Incident Reporting Systems

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Contents

1. Background / Context
2. Why do we need safety reporting and learning?
3. What is the role of an event reporting system?
4. Purposes of mandatory event reporting
5. Purposes of voluntary event reporting
6. Internal and external event reporting in practice
7. Incidents and near-misses in practice

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Background

1. Starting point: Radiotherapy has significant global importance

- An estimated 5.1 million courses of radiotherapy treatment were administered annually between 1997 and 2007 (up from an estimated 4.3 million in 1988)*
  - 50-60% of cancer patients could benefit from radiation therapy
  - The fraction of cancer patients treated is increasing, where RT is available

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* UNSCEAR 2008 Report

Background

2. Safety in radiotherapy is crucial

Ottawa

Short-staffing led to dosage error

TRACEY TONG
tracey.tong@metronews.ca

An Ottawa Hospital department was short-staffed by about half at the time that a calculation error was made that caused hundreds of cancer patients to receive lower than required radiation doses over three years.

A report by Cancer Care Ontario, ordered by the hospital, found the error occurred after an ortho-voltage radiation treat-

ment unit was moved from the General campus to the Civic campus of the Ottawa Cancer Centre in November 2004.

It resulted in 326 skin cancer patients receiving

department of medical physics.

"We were seriously understaffed," she said.

There were up to seven physicists at the time of the incident, compared to

Patient patients

• Although patients in a few instances were upset about the error, most were forgiving and understand-

The individual who made the error on the machine, whom Turnbull called "very competent," has since retired.

Turnbull doesn't expect any adverse results for pa-

Pub goes all-Ame

American citizens living in the national various parties here on Tuesday night election. Susan Smith is organizing an pub on Sparks Street. "We have bobble have paper dolls. We have buttons. We ma, and we've got McCain stuff that's

Cancer error

Report s

LADEPECHE.fr

ACCUEIL

Vendredi 21 Août - 17:16
Fête : St Christophe

ACTUELLEMEN
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PUBLIÉ LE 15/04/2008 17:23 - MODIFIÉ LE 15/04/2008 À 17:25 | LADEPECHE.FR

Radiothérapie. Après les accidents de Toulouse et Epinal, les rapports d'inspection bientôt en

L'Autorité de sûreté nucléaire (ASN) va mettre "à disposition du public", sur son site internet, les conclusions des inspections réalisées dans les centres de radiothérapie à la suite de l'accident d'Epinal, a-t-elle indiqué mardi dans un communiqué.

L'ASN mettra à l'été, sur son site www.asn.fr, "l'ensemble des lettres de suite des inspections qu'elle a réalisées en 2007 et 2008 dans les

", comme elle le fait déjà pour les installations nucléaires. Ces "lettres de suite" uels constatés lors de l'inspection.

ctions menées en 2007 dans les centres de radiothérapie, disponible sur une situation contrastée", souligne l'ASN : "il existe des centres dont la des traitements est bien initiée, voire bien avancée; d'autres centres, moins contre des faiblesses organisationnelles qu'il conviendra de corriger en

ces centres doit être réalisée d'ici fin juin "afin d'évaluer les premières actions e", indique l'ASN

treatment error

cancer error: seven patients may have ered harm (ABC)

SKY NEWS

Teen May Die After Radiation Blunder

9:59pm UK, Wednesday February 08, 2006

A teenager faces an uncertain future after a top canc

ly fatal overdose of
s given the overdose 17
atment for a brain tumou
e in Glasgow.

en blamed for the mistakes which happened
oy sessions.

under are not yet known - but doctors have w
could be devastating.

"I've got burns down the back of my neck anc
ally sore and I can't really do much."

he future holds for Lisa and she said:"I could
brain damaged, I could be paralysed, I could not be here, time wil

The problems with radiotherapy came after Lisa had undergone a operation and a course of chemotherapy.

The effects of the treatment

Professor Alan Rodger, medical director of Beatson Oncology Ce said: "Initial meetings have taken place with the girl and her family

"We will do everything in our power to support both them and thei daughter in the challenges ahead."

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.

The New York Times

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THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

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PRINT
SINGLE PAGE
REPRINTS
SHARE

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Enlarge This Image

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear

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Background

2. Safety in radiotherapy is crucial

- Over the last three decades, at least 3000 patients have been affected by radiotherapy incidents and accidents
- Radiation accidents involving medical uses have accounted for more acute radiation deaths than any other source, including Chernobyl
- These accidents do not only affect patients directly (e.g. harm and death), but might also undermine the public's confidence in the treatment
- Preventable medical errors overall also cost countries billions of dollars each year

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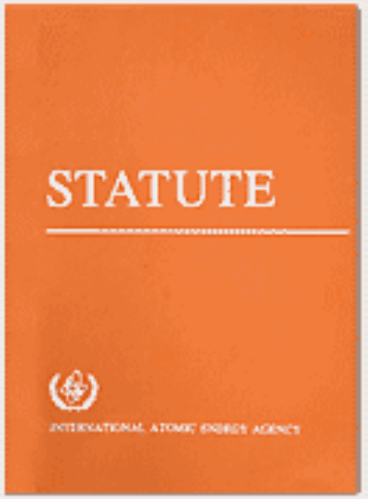
Background

Statute of the International Atomic Energy Agency:



1. Came into force on 29 July 1957

2. "The Agency shall seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world."

3. "To establish or adopt … standards of safety for protection of health and minimization of danger to life … and to provide for the application of these standards"

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Background

Director General

Department of Nuclear Energy

Department of Safeguards

Department of Nuclear Safety and Security

Department of Nuclear Sciences and Applications

Department of Management

Department of Technical Cooperation

Division of Radiation, Transport and Waste Safety

Division of Human Health

Radiation Safety and Monitoring Section

Radiation Protection of Patients Unit

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Protection from Risks

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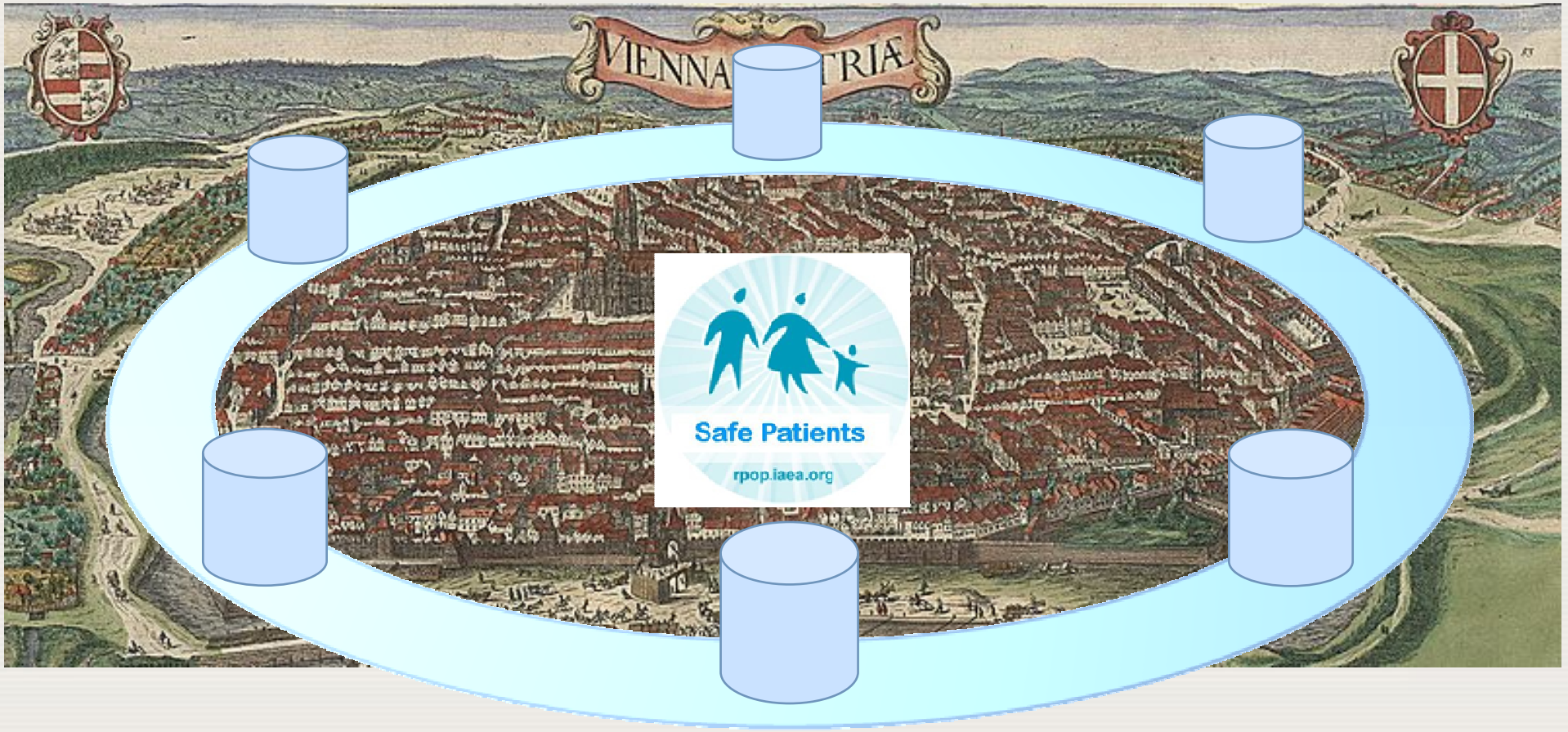
Protection from Risks



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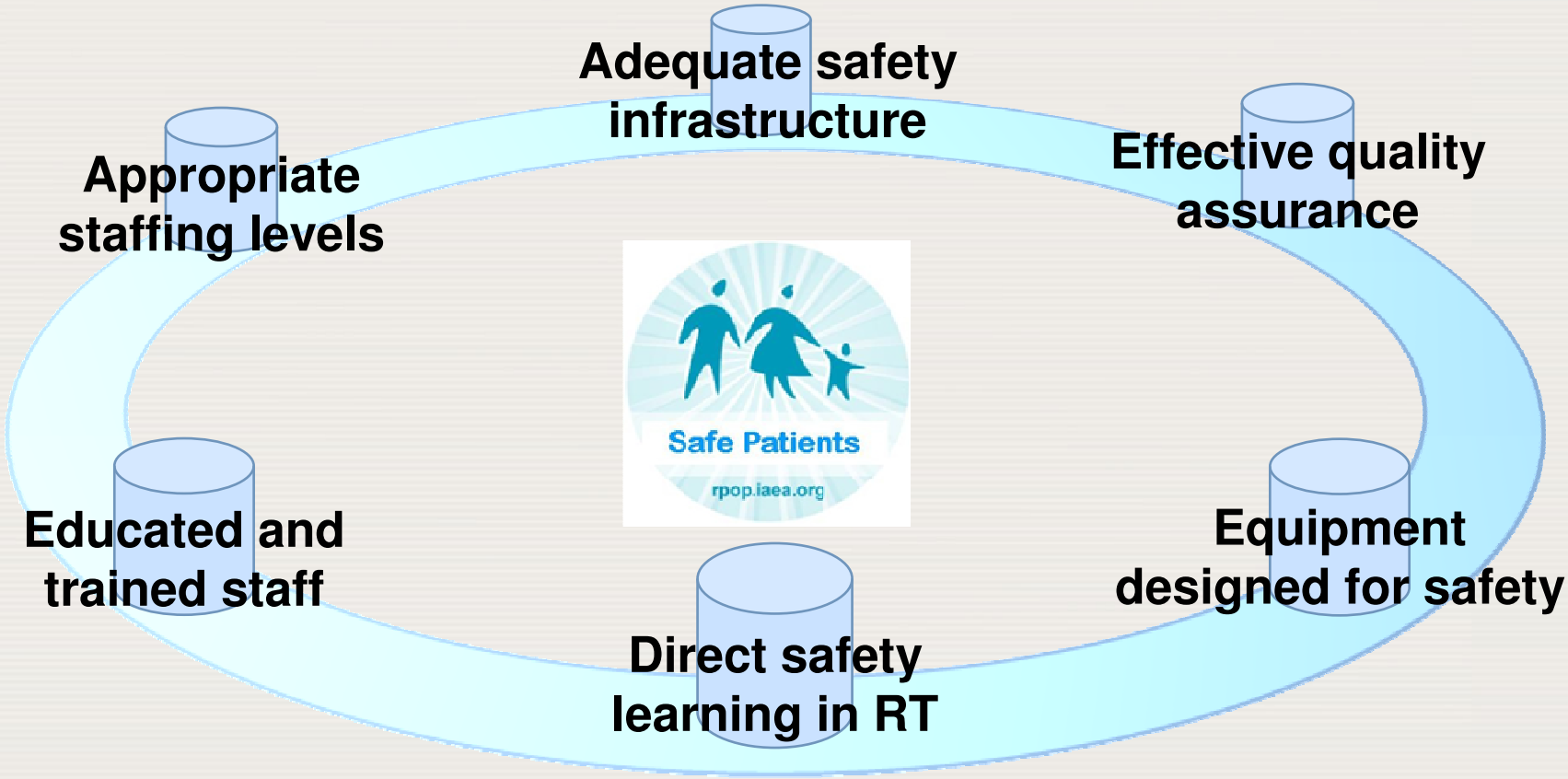
Protection from Risks



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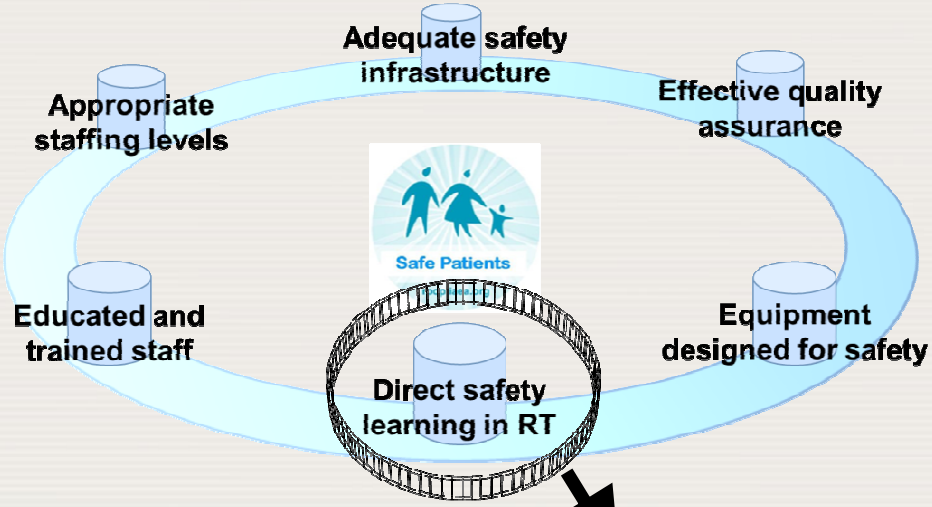
Protection from Risks



- Dedicated website (rpop.iaea.org) for global knowledge exchange on radiation protection of patients (>1,000,000 hits per month)
- Training material and books on radiotherapy safety
- Safety reporting and learning system – SAFRON (Safety in Radiation Oncology)

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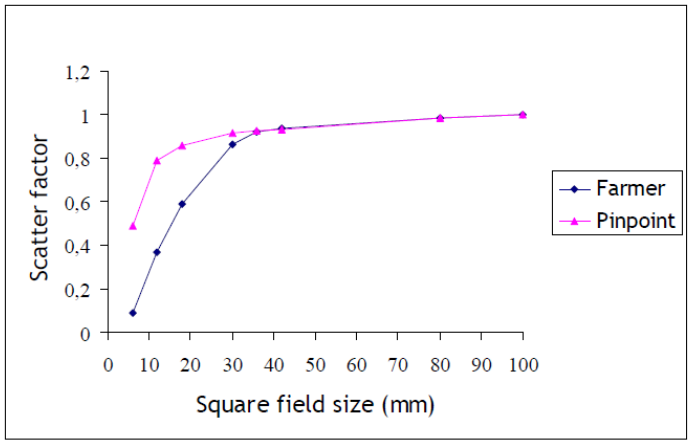
Why Safety Reporting and Learning?

France 2007 (1-year period)



« Farmer » chamber : 0,65 cm^3
« Pinpoint » chamber : 0,03 cm^3

From: S. Derreumaux, IRSN, France

USA 2009 (5-year period)

Radiation Errors Reported in Missouri

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

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Why Safety Reporting and Learning?

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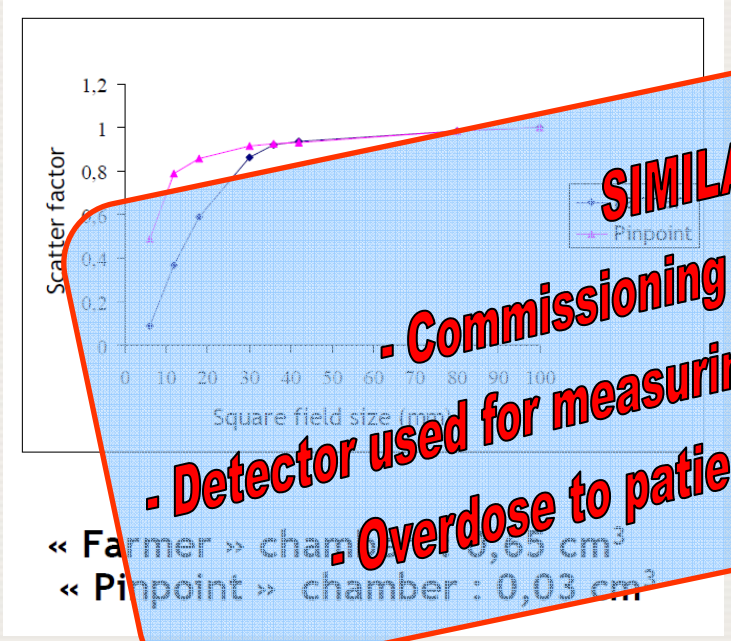
USA 2009 (5-year period)



From: S. Derreumaux, IRSN, France

- 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)

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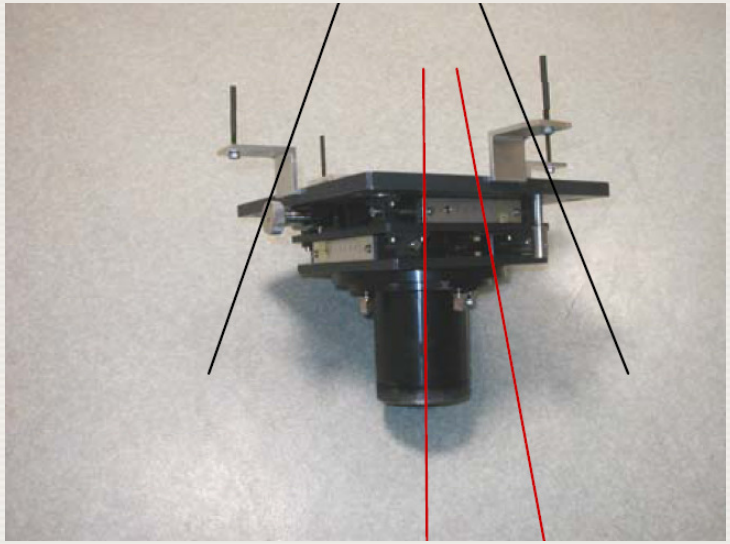
Why Safety Reporting and Learning?

France 2004

USA 2009?



From: S. Derreumaux, IRSN, France

The New York Times

© 2010 The New York Times 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 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, including 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 sys-

Continued on Page A12

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 GRÖNDAHL AND BILL MARSH/THE NEW YORK TIMES

Marci Faber is nearly comatose after a treatment mistake.

THE RADIATION BOOM

Missing the Target

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

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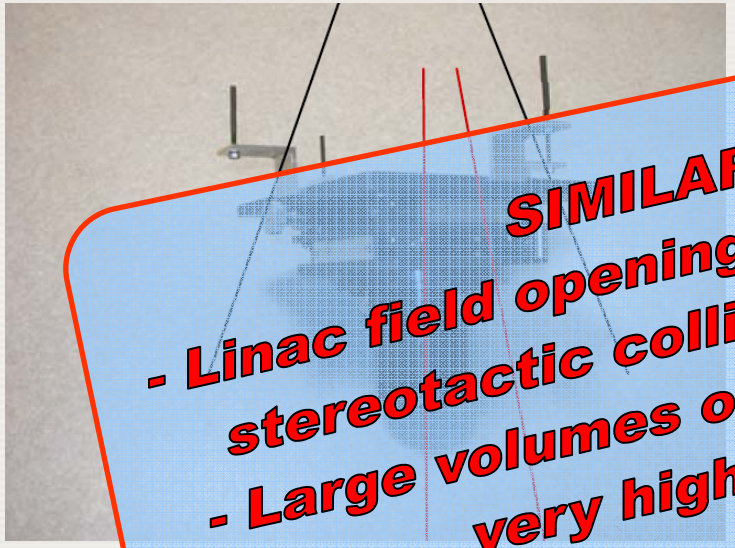
Why Safety Reporting and Learning?

France 2004

USA 2009?



From: S. Derreumaux, IRSN, France

SIMILAR ACCIDENTS:

- Linac field opening set too large when using stereotactic collimator mounted on linac

- Large volumes outside target were given very high absorbed dose

The New York Times

TUESDAY, DECEMBER 29, 2010

Beam Strays ... ming Instead of Healing

Leads to injury

BY WALT B... and ...

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THE ... RADIATION BOOM

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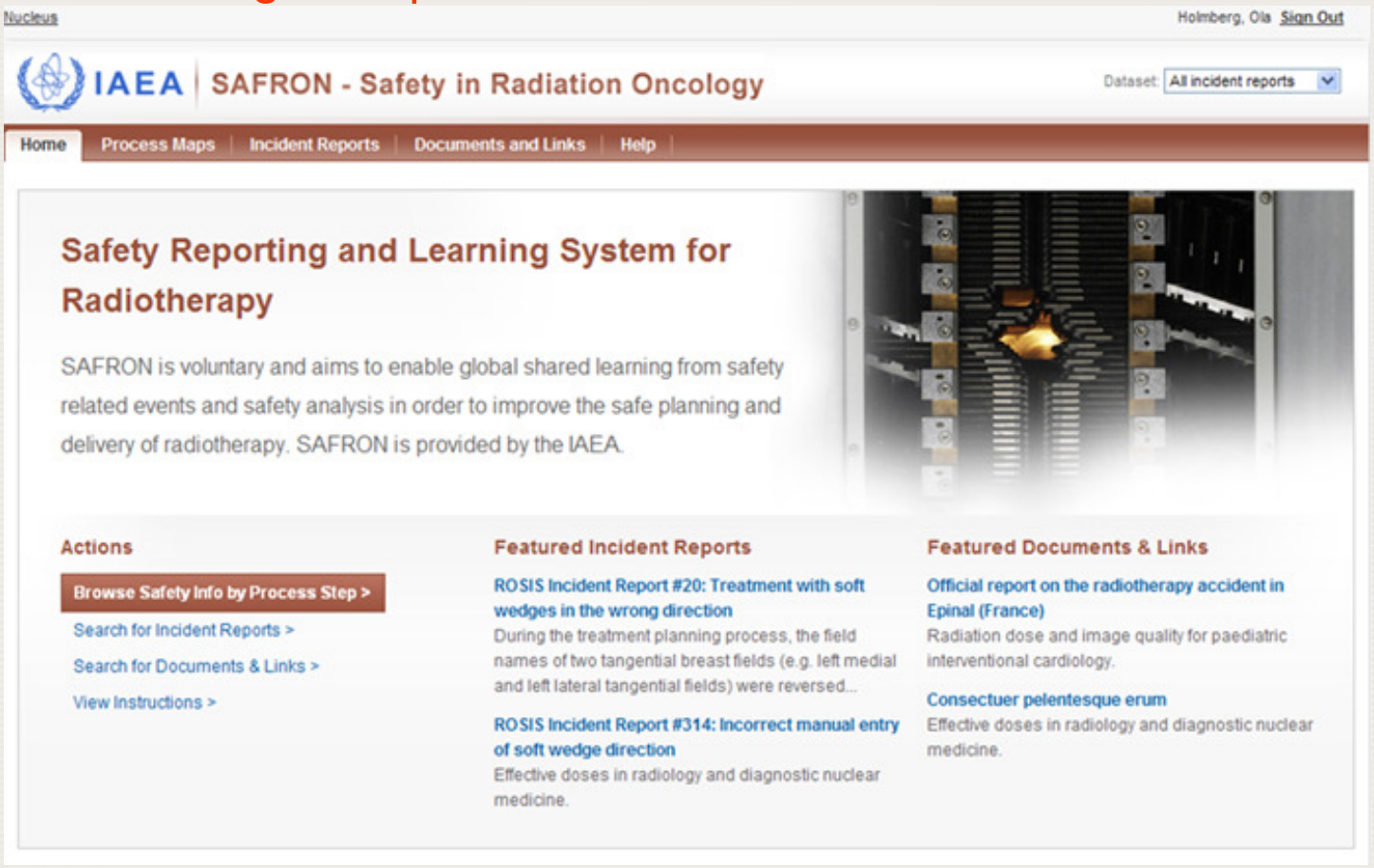
Why Safety Reporting and Learning?

Accidents and incidents still tend to “repeat themselves” – i.e. we need to be better at learning from previous events



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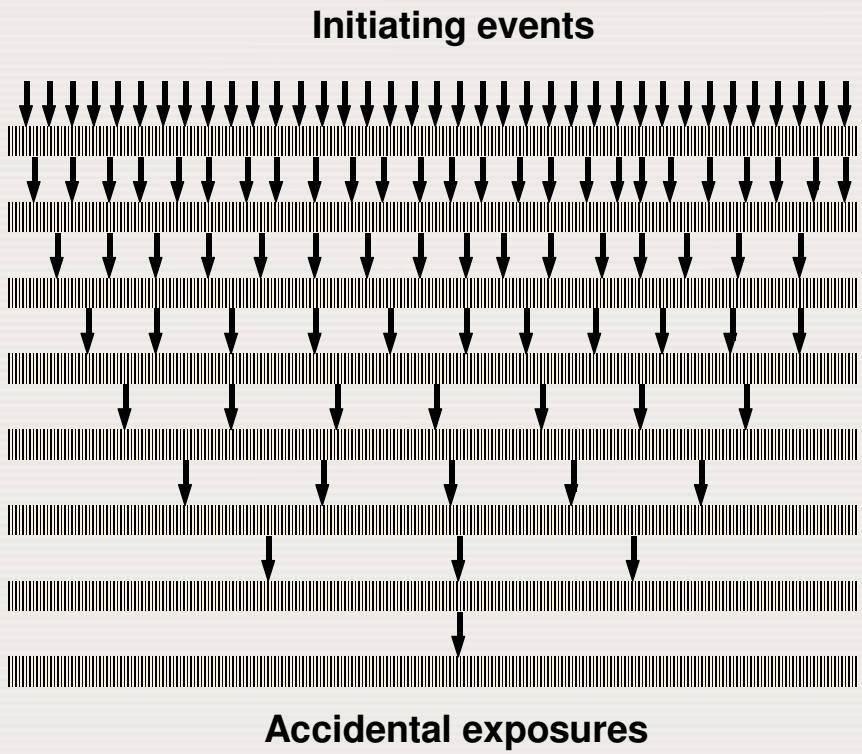
Why Safety Reporting and Learning?

Safety in radiotherapy requires many safety-layers

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



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Event reporting

What is the role of an event reporting system?

An event 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

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Event reporting

What makes incident reports meaningful?

"the narrative"

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

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Event reporting

Mandatory event reporting systems:

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

Voluntary event reporting systems:

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

and

Internal event reporting systems:

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

External event reporting systems:

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

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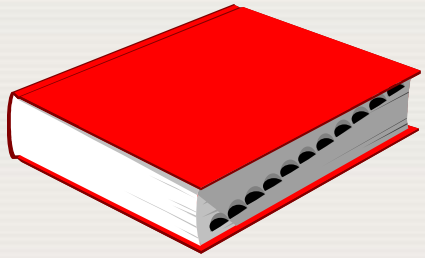
Mandatory event reporting

Mandatory event 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



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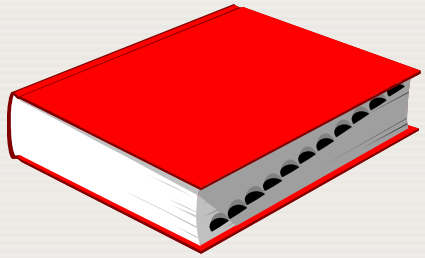
Mandatory event reporting

Mandatory event reporting systems

Two main 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

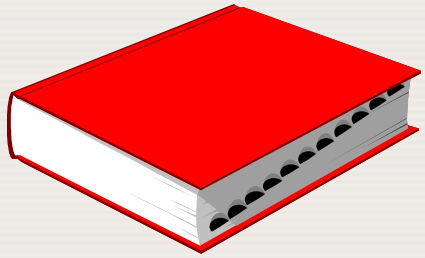


Mandatory event reporting

Mandatory event 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



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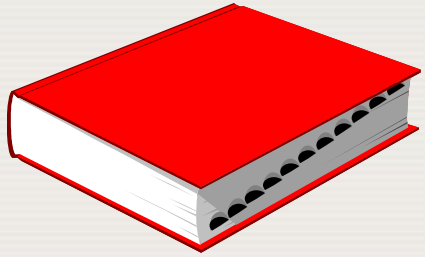
Mandatory event reporting

Mandatory event 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 countries, radiation protection regulations make it mandatory to report radiotherapy incidents to a regulatory authority
- In some countries, health regulations make it mandatory to report radiotherapy incidents to another regulatory authority
- Some countries stipulate that local recording of incidents is mandatory. Potential incidents are covered in some countries



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Voluntary event reporting

Voluntary event 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

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Voluntary event reporting

Voluntary event 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

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Internal event reporting

Internal event 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

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Internal reporting in practice

TABLE 17.1 Information Requested in 27 Local Incident Reporting Systems in European Clinics

Category	Description	Sub-Description	Frequency
Incident information	Description of incident		25 of 27
	Cause of incident		9 of 27
	Number of fractions affected		10 of 27
	When did it occur?	Date	18 of 27
		Time	12 of 27
		Weekday	1 of 27
	Detection of incident	How	4 of 27
		By whom	2 of 27
		Where in process	1 of 27
		Date	3 of 27
	Estimate of deviation	Absorbed dose	2 of 27
		Dose after correction	2 of 27
		Field location	1 of 27
		Correctable or not	3 of 27
	Clinical significance or risk to patient		12 of 27
	Contributing factors	General comment	4 of 27
		Treatment plan complexity	1 of 27
		Staffing levels	4 of 27
		Staffing composition	2 of 27
		Staff on leave	1 of 27
		Distractions	1 of 27

From: “Quality and Safety in Radiotherapy (ed.: Pawlicki et al), Holmberg, pp 81-85

Internal reporting in practice

TABLE 17.1 Information Requested in 27 Local Incident Reporting Systems in European Clinics

Category	Description	Sub-Description	Frequency
Action information	Corrective action	Action to be performed and/or already taken	22 of 27
		Responsible for this	3 of 27
		Date for completion	5 of 27
	Preventive action	Recommended action to prevent recurrence	10 of 27
		Procedural changes	2 of 27
		Confirmation of preventive action	3 of 27
	Communication	Patient informed	4 of 27
		Responsible physician informed	13 of 27
		Authority informed	9 of 27
		General	6 of 27

Source: Radiation Oncology Safety Information System, unpublished survey, 2002.

From: "Quality and Safety in Radiotherapy (ed.: Pawlicki et al), Holmberg, pp 81-85

External event reporting

External event 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

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External reporting in practice

Inadvertent loss of wedge code information (ROSIS report #284)

Due to the breakdown of a linear accelerator, a patient was moved to another accelerator for a single fraction.

As an inherent part of the design of the R&V system, the wedge information in the R&V system was not transferred automatically to the new treatment unit.

The wedge code was manually input properly for the single fraction at the second unit, but when the patient was transferred back to the original unit, the wedge code was not put in again.

As a result, the patient received treatment without wedges for three fractions before discovery, causing accidental delivery of the incorrect absorbed dose and dose distribution.

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External reporting in practice

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Procedure insufficient

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External reporting in practice

Inadvertent rotational treatment of a patient (ROSIS report #284)

During the first treatment of a patient with an electron field, it was noted that the gantry started to rotate.

The prescription was for static treatment, not rotational. An error had been made when preparing the R&V entry of the treatment, where a checkbox had been accidentally checked for rotational treatment.

It was also noted in another report to ROSIS (Incident Report #689) that, for this particular type of R&V system, the checkbox for rotational treatment on the screen was placed near the icon for closing the window after finalising the R&V entry, leading to inadvertent activation of rotational treatment.

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Lacking awareness and alertness

Insufficient system design

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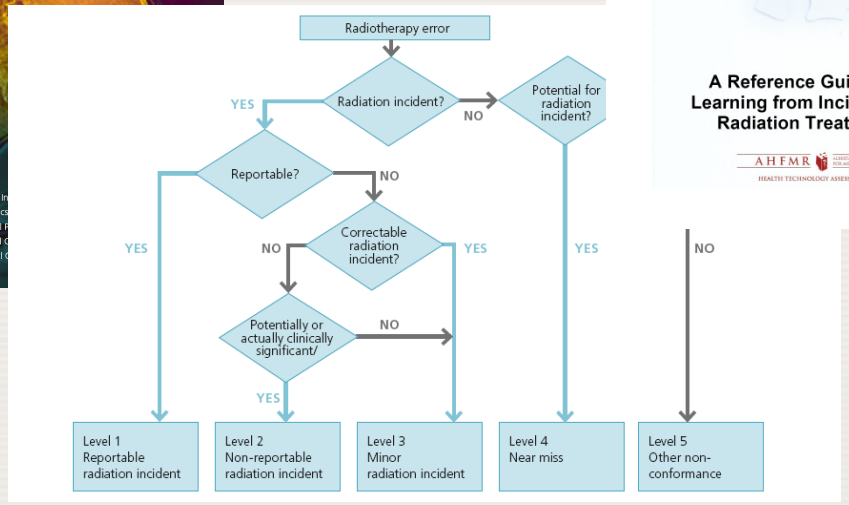
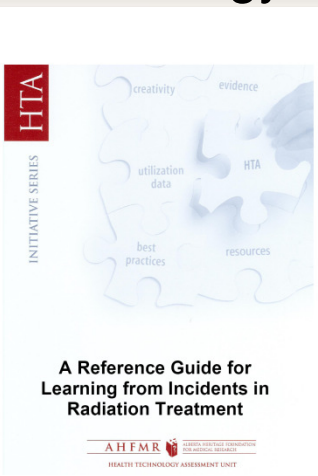
External reporting in practice

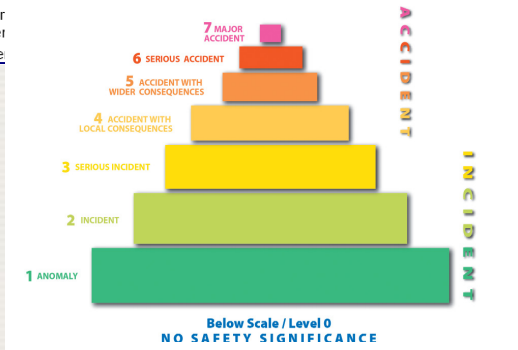
Common terminology for event reporting systems would be of value

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.	*Immediately notify*: 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.).	*Immediately notify*: Senior Management, Manager, Supervisor, Physician
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 poter Patie	Supervisor, Physician*



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Incidents and near-misses

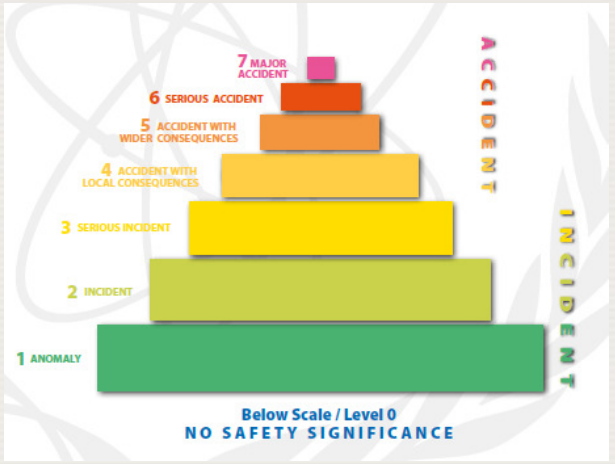
Accident:

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)



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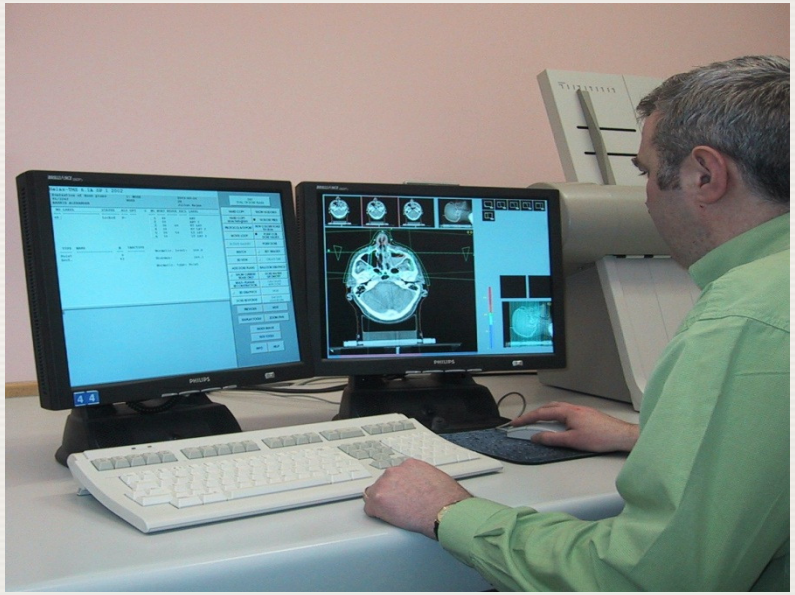
Incidents are important

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%).



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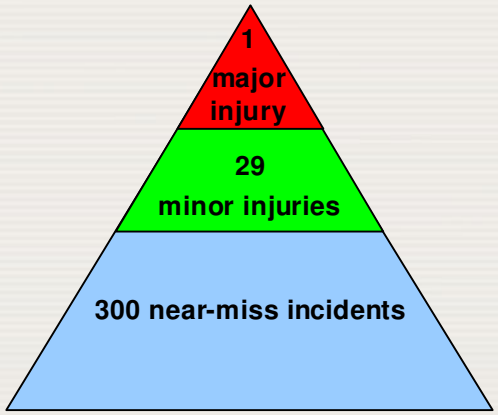
Incidents are important

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)

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Ranking risks

- Risk ranking matrix:

consequence ranges				
catastrophic				
critical				
marginal				
negligible				

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Ranking risks

- Risk ranking matrix:

likelihood ranges / consequence ranges	improbable 10^{-6}	remote 10^{-5}	occasional 10^{-3}	probable 10^{-2}
catastrophic				
critical				
marginal				
negligible				

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Ranking risks

- Risk ranking matrix:

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catastrophic	III	II	I	I
critical	IV	III	II	I
marginal	IV	IV	III	II
negligible	IV	IV	IV	III

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Ranking risks

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risk rank	CATEGORY
I	unacceptable
II	undesirable
III	acceptable with controls
IV	acceptable as is

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Ranking risks

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marginal	IV	IV	III	II
negligible	IV	IV	IV	III

Major systematic accident

risk rank	CATEGORY
I	unacceptable
II	undesirable
III	acceptable with controls
IV	acceptable as is

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Ranking risks

- Risk ranking matrix:

likelihood ranges / consequence ranges	improbable 10^{-6}	remote 10^{-5}	occasional 10^{-3}	probable 10^{-2}
catastrophic	III	II	I	I
critical	IV	III	II	I
marginal	IV	IV	III	II
negligible	IV	IV	IV	III

Non-systematic incident

risk rank	CATEGORY
I	unacceptable
II	undesirable
III	acceptable with controls
IV	acceptable as is

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Incidents and near-misses in practice

- 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

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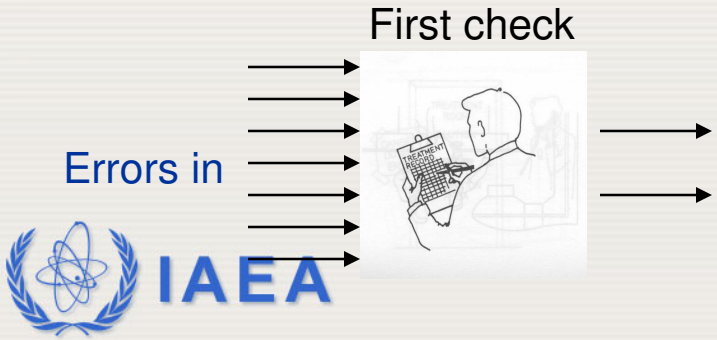
Incidents and near-misses in practice

- 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



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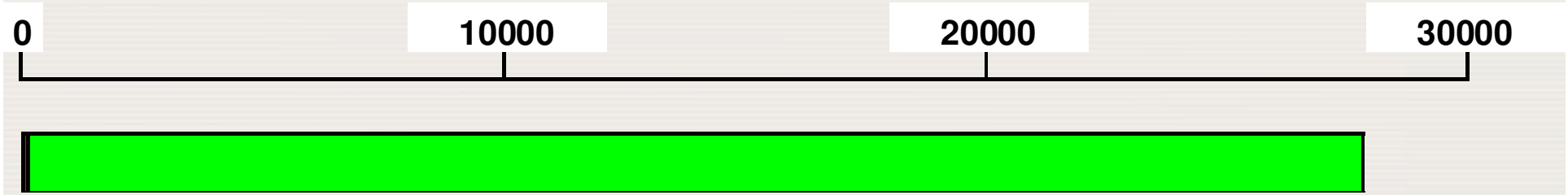
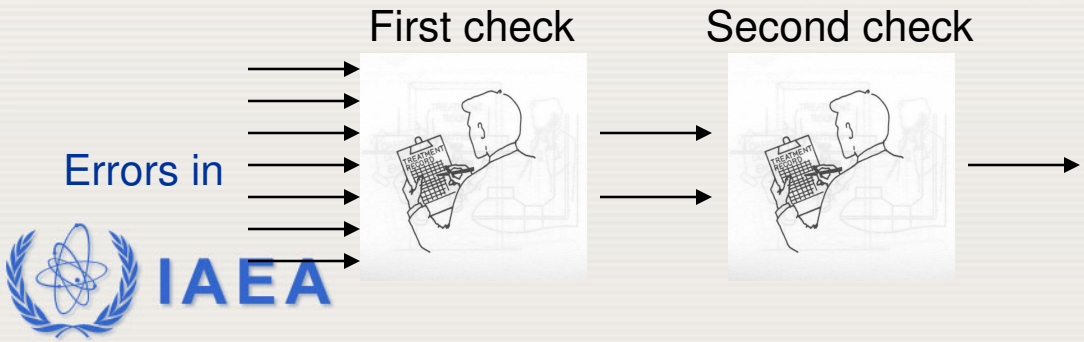


- The second check found mistakes in 0.5% of all charts / treatment plans – 0.3% remained



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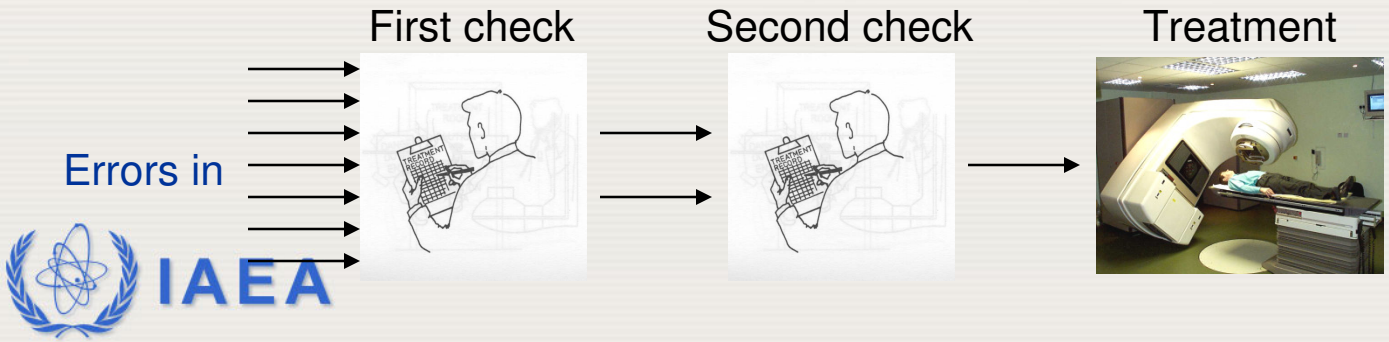

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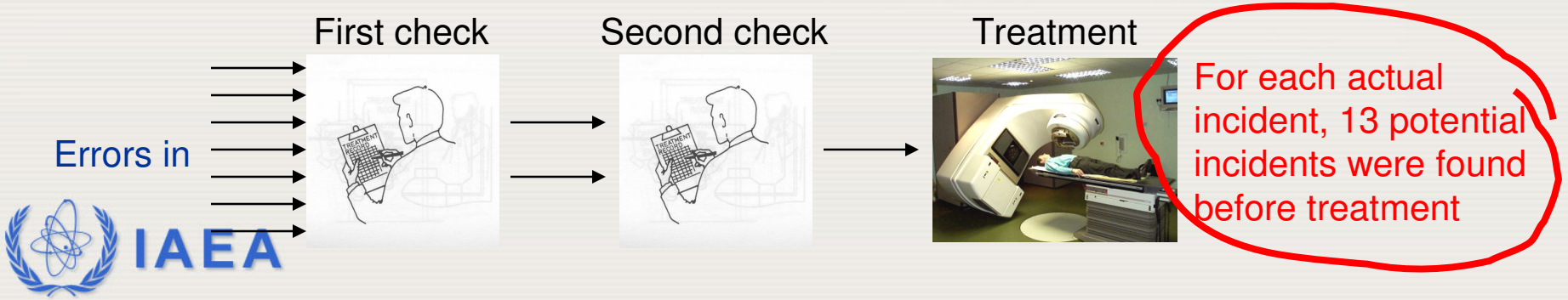

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Safety Improvement Initiatives

A good city wall with properly built bastions can be effective

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HEADQUARTERS
INTERNATIONAL ATOMIC ENERGY AGENCY
Thank You!

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