

Safety reporting and learning

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IAEA

International Atomic Energy Agency

Outline

1. Background
2. Learning from incidents as well as accidents
 - i. Why is it important?
 - ii. What can we learn?
3. Radiation safety reporting systems in medicine
 - i. Mandatory and voluntary reporting
 - ii. Internal and external reporting
4. Some terminology

Background

Accident:

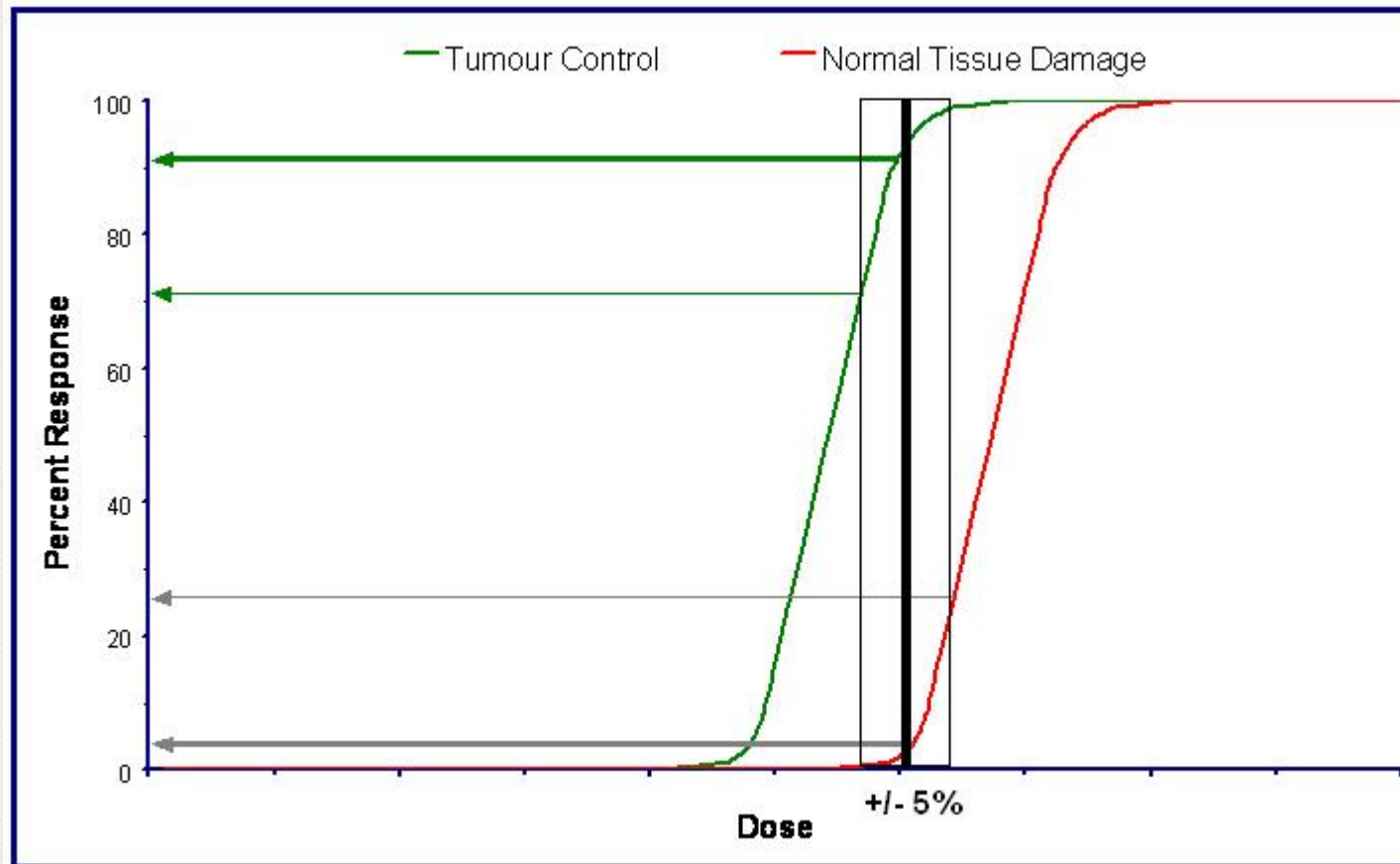
Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Incident:

Any unintended event, including operating errors, equipment failures, initiating events, **accident precursors**, **near misses** or other mishaps, or **unauthorized act, malicious or non-malicious**, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

(Source: IAEA Safety Glossary, 2007)

Learning from incidents



ICRU 62 - "... a dose difference as small as 5% may lead to real impairment or enhancement of tumour response, as well as to an alteration of the risk of morbidity."

Learning from incidents

Variable magnitude:

Many incidents (*e.g.* mistake in calculation of monitor units for a single patient) can have a **variable magnitude** (*e.g.* for Patient 1, the mistake causes a dose deviation of 5%, while for Patient 2, the same type of mistake causes a dose deviation of 50%).

Learning from incidents

More events:

Incidents are more numerous than accidents, so there are more opportunities to learn and improve the safety, than by only looking at major accidents



H.W. Heinrich (1931)

Learning from incidents

- Independent calculation checks monitored between 1998 and 2003 (27830 charts / treatment plans were checked)



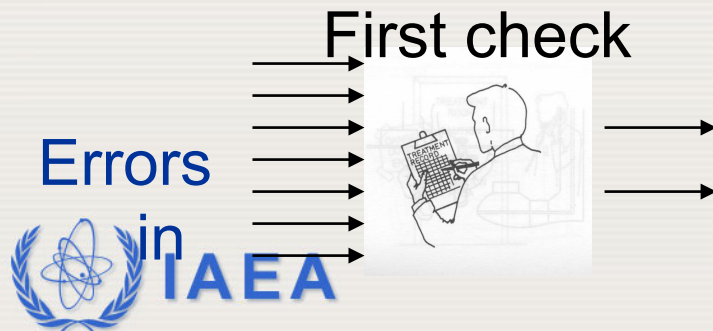
- In total, 4.3% of charts / treatment plans had mistakes found at some point: either prior to treatment or when treatment had started

Learning from incidents

- Independent calculation checks monitored between 1998 and 2003 (27830 charts / treatment plans were checked)



- The first check found mistakes in 3.5% of all charts / treatment plans – 0.8% remained

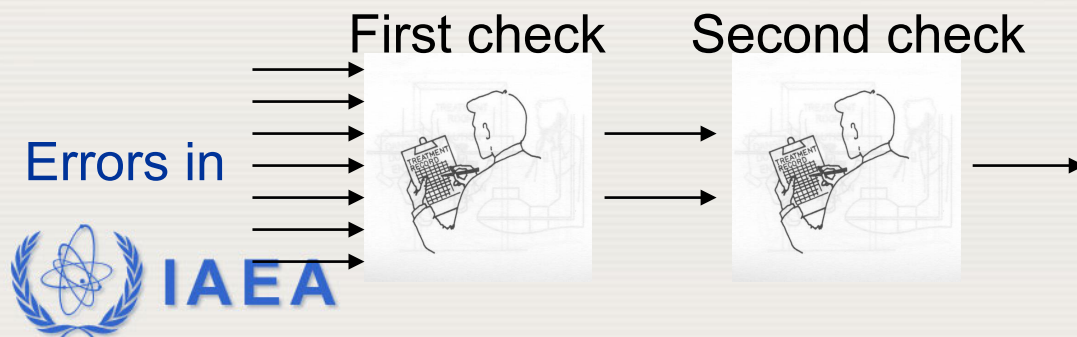


Learning from incidents

- Independent calculation checks monitored between 1998 and 2003
(27830 charts / treatment plans were checked)



- The second check found mistakes in 0.5% of all charts / treatment plans
– 0.3% remained

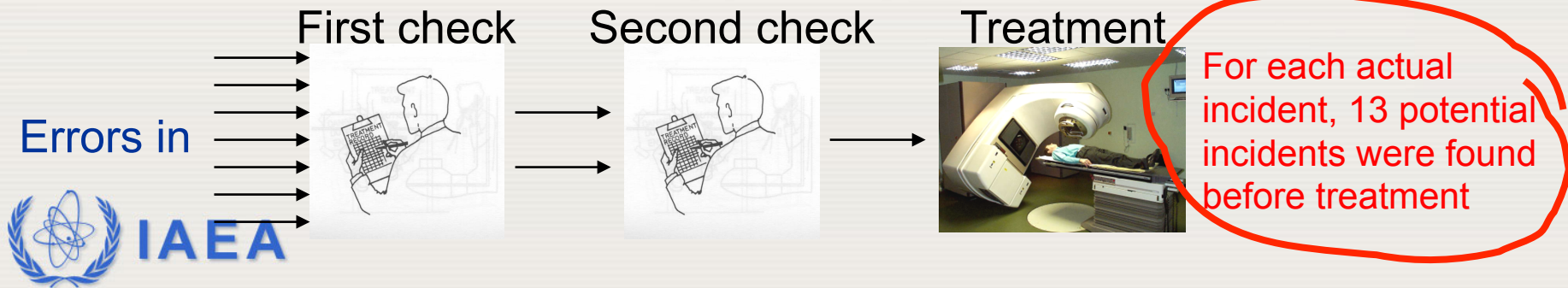


Learning from incidents

- Independent calculation checks monitored between 1998 and 2003 (27830 charts / treatment plans were checked)



- The second check found mistakes in 0.5% of all charts / treatment plans – 0.3% remained



Learning from incidents

Examples:

(B) Mistake during the act of manually creating new information for input into TPS

1. Field name	14	
2. Volume matrix	8	
3. Patient orientation	4	
4. Wedge direction	1	
5. Isocentre position	1	
6. Dose plan addition	1	
TOTAL	Σ 29	0.3 %

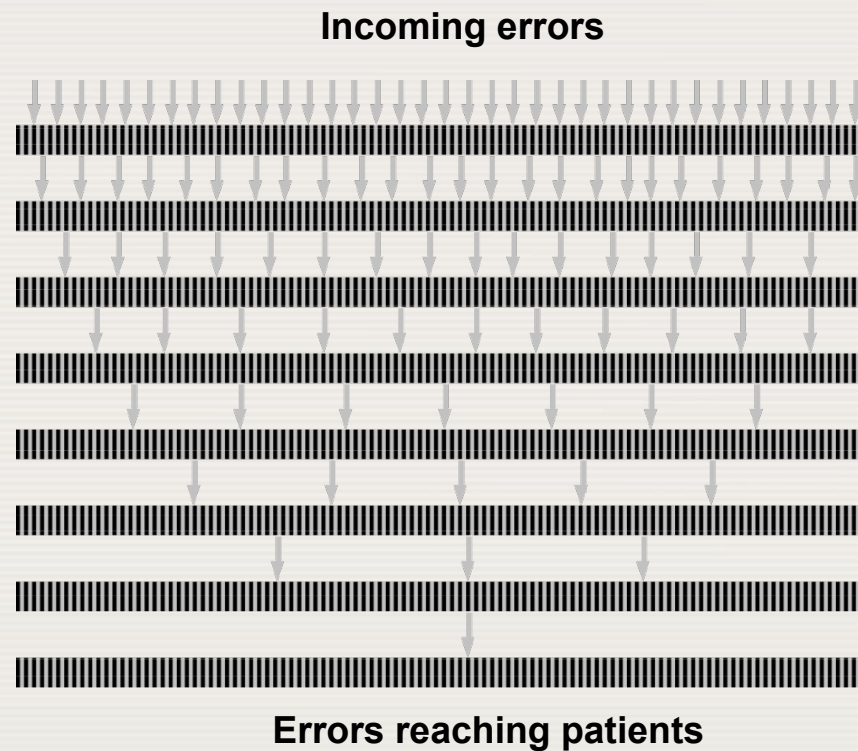
(C) Mistake during the act of doing manual calculations for TPS plan

1. Arithmetic	110	
2. Tray factor	94	
3. Dose per fraction	30	
4. Isodose level	27	
5. Addition of open+wedged MU's	8	
6. Equivalent square	2	
TOTAL	Σ 271	2.6 %

Radiation safety reporting systems

When addressing medical errors...

...we aim to minimise the risk through **multilayered prevention**



Radiation safety reporting systems

These layers should encompass:

Actions where potential deviations from intended dose and geometry can be found before the first irradiation fraction of the patient (e.g. chart-checking)

Ī SAINT LUKE'S HOSPITAL Ī					
UNIT NAME:		CONSULTANT:			
Name:		Contact No.:			
Address:		<input type="checkbox"/> TRANSPORT <input type="checkbox"/> Own <input type="checkbox"/> Taxi <input type="checkbox"/> Ambulance			
D.O.B.:	Patient ID No.:				
Diagnosis:					
Stage:		<input type="checkbox"/> RESIDENCE <input type="checkbox"/> IP St. Luke's <input type="checkbox"/> Out Patient <input type="checkbox"/> IP Other Hospital			
TNM:					
PATIENT AND TREATMENT STATUS		BOOKINGS FOR			
<input type="checkbox"/> New Patient <input type="checkbox"/> Radical <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Phase I <input type="checkbox"/> Other		<input type="checkbox"/> Phase II <input type="checkbox"/> Electron boost <input type="checkbox"/> MDR <input type="checkbox"/> HDR			
<input type="checkbox"/> Re-treat Patient <input type="checkbox"/> Palliative <input type="checkbox"/> Trial <input type="checkbox"/> Phase II		<input type="checkbox"/> BREAK CATEGORY <input type="checkbox"/> Category 1 (no break) <input type="checkbox"/> Category 2 (maximum = d) <input type="checkbox"/> Category 3 (flexible)			
TREATMENT PRESCRIPTION					
Target	A	Date:	B	Date:	C
Target Description					
Target Dose					
Dose per Fraction					
Total No. of Fractions					
Fractions per Day					
Fractions per Week					
Prescr. Isodose Level					
Re-evaluation Dose					
Field Number					
Field Name					
Dose per Fraction / Field					
Photon Energy (MV)					
Electron Energy (MeV)					
Diaphragm Setting [w x l]					
Fixed SSD / Isocentric					
Bolus					
Signature					

Radiation safety reporting systems

These layers should encompass:

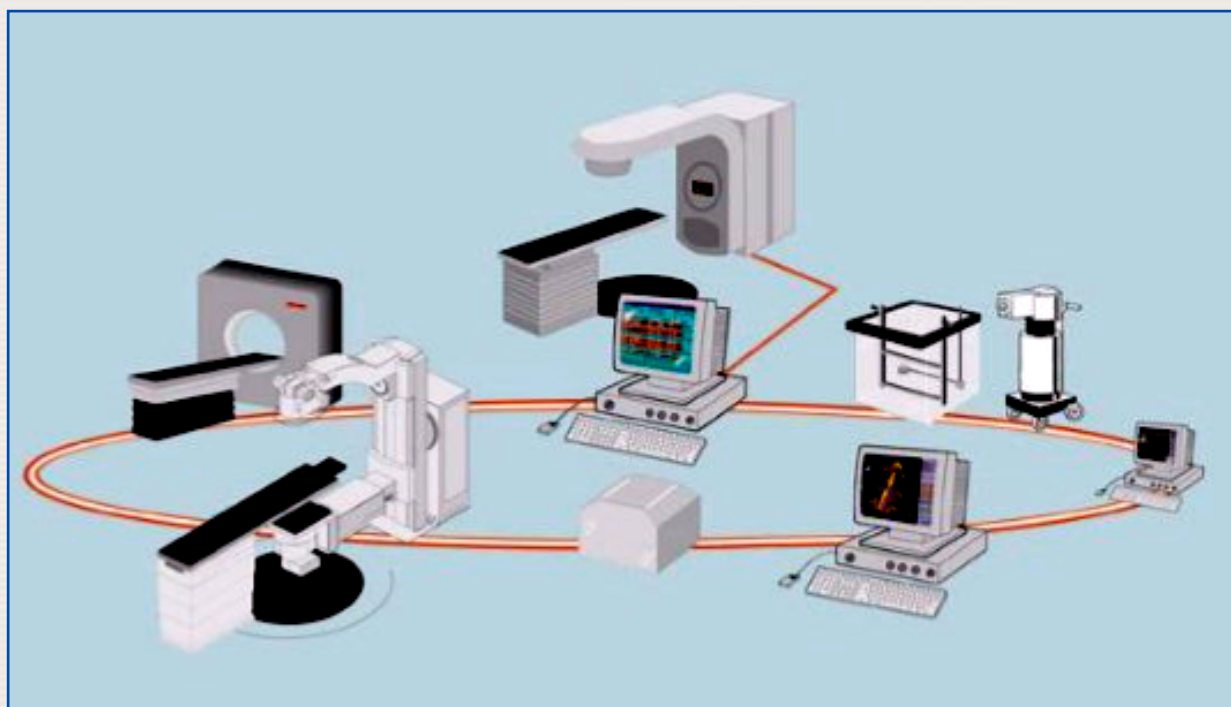
Actions where deviations can be found during or after the treatment course (e.g. in-vivo dosimetry)



Radiation safety reporting systems

These layers should encompass:

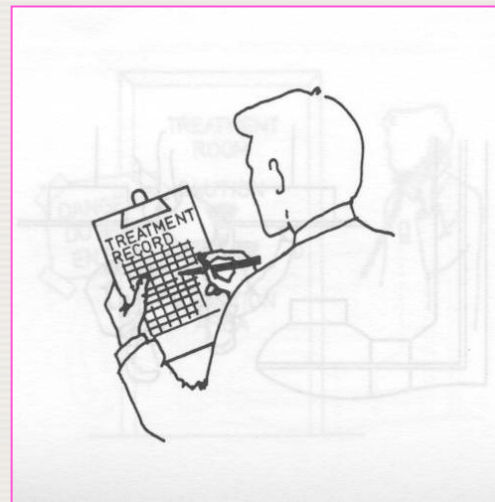
Application of safety technology (e.g. integrated radiotherapy networking)



Radiation safety reporting systems

These layers should encompass:

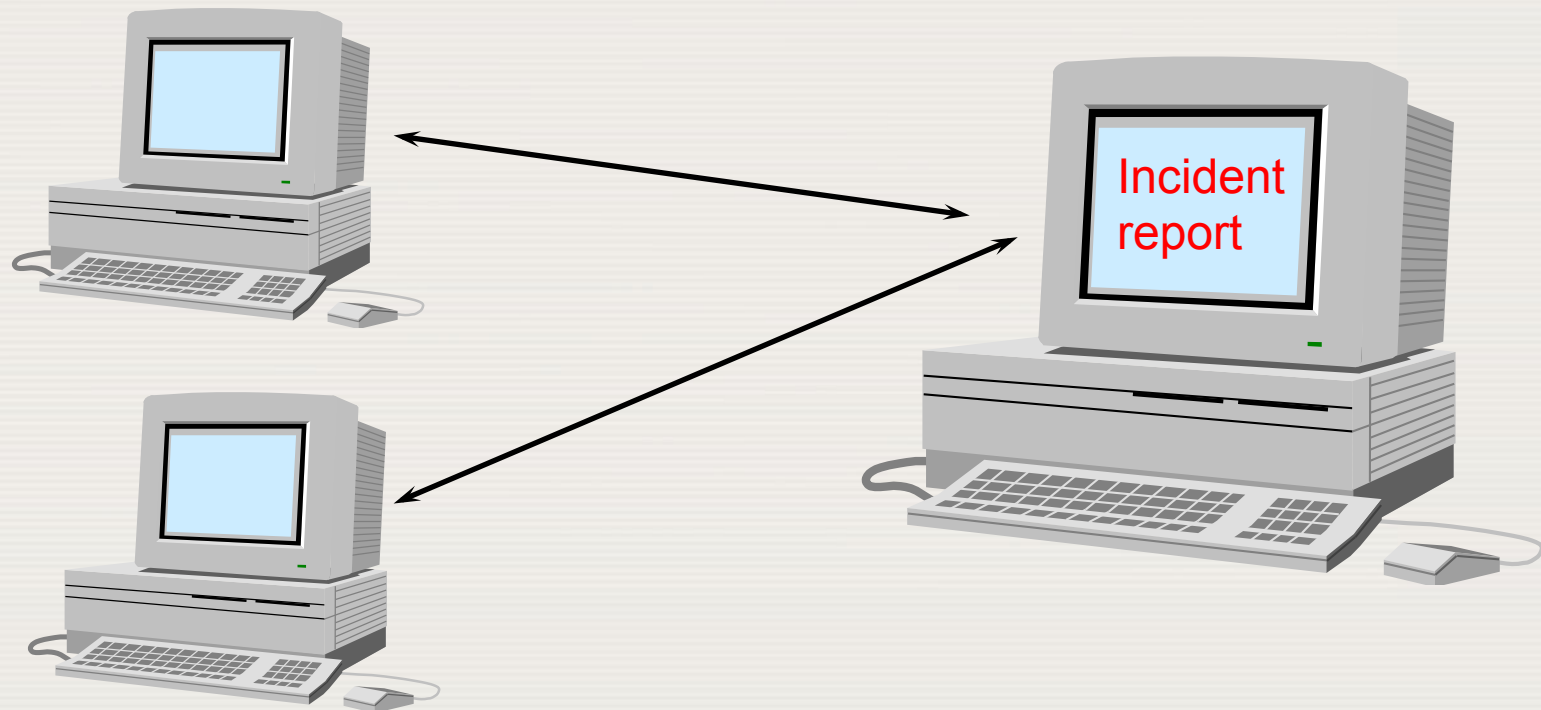
Actions where contributing factors such as staffing-levels and structure, training and communication are addressed (e.g. monitoring of workload)



Radiation safety reporting systems

These layers should encompass:

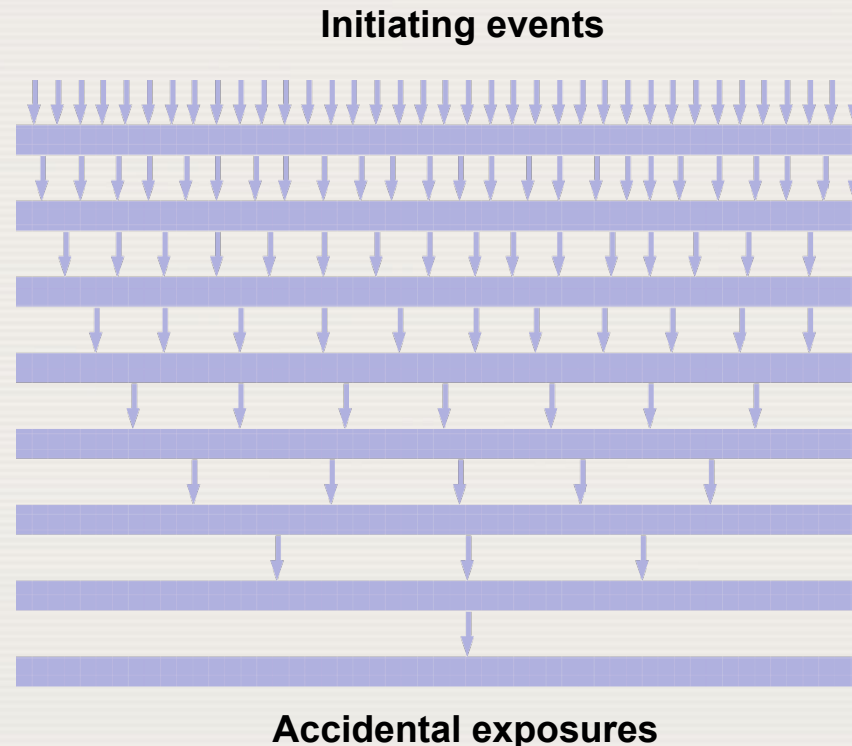
Application of safety procedures (e.g. incident reporting systems)



Radiation safety reporting systems

Safety in radiotherapy requires many safety-layers

- Implementing lessons learned from **reported events** is only one of these layers



Why Safety Reporting and Learning?

Reported by a hospital in Toulouse, France.

In April 2006, a hospital physicist commissioned the new stereotactic unit.

This unit can operate with **microMLC's** (3 mm leaf-width) or **conical standard collimators**.

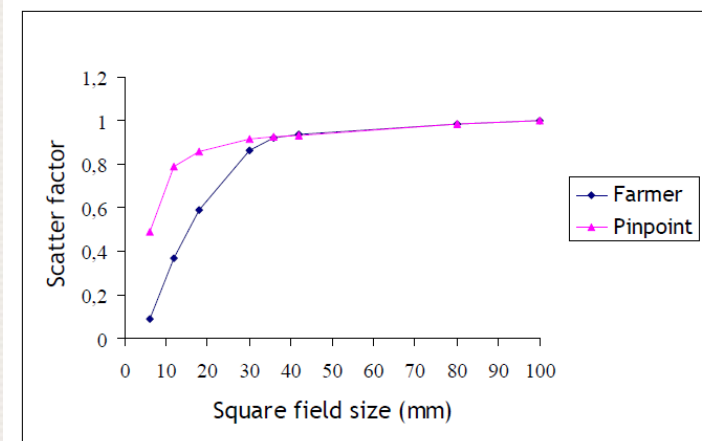


Why Safety Reporting and Learning?

High dose to a **6 x 6 mm** field is within capability. **Measuring device not suitable** for the smallest micro-beams was used (Farmer 0.6 cm³ ion chamber)

Incorrect data was entered into TPS. All patients treated with micro MLC were planned based on this incorrect data.

All patients treated with microMLC for a year were affected (145 of 172 stereotactic patients). **Maximum overdose** of about **200%**



« Farmer » chamber : 0,65 cm³
« Pinpoint » chamber : 0,03 cm³

From: S. Derreumaux, IRSN, France

Why Safety Reporting and Learning?

2009: Report from Missouri, U.S.A., on overdose of 76 patients during 5-year period

- Commissioning of stereotactic equipment
- Detector used for calibration of the smallest fields was too large
- Overdose to patients as a result

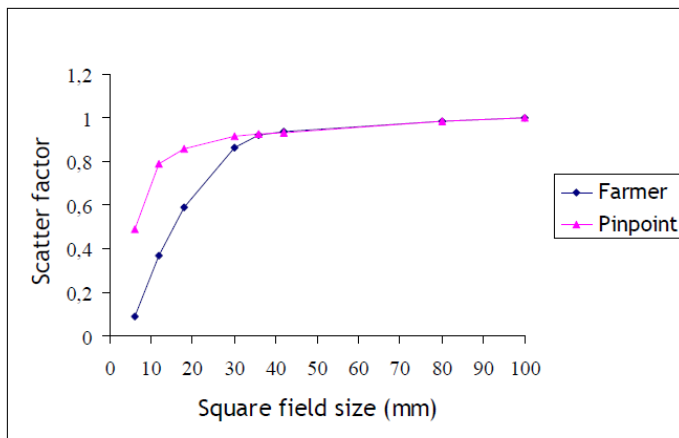
Why Safety Reporting and Learning?



France 2007 (1-year period)



USA 2009 (5-year period)



« Farmer » chamber : 0,65 cm³
« Pinpoint » chamber : 0,03 cm³

From: S. Derreumaux, IRSN, France

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

A hospital in Missouri said Wednesday that it had overradiated 76 patients, the vast majority with brain [cancer](#), during a five-year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

From: W. Bogdanich, N.Y.Times, USA

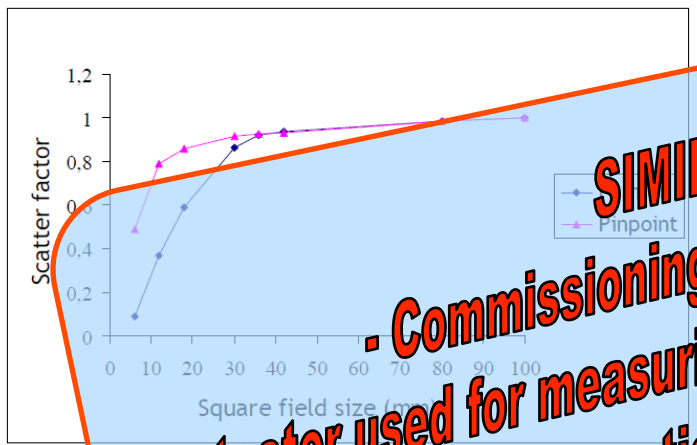
Why Safety Reporting and Learning?



France 2007 (1-year period)



USA 2009 (5-year period)



« Farmer » chamber : 0,65 cm³
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From: S. Deneux, IRSN, France

Radiation Errors Reported in Missouri

By ALYCE BOGDANICH and REBECCA R. RUIZ
 Published: February 24, 2010

A hospital in Missouri Wednesday that it had overradiated 76 patients, a majority with brain cancer, during a five-year period because powerful radiation therapy equipment had been set up incorrectly, a representative of the manufacturer watching

From: Alyce Bogdanich, N.Y. Times, USA

SIMILAR ACCIDENTS:

- Commissioning of stereotactic equipment
- Detector used for measuring in the smallest fields was too large
- Overdose to patients as a result (>200 in total)

Why Safety Reporting and Learning?

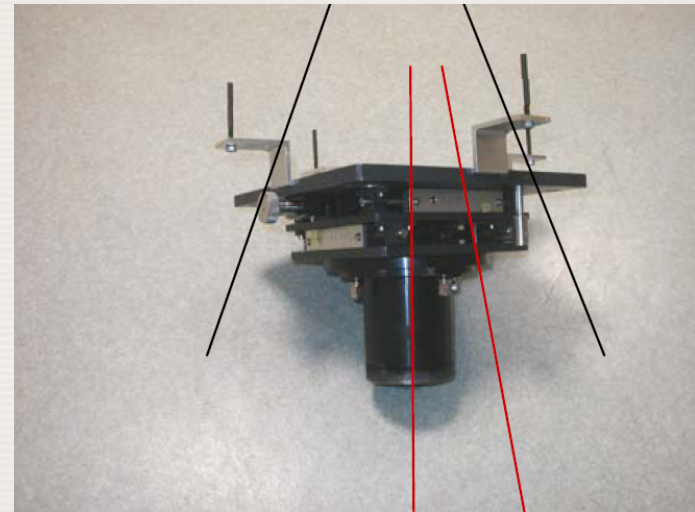
A clinic was using a linac for stereotactic treatment using additional **cylindrical collimators** (\varnothing 10-30 mm) mounted on opaque brass tray.

For correct use, it is necessary to set jaws to 4 cm x 4 cm

When treating one patient, operator was verbally instructed to narrow aperture to **“40 40”**.

Instead of setting 40 mm x 40 mm as intended, the operator set 40 cm x 40 cm

Large volumes **outside target were given nearly full absorbed dose**



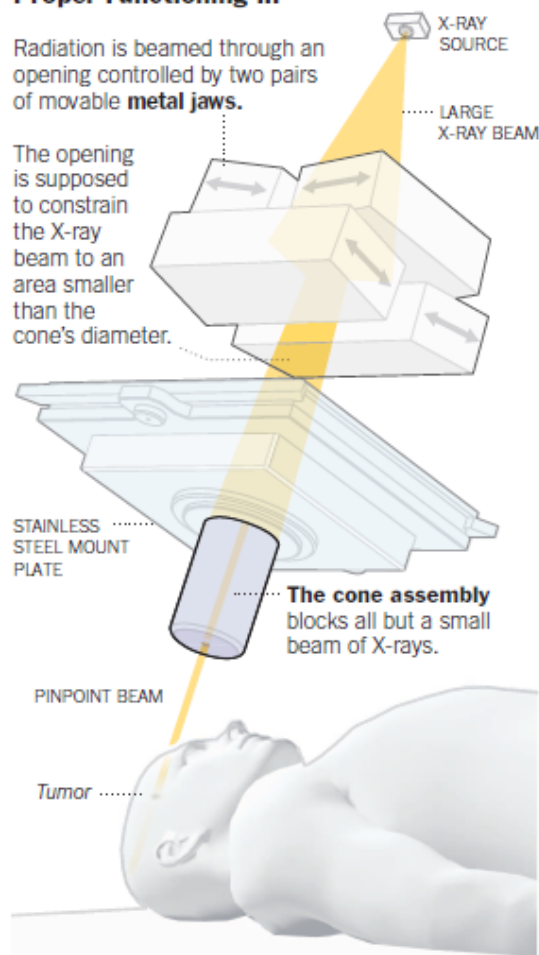
From: S. Derreumaux, IRSN, France

Why Safety Reporting and Learning?

Proper Functioning ...

Radiation is beamed through an opening controlled by two pairs of movable **metal jaws**.

The opening is supposed to constrain the X-ray beam to an area smaller than the cone's diameter.



... And Missteps That Have Caused Injuries

1 JAW SETTINGS WRONG

If the opening made by the jaws is too large, the X-ray beam is sent spilling beyond the edges of the cone, overradiating the patient.

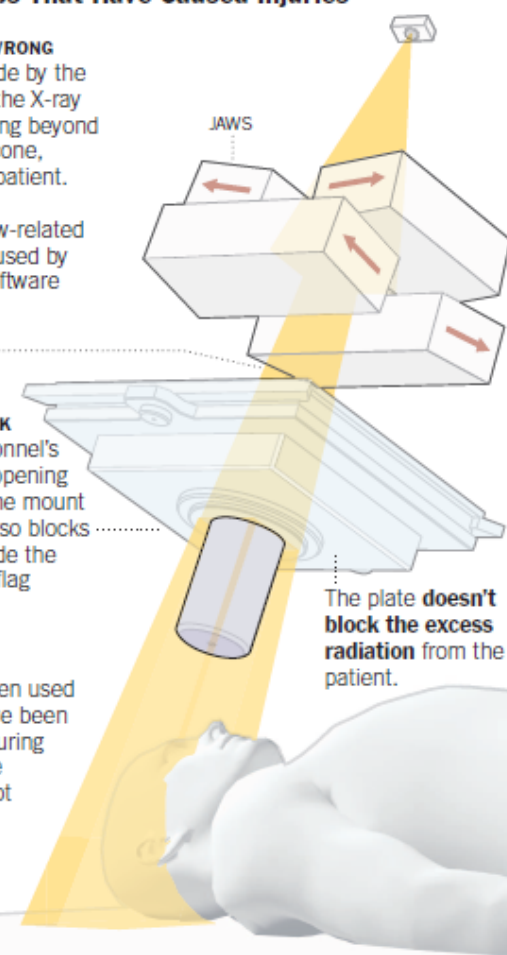
In some cases, jaw-related mistakes were caused by human error or software problems.

BEAM TOO LARGE

2 NO VISUAL CHECK

The hospital personnel's view of the jaw's opening is obstructed by the mount plate. The plate also blocks a light source inside the gantry that could flag such problems.

3 CONES have been used improperly, or have been **left off entirely** during treatments. Some machines were not designed to alert operators to these errors.



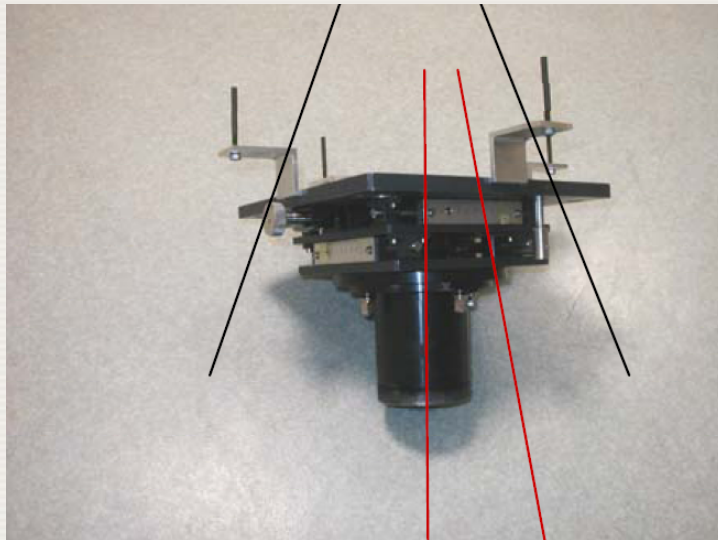
Why Safety Reporting and Learning?



France 2004



USA 2009?



From: S. Derreumaux, IRSN, France

The New York Times

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NEW YORK, WEDNESDAY, DECEMBER 29, 2010

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO

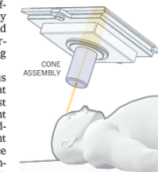
The initial accident report offered few details, except to say that an unidentified hospital had administered radiation overdoses to three patients during identical medical procedures.

It was not until many months later that the full import of what had happened in the hospital last year began to surface in urgent nationwide warnings, which advised doctors to be extra vigilant when using a particular device that delivers high-intensity, pinpoint radiation to vulnerable parts of the body.

Marci Faber was one of the three patients. She had gone to Evanston Hospital in Illinois seeking treatment for pain emanating from a nerve deep inside her head. Today, she is in a nursing home, nearly comatose, unable to speak, eat or walk, leaving her husband to care for their three young daughters.

Two other patients were overdosed before the hospital realized that the device, a linear accelerator, had inexplicably allowed radiation to spill outside a heavy metal cone attachment that was supposed to channel the beam to

An Incorrect Setting Leads to Injury
Problems involving machines that deliver therapeutic radiation have led to patient injuries.



CORRECT SETUP

A beam passes through an adjustable opening and then through a heavy metal cone that focuses the beam on the treatment area.



INCORRECT SETUP

The beam passes through a mistakenly large opening, exceeding the cone's diameter, and irradiates healthy tissue, causing injury.

MIKA GRÖNDÅHL AND BILL MARSH/THE NEW YORK TIMES

a specific spot in the brain. One month later, the same accident happened at another hospital.

The treatment Ms. Faber received, stereotactic radiosurgery, or SRS, is one of the fastest-growing radiation therapies, a technological innovation designed to target tiny tumors and other

anomalies affecting the brain or spinal cord, while minimizing damage to surrounding tissue.

Because the radiation is so concentrated and intense, accuracy is especially important. Yet, according to records and interviews, the SRS unit at Evanston lacked certain safety features, in-



Marci Faber is nearly comatose after a treatment mistake.

THE RADIATION BOOM

Missing the Target

cluding those that might have prevented radiation from leaking outside the cone.

The mistakes in Evanston involve linear accelerators — commonly used for standard radiation therapy — that were redesigned by the manufacturer, Varian Medical Systems, so they could also perform SRS. As the devices became more versatile and complex, problems arose when vital electronic components could not communicate with one another.

In the last five years, SRS systems

Continued on Page A12

From: W. Bogdanich, N.Y.Times, USA



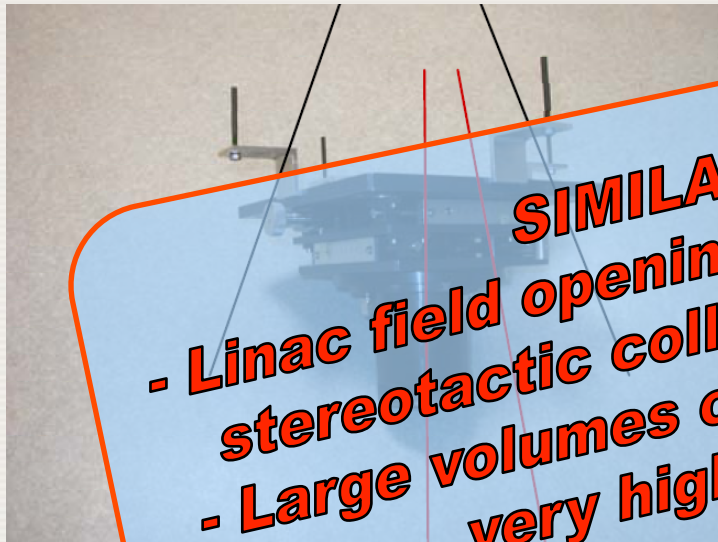
Why Safety Reporting and Learning?



France 2004



USA 2009?



SIMILAR ACCIDENTS: when using stereotactic collimator mounted on linac

- Linac field opening set too large
- Large volumes outside target were given very high absorbed dose

From: S. Derreumaux, IRSN, France



From: W. Bogdanich, N.Y.Times, USA

Radiation safety reporting systems

What is the role of a safety reporting system?

A safety reporting system can play an important role in ...

- identifying **system design flaws** and **safety critical steps** in the radiotherapy pathway
- highlighting critical problems and **patterns of causes** of these problems
- spreading knowledge on new risks or involving **new technology**
- promoting **safety culture** and safety awareness through involvement of and feedback to staff and managers

To fulfil this role, the event reporting needs to be a link in a longer chain:

- Incident Identification => **Reporting** => Investigation => Analysis => Management
=> Learning

Radiation safety reporting systems

What makes safety reports meaningful?

“the narrative”

Charles Billings (the designer of the Aviation Safety Reporting System in the USA)

Radiation safety reporting systems

Mandatory safety reporting systems:

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

Voluntary safety reporting systems:

- Reporting is **encouraged** (*e.g. reporting to professional organization or international organization, voluntarily*)

and

Internal safety reporting systems:

- Reporting **inside** organisation (*e.g. local incident reports*)

External safety reporting systems:

- Reporting **outside** organisation (*e.g. sharing with peers*)

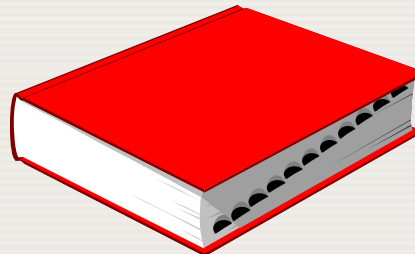


Radiation safety reporting systems

Mandatory safety reporting systems

Mandatory reporting (to authorities) should ...

- ... focus on **serious errors** resulting in injury or death
- ... ensure providers of medical care are held **accountable** to the public
- ... require reporting of information in a **standardised format** to a national database

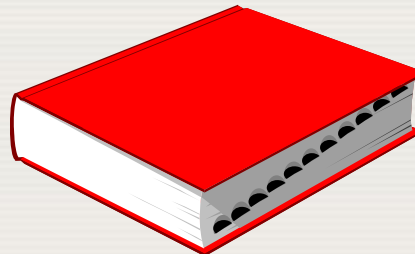


Radiation safety reporting systems

Mandatory safety reporting systems

Two purposes:

- ... to provide public with certain level of protection by assuring that **most-serious errors are reported and investigated**, and action is taken
- ... to provide an **incentive** to hospitals to improve and invest in patient safety, helping to assure that hospitals offer comparable care

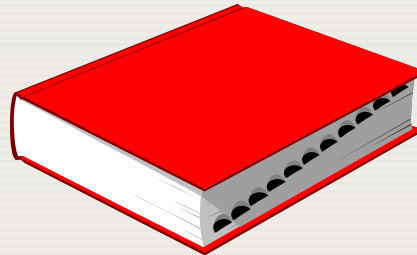


Radiation safety reporting systems

Mandatory safety reporting systems

Filing of a report should not trigger a release of information:

- ... reporting should trigger an **investigation**
- ... release of information should occur only after incident has been investigated thoroughly, and information released should be **accurate and verified**
- ... employees should feel confident that response to reporting of significant error will be **reasonable and justified**



Radiation safety reporting systems

Mandatory safety reporting systems –

Radiotherapy: A mix of radiation and medicine

- Legislation and regulations concerning reporting of incidents in radiotherapy can be covered in relation to radiation protection and / or health
- In some European countries, radiation protection legislation makes it mandatory to report radiotherapy incidents to a higher authority
- In some European countries, health legislation makes it mandatory to report radiotherapy incidents to a higher authority
- Some countries stipulate that local recording of incidents is mandatory. Potential incidents are covered in some countries

Radiation safety reporting systems

Voluntary safety reporting systems

Voluntary reporting should ...

- ... focus on errors that result in **little or no harm** to patients
- ... encourage hospitals to focus on **improvement of safety environment**
- ... have mechanisms to ensure that information and lessons learned can be **shared effectively**



Radiation safety reporting systems

Voluntary safety reporting systems

Voluntary reporting should ...

- ... have mechanisms that allow for **anonymous reporting** of errors or circumstances that could lead to errors, and allow **handling in confidence**

Staff reporting should not fear punishment



Radiation safety reporting systems

Internal safety reporting systems

Reporting of incidents within organisation

- Specific in relation to intra-organisation ...
 - ... procedures
 - ... equipment
 - ... characteristics
- “Lessons to learn” become more direct and explicit
- Follows up management of actual patients affected by the incidents

Radiation safety reporting systems

Internal safety reporting systems

Local report forms (European sample) – Some results:

General sections:

- Administrative information
- Patient information
- Incident information
- Action information

Radiation safety reporting systems

Internal safety reporting systems

Local report forms (European sample) – Some results:

General sections:

- Administrative information
- Patient information
- **Incident information**
- Action information

Radiation safety reporting systems

Internal safety reporting systems

Section: **Incident information** (a sample of results)

- **Description** of event (25 / 27)
- Possible **cause** of error (9 / 27)
- Number of **fractions** affected (10 / 27)
- **Occurrence**: date (18 / 27), time (12 / 27) and day (1 / 27)
- **Detection**: how (4 / 27), who (2 / 27), work area (1 / 27), date (3 / 27)

Radiation safety reporting systems

Internal safety reporting systems

Section: **Incident information** (a sample of results)

- Estimation of **deviation**: dose (2 / 27), dose after correction (2 / 27), field location (1 / 27), correctable or not (3 / 27)
- **Clinical significance** or **risk** to patient (12 / 27)
- **Contributing factors**: general comment (4 / 27), complex or simple treatment plan (1 / 27), staffing levels (4 / 27), experienced staffing levels (2 / 27), staff on leave (1 / 27), distractions (1 / 27)

Radiation safety reporting systems

Internal safety reporting systems

Local report forms (European sample) – Some results:

General sections:

- Administrative information
- Patient information
- Incident information
- **Action information**

Radiation safety reporting systems

Internal safety reporting systems

Section: **Action information** (a sample of results)

- **Corrective action**: action to be performed and / or already taken (22 / 27), responsible for this (3 / 27), date for completion (5 / 27)
- **Preventive action**: recommended action to prevent recurrence (10 / 27), procedural changes (2 / 27), confirmation of preventive action (3 / 27)
- **Communication**: patient informed (4 / 27), responsible physician informed (13 / 27), authority informed (9 / 27), general (6 / 27)

Radiation safety reporting systems

External safety reporting systems

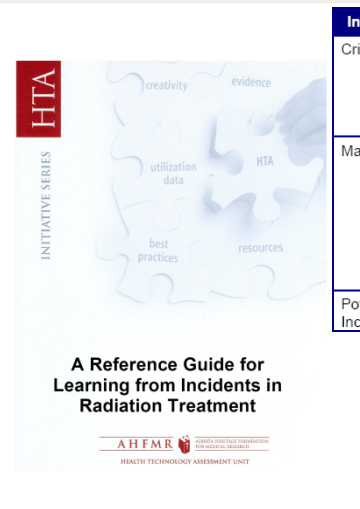
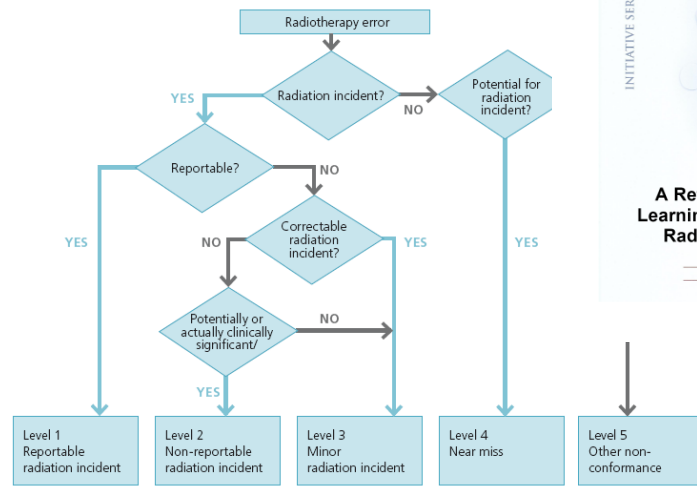
Reporting of incidents outside organisation

- “Lessons to learn” will come from a **bigger pool of events**
- An incident in another hospital can lead to identification of the hazard before a similar incident is realised in your own hospital
- More extensive pool of events → better identification of **safety-critical steps** in the radiotherapy process where errors are likely to occur or be detected
- A general culture of **safety awareness** can be created by making information available on details of incidents, near-incidents and corrective actions

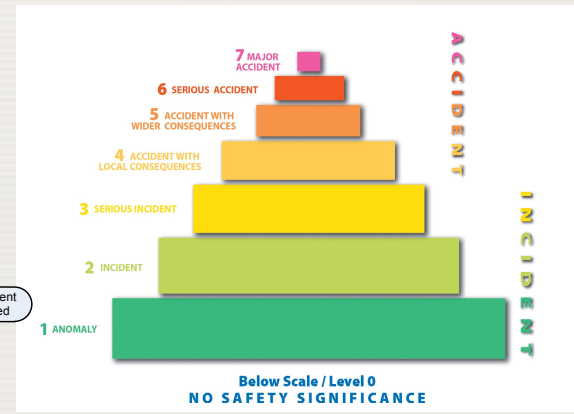
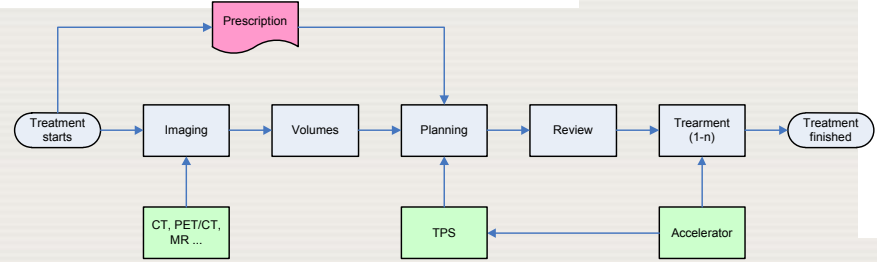
Radiation safety reporting systems

Taxonomy for safety reporting systems

Severity classification; Causes / contributing factors classification; Standardized process map; Other terminology



Incident Severity	Examples: Clinical Incident	Individuals to be notified
Critical Incident	Radiation dose or medication error causing death or disability. Dose variation from prescribed total dose of >20%. Completely incorrect volume.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Major Incident	Dose variation from prescribed total dose of 10 – 20%. Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization. Set up variation that will/could impact on normal tissue effects (e.g. Heart, lung, eyes, kidney etc.).	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor



Severity Classification – HPA (GBR)

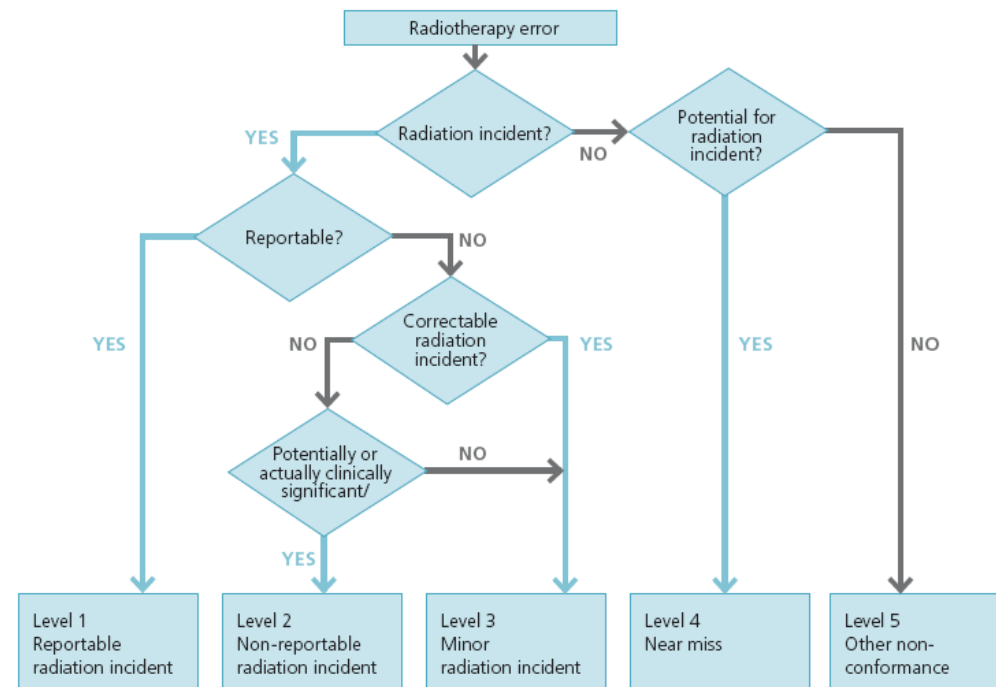


Towards Safer Radiotherapy

Guidance to the legislation issued by the Department of Health in 2000 indicated that the term 'much greater than intended' should be interpreted as 10% or more than that intended for a whole course of treatment, or 20% or more than that intended for any given fraction. This threshold was based on a judgement of the level of overexposure that would place the patient at risk of adverse outcome from their treatment. However, it should be noted that only incidents where the dose is *greater* than that intended are reportable, even though underdose can also result in adverse outcome for the patient. This guidance is currently under revision.³³



British Institute of Radiology
 Institute of Physics and Engineering in Medicine
 National Patient Safety Agency
 Society and College of Radiographers
 The Royal College of Radiologists



Severity Classification – TBCC (CAN)



A Reference Guide for Learning from Incidents in Radiation Treatment

AHFMR ALBERTA HERITAGE FOUNDATION FOR MEDICAL RESEARCH
HEALTH TECHNOLOGY ASSESSMENT UNIT

Clinical incident severity

Incident Severity	Examples: Clinical Incident	Individuals to be notified
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Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor
Serious Incident	Dose variation from prescribed total dose of 5 - <10%. Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment. Set up variation > 1cm – no critical structures included.	Within 24hrs notify: Manager, Supervisor, Physician
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor
Minor Incident	Dose variation from prescribed total dose of <5%. Near miss or unsafe condition which could potentially cause a treatment error.*	Supervisor, Physician*

Table 4: Occupational incident severity

Incident Severity	Examples: Occupational Incident	Individuals to be notified
Critical Incident	Death, life-threatening injury or illness, or	<i>Immediately notify:</i> Senior

Table 5: Operational incident severity

Incident Severity	Examples: Operational Incident	Individuals to be notified
Critical Incident	Equipment failure and/or damage not considered normal wear and tear costing more than \$50,000.	<i>Immediately notify:</i> Senior Management, Manager.

Table 6: Environmental incident severity (cont'd)

Incident Severity	Examples: Environmental Incident	Individuals to be notified
Serious Incident	Radiation - • Source found to be leaking.	<i>Within 24hrs notify:</i> Manager, Supervisor, Radiation Safety Officer

Table 7: Security/other incident severity

Incident Severity	Examples: Security Incident	Individuals to be notified
Critical Incident	Events that result in a formal investigation by a regulatory body or public agency.	<i>Immediately notify:</i> Senior Management, Manager,

Severity Classification – TBCC (CAN)

Incident Type	Process or System that Failed
Clinical	Patient safety or treatment-related processes
Occupational	Staff, student and visiting worker safety
Operational	Operational and technical systems related to machines, equipment, facilities, procedures, patient flow and staff scheduling
Environmental	Processes preventing environmental exposure to radiation, drugs or chemicals
Security/Other	Personal and public security, information security, system integrity and public image

Severity Classification – TBCC (CAN)

Actual Incidents

- 1 Critical
- 2 Major
- 3 Serious
- 4 Minor

Potential Incidents

- 5 Major
- 6 Serious
- 7 Minor

The guide clearly indicates the appropriate notification process at each level

Severity Classification – TBCC (CAN)

Desription	Actual	Potential
$\Delta D > 25\%$ Incorrect vol, wrong pt	Critical	
$10\% < \Delta D < 25\%$ Wrong beam parameters or shielding for $> 10\%$	Major	Major
$5\% < \Delta D < 10\%$ Set up variation $> 1\text{cm}$	Serious	Serious
$\Delta D < 5\%$	Minor	Minor

The guide clearly indicates the appropriate notification process at each level



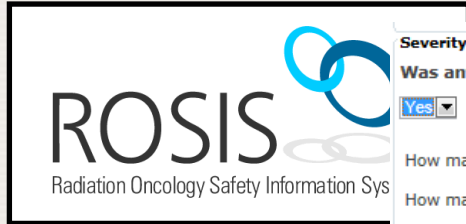
From: Brenda Clark (Ottawa) - The Incident Learning System as an Error Management Tool

Severity Classification – SAFRON

Incident Severity Help ✕

- **Minor Incident**
 - Dose variation from prescribed total dose of <5%
 - Near miss or unsafe condition which could potentially cause a treatment error
 - Patient complaint
- **Potential Serious Incident**
 - A near miss that could have been a serious incident
- **Serious Incident**
 - Dose variation from prescribed total dose of 5 - 10%
 - Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment
 - Set up variation > 1cm - no critical structures included
- **Potential Major Incident**
 - A near miss that could have been a major incident
- **Major Incident**
 - Dose variation from prescribed total dose of 10 - 20%
 - Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization
 - Set up variation that will/could impact on normal tissue (e.g. heart, lung, eyes, kidney etc.)
- **Critical Incident**
 - Radiation dose or medication error causing death or disability
 - Dose variation from prescribed total dose of >20%
 - Completely incorrect volume

Severity Classification – ROSIS (Int.)



Severity:

Was any part of the treatment delivered incorrectly?

How many fractions were delivered incorrectly?:

How many fractions were prescribed in total?:

Outcome for the patient(s)/person(s) affected

- None: Event without consequences
- Light (grade 1): Event with dosimetric consequences but no expected clinical consequence - No expected symptom
- Moderate (grade 2): Event leading to or liable to lead to a moderate impairment of an organ or function - Dose higher than recommended doses liable to lead to unexpected but moderate complications
- High (grade 3): Event leading to a severe impairment of one or more organs or functions - Dose or irradiated volume higher than tolerable doses or volume
- Severe (grade 4): Serious life-threatening event, disabling complication or sequelae - Dose or irradiated volume far higher than tolerable doses or volumes
- Death (grade 5): - Dose or irradiated volume far higher than normal leading to fatal complications or sequelae

Comments regarding actual outcome

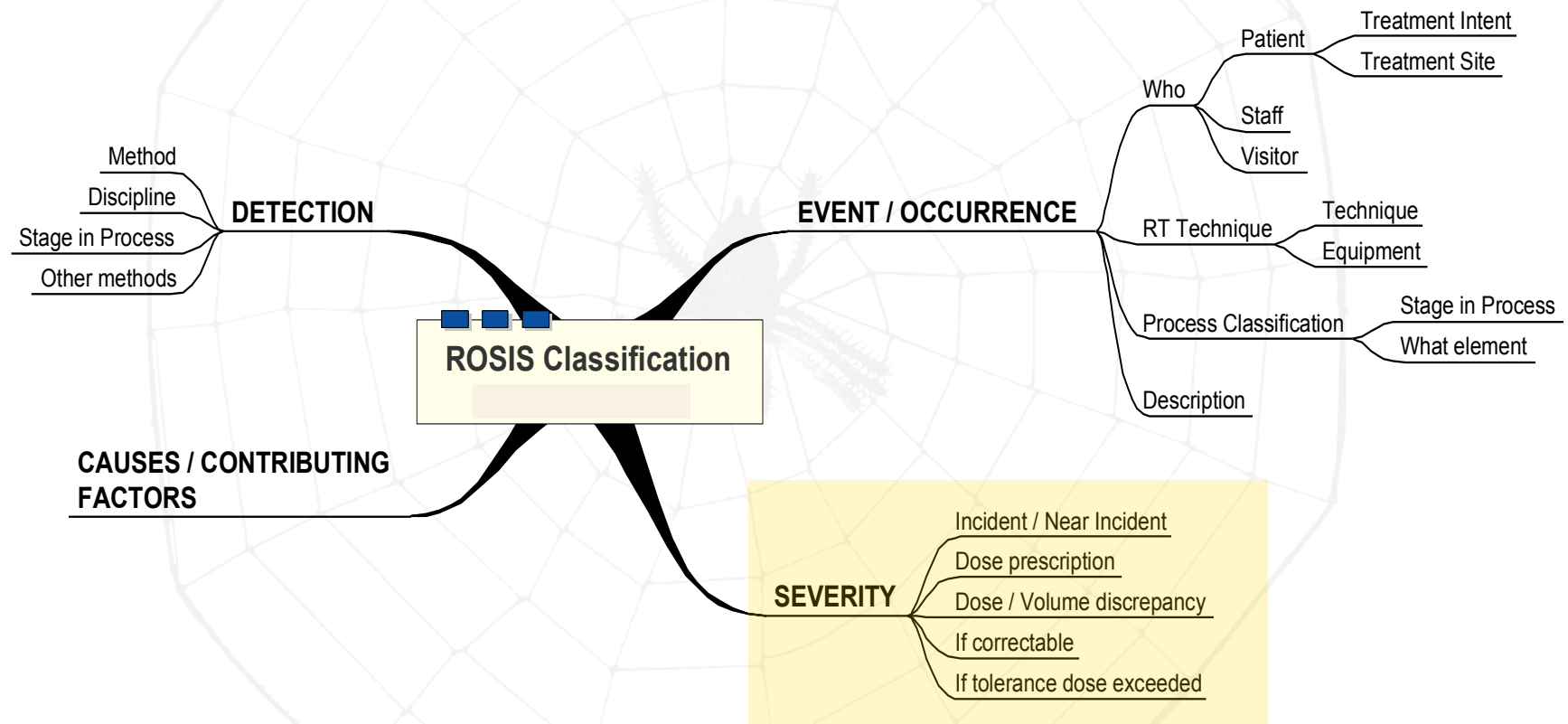
Potential outcome for the patient(s)/person(s) if the incident was not detected/corrected

- None: Event without consequences
- Light (grade 1): Event with dosimetric consequences but no expected clinical consequence - No expected symptom
- Moderate (grade 2): Event leading to or liable to lead to a moderate impairment of an organ or function - Dose higher than recommended doses liable to lead to unexpected but moderate complications
- High (grade 3): Event leading to a severe impairment of one or more organs or functions - Dose or irradiated volume higher than tolerable doses or volume
- Severe (grade 4): Serious life-threatening event, disabling complication or sequelae - Dose or irradiated volume far higher than tolerable doses or volumes
- Death (grade 5): - Dose or irradiated volume far higher than normal leading to fatal complications or sequelae

Comments regarding potential outcome



Severity Classification – ROSIS (Int.)



From: Joanne Cunningham (Dublin) – ROSIS: An Overview

Process steps – ROSIS

Process Classification:

During which activity did the error originate?

.....

.....

- Imaging
- Simulation
- Planning
- Prescription
- Dose Calculation
- Treatment Preparation
- Treatment Delivery

Further Details On Incident:

.....

.....

Process steps – ROSIS

Process Classification:

During which activity did the error originate?

Treatment Delivery

What activity of treatment delivery was affected?

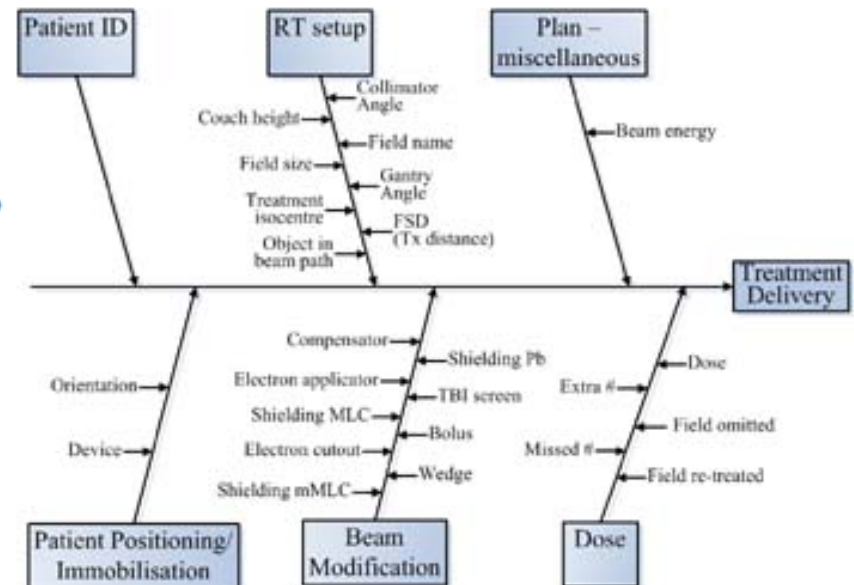
RT Set-Up

Which parameter was affected?

Field Size

Please Give Any Further Details On Incident:

Enter here...



Process steps – SAFRON



IAEA

SAFRON - Safety in Radiation Oncology

Dataset: All incident reports

Home

Process Steps

Incident Reports

Documents and Links

Registrations

Help

Browse Process Steps

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

All process step for: External beam radiotherapy

2.1. Other

3. Treatment phase

3.1. Treatment setup

3.1.1. Patient setup

3.1.1.1. Patient ID process

3.1.1.2. Patient data ID process

3.1.1.3. Explanation/instructions to patient

3.1.1.4. Patient positioning

3.1.1.5. Use of reference marks

3.1.1.6. Other

3.1.2. Treatment unit setup

3.1.2.1. Setting of treatment machine parameters

3.1.2.2. Setting of collimator angle

3.1.2.3. Setting of jaw position

3.1.2.4. Setting of asymmetry

3.1.2.5. Setting of couch position/angle

3.1.2.6. Setting of energy

3.1.2.7. Setting of monitor units

3.1.2.8. Other

3.1.3. Use of treatment accessories

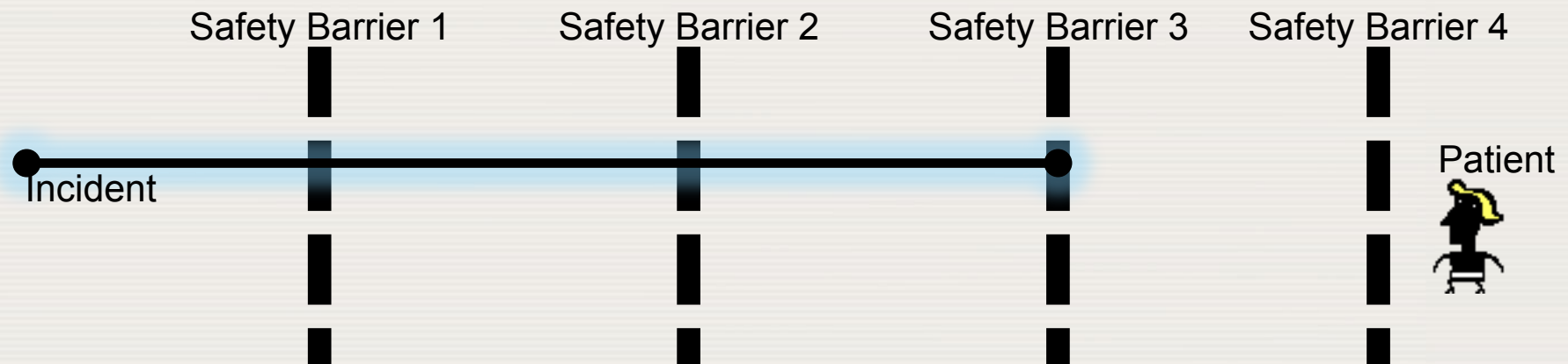


IAEA

Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

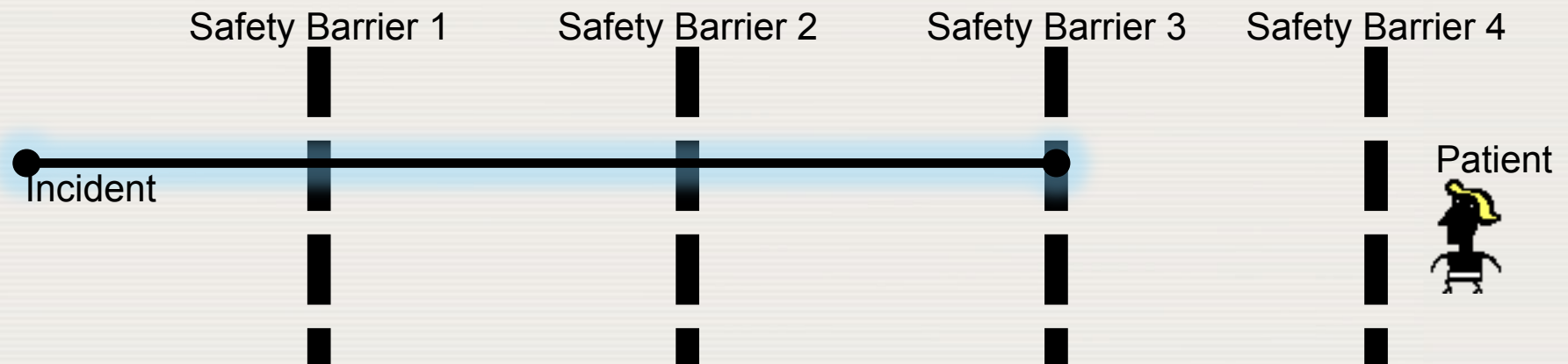
- Which safety barriers did NOT find the incident?
- Which safety barrier found the incident?
- If this safety barrier had not found the incident, which of your subsequent barriers might have found it?



Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

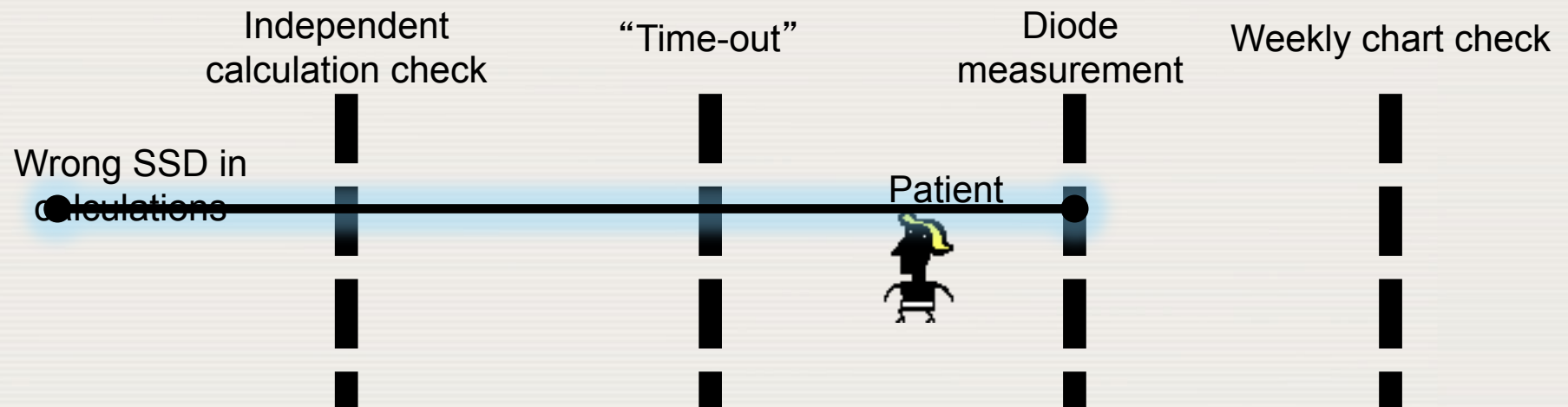
- Overall available safety barriers queried in Registration form (check-boxes)
- Relevant safety barriers in context of incident queried in Incident Report form
- Might influence reporter to think about defence-in-depth, effectiveness of safety barriers, and what safety barriers are in place for safety critical steps



Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

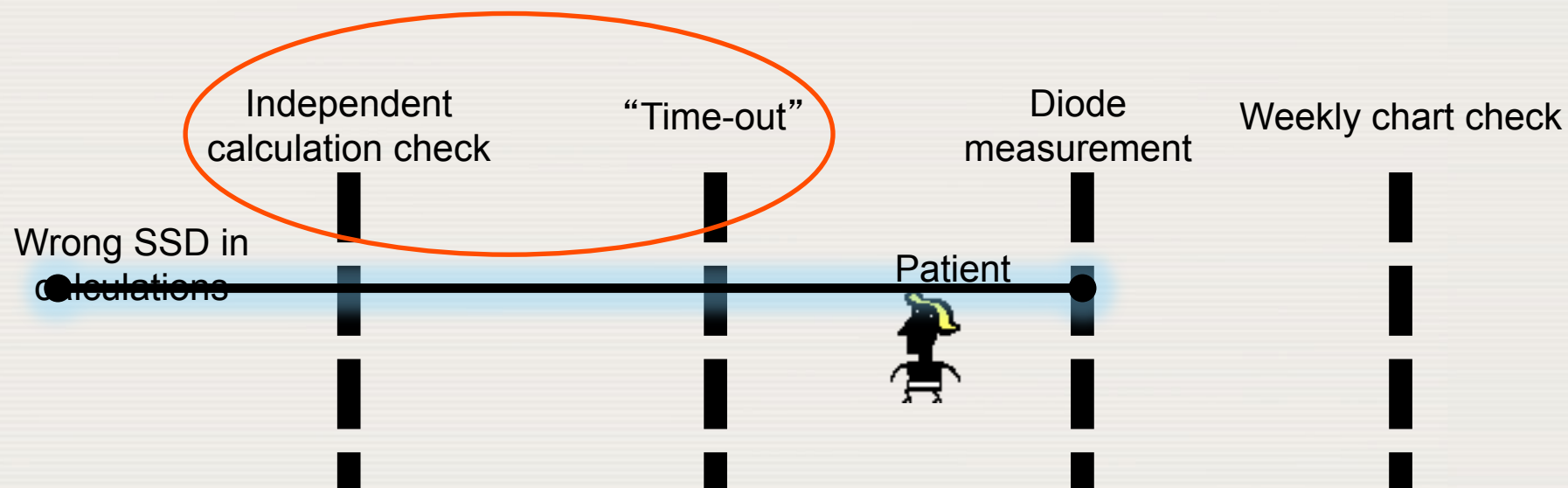
- Example: Wrong SSD used for manual inverse square calculation of MU for manually calculated patient plan



Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

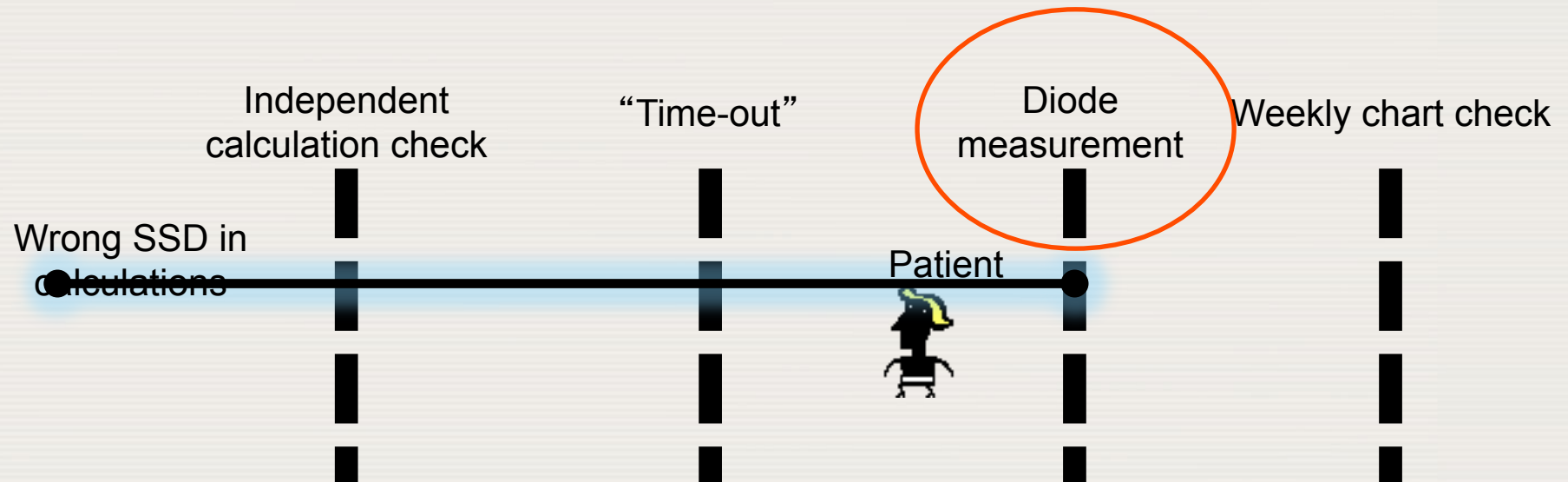
- Example: Wrong SSD used for manual inverse square calculation of MU for manually calculated patient plan
- **Which safety barriers did NOT find the incident?**



Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

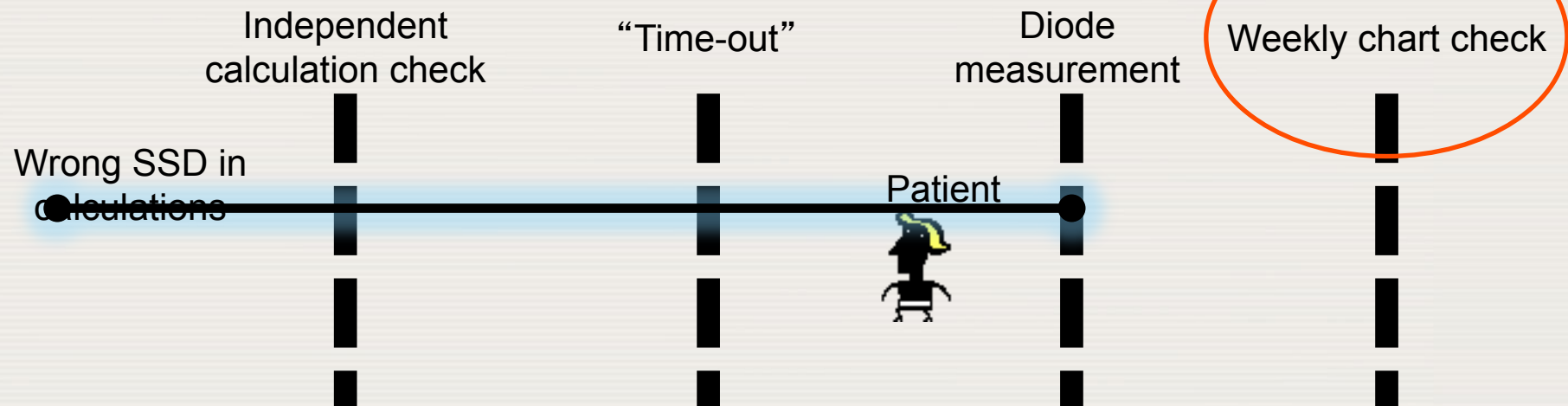
- Example: Wrong SSD used for manual inverse square calculation of MU for manually calculated patient plan
- **Which safety barrier found the incident?**



Safety barriers – SAFRON

New feature introduced in SAFRON: **Safety Barriers**

- Example: Wrong SSD used for manual inverse square calculation of MU for manually calculated patient plan
- **If this safety barrier had not found the incident, which of your subsequent barriers might have found it?**



Safety barriers – SAFRON

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verification that pretreatment condition have been taken into account	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verification reference points	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physician peer review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Review of treatment plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Independent confirmation of dose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Time out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of record and verifying system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verification of treatment accessories	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Image based position verification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In vivo dosimetry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intra-treatment monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regular independent chart checks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regular clinic patient assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Post treatment evaluations (evaluation of clinical and process)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Independent review of commissioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regular internal audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regular external audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regular equipment performance verification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, please specify	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Standardized causes – SAFRON

Job Factors

- Standards/Procedures/Practices
 - 1.1 Not developed
 - 1.2 Inadequate standard/procedure/practice
 - 1.3 Standard/Procedure/Practice not followed
 - 1.4 Inadequate communication of procedure
 - 1.5 Inadequate assessment of risk
 - 1.6 Not implemented
- Materials/Tools/Equipment
 - 2.1 Availability
 - 2.2 Defective
 - 2.3 Inadequate maintenance
 - 2.4 Inspection
 - 2.5 Used incorrectly
 - 2.6 Inadequate assessment of materials/tools/equipment for task
- 3. Design
 - 3.1 Inadequate hazard assessment
 - 3.2 Inadequate design specification
 - 3.3 Design process not followed
 - 3.4 Inadequate assessment of ergonomic impact
 - 3.5 Inadequate assessment of operational capabilities
 - 3.6 Inadequate programming
- Systemic/Management Factors
- 4. Planning
 - 4.1 Inadequate work planning
 - 4.2 Inadequate management of change
 - 4.3 Conflicting priorities/planning/programming
 - 4.4 Inadequate assessment of needs & risks
 - 4.5 Inadequate documentation
 - 4.6 Personnel availability
- 5. Communication
 - 5.1 Unclear roles, responsibilities, and accountabilities
 - 5.2 Lack of communications
 - 5.3 Inadequate direction/information
 - 5.4 Misunderstood communications

6. Knowledge/Skills

- 6.1 Inadequate training/orientation
- 6.2 Training needs not identified
- 6.3 Lack of coaching
- 6.4 Failure to recognize hazard
- 6.5 Inadequate assessment of needs and risks

Personal Factors

7. Capabilities

- 7.1 Physical capabilities (height, strength, weight, etc.)
- 7.2 Sensory deficiencies (sight, sound, sense of smell, balance, etc.)
- 7.3 Substance sensitivities/allergies

8. Judgment

- 8.1 Failure to address recognized hazard
- 8.2 Conflicting demands/priorities
- 8.3 Emotional stress
- 8.4 Fatigue
- 8.5 Criminal intent
- 8.6 Extreme judgment demands
- 8.7 Substance abuse

Natural Factors

9 Natural Factors

- 9.1 Fires
- 9.2 Flood
- 9.3 Earthquake
- 9.4 Extreme weather
- 9.5 Other

Submit