Incident Learning Systems in Radiation Therapy

SAMs Session

AAPM 2014 Spring Clinical Meeting, Denver, CO

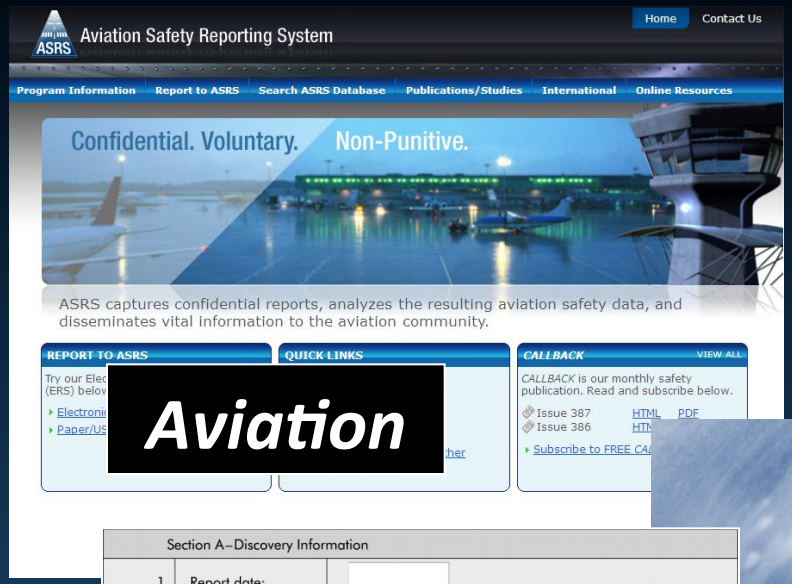
Sunday 7:30-9:30 am

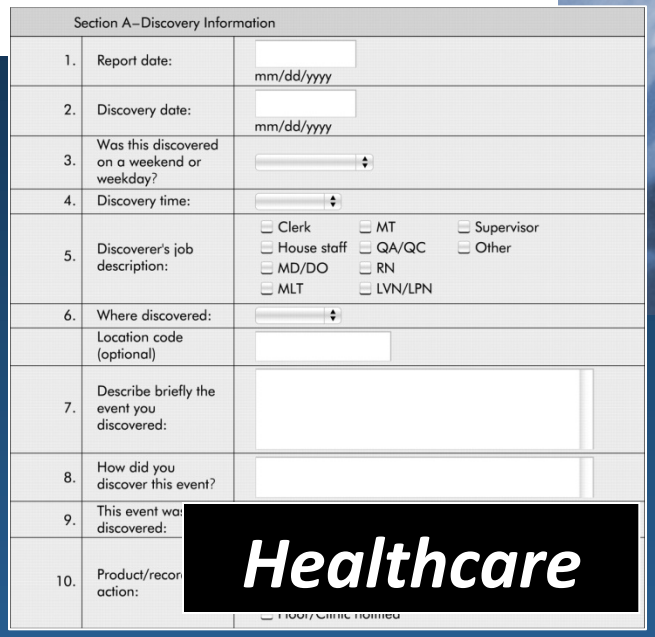
March 16, 2014

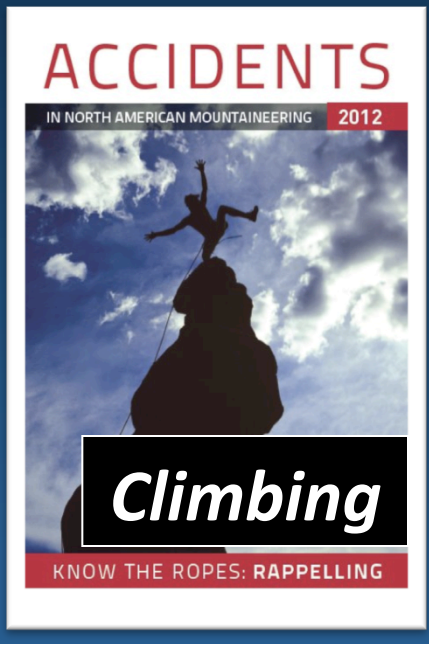
Disclosures

- Debbie Gilley
  - None
- Gary Ezzell
  - None
- Eric Ford
  - R18 HS22244-01

Incident Learning

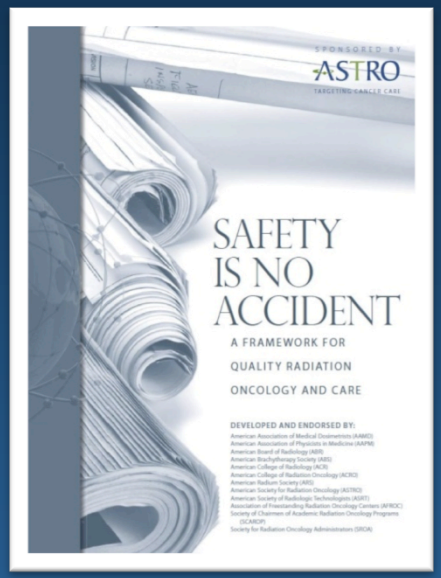






Incident Learning: Why Participate?

- ✓"Each department should have a department-wide review committee which monitors quality problems, near-misses and errors."



- ✓"Employees should be encouraged to report both errors and near-misses."

Safety is No Accident, Zietman et al. 2012

Incident Learning: Why Participate?

- **ASTRO report 2012**

  Safety is No Accident: A Framework for Quality Radiation Oncology and Care. Zeitman A, Palta J, Steinberg M. ASTRO; 2012

- **AAPM white-paper 2012**

  Consensus recommendations for incident learning database structures in radiation oncology. Ford EC, Fong de Los Santos L, Pawlicki T, Sutlief S, Dunscombe P. Med Phys. 2012;39(12):7272-90.

- **ASTRO safety white-papers**

  Safety considerations for IMRT: Executive summary. Moran JM, Dempsey M, Eisbruch A, Fraass BA, Galvin JM, Ibbott GS, et al. Pract Radiat Oncol. 2011;1(3):190-5.

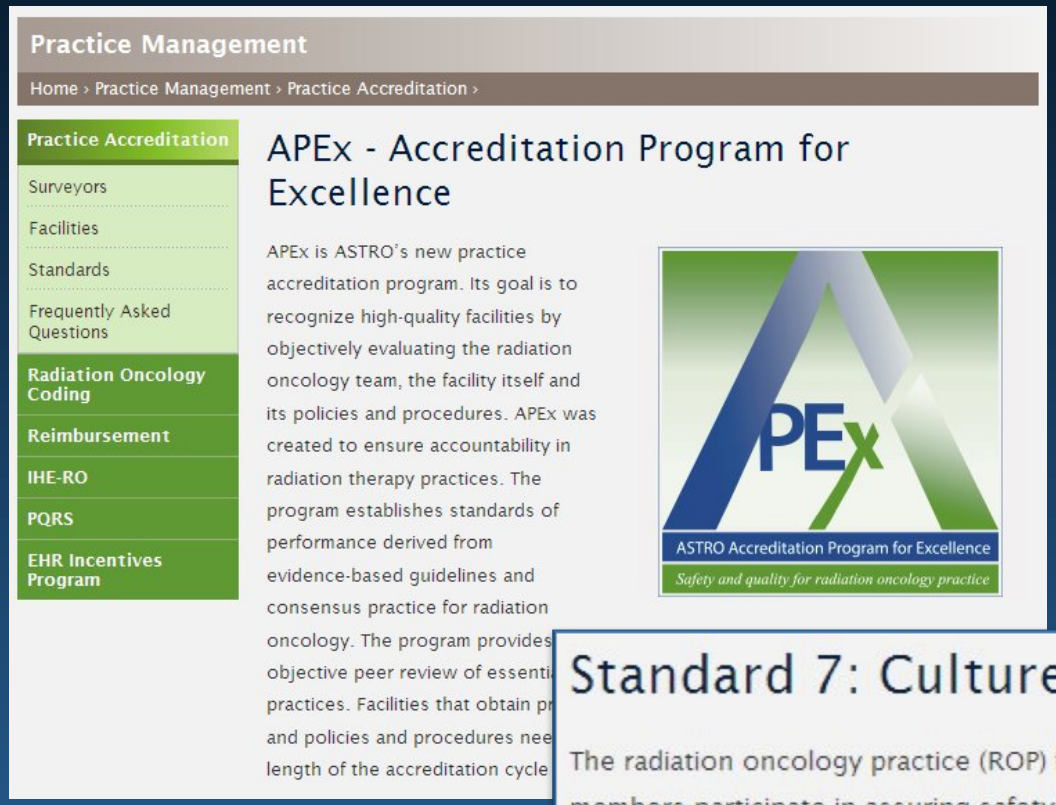
  Assuring safety and quality in image-guided delivery of radiation therapy. Jaffray D, Langen KM, Mageras G, Dawson L, Yan D, Adams R, et al. Pract Radiat Oncol. 2013;in press.

- **ASRT safety white-paper**

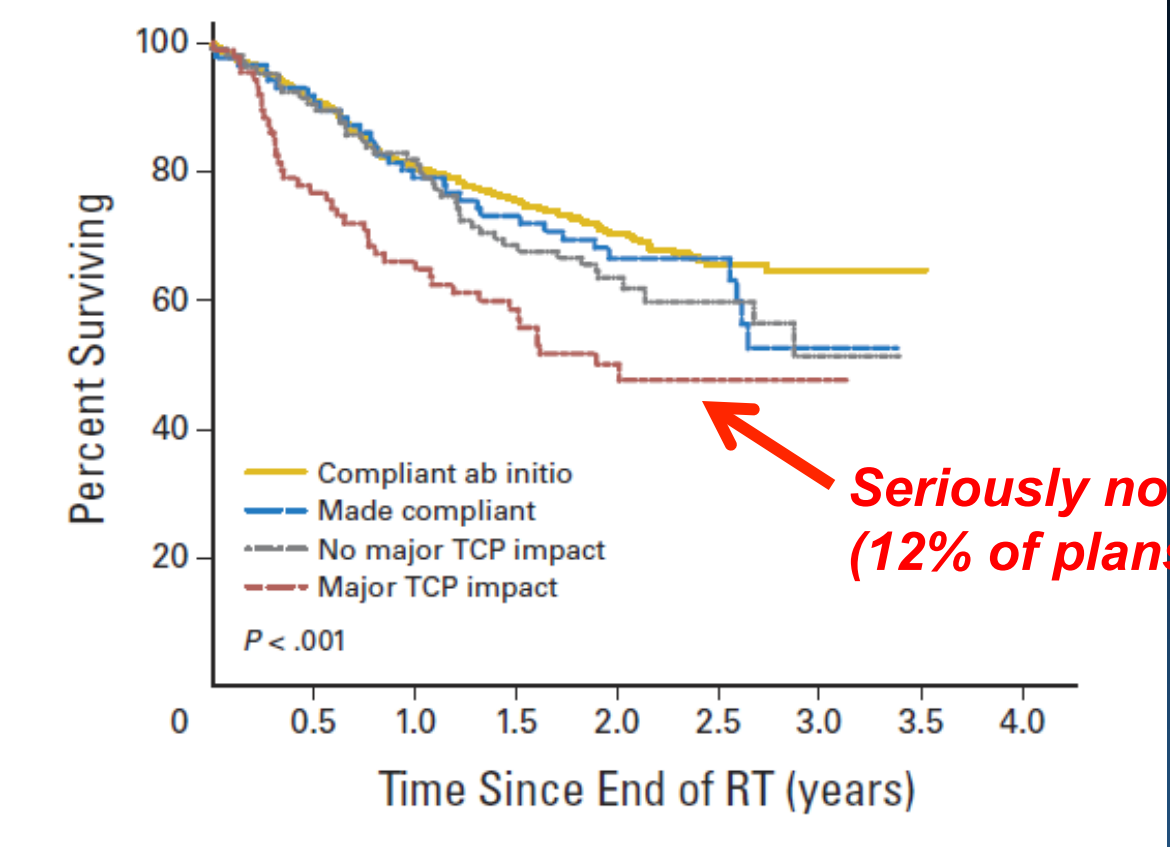
  Radiation Therapy Safety: The Critical Role of the Radiation Therapist. Odle, T, Rosier, N. ASRT Education and Research Fnd. 2012.

Incident Learning: Why Participate?

A key component of practice accreditation



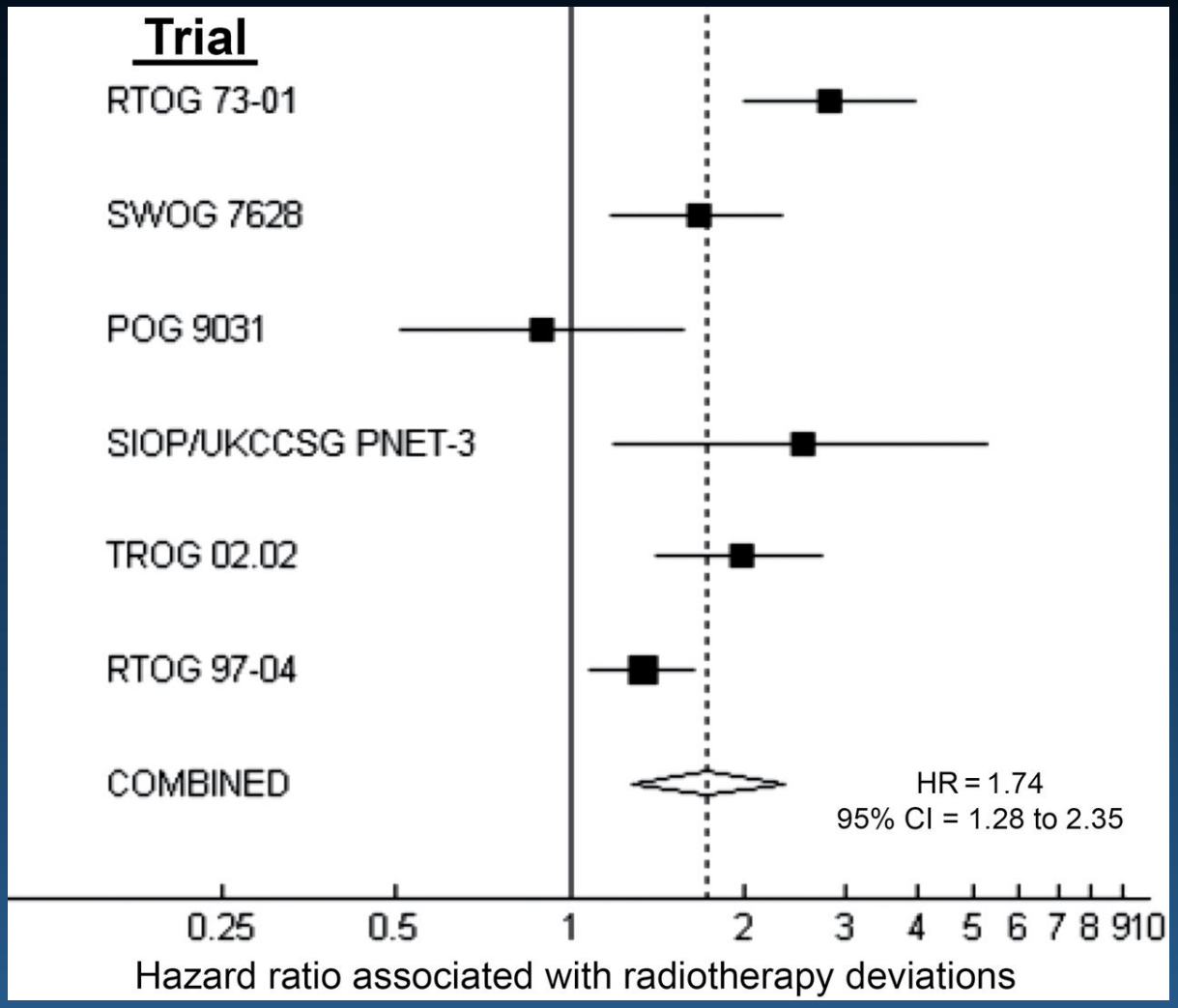
Quality and Outcomes in RO



Seriously non-compliant (12% of plans)

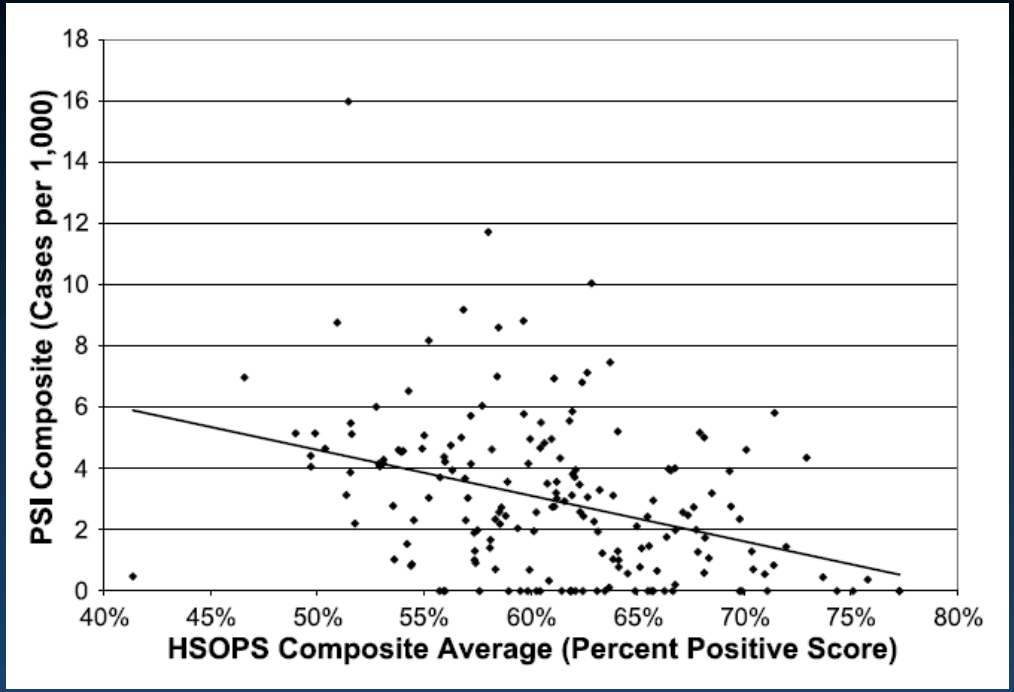
Peters et al. JCO, 28(18), 2996, 2010

Protocol deviations and overall survival



Ohri N et al. J Natl Cancer Inst, 105, 387 (2013)

More reports = Safer



Mardon et al. AHRQ, J Patient Saf, 6, 226-232, 2010

NUMBER OF REPORTS vs. NUMER of patient safety incidents
***R^2* = 0.33 *p*<0.001**

Incident Learning: Why Participate?

- Data linking treatment quality to patient outcomes
- Recommended at the society level
- Data suggests more reports = safer

The following sources recommend incident learning for near-miss events:

20%	1. Code of Federal Regulation 10CFR20
20%	2. NRC Regulations
20%	3. ASTRO Safety is No Accident Report
20%	4. State Reporting Guidelines from CRCPD
20%	5. AAPM Task Group 100

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REFERENCE: Safety is No Accident, Zietman et al. 2012

Outcomes data indicate that patient survival is associated with:

20%	1. Academic vs. non-academic center
20%	2. Plan quality
20%	3. Use of image-guidance
20%	4. Volumes of patients treated
20%	5. Board certification of medical physicist

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REFERENCE: *Peters et al. JCO, 28(18), 2996, 2010*

The following factor is associated with fewer patient safety incidents:

20%	1. Higher staffing levels
20%	2. More handoffs
20%	3. More safety incident reports
20%	4. More complex technology
20%	5. Better educated workforce

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Objectives:
What you will learn in this session

- Definitions of key terms
- Requirements and recommendations for reporting
- Key aspects of a new national incident learning system
- The value of incident learning through example

Outline

- Debbie Gilley, MPA, AAPM
  - Incident learning – What is incident learning?
- Gary Ezzell, PhD, Mayo Clinic, Arizona
  - The ASTRO/AAPM Radiation Oncology-ILS
- Eric Ford, PhD, University of Washington
  - Examples of incident learning – Wrong isocenter

Incident Learning in Radiation Oncology: An Update

What is incident learning?

Debbie Gilley
AAPM

Patient Safety

Patient safety: the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of health care.

National Institute of Health, US National Patient Safety Foundation

Definitions

- Medical Error
- Reportable Medical Error or Event
- Near Miss
- Unsafe Practices

Medical Error

A preventable event that may cause or lead to patient harm while under the care of a professional health care provider.

Agency for Healthcare Research and Quality (AHRQ) common formats, 2014

Reportable Medical Event

- Established by regulatory authority.
- Establishes a threshold for reporting based on what was prescribed in the written directive and what was given or based on the outcome of the event.
- Does not reflect patient harm but a variance in the actual activity versus the planned activity.

Near Miss

Any event that could have had an adverse patient consequence but did not, and was indistinguishable from a full-fledged adverse event in all but outcome.

National Institute of Health

Unsafe Condition

Any circumstances that increase the probability of a patient safety event.

Agency for Healthcare Research and Quality (AHRQ) common formats, 2014

Scope of Medical Errors in the United States

US Medical Errors

- Third leading cause of death
- 440,000 Americans are dying annually from preventable hospital errors
- Of the 2,539 general hospitals issued a Hospital Safety Score, 813 earned an "A,"
  661 earned a "B,"
  893 earned a "C,
  15 earned a "D"
  22 earned an "F"

Saved from URL: http://www.news-medical.net/news/20131023/Medical-errors-The-third-cause-of-death-in-the-US.aspx

US Radiation Related Medical Events

US NRC NMED 2012 Report to Congress

*Radioactive Materials 19 reports

Isotope	Number of Reports	Number of Patients
Yttrium-90	5	5
Irridium-192 (HDR)	7	7
Iodine-131	2	2
Iodine-125	3	18
Palladium-103	2	35

US Radiation Therapy Data

Conference of Radiation Control Program Directors (CRCPD)

Presentation on May 20, 2013 given by J. Elee, CRCPD

Linear Accelerators

63 events reported from 26 states

Types of Medical Events	Number of Medical Events
Wrong patient	10
Wrong anatomical treatment site	25
Weekly does greater than 30 or prescribed dose	6
Total dose greater than 20% of the prescribed dose	6
Single fraction dose was greater than 50% of the prescribed dose	6
Unintended overdose to normal tissue	9
Geographical miss	1

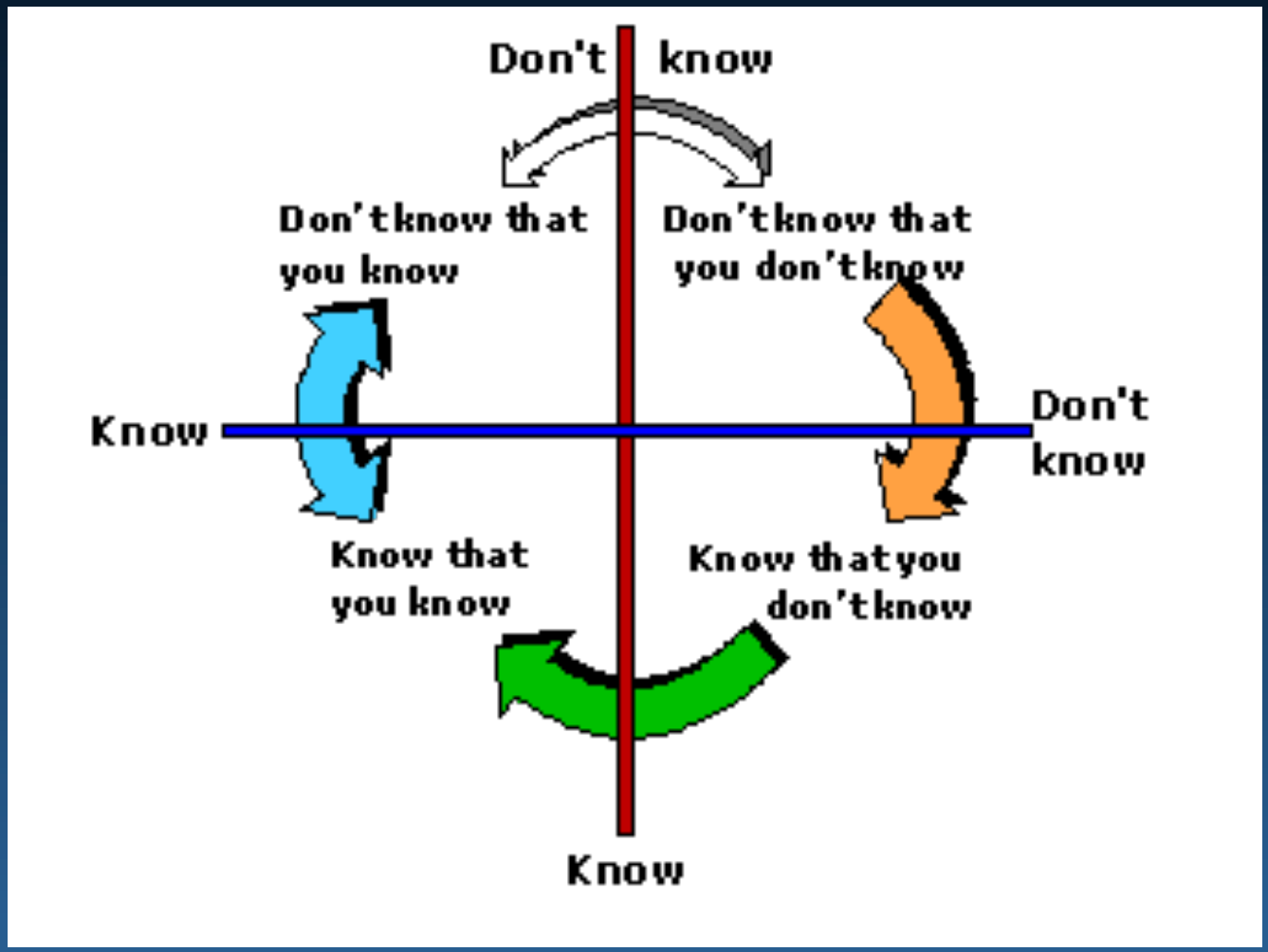
US Food and Drug Administration Manufacturer and User Facility Device Experience

Mandatory for manufacturers, voluntary for users

2013

Linear Accelerators Types of Report	Number of Cases
Death	3
Injury	8
Malfunction	46

No comprehensive reporting system in the US



What is the Value of Reporting Errors

- Reporting systems can provide warnings.
- Reporting systems can identify important problems.
- Reporting systems can provide some understanding of causes.
- Reporting systems can be used to raise awareness.

What is the Value of Reporting Errors

- Identify strength and weakness in patient safety.
- Identify basic details of the event.
- Purpose should be to learn from the incidents and near misses (counting incidents is of no value).

British Medical Journal, 2007 January 13; 334(7584): 51

Types of Reporting Systems

- Institutional Reporting System
  - Facility Based
  - Department Specific
- National Required
- National Voluntary
- International Voluntary
- International Required

Institutional Reporting Systems

Types

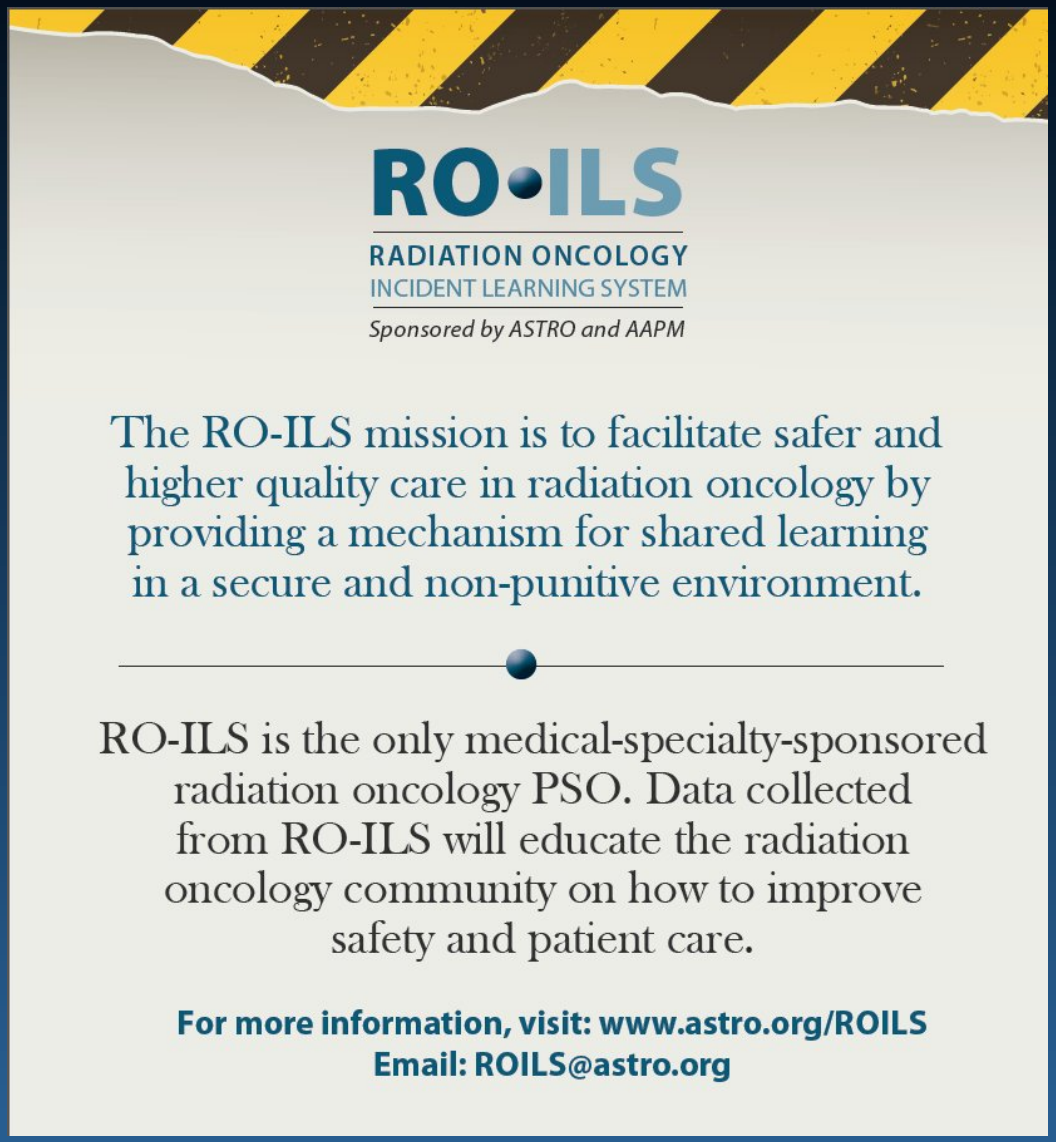
- Facility Based
- Department Specific

- Many varieties, using many different formats.
- Most designed to address patient falls and medication errors.
- Not able to benchmarked with other like institutions.
- Information is not shared outside of the organization.
- Usually not evidenced based but more of a reporting system (hospital grading).

Regulatory Required Reporting

- US NRC Nuclear Materials Event Database (NMED) Includes activities with fuel processing and nuclear reactors
- US FDA MAUDE required for manufacturers
- State Regulations (26 states have reporting requirements for medical radiation events)

National Voluntary System



SAFRON 

Safety in Radiation Oncology (SAFRON) is an IAEA-developed user system for improving the safety and quality of care in radiation therapy through sharing of knowledge.

- SAFRON collaborates with other reporting systems, and currently contains incident information gathered by the IAEA, ROSIS, French Nuclear Regulatory Authority and individual clinics. Clearinghouse for international sharing.
- SAFRON has over 1200 incidents and near misses events in its database
- SAFRON is non-punitive, anonymous, and voluntary
- SAFRON is a comprehensive source of information for radiation safety related events
- SAFRON includes information on a wide variety of published scientific journals and incident reports

RPOP.IAEA.org

SAFRON

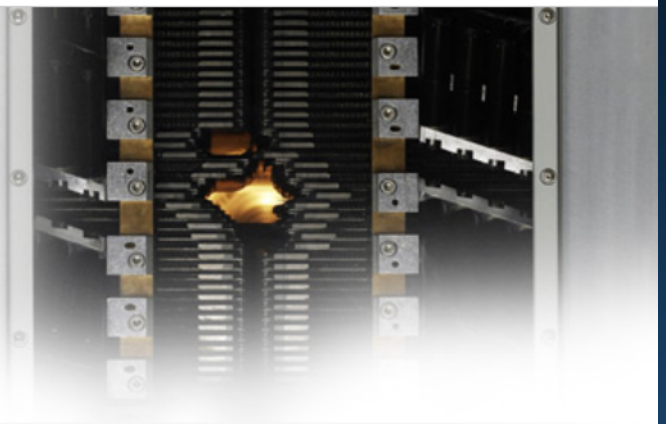
IAEA | SAFRON - Safety in Radiation Oncology

Dataset: All incident reports

Home | Process Steps | Incident Reports | Documents and Links | Registrations | 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 >

Submit Incident Report >

Search for Documents & Links >

Request Registration >

View Instructions >

Featured Incident Reports

Incorrect calibration of machine output

Electron beams of 7 and 11 MeV were calibrated incorrectly, resulting in underdosage of 17-18%. On the same machine, a photon beam was calibrated incorrectly, resulting in overdosage of 5%. In...

Misapplication of distance correction

An institution treated most patients with a constant source-skin distance (SSD) technique, although some patients were treated with a constant source-axis distance (SAD) or isocentric technique....

Featured Documents & Links

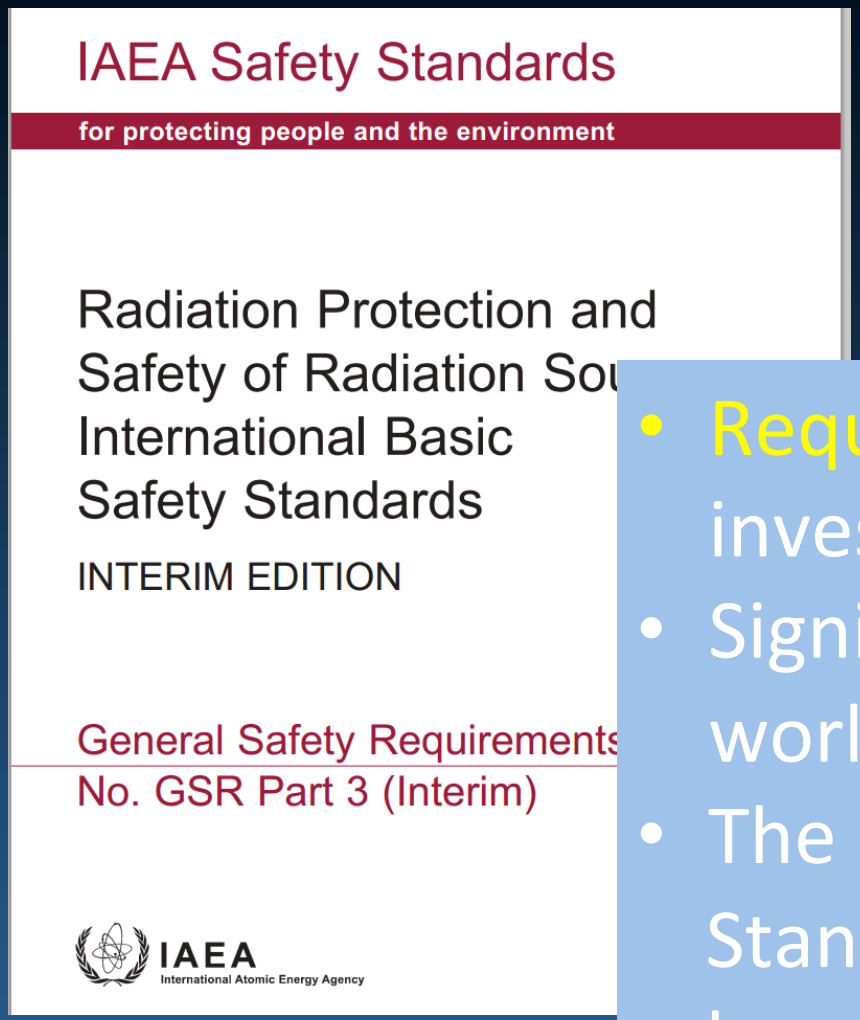
Task Group 142 report: Quality assurance of medical accelerators

This is an AAPM report on quality assurance of medical accelerators. It provides the reader with information on up-to-date recommendations of Table II of the AAPM TG-40 report on quality assurance...

Acceptance Testing and Commissioning of Linear Accelerators

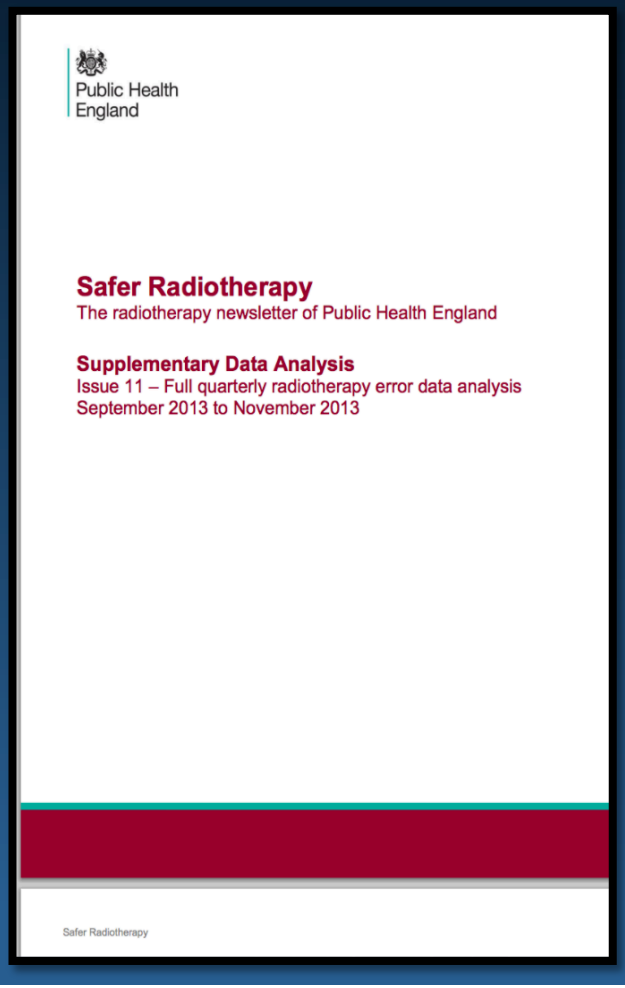
This Report gives guidance for the acceptance testing and commissioning of radiotherapy linear accelerators and comprises a comprehensive account, including some of the most recent clinical...

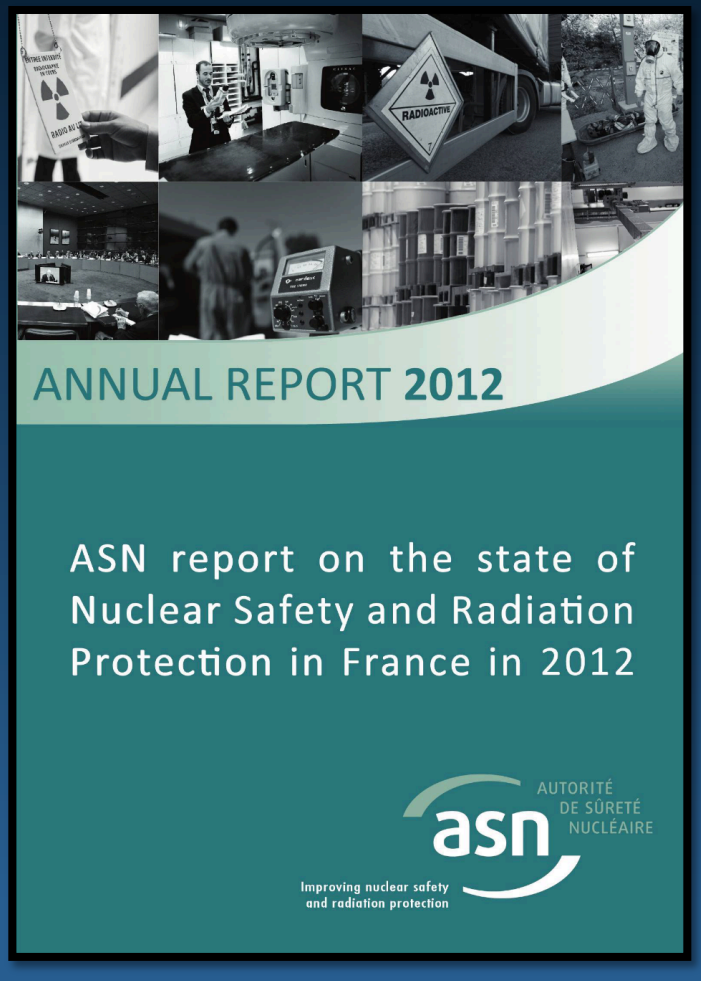
International Basic Safety Standards



- Requires reporting and investigation of medical errors.
- Significant for most of the world.
- The European Basic Safety Standards also adopted similar language for EU.

Other Incident Reporting Systems





Incident Learning Systems

- Demographics of the event or near miss
- Narrative of the event
- Conclusions for the cause of the event
- Corrected actions to prevent the reoccurrence of the event
- Easy to complete
- Can measure activities over time (improvements)
- Can be benchmarked to other organizations based on size a complexity (industry standards)
- Uses common nomenclature and format (process steps)
- Information can be shared with others

The following is an example of an incident reporting system required by regulations:

20%	1. Institutional systems
20%	2. SAFRON system from IAEA
20%	3. RO-ILS system from AAPM and ASTRO
20%	4. MAUDE system from the US FDA
20%	5. ROSIS system from Europe

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20%	**4. MAUDE system from the US FDA**
20%	5. ROSIS system from Europe

REFERENCE: CFR Title 21

Characteristics of a good incident learning system include which of the following?

A. Incident demographics
B. Patient Identification
C. Description of the event
D. Potential causes of the event
E. Proposed corrective actions to prevent reoccurrence

20%	1. B,C, and E
20%	2. All are correct
20%	3. A, C, E
20%	4. A, C, D, E
20%	5. A,B,C,E

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REFERENCE: IAEA

US federal regulations require that the following type of medical error be reported:

20% 1. Any error that harms a patient

20% 2. Overdose by >20% on a linac

20% 3. Errors requiring further patient treatment

20% 4. Wrong-site radiation misadministration

20% 5. Death or serious injury from a device

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REFERENCE: CFR Title 21

Incident Learning in Radiation Oncology: An Update

RO-ILS from AAPM and ASTRO

Gary Ezzell, PhD
Mayo Clinic, Arizona

Motivation for a shared system

- Learn from each other
  - Equipment "oddities"
  - Unanticipated failure modes
  - Best practices
- Why this structure?
  - Authorized by federal statute that provides protection against litigation prompted by shared information
  - Can be used as the local incident learning system as well as input to the national system

RO•ILS | RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

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Mission Statement

Facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure non-punitive environment.

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The Patient Safety and Quality Improvement Act of 2005

- Patient Safety and Quality Improvement Act of 2005 (PSQIA)
  - Signed into law July 29, 2005
  - Allowed for the creation of Patient Safety Organizations (PSOs)
- Impetus for the Act
  - Healthcare providers ***fear*** discoverability and liability
  - Variation in State-to-State protections
    - ***Limited*** in scope
    - ***Not*** necessarily the ***same*** for ***all healthcare providers***
  - ***No*** existing ***federal protections***
  - ***Data*** reported within an organization is ***insufficient***, viewed in ***isolation*** and ***not*** in a ***standard format***

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What is a PSO ?

- A PSO is an entity (listed by AHRQ) that allows providers to:
  - Participate in patient safety activities and share sensitive information relating to patient safety events without fear of liability
- The work done by/with providers within the confines of a PSO:
  - Fosters a culture of safety in a safe environment
  - Provides a better way to share and learn about quality and safety of healthcare delivery

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How are adverse event data protected now?

- Medical Studies Acts
  - State specific acts to protect information collected for quality assurance purposes
  - Largely written to protect hospitals and the peer review process
  - Differ from state to state and generally do not cover the work of physicians in private practice or clinics not owned by a hospital
- Attorney – client privilege (work product)
  - Tied to a specific case or claim where the physician, clinic or hospital may be/are named defendants in a lawsuit

New Protection Afforded by PSQIA

- Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

  And that:

  - Are 'assembled or developed' by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a Patient Safety Evaluation System

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PSES: Patient Safety Evaluation System
(Provider & PSO Specific Process)

What protections are afforded by working with a PSO?

- Privileged and not subject to:
  - Subpoena or order
  - Discovery
  - Freedom of Information Act
  - Legal or administrative proceedings including those against a provider
  - Disciplinary proceeding of a professional disciplinary body

- Confidential and not disclosed…except in:
  - Criminal proceedings
  - Provider authorization
  - Non-identifiable data
  - Law enforcement
  - FDA reporting
  - Patient safety activities
  - Business operations
  - Equitable relief
  - Research sanctioned by Secretary
  - Voluntary disclosure to an accrediting body

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Federal Pre-emption of State Laws to Level the Playing Field in Terms of Reporting of Near misses and Events in a Protected Space

Radiation Oncology- Incident Learning System (RO-ILS)

- Designed by ASTRO-AAPM based on the 2012 AAPM report: *Consensus recommendations for incident learning database structures in radiation oncology* Med. Phys. 39, 7272 (2012)
- Comprised of:
  - An electronic web-based reporting system to report events within the practice or department
  - A process the national level to receive, review and digest reports and inform the community

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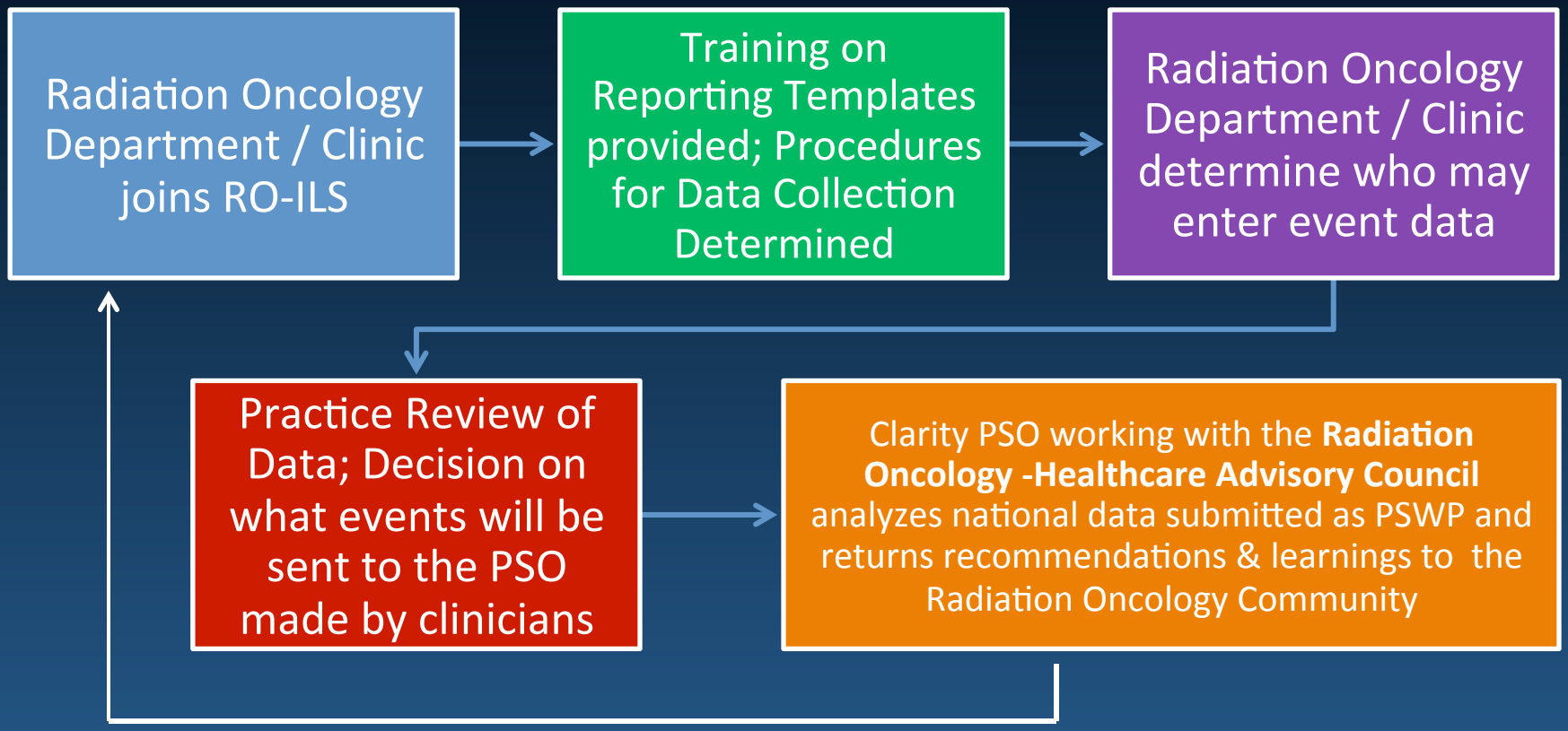
The Basics of how the Radiation Oncology Community can participate in the RO-ILS



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Chronology – Commitments

- National Incident Learning System is part of AAPM and ASTRO strategic plans
  - Subsequent to the 2010 meeting on safety in radiation therapy
- Partnership proposed at meeting of ASTRO and AAPM leadership in March, 2012
- Approved in principle by both governing boards during summer, 2012

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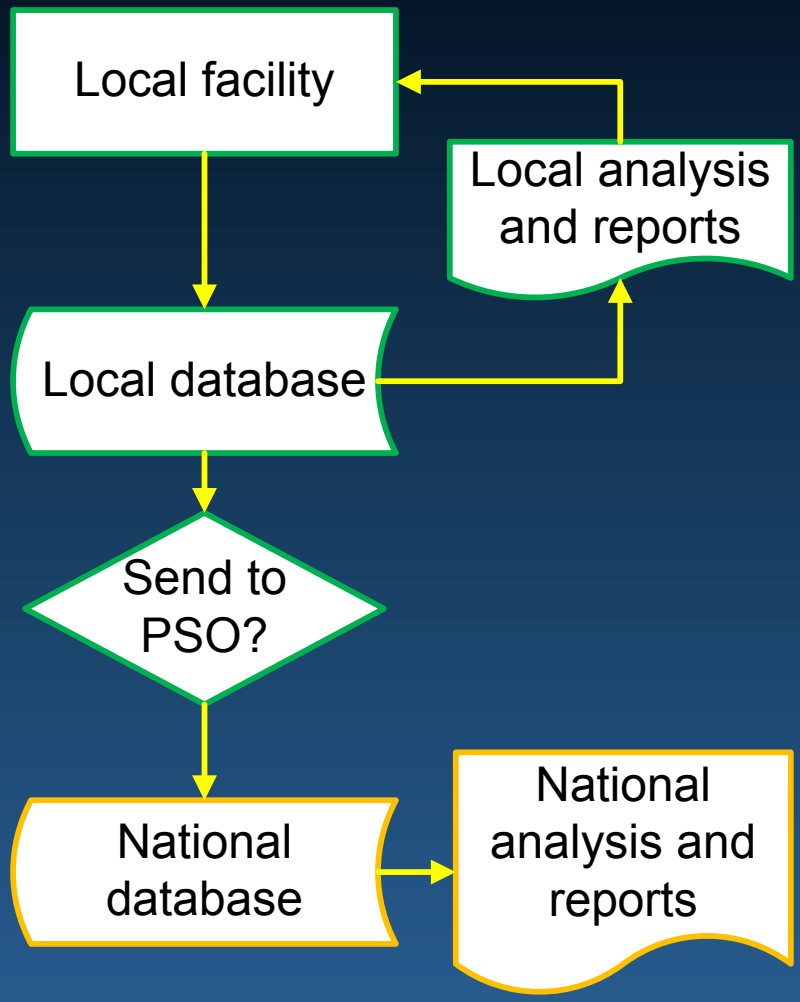
Basic data flow

- Each facility will enter local events
  - Can analyze and report locally
  - Decide which events to upload to national
- National group will analyze and report to community



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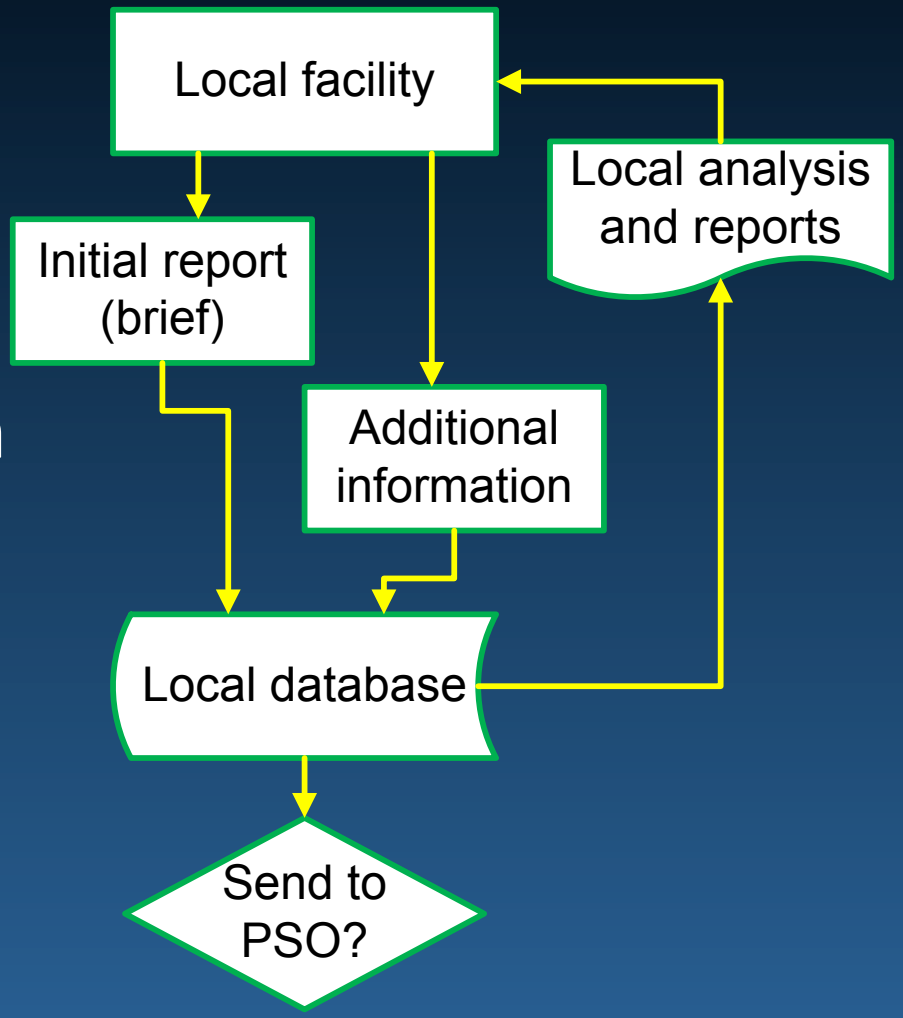
Basic flow – Local

- First report is brief, could be done by "anyone"
- Follow-up information will then be added by facility's designees
  - Uses AAPM taxonomy



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3 types of events to be reported

- Incident that reached the patient with or without harm
- Near-miss event that did not reach the patient
- Unsafe condition that increases the probability of an event

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Example event – wrong site near-miss

- Patient with sarcoma of left calf
- CT sim feet first for treatment feet first; MD not present; temporary marks on left leg
- On treatment planning computer, MD sets isocenter and draws fields on wrong leg, not realizing the left/ right reversal on the screen
- Plan is done, approved, and passes physics check
- Error caught by therapists at first treatment day – saw that Rx was for left leg but fields on right leg

Initial report

***Location:**

Location 1

***Sub Location:**

Sub Location 1

***Event Type:**

External Beam

***What is being reported?**

Incident that reached the patient: A safety event that reached the patient, with or without harm

***Likelihood of incident being harmful to the patient:**

○ Unlikely to be harmful ◉ Likely to be harmful

***Narrative: (Briefly describe the event that occurred or the unsafe condition, 4000 character limit)**

Patient with sarcoma of left calf had CT Sim done feet first. On treatment planning computer, clinician set the isocenter and drew field shape on wrong leg. Plan done and approved; physics check completed. At first setup, therapists noted that Rx was for left

***Patient's Age:**

18-64 years

***Patient's Gender:**

○ Female ◉ Male ○ Unknown, N/A

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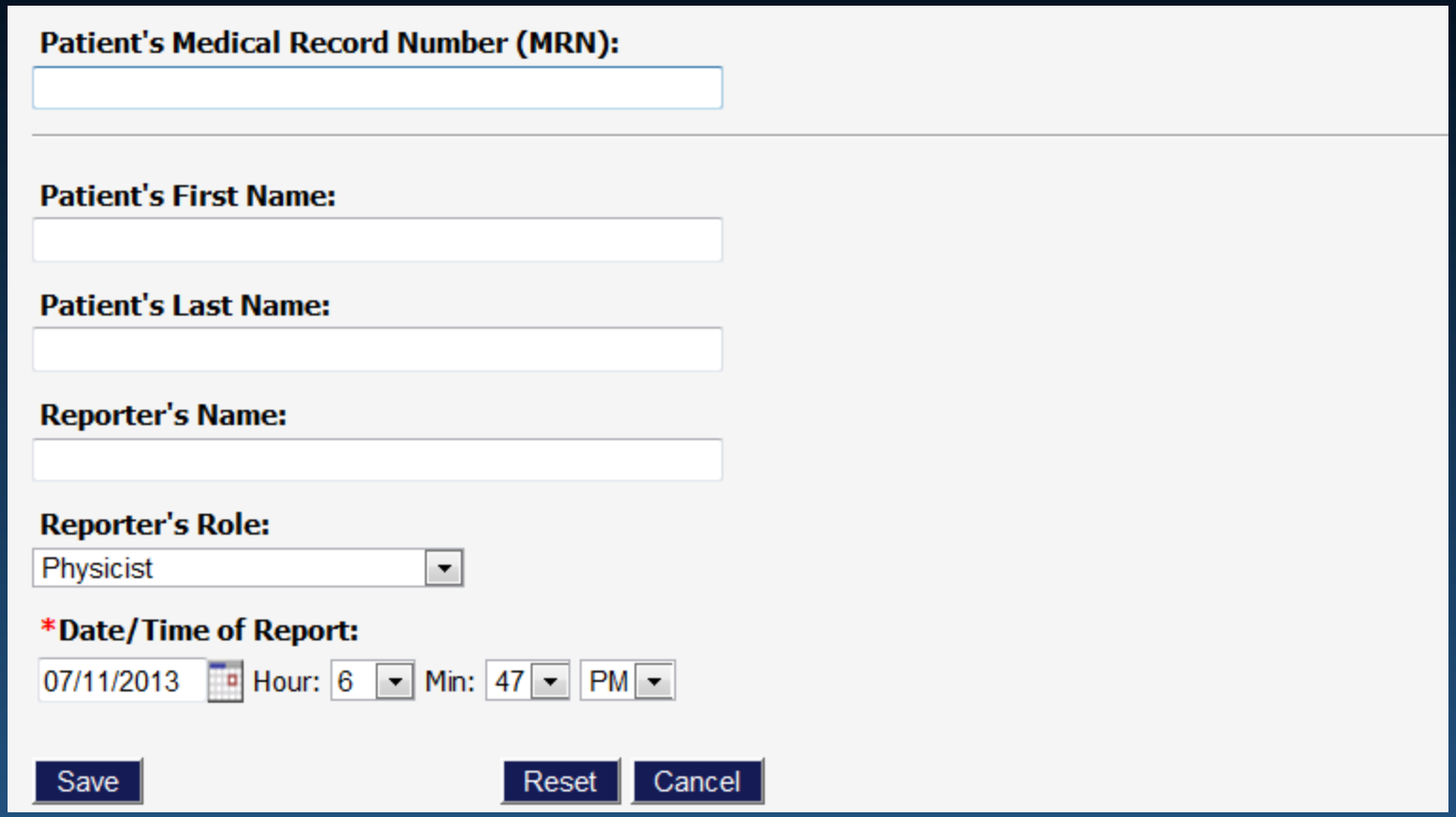
Initial report



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Follow-up to be added later

- Add information
- Classify event
- Identify contributing causes
- Record corrective actions

RO•ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

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Short Description of Event: (200 character limit)

Near-miss: wrong leg set up for treatment

Which of the following best characterizes the event or condition?

- [ ] Desired Procedure Inadvertently Omitted
- [ ] Wrong Anatomical Treatment Site
- [ ] Wrong Dose to All or Part of the Tumor or Normal Tissue
- [x] Wrong Laterality
- [ ] Wrong Patient Treated
- [ ] Wrong Procedure Done to the Patient
- [ ] Wrong Treatment Modality
- [ ] Not Sure How to Characterize This Event or Condition

Supplemental Information/Additional Follow-up to Event:

- Patient with sarcoma of the Left calf.
- CT simulation performed with scan feet first (to accommodate treatment feet-first)
- Temporary alignment marks are set at the time of sim. Patient is released.
- Clinician sets the isocenter and draws blocks for involved fields, accidentally placing it on the Right calf

Dosimetric severity scale:

100 percent absolute dose deviation from the total prescription for any structure

What is the clinically observed toxicity?

No harm

What is the potential future toxicity?

Life threatening, intervention essential. Possible recurrence due to underdose.

Name of person who discovered the event:

Role of person who discovered the event:

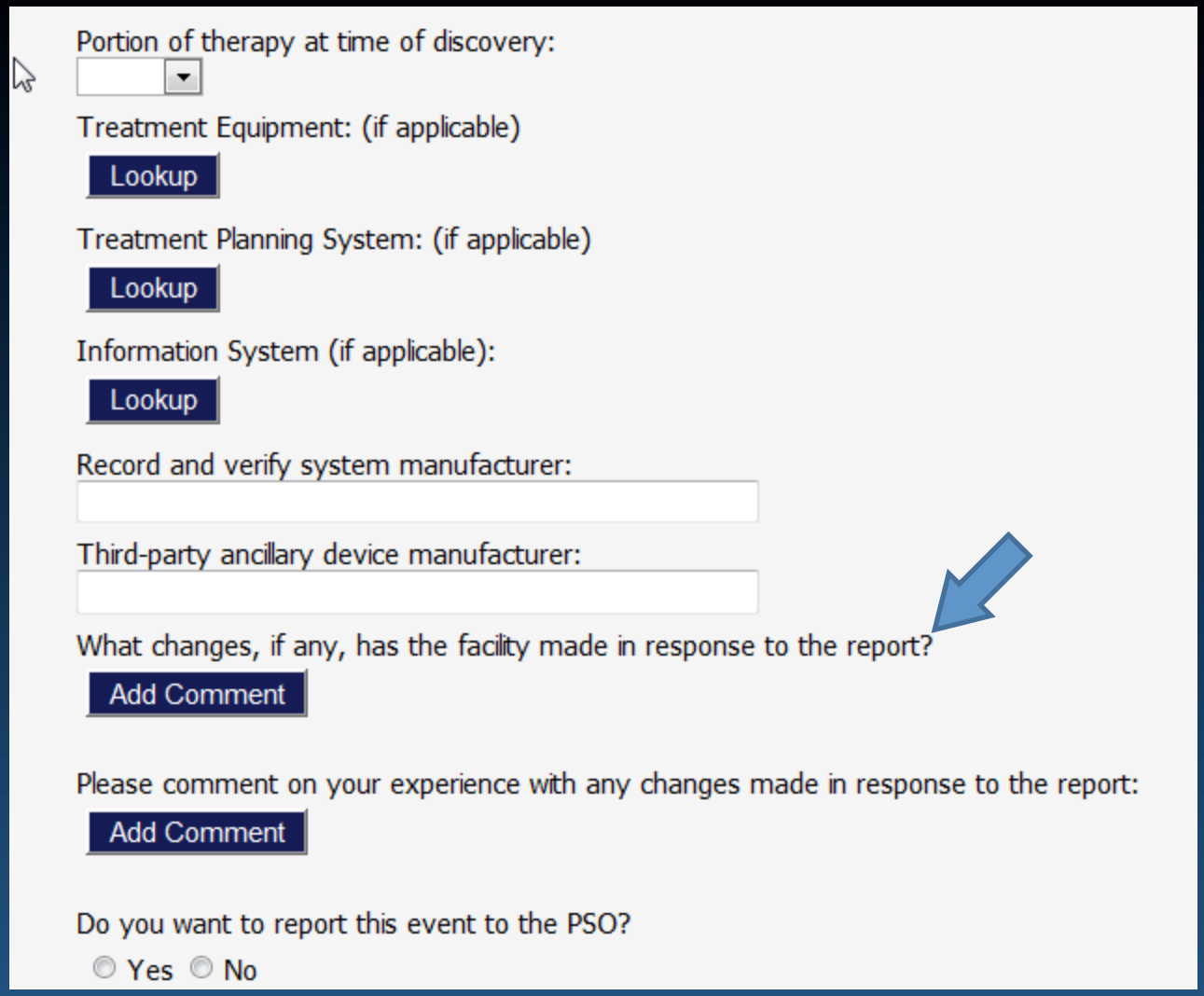
Radiation Therapist

*When was the event or condition discovered?

At first treatment

*At first treatment, when was the the event or condition discovered?

Before treatment initiation



RO•ILS
RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

Option: add contributing factors

Would you like to identify contributing factors to any errors in the care delivery process?

(•) Yes ( ) No

At what point in the care delivery process did the error occur?

Treatment Planning

Select one or several places where error(s) were made during Treatment Planning:

- [ ] Registration of image sets
- [x] Delineation of Target(s)
- [ ] Delineation of Organs-at-Risk
- [ ] Preliminary prescription parameters, constraints and Technique (i.e. physician intent)
- [ ] Physics consult
- [x] Isocenter definition
- [ ] Dose distribution optimization
- [ ] Dose distribution calculation
- [x] Primary evaluation of treatment plan by physicist
- [x] Primary evaluation of treatment plan by physician
- [ ] Iteration of treatment plan
- [ ] Set up for image-guidance/motion management
- [x] Final plan and prescription approval by physician
- [ ] Plan information transfer to radiation oncology inform
- [ ] Scheduling treatment session(s)
- [ ] Image Import
- [ ] Other

Unsafe Acts:

- [x] Unintended action - Attention failure
- [ ] Unintended action - Memory failure
- [x] Unintended action - Mistakes
- [ ] Intended violation - Routine
- [ ] Intended violation - Exceptional

What to report to the national ILS?

Events of possible general interest

- Events for which there was no safety barrier
  - i.e. “Here is a failure mode we never thought of”
- Events which passed through at least one barrier – indicating need for better systems
  - i.e. “This got through the plan check and made it to the machine”
- Events involving equipment performance or communication between equipment

RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

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What will happen to the data in the national system?

- Protected from legal discovery
- Analyzed by…
  - Patient Safety Organization (PSO) staff
  - Subject matter experts: Radiation Oncology Healthcare Advisory Council
- Summarized for reports back to participants and community at large

RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

Initial "RO-HAC"

- **Adam Dicker, MD, PhD**
- Jefferson Medical College of Thomas Jefferson University
- **Gary Ezzell, PhD**
- Mayo Clinic Arizona
- **Eric Ford, PhD**
- University of Washington
- **Benedick A. Fraass, PhD**
- Cedars-Sinai Medical Center
- **David J. Hoopes, MD**
- David Grant Medical Center
- **Theresa Kwiatkowski, CMD, RT**
- Rochester General Hospital
- **Kathy Lash, RT**
- University of Michigan
- **Gregory Patton, MD, MBA, MS**
- Compass Oncology

What will be the outcome?

- Reports
  - Anonymized descriptions of interesting events
  - Aggregated information about common types of events
    - Vendor–specific
    - Frequent factors
- Improved practices
- Improved equipment
- Improved safety

RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

Which property applies to the availability of information in the patient safety work product uploaded into RO-ILS:

20% 1. Subject to Freedom of Information Act reques

20% 2. Subject to subpoena

20% 3. Commonly demanded by an accrediting body

20% 4. Privileged and confidential

20% 5. Part of the patient's medical record

Which property applies to the availability of information in the patient safety work product uploaded into RO-ILS:

20% 1. Subject to Freedom of Information Act reques

20% 2. Subject to subpoena

20% 3. Commonly demanded by an accrediting body

20% **4. Privileged and confidential**

20% 5. Part of the patient's medical record

REFERENCE: *The Patient Safety and Quality Improvement Act of 2005*. Overview, June 2008. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/psoact.htm

Participation in the RO-ILS system requires which of the following:

20% 1. A contract with the PSO

20% 2. Web-based sign-up

20% 3. Willingness to forego mandatory reporting

20% 4. Internal IT support

20% 5. Membership in AAPM or ASTRO

Participation in the RO-ILS system requires which of the following:

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20% 4. Internal IT support

20% 5. Membership in AAPM or ASTRO

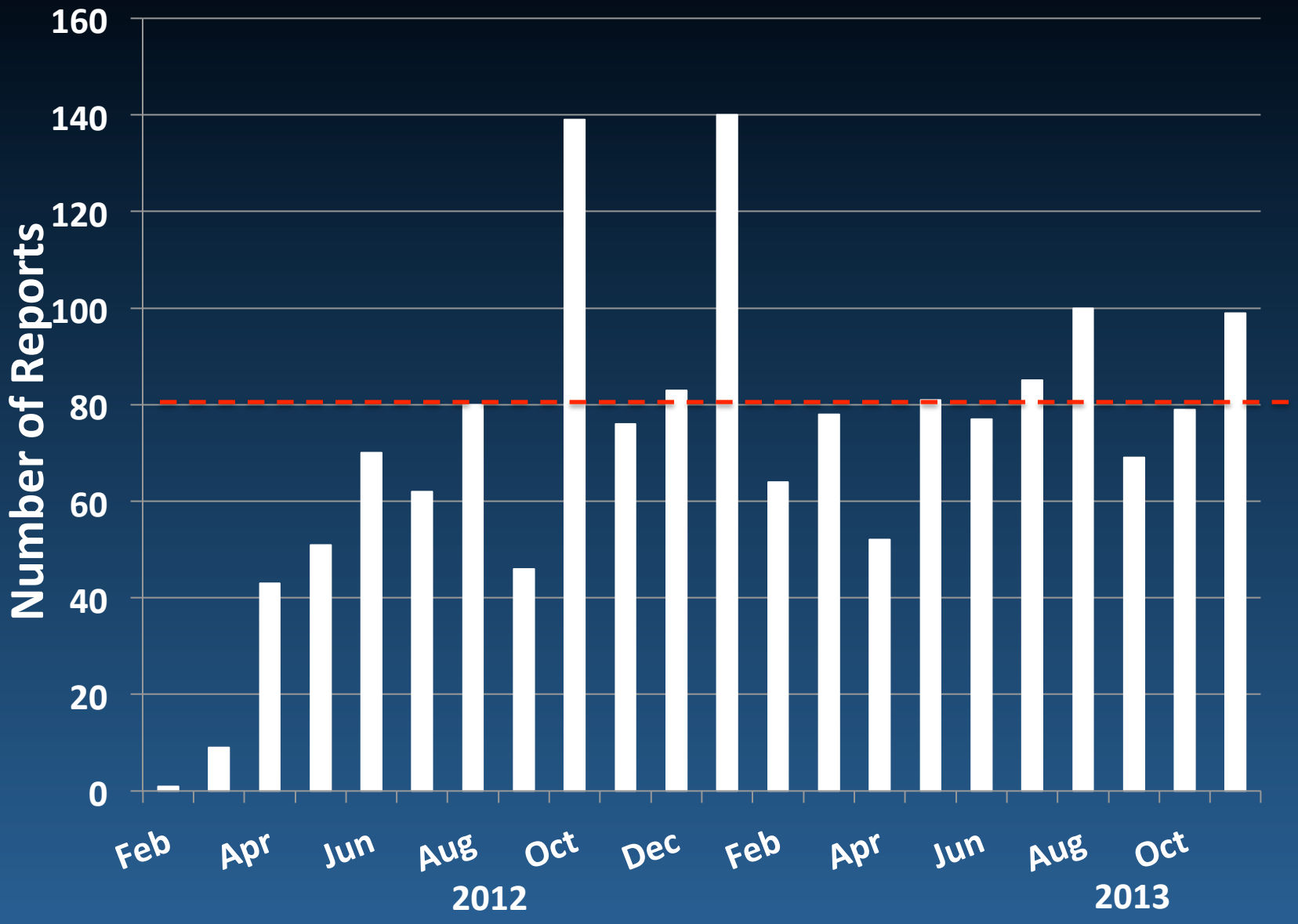
REFERENCE: Safety Improvement Through Incident Learning. Symposium at 2013 AAPM annual meeting: https://live.blueskybroadcast.com/bsb/client/CL_DEFAULT.asp?Client=1&PCAT=64&CAT=7090

Incident Learning in Radiation Oncology: An Update

Examples in Incident Learning

Eric Ford, PhD
University of Washington, Seattle

Incident Reporting: UWMC Experience



Examples in Incident Learning

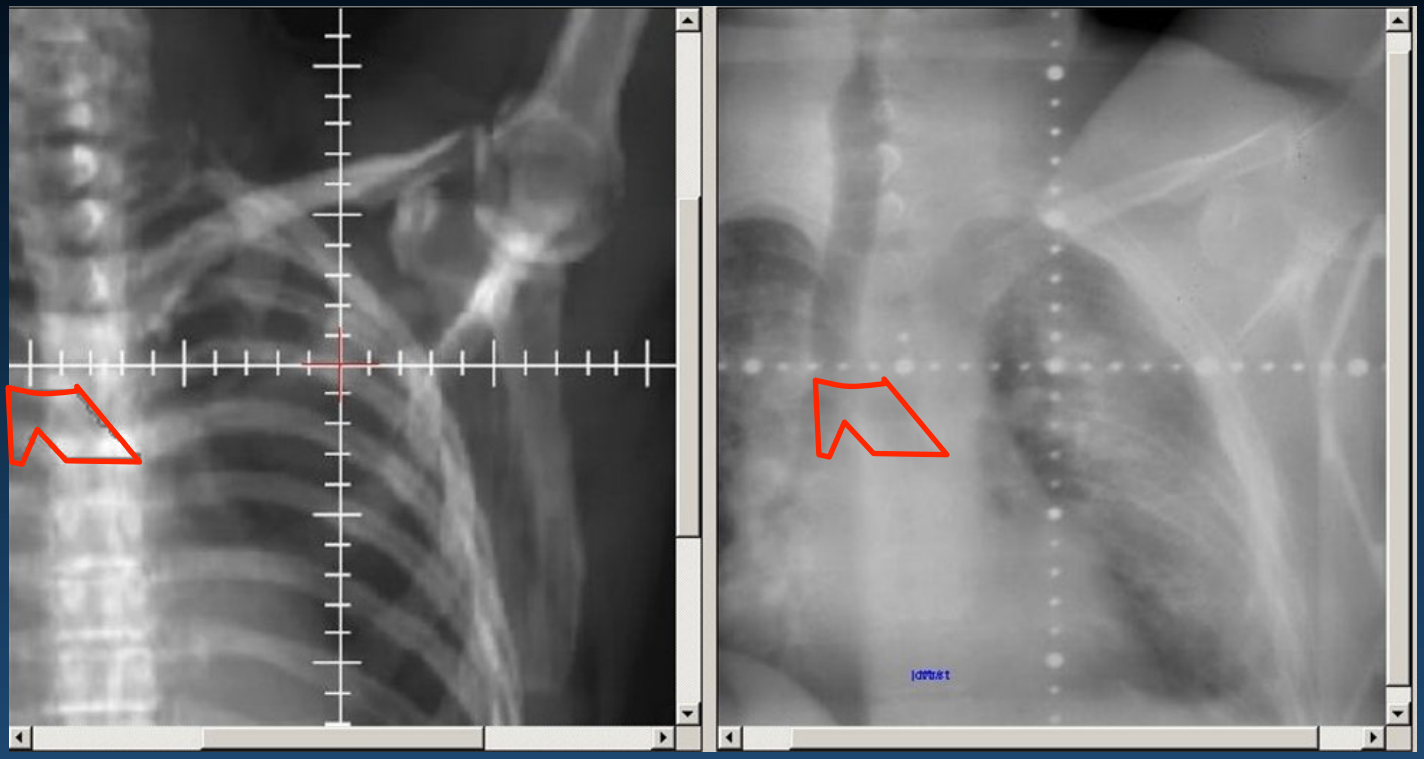
- Wrong CT scan used for planning
- Wrong MR fusion images loaded for contouring
- Wrong vertebral body treated
- Confusing policy for online imaging
- Patients not taking oral chemo at the correct time

Example Incidents

- Many flavors of incident are possible.
- We will focus on several examples of wrong isocenter treated or almost treated.
- The statement of incident (e.g. “wrong vertebral body treated”) is almost meaningless.
- Real meaning comes from exploring and addressing the causal factors at work.

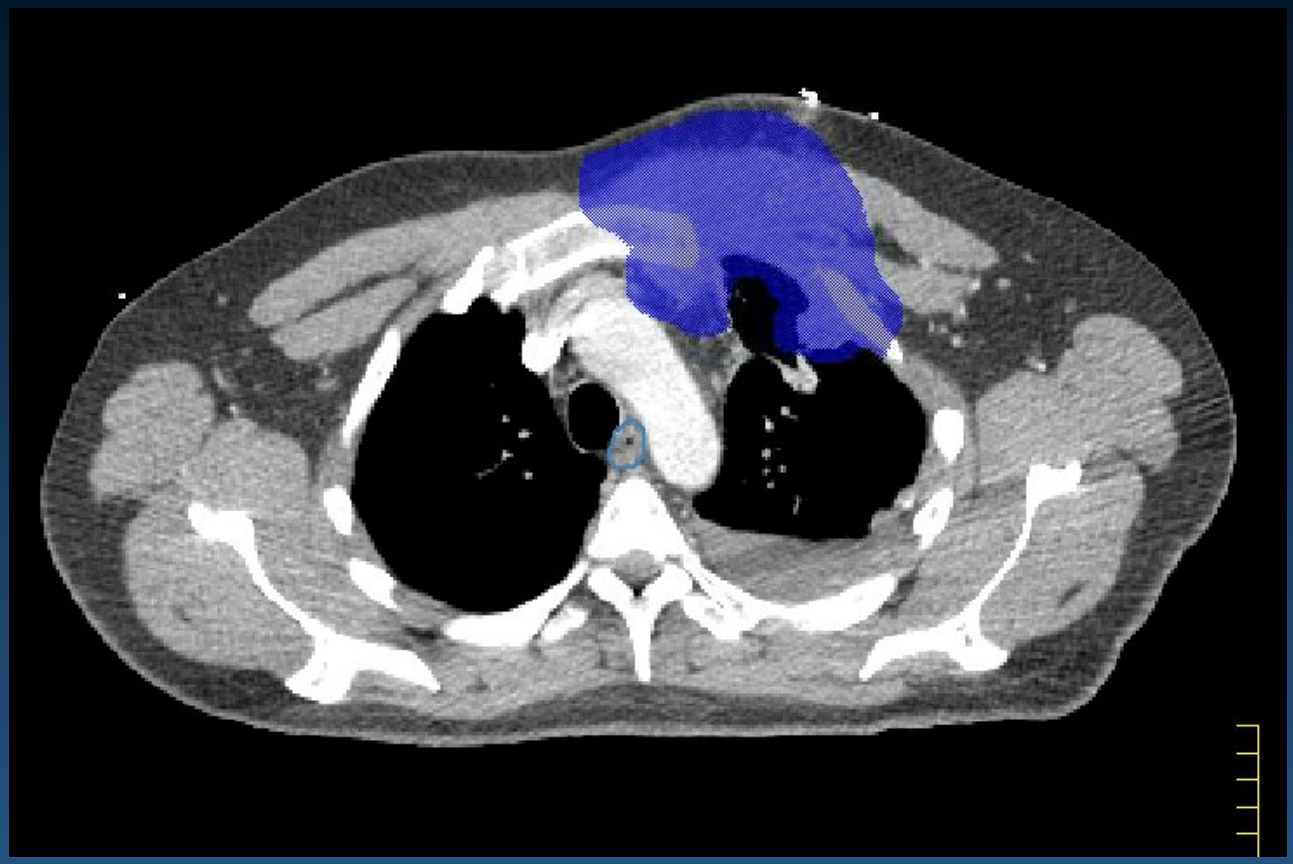
Wrong Isocenter

Wrong Isocenter: Case #1

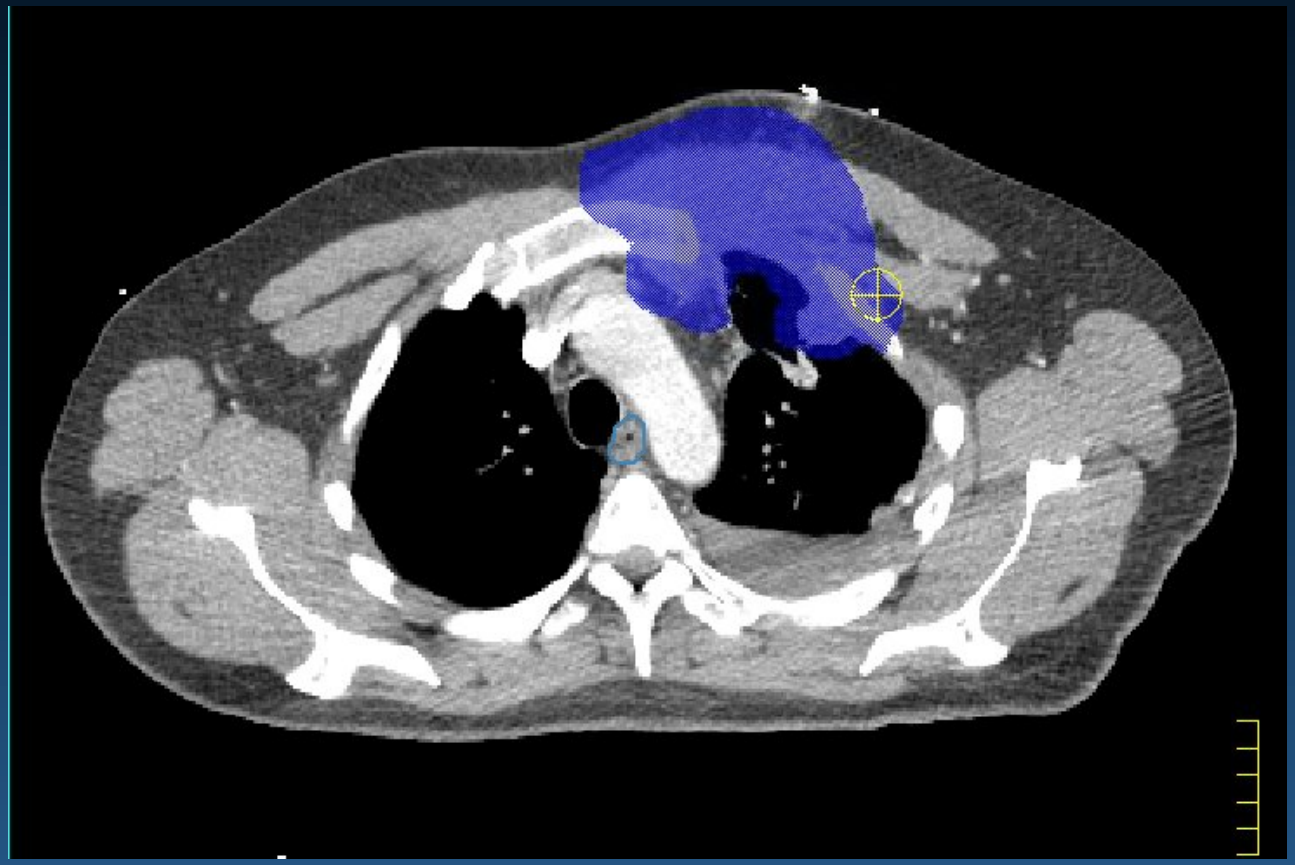


- 3 cm shift (wrong isocenter) noted on day 1 films
- Patient shifted. Correct treatment delivered
- Near miss

Identify Isocenter on Sim CT

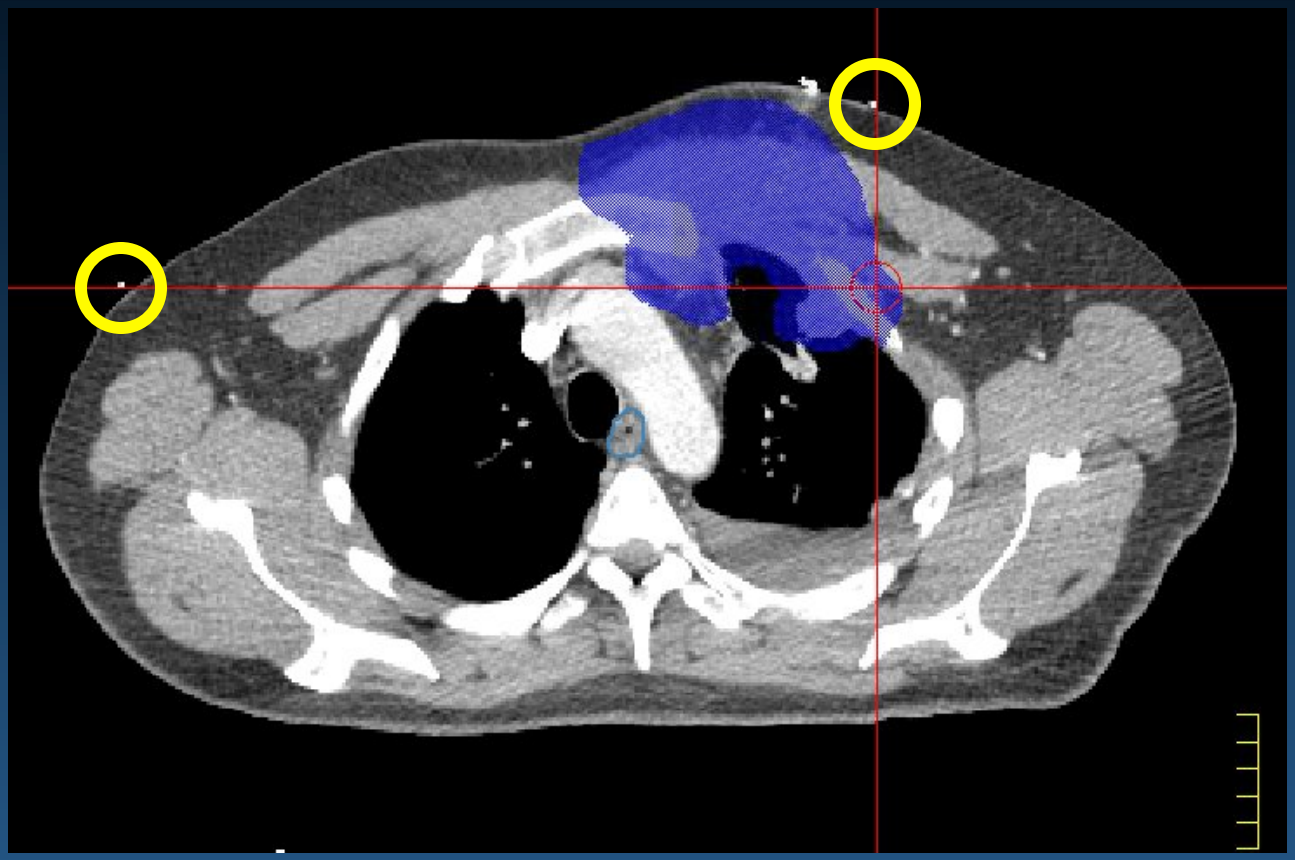


Identify Isocenter on Sim CT



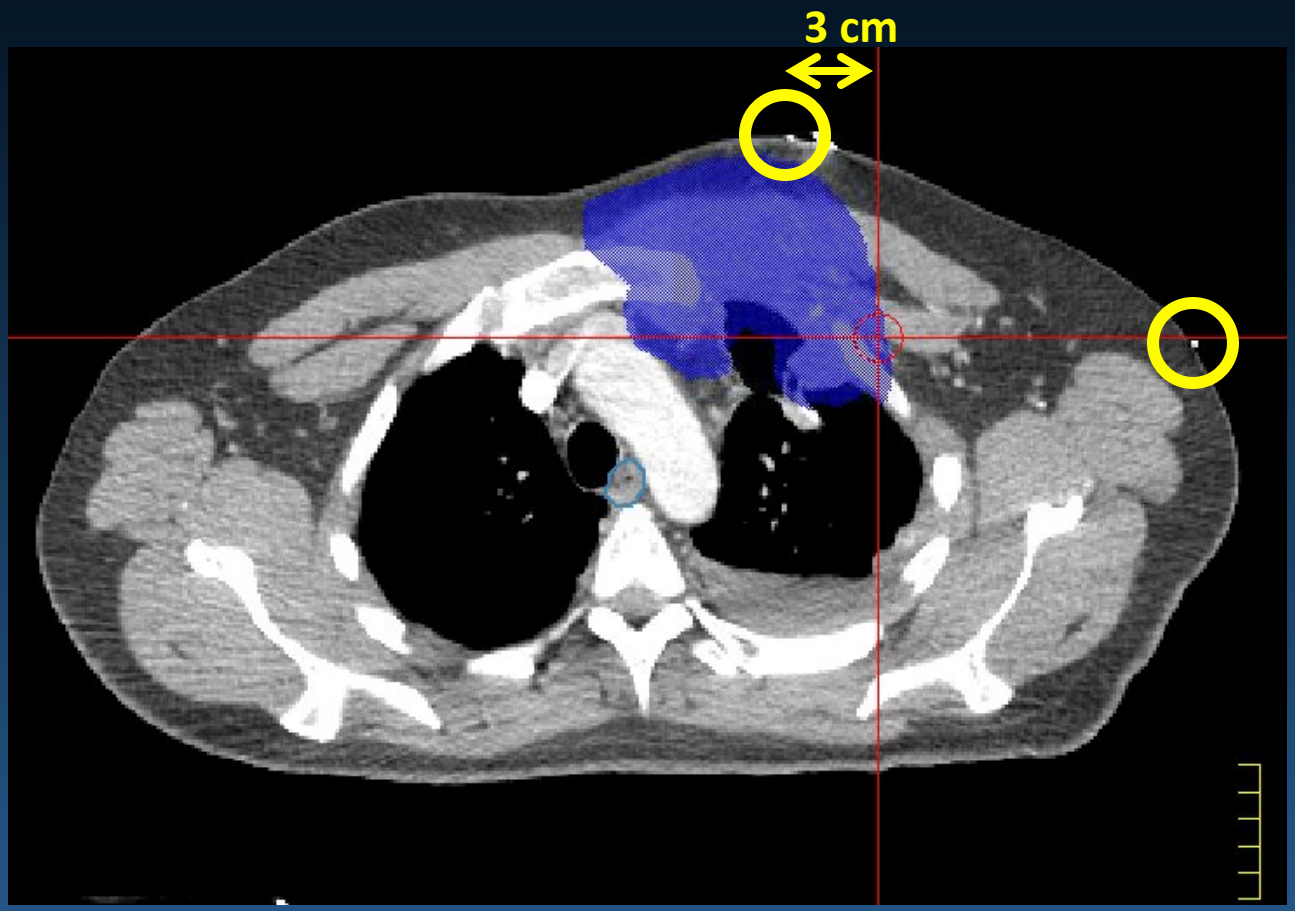
- Place isocenter in treatment planning system

Identify Isocenter on Sim CT

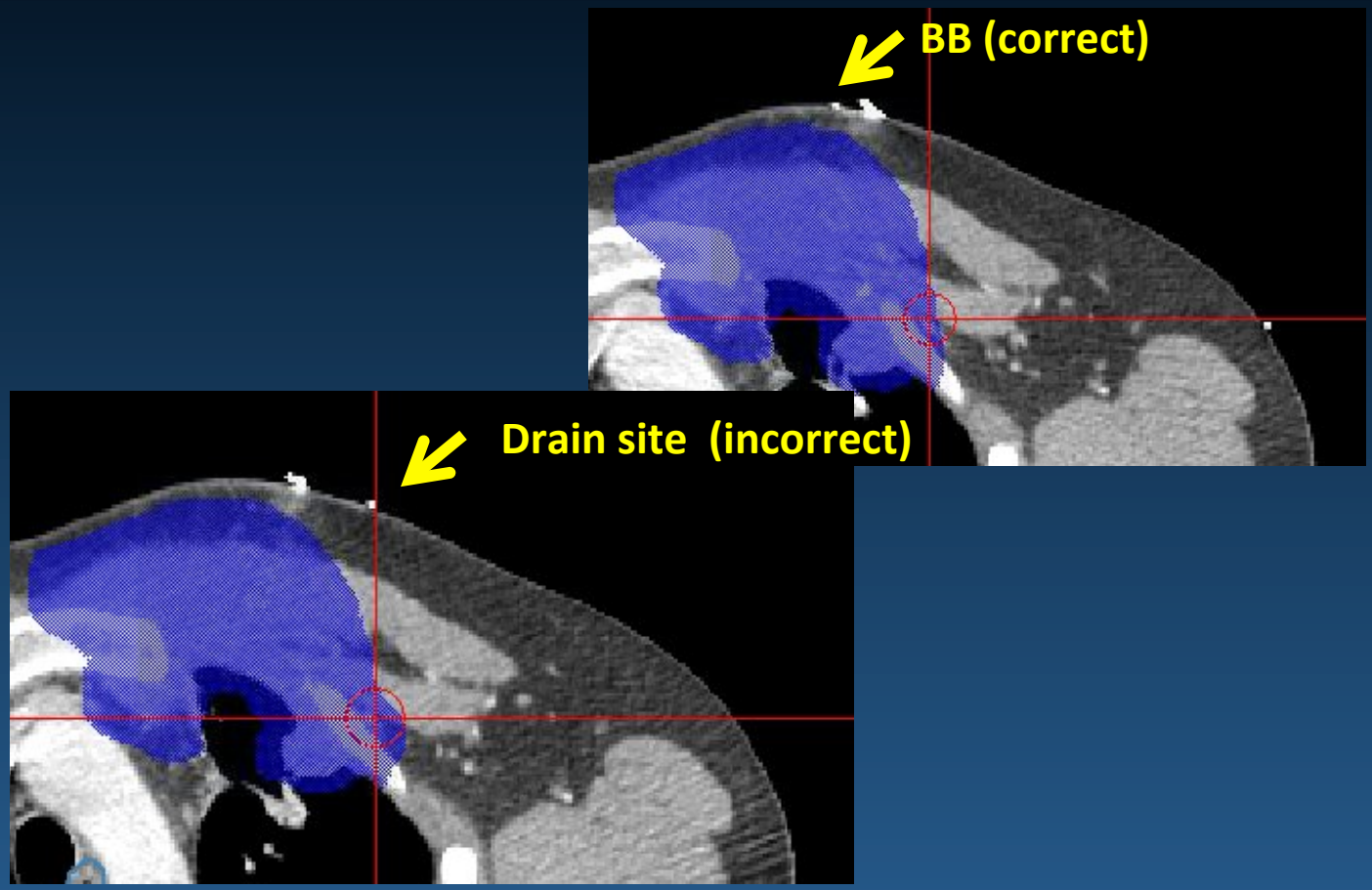


- Place isocenter in treatment planning system

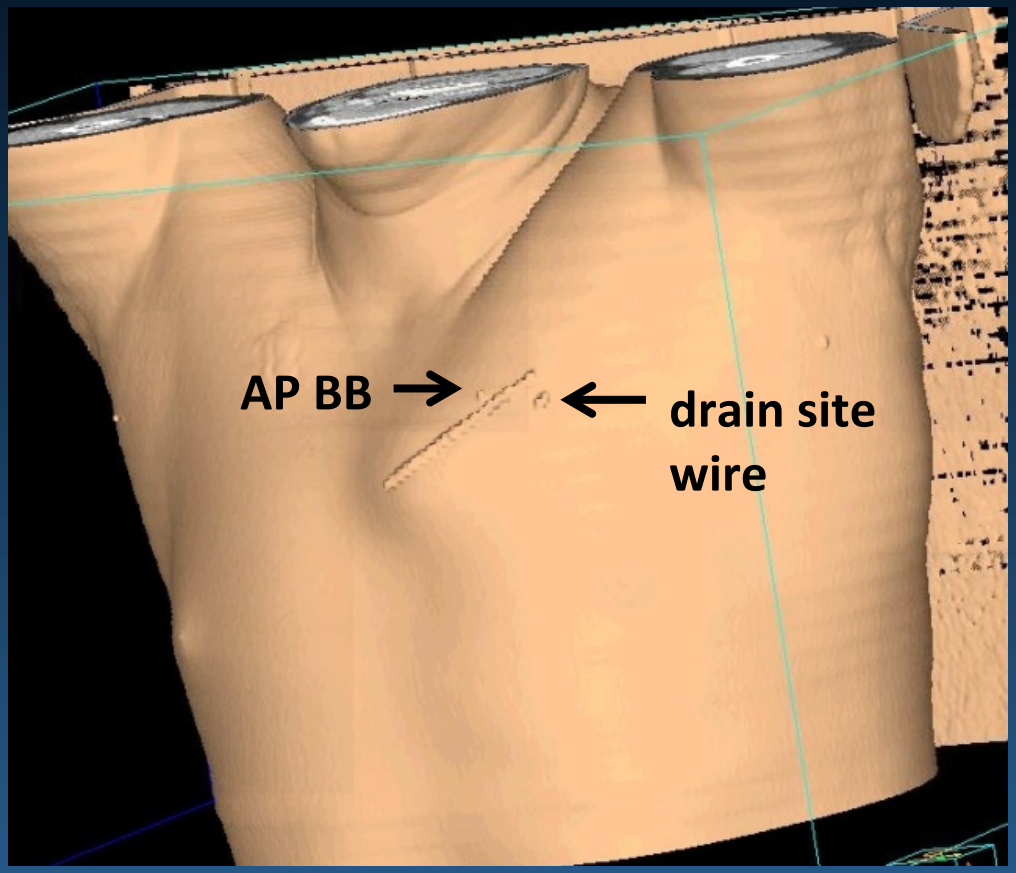
Wrong Mark Identified



Wrong Mark Identified

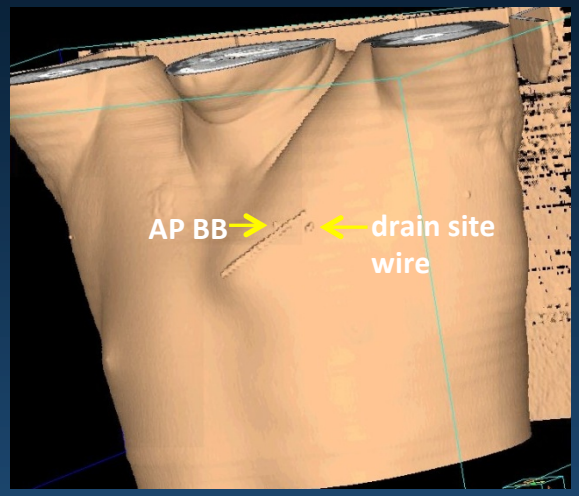


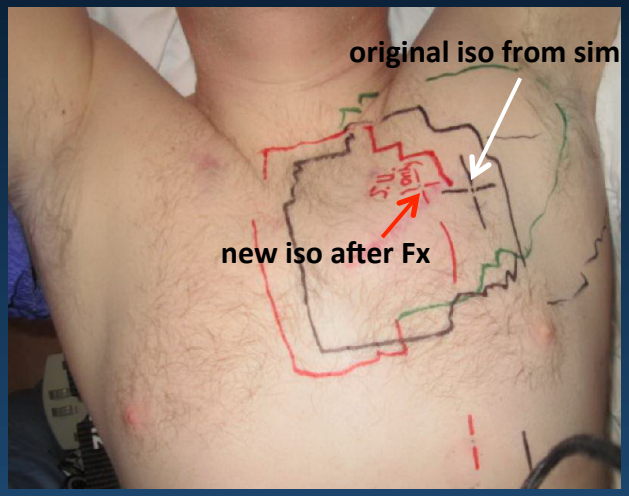
Wrong Mark Identified



Wrong Isocenter

Mark Correct Isocenter





Wrong Isocenter: Case #1

Contributing Factors

- Multiple features to be marked (unusual)
- Drain site marker similar to a BB
- Dosimetrist was confused but no follow-up
- No double check of CT localization

Wrong Isocenter: Case #1

Possible Solutions

- Sim staff to add POI in planning system

Wrong Isocenter: Case #1

Possible Solutions

- ~~Sim staff to add POI in planning system~~
- Increase communication about unusual situations

Wrong Isocenter: Case #1

Possible Solutions

- ~~Sim staff to add POI in planning system~~
- ~~Increase communication about unusual situations~~
- Physics check of CT localization

Wrong Isocenter: Case #1

Possible Solutions

- ~~Sim staff to add POI in planning system~~
- ~~Increase communication about unusual situations~~
- ~~Physics check of CT localization~~
- Plastic washer for drain sites

Wrong Isocenter: Case #1

Possible Solutions

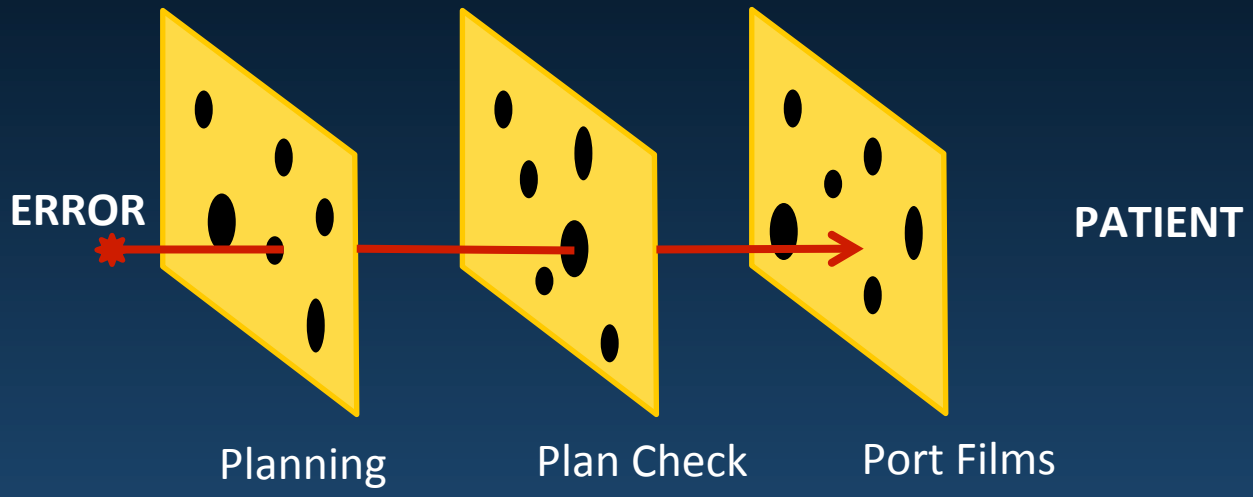
- ~~Sim staff to add POI in planning system~~
- ~~Increase communication about unusual situations~~
- ~~Physics check of CT localization~~
- ~~Plastic washer for drain sites~~

- Replace BBs with a different type of marker

Arguments Against Incident Learning

1. The patient was treated correctly. Why do you need an extensive investigation? No harm, no foul.
2. This was a perfect storm.
3. This will be caught on cone-beam CT.
4. This will be caught on port films.

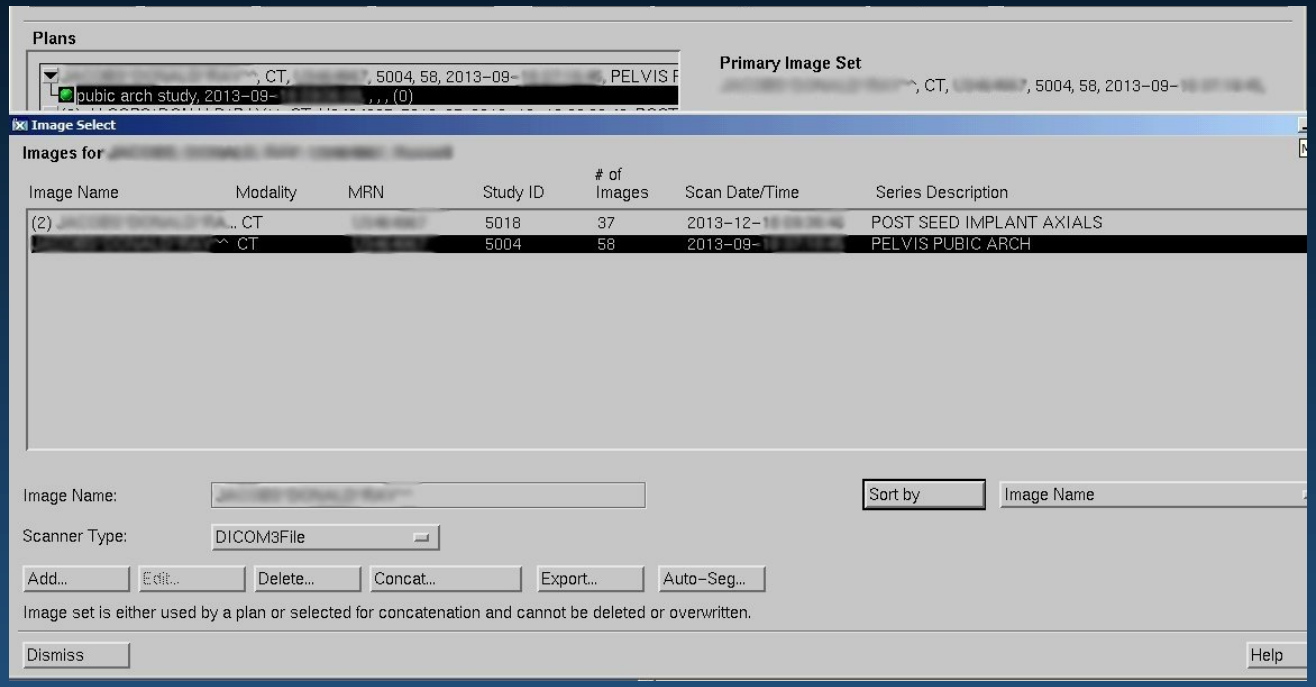
Swiss Cheese Model of Accidents



Wrong Isocenter: Case #2

- Patient present for R neck Tx. Previous RT.
- CT sim, isocenter marked.
- Dosimetrist picks prior CT instead of current CT.
- On first Tx: IGRT indicates 2 cm shift.
- RTT discusses with dosimetrist. Standard fractionation. MD not present.
- Elect to treat.
- Dosimetrist discusses with colleague and finds the error.
- Correction made for next treatment.

Select Correct CT Scan



Multiple CT scans

Check for Correct CT Scan

Patient Name:		Time:	2013−08−
Patient ID:		Comment:	
Plan Name:	L5−S2	Institution:	UWMC Pin_9.0
Trial Name:	l__ Approved	Physician/Physicist:	I
Revision:	**R04.P03.D03**	Planner:	
Lock Status:	The plan was locked by '		

Plan Setup

PT firstname, lastname

Primary Data Set Name:	[redacted]
Primary Data Set Dimensions:	232 slices, 512 x 512 pixels
CT to Density Table Name:	*CT Sim Aug05*
Patient Position:	On back (supine) Head First
Couch:	Removed at Y = −10.29
Body Board Angle:	None
Number of Photon Beams:	2
Number of Stereo Beams:	0
Number of Electron Beams:	0
Number of Brachy Sources:	0
Outside−Patient Air Threshold:	0.60 g/cm^3

Dose Grid Geometry

	Lateral	Ant−Post	Sup−Inf	Units
Resolution	0.400	0.400	0.400	cm
Dimension	119	97	109	Pixels
Origin	−23.415	−22.922	−18.840	cm
Reference Point	−0.00	4.61	0.00	cm

Top Slice of CT Extended:	0.00 cm
Bottom Slice of CT Extended:	0.00 cm

Region of Interest Density Overrides:

Wrong Isocenter: Case #2

Possible Solutions

- Include date in the name of the scan
- Greater awareness during physics checks

Wrong Isocenter: Case #2

Possible Solutions

- ~~Include date in the name of the scan~~
- ~~Greater awareness during physics checks~~
- Introduce error checks into software
- Vendors: please help!

Which of the following is the best error-proofing intervention?:

20%	1. Greater awareness during physics checks
20%	2. Implement staff continuing education
20%	3. Email daily reminders to check work
20%	4. Purchase a new device for IMRT QA
20%	5. Automatic software check for correct CT

Which of the following is the best error-proofing intervention?:

20% 1. Greater awareness during physics checks

20% 2. Implement staff continuing education

20% 3. Email daily reminders to check work

20% 4. Purchase a new device for IMRT QA

20% **5. Automatic software check for correct CT**

REFERENCE: *Quality and Safety in Radiotherapy, AAPM Summer School 2013, Eds. Thomadsen et al. Medical Physics Monograph 36, Chapter 5*

Incident Learning in Radiation Oncology: An Update

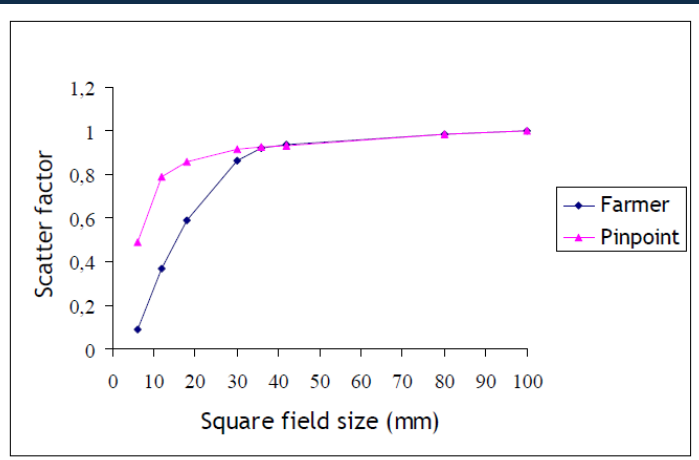
Incident Learning … Examples from SAFRON

Debbie Gilley
AAPM

Why Safety Reporting and Learning?

France 2007 (1-year period)

USA 2009 (5-year period)



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

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

SIMILAR ACCIDENTS:
- Commissioning of stereotactic equipment
- Detector used for measuring in the smallest fields was too large
- Overdose to 200 patients as a result

Why Safety Reporting and Learning?

France 2004

From: S. D

USA 2009?

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

An Incorrect Setting Leads to Injury

Problems involving machines that deliver therapeutic radiation have led to patient injuries.

CONE ASSEMBLY

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

spot in the brain. One ter, the same accident at another hospital. eatment Ms. Faber re- ereotactic radiosurgery, one of the fastest-grow- ion therapies, a techno- novation designed to y 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

Marci Faber is nearly comatose after a treatment mistake.

THE RADIATION BOOM

Missing the Target

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

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

SAFRON

Medical Events and Near Misses
ISOCENTER

What phase in the process is the incident associated with?	Number of events
Non-clinical phase	1
Pre treatment phase	34
Treatment Phase	42
Who discovered the incident	
Radiation Oncologist	3
Medical Physicists	4
Therapists on the treatment unit	41
Simulation staff	5
No information provided	24

SAFRON 

Medical Events and Near Misses
ISOCENTER

How was it discovered? (Barriers)	Number of events
Chart checks	13
In vivo Dosimetry	1
Portal Imaging	13
Clinical review	0
Found at the time of patients first treatment	18
Found at a later stage of the treatment	8
No information provided	14

SAFRON 

Medical Events and Near Misses
ISOCENTER
What can we learn from this information?

Pre treatment Phase Commissioning Error
ERROR in treatment planning adding a correction factor to the isocenter plans when it was already incorporated into the treatment planning calculations
More than 1045 patients affected
Serious

Corrective actions

- Additional Training
- Improve procedures
- Improved quality assurance procedures
- Justification for independent verification of calibrations

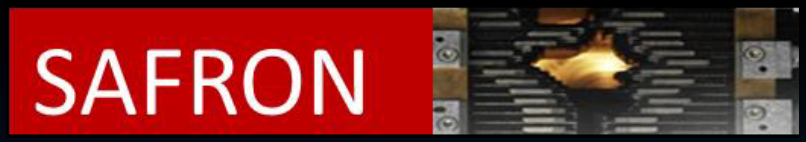
SAFRON

Medical Events and Near Misses
ISOCENTER

Pre-treatment Phase	Number of events
Positioning and immobilization	3
Simulation, imaging and volume determination	12
Treatment planning	15
Treatment information transfer	4
Pre treatment patient preparation	4
Not specified	6

Consistent themes in the cause of the incident or near miss

- Communication hand-off
- Lack of procedures
- Not following procedures
- Not adequately trained



Medical Events and Near Misses
ISOCENTER
What can we learn from this information?

Treatment planning incidents

Corrective actions

- Additional Training
- Improve procedures
- Improved quality assurance procedures
- Justification for independent verification of calibrations

SAFRON

Medical Events and Near Misses
ISOCENTER

What can we learn from this information?

Causality
Lack of training
Lack or poor communication
Lack of procedures to address the issue
Radiation Oncology team not following procedures
Set up sheet or checklist inadequate or not followed
No procedure in place to address variance in patient set up from standard practices
Human error*

SAFRON

Medical Events and Near Misses
ISOCENTER

What can we learn from this information?

Corrective Actions

The need for constant training and education
The need for continuous improvement through updated policies and procedures
The need for an effective safety culture
The need for effective communications

Errors in calibration of small fields have been reported in which 2 countries?

20%	1. Germany and Switzerland
20%	2. Germany and France
20%	3. United States and Germany
20%	4. United State and France
20%	5. United States and Switzerland

Errors in calibration of small fields have been reported in which 2 countries?

20%	1. Germany and Switzerland
20%	2. Germany and France
20%	3. United States and Germany
20%	**4. United State and France**
20%	5. United States and Switzerland

REFERENCE: S. Derreumaux, IRSN, France; W. Bogdanich, N.Y.Times, USA, 2010

Conclusions

1. Incident reporting improves safety and quality
2. We are supposed to be doing it!
3. The RO-ILS will provide an established and protected means of doing this
4. Sharing information on root causes and error-proofing