6.1 Development of skills and knowledge- Lack of training

1.3 Practice, protocols, procedures or standards-Non-compliance

1.2 Practices, protocols, procedures or standards-Inadequate

4 CONCLUSIONS

The results of radiological risks analysis in radionuclide therapy in the Cuban studied nuclear services are not uniform. This research facilitates their improvement and safer practices for workers, patients and the public; creates a superior satisfaction for patients and their families and allows strengthening of the safety culture. Besides, the decision makers could better optimize efforts and resources, eliminate of weaknesses and apply good practices in radionuclide therapy. The developed tools and recommendations to organizations and regulators could be useful for other medical practices.

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[1]zabalbona@centis.edu.cu