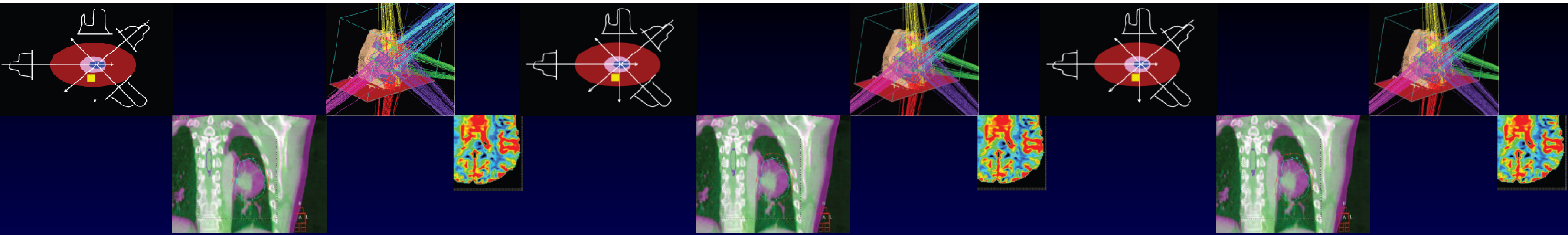

SEAAPM Symposium

The Practice of Quality Assurance in an Era of Change

Directors: Dan Bourland and Ingrid Marshall

- Vendors, breaks, and food next door
- Thank you to SEAAPM EXCOM, Commercial Partners, Faculty, and Participants
- Cell phone reminder

Radiation Treatment Events: Cases, Causes, and Culture of Safety

JD Bourland, PhD
Associate Professor
Department of Radiation Oncology
Wake Forest University School of Medicine
Winston-Salem, NC USA
bourland@wfubmc.edu

Outline

- Advanced radiation treatment technologies
- Events in imaging and treatment: cases, causes
- Opinions on high technology
- Summary and Conclusions

Advances in Radiation Technologies and Significance for Radiological Community

- *Now available!:* Advanced imaging and treatment procedures for benefit of our patients
- New technologies require: higher-level education and training for understanding and operating devices
- Operator roles have changed: from "active, manual mode" to "observer mode"
- Quality Assurance: all steps and devices undergo QA. Now, QA is for processes & software in "black boxes"
- These days: very important to verify initial parameters as correct – they may be used for entire procedure
- **Challenge:** Tendency that "computer is always right"
- **Challenge:** Recognizing correct / incorrect operation

US: NY Times Articles (W Bogdanich) Cases Reviewed

- **Imaging Overdoses:** October, 2009
  - 206 stroke patients: pre-sets edited to other settings
  - Pediatric CT case: operator error with older CT
- **Radiation Treatment:** January, 2010
  - IMRT delivery error: field open, no MLC operation
  - Breast delivery error: wedge reversed – OUT, not IN
  - Prostate brachytherapy: poor implantation technique
  - Linac SRS overdose x 1.5: calibration error in spreadsheet
  - And others

Some Recent Radiation "Events"

Have called attention to treatment safety

- Imaging: 2009
- Treatment: 2005 - 2010

FDA Advisory: CT Brain Perfusion Dose

3-4 Gy (avg 0.5 Gy or 500 mGy) delivered:

Cause: operator error, and training – pre-set imaging parameters adjusted and stored at higher levels

U.S. Department of **Health & Human Services** www.hhs.gov

FDA U.S. Food and Drug Administration

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Anima

Medical Devices

Home > Medical Devices > Medical Device Safety > Alerts and Notices (Medical Devices)

Safety Investigation of CT Brain Perfusion Scans: Update 12/8/2009

Date Issued: December 8, 2009

Audience: CT facilities, Emergency Medicine Physicians, Radiologists, Neurologists, Neurosurgeons, Radiologic Technologists, Medical Physicists, Radiation Safety Officers

Medical Specialties: Emergency Medicine, Radiology

Device: Multi-slice CT machines.

Summary of Problem and Scope:

On October 8, FDA issued an Initial Communication about excess radiation during perfusion CT imaging to aid in the diagnosis and treatment of stroke. At that time, we knew of 206 patients who had been exposed to excess radiation at one facility.

Together with state and local health authorities, FDA has identified at least 50 additional patients who were exposed to excess radiation during CT perfusion scans. These cases involved more than one manufacturer of CT scanners. FDA has also received reports of possible excess exposures at facilities in other states. Some patients reported hair loss or skin redness following their scans.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

Recent CT Overdose: Pediatric, CA

AuntMinnie.com

"151 scans"
2.5 – 11 Gy; 39% increased risk of Ca
Cause: operator error in programming the CT unit

California RT gives deposition in CT overdose case

By Donna Domino
AuntMinnie.com contributing writer
December 10, 2009

The California radiologic technologist accused of operating the CT scanner that delivered a massive radiation overdose to a 23-month-old boy in 2008 testified last week that she only pushed the CT scan button a few times, and she doesn't understand how the toddler received 151 scans in a single imaging session.

Raven Knickerbocker, who is accused of subjecting Jacoby Roth to more than an hour of continuous scanning, said she only pressed the scan button "two to four times," according to the Roth family's attorney, Don Stockett, who questioned her during a December 4 deposition in preparation for a civil trial in a lawsuit filed by the boy's parents.

Knickerbocker testified during the deposition that she performed two scout scans and then tried to start the examination, but the machine did one rotation before it stopped and displayed a fault code, said Stockett, whose practice is based in Folsom, CA. She asserted the scanning procedure lasted only about 20 minutes.

In January 2008, the boy was taken to the emergency room at Mad River Community Hospital in Arcata, a small town 290 miles north of San Francisco, after he fell out of bed and could hardly move his head.

The ER doctor ordered x-rays and CT scans to check for damage to the child's cervical spine. The boy was taken to the scanning room, where Knickerbocker performed CT scans at C-spine levels C1 through C4 in the same section of the midmaxillary sinuses, midclivus, and posterior fossa. Over the next 68 minutes, the toddler was exposed to 151 scans.

Within a few hours, the child developed a bright red ring around his head from the massive radiation overdose. Photographs of the left side of the boy's face show a clear line extending from the infraorbital ridge backward through the ear and nape of the neck; a similar line extends from the infraorbital ridge through the ear on the right side.

In off-the-record comments, one state official called it the worst case of radiation overdose of a child in the U.S.

Dave Laumann, the head technologist at Mad River at the time, told the state agency that he had stopped in to check on Knickerbocker, saw she was having problems, and suggested that she reboot the scanner. But Knickerbocker testified last week

The New York Times

October, 2009

October 16, 2009

Radiation Overdoses Point Up Dangers of CT Scans

By WALT BOGDANICH

At a time when Americans receive far more diagnostic radiation than ever before, two cases under s
involving a large, well-known Los Angeles hospital, the other a tiny hospital in the northern part of t
risks that powerful CT scans pose when used incorrectly.

A week ago, Cedars-Sinai Medical Center in Los Angeles disclosed that it had mistakenly administer
normal radiation dose to 206 possible stroke victims over an 18-month period during a procedure in
of the brain. State and federal health officials are investigating the cause.

Hundreds of miles north at Mad River Community Hospital in Arcata, the other case — involving a
of neck pain after falling off his bed — has led to the revocation of an X-ray technician's state license
more than an hour of CT scans. The procedure normally takes two or three minutes.

The hospital's radiology manager at the time, Bruce Fleck, called the overdose a "rogue act of insani

Photo: NY Times, Aug 1, 2010

The New York Times

January, 2010

January 24, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — w
unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nau
unable to breathe — be studied and talked about publicly so that others might not have to li

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His f
the beach where they had played as children so he could touch it, feel it and remember bett

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 err
blast his brain stem and neck with errant beams of radiation. Not once, but on three consecu

Soon after the accident, at St. Vincent's Hospital in Manhattan, state health officials cautione

Photo: NY Times, Jan, 2010

Medical Radiation: An Overview of the Issues

http://energycommerce.house.gov

Committee On Energy And Commerce

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Home ▸ Hearings ▸ Subcommittee on Health ▸ Medical Radiation: An Overview of the Issues

Medical Radiation: An Overview of the Issues

Hearings - Subcommittee on Health

Friday, 26 February 2010 08:19

The Subcommittee on Health held a hearing entitled "Medical Radiation: An Overview of the Issues" on Friday, February 26, 2010, at 10:00 a.m. in room 2123 of the Rayburn House Office Building. This hearing examined the potential benefits and risks of the use of radiation in medicine.

Witnesses

- James and Donna Parks, Gulfport, Mississippi
- Suzanne Lindley, Canton, Texas
- Rebecca Smith-Bindman, M.D., Professor in Residence, Radiology and Epidemiology and Biostatistics, Obstetrics, Gynecology, and Reproductive Medicine, University of California, San Francisco
- Eric E. Klein, Ph.D., Professor of Radiation Oncology, Washington University in St. Louis
- Cynthia H. McCollough, Ph.D., Director, CT Clinical Innovation Center, Department of Radiology, Mayo Clinic, Professor of Radiological Physics, College of Medicine, Mayo Clinic

Witnesses

- **James and Donna Parks**
- **Suzanne Lindley**
- **R Smith-Bindman, MD, UCSF**
- **Eric E Klein, PhD, Wash U**
- **CH McCollough, PhD, Mayo**
- **Tim R Williams, MD, ASTRO**
- **Michael G Herman, PhD, AAPM**
- **Sandra Hayden, BS,RT(T), ASRT**
- **E Steven Amis, Jr., MD, ACR**
- **Kenneth Mizrach, VA-NJ**
- **David N Fisher, MITA**
- **John J Donahue, Medicalis, Inc**

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House Hearings: Medical Radiation

Points from Testimony

- “inept team of therapists”
- Minimally-invasive procedure → nightmare
- Wife’s request to stop was ignored
- “what killed Scott, was human error”
- CARE Bill is “common sense”
- Patients should be the #1 focus

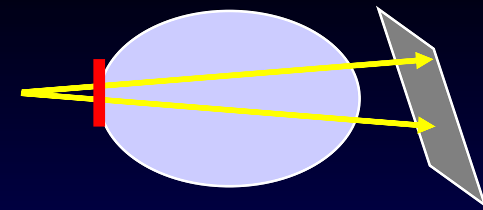
Radiation “Events” are Not New
However, perhaps more visible

- Initial “events” after ionizing radiation discovered 115 years ago
- Occupational exposures

- More recent events associated with practices and technologies
- A review – some cases and causes …

Imaging Event (yr 2000)

Imaging Injury At 100 kV



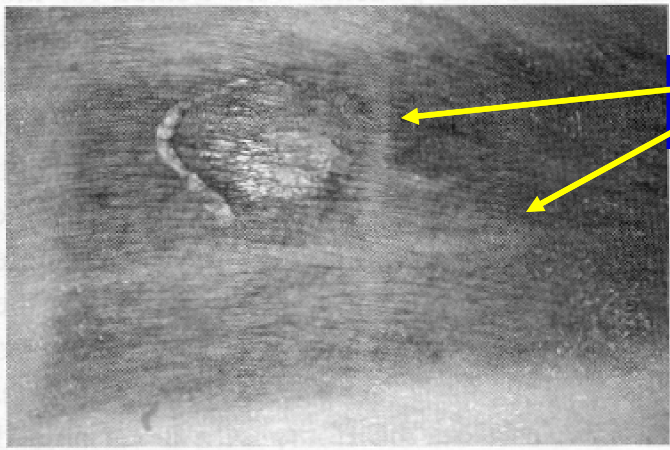


FIG. 1. Showing the radiation-induced ulceration in one of the patients. Notice the well-demarcated x-ray field, and the protection of skin shielded by the lead cross hairs.

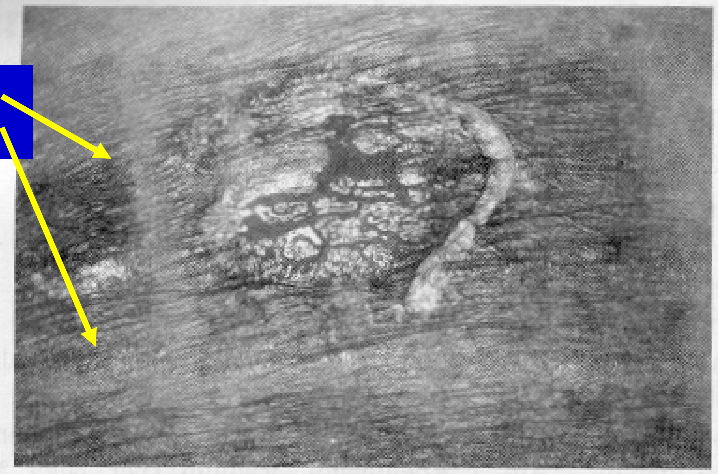


FIG. 2. Showing the progression of the injury into an ulcer.

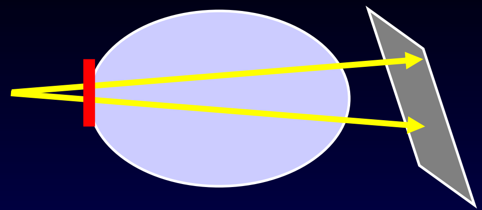
Radiation injury from x-ray exposure during brachytherapy localization B. R. Thomadsen, B. R. Paliwal, D. G. Petereit, and F. N. Ranalloo) *University of Wisconsin-Madison, Department of Medical Physics, Madison, Wisconsin 53706* ***Med Phys 2000***.

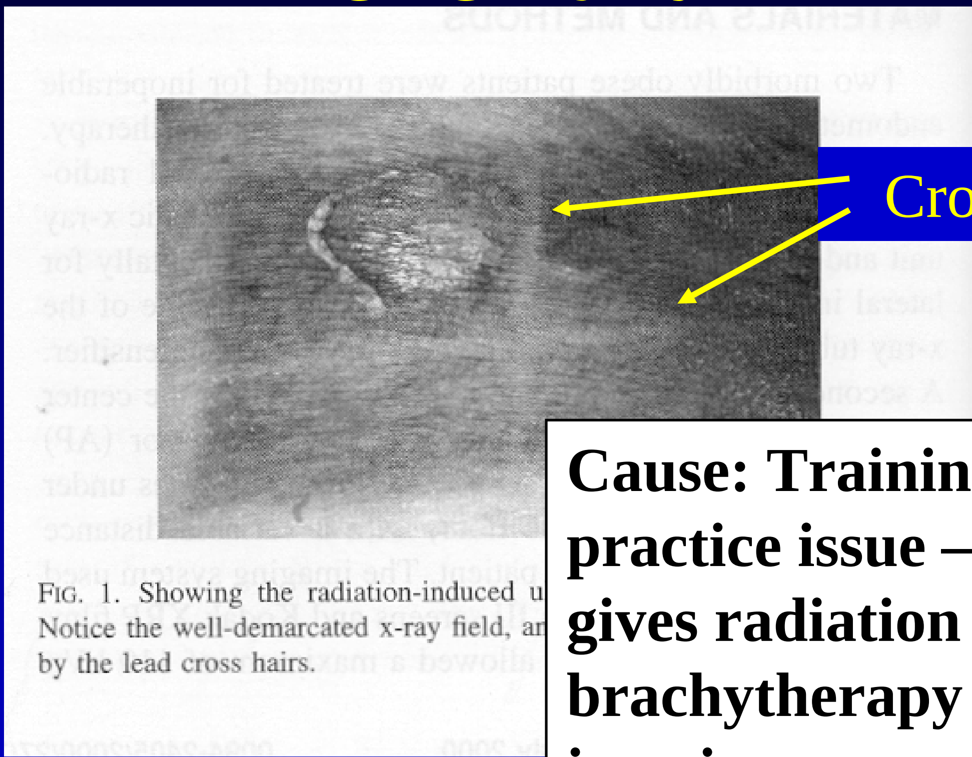
Dose to the entrance skin due to imaging radiographs.

	Patient 1	Patient 2
Cal'd Exp Rate	0.17 mGy/mAs @ 76cm	0.17 mGy/mAs @ 76cm
ISL correction	(76 cm/23 cm)^2	(76 cm/23 cm)^2
Technique Fac	500 mAs/exposure	500 mAs/exposure
Exposures / film	12 exposures/film	12 exposures/film
Films / Rx Course	5.75 films	2 films
BSF	1.3	1.3
Tot Equiv Dose	**83 Gy**	**29 Gy**

Imaging Event (yr 2000)

Imaging Injury At 100 kV





Cross hairs

Cause: Training/education and practice issue – "forgot" imaging gives radiation dose; focused on brachytherapy procedure, not imaging process

Radiation injury from x-ray exposure during brachytherapy localization B. R. Thomadsen, B. R. Paliwal, D. G. Petereit, and F. N. Ranalloo) *University of Wisconsin-Madison, Department of Medical Physics, Madison, Wisconsin 53706* ***Med Phys 2000***.

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		Patient 2
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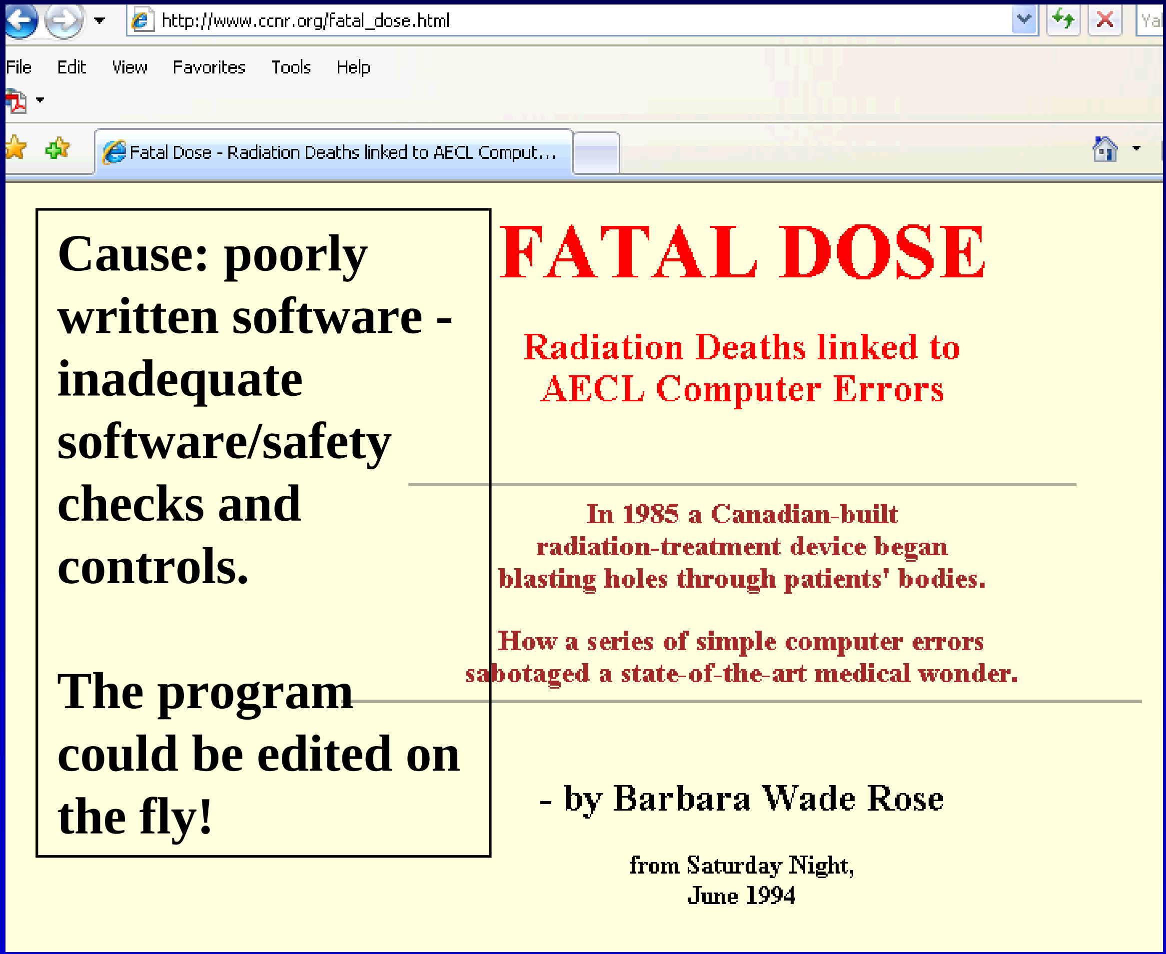
The **Original** Computer Radiation Dose Event

“**Malfunction 54**” 1985-87 US, Canada

- First “computer-controlled” linear accelerator
- Basic programming language
- Therapist able to out-run the computer program
- Reprogrammed for electron treatment at photon beam current
- **Result: 250 Gy in ~ 2s**
- Patients injured, died from localized overdoses



ComputingCases.org

Cause: poorly written software - inadequate software/safety checks and controls.

- **How to Produce a Malfunction 54 on a [AECL] Therac-25 Linear Accelerator**
- **This statement was written by the East Texas Cancer Center physicist after he discovered how to reproduce the Malfunction 54 error**
- Enter the room and **set up the machine for an electron beam treatment** by selecting a field size and installing the trimmers. Press the set button. Leave the room and close the door. At the control console proceed to the patient set-up display. **For Mode enter "X".** The machine will default to 25 MeV and go to dose rate of 250 rads/min. Use return key to go to dose. Enter 200. Use return key to go to time. Enter 0.8 min. Use the return key to rapidly advance to the bottom of the display. Immediately use the up arrow to move from the bottom of the display. You are now in the edit mode. **Use the up arrow to go to the top of the display and change the mode "X" to "E" for electrons.** Change the energy from 25 to 10. Use the return key to go back down to the bottom of the display. Wait for the "beam ready" message then type "B" return. The unit will have no indications on dose rate or dose 1 or dose 2 for about 3 to 4 seconds. Then the dose rate will flash 550 to 575 for one cycle and return to zero. Dose 1 and Dose 2 will count to -6. **A malfunction 54 message will appear at the bottom of the display. You have just delivered a dose of approximately 25,000 rads of 25 MeV electrons in less than two seconds.**

Classic case of “no bug in program until found”

Scotland: Brain Radiation Treatment: 2006

Event

- Brain radiation treatment
- 19 overdoses

Cause?

- Incorrect calculation point?
- Missing wedge?

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Last Updated: Thursday, 19 October 2006, 12:06 GMT 13:06 UK

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Radiation overdose teenager dies

A 16-year-old cancer patient who was given massive overdoses of radiation earlier this year has died.

VIDEO Lisa told of her fears in an interview in February

Lisa Norris, from Girvan in Ayrshire, received at least 17 overdoses during treatment for a brain tumour at the Beatson Oncology Centre in Glasgow.

Sir John Arbuthnott, the chairman of NHS Greater Glasgow and Clyde, said everyone was "extremely upset at the sad news".

The cause of Lisa's death is not known at this stage.

It is understood that Lisa died at her home in Girvan on Wednesday.

"She was determined not to give up her fight and she stayed fighting until the end"

VIDEO AND AUDIO NEWS
Tests will aim to identify the cause of Lisa's death
Watch

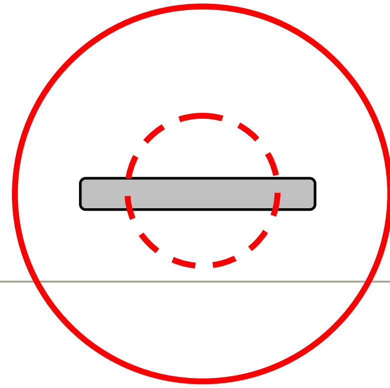
SEE ALSO
- Radiation girl back in hospital 25 Sep 06 | Glasgow and West
- Beatson centre gave 39 overdoses 12 May 06 | Glasgow and West
- Radiation girl 'feeling better' 28 Feb 06 | Scotland
- Radiation overdose girl improving 17 Feb 06 | Scotland
- Apology for radiation error girl 08 Feb 06 | Scotland

RELATED INTERNET LINKS
- NHS Greater Glasgow
- Beatson Oncology Centre
- Cancer Research UK
- Cancer BACUP Scotland

The BBC is not responsible for the

"New Event" Feb 2010: 76 Cases, Linac SRS

The New York Times Reprints



February, 2010

50% overdose for "small fields"
Cause: calibration error by physicist (wrong size ionization chamber)

February 24, 2010

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ

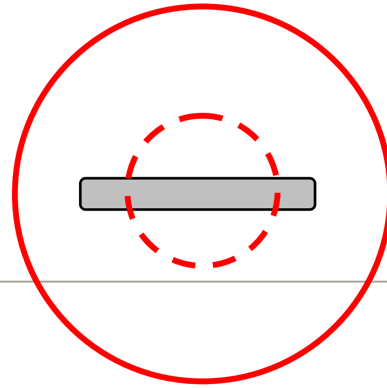
A hospital in Missouri said Wednesday that it had overradiated 76 patients, the vast majority with brain cancer, during a five-year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

The hospital, CoxHealth in Springfield, said half of all patients undergoing a particular type of treatment — stereotactic radiation therapy — were overdosed by about 50 percent after an unidentified medical physicist at the hospital miscalibrated the new equipment and routine checks over the next five years failed to catch the error.

The revelation comes at a time of growing concern about safety procedures for a new generation of powerful, computer-controlled medical radiation equipment.

Stereotactic therapy delivers radiation in such high doses that usually only one treatment is required. It is commonly used to treat small tumors in the head, which must be firmly stabilized, allowing radiation to be delivered to a precise location.

The New York Times Reprints



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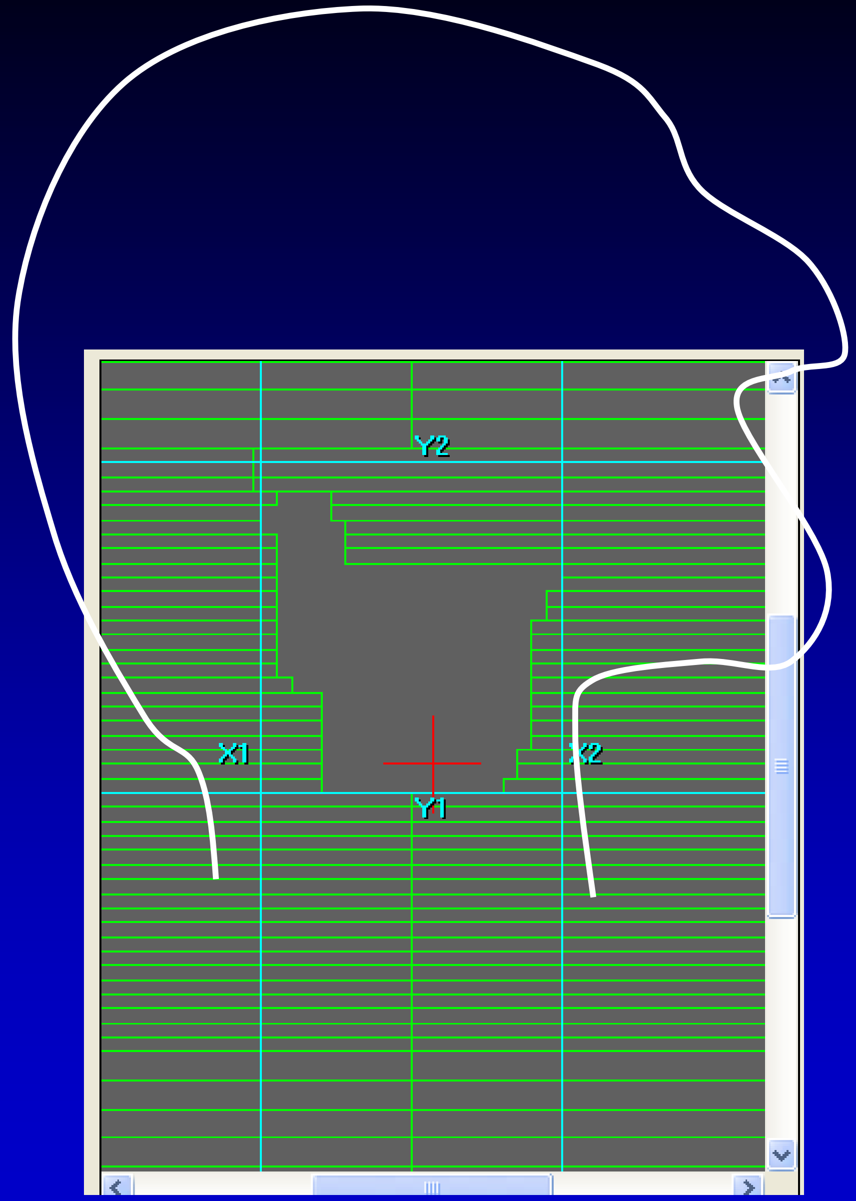
Florida: another linear accelerator radiosurgery case:

- **77 patients**
- **50% overdose due to calibration error: due to a spreadsheet programming/calculation error**

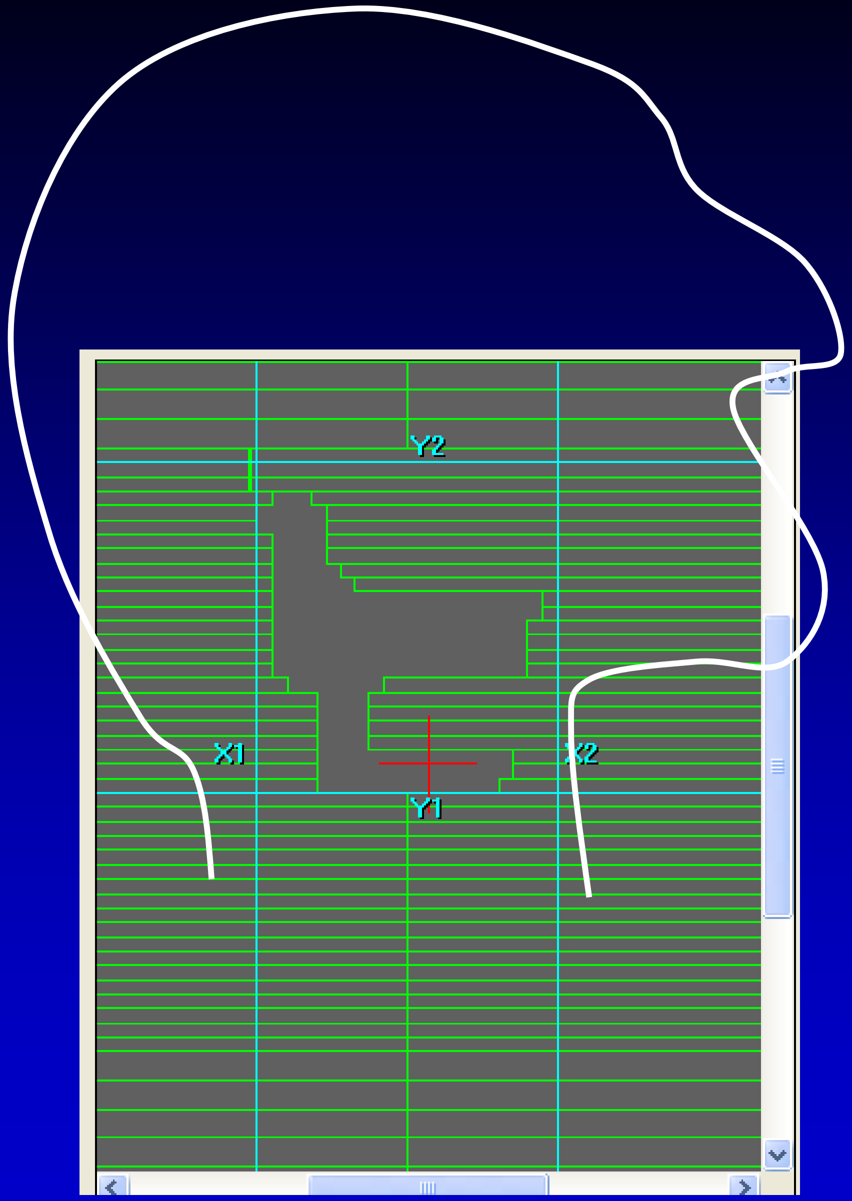
Stereotactic therapy delivers radiation in such high doses that usually only one treatment is required. It is commonly used to treat small tumors in the head, which must be firmly stabilized, allowing radiation to be delivered to a precise location.

New York: IMRT

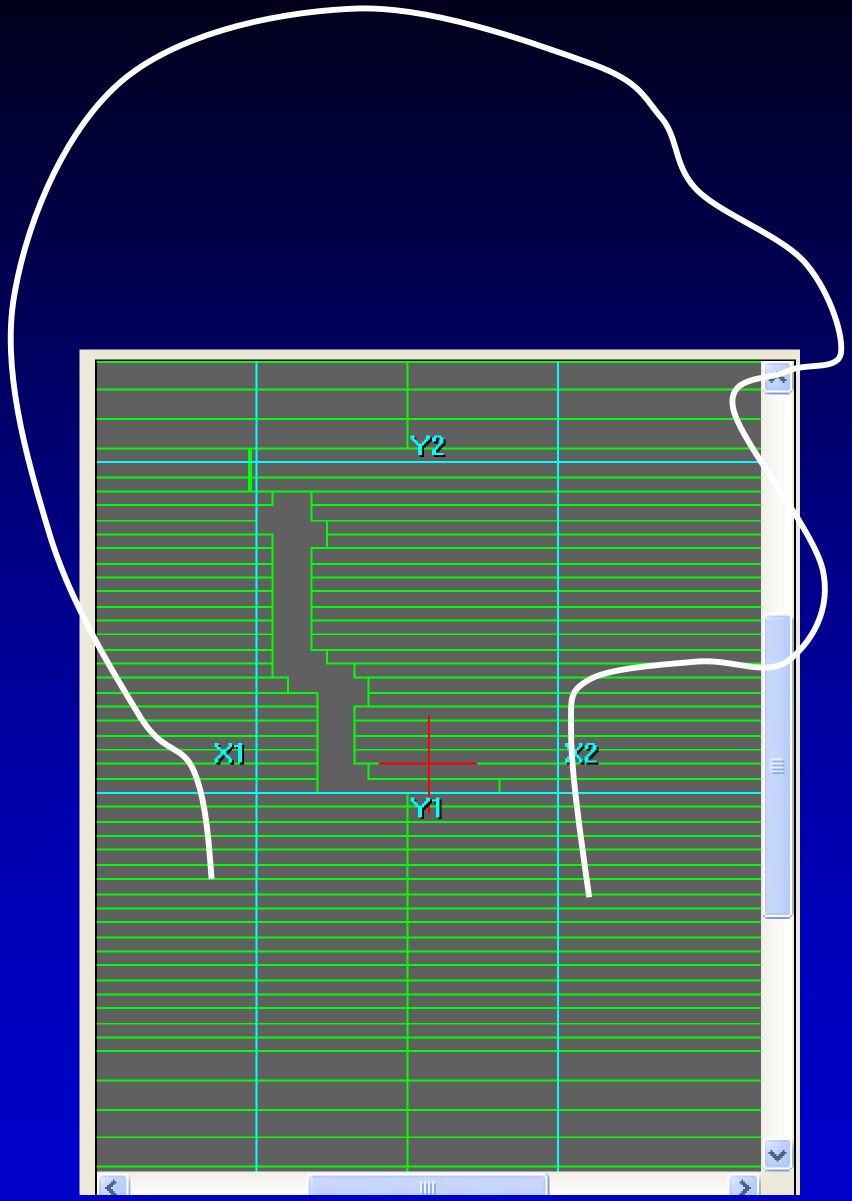
- IMRT – individual MLC leaves move to modulate the field intensity
- Field shape changes as a function of time and dose



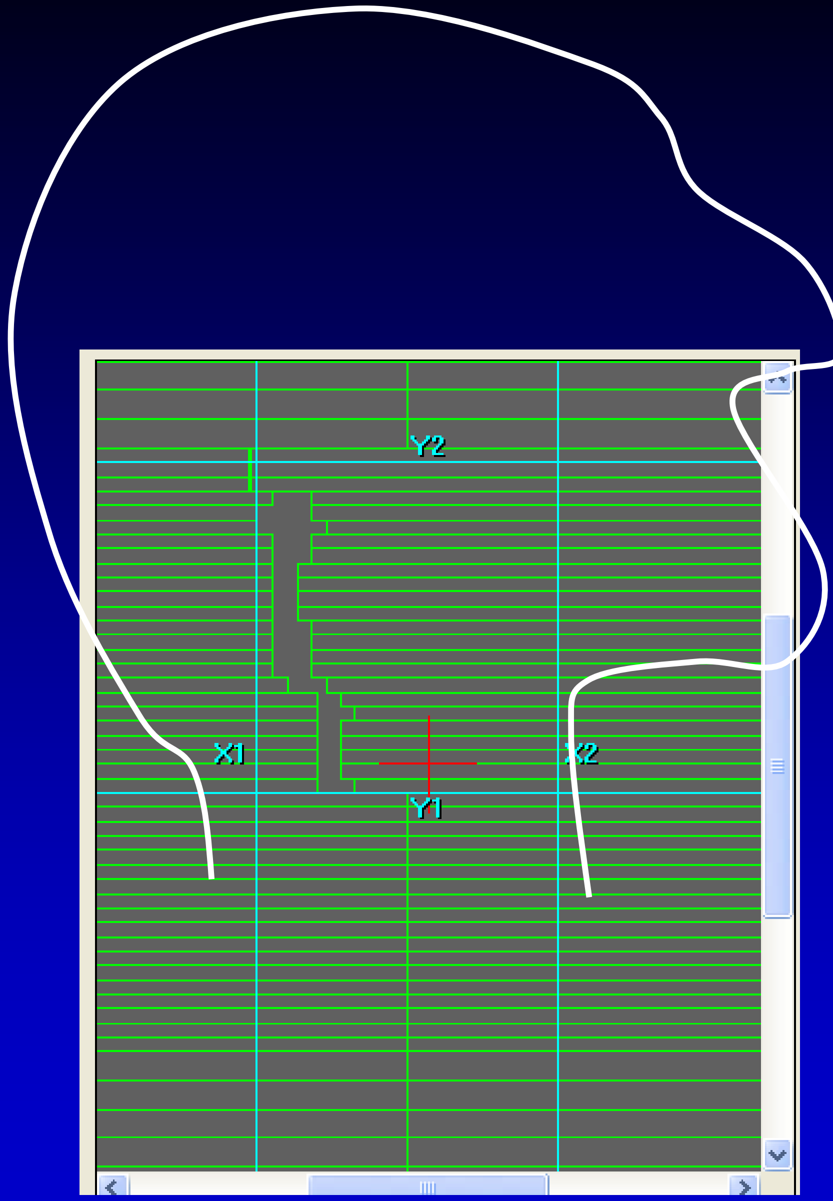
New York: IMRT



New York: IMRT



New York: IMRT



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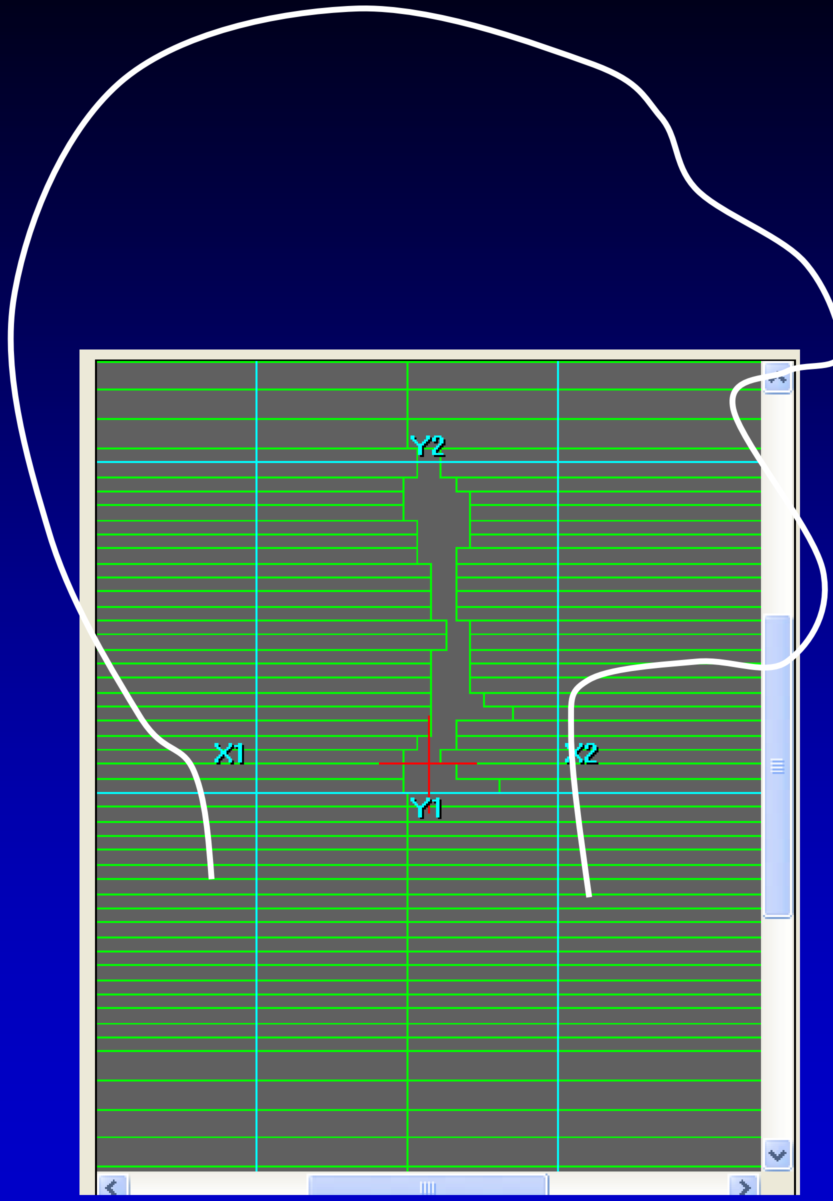
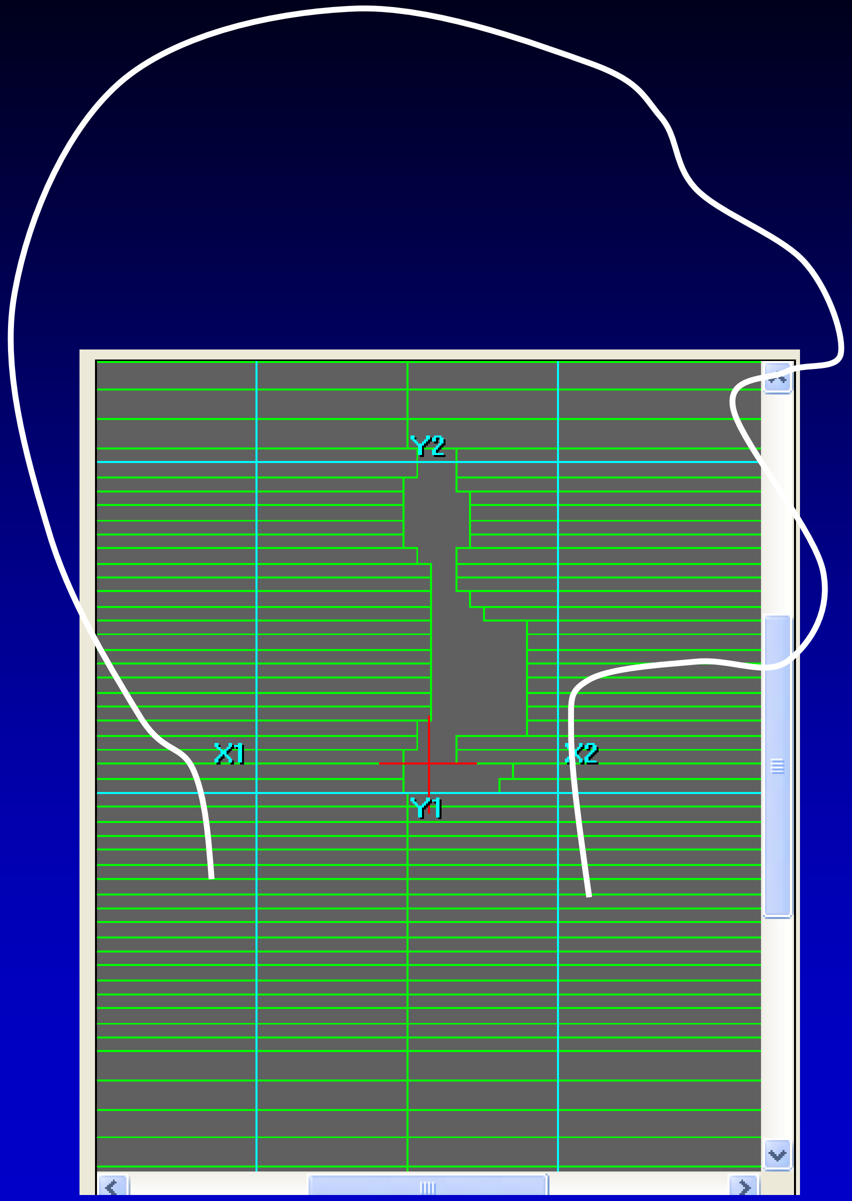


New York: IMRT



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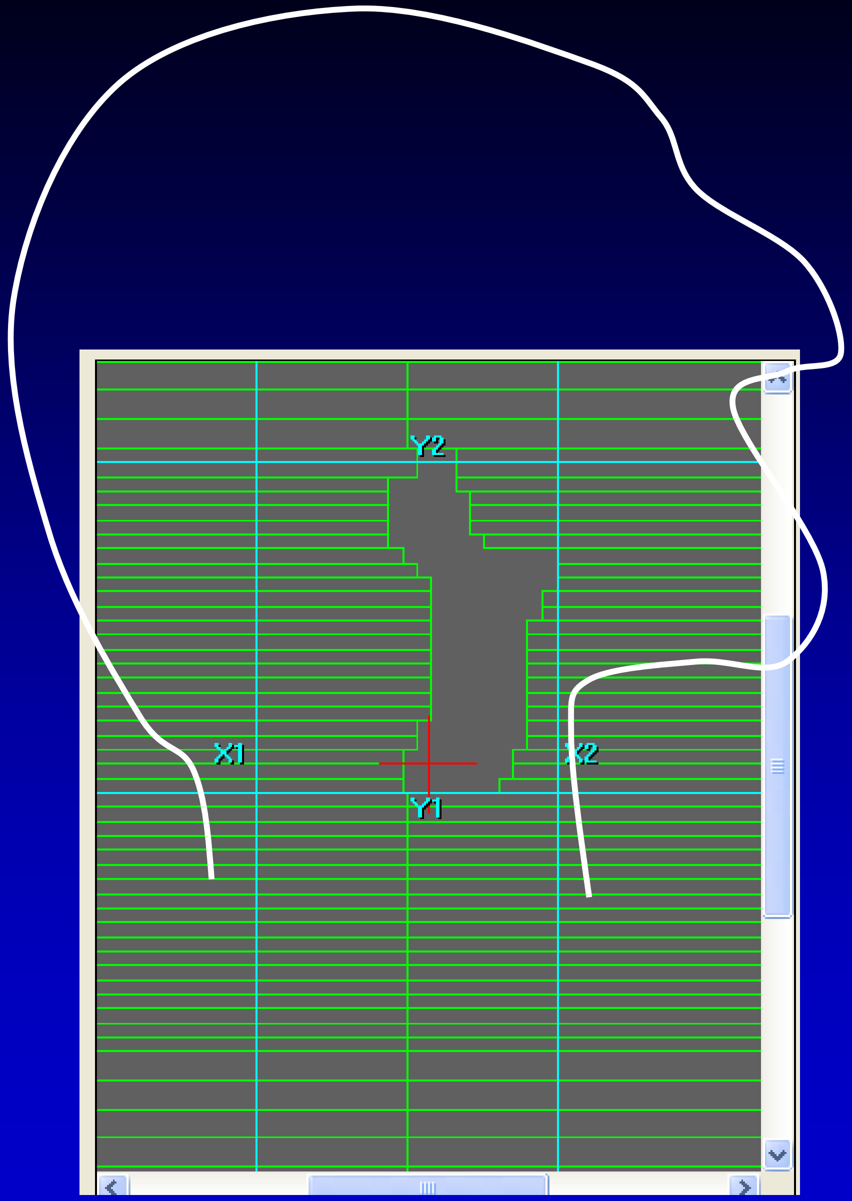
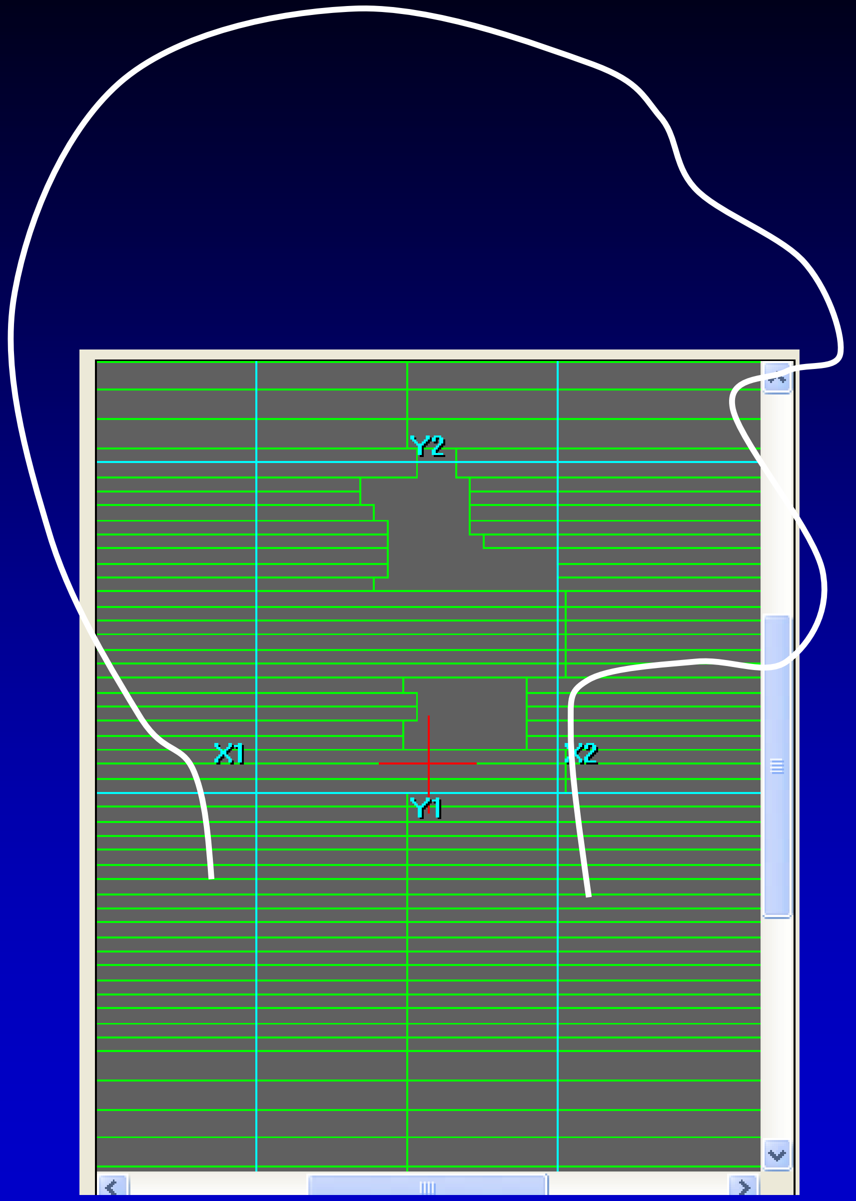


New York: IMRT



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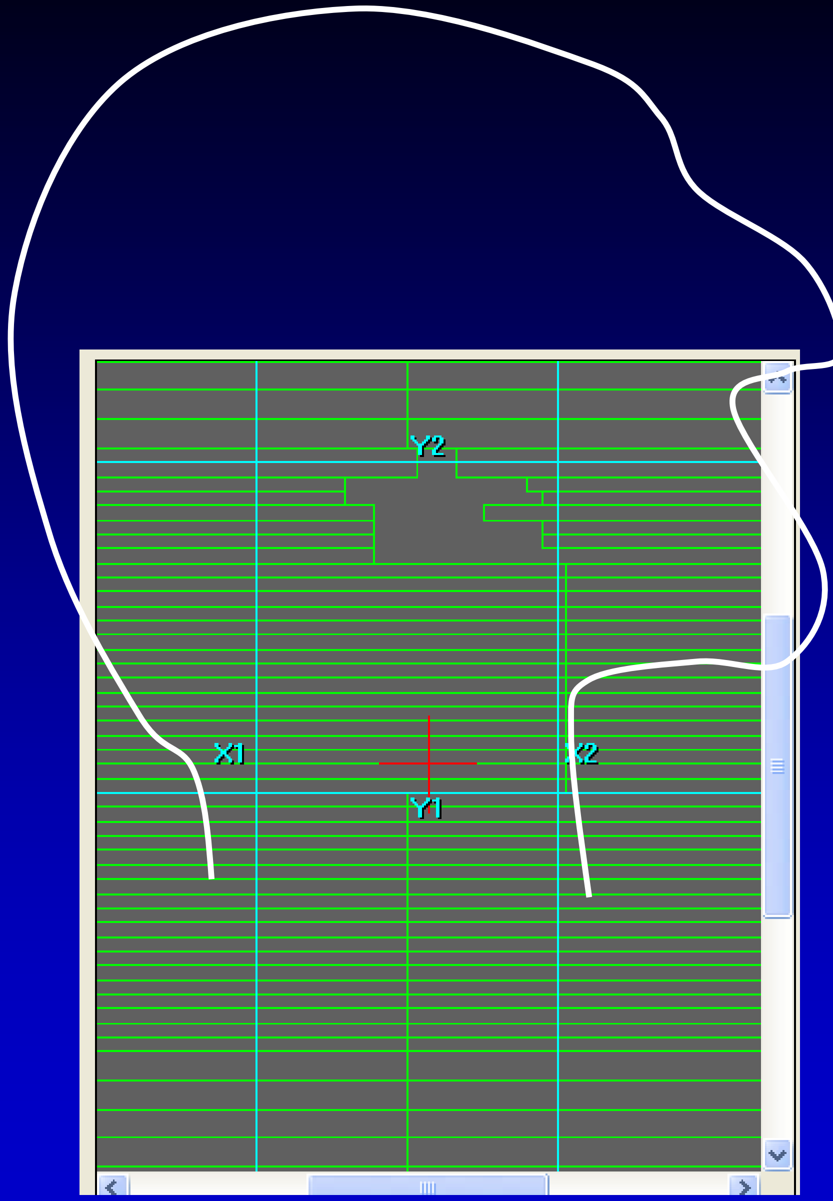
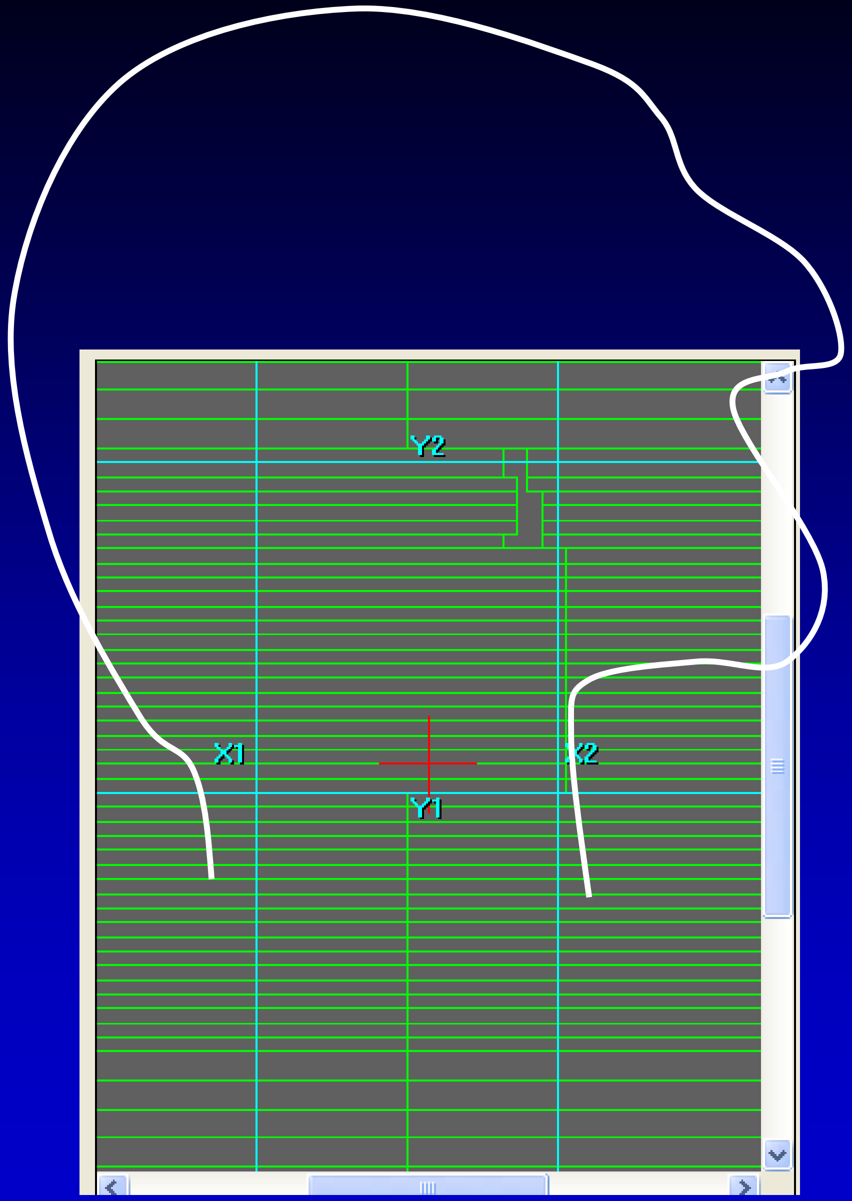


New York: IMRT

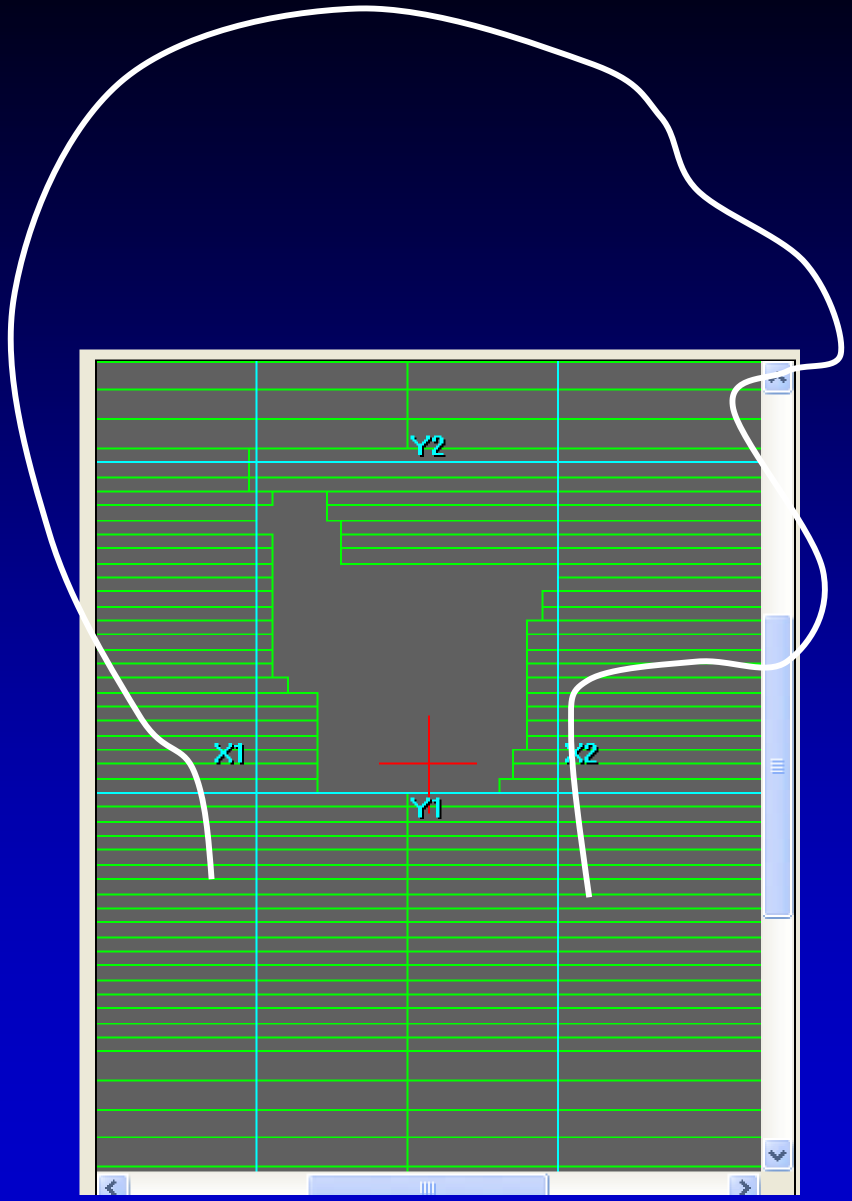


New York: IMRT

- 1st 3 fxs delivered without issue
- Upon IMRT plan revision: "Save All"
- However, not all data saved
  - Fluence data saved; DRR saved in part
  - MLC control points NOT saved
- No verification plan created (for physics QA)
  - Verification plan would have shown no MLC in use
- Treatment plan has valid MUs

  but no MLC control points
- Patient treated for 3 fractions: beams delivered without MLC shapes or motions

  field was "wide open"
- We received and reviewed a 9-page letter from the vendor to explain various manners of incorrect program terminations



What can go wrong in radiation treatment?
Ola Holmberg, Ph.D., IAEA, Vienna, Austria
Safety in Radiation Therapy – A Call to Action, June 24-25, 2010

New York: IMRT

- 1st 3 fxs delivered without issue
- Upon IMRT plan revision: "Save All"
- However, not all data saved – **computer "crash"**
  - Fluence data saved; DRR saved in part
  - MLC control points NOT saved
- No verification plan created (for physics QA)
  - Verification plan would have shown no MLC in use
- Treatment plan has valid MUs

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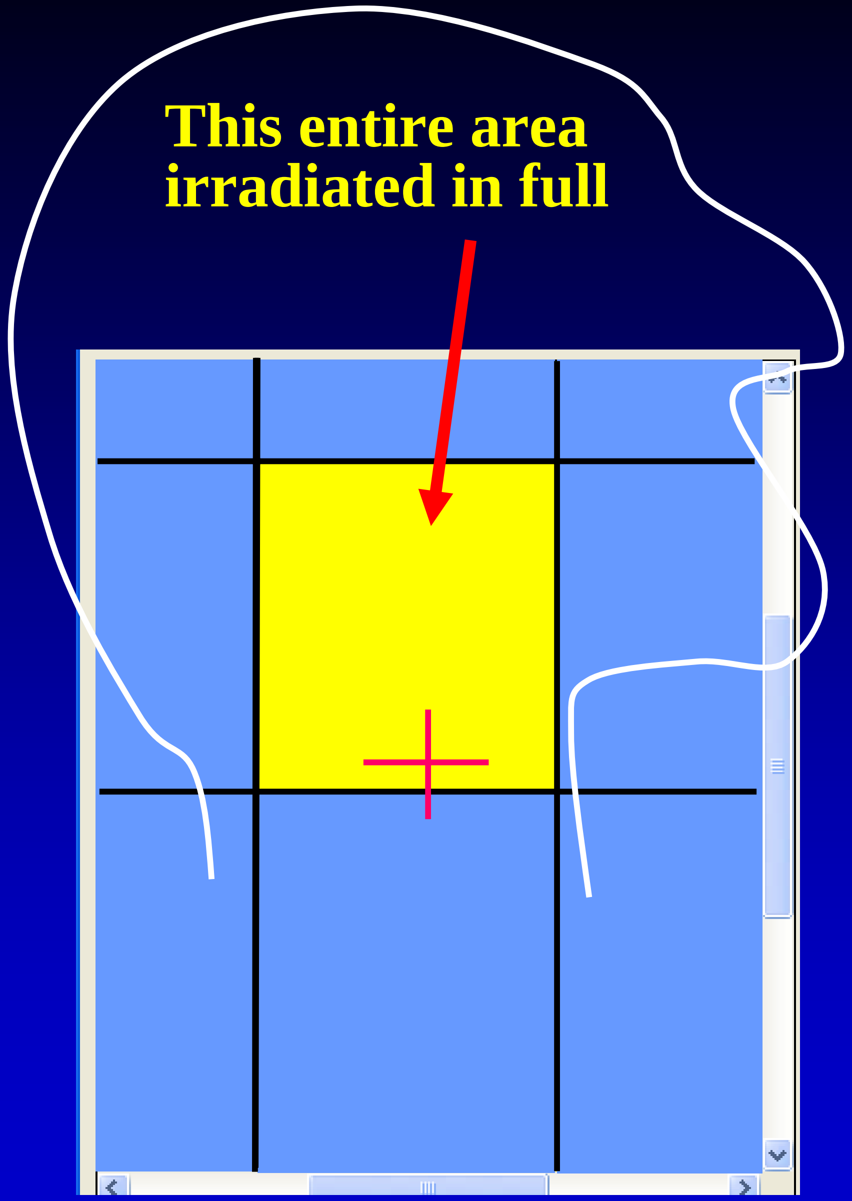

What can go wrong in radiation treatment?
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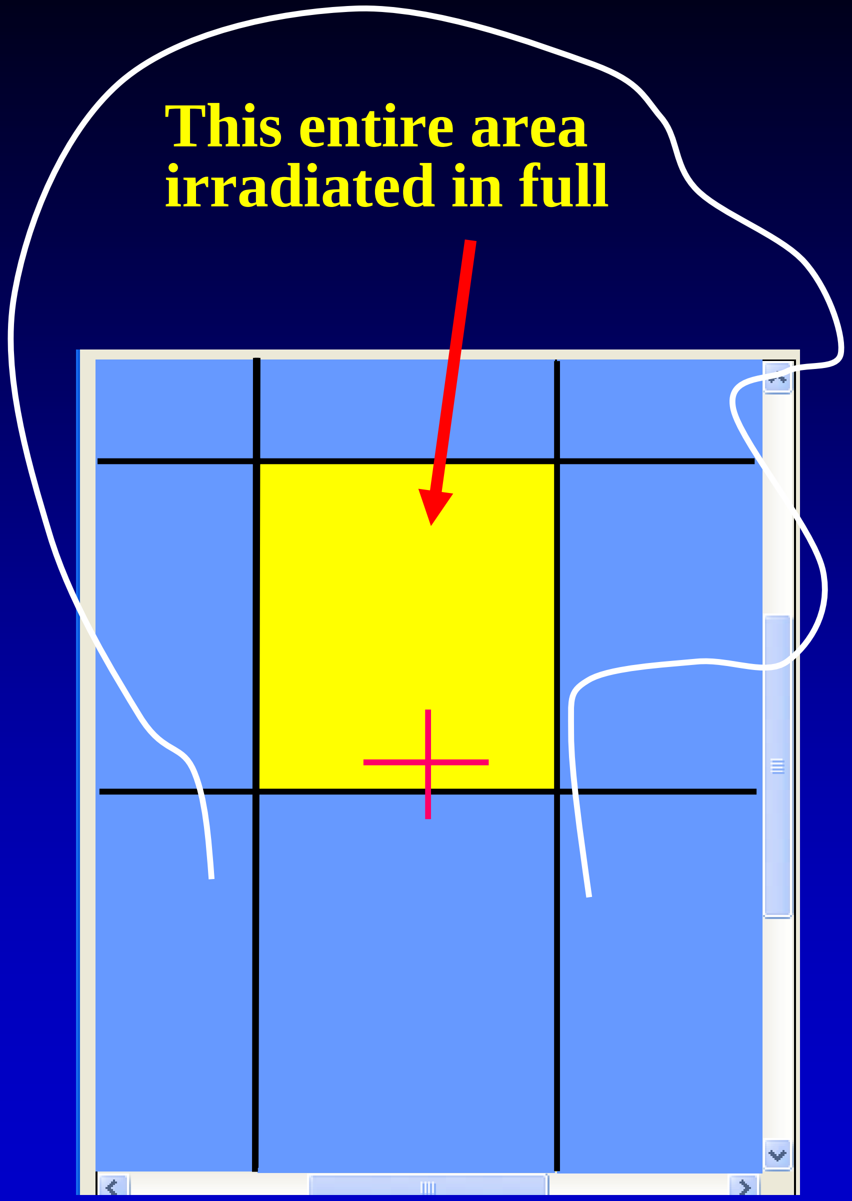
New York: IMRT

- IMRT MUs about 4-5 times higher than 3D-CRT
- High dose received to non-target volumes

3 x 13 Gy = 39 Gy

Reportedly -

- Plan was revised
- IMRT QA not done
- Overworked and rushed personnel
- Control console not observed
- Patient concerns not listened to



Can **Digital Image** Errors Occur?

Yes – Example: **Mirror-Image** Mistakes

GAMMA KNIFE TREATMENT TO WRONG SIDE OF BRAIN

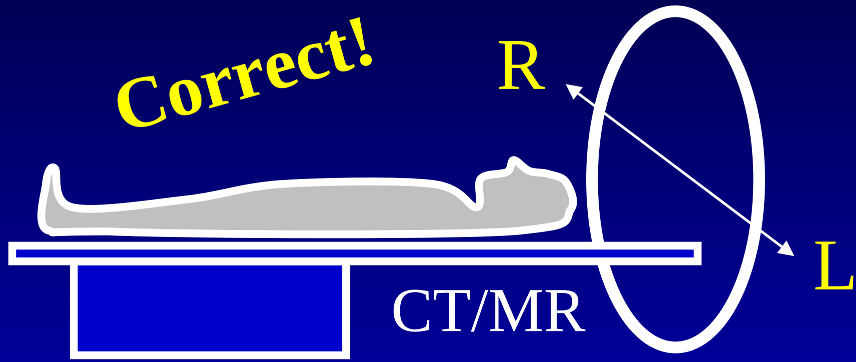
"On October 24, 2007, a medical event occurred at Leksel Gamma Knife facility which resulted in the total dose delivered differing from the prescribed dose by more than 20%.

"Due to a left - right reversal of the treatment planning MRI images, the patient's left side was targeted and treated rather than the right side. The error resulted in an 18 mm shift of isocenter across midline of the brain. The collimator diameter selected for the treatment was 18 mm, thus resulting in some overlap of the delivered 50% isodose volume with the correct intended target lesion volume. The event resulted in approximately 7% of the lesion volume receiving the prescribed dose of 18 Gy to the 50% isodose, rather than the preferred 95% of the lesion volume.

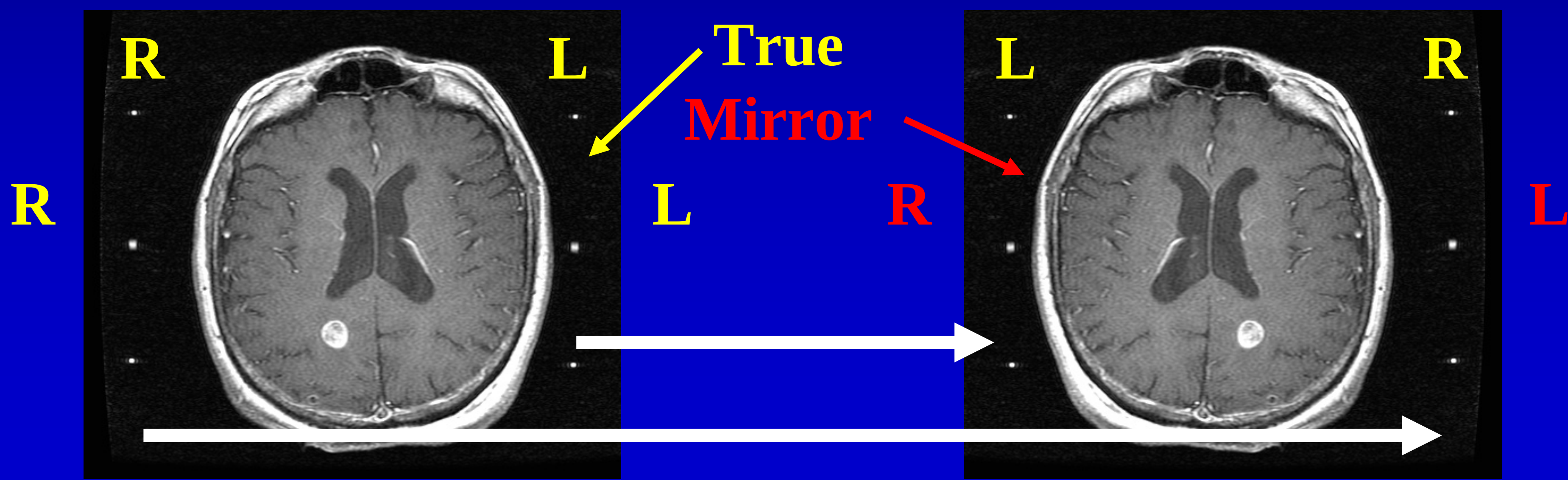
http://www.nrc.gov/reading-rm/doc-collections/event-status/event/2007/20071029en.html

Patient + Scan Orientations

Patient + Scan Label:
Supine, Head First



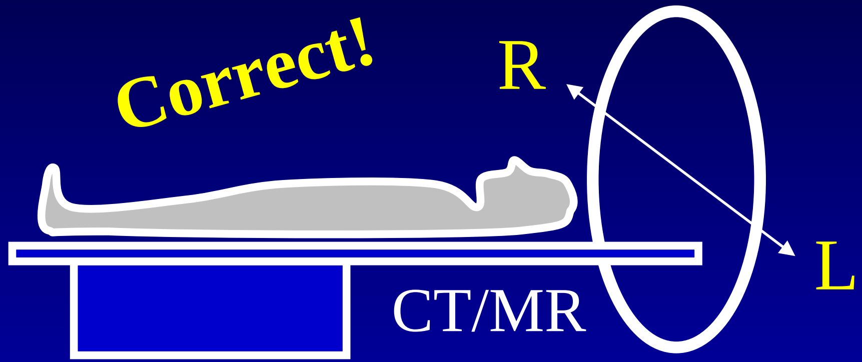
Patient: Supine, Head First
Scan Label: Supine, Feet First

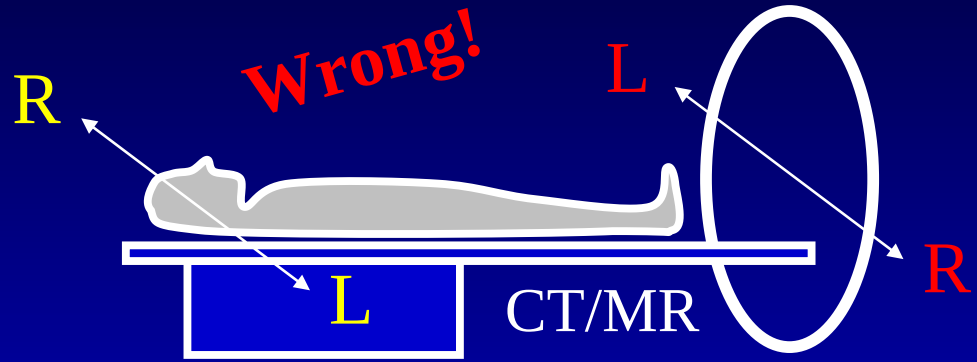


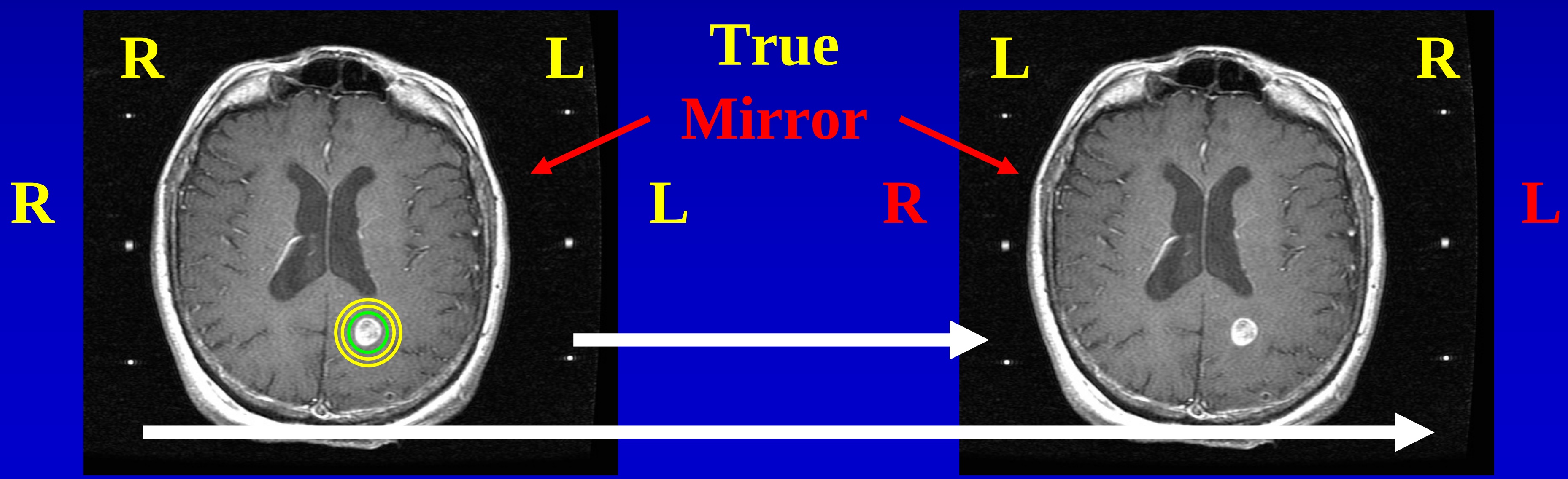
What They Thought They Were Doing

Patient + Scan Label:
Supine, Head First

Patient: Supine, Head First
Scan Label: Supine, Feet First

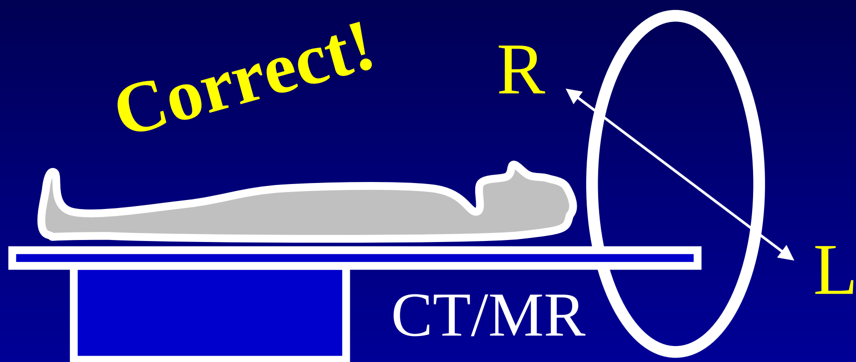




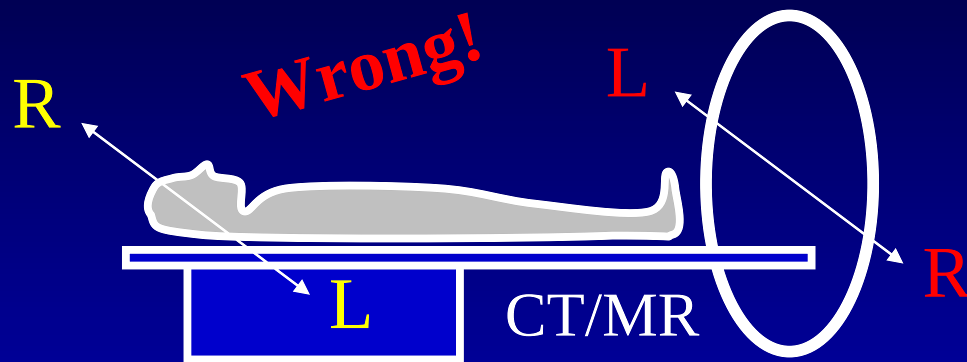


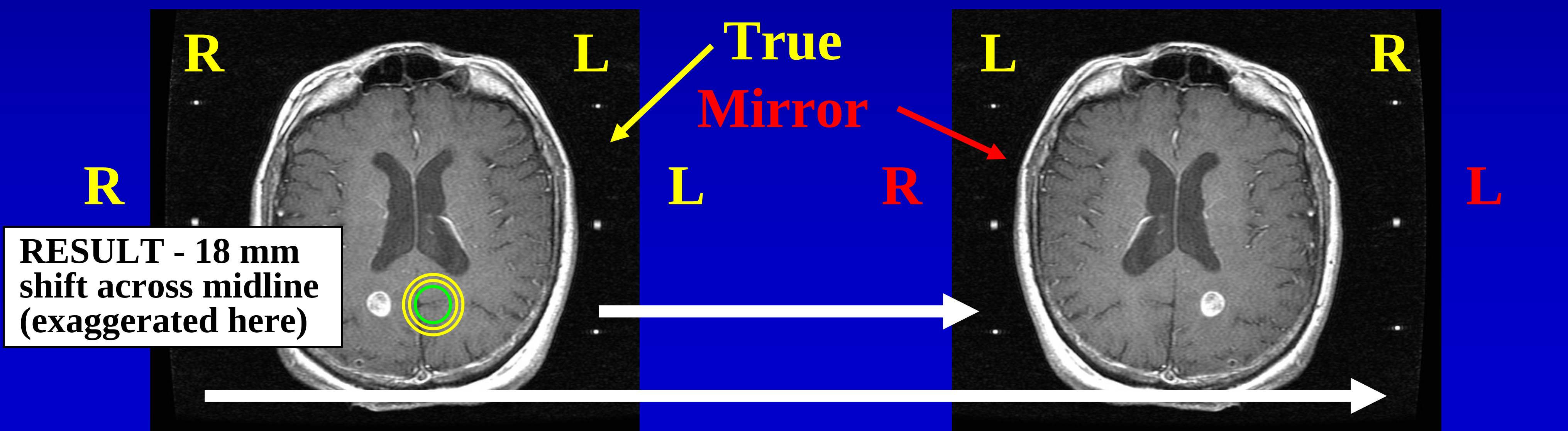
What Really Happened

Patient + Scan Label:
Supine, Head First



Patient: Supine, Head First
Scan Label: Supine, Feet First

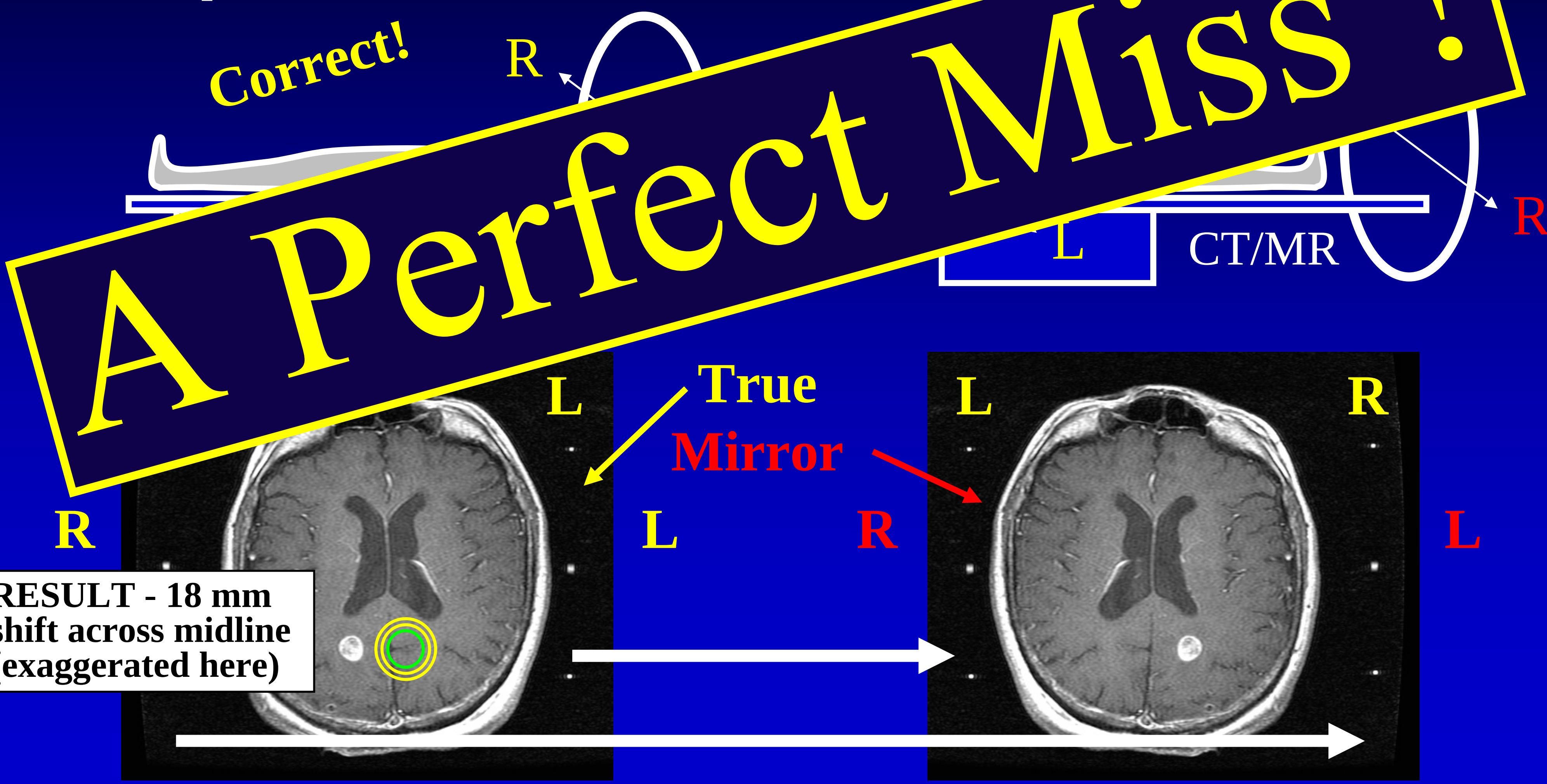




What Really Happened

Patient + Scan Label:
Supine, Head First

Patient: Supine, Head Fi
Scan Label: S



New Kinds of Errors

ELSEVIER

Annals of the ICRP

JEAN-MARC COSSET

ICRP Publication 112

Guest Editorial

NEW TECHNOLOGIES, NEW RISKS

ICRP *Publication 86*, 'Prevention of accidental exposures to patients undergoing radiation therapy', was published in 2000 (ICRP, 2000). The usual life span of the ICRP recommendations exceeds, sometimes by far, a full decade. Consequently, it may appear somewhat surprising to see ICRP publishing a new document focusing on the risks of accidents in radiotherapy less than 10 years after ICRP *Publication 86*.

In fact, the authors of ICRP *Publication 86* had somehow anticipated such a need: a few sentences found in the text appear to foreshadow this publication. A full section (5.9) was devoted to 'The potential for accidental exposures in the future'.

ICRP Pub 86 (2000)   ICRP Pub 112 (2010)

ICRP 86 – "A Forecast" (2000)

'The recommendations ... [in this publication] are based on a retrospective analysis of accidental exposures in radiation therapy with past and current types of equipment. There are, however, a number of factors that may cause a change in this picture in the future:

- With the worldwide expansion of radiotherapy there may be more accidents related to inadequate staff training ....
- There is a common misperception that modern equipment is safer and will require less quality assurance.
- ...Accidents may occur due to inadequate accelerator maintenance .... The increased number of computer-controlled systems may also lead to more computer related accidents, compared to mechanical failures.
- The new technologies of high dose rate (HDR) brachytherapy, "gamma knife" therapy units, multi-leaf collimators, and intensity modulated radiotherapy (IMRT) may produce new types of accidental exposures.'

ICRP 86 – “A Forecast” (2000)

Moreover, the Summary of ICRP *Publication 86* notes that ‘Major accidental exposures are rare, but it is likely that they will continue to happen unless awareness is increased. Accidents will usually occur as the result of inadequate education and training, lack of quality assurance, poor infrastructure, equipment failure, and improper decommissioning. Unless these issues are properly addressed and dealt with, more accidental exposures are likely to occur, as current and new technologies developments are disseminated.’

Actually, the authors of ICRP *Publication 86* would clearly have preferred to be wrong! Unfortunately, they were not and it has recently become apparent that their pessimistic predictions were partly right.

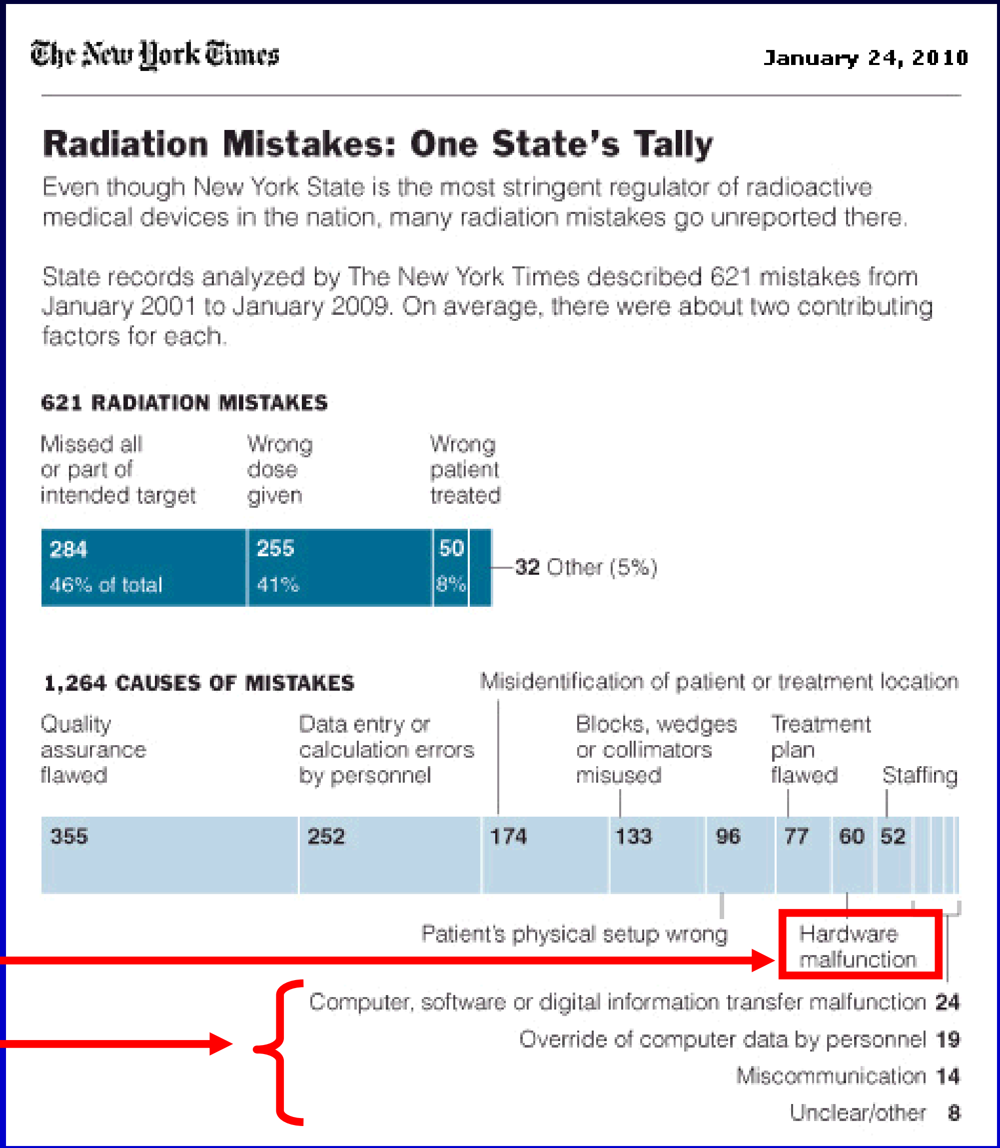
Classes and Causes of Events

Classes of Errors

• **Missed all/part of target**	**46%**
• **Wrong dose**	**41%**
• Wrong patient	8%
• Other – eg, technology	5%

Causes of Errors

• **QA flawed**	**28%**
• **Data entry & calc errors**	**20%**
• Mis-ID: patient, site	14%
• Setup error (blocks, wedges)	11%
• Patients physical setup wrong	8%
• Flawed treatment plan	6%
• Hardware malfunction	5%
• Software/data transfer, software overrides, communication	5%



A Few Quotes

- Howard Amols, MSK: "… hospitals, he said, are often too trusting of the new computer systems and software, relying on them as if they had been tested over time, when in fact they have not."
- Amols: "The problem is that computers are better at checking humans than humans are at checking computers. The responsibility on Day 1 to make everything right is much more important than it used to be," he said. "We are still grappling with how we do that."
- Amols on the ASTRO plan: "They're telling the public that radiation is a safe and effective cancer treatment, but we know it can be made even safer,"

Noting that airlines have an even better safety record than radiotherapy: "We need to learn from them."

Source: NY Times, January 2010

Radiotherapy incidents

Trend analysis of radiation therapy incidents over seven years

Jean-Pierre Bissonnette*, Gaylene Medlam Radiotherapy and Oncology 96 (2010) 139–144

Radiation Medicine Program, Princess Margaret Hospital, Toronto, Ontario, Canada

PMH 2010

- 8,300 treatment courses/year
- 1,063 incidents and near-misses, 2001-07
- New technologies over this same period
- Actual events stabilized at 1.22 per 100 courses
- Moderate/severe events = 0.06 per 100 courses

Table 1
Taxonomy for classification of treatment incidents.

Dimension	Subtype	Definition
Type	Dosimetric	Inaccurate execution of a prescription to a volume leading to a variation of 5% in daily dose
	Geometric	Execution of a prescription to the wrong volume; any spatial discrepancy exceeding 5 mm
Cause	Location	Inappropriate isocentre shifts are applied, skin marks are misidentified, junctions are mismanaged, or an inappropriate anatomy is planned or treated
	Laterality	Subclass of location errors, defined by the transposition of left and right
	Documentation	Documentation or instructions are unclear, incomplete, or incorrect
	Non-compliance	Procedures are not carried out according to instructions, including research protocols, policies and procedures, or physician requests
	Change	Improper execution of a requested change in a radiotherapy course that has already begun
	Planning/dosimetry	Involves patient data import (ID, radiographic studies, and demographic data), dose calculation, programming of the record and verify system
	Infrastructure malfunction	Equipment breakdown or software bug; hardware or software that does not operate according to specification, resulting in prevention of treatment or mistreatment
	Accessory	Omission, addition, or incorrect use of any treatment accessory, including wedges, bolus, electron cones and inserts, or immobilization devices
	Human error	Improper operation of equipment of software; may involve environmental factors or relational issues
Clinical impact	Near miss	A declared incident that has been caught and remedied before reaching the patient. Score = 0
	None	[illegible]
	Minor	[illegible] core = 2
	Moderate	[illegible]
	Severe	[illegible] ancy in
Stage	Booking	[illegible]
	Imaging	[illegible]
	Planning	[illegible]
	Review	[illegible]
	Treatment	[illegible]

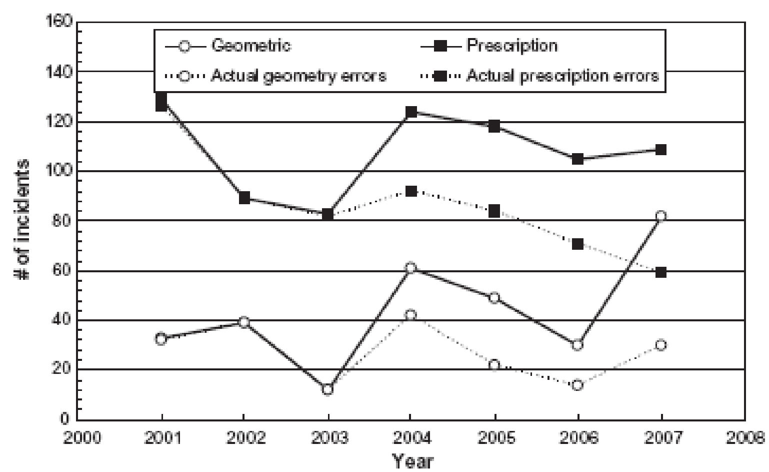


Fig. 2. Annual time trends for all incidents, classified as geometric and dosimetric incidents.

THE IMPACT OF ADVANCED TECHNOLOGIES ON TREATMENT DEVIATIONS IN RADIATION TREATMENT DELIVERY

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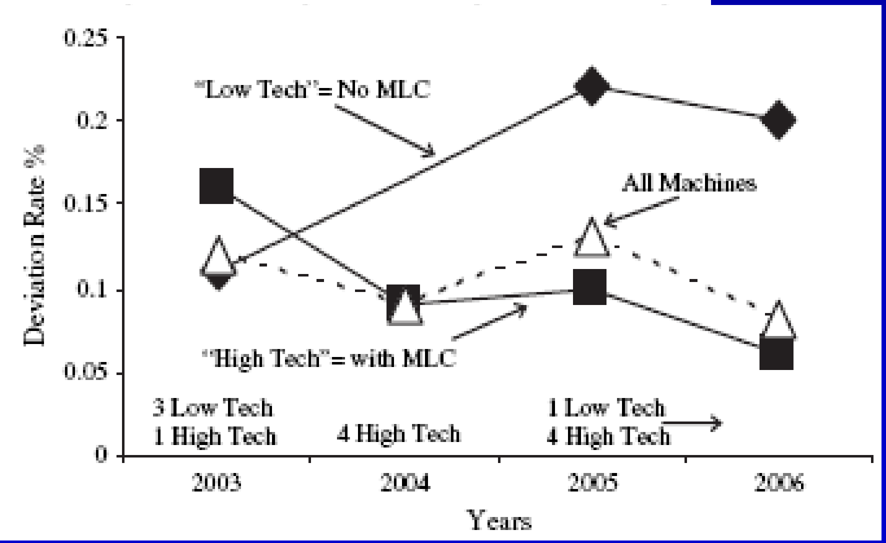
Int. J. Radiation Oncology Biol. Phys., Vol. 69, No. 5, pp. 1579–1586, 2007

Duke 2007

Table 2. Categorization of deviations

	2003	2003	2004	2004	2005	2005	2006	2006
Type of deviation	Low	High	Low	High	Low	High	Low	High
Data entry* (d)	3	2		7	0	7	0	2
Calculation† (d)	3	1		5	2	2	0	1
Chart write-up‡ (d)	1	0		2	0	1	0	0
CT simulation§	0	0		0	1	3	0	0
Arithmetic‖ (t)	2	0		0				
Cerrobend block¶ (t)	4	0		0				
Patient/field setup# (t)	2	1		6				
Total dose delivered** (t, p)	6	1		3				
Other††	2	1		0				
Totals	23	6		23				



- New and old technology

Deviation Rates [~ 1.2- 4.7% per course]

Table 5. Literature review

Author, year, institution (Ref.)	Deviation rates*
Huang, 2005, Princess Margaret Hospital (1)	1.97% (per treatment course)
	1.28% (per treated volume)
	0.29% (per treatment fraction)
Yeung, 2005, Northeastern Ontario Regional Cancer Center (5)	4.66% (per treatment course)
	0.25% (per treatment fraction)
Patton, 2003, University of Utah (3)	3.3% (per treatment course)
	0.17% (per treatment session)
Barthelemy-Brichant, 1999, Universitaire de Liege (4)	3.22% (per treatment field)
Fraass, 1998, University of Michigan (2)	1.2% (per treatment course)
	0.13% (per segment)
	0.44% (per treatment session)
Macklis, 1998, Cleveland Clinic Foundation (6)	3.06% (per treatment course)
	0.18% (per treatment field)
Current study, 2007, Duke University	0.10% (per treatment sessions)

Huang, Yeung, Patton, and Fraass conducted a retrospective analysis of deviations documented in therapist-reported or QA review. Macklis conducted a prospective and retrospective analysis of deviations documented in therapist-reported or QA review. Barthelemy-Brichant conducted a prospective blinded study comparing recorded parameters entered into record and verify with the prescriptions.

* Some data estimated from published reports

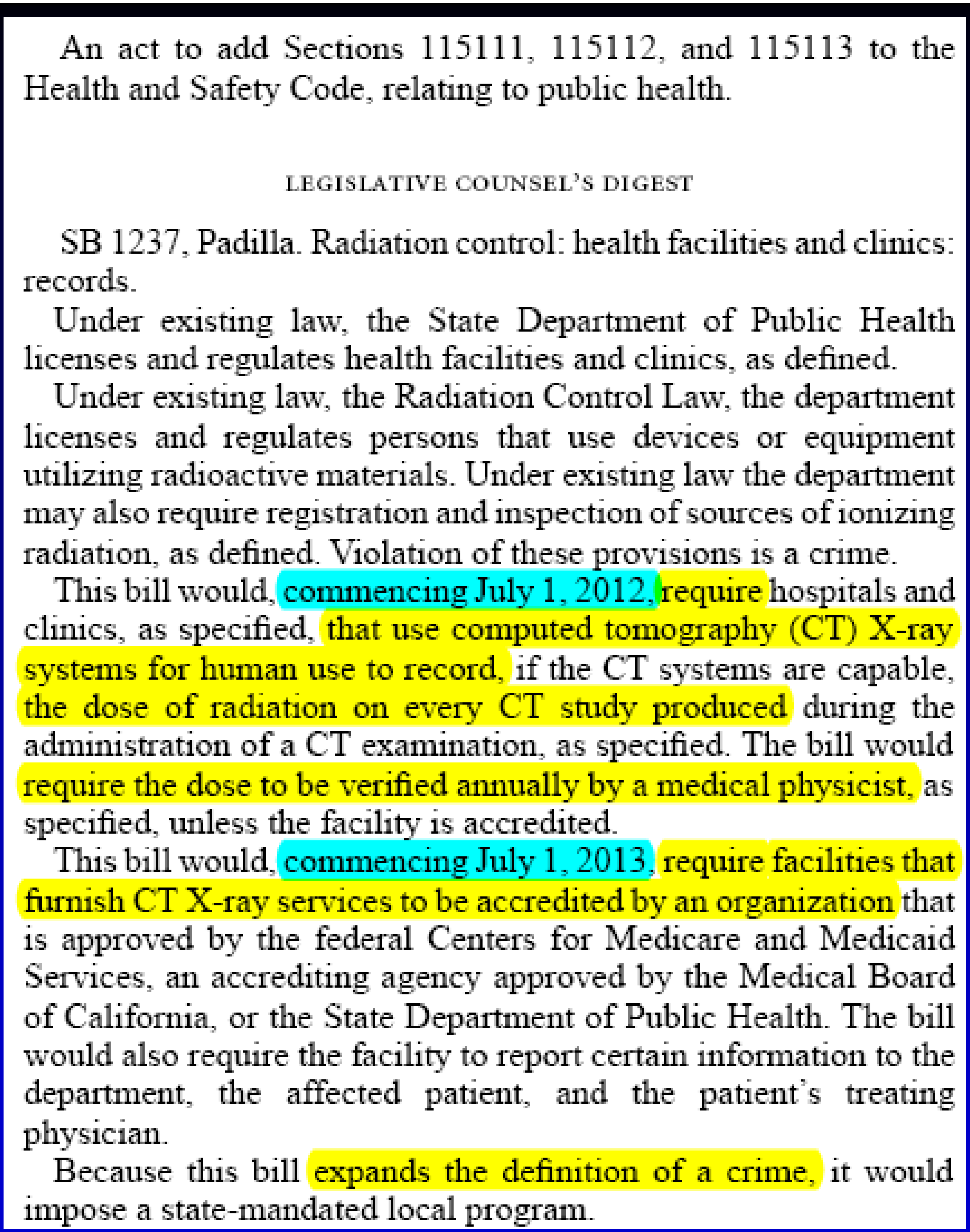
Int. J. Radiation Oncology Biol. Phys., Vol. 69, No. 5, pp. 1579–1586, 2007

Deviation Rates [~ 1.2- 4.7% per course]

- Error rate is greater than zero
- Various definitions exist for error rates
- Severity of errors can vary
  - From inconsequential to severe
- Radiation oncology field operates on probability
  - Physics ~ 3%
  - Geometry, positioning ~ 5%
  - Biology ~ variable (site, patient, etc)
  - Goal: Dose delivered within 10% (biology from there)

State of California Response September, 2010

- Required CT dose record
- Required facility accreditation



An act to add Sections 115111, 115112, and 115113 to the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, Padilla. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined.

Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law the department may also require registration and inspection of sources of ionizing radiation, as defined. Violation of these provisions is a crime.

This bill would, commencing July 1, 2012, require hospitals and clinics, as specified, that use computed tomography (CT) X-ray systems for human use to record, if the CT systems are capable, the dose of radiation on every CT study produced during the administration of a CT examination, as specified. The bill would require the dose to be verified annually by a medical physicist, as specified, unless the facility is accredited.

This bill would, commencing July 1, 2013, require facilities that furnish CT X-ray services to be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health. The bill would also require the facility to report certain information to the department, the affected patient, and the patient's treating physician.

Because this bill expands the definition of a crime, it would impose a state-mandated local program.

Collective Responses

- National Practice Standards: medicine, physics, technology
- National Standards for Education and Training

  Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act of 2010 (CARE Act), S. 3737
- Accreditation: relevant to technology
- National database for reporting of radiation procedure errors - voluntary, self-administered
- Industry – device design and manufacturing

Impact of Errors

Individual	Impact	Example
Physician	- Individual patient - Class of patients	- Prescription error - Poor brachytherapy technique
Therapist	- Individual patient - Particular technique	- Wrong isocenter; wrong data - Incorrect beam matching
Physicist	- Individual patient - Class of patients - All patients (eg, an irradiation device)	- MU calculation error - Incorrect wedge use (RTP) - Linac calibration error

Therapists often assigned blame -

- there is no error in dose delivery until "ON" is pushed

Now What Do We Do?

- High standards for Quality Assurance of radiation treatments
  - Comprehensive QA, from the Start and End-to-End, based on nat’l consensus documents and practices, state/federal regulations
  - QA for all devices, computer systems, and data transfer processes, with clinical oversight by designated individuals
  - Two pairs of eyes – double check; the in-house “time-out”
  - Possible errant or unsafe conditions must be questioned
  - Team: “we’re in this together” – we must communicate
- Education and training for all participants – “technology”
  - We must be the experts for our devices, systems, and processes
  - Each one must know his/her roles and responsibilities

A Few Opinions

- Everything looks great in the computer - are treatment parameters valid, can treatment be delivered with acceptable accuracy and precision?
- Most treatments go just fine – can an errant process with advanced technology be readily recognized?
- Everything is now automated and computerized – we are still the caretakers. The computer is in control, however, we control the computer.
- Simple things are still very important - eg, patient ID matched with the patient's treatment parameters.

A Few Opinions

- Technology requires expertise - revised education and training should emphasize computerized processes
- Diligence and personal responsibility are very important
  - "the right thing" independent of legislation (eg, CARE)
  - complacency brings increased risk of error
- Checklists very helpful for complex processes
  - Advantage – all items listed and verified
  - Disadvantage – may be incomplete, becomes routine
- Most errors are not technology failures …

…they are human errors

Conclusions

- Radiation imaging and treatment are on the national scene
- Radiation imaging and treatment very safe, beneficial, and effective, but is not without risk to patients
- Professional societies, government now addressing very important issues
- Culture of Safety – at each institution

Conclusions

- Radiation Oncology is an assembly line of a complex process. Team members must be empowered to act and answer to the best interests of patients for their health and safety.
- Technology is a key tool – it must be understood and used safely
- CARE Act – each individual needs to "care"

"The patient comes first"

This Symposium

- Quality assurance for automated, computerized, high technology radiation treatment
- Speakers will address quality assurance processes
  - All phases of radiation treatment process
  - Special procedures
  - Oversight and specific QA procedures and analyses
  - National recommendations
  - Accreditation process
- Panel Discussions with our faculty – Participate!