# Design of education and training program based on the experiences from risk analysis in therapeutic nuclear medicine

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# INTRODUCTION

- ✓ The education and training (E&T) on the risk analysis results is a necessity for the continuous improvement of quality and safety in the health care.
- ✓ The Bonn Call asks to improve prevention of medical radiation incidents and accidents and E&T activities have a very much contribution to this purpose.
- ✓ This study focuses in E&T program for radionuclide therapy staff as a way to improve its risk perception and increase its quality and safety cultures.

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# OBJECTIVE

**Share a structured E&T program on quality and safety specifically designed for a generic service of therapeutic nuclear medicine (TNM), as an answer of the Bon Call for action, based on the main contributors obtained from the risk analysis (RA).**

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# Materials and Methods

- Taking into account the experiences and results of the application in 5 services of Nuclear Medicine (NM) of the combined RA in Cuba, it is elaborated the syllabus of this course.
- A revision of E&T programs for NM staff in the world is performed. This shows there is a lack of a holistic approach for RA.
- An informational compendium on risk management was made in .html with Dreamweaver version 8.0 and could use as a desk tool for the syllabus.

# Materials and Methods

- The first course of a combined RA on February 2018 belongs to national project ¨Strengthen of Quality Management Systems in Nuclear Medicine Services from National Health System in Cuba¨ and this provides useful experiences.

# Materials and Methods

- **Therapeutic applications:**

  **- Benign and malignant thyroid diseases.**

  **- Hematological disorders (e.g. polycythemia Vera).**

  **- Metastatic bone disease.**

  **- Radiosynoviorthesis.**

- **Cuban code SECURE-MR-FMEA version 3.0 is used for adapting generic models of therapeutic NM and radionuclide patient specific therapy and making exercises of conversion of RM to FMEA and matching models with the international incident data base (IDB)**

# Results and discussion

**Six key topic areas were identified in the syllabus of course, drawn from recommendations on safety and quality:**

- **Incidents and near-misses in radionuclide therapy**
- **Risk matrix**
- **Failure mode and effect (FMEA)**
- **Incident learning and safety culture**
- **Principles in error proofing and quality improvement**
- **Quality audits**

# Results and discussion

## Table 1. Syllabus of course

| Topic area | Aspects | REFERENCE MATERIALS |
|---|---|---|
| 1. Incidents and near-misses in radionuclide therapy | • Incident and near miss concepts<br>• Adapted SAFRON incident scale for patient, workers and public<br>• Adapted scale for near-misses | 1. International Atomic Energy Agency, Safety in Radiation Oncology, SAFRON, Disponible en: htps://rpop.iaea.org/SAFRON/Default.aspx, Last accessed February 21, 2017<br>2. Nyflot MJ, Zeng J, Kusano AS, Novak A, Mullen TD, Gao W, et al. Metrics of success: Measuring impact of a departmental near-miss incident learning system, Practical Radiation Oncology (2015) 5, e409-e16. http://dx.doi.org/10.1016/j.prro.2015.05.009<br>3. Larcos G, Collins L, Georgiou A, Westbrook J. Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register. MJA. 2014; 200:37–40. doi: 10.5694/mja13.10145.<br>4. Saiful Huq M, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management, Med. Phys. 2016, 43 (7): 4209-4262.<br>5. International Standard Organization, Guidelines for auditing management systems. ISO 19011. 2018<br>6. International Atomic Energy Agency, Quality Management Audits in Nuclear Medicine Practices, Second Edition, IAEA Human Health Series No. 33, 2015, Vienna, Austria |
| 2. Risk matrix | • How to formulated the initiating events<br>• Identifying safety barriers and frequency and consequences reducers<br>• Defining 4 levels for frequency and consequences and adapting for radionuclide therapy<br>• Defining 4 levels of strength of safety barriers and reducers<br>• Exercises adapting generic models | |
| 3. Failure mode and effect (FMEA) | • Defining 4 ranges for occurrence, severity and non-detectability adapting for radionuclide therapy.<br>• Root-cause analysis and list of basic causes for reference<br>• Exercises converting MR to FMEA<br>• Exercises converting control elements to basic causes and determining the most contributors | |
| 4. Incident learning and safety culture | • Lesson learned from an international incident database and ARIR<br>• Results from combined risk analysis in therapeutic nuclear medicine<br>• Role of culture in incident learning safe practices<br>• Safety culture | |
| 5. Principles in error proofing and quality improvement | • Common error-proofing techniques and the variable effectiveness<br>• Difference between identifying an error (e.g., QA) and addressing the drivers of error | |
| 6. Quality audits | • Auditory taking QUANUM methodology and examples of its application in Latin-America<br>• To plan and conduct internal audit<br>• Management of non-conformities | |

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# Results and discussion

**The informational compendium on risk management as a tool in the syllabus**


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# Experiences from the first course on February 2018

- ✓ **The duration of this course was a week in two working sessions for each day.**
- ✓ **The participating staff from services of NM were medical physicists, nuclear medicine physicians, nurses and technologists. Also was invited the Nuclear Regulatory Body, teachers and students.**


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# Experiences from application CRA in 5 services of NM in Cuba

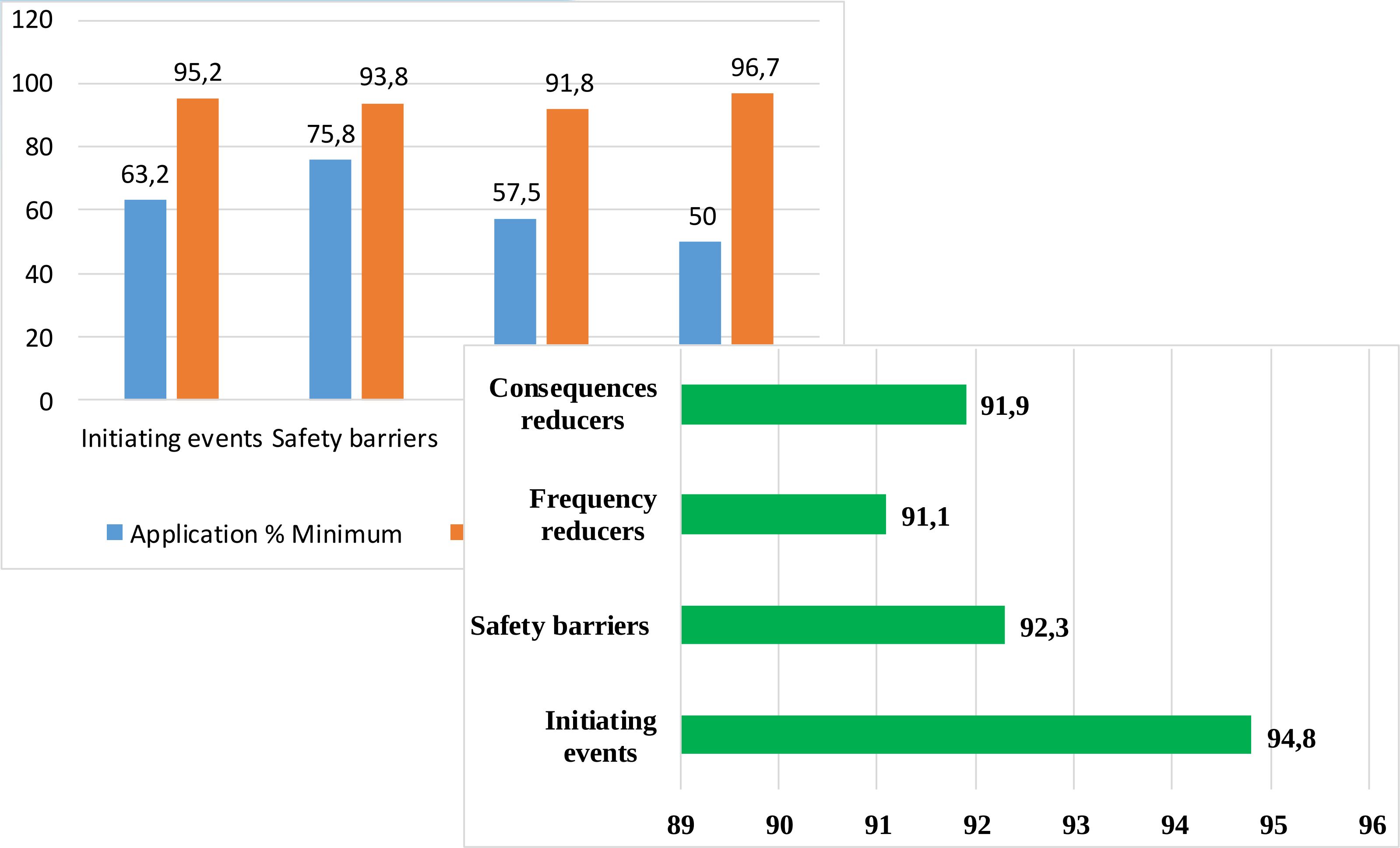


**Figure 1. Percent of application of generic models for radionuclide therapy**

# Results and discussion

**Most contributors stages in CNM:**

- ✓ clinical prescription of the treatment and
- ✓ preparation of radiopharmaceuticals

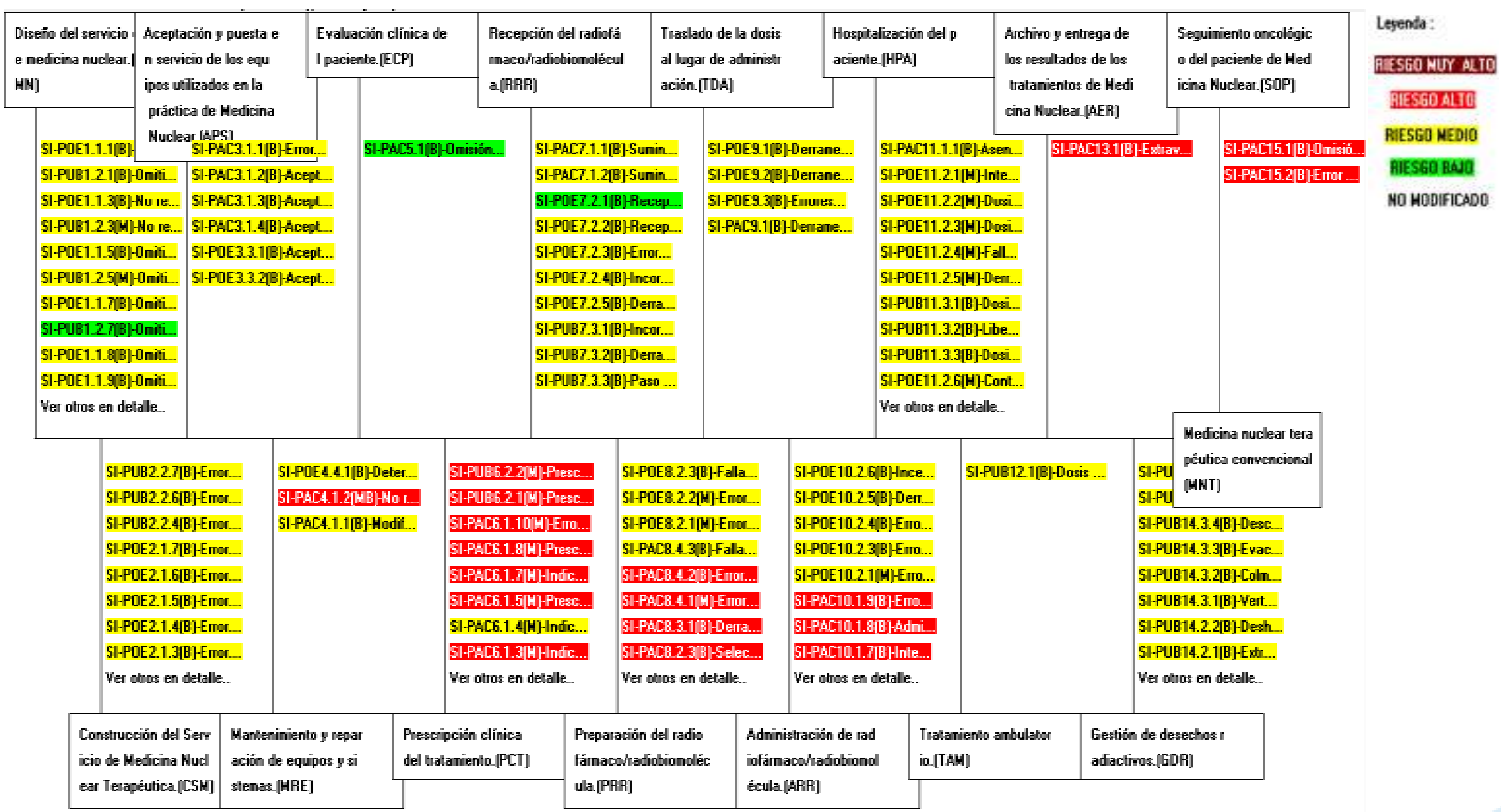


**Figure 2. Event tree from RM of Conventional NM**

# Results and discussion

**Most contributors stages in patient specific NM**

- ✓ pre and post treatment image acquisition and
- ✓ preparation of radiopharmaceuticals

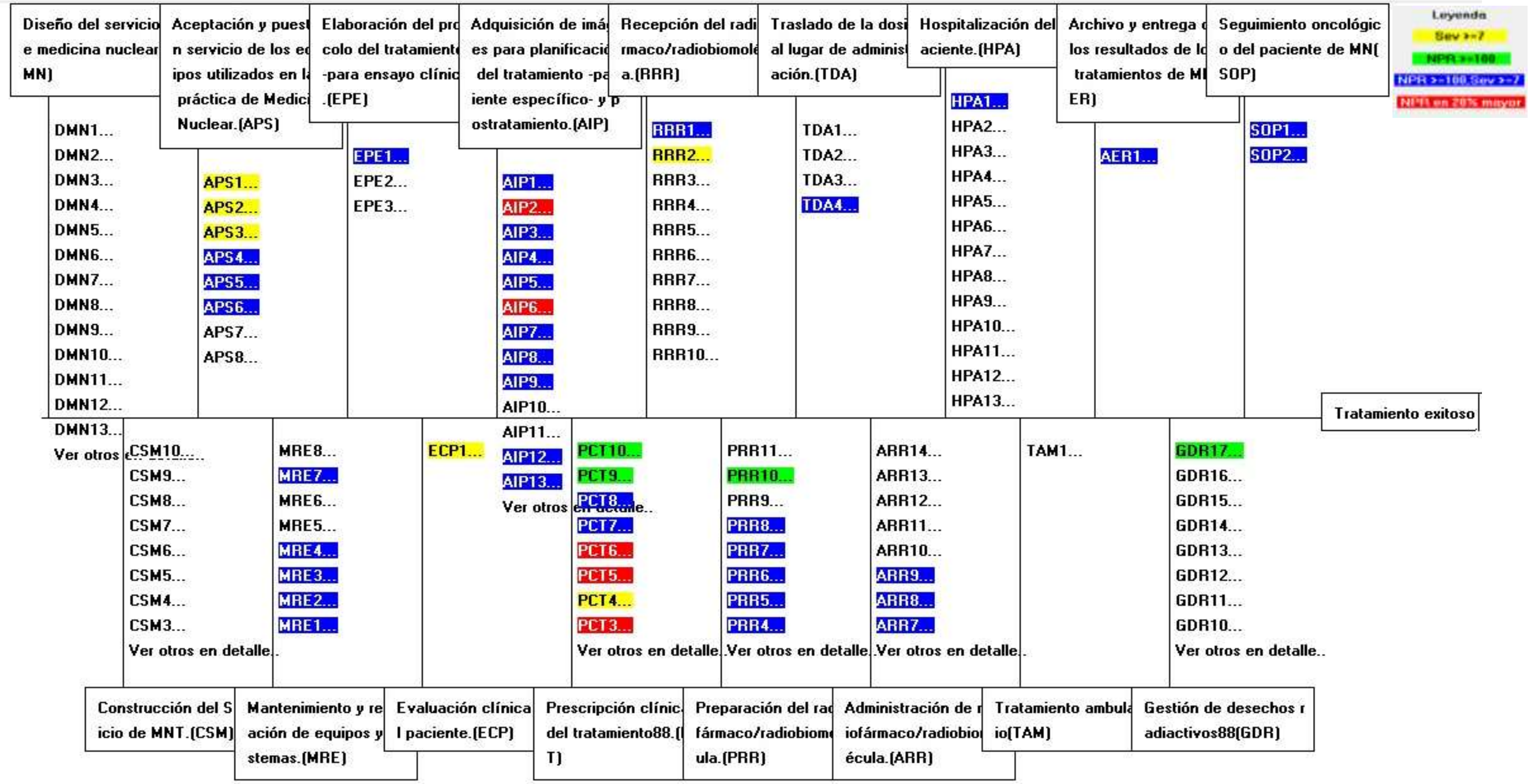


**Figure 3. Ishikawa tree from FMEA of PSNM**

# Results and discussion

**Main contributors control elements for radiological risk of conventional NM**

- ✓ **project revision based on the applicable safety regulations,**
- ✓ **initial radiological monitoring from different services areas,**
- ✓ **a survey of civil construction works and equipment assembly before work began,**
- ✓ **establish of a moderated workload,**
- ✓ **training of nuclear medicine doctor(s) in related aspects of nuclear medicine treatments, and**
- ✓ **existence of placards or warning signs for pregnant women and breastfed infant.**

**Human errors have more than 80% of contribution to radiological risk in radionuclide therapy**

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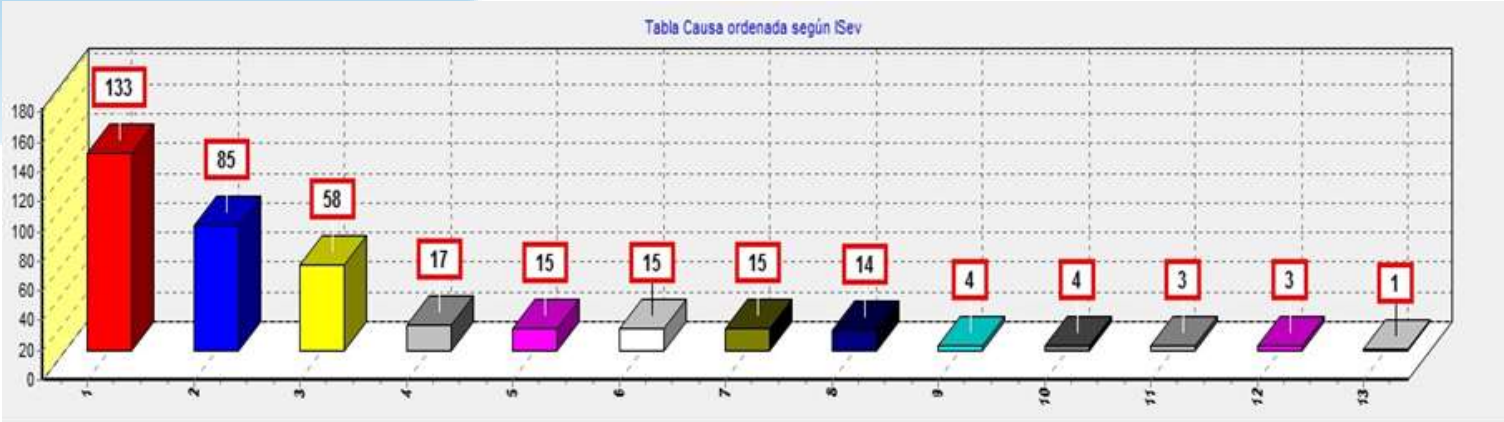
# Results and discussion




| No | Causa | ISV(#S>=7) | IQ(#NPR>=100) |
|---|---|---|---|
| 1 | 1.3 | | |
| 2 | 6.1 | | |
| 3 | 8.4 | | |
| 4 | 2.1 | | |
| 5 | 4.1 | 15(4) | 60(4) |
| 6 | 4.7 | 15(3) | 30(2) |
| 7 | 1.2 | 15(4) | 60(4) |
| 8 | 2.3 | 14(4) | 56(4) |

Practices, protocols, procedures or standars-Unfulfillmen
Development of skills and knowledges- Lack of training
Worker perception-Fatigue of staff

Índice Severidad
#S>=Slim
Índice Calidad
#NPR>=NPRlim
Ordenar
Guarda Ref.
Comparador
Salir

**Figure 4. Basic causes with the most contribution to risk from FMEA for CNM**

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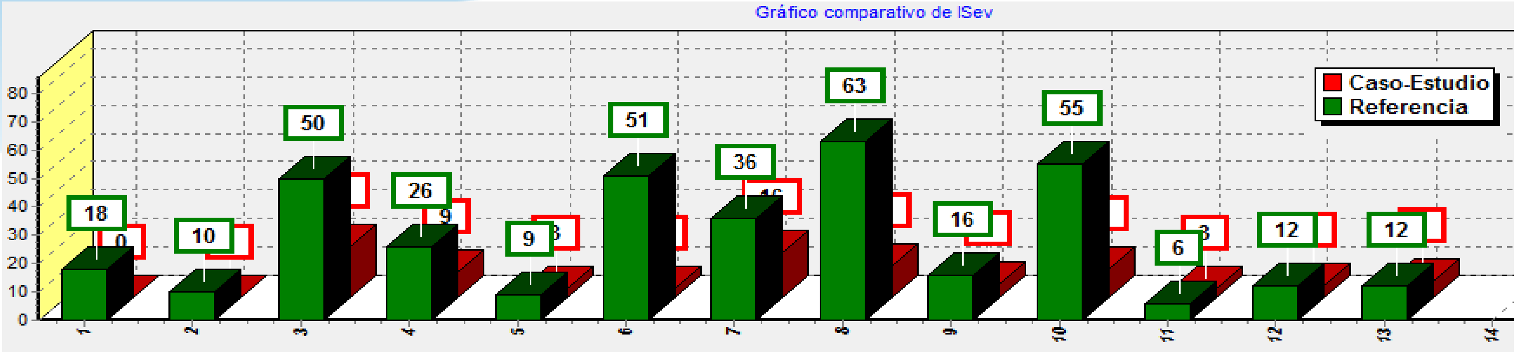
# Results and discussion



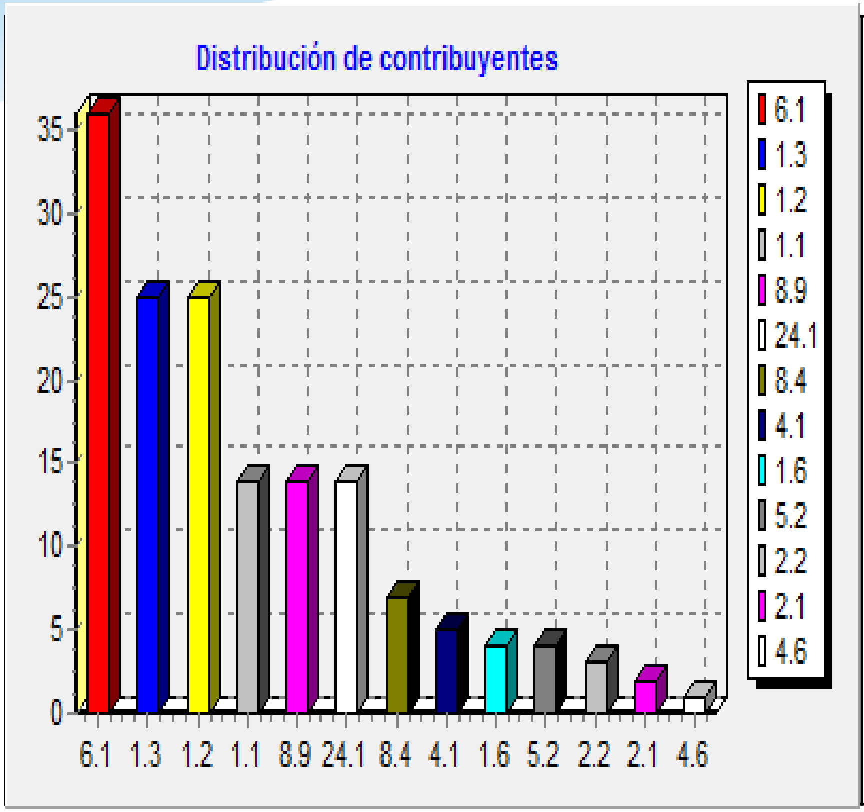

| No | Subproceso | ISV(#S>=7) | IQ(#NPR>=100) |
|---|---|---|---|
| 6 | Prescripción clínica del tratamiento.(PCT) | 3(1) | 3(1) |
| 7 | Recepción del radiofármaco/radiobiomolécula.(RRR) | 16(2) | 16(1) |
| 8 | Preparación del radiofármaco/radiobiomolécula.(PRR) | 11(2) | 22(2) |
| 9 | Traslado de la dosis al lugar de administración.(TDA) | 5(1) | 5(1) |
| 10 | Administración de radiofármaco/radiobiomolécula.(ARR) | 10(2) | 30(3) |
| 11 | Archivo y entrega de los resultados de los tratamientos de Medicina Nucle | 3(1) | 3(1) |
| 12 | Gestión de desechos radiactivos.(GDR) | 4(0) | 0(0) |
| 13 | Seguimiento del paciente de Medicina Nuclear.(SOP) | 6(2) | 12(2) |

Índice Severidad
#S>=Slim
Índice Calidad
#NPR>=NPRlim
Ordenar
Guarda Ref.
Comparador
Salir

**Figure 5. Comparative risks by sub-processes in RSV and treatment of PV (green: initial state and red: causes 1.3, 6.1 and 8.4 were eliminated)**

**1.3 Practices, protocols, procedures or standars-Unfulfilled**
**6.1 Development of skills and knowledges- Lack of training**
**8.4 Worker perception-Fatigue of staff**

# Results and discussion




**6.1** Development of skills and knowledges- **Lack of training**

**1.3** Practices, protocols, procedures or standars-**Unfulfilled**

**1.2** Practices, protocols, procedures or standars-**Inadequate**

**Figure 5. Basic causes with the most contribution to risk from IDB**

# Results and discussion

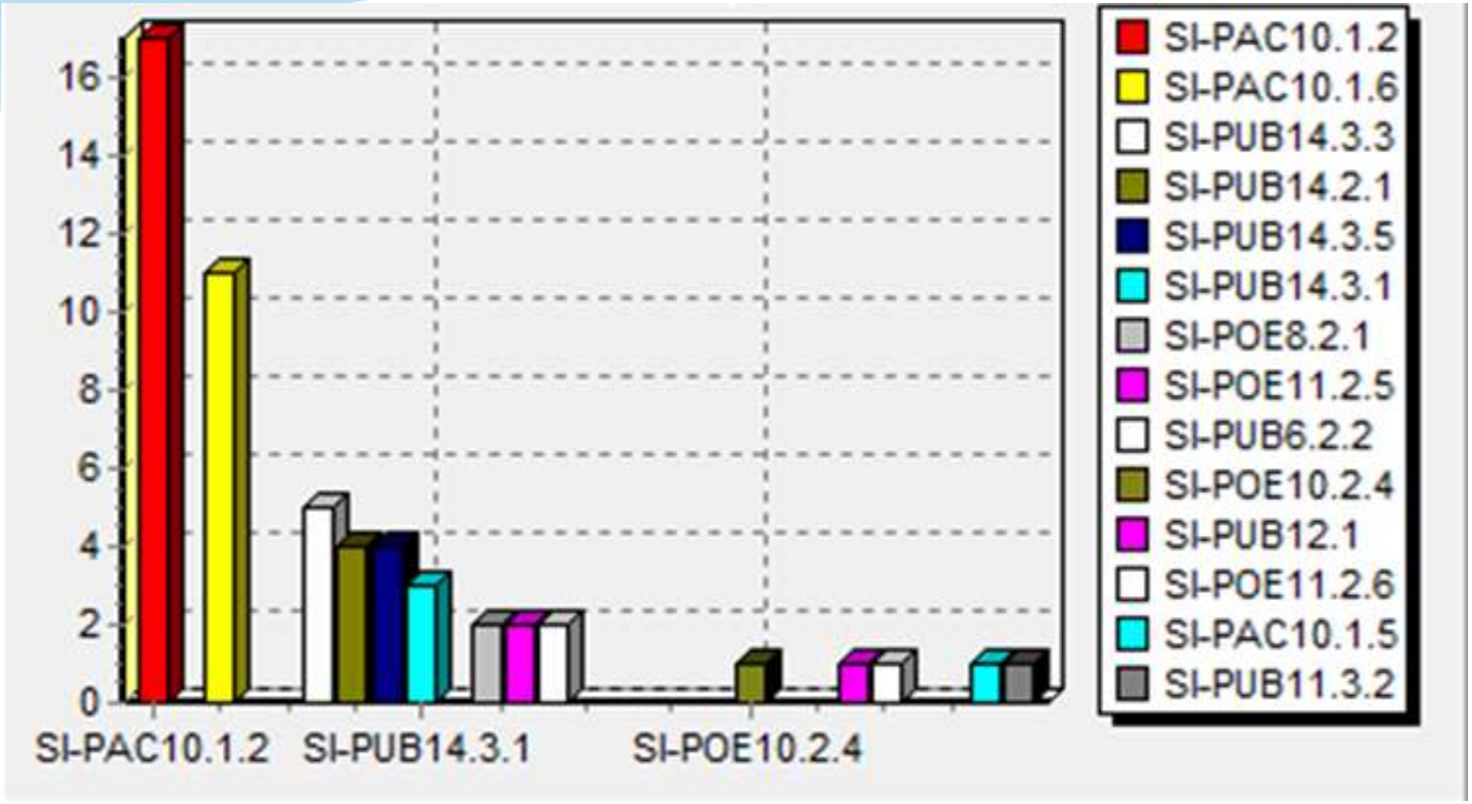



**Figure 6. Accidental sequences from generic models which matching with events in IDB**

**SI-PAC10.1.2 Mistake in the administration of higher dose to patient than prescribed dosage (overdose)**

# Conclusions

1. **The ET program supports the reducing of the contribution of the human errors to the incidents during the radionuclide treatment of the patients, workers and public.**
2. **Based on the outputs of this study the medical physicist could make E&T activities for each workplace in their services.**
3. **In addition this program may be adapted for medical physics graduate programs or certificate programs, nuclear medicine physicians, or as a self-directed educational project for practicing physicists.**

# Conclusions

4. **The program described here is expected to evolve and develop further. One future direction might be a distributed program that is coordinated between a few centers. This might include a combined teaching component, which leverages the expertise of faculty at various centers, and/or a resident exchange program which facilitates a shared learning experience.**

# REFERENCES


1. International Atomic Energy Agency, Bonn Call for Action Platform. Available from: https://rpop.iaea.org/,RPOP/RPoP/Content/AdditionalResources/Bonn_Call_for_Action_Plant form/index.htm, 2012. Last accessed November 15, 2016.
2. Vano E, Jimenez P, Ramírez R, Zarzuela J, Larcher A, Gallego E, et al. Main problems and suggested solutions for improving radiation protection in medicine in Ibero-American countries. Summary of an International Conference held in Madrid, 2016. J Radiol Prot. 2018;38:109–20.
3. International Atomic Energy Agency, Medical Physics Staffing Needs in Diagnostic Imaging and Radionuclide Therapy: An Activity Based Approach, IAEA HUMAN HEALTH REPORTS No. 15, Vienna, Austria, 2018.
4. Muylle K and Maffioli L, Nuclear Medicine Training in Europe: "All for One, One for All", J Nucl Med. 2017;58:1904-1905. doi: 10.2967/jnumed.117.201012
5. European Union of Medical Specialist, Training Requirements for the Specialty of Nuclear Medicine, European Standards of Postgraduate Medical Specialist Training, 2017.
6. International Atomic Energy Agency, Safety in Radiation Oncology, SAFRON, Disponible en: https://rpop.iaea.org/SAFRON/Default.aspx, Last accessed February 21, 2017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# REFERENCIAS


7. Nyflot MJ, Zeng J, Kusano AS, Novak A, Mullen TD, Gao W, et al. Metrics of success: Measuring impact of a departmental near-miss incident learning system, Practical Radiation Oncology (2015) 5, e409-e16. http://dx.doi.org/10.1016/j.prro.2015.05.009
8. Larcos G, Collins L, Georgiou A, Westbrook J. Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register. MJA. 2014;200:37–40. doi: 10.5694/mja13.10145.
9. Saiful Huq M, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management, Med. Phys. 2016, 43 (7): 4209-4262.
10. Torres Valle A, User Manual of Cuban Code SECURE-MR-FMEA 3.0, Software for risk analysis with risk matrix, FMEA and ILS, La Habana, Cuba, 2017.
11. International Standard Organization, Guidelines for auditing management systems. ISO 19011, 2018.
12. International Atomic Energy Agency, Quality Management Audits in Nuclear Medicine Practices, Second Edition, IAEA Human Health Series No. 33, 2015, Vienna, Austria.


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