

SAFRON – SEVRRRA (RISK MATRIX) INTEGRATION

ERPAN meeting - Paris

June 16th - 2016

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1 SAFRON

RADIOLOGICAL INCIDENTS REVIEW PANEL

i. SAFRON

<https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm>

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Radiation Protection of Patients (RPOP)

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SAFRON

**IAEA****SAFRON**Safety Reporting and Learning System
for Radiotherapy[What is SAFRON](#)[User Instructions](#)[SAFRON Newsletters](#)[Related Articles & Links](#)

What is SAFRON

SAFRON, Safety in Radiation Oncology is an integrated voluntary reporting and learning system of radiotherapy incidents and near misses. The main goal of SAFRON is to improve the safe planning and delivery of radiotherapy by sharing safety-related events and safety analysis around the world.

Information submitted is dependent on facilities registering and sharing incidents that occur in their institutions. Having started in December 2012, SAFRON has over 50 registered radiotherapy facilities and hospitals all over the world. The system has over 1300 radiotherapy incident reports covering various types of incidents including errors and near misses.

To access SAFRON, users need to be registered with [NUCLEUS](#). To contribute to SAFRON reporting, users need to register with both NUCLEUS and SAFRON. A self-study instructional video is available in the section entitled "User Instructions" below.

Access to SAFRON is here: <http://rpop.iaea.org/SAFRON>

SAFRON aims to:

**SAFRON
FAQs****SAFRON
Registration
instructions****SAFRON
Self-Study
Training****Related Links**



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Access to SAFRON is here: <http://rpop.iaea.org/SAFRON>

SAFRON aims to:

- Promote patients safety in radiotherapy facilities by learning about reported events in an effort to reduce the likelihood of the events being repeated.
- Assist radiotherapy facilities in promoting safety culture and improving patient safety through analysis of near misses and incidents.
- Establish a database of radiotherapy safety related resources.
- Provide users with the ability to analyze and benchmark safety improvement efforts.

Features of SAFRON include:

- A simple way to submit information on near misses and errors that occur in a radiotherapy facility
- Open source capabilities for reviewing incident reports
- Learning about near misses and events in an effort to educate and improve radiotherapy safety
- Central location of related documents and links of safety related peer reviewed articles and reports
- Ability to perform statistical analysis on reported events for both the contributors and the viewers. For the contributors the ability to perform extensive analysis of their facilities reports, benchmarking capabilities to compare own incident reports against all submitted incident reports



User Instructions

[Self-Study Training](#)

This instructional video explains how to use SAFRON as a viewer/contributor and guides you through specific

Related Links

- Training material:

[Radiotherapy](#)

[Accidental Exposure](#)

- Information for:

[Health Professionals](#)

[Patients and Public](#)

1 SAFRON

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i. SAFRON

<http://rpop.iaea.org/SAFRON>



Implementing Bonn Call for Action No. 7

“Improve prevention of medical radiation incidents and accidents” via learning from the return of experience of safety related events in medical uses of radiation, and implementing effective risk analysis methods

[New User?](#)

[Request Registration](#)

Actions

[Browse Safety Info by Process Step](#)

[Search Reports](#)

[Search Documents & Links](#)

[See Statistical Reports](#)

[View Instructions](#)

[Download Reports](#)

Featured Incident Reports

[Vertebral body adjacent to the target vertebral body received therapy administration.](#)

Auto fusion software was “zoomed in” to the incorrect vertebral body, as set up by therapist. The error was found upon review by physicist on May 20th and the 2nd and 3rd treatments were reviewed...

Wrong vertebrae treated

The patient had been treated previously to T6-T8, and we wanted to treat T10-T12. The plan was to set up to the old tattoo and shift 6.5 cm inferiorly. The shift did not happen and the field wound...

Featured Documents & Links

[Impact of setup error and anatomical change on dose distribution during conventional radiation therapy](#)

Publication on treatment setup and the need to reimage or replan when patients have marked anatomical changes.

[Quantitative cone-beam CT imaging in radiation therapy using planning CT as a prior: first patient](#)

This study looked at the difficulties of using CBCT for patient positioning because of poor imaging and scatter contamination. By using a correction method using the planning CT the capabilities of...



Search for Incident Reports

You can search own/all incident reports by process step, who and how the incident was discovered, specific words in the free text fields, or combination of these parameters.

Please choose your preferred dataset in the top right corner of this screen. Based on this selection, you can browse your own or all incident reports.

What phase in the process is the incident associated with?

 SELECT

Who discovered the incident?

How was the incident discovered?

Any word in the free text fields:

Clinical incident severity:

 HELP TEXT

Did the incident reach the patient?

☐ Yes ☐ No

Was any part of the prescribed treatment delivered incorrectly?

Was anyone affected by the incident?

Describe the causes of the incident (Select one or several)

Search for Incident Reports

You can search own/all incident reports by process step, who and how the incident was discovered, and the combination of these parameters.

Please choose your preferred dataset in the top right corner of the page.

What phase in the process is the incident associated with?

Who discovered the incident?

How was the incident discovered?

Any word in the free text fields:

Clinical incident severity:

Did the incident reach the patient?

Was any part of the prescribed treatment delivered incorrectly?

Was anyone affected by the incident?

Select a Process Step

- 1. Non-clinical phase
 - 1.1. Equipment and software specific activities
 - 1.1.1. New equipment
 - 1.1.1.1. Installation
 - 1.1.1.2. Acceptance tests
 - 1.1.1.3. Customization and configuration of equipment
 - 1.1.1.4. Commissioning
 - 1.1.1.5. Data recording
 - 1.1.1.6. Preparation of data files for planning computers
 - 1.1.1.7. Other
 - 1.1.2. Routine machine QA
 - 1.1.2.1. Daily consistency checks
 - 1.1.2.2. Planned QA programme checks
 - 1.1.2.3. Regular preventive maintenance and repair programme
 - 1.1.2.4. Handover of radiotherapy equipment
 - 1.1.2.5. Routine radiation safety checks
 - 1.1.2.6. Other

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for Radiotherapy

Select Dataset: All incident reports ▼

[Home](#)[Process Steps](#)[Incident Reports](#)[Documents and Links](#)[Statistical Reports](#)[Help](#)

Browse Process Steps

You can view all the process steps for a selected treatment modality.

Please choose your preferred dataset in the top right corner of this screen. Based on this selection, you can browse your own or all incident reports.

All process step for:

External beam radiotherapy ▼



2.5.2.1. Positioning of patient

2.5.3. Localization of intended volume

2.5.4. Production of images

2.5.5. Labelling of images

2.5.6. Saving and recording of data

2.5.7. Other

☐ 2.6. Treatment planning

2.6.1. Verification of patient ID

2.6.2. Importing of data from external data sources

2.6.3. Choice of technique

2.6.4. Target and organ at risk delineation

2.6.5. Generation of plan for approval

2.6.6. Authorization of plan

2.6.7. Recording of definitive treatment prescription

2.6.8. Calculation for non-planned treatments

2.6.9. Other

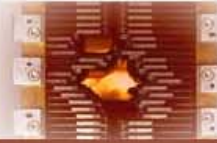
☐ 2.7. Treatment information transfer



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Select Dataset: All incident reports ▼

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View Safety Information for 2.6.1. Verification of patient ID

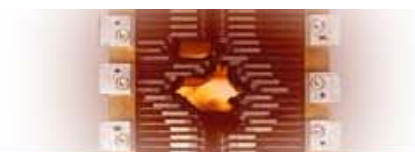
You can view own/all incident reports and other safety information related to a specific process step.

Incident Reports

Incident Headline	Actions
Incorrect identification of patient	 VIEW
Mix up of patients	 VIEW

Related Document and Links

No Document & Link record found.



New Incident Report

You can view incident report details below.

Mix up of patients

Treatment modality:	External beam radiotherapy
Equipment used:	
Date of discovery:	2008-09-25
Who discovered the incident?	No information provided
How was the incident discovered?	Chart check
What phase in the process is the incident associated with?	2.6.1. Verification of patient ID
Where in the process was incident discovered?	1. Non-clinical phase
Was anyone affected by the incident?	No, but someone could have been; potential incident
Was any part of the prescribed treatment delivered correctly?	No information provided
First day of treatment:	
How many fractions were delivered incorrectly?	
Estimated number of fractions correctly delivered:	

al number of fractions prescribed:

scribed dose per fraction (Gy):

relevant, please estimate the dose deviation from the
scribed dose per fraction:

ical incident severity:

No information provided

he incident-cause is related to equipment (hardware or
tware), please specify the make, model and version
umber:

scribe the incident in detail:

At the preparation of the new patient at the machine, we couldn't import the patient in Visir. Physicist sends the plan again. We import, but fraction dose and number of fractions are not filled in, monitor units were wrong and no dose calculation performed. We find out that the physicist who, the day before, were responsible for dose calculation had used another patient's plan and protocol. The chart had also been filled in wrong. This physicist was not available, but then we contact today, sends the plan for the correct patient, however no dose calculation was performed. But he had produced 2 protocols, none for our patient. We find out that there were 2 patients at the CT that day with the same diagnosis, and their treatment charts were mixed up. It caused delays, less time to prepare and check. (ROSIS 1224631117)

scribe the causes of the incident:

l the incident reach the patient?

at safety barrier failed to identify the incident?

at safety barrier identified the incident?

at safety barrier might have identified the incident?

scribe contributing factors to the incident:

uggest preventive action(s):

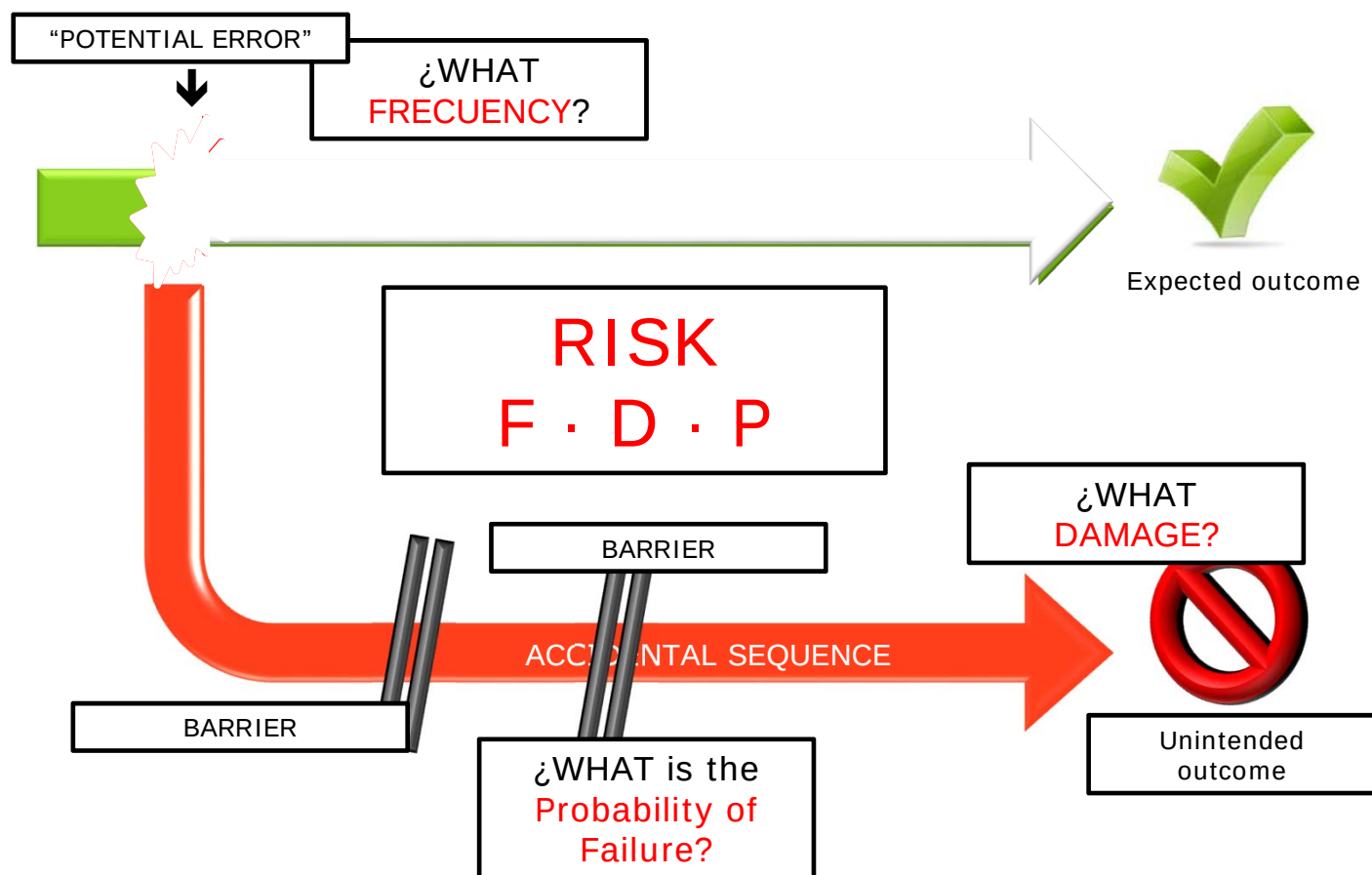
risk assessment complete?

No

2 Risk Matrix - SEVRRRA

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Risk Matrix Methodology

Initiating event were identified and its potential harm were analyzed also the safety barriers existing in the radiotherapy department to avoid it were recorded. The frequency of occurrence of the initiating events were computed according with the following criteria.

Annual frequency (for 500 patients/year)	Frequency level	Acronym	Qualitative
More than 50/year	High	FH	The event occurs frequently
Between 1 and 50 /year	Medium	FM	The event occurs occasionally
Between 1/year and 1 every 100/years	Low	FL	It is unusual or rare, although it is assumed that it has occurred
Less than 1every 100/years	Very low	FVL	It is very unusual, and it is not known to have occurred but there is a remote possibility

Risk Matrix Methodology

Safety measures or barriers in place to avoid, prevent, detect and stop an accidental exposure or to mitigate its consequences were identified. Safety measures may be of a technological (such as interlocks) or organizational nature (such as procedures or double checks to avoid or detect an error.) Their probability of failure were determined, in a first step, according with the following criteria.

Probability level	Acronym	Number of barriers
High	PH	There is no barrier at all
Medium	PM	There are one or two barriers
Low	PL	Three barriers
Very Low	PVL	Four or more barriers

Risk Matrix Methodology

The scale of consequences should take account of the severity and the number of patients affected. It ranges from the death of the irradiated patient to a simple loss of defense in depth with no health effect. The table shows the scale for the consequences used for patients, adapted from the definitions in ICRP 86 (ICRP 2002).

Severity level	Acronym	Description
Very high, catastrophic.	CVH	Causing multiple deaths or limiting damage to multiple patients (roughly more than 25% under or overdosage can cause this effect).
High	CH	Causing single death or limiting damage to multiple patients. Also deviation of 10 and 25% to multiple patients are included in this level
Medium or moderate	CM	No risk to patient life, only recoverable deviation affecting one or a few sessions
Low	CL	Reduction of defense in depth with no dose deviation.

2 Risk Matrix - SEVRA

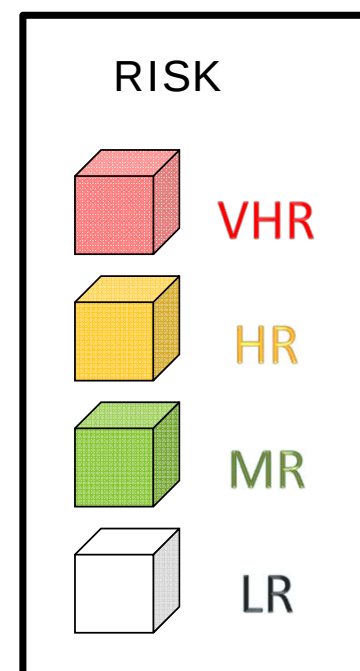
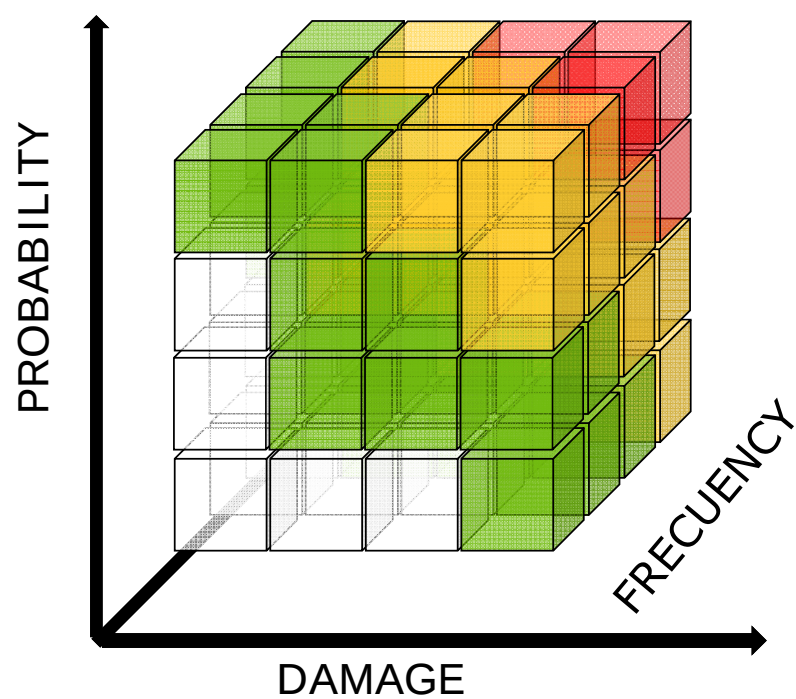
PH	CVH	CH	CM	CL
FH	RVH	RVH	RH	RM
FM	RVH	RH	RH	RM
FL	RH	RH	RM	RM
FVL	RH	RH	RM	RM

PM	CVH	CH	CM	CL
FH	RVH	RH	RH	RM
FM	RH	RH	RM	RM
FL	RH	RH	RM	RL
FVL	RH	RM	RM	RL

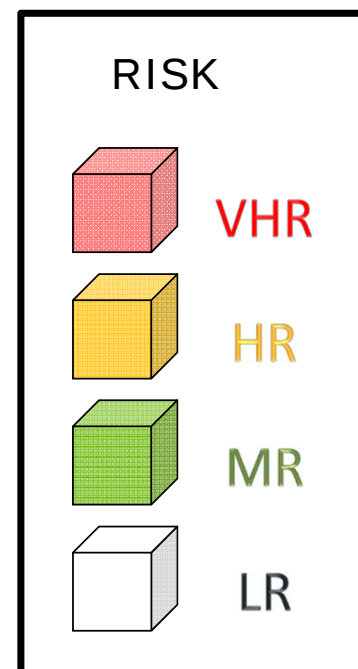
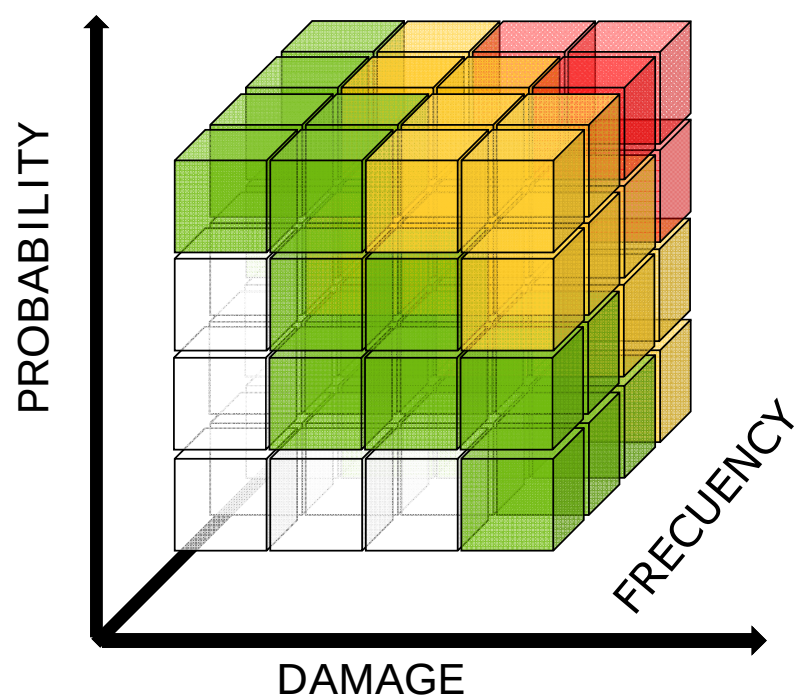
PL	CVH	CH	CM	CL
FH	RH	RH	RM	RL
FM	RH	RH	RM	RL
FL	RM	RM	RM	RL
FVL	RM	RM	RM	RL

PVL	CVH	CH	CM	CL
FH	RH	RM	RM	RL
FM	RM	RM	RM	RL
FL	RM	RL	RL	RL
FVL	RM	RL	RL	RL

2 Risk Matrix - SEVRA



2 Risk Matrix - SEVRA



3 Integration

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3 Integration

MAIN OBJECTIVE

To improve safety through a connection between incidents report (SAFRON) and risk assessment tool (SEVRRRA)

SAFRON users have access to:

- Assess the safety robustness of their radiotherapy practice, analyzing the risk level achieved with the safety barriers/reducers already implemented
- Identify safety elements that produce an important risk reduction

3 Integration

1206 SAFRON events report were analyzed

Nearly 86% of SAFRON events report match with one or more
SEVRRRA initiating events

62 SAFRON reports do not have correspondence with SEVRRRA IE's:

- Errors associated with Clinical issues (i.e. prescription errors)
- New technologies (i.e. IMRT) out of the current scope

4 Demo

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4 Demo

RADIOLOGICAL INCIDENTS REVIEW PANEL

<https://rpop.iaea.org/SAFRON/IncidentReport/IncidentReportView.aspx?id=620>

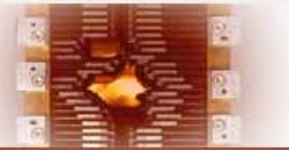
iv. Demo



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Select Dataset: All incident reports ▼

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View Incident Report

You can view incident report details below.

Bolus missed at simulation

Treatment modality:	External beam radiotherapy
Equipment used:	
Date of discovery:	2007-02-12
Who discovered the incident?	Radiation therapist/staff at treatment unit treating patients
How was the incident discovered?	Found at the time of first patient treatment during regular checks
What phase in the process is the incident associated with?	3.1.3.4. Use of compensators
Where in the process was incident discovered?	3. Treatment phase
Was anyone affected by the incident?	Yes, one patient
Was any part of the prescribed treatment delivered incorrectly?	No
First day of treatment:	

First day of treatment:

How many fractions were delivered incorrectly? 0

Total number of fractions prescribed:

Prescribed dose per fraction (Gy):

If relevant, please estimate the dose deviation from the prescribed dose per fraction:

Clinical incident severity: No information provided

If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:

Describe the incident in detail: In the treatment chart it said that a bolus should be used, but it was not specified. It was missed at the simulator. The patient spent an extra hour at the treatment table, since it was difficult to find anyone with knowledge of the bolus. (ROSIS 1171930472)

Describe the causes of the incident:

Did the incident reach the patient?

What safety barrier failed to identify the incident?

What safety barrier identified the incident?

What safety barrier might have identified the incident?

Describe contributing factors to the incident:

Suggest preventive action(s):

Is risk assessment complete? No

4 Demo

RADIOLOGICAL INCIDENTS REVIEW PANEL

<https://rpop.iaea.org/SAFRON/IncidentReport/IncidentReportView.aspx?id=620>

iv. Demo

4 Demo

RADIOLOGICAL INCIDENTS REVIEW PANEL

<http://sevrra.foroiberam.org/riesgo/assess.php?id=620>

iv. Demo

4 Demo

RADIOLOGICAL INCIDENTS REVIEW PANEL

<http://sevrra.foroiberam.org/riesgo/assess.php?irid=620>

iv. Demo

Initiator Event

AL-PAC6.1

Patient identification error during preparation of treatment plan. Treatment plan for a patient prepared with data from another patient.

Modality: Linear Accelerator

e process: Volume delineation

b-phase: None

Default Risk

PH

CH

=

RH

st below, choose those barriers and reducers that are implemented in your facility:

Frequency reducers	Barriers	Consequence reducers
☐ Maintaining the working conditions of the radiotherapy technologist such that concentration and avoidance of distraction is fostered	☐ Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist	☐ At the daily patient setup, the radiotherapy technologists can detect geometric errors by visual signs, such as skin reddening, etc.
☐ Moderate workload	☐ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☐ Weekly medical evaluation of the patient can detect errors in treatment delivery from previous stages
☐ Safety procedure for patient's verification and traceability of history purposes	☐ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☐ Weekly portal image, with which geometric errors can be detected
	☐ 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	
	☐ Review of the delineated volumes and organs at risk by the radiation oncologist	
	☐ TPS Patient identification system with unique identification (ID) number	
	☐ TPS patient identification system, which provides a unique identification (ID) number for each patient	
	☐ Verification of the PTV location by checking that the actual SSD and the table top to isocenter distance coincide with the values indicated in the treatment plan	

Risk level

 Get the report of its current assessment 

 Would you like to analyze your entire radiotherapy service? 

Initiator Event

	AL-PAC6.1
	Patient identification error during preparation of treatment plan. Treatment plan for a patient prepared with data from another patient.
Modality:	Linear Accelerator
Preprocess:	Volume delineation
Post-phase:	None

Risk with barriers and reducers

PH	CM	=	RM
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Below, choose those barriers and reducers that are implemented in your facility:

Frequency reducers	Barriers	Consequence reducers
Maintaining the working conditions of the radiotherapy technologist such that concentration and avoidance of distraction is fostered	☐ Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist	☒ At the daily patient setup, the radiotherapy technologists can detect geometric errors by visual signs, such as skin reddening, etc.
Moderate workload	☐ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☒ Weekly medical evaluation of the patient can detect errors in treatment delivery in previous stages
Safety procedure for patient's verification and traceability of history purposes	☐ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☒ Weekly portal image, with which geometric errors can be detected
	☐ 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	
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	☐ TPS Patient identification system with unique identification (ID) number	
	☐ TPS patient identification system, which provides a unique identification (ID) number for each patient	
	☐ Verification of the PTV location by checking that the actual SSD and the table top to isocenter distance coincide with the values indicated in the treatment plan	

Risk level

Get the report of its current assessment Would you like to analyze your entire radiotherapy service? 

Initiator Event

	AL-PAC6.1
	Patient identification error during preparation of treatment plan. Treatment plan for a patient prepared with data from another patient.
Modality:	Linear Accelerator
Process:	Volume delineation
Phase:	None

Risk with barriers and reducers

PVL	CM	=	RL
-----	----	---	-----------

Below, choose those barriers and reducers that are implemented in your facility:

Frequency reducers	Barriers	Consequence reducers
Maintaining the working conditions of the radiotherapy technologist such that concentration and avoidance of distraction is fostered	☒ Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist	☒ At the daily patient setup, the radiotherapy technologists can detect geometric errors by visual signs, such as skin reddening, etc.
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Safety procedure for patient's verification and traceability of history purposes	☒ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☒ Weekly portal image, with which geometric errors can be detected
	☒ 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	
	☒ Review of the delineated volumes and organs at risk by the radiation oncologist	
	☒ TPS Patient identification system with unique identification (ID) number	
	☒ TPS patient identification system, which provides a unique identification (ID) number for each patient	
	☒ Verification of the PTV location by checking that the actual SSD and the table top to isocenter distance coincide with the values indicated in the treatment plan	

Risk level

Get the report of its current assessment Would you like to analyze your entire radiotherapy service? 



Risk Assessment

Initiator Event	
	AL-PAC6.1
	Patient identification error during preparation of treatment plan. Treatment plan for a patient prepared with data from another patient.
Modality:	Linear Accelerator
Process:	Volume delineation
Phase:	None

Risk with barriers and reducers

PL	CM	=	RM
----	----	---	-----------

Below, choose those barriers and reducers that are implemented in your facility:

Frequency reducers	Barriers	Consequence reducers
Maintaining the working conditions of the radiotherapy technologist such that concentration and avoidance of distraction is fostered	☒ Joint dosimetric plan evaluation by the radiation oncologist and the medical physicist	☒ At the daily patient setup, the radiotherapy technologists can detect geometric errors by visual signs, such as skin reddening, etc.
Manage workload	☐ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☒ Weekly medical evaluation of the patient can detect errors in treatment delivery in previous stages
Safety procedure for patient's verification and traceability of history purposes	☒ Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	☒ Weekly portal image, with which geometric errors can be detected
	☐ 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	
	☐ Review of the delineated volumes and organs at risk by the radiation oncologist	
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	☐ TPS patient identification system, which provides a unique identification (ID) number for each patient	
	☐ Verification of the PTV location by checking that the actual SSD and the table top to isocenter distance coincide with the values indicated in the treatment plan	

Risk level

Get the report of its current assessment Would you like to analyze your entire radiotherapy service? 