







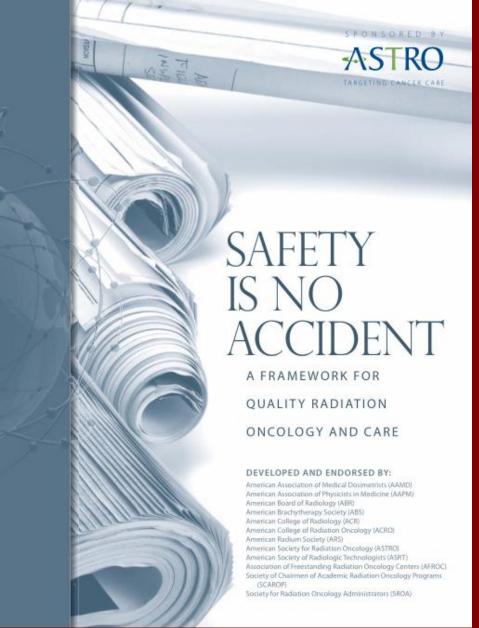
PREVENTION OF INCIDENTS IN RADIOTHERAPY

ICTP School on Medical Physics for Radiation Therapy DOSIMETRY AND TREATMENT PLANNING FOR BASIC AND ADVANCED APPLICATIONS MARCH 27 - APRIL 7, 2017 MIRAMARE, TRIESTE, ITALY

YAKOV PIPMAN, D.Sc.

What did we learn?

- Accidents happen
- When they happen there is more than one factor
- •Many more 'almost accident's than big ones
- Common factors:
 - Training,
 - Communication, internal and external
 - Barriers,
 - Authority To Question (or lack thereof)
 - Lack Of Redundancies
 - Distractions / Attention
 - Procedural Variations
- Lack of clarity in analysis and reports of what happened





Special Article

Improving patient safety in radiation oncology

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aMedical College of Wisconsin, Rochester, Minnesota

Received 5 November 2010; accepted 12 November 2010

Abstract Beginning in the 1990s, and emphasized in 2000 with the release of an Institute of Medicine report, health care providers and institutions have dedicated time and resources to reducing errors that impact the safety and well-being of patients. However, in January 2010, the first of a series of articles appeared in The New York Times that described errors in radiation oncology that grievously impacted patients. In response, the American Association of Physicists in Medicine and the American Society for Radiation Oncology sponsored a working meeting entitled "Safety in Radiation Therapy: A Call to Action." The meeting attracted 400 attendees, including medical physicists, radiation oncologists, medical dosimetrists, radiation therapists, hospital administrators, regulators, and representatives of equipment manufacturers. The meeting was co-hosted by 14 organizations in the United States and Camada. The meeting yielded 20 recommendations that provided a pathway to reducing errors and improving patient safety in radiation therapy facilities everywhere.

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The problem

In the early 1990s, articles began to appear in the scientific literature^{1,2} describing the frequency of medical mistakes that place patients at risk. Soon thereafter, reports surfaced in the public media regarding medical errors (eg, chemotherapy overdose, wrong-sided surgery, anesthesia error) that caused the death or severe disability of patients. Partly in response to these reports, an international conference was held in 1993 (in Rancho Palos Verdes, CA) to examine the causes and consequences of severe errors in medicine. The conference was hosted by the American Medical Association and had several organi-

zational co-sponsors. This conference spawned the National Patient Safety Foundation3 and several other initiatives (eg. the Veterans Administration National Patient Safety Partnership) that devoted substantial resources to the identification and mitigation of medical errors. The National Academy of Sciences Institute of Medicine formed the Committee on Quality of Health Care in America that published a seminal report in 2000. entitled "To Err is Human: Building a Safer Health System.¹⁴ This report estimated that between 44,000 and 98,000 patients died in the United States in 1997 as a consequence of medical errors, and it captured the attention of health care providers and public interest groups. For the past decade, programs to reduce medical errors have been established in most of the nation's hospitals and health care organizations.

Errors are known to occur in radiation oncology. The treatment of cancer patients with radiation is complicated for several reasons: the complexity of the disease, the sophistication of the technologies employed, the

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^bDepartment of Radiation Oncology, Mayo Clinic, Rochester, Minnesota

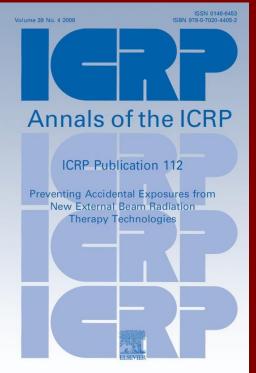
This article is being published simultaneously in the January issue of Medical Physics.

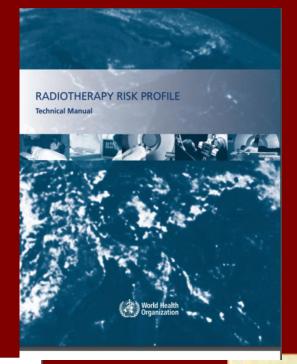
Conflicts of interest: None.

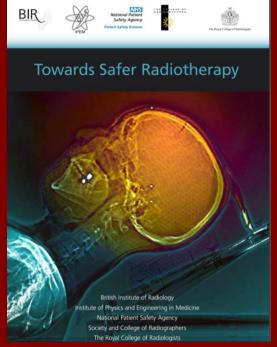
^{*}Corresponding author. Department of Radiation Oncology, Mayo Clinic, 200 First St SW, Rochester, MN 55905.

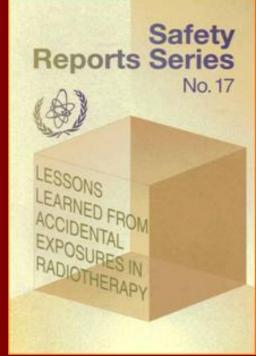
E-mail address: herman.michael@mayo.edu (M.G. Herman).

doi:10.1016/j.prro.2010.11.003









What can we do?

Abundant Recommendations

Report	Advice
Towards safer Radiotherapy	37
Radiotherapy Risk Profile	15
Preventing Accidental	15
Hendee and Herman	20
Heirarchy of Actions	19
ASTRO	6
TG 100	5
Total	117

Recommendations for safer radiotherapy: what's the message?

Peter Dunscombe*

Education/Training (7)

Staffing/skills mix(6)

Documentation/SOP (5)

Incident Learning System (5)

Communication/questioning (4)

Check lists (4)

QC and PM (4)

Dosimetric Audit(4)

Accreditation (4)

Minimizing interruptions (3)

Prospective risk assessment (3)

Safety Culture (3)

What can we do?

Education and Training

Multilayered prevention

Risk assessment – (FMEA)

Learning and Reporting Systems

Analyzing – Root Cause Analysis (RCA)

Safety Culture

IAEA Training Course

https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/AccidentPreventionRadiotherapy.htm

PREVENTION OF ACCIDENTAL EXPOSURE IN RADIOTHERAPY

Part 5: Reporting, investigating and preventing accidental exposures



Preventing accidental exposures

Communication

There should be clear and concise written rules for communication critical to safety. These rules should be posted and understood.

- Example: Handing over an accelerator to a physicist following maintenance should be formalized and adhered to. (e.g. case history on incorrect repair followed by insufficient communication – Spain, 1990)

Documents critical to safety, for example prescriptions, basic data and treatment plans, should be signed by staff who are responsible and qualified.

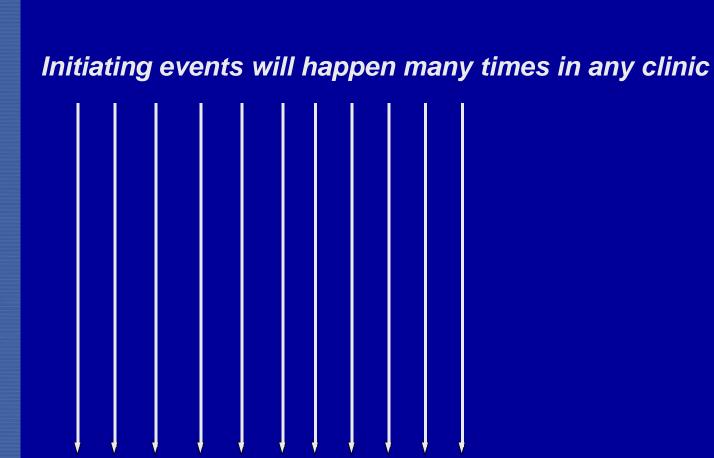


- The term "defence in depth" is defined in the BSS as "the application of more than one single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fail".
- "Defence in depth" can be viewed as several layers of safety provisions, such as physical components and procedures.

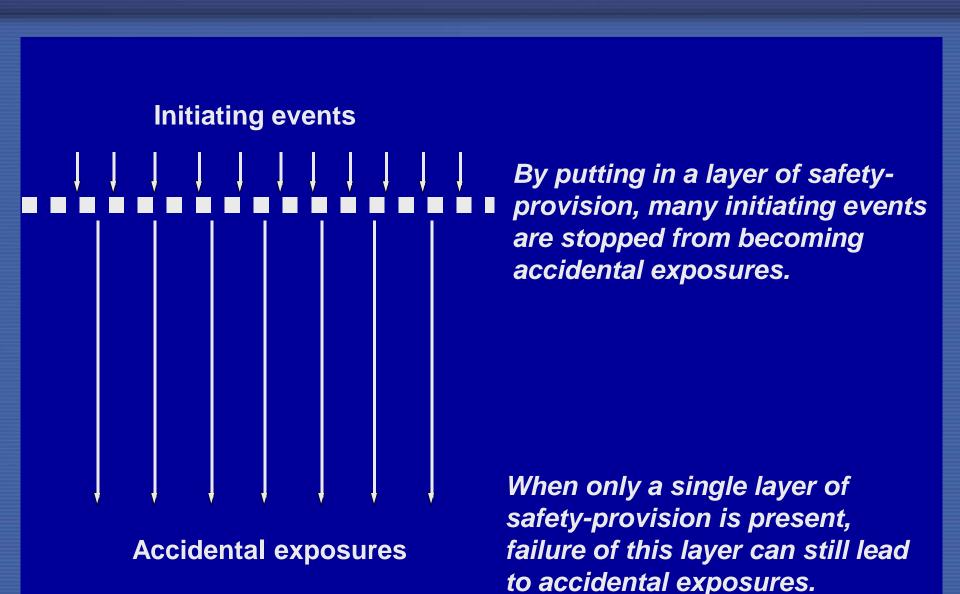


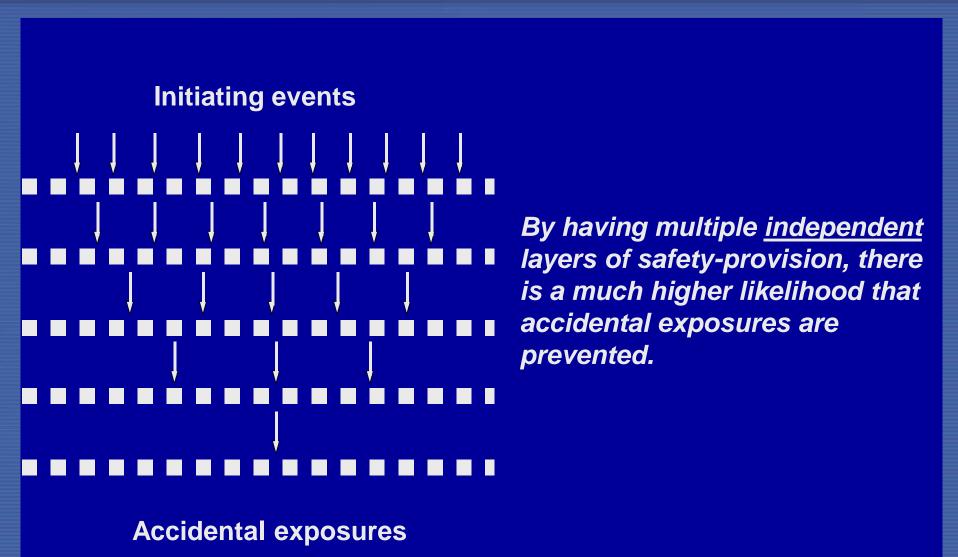
- Multilayered prevention includes aspects of "defence in depth" but also includes aspects such as awareness and alertness which could be termed "conceptual defence"
- For this multilayered prevention of accidental exposures to work, these layers need to be independent of each other.
- An implemented Quality Assurance program might provide the layers. Part of the QA should be to verify that this is the case!



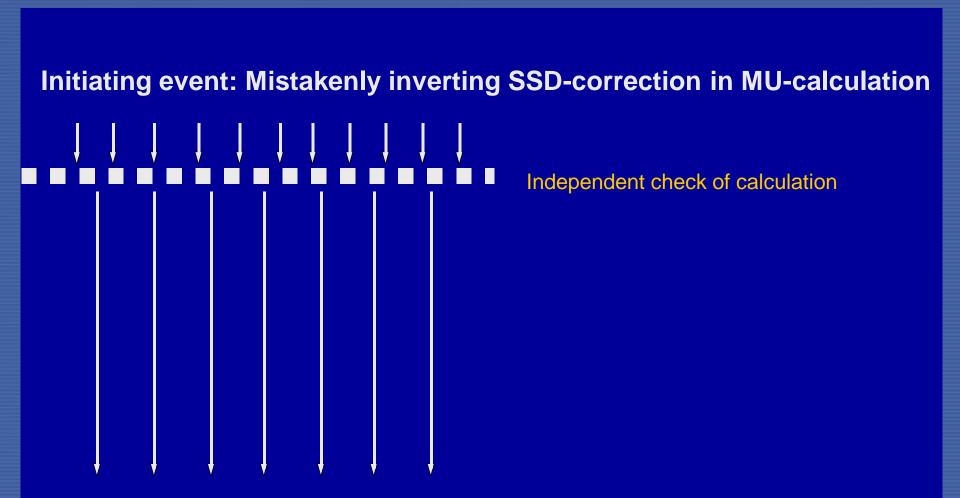


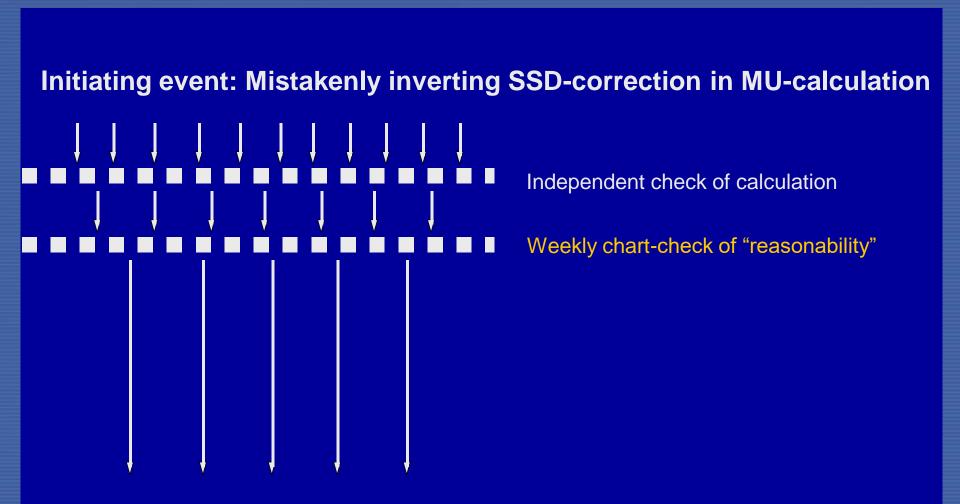
If there are no layers of safety provision, these events will lead to accidental exposures

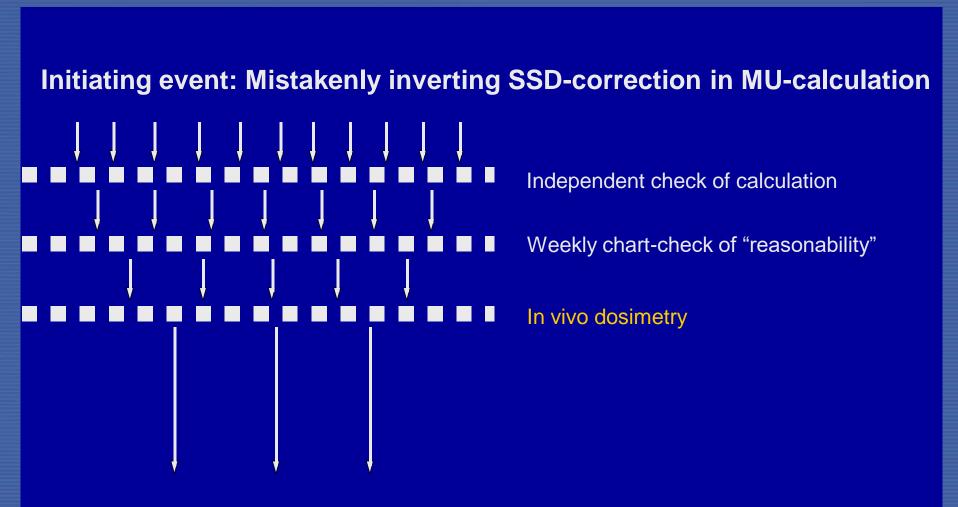


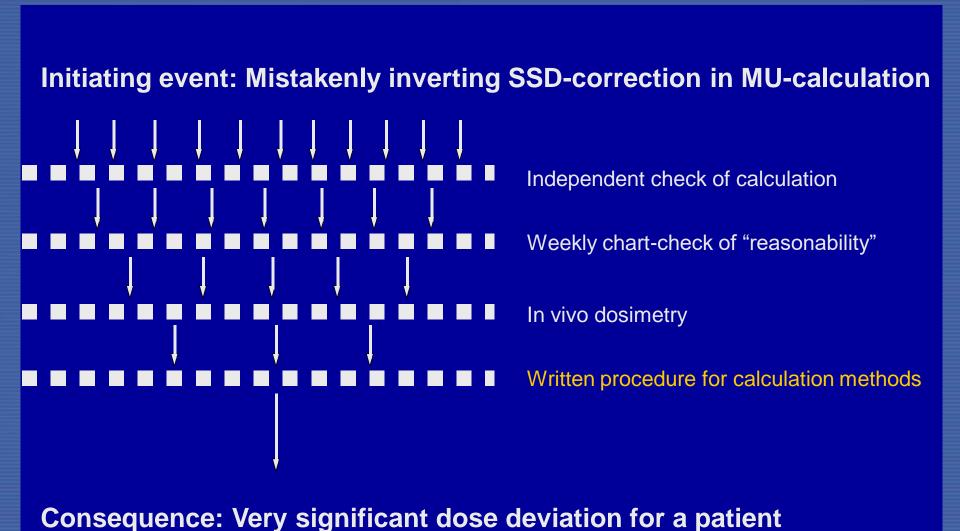


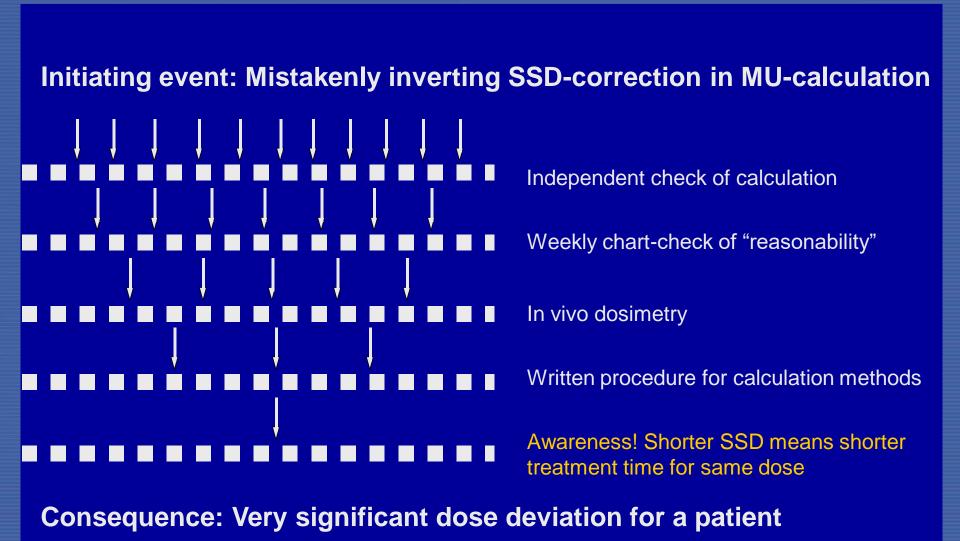


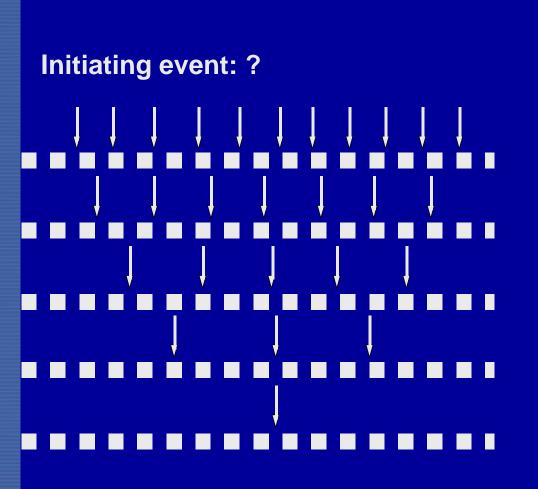












TRY IT AS AN EXERCISE!

Examples of initiating events:

Calibration of beam made in penumbra

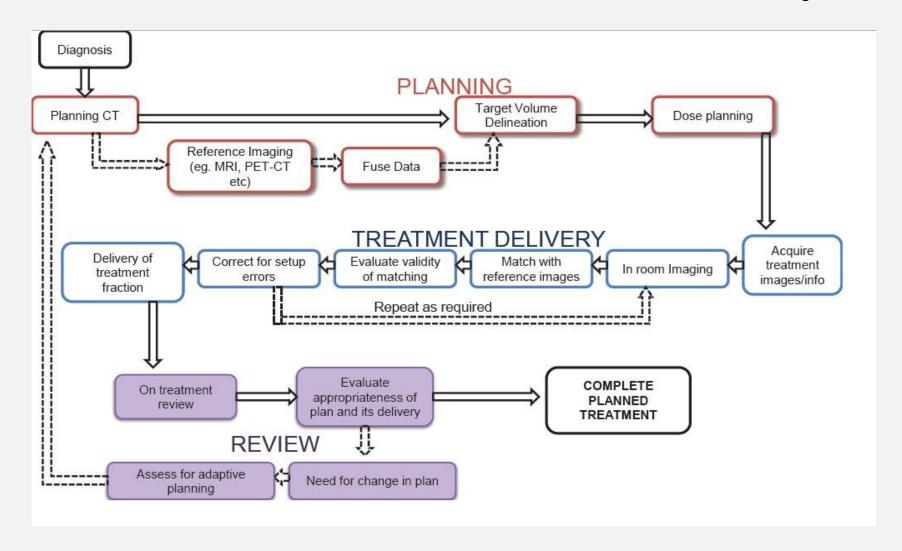
Pancake chamber used upside down

Use of wedge factor twice in calculation of treatment time

Misunderstanding of verbal prescription

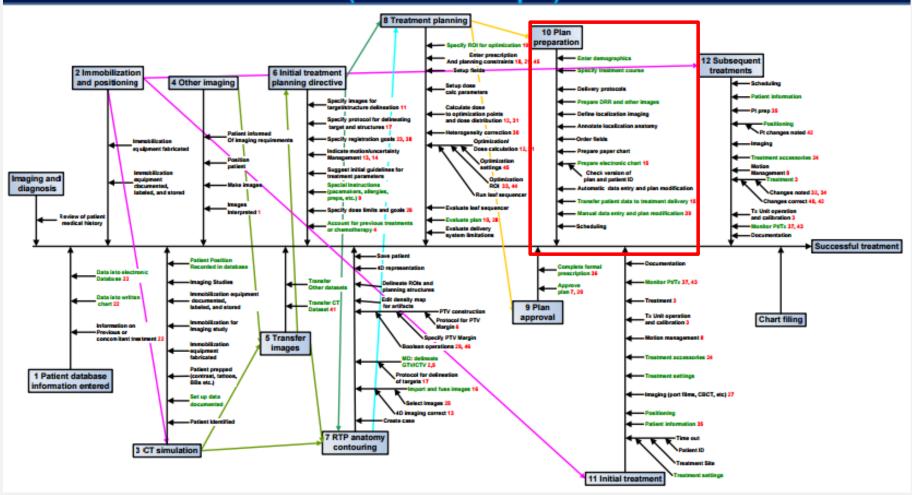
Consequence: ?

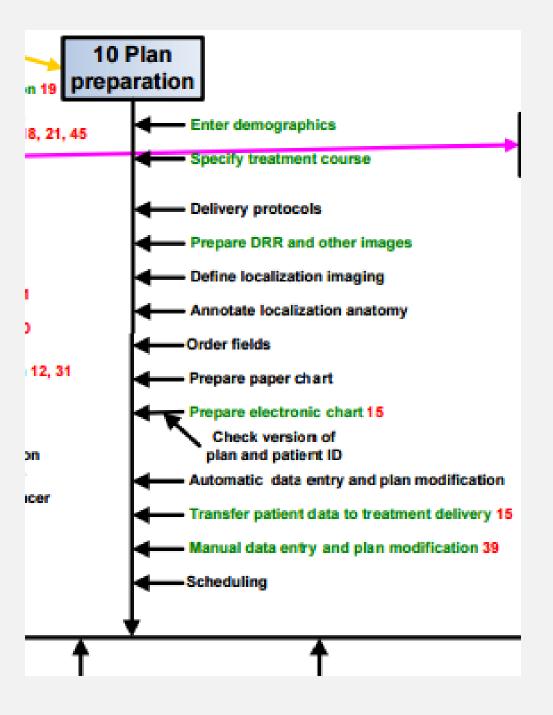
To Create Barriers, we use Process Maps



Process Map for IMRT

(TG 100 Example)





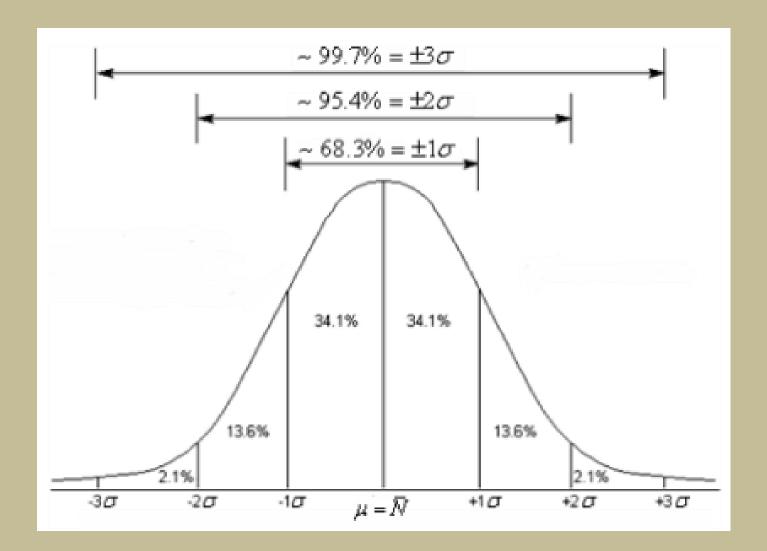
What is Safety?

- The absence of an unacceptable risk of harm.
- O What is harm in RT?
 - excess morbidity
 - sub-optimal tumour control.

Quality in Radiotherapy

The degree to which radiation therapy is consistent with current professional knowledge:

- The prescription is appropriate, i.e. evidence based
- The prescription is delivered within tolerances determined by consensus in the profession



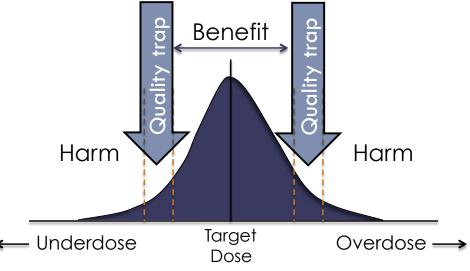
Is Safety an issue in Radiotherapy?

	"Serious" Incidents per course
New York State	0.012%
Varian	0.002%
UK	0.003%

The chance of dying or being injured on a U.S. domestic flight is about 0.00001% - Ford and Terezakis IJROBP 2010

How many patients fall into the "Quality Trap"?

There are about 750,000 patients receiving RT per year in the U.S.



At 0.01% that would be 75 serious accidents per year in the US alone!

If we ignore retreats, that is approximately 750,000 courses per year.

2.6% of 750,000 is about 20,000



Department of Radiation Oncology TREATMENT VARIANCE REPORT

Reported on _ Patient ID:	_//200_ Reported by; Attending M.D.:	<u> </u>	Occurrence date(s)://200 Assigned Physicist:	وا
Details:	Blocks / MLC / MU / Wedglation / Plan / # of Fx's / I Other	ges / Geom	etry / Energy / Mode / Setup / Mad	hine/
Descriptio	Therapist(s): on of Variance (repor	rting staff):	
Summary	of Variance analys	is (Physi	rs) (report attached	I D
	EFFECT CATEGORY	1	REPORTING CLASS	4
-	Prevented Corrected		Minor Recordable	
	Uncorrectable		Misadminis tration	
DEPARTM Comment	IENTAL REVIEW:		Date;//20	0_
Correctiv	e action:			

Variance?

 A difference between what is expected and what actually occurs.

 An event that departs from the normal, the routine or from what we expected.



What information we collected?

	Department of R	Radiation Oncology
	TREATMENT VA	RIANCE REPORT
Reported on//200_	Reported by:	Occurrence date(s)://200_,
		Assigned Physicist:
		etry / Energy / Mode / Setup / Machine/
		's/ Machine function / Identification
Description of Variance		
	BOVE SECTION TO BI	E COMPLETED BY REPORTER

What did we do with it?



- Bring to the attention of the attending Physician since s/he is ultimately responsible for the patient's treatment
- As the case may be, bring to the immediate attention of a supervisor or Physics.
- "Treatment Variance" forms are collected by Sherin



What did we do with the information?

- Analyze the specifics of the variance with three goals in mind
 - What is the effect on the patient
 - Is there a lesson to learn and changes to be made
 - What reporting category does the variance fall into.



Each case would be evaluated by the QA team, and the analysis reported

Uncorrectable



nmary of Variance analysis (Physics)		cs) (report attach	(report attached[])	
EFFECT CATEGORY	√	REPORTING CLASS	1	
Prevented		Minor		
Corrected		Recordable		

THE ABOVE SECTION TO BE COMPLETED BY PHYSICS



Misadministration

When evaluating the significance of an error, its effect has to be evaluated on the assumption that the patient's treatment will be solely determined by that particular error.

A measure, or action, is <u>truly</u> <u>redundant</u> if it can perform its function as if there was no other system or action in place.

Proposed Corrective Action and Discussion

- Let's change "xy"
- We should replace "yzz" with "rstuv"
- The last person to "zxttt" will do "abcd"
- We will never again "defgh"!





Monthly Presentation to the departmental QA Committee



Effect Category	- 44	Dan	orting Class	Ι.,
Number of cases reviewed: _ Number of cases identified: _	I16	elds	ESTV 's	
OVERALL ANALYSIS:	~	1.1	POTE	

Effect Category	#	Reporting Class	#
Prevented		Minor	
Corrected		Recordable	
Uncorrectable		Misadministration	

SPECIFIC CONCLUSION:

ACTION:

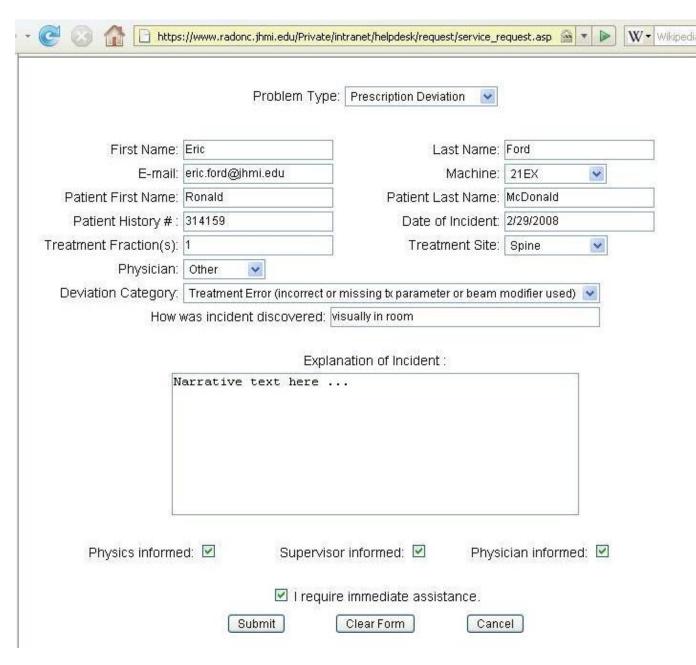
Newer incident reporting systems

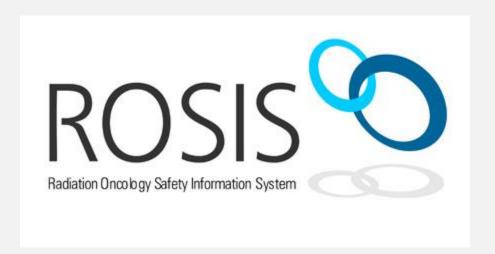
- ■In-house web-based system available since 2007
- Includes near-misses
- 600 "minor incident"

for every 1 "critical

error"

(Bird and Germain 1996)





http://www.rosis.info/index.php

About ROSIS

ROSIS, an acronym for Radiation Oncology Safety Information System, is a patient safety tool specific to radiation oncology. It was established in 2001 under the auspices of the professional body "European Society of Therapeutic Radiology and Oncology" (ESTRO), and has successfully established an international voluntary incident and near incident reporting system, a supporting website and an annual teaching course on Patient Safety in Radiation Oncology.

abornama rabotrore

Home About Us ROSIS Safety Information ROSIS Workshops Spotlight Cases Register Your Clinic Submit A Report ROSIS Publications ROSIS Discussion Forum

http://www.rosis.info/



DEPARTMENT REGISTRATION FORM

Radiation Oncology Safety Information System a voluntary reporting system for radiation oncology

The first step in becoming an active ROSIS participant is registration.

This means that you must first complete and return this registration form giving details of your clinic and the local contact person/people who will be responsible for submitting reports. This will be the only time that you will be asked for this information.

General Information
Infrastructure(Equipment, etc)
QA procedures
Risk management (Reporting system, etc)

http://www.rosis.info/docs/Registration_Form_March_11.pdf

Incident ID	Date	Summary	_
1372689757	1-7- 2013	being miss-ray treatment by not correct adjusted target volume	
1366098290	16-4- 2013	High density materials in IGRT carbon fiber tabletop interface to the head and neck Posifix extension.	
1347270437	2012	Pt was scheduled for IMRT treatment 25 x 2 Gy. The IMRT planning was accidently done with a number of fractionations of 16 (as is also often used for treatment of the breast; 16 x 2.66Gy). The planning objectives was 50Gy in the PTV, as intended. Thus, 50 Gy was planned in 16 fractions instead of 25, resulting in a fraction dose of approx 3.13 Gy. The plan (field sizes, MU etc) was sent to the R&V system, but not the number of fractions. This is not possible with the current configuration of the R&V system. The fields were checked but the discrepancy between planned and intended number of fractions was not noted. The patient received 25 x 3.13 Gy = approx 78.25 Gy instead of 50Gy. The patient also received a boost (planned 8 x 2Gy). Due to severe skin reaction the treatment was checked and the error found. The last fraction of the boost was omitted.	
1343040776		Wrong treatment couch height selected due (SSD too large) to unusual treatment technique/geometry. Thoracic wall irradiation was interpreted as mamma irradiation.	
			1 *

Pipman, Yakov Sign Out

Dataset: All incident reports

Home

Process Steps

Incident Reports

Documents and Links

Help

Safety Reporting and Learning System for Radiotherapy

SAFRON is voluntary and aims to enable global shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy. SAFRON is provided by the IAEA.



Actions

Browse Safety Info by Process Step >

Search for Incident Reports >

Search for Documents & Links >

Request Registration >

View Instructions >

Featured Incident Reports

Plan with two isocenters, patient is not repositioned in between

Craniospinal irradiation with three isocenters. Spinal field had two isocenters. Patient was not repositioned for one fraction and part of the upper spine got 100% higher dose than intended and lower...

Isocentre Co-ordinates in Mosaiq incorrect, and first

Featured Documents & Links

Quantitative cone-beam CT imaging in radiation therapy using planning CT as a prior: first patient

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

Automatic patient alignment system using 3D



Information and Instructions for Registering with NUCLEUS

Prior to registering with Safety Reporting and Learning System for Radiotherapy (SAFRON), the registrant must register with NUCLEUS, the Agency's information resource catalogue. The link to NUCLEUS is: http://nucleus.iaea.org/Home/index.html

Instructions for Registering with SAFRON

SAFRON is an integrated voluntary reporting registry of radiation oncology incidents and near misses. Its success is dependent on facilities registering and sharing incidents that occur in their institutions. The registration form includes details on the equipment, staff and environment in your centre. This information indicates the complexity of the processes within departments. It will be used to carry out trend analyses of incidents in relation to complexity of practice, working environment and educational background of professional staff in a range of clinic types. The information will not be seen by other users of SAFRON.

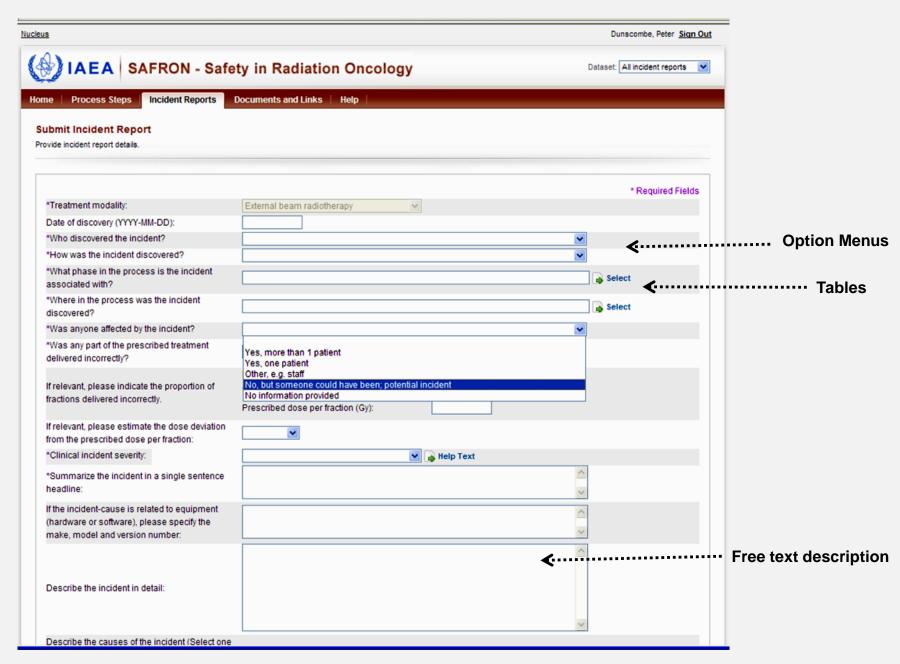
https://rpop.iaea.org/SAFRON/StaticContent/safron-instructions.pdf



- 1. Non-clinical phase
- 2. Pre-treatment phase
- 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

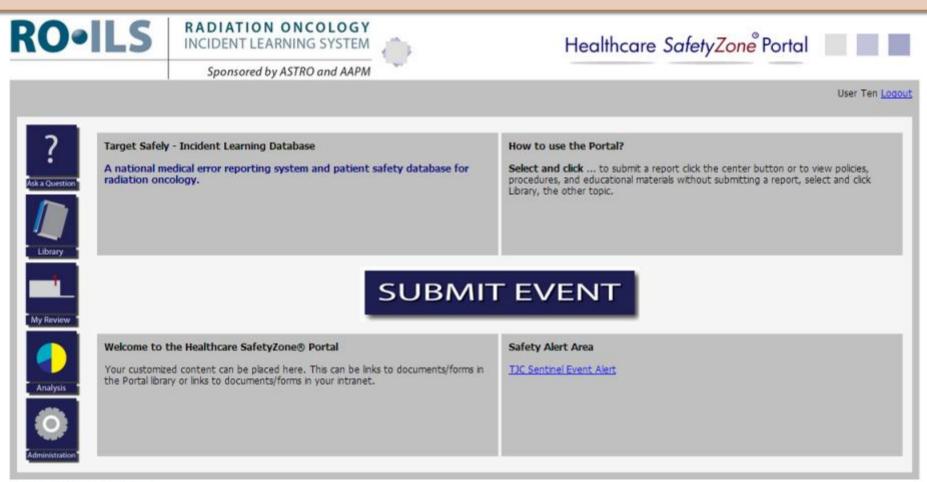
*Number of staff:	*Radiation oncologists (physicians):	
	*Medical physicists:	
	*Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at treatment units treating patients:	
	*Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at simulator and/or in-house CT:	st
	*Staff doing dosimetry i.e. treatment planning etc:	
	*Staff doing technical maintenance on radiotherapy equipment:	
*How is most of your equipment maintenance performed?	•	
Safety infrastructure in place at the clinic: (Select all that apply to your clinic)	There are documented policies and procedures for most of the clinical processes There are written policies and procedures for equipment quality control (including software) There are appropriate education and training for staff There is a committe with responsibility for on-going quality and safety improvement	
Safety barriers in place at the clinic: (Select all that apply to your clinic)	□Verification of patient ID □Verification that pretreatment condition have been taken into account □Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	
	Verification reference points	
	Physician peer review	
	Review of treatment plan	
	☐Independent confirmation of dose	
	☐Time out	
	Use of record and verifying system	
	Verification of treatment accessories	
	☐Image based position verification	
	□ In vivo dosimetry	

https://rpop.iaea.org/SAFRON/ClinicRegistration/ClinicRegistrationEdit.aspx



ASTRO and the AAPM (2014) - medical specialty society sponsored radiation oncology PSO.

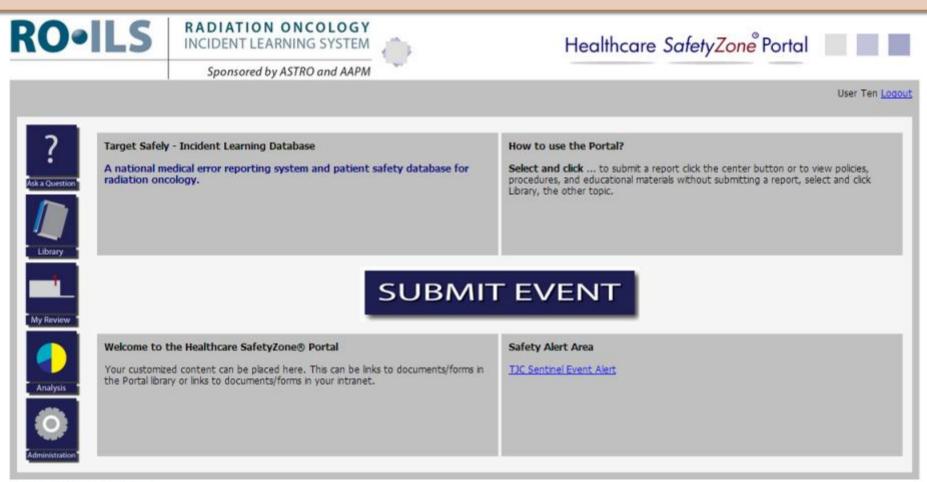
Goal: Educate the radiation oncology community on how to improve safety and patient care.



Clarity Group, Inc. Copyright @ 2013

ASTRO and the AAPM (2014) - medical specialty society sponsored radiation oncology PSO.

Goal: Educate the radiation oncology community on how to improve safety and patient care.



Clarity Group, Inc. Copyright @ 2013

What to Report or Track

- Explicit events frequent events
- Random events
- Actual errors
- Potential errors (near misses)
- Corrective measures





Incident Reporting Depends on Factors

- Culture
- Reporting system and guidelines
- Competence to interpret reported data
- Willingness to implement
 - Changes based on collected data and analyses
- Ability to share data and provide feedback
 - Power distance index





Organizational Culture

Pathological Culture	Bureaucratic Culture	Generative Culture
Do not want to know	May not find out	Actively seek it
Messengers (whistle blowers) are "shot"	Messengers are listened to if they arrive	Messengers are trained and rewarded
Responsibility is shirked	Responsibility is compartmentalized	Responsibility is shared
Failure is punished or concealed	Failures lead to local repairs	Failures lead to far reaching reforms
New ideas are actively discouraged	New ideas often present problems	New ideas are welcomed

Reason, J., Managing the risks of organizational accidents. Different organizational cultures





Final Disposition

- Resolution and corrective action
- Responsible person
- Implementation plan
- Evaluation plan
- Follow up plan

ute received: 2,005/6 eport Index: <u>IRF</u>			
epon muex			CANCER CENTRE DENT REPORT - INVESTIGATION
Incident: an unu			nal system behavior, which causes, or has a potential to
	effect to persons		an system ownersor, which course, or his a potential to
Administrative	information		Incident Impact (Complete all that apply)
Persons interview	ed:	15	Patients:
	ame	Date interviewed	# patients affected: 1
Floor Therapist		2005/06/02	·
Calo room. Then	pist	2005/06/02	# fractions per patient affected: 1
		YYYY/MM/DD	# fields per fraction affected: <u>1</u>
		YYYY/MM/DD	Deviation from prescribed dose: <u>minimal</u>
		YYYY/MM/DD	Deviation from prescribed volume: <u>nainimal</u>
Verification of		ant information	Dosimetrist/medical physicist who analyzed incident:
Please indicate by	preliminary repo either sergement or	r a revised response for	Name: P. Dosinetrist Date: 2005/06/05
each element of th			
Info	Agreement	Revised Response	Signature: P. Doslivactrist
Warrants incident report	٧		Name: Date: YYYY/MM/DD
manual report	4	_	
Who			Signature:
Who What	4		Persons:
What	4		Persons: Yes No
	4		Persons:
What Where When	4		Persons: Yes No
What Where When Initial severity	√ √ Minor		Persons: Yes No B First Aid required
What Where When Initial severity classification*	√ √ Minor	nal people notified:	Persons: Yes No Thirt Aid required Medical attention required
What Where When Initial severity classification*	√ √ Minor	nal people notified:	Persons: Yes No S First Aid required Medical attention required Hospitalization required
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What Where When Initial severity classification*	√ √ Minor	nal people notified:	Persons: Yes No S First Aid required Medical attention required Modical attention required G Ongoing treatment therapy required (staff) days of work lost:
What Where When Initial severity classification*	√ √ Minor	nal people notified:	Persons: Yes No S First Aid required S Medical attention required S Logical attention required S Cogning treatment therapy required S Capting treatment therapy required S (satisf) days of treatment lost:
What Where When Initial severity classification* *If initial severity.	A Minor revised, list addition	nal people notified:	Persons: Yes No Signature State Stat
What Where When Initial severity classification* *If buttal severity. Related docum	√ √ Minor revised list addition	nal people notified:	Persons: Yes No Statistical attention required Medical attention required
What Where When Initial severity classification* *If initial severity.	√ √ Minor revised list addition	not people notified:	Persons: Yes No Similar First Aid required Medical attention required Medical fides of work lost Mesources: Total overtime hours (TBCC staff): Total down (outside service): Replacement/repair costs:
What Where When Initial severity classification* *If buttal severity. Related docum	√ √ Minor revised list addition	nat people notified:	Persons: Yes No Similar Aid required Medical attention required Hospitalization required Ongoing treatment therapy requi
What Where When Initial severity classification* *If buttal severity. Related docum	√ √ Minor revised list addition	not people notified:	Persons: Yes No Signature
What Where When Initial severity classification* *If buttal severity. Related docum	√ √ Minor revised list addition	nal people notified:	Persons: Yes No Similar Aid required Medical attention required Medical attention required Ongoing treatment therapy required Similar of medical treatment therapy required Resources: Total overtime hours (TBCC staff): Total hours (outside service): Replacement repair costs: Total hours for incident analysis: Additional costs: Operations:
What Where When Initial severity classification* *If buttal severity. Related docum	√ √ Minor revised list addition	not people notified:	Persons: Yes No Signature





Root Cause Analysis - when

- 1. Any single obviously serious event
- 2. Systematic events
- 3. High frequency sporadic events

Root Cause Analysis - how

- 1. Collect information WHAT happened
- 2. Identify causes WHY, WHY, WHY, WHY, WHY
- 3. Recommendations for remediation
- 4. Implement and Monitor

Incident Reporting and Learning systems must be:

Friendly for reporting Responsive Dynamic

Safety culture - free of fear

MANY TOOLS!!

Safety culture - free of fear

Incident Learning systems-Friendly for reporting, responsive and dynamic

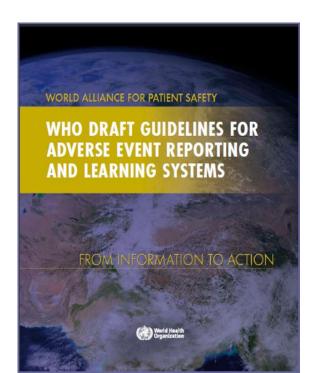
Root cause analysis methods

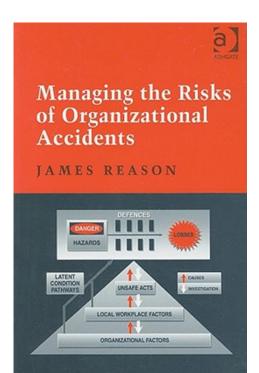
Check lists

Standard procedures and handoffs

Resources

- IAEA -> http://www.iaea.org/
- Lessons learned from accidents in radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).
- ICRP-> Prevention of accidental exposures to patients undergoing radiation therapy. Publication 86, Volume 30 No.3 (2000)
- AAPM > http://www.aapm.org/
- ASTRO -> https://www.astro.org/
- TreatSafely -> http://www.treatsafely.org/index.php
- AHRQ (Agency for Healthcare Research and Quality)
 - http://www.ahrq.gov/patients-consumers/care-planning/errors/index.html





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