



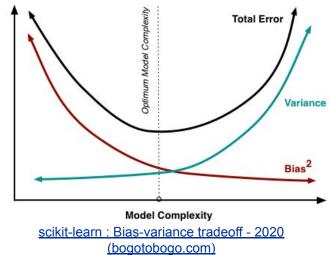
Summary of events reported in IAEA database SAFRON

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1. Importance of radiation protection in Radiotherapy (1/3)

Radiotherapy is a highly complex, multi – step process that requires the input of many V different staff groups in the planning and delivery of the treatment





Error



Physical and Radiobiological Evaluation of Radiotherapy Treatment Plan | IntechOpen

1. Importance of radiation protection in Radiotherapy (2/3)

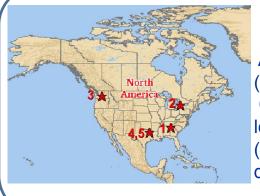
Though errors are rare, when they do occur the consequences can be significant for the



Incorrect repair of accelerator (Spain) 15 of 27 patients died as a consequence of overexposure



Wrong treatment planning (Panama) 8 of 28 patients died



Accelerator software problems (USA & Canada) 6 accidents, 4 patients died, 2 left with severe disability (2 – 100 times higher dose delivered in 1-3 sec)

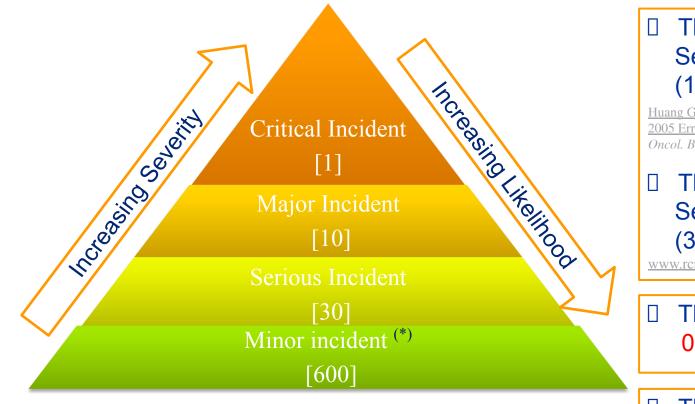






Accelerator interlock failure (Poland) 5 patients severely affected, 3-37 times higher doses

1. Importance of radiation protection in Radiotherapy (3/3)



Bird F E and Germain G L 1992 Practical Loss Control Leadership (Loganville, GA: International Loss Control Institute)

~90 % human factors associated!

The New York State experience: Serious incident rate: 0.012 % per course (12 in every 100 000 courses)

Huang G, Medlam G, Lee J, Billingsley S, Bissonnette J-P, Ringash J, Kane G and Hodgson D C 2005 Error in the delivery of radiation therapy: results of a quality assurance review *Int. J. Radiat. Oncol. Biol. Phys.* **61** 1590–5

The UK experience: Serious incident rate: 0.003 % per course (3 in every 100 000 courses)

www.rcr.ac.uk/system/files/publication/field publication/files/Towards saferRT final.pdf

The chance of death on a commercial flight:
 0.000005% <u>Safety Reports (icao.int)</u>

The risk for fatal consequences in radiotherapy is
 ~1000 times higher then in a commercial flight.

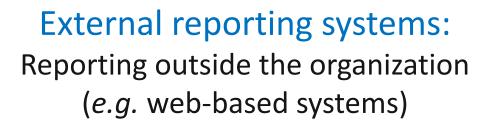
SAFETY IS AN ISSUE IN RADIATION THERAPY!

^(*) Different categorization of the type of incidents

2. Incident reporting systems

(1/2)

Internal reporting systems Reporting inside the organization (*e.g.* local incident reports)





2. Incident reporting systems

(2/2)

Mandatory reporting

Reporting of certain events is required *e.g.* reporting to regulatory authorities of events above certain magnitude (significant events)



Voluntary reporting

Reporting is encouraged (*e.g.* reporting to a professional body)



3. Unintended and accidental exposure of patients



4. IAEA Safety Reporting and Learning System for Radiotherapy (SAFRON)

English -Gershan, Vesna NUCLEUS IAEA.org IAEA SAFRON Safety Reporting and Learning System for Radiotherapy Reports - Documents & Links Process Steps Admin - Help My Clinic Registration Home . . Submit Incident Report SAFRON **Quick Actions Documents & Links** You can search all documents and links b process step. 0 Search Treatment modality Document Welcome to new version of & Links External beam radiotherapy Process Step Ϋ́Ξ Click on select loon to select a Proc 🛛 🛍 View Instructions Browse Incidents by Treatment modality Any word in document/link title Process Step SAFRON system! External beam radiotherap Enter Title text here Equipment used adiation Protection of Patients Did the incident reach the patient Yes No In new mobile mode, you can search for incidents, submit incidents, view First day of treatment Type : Documents & Links Yes No statistical reports, search documents and links, browse incidents by Title : Radiation Safety Culture Trait Treatment method Talks Handbook process step and view instructions. Process Step : 1. Non-clinical phas Date of discovery Addified : 2022-05-27 10:48 iation Protection of Patients (BPD)

 $\bullet \bullet \bullet \bullet \bullet$

http://rpop.iaea.org/SAFRON

4. IAEA Safety Reporting and Learning System for Radiotherapy (SAFRON)

- Safety in Radiation Oncology (SAFRON) is an integrated voluntary reporting and learning system for radiotherapy (external beam radiotherapy and brachytherapy) and radionuclide therapy incidents and near-misses.
- The main goal of SAFRON is to improve the safe planning and delivery of radiotherapy and radionuclide therapy by sharing safety-related events and safety analysis around the world.
- To establish a database of safety related resources;
 To provide users with the ability to analyse and benchmark safety improvement efforts.





Register your hospital

Total of 1831 reported incidents (status 3 July 2024)

4. IAEA Safety Reporting and Learning System for Radiotherapy (SAFRON)



Purpose:

To examine whether any discernible **patterns exist in the causes of reported incidents and safety barriers** within the SAFRON system concerning external beam radiotherapy.

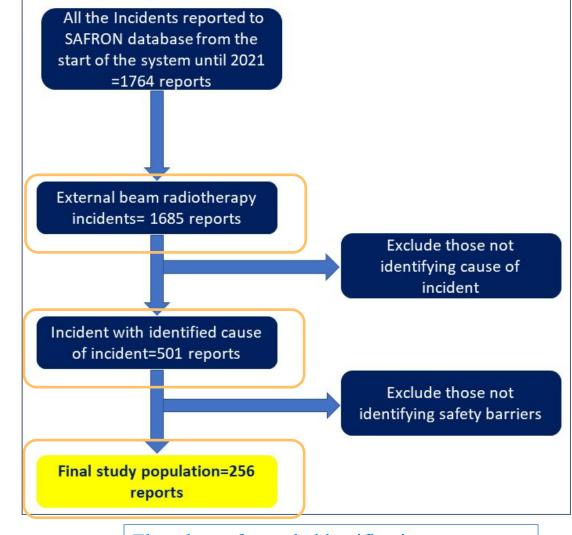


Methods and materials:

This study focuses on external beam radiotherapy incidents, reviewing **1685 reports** since the inception of SAFRON until December 2021.

Simple 2D RT - 97 reports, 3D Conformal RT - 39 reports, Modulated arc therapy - 12 reports, IMRT - 11 reports, Stereotactic radiosurgery - 4 reports Radiotherapy with protons or other particles - 1 report,

No information on treatment method had been provided in 92 reports.



Flowchart of sample identification

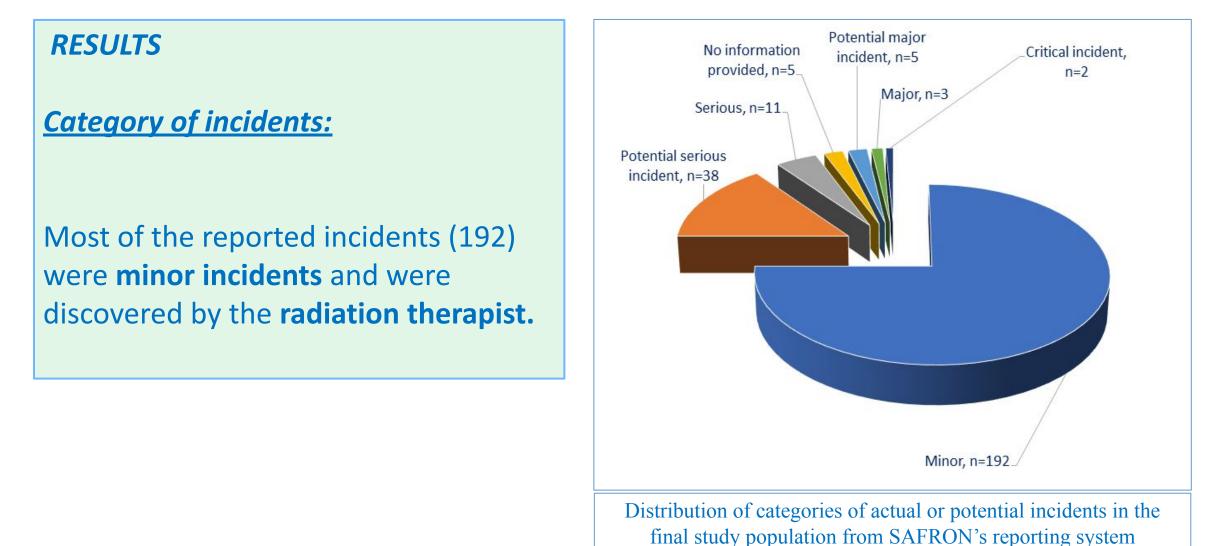
Methods and materials:

Severity metrics in SAFRON system;

Safety barriers are determined by the reporters.

The SAFRON system allows for the reporting of incidents with multiple safety barriers



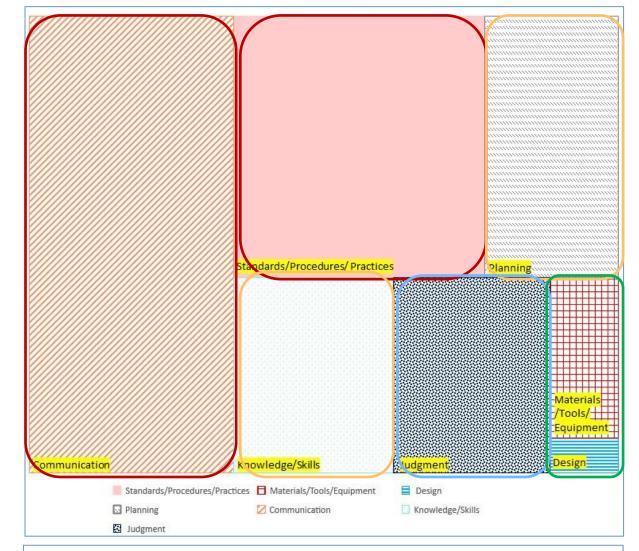


RESULTS

Cause of incidents:

- Communication
- Standards / Procedures / Practices
- Planning and Knowledge / Skills
- Judgement
- Material / Tools / Equipment
- Design



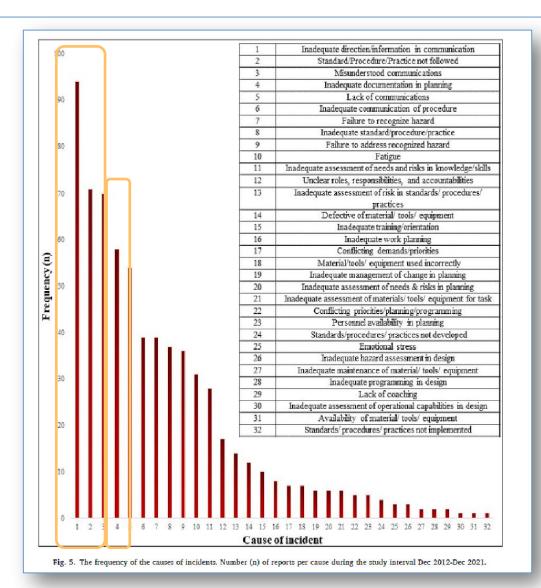


Tree-map chart on all categories of causes of incidents in the reports

RESULTS

Frequency of the Cause of incidents:

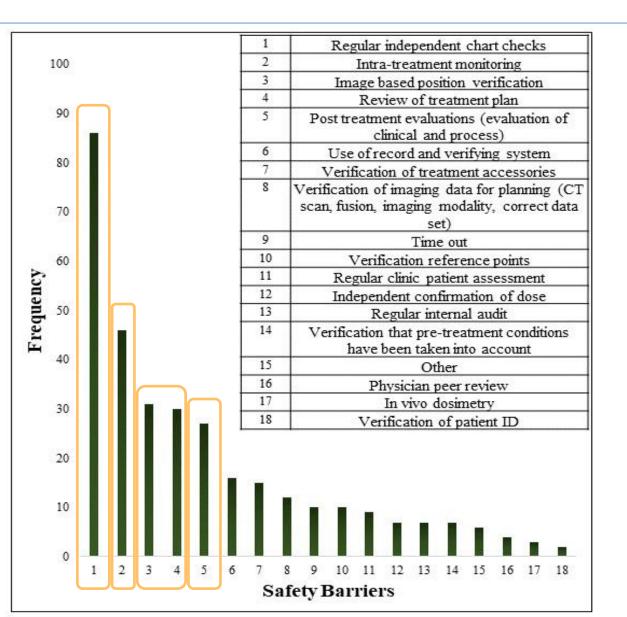
- Communication problems and failure to follow standards/ procedures/practices were the most frequent causes of incidents [1-3]
- Furthermore, inadequate documentation in planning was the most frequent cause of incidents [4]



RESULTS

Safety barriers failed:

- Regular independent chart checks [1]
- Intra treatment monitoring [2]
- Image based position verification and Review of treatment plan [3-4]
- Post treatment evaluation (evaluation of clinical and process) [5]



Findings:

- The importance of education and training radiation therapists in incident prevention and patient safety in radiotherapy should not be underestimated since they have discovered almost two-thirds of the reported incidents.
- Although the majority of the reported incidents were minor, **they could provide numerous learning opportunities and may aid in the prevention** of more serious events.
- Different types of **communication-based issues**, such as insufficient communication direction or information, misunderstood communications and a lack of communication were frequently the causes of incidents.
- Regular **independent chart checking was the most effective type of safety barrier** in the identification of the reported incidents, and they highlighted the significance of awareness required during the chart check.

6. SAFRON reports related to radiotherapy imaging

- None directly related to patient dose
- Dozens illustrating other types of errors or near-misses
- Most were <u>near-misses</u>, identified and corrected before incorrect treatment delivery occurred
- Several resulted in treatment errors

Example 1: Image mismatch (near miss)

from a different

IAEA SAFRON Safety Reporting and Learning System for Radiotherapy		Select Dataset: All incident reports V
Home Process Steps Incident Reports Documents and Links Statistical Reports Hell //iew Incident Report ou can view incident report details below.	p	
Incorrect DRRs transferred to patient database		Planning department transferred incorrect DRR's
Treatment modality:	External beam radiotherapy	to the metions detelors
Equipment used:		to the patient database.
Date of discovery:		
Who discovered the incident?	Radiation therapist/staff at tr	
low was the incident discovered?	Portal imaging	
Vhat phase in the process is the incident associated with?	2.7.2. Use of correct data	
Where in the process was incident discovered?	3. Treatment phase	When the first day images were taken on set, the
Vas anyone affected by the incident?	Yes, one patient	
Vas any part of the prescribed treatment delivered incorrectly?	No	radiographers noticed large discrepancies between the
irst day of treatment:		radiographers noticed large discrepancies between the
low many fractions were delivered incorrectly?		two sats of images
otal number of fractions prescribed:		two sets of images.
Prescribed dose per fraction (Gy):		
f relevant, please estimate the dose deviation from the prescribed dose per fraction:		
Clinical incident severity:	No information provided	
f the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:		Further investigation revealed that images from a differen
Describe the incident in detail:	Planning dept transferred inc plan (same patient) had beer	plan (same patient) had been sent.
Describe the causes of the incident:		pian (same parent) had been sent.
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?		<u>Near miss: The incident did not reach the patient</u>
Describe contributing factors to the incident:	Human error	
Suggest preventive action(s):	Better labelling of the images	

No

Is risk assessment complete?

Example 2: Wrong patient's CT images (near miss)

IAEA SAFRON Safety Reporting and Learning System for Radiotherapy Home Process Steps Incident Reports Documents and Links Statistical Reports Help View Incident Report You can view incident report details below. CT images of one patient have been read into another patient External beam radiothera Treatment modality Equipment used: Date of discovery Who discovered the incident? No information provided No information provided How was the incident discovered? 2.6.2. Importing of data fi What phase in the process is the incident associated with? 2. Pre-treatment phase Where in the process was incident discovered? Was anyone affected by the incident? Yes, one patient Was any part of the prescribed treatment delivered incorrectly? No First day of treatment 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 No information provided Clinical incident severity If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number Describe the incident in detail The treatment planning i contours and dose plann 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 Misattention, and the fact Suggest preventive action(s): Is risk assessment complete? No

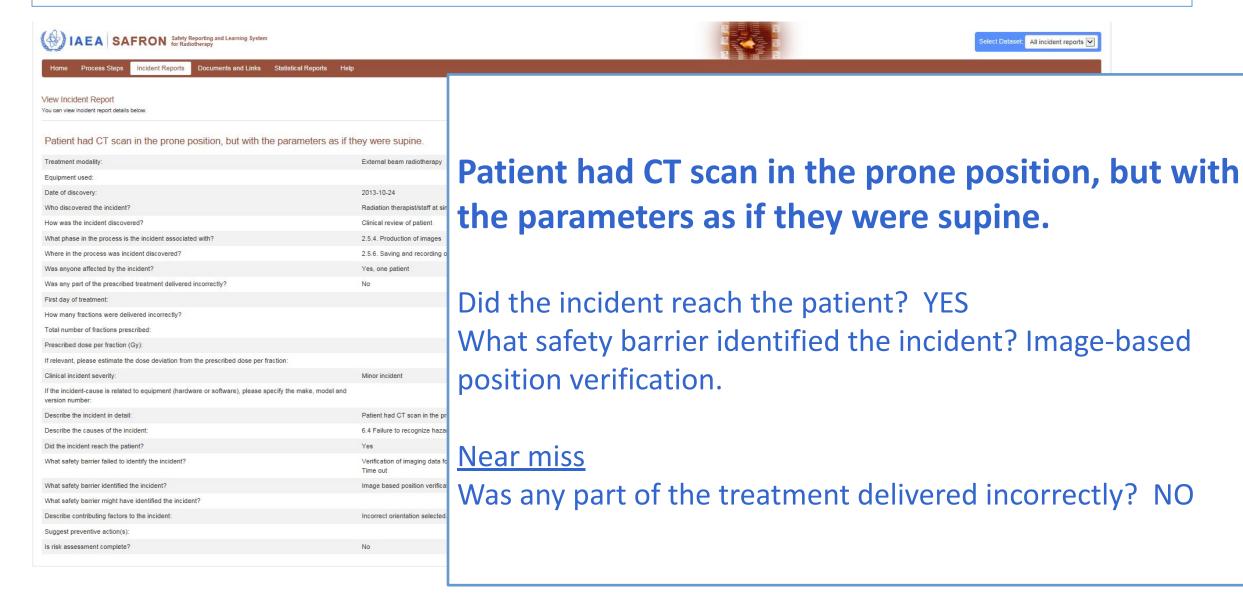
A set of CT images have been transferred from the CT unit and introduced in the records of another patient.

Select Dataset: All incident reports

The dosimetrist that came afterwards...detected the error.

<u>Near miss</u>, no part of the treatment was delivered incorrectly.

Example 3: Incorrect image parameters (near miss)



Example 4: wrong CT scan used (near miss)

IAEA SAFRON Safety Reporting and Learning System

risk assessment complete

Home Process Steps Incident Reports Documents and Links Statistical Reports Help

ou can view incident report details below.	
Wrong CT scan used	
Treatment modality:	External beam radiot
Equipment used:	
Date of discovery:	2011-11-26
Who discovered the incident?	Other, please specify
How was the incident discovered?	Chart check
What phase in the process is the incident associated with?	2.6.2. Importing of da
Where in the process was incident discovered?	2.6.5. Generation of p
Was anyone affected by the incident?	No, but someone cou
Was any part of the prescribed treatment delivered incorrectly?	No
First day of treatment:	
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:	
Clinical incident severity:	Potential serious inci
If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:	
Describe the incident in detail:	RO planned a patient
Describe the causes of the incident:	1.3 Standard/Proced
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:	Time pressures

Radiation oncologist planned a patient's treatment using a previous CT scan rather than the current valid scan.

All incident reports

Near miss: "no part of the treatment was delivered incorrectly."

Was anyone affected by the incident? "No, but someone could have been, potential incident."

Example 5: Wrong imaging protocol (minor incident)

IAEA SAFRON Safety Reporting and Learning System

Home Process Steps Incident Reports Documents and Links Statistical Reports Help

View	Incide	ent R	epor	t	
You can	view in	cident	report	details	belo

Bony match done for patient that was supposed to have soft tissue match imaging

Treatment modality:	External beam radiotherapy
Equipment used:	
Date of discovery:	2014-11-26
Who discovered the incident?	Radiation therapist/staff at treatm
How was the incident discovered?	Found at later stage during patie
What phase in the process is the incident associated with?	3.3.1. On-set imaging process
Where in the process was incident discovered?	3.3.3. Other
Was anyone affected by the incident?	Yes, one patient
Was any part of the prescribed treatment delivered incorrectly?	Yes
First day of treatment:	
How many fractions were delivered incorrectly?	1
Total number of fractions prescribed:	30
Prescribed dose per fraction (Gy):	2.00
If relevant, please estimate the dose deviation from the prescribed dose per fraction:	No information provided
Clinical incident severity:	Minor incident
If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:	
Describe the incident in detail:	Standard Chest imaging is predo Picked up in offline image review
Describe the causes of the incident:	8.1 Failure to address recognize
Did the incident reach the patient?	Yes
What safety barrier failed to identify the incident?	Image based position verification
What safety barrier identified the incident?	
What safety barrier might have identified the incident?	Time out In vivo dosimetry
Describe contributing factors to the incident:	patient was not receiving imagin
Suggest preventive action(s):	na
Is risk assessment complete?	No

The patient was to be **soft-tissue matched** as per imaging note.

All incident reports 🗸

Staff performed bony match in error for one treatment, resulting in 0.9 cm variation in the superior/inferior dimension.

Was any portion of the treatment delivered incorrectly? Yes

One fraction was delivered incorrectly Classified as "<u>minor incident</u>."

Example 6: CT simulation information transferred incorrectly

View Incident Report You can view incident report details below.	
	Pat
CT simulation information transferred incorrectly	1.40
Treatment modality:	CT
Equipment used:	
Treatment method:	
Date of discovery:	
Who discovered the incident?	Th
How was the incident discovered?	The
What phase in the process is the incident associated with?	
Where in the process was incident discovered?	but
Was anyone affected by the incident?	
Was any part of the prescribed treatment delivered incorrectly?	inf
First day of treatment:	
How many fractions were delivered incorrectly?	wa
Total number of fractions prescribed:	vva
Prescribed dose per fraction (Gy):	
If relevant, please estimate the dose deviation from the prescribed dose per fraction:	
Clinical incident severity:	Th
If the incident-cause is related to equipment (hardware or software), please specify the make, model version number:	The
Describe the incident in detail:	inv
Describe the causes of the incident:	10
Did the incident reach the patient?	TO
What safety barrier failed to identify the incident?	
What safety barrier identified the incident?	
What safety barrier might have identified the incident?	V CT
Describe contributing factors to the incident:	Aft
Suggest preventive action(s):	
Is risk assessment complete?	not

Patient treated for a tumour of the leg. CT used for the simulation and the dosimetry.

The simulation was done with the foot first instead of the head, but when the images were transferred to the TPS this information was not evident for the physicist and the position was inverted.

The patient was treated as for the CT so the lateral beams were inverted.

LO fractions were done in this condition.

After correction a dosimetry was done and the differences were not very important .

Example 7: Deviation of protocol for patient setup

Deviation of protocol for patient setup.

What safety barrier might have identified the incident? Describe contributing factors to the incident:

The patient was setup for radiation therapy treatment for right lung 25 Treatment modality Equipment used: fractions. Treatment method Date of discovery Who discovered the incident On the initial setup day the treatment isocenter was correctly localized and How was the incident discovered? What phase in the process is the incident associated with? verified with approved portal images prior to treatment. Where in the process was incident discovered? Was anyone affected by the incident' The patient was taken off the table before marking this position. Was any part of the prescribed treatment delivered incorrect First day of treatment The next day the patient was shifted in the opposite direction from the day How many fractions were delivered incorrectly? Total number of fractions prescribed: before and incorrectly marked without taking verification portal images Prescribed dose per fraction (Gy): If relevant please estimate the dose deviation from the prescribe **before treatment.** This process was not communicated to the physician or Clinical incident severity If the incident-cause is related to equipment (hardware or softwar version numbe physicist at the time. Describe the incident in detail After 6 treatments, 1 at the correct location and 5 incorrect, Describe the causes of the incident verification-portal image were acquired and the error was discovered. Did the incident reach the patient? What safety barrier failed to identify the incident? Fractions 2,3,4,5 and 6 were treated to the incorrect setup position. This was a What safety barrier identified the incident lapse in the facility patient treatment protocol.

Classified as minor incident

Example 8: Treatment was delivered to the wrong site

Treatment was delivered to the wrong site.

Treatment modality:
Equipment used:
Treatment method:
Date of discovery:
Who discovered the incident?
How was the incident discovered?
What phase in the process is the incident associated with?
Where in the process was incident discovered?
Was anyone affected by the incident?
Was any part of the prescribed treatment delivered incorrectly?
First day of treatment:
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:
Clinical incident severity:
If the incident-cause is related to equipment (hardware or software), please specify the make, mo version number:
Describe the incident in detail:
Describe the source of the insident

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)

A patient undergoing radiation therapy to the left breast received an unintended dose of approximately 0.22 Gy to an area 7.5 cm inferior to the intended treatment site.

Therapists observed by closed circuit video and audio intercom that the patient was unsure of treatment site and interrupted treatment upon its discovery.

The event was caused due to human error in the alignment of the newly acquired Cone Beam CT (CBCT) to the original planning CT. Incorrect alignment of treatment and reference images caused incorrect couch parameters to be applied for treatment.

Classified as minor incident

Example 9: CBCT misalignment lead to treatment inferior to intended treatment field (Minor incident)

The CBCT alignment was inadvertently shifted inferior approximately 8 cm by the covering physician while reviewing the images.

The shift was then applied and patient treated with AP/PA fields.

The therapist realized the misalignment when getting the patient off the table. The physician also noticed the error when reviewing images in Offline Review.

Minor incident

Example 10: Isocentre information for the CBCT was incorrect (Major incident)

Isocentre information for the CBCT was incorrect in Mosaiq by approximately 2.5cm in two directions.

Patient was treated for the entire course of treatment on the incorrect isocentre. Probable human error, the isocentre co-ordinates had been edited incorrectly and not appropriately checked prior to or during the treatment.

12 fractions were delivered incorrectly (4 Gy per fraction)

Contributing factor: The CBCT isocentre co-ordinates are editable, but are not standardly edited. The Xio system transposes two of the co-ordinates when they are sent to Mosaiq, but these seem to have been changed back to how they read in Xio. <u>Major incident</u>

Example 11: Treatment positioned 2-4 cm incorrect by CBCT imaging (Serious incident)

Patient is given abdominal palliative treatment, 25 fractions of 2 Gy.

VMAT and daily kV-CBCT is used due to one of the kidneys close to high dose area. At the 5th fraction, the patient has less pain than before, and seems to be rotated compared to planning CT.

Also, **the kidney is not sufficiently visible in the images**, and after discussion with a physicist, **it is decided to increase the CBCT from half arc (0-180°) to full arc (0-360°)** from the next fraction on.

At the next fraction, there is still a rotation, and when all the former CBCTs are reviewed, it was discovered that **there is an incorrect bone match in the longitudinal direction for 4 fractions.**

Serious incident

Example 12: Improper positioning of the patient for treatment (critical incident)

Improper positioning of the patient for treatment

······································
Treatment modality:
Equipment used:
Treatment method:
Date of discovery:
Who discovered the incident?
How was the incident discovered?
What phase in the process is the incident associated with?
Where in the process was incident discovered?
Was anyone affected by the incident?
Was any part of the prescribed treatment delivered incorrectly?
First day of treatment:
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:
Clinical incident severity:
If the incident-cause is related to equipment (hardware or software), please specify th version number:
Describe the incident in detail:
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?

A patient with metastatic lung disease received a bone scan in the prone position. A metastatic lesion was found in the left hip, for which the patient was to receive 27 Gy.

For radiation therapy, **the patient was positioned in the supine position.**

The orientation of the bone scan was misinterpreted and the patient was treated on the right hip rather than the left hip. The treatment continued for two weeks, until a resident oncologist discovered the error while reviewing the patient's chart. <u>Critical incident (>50% deviation from the prescribed dose)</u>

Example 13: CBCT performed on the incorrect reference point (Potential serious incident)

Patient setup and CBCT performed on the RR.

On review of the image, staff realised that they hadn't moved laterally to the ISO. Second CBCT required due to daily imaging requirement for IMRT patients.

Contributing factors to the incident: Tolerance tables are set for IMRT patients, but do not activate on imaging fields. Staff reminded to confirm Site Setup together before recording.

Classified as **Potential serious incident**

Example 14: Patient received 4 treatments to healthy tissue due to unnoticed shifting of the tumor

A patient treated for non-small cell lung cancer to the mediastinal area and a left lateral lung nodule adjacent to the chest wall. Since the two areas being treated were abutting, one treatment plan was developed.

A CT simulation was performed with the treatment plan following.

Between March 3 and March 15, the small lung nodule shifted downward due to the patient's plueral effusion spontaneously resolving which caused it to move out of the treatment volume area. On March 15 a verification simulation was performed. It was not noticed on the verification simulation that the nodule had shifted. On March 16, 17, 20, and 21, 2017 the patient received the first **<u>4 treatment fractions</u>**. CBCT images were taken each day prior to treatment as prescribed by the physician. The images were reviewed by the therapists and the physician with no one noticing that the nodule had shifted. Prior to the 5th treatment fraction the CBCT image was reviewed by a therapist who discovered that the lung nodule had shifted. The first four treatment fractions resulted in a small volume of healthy lung receiving treatment. Classified as minor incident



To conclude:



- The delivered dose to the treated volume in radiotherapy is very high;
- Any accident or incident can have a significant impact on the patient's outcome.
- Radiation protection infrastructure and practices should be implemented in line with the highest safety standards.
- SAFRON can be used as a resource for safety learning from incidents and near-misses in radiotherapy imaging
- A radiotherapy facility should perform a risk assessment, including consideration of a range of possible errors, before beginning an IGRT program



Thank you

