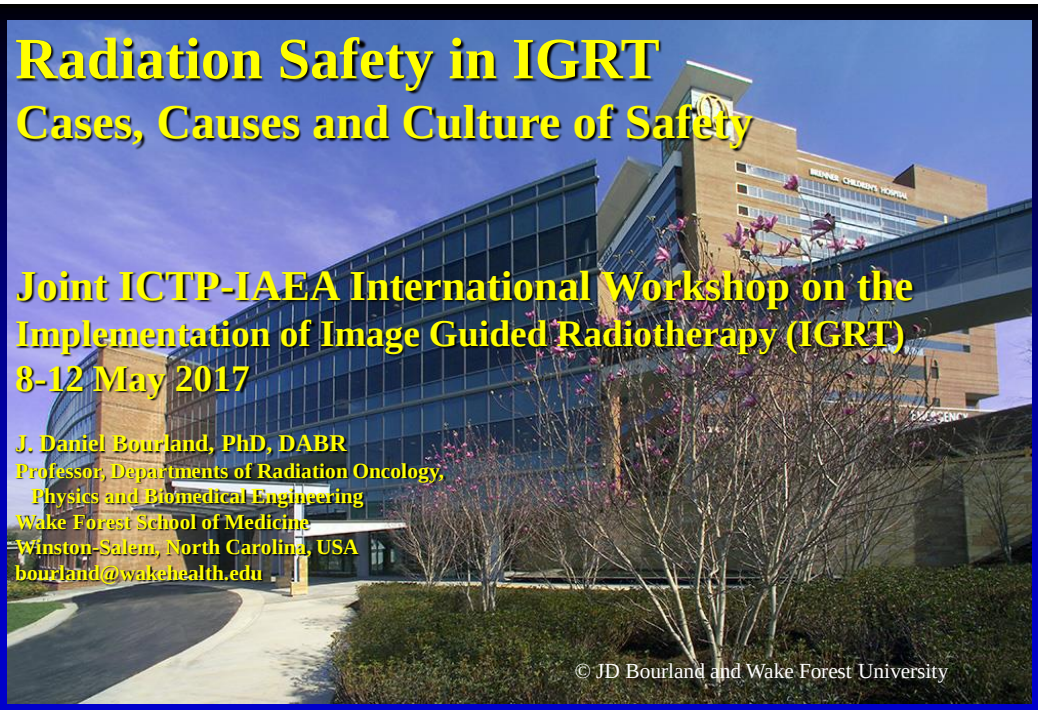
Radiation Safety in IGRT

Cases, Causes and Culture of Safety



Joint ICTP-IAEA International Workshop on the Implementation of Image Guided Radiotherapy (IGRT)
8-12 May 2017

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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

Medical Uses of Ionizing Radiation

- No regulations limit medical radiation dose
  - Practice guidelines, recommendations and regulations specify the accuracy and safety aspects of medical radiation procedures

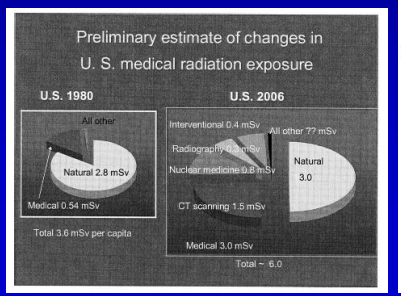
    "no ionizing radiation dose without benefit"
- Imaging procedures
  - Accuracy and safety aspects include: device performance, quality assurance of images per dose, safety interlocks, "5 min fluoro timer", dose rate calibration, patient ID, radioactive agent
- Treatment procedures
  - Accuracy and safety aspects include: device performance, quality assurance, safety interlocks, dose rate calibration, patient ID, daily, weekly, and total dose accuracy

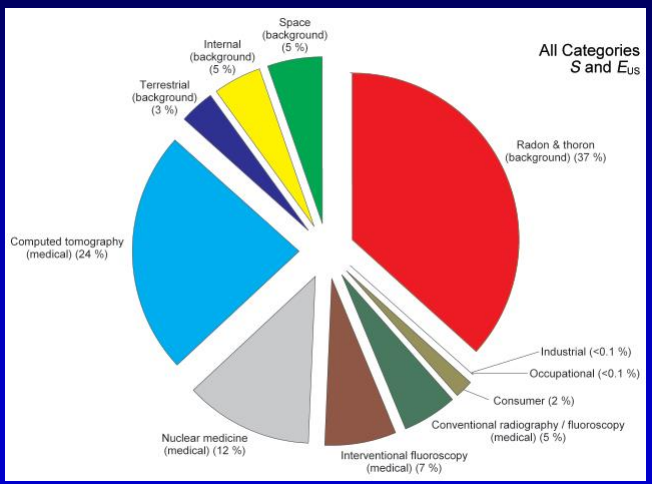
"Correct patient, anatomic site, and dose"

MEDICAL RADIATION EXPOSURE IN THE U.S. IN 2006: PRELIMINARY RESULTS

Fred A. Mettler, Jr.,* Bruce R. Thomadsen,† Mythreyi Bhargavan,‡ Debbie B. Gilley,§ Joel E. Gray,** Jill A. Lipoti,†† John McCrohan,‡‡ Terry T. Yoshizumi,§§ and Mahadevappa Mahesh***

- NCRP Report 160





Some "Recent" Radiation "Events"

Have called attention to treatment safety
Many were published in the NY Times

- Imaging: 2009
- Treatment: 2005 - 2010

FDA Advisory: CT Brain Perfusion Dose

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

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

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

Medical Devices

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

- Medical Device Safety
- Alerts and Notices (Medical Devices)
- Information About Heparin
- Luer Misconnections
- Safety Communications
- Public Health Notifications (Medical Devices)
- Tips and Articles on Device Safety
- Patient Alerts (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

California RT gives deposition in CT overdose case

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

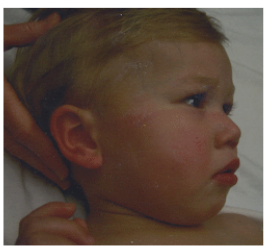
"151 scans"
2.5 – 11 Gy; 39% increased risk of Ca
Cause: operator error in programming the CT unit

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
involving a large, well-known Los Angeles hospital, the other a tiny hospital in the northern part of
risks that powerful CT scans pose when used incorrectly.

A week ago, Cedars-Sinai Medical Center in Los Angeles disclosed that it had mistakenly administe
normal radiation dose to 206 possible stroke victims over an 18-month period during a procedure i
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 insan

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, na
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
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

Radiation "Events" are Not New

However, perhaps more visible

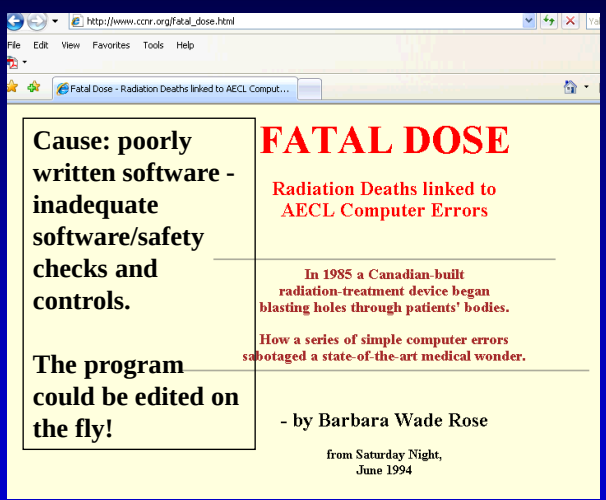
- Initial "events" after ionizing radiation discovered 115 years ago
- Occupational exposures

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

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



Scotland: Brain Radiation Treatment: 2006

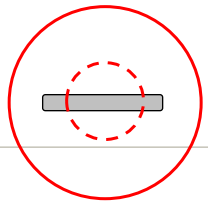
Event

- Brain radiation treatment
- 19 overdoses

Cause?

- Incorrect calculation point?
- Missing wedge?

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



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.

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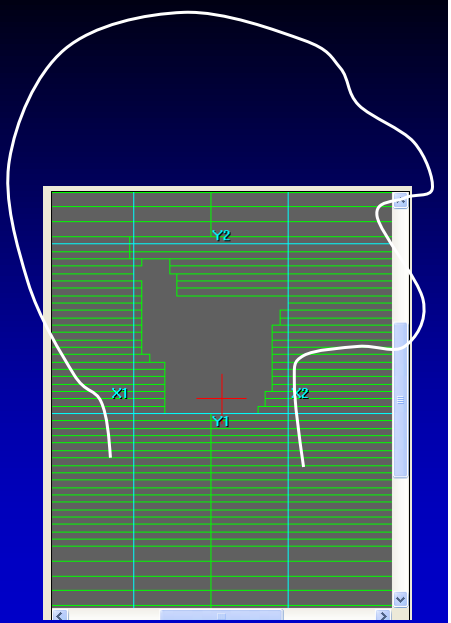
Florida: another linear accelerator radiosurgery case:
- **77 patients**
- **50% overdose due to calibration error: due to a spreadsheet programming/calculation error**

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

- 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
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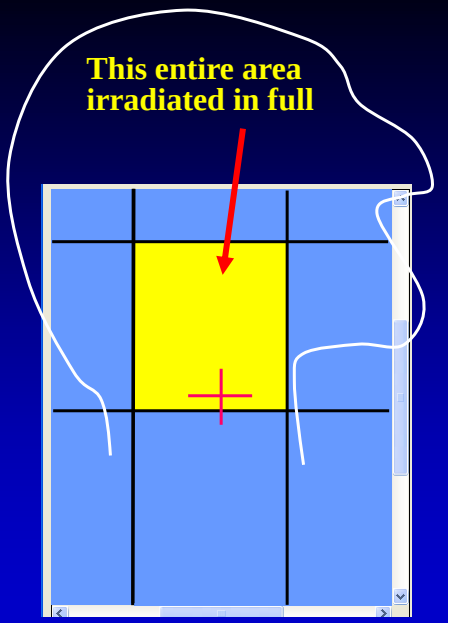

What can go wrong in radiation treatment?
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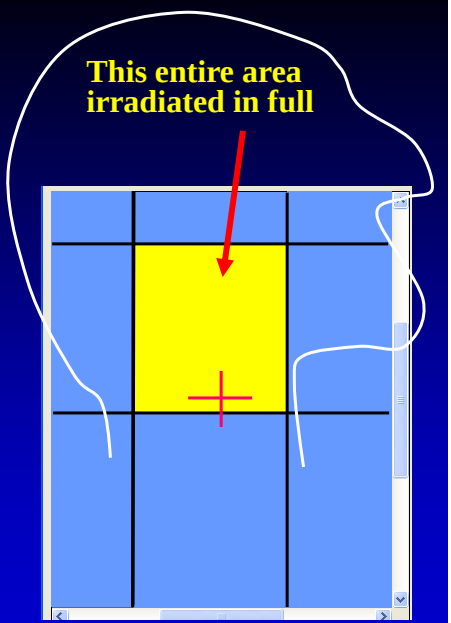
New York: IMRT

- 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

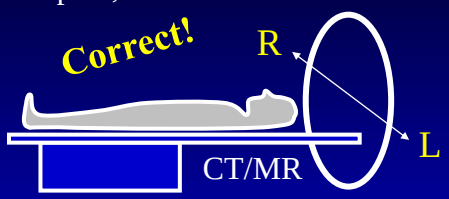
"On October 24, 2007, a medical event occurred at Leksel Gamma Knife facility which resulted in the total dose delivered differing from the prescribed dose by more than 20%.

"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.

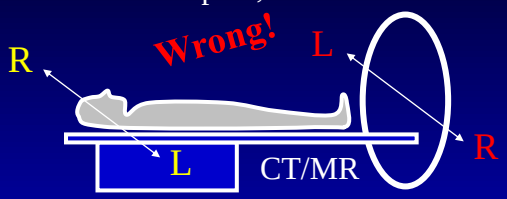
http://www.nrc.gov/reading-rm/doc-collections/event-status/event/2007/20071029en.html

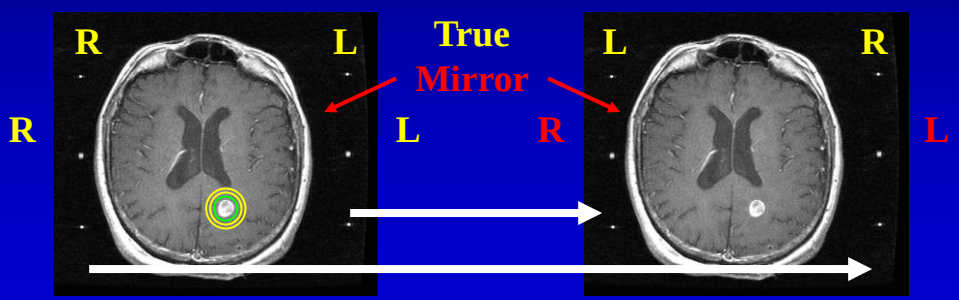
What They Thought They Were Doing

Patient + Scan Label:
Supine, Head First



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

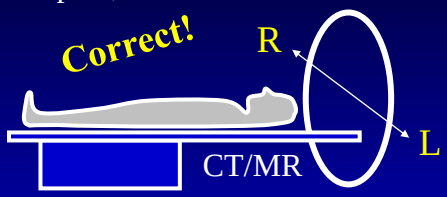




What Really Happened

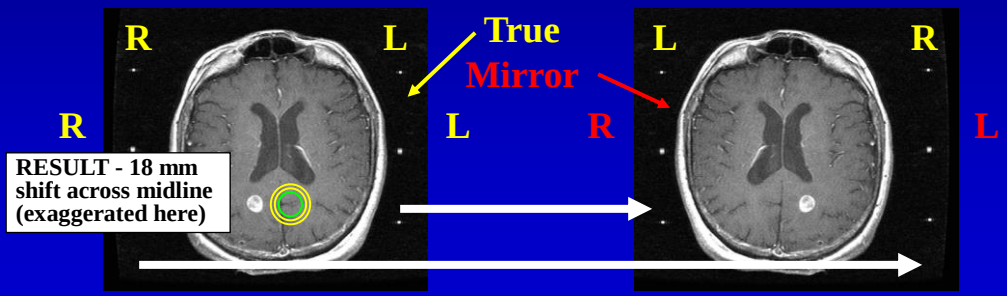
Patient + Scan Label:
Supine, Head First

Correct!



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

Wrong!



RESULT - 18 mm shift across midline (exaggerated here)

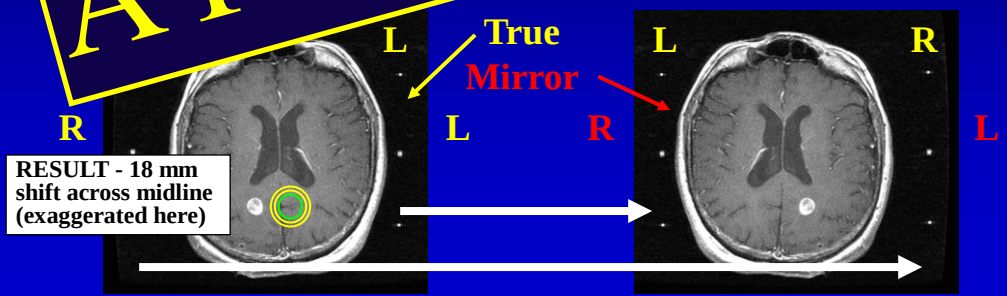
What Really Happened

Patient + Scan Label:
Supine, Head First

Patient: Supine, Head F
Scan Label: S

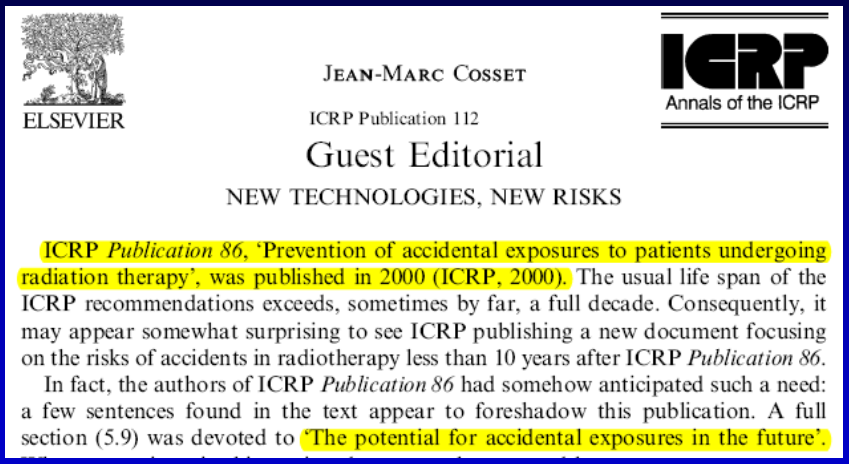
A Perfect Miss !

Correct!



RESULT - 18 mm shift across midline (exaggerated here)

New Kinds of Errors



ELSEVIER

JEAN-MARC COSSET

ICRP Publication 112

Annals of the ICRP

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.

IGRT Safety

Special Article

Practical Radiation Oncology (2013) **3**, 167–170

Safety considerations for IGRT: Executive summary

David A. Jaffray PhD [a,*], Katja M. Langen PhD [b], Gikas Mageras PhD [c], Laura A. Dawson MD [d], Di Yan DSc [e], Robert Adams EdD [f], Arno J. Mundt MD [g], Benedick Fraass PhD [h]

IGRT safety includes:

- Technical components
- Process components
- Culture aspects
- Team aspects

- Risk of geometric miss
- Risk of inadequate communication

Table 1 Recommendations to establish a foundation for safe and effective IGRT practices

Recommendation
1. Establish a multi-professional team responsible for IGRT activities.
2. Establish and monitor a program of daily, monthly, and annual QA for all new or existing IGRT sub-systems.
3. Provide device- and process-specific training for all staff operating IGRT systems or responsible for IGRT delivery.
4. Perform 'end-to-end' testing for all new IGRT procedures (from simulation to dose delivery) and document performance prior to clinical release.
5. Establish process-specific documentation and procedures for IGRT.
6. Clearly identify who is responsible for approval of IGRT correction decision and the process whereby this decision is made and documented.
7. Establish and document site-specific planning procedures; specifically, the procedure for defining PTV margins. Link these planning procedures to IGRT procedures.
8. Multi-professional peer-review of PTV volumes. Peer-review of GTV/CTV volumes by ROs.
9. Verify proper creation and transfer of IGRT reference data (PTV, OARs, DRRs, etc) to IGRT system.
10. Establish a reporting mechanism for IGRT-related variances in the radiation treatment process.

GTV/CTV, gross tumor volume/clinical target volume; IGRT, image guided radiation therapy; PTV, planning target volume; OARs, organs at risk; QA, quality assurance; ROs, radiation oncologists.

IGRT Safety -Checklist Approach

Journal of Applied Clinical Medical Physics, Vol. 16, No. 3, 2015

Medical Physics Practice Guideline 4.a: Development, implementation, use and maintenance of safety checklists

Task Group Authors: Luis E. Fong de los Santos, Chair, Suzanne Evans, Eric C. Ford, James E. Gaiser, Sandra E. Hayden, Kristina E. Huffman, Jennifer L. Johnson, James G. Mechalakos, Robin L. Stern, Stephanie Terezakis, Bruce R. Thomadsen, Peter J. Pronovost, Lynne A. Fairobent,

IGRT safety includes:

- Technical components
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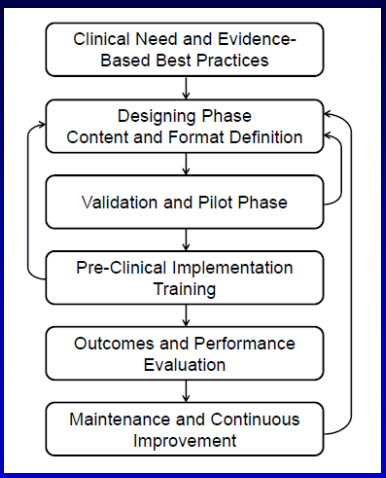


Fig. 1. Diagram of end-to-end checklist development, implementation, and maintenance process.

IGRT Safety Events

- FDA MAUDE Adverse Event Report: 06/07/16
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5702676&pc=IYE
- Event Description: **The kv source arm was not in the extended (imaging) position; however, the kv beam was not inhibited**. This means that kv images used for patient positioning could be taken with the kv source at an incorrect position. With the kv source shifting in the g direction the kv iso-centre will shift also in the g direction by an amount proportional to the ratio between the kv source/iso centre and the panel/iso centre. **Trainee personnel were present at the hospital and it was reported that the users were heavy handed** with the kv source during arm extension. The dampener on the kv source arm assembly was checked and appeared to function correctly. The shift of the kv source position was estimated to be **approximately 8mm out of position** in the g direction, this was the closest the arm could be without dropping into the locked position. The issue was fixed on site by turning the switch on the atp pcb in the kv generator off and then on again. Xvi 4. 2. 1 should have the switch in the off position. The inhibit then worked as intended. **The hospital added a visual marker on the kv source (room lasers) and added kv source position to daily qa check**. Customer is reviewing cases that had a shift larger than 8mm.

IGRT Safety Events

- FDA MAUDE Adverse Event Report: 06/07/16
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5702676&pc=IYE
- Manufacturer Narrative: A shift of kV source of 8mm would result in an image (and therefore patient shift) of 4.3mm. However, the risk assessment will consider that the kv source arm could stop at any position either greater or less than this amount under the fault condition. Detection of a small shift would be difficult compared to a large shift, though a small shift has a low severity. To consider worst case scenario, a shift of kv iso centre of 10mm has been applied (high severity but low detectability), kv source shift of 18.7mm. Severity: normal treatment: a 6mm error would represent a major mistreatment. Normal treatments are unlikely to be non coplanar. Stereotactic treatment: a 3mm error would represent a major mistreatment. Likelihood: occasional - this an uncommon use error (heavy handed use). **This fault has not been reported before.**
- Cause: operator error, device interlock failure

IGRT Safety Events

- FDA MAUDE Adverse Event Report: 05/31/16
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5652840&pc=IYE
  - Event Description: **When xvi registration results were sent** to mosaiq (msq), **an error appeared on xvi stating msq had not received the registration results.** The customer had already shifted the patient but as they wanted **to record the shift, a retry was attempted, which caused the patient to be moved off target**. Due to this xvi was re-scanned and the patient shifted back to the correct treatment position. Analysis of the msmq logs on the sequencer and xvi for the affected patient confirmed that the issue occurred due to an msmq exception logged on xvi. This indicates there was a fault in the windows messaging queuing service on the xvi workstation. … **Xvi was unaware that the shifts had been received by msq** and displayed the warning with the prompt to cancel or retry sending the shifts. Initial investigation highlights the 'retry' message is not applicable to this particular failure mode and could be **confusing to the user**.

IGRT Safety Events

- FDA MAUDE Adverse Event Report: 05/31/16
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5652840&pc=IYE
  - Manufacturer Narrative: The risk assessment concluded as follows: **severity: if unnoticed, a shift performed twice could put an organ-at-risk in the path of the mv beam, and potentially result in death or severe injury. (major).** Likelihood: **the initiating event is human error, the likelihood probable**. The workflow is unusual, to result in harm, the user must: choose to resend the move when there is a visual indicator on the cma activation that the results have been received by msq and move the patient using the asu buttons even though this task will have been recently completed.
- Cause: operator error, lack of knowledge

IGRT Safety Events

- FDA MAUDE Adverse Event Report
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=4181365&pc=IYE
  - Event Description: …one of the **three transponder beacons**, implanted into a pt for a prostrate treatment, was not working properly (however, it was). **The user utilized a custom crf** (coordinate reference frame) not supported …This **resulted in a prone/supine inversion** from the treatment plan versus the beacon plan. The user attempted to localize the pt with all 3 beacons and ... received a rotational alignment error, warning that the threshold of 60 degrees of rotation was exceeded …The user attempted to localize 14 times and received the same error message. The **user then disabled one of the three beacons** in order to localize using only two beacons. The system detected a **target rotation of 50 degrees** … and presented a warning … The **user decided to override this warning** and localize the pt with data provided and … the **pt received 10 fractions of treatment** … the localization of the **isocenter was off by 1.13 cm** … The user alleges that there was no misadministration and that they treated the pt as they intended.

IGRT Safety Events

- FDA MAUDE Adverse Event Report
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=4181365&pc=IYE
- Event Description: Based on the analysis of the information obtained, the manufacturer believes that **an unintended exposure to radiation potentially occurred**. The method used to investigate the device consisted of evaluating the log files form the system which tracks inputs and outputs from the system and allow analysis of the use of the device. The results of the investigation show that **the system operated as intended**. The customer installed a new treatment planning system and started using a custom crf that was different from the manufacturer's crf, but did not change how they entered the plan. **This is the root cause for the prone/supine inversion**.
- Cause: operator error, lack of knowledge

IGRT Safety Events

Conclusions

- Device faults resulting in systematic errors can occur with IGRT
- Device mis-calibration resulting in systematic errors could occur with IGRT
- Operator error/lack of knowledge resulting in single or systematic errors can occur with IGRT

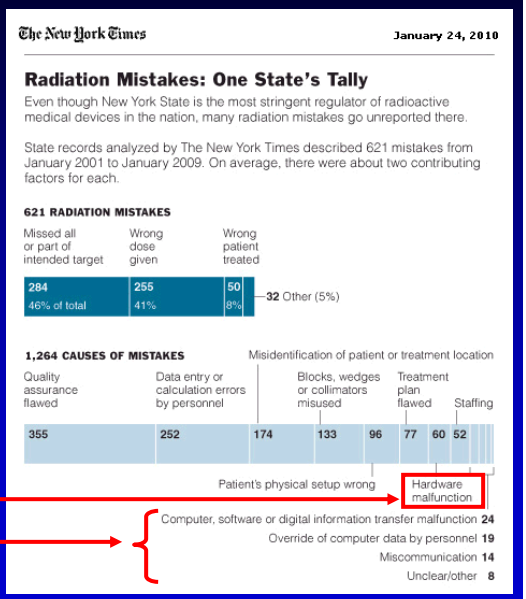
Classes and Causes of Events

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%



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

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Deviation Rates [~ 1.2- 4.7% per course]

- Error rate is greater than zero ($\Delta > 0$)
- Various definitions exist for error rates
- Severity of errors can vary
  - From inconsequential to severe
- Radiation oncology field operates on probability
  - Physics ~ 3% *how well can you calibrate?*
  - Geometry, positioning ~ 5%
  - Biology ~ variable (site, patient, etc)
  - Goal: Dose delivered within 10% (biology from there)

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 -

- because, 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

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 Treatment 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
- To Err is Human: we must be careful out there

"The patient comes first"