

SAFETY IN RADIATION ONCOLOGY https://rpop.iaea.org/SAFRON/Default.aspx



Updates on Patient Safety in Radiotherapy

December 2017

SEVRRA-SAFRON

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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 preempt 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 Since technology in radiotherapy is evolving rapidly the analysis is likely to be out-of-date before completed.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.





Links to IAEA Publication for Radiotherapy Training on Radiation Protection of Patients Website: https://rpop.iaea.org/RPoP/RPoP/Content/index.htm





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

IAEA SAFRON Safety Reporting and Learning System					Select Dataset All incident reports 🔹	
Home Process Steps Incident Reports Documents and Links Registrations St	tatistical Reports Admin He					
ew Incident Report						
u can view incident report details below					🗿 ADD TO HOME RKGE 📝 EDIT INCIDENT REPORT	
Offsets not noticed when preparing treatment						
reatment modality:	External beam radiotherapy					
quipment used.						
reatment method.						
tate of discovery:						
Who discovered the incident?	Radiation therapist/staff at treat	tment unit treating patients				
ow was the incident discovered?	No information provided	No information provided				
What phase in the process is the incident associated with?	2.6.7. Recording of definitive tre	satment prescription				
Where in the process was incident discovered?	2. Pre-treatment phase					
Vas anyone affected by the incident?	Yes, one patient					
las any part of the prescribed treatment delivered incorrectly?	No					
inst day of treatment:						
low many fractions were delivered incorrectly?						
atal number of fractions prescribed:						
rescribed dose per fraction (Gy):						
relevant, please estimate the dose deviation from the prescribed dose per fraction:						
linical incident severity:	No information provided					
The incident-cause is related to equipment (hardware or software), please specify the make, mode nd varsion number:	N					
lescribe the incident in detail:	When checking MLC of Left Su before the patient starts treatme	praciav in treatment room, the field ligh ent where there is Pb, MLC or offsets."	t did not correspond to the field borders on the simulation film. It was The field size was adjusted accordingly and the offsets were noted	is noticed that there was a 0.6cm offset to Rt whic on the treatment sheet. (ROSIS 1045094427)	ch was written on film. This is a routine check done	
lescribe the causes of the incident						
ld the incident reach the patient?	Yes					
What safety barrier failed to identify the incident?						
that safety barrier identified the incident?						
that safety barrier might have identified the incident?						
rescribe contributing factors to the incident:	Offsets not noticed when prepa	ring treatment. Offsets not written elser	where (e.g. sim sheet)			
uggest preventive action(s):	Information must be entered int planning/acceptance for treatm	io all relevant places - e.g. on film, on s ent.	in sheet, on treatment sheet. If unusual, it could be highlighted. All	treatment-related papers and films to be checked	d for all treatment information prior to	
nisk assessment complete?	Yes					
tisk assessment urt	http://sevma.foroiberam.org/ries	igolassess php?id+202 🔒				
		ls risk asse	essment complete?	Yes		
		Risk asses	sment url:	http://sevrra	a.foroiberam.org	l

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.

	SEVERA Fore bersamerikans de Organisme Regulatores Hudelsdores y husikanse Sistema de Evolusio fin del Rieson en Rotfinderania (SE//RRA)	
First time in SAFRON-SEVRRA?	DISCLAIMER	
	The aim of the SAFRON-SEVRRA application is to improve patient safety in radiotherapy by the synergy of the learned lessons from reported events (reactive approach) with potential risk scenarios (proactive approach).	
Frequent user of SAFRON-SEVRRA	This is carry out by matching, whenever feasible, an incident report of SAFRON (SAFety in Radiation ONcology) to the correspondent initiating events (IE) included in SEVRRA.	
Trequent user of SALIKON-SEVRKA	Regarding the matching process between IR SAFFRON - IE SEVRRA, it is important to highlight that:	
	 the matching considers the stage process step in which the incident was originated, the IE is assigned as a result of favoring the most conservative risk scenario/sequence, 	
	 Some of the IRs may not have none available match to the IEs due to: lack of information on some of the SAFRON IR; the IR is out of the scope defined in the SEVRRA risk model, i.e. related with equipment or step processes used in old technologies, etc. 	
	Statema de Evaluación del Riesgo en Radiolerapia (SEVRRA)	
You can then select th consequences reducer	e situation in your clinic by identifying the frequency reducers, safety l s.	oarrie



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Rick Assessment							
KISK ASSESSMENT							
Initiating Event							
Code:	AL-PAC7.10 Bis						
Name:	Error in the geometric preparation of the treatment plan						
Treatment Modality:	Linear Accelerator						
Phase in the process:	Treatment Planning						
Process sub-phase:	None						
Default Risk FM PH CH = RH Choose the barriers and reducers that are being used in your facility: Encurrence reducers Conservations							
FM FH CH = RM Choose the barriers and reducers that are being used in your facility: Frequency reducers	Safety Barriers	Consequence r					
FM PH CH = RM Choose the barriers and reducers that are being used in your facility: Frequency reducers Moderate workload	Safety Barriers	Consequence r					
FM FH CH = RH Choose the barriers and reducers that are being used in your facility: Frequency reducers Image: Second secon	Safety Barriers Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist Postal image taken during the initial revenue seasion for evaluation by the radiation oncologist and the medical physicist, whereby geometric treatment errors can be	Consequence r At the daily patient setup, the radiotherapy te errors by visual signs, such as sin redden Weekly medical evaluation of the patient car previous stages					
FM PH CH = RM Choose the barriers and reducers that are being used in your facility: Frequency reducers Image: Program of the dosimetrist and the medical physicist	Safety Barriers Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist Portal image taken during the initial treatment session for evaluation by the radiation oncologist and the medical physicist, whereby geometric treatment errors can be detected Treatment simulation, either virtual or real, which allows for detection of geometric and patient positioning errors	Consequence r At the daily patient setup, the indicatory is errors by visual signs, such as solv readwrin Weakly medical evaluation of the patient car previous stages Weekly portal image, with which geometric e					

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.



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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 (hard- ware 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 inci- dent?	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 Com- missioning 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 indi- cated 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.		



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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 admin- istered. This error unfortunately resulted in major differences in planned vs. de- livered 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 Tan- dem (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
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.



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SAFRON Updates



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 <u>Dosimetry of Small Static</u> <u>Fields Used in External Beam Radiotherapy: An</u> <u>International Code of Practice for Reference and</u> <u>Relative Dose Determination</u> 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 <u>English</u> and in <u>French</u>



Public Health England Safer Radiotherapy





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