SAFRON

SAFety in Radiation ONcology

https://rpop.iaea.org/SAFRON/Default.aspx

Updates on Patient Safety in Radiotherapy

December 2017

SEVRRA-SAFRON

In this update:

Quote

"Wise men say, and not without reason, that whoever wished to foresee the future might consult the past."

Machiavelli

New prospective risk analysis using SAFRON events

SAFRON is pleased to announce the partnership with SEVRRA to provide SAFRON users with a quick method to evaluate the safety of their facility based on events reported in SAFRON.

The International Basic Safety Standards requires facilities to investigate accidental medical exposures and adopt corrective actions necessary to avoid a recurrence. SAFRON reports provide information on the lessons learned, the causes of such events and contributing factors to enable preventive measures.

However, they do not address all possible errors or errors that have not yet occurred. If we could pre-empt the situation where errors occur based on what we know has occurred, we may be able to prevent the error from ever occurring in the first place.

Using tools such as probabilistic safety analysis is one such tool but it takes highly trained professionals and many hours to complete even the simplest analysis. Since technology in radiotherapy is evolving rapidly the analysis is likely to be out-of-date before completed.

The approach developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) with support from the IAEA is a tool for self-evaluation of radiotherapy services to analyse errors or failures that might give rise to errors that reach the patient.

The results of the evaluation are a set of safety tools or safety barriers that could be added to the process to increase the safety of radiotherapy and reduce the likelihood of an error.

How does it work?

The risk matrix establishes risk management priorities based on analysis of frequent and undesirable events and consequences, allowing the classification of risk into levels which can then be used to prioritize activities.

For the SEVRRA-SAFRON synergy, the first step is to analyse the reported error and determine the initiating event that correspond with such error. This does not have to be human errors or equipment failures that reached the patient; it can also include reports of near events or near misses.

The next step is to look at the sequence of events, what are the possible safety measures to cope with it and their consequences. Safety measures or safety barriers are the measures put in place to avoid, prevent, detect, control and reduce or mitigate the consequences of an accident once an initiating event has occurred. One common example is the use of seat belts to prevent injury in the event of an automobile accident. Seats belts do not prevent the accident, but reduce the potential harm when an accident happens. Safety barriers can be interlocks (physical) such as the door locks in radiotherapy to prevent access when the machine is turned on, alarms such as the alarm that is flashing when a source is in the unshielded position, or work processes such as checklist or procedures.

The risk matrix looks at the reduction of the frequency of the event (avoidance) and their consequences (reaching and or harming the patient) as well as it identifies the number and strength of safety barriers and reducers needed to cope with the reported error. The risk matrix determines the risk level "R" combining the different levels of the independent variables, "F" the frequency of the initiating event, "P" the probability of failure of the defenses in place and the "C" severity of the consequences.

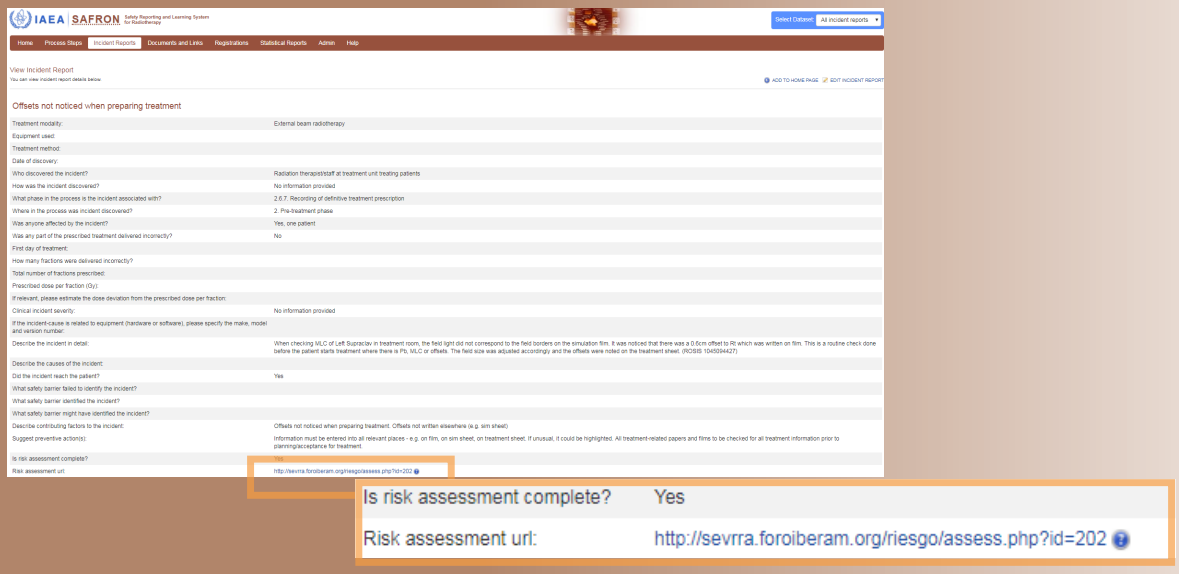
To conduct the analysis, the radiotherapy professionals must analyze the existing safety barriers as well as the frequency and consequences reducers of their service in order to determine if those elements, are enough and sufficiently robust to reduce the risk of potential harms when an human error or equipment failure occurs.

The risk assessment tool allows introducing new barriers or new frequency and consequences reducers. A results report is provided with suggestion on how to manage the risk.

Radiotherapy professionals and nuclear engineers developed the risk matrix. To test the matrix, risk assessment were applied in several radiotherapy services. For the SAFRON correspondence with SEVRRA, they evaluated over 1000 events in SAFRON. SAFRON events that provided enough information were categorized and a risk assessment completed.

How to use SEVRRA-SAFRON

The SAFRON events have been mapped to the risk matrix are identified on the event report under the question "Is risk assessment complete? As indicated below

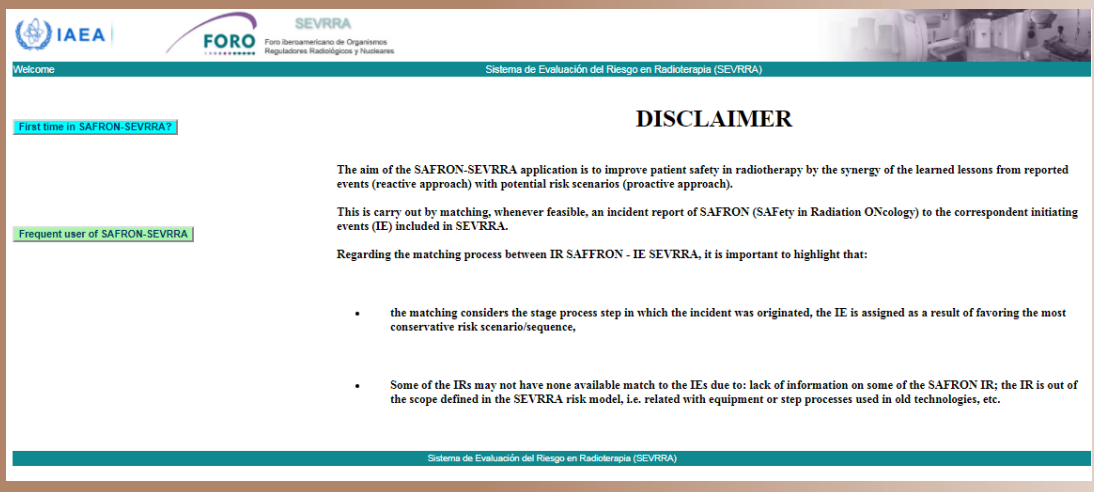


When you access the link, you will be redirected to the SAFRON-SEVRRA site. This is outside of the IAEA website. There are a few disclaimers and then you will reach the site below.

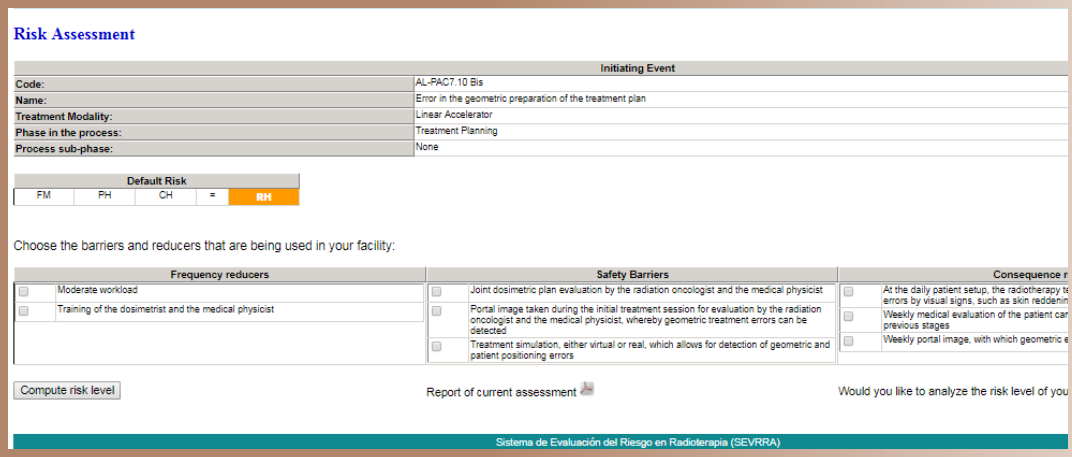
First time users will be directed to a short presentation on how to use the risk matrix. Frequent users will go the to the risk assessment of the situation in your facility.

How to use SEVRRA-SAFRON

If you are interested in evaluating your facilities vulnerability for a similar event to happen you can simply click on the risk assessment url.



You can then select the situation in your clinic by identifying the frequency reducers, safety barriers and consequences reducers.



Assessing and selecting what Frequency reducers, Safety barriers and Consequence reducers are already in place in your facility, you can then obtain a risk level and an assessment report. The Frequency reducers, Safety barriers and Consequence reducers are weighted based on the review of specific scenario conditions by a group of radiotherapy experts.

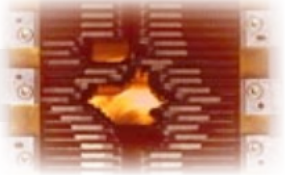
Disclaimer

This risk matrix has value to those looking to improve patient safety. However it is based on anonymous data and assumptions were made into the initiating event. There may be other initiating events that contributed to the errors. It does assume that radiotherapy facilities follow basically the same process steps as identified in SAFRON. The methodology assumes that there are sufficient staffing of all medical specialists, equipment manuals are available, calibration of equipment have been performed and are accurate, that quality assurance programs are in place, procedures have been developed and are followed and workloads are manageable. For more information on the methodology review IAEA TECDOC 1685 at http://www-pub.iaea.org/books/IAEABooks/10904/Application-of-the-Risk-Matrix-Method-to-Radiotherapy.

Technical Meeting on Strengthening of Safety Culture in Radiotherapy through the Use of Incident Learning Systems

10-13 October 2017
Vienna, Austria

The Technical Meeting objectives were to provide Member States, International, Regional and National Organizations an opportunity to evaluate and discuss the use of incident learning systems and how the information can be used to strengthen safety culture in radiotherapy. The meeting explored methods of using incident learning systems, how they can be improved and how they can strengthen safety Culture in Radiotherapy. The meeting was attended by 50 professionals from 41 countries and seven professional organizations. The meeting allowed the sharing of ideas and activities in an effort to strengthen safety culture in radiotherapy. Participants heard about the many different incident reporting and learning systems available from around the world and how they are using the information to disseminate information to the radiotherapy community. Outcomes of the meeting and future activities include the continuation of sharing information about events and improvements in the processes. Identify and share best practices at the local, national regional and international level to improve patient safety in radiotherapy.



Maximizing the benefits of event reporting and learning

One of the challenges with learning from incident reporting is how much and what kind of information is needed to translate a report to an opportunity to learn from errors. It is not the volume of material but the type of material that is communicated to the reader. The information in the reported event is important in determining what happened and what can be learned from the event. The event below provides information that can be used to prevent similar events from occurring. The corrective actions can be applied as a safety feature to prevent this type of event from happening in your facility.

Incorrect source positioning because of wrong source transfer tube length.	
Treatment modality:	Brachytherapy
Equipment used:	
Treatment method:	High dose rate remote afterloader
Date of discovery:	2016-10-31
Who discovered the incident?	Radiation oncologist (physician)
How was the incident discovered?	Clinical review of patient
What phase in the process is the incident associated with?	1.2.1. New equipment
Where in the process was incident discovered?	3.4. Post-treatment completion
Was anyone affected by the incident?	Yes, more than 1 patient - 68
Was any part of the prescribed treatment delivered incorrectly?	Yes
First treatment fraction (for multi-fraction course of treatment)	Not applicable
How many fractions were delivered incorrectly?	
Total number of fractions prescribed:	
Prescribed dose per fraction (Gy):	
If relevant, please estimate the dose deviation from the prescribed dose per fraction:	20-50%
Clinical incident severity:	Major incident
If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:	Varian VariSource iX HDR & BrachyVision V13.5
Did the incident reach the patient?	Yes
What safety barrier failed to identify the incident?	Verification of treatment accessories Verification of correct transfer tube length In vivo dosimetry
What safety barrier identified the incident?	Verification of correct transfer tube length
What safety barrier might have identified the incident?	Review of treatment plan Verification of treatment accessories Verification of correct transfer tube length In vivo dosimetry Independent review of commissioning
Describe contributing factors to the incident:	Commissioning of equipment before clinical implementation Commissioning of equipment after major upgrades/changes to systems and implementation of new techniques using new auxiliary treatment parts-like transfer tubes and applicators Miscommunication between staff Non Elimination of Risk factors Supplier shortfalls – No measurements indicated to users on Equipment and connectors. Incorrect distances used on their demo plans. The planning system has an inherit risk that does not allow you to select preset transfer tube lengths but requires you to type in lengths for each treatment.

Maximizing the benefits of event reporting and learning

Describe the incident in detail:	Error 1 (11 Patients) : The Varisource iX HDR system in question uses click-fit transfer tubes which are specific lengths and transfers the source from the after-loader into the respective applicator. The system was commissioned with a click-fit set of predefined length named "Click-fit Set A ". A few months following commissioning a new Miami applicator was procured with a new "Click-fit set B" that is 10cm longer than "Click-fit set A" . In July 2016 the central channel of "Click-Fit set A" broke and the planning team decided to use the transfer tubes from "Click-Fit Set B" until it can be replaced. Hence the planning team planned treatments using "Click Fit Set B" for the central channel and used "Click fit Set A" for the 2x oviods. The above was communicated to the radiotherapists responsible for connecting the Click-fit tubes and administering the treatment of the patients. Unfortunately some radiotherapists misunderstood the change and thought all 3 connections must now use "Click-Fit Set B". This resulted in 11 patients being treated on the ovoids 10 cm lower than they should have been treated. An in-depth investigation was done on all brachytherapy patients treated from June 2016. All affected patient plans were re-planned including the error showing the differences in doses from what was prescribed and what was administered. This error unfortunately resulted in major differences in planned vs. delivered dose. Error 2 (57 Patients) : During investigation of Error 1 it was decided to remeasure and confirm lengths of all the brachytherapy transfer tubes and applicators used at this facility. During this verification it was found that the Tandem (channel 1) for the Miami applicator was incorrect. When using " Click-fit set B" measured 133.5 on the tandem the Miami. Varian was emailed to confirm the applicator length and they confirmed that we should measure 133.5 cm which will mean that the planning applicator length should be 132 cm (the extra 1.4 cm accounted Quick Connect part of the machine). The planning team was using 130cm planning length which was incorrect as this should have been 132cm. The 130 cm that had been used to plan the patient plans was a default applicator length and was also on the BrachyVision demo plans. This hadn't been manually measured or tested at this facility after the new applicator was procured. This resulted in all patients in error 1 being treated a further 2cm lower that prescribed and an additional 57 patients also treated 2cm lower that what was required. All affected patient plans were re-planned including the error showing the differences in doses from what was prescribed and what was administered. A contributing factors is that the BrachyVision planning system does not allow you to select you applicator and transfer tubes from a pre-set list but you are required to enter the actual length of the transfer tubes used for each treatment.
Describe the causes of the incident:	1.2 Inadequate standard/procedure/practice 1.4 Inadequate communication of procedure 1.5 Inadequate assessment of risk 3.6 Inadequate programming 4.2 Inadequate management of change 5.4 Misunderstood communications
Suggest preventive action(s):	All new equipment to be commissioned and measured manually and double checked before being put into clinical use. Independent check to be done by experienced physicist to confirm full commissioning process was done and the accuracy of the obtained results assessed. All new equipment to be commissioned and measured manually and double checked before being put into clinical use. SOPs to be put in place immediately after a change is implemented and in service training to be done and documented. Risk factors to be identified and removed immediately. Consistency between equipment used. Communicate shortfalls to supplier. This incident has highlighted the extreme important of the basics of radiotherapy and the importance of good QC policies and procedures. The importance of training and the essential nature of good and proper commissioning was also reiterated. Everyone has learned from it and has created safety awareness in all different roles involved. Many extra safety measures have been put in place.

International Conference on Radiation Protection in Medicine

11-15 December 2017, the IAEA will host the International Conference on Radiation Protection in Medicine, Achieving Change in Practice. During the conference there will be several sessions devoted the patient protection in radiotherapy and two special events on 12 of December 2017. The program will be live streamed for those who cannot attend. Visit https://www.iaea.org/events/radiation-protection-in-medicine-conference-2017 for information to watch the conference online For those attending the conference download the app for information on the special events planned during the week.

New publication from International Atomic Energy Agency

The publication entitled Dosimetry of Small Static Fields Used in External Beam Radiotherapy: An International Code of Practice for Reference and Relative Dose Determination Prepared Jointly by the IAEA and AAPM. It has now been officially released on the IAEA publications website.

Links to other safety in radiotherapy updates

ASTRO and AAPM RO-ILS Quarterly report Q2 2017

Autorité De Sûreté Nucléaire (French Nuclear Safety Authority) in English and in French

Public Health England Safer Radiotherapy