Radiotherapy in the 21st Century: Risks and Benefits

Ellen Yorke

Memorial Sloan Kettering Cancer Center

The New York Times

At V.A. Hospital, a Rogue Cancer Unit

By WALT BOGDANICH
Published: June 20, 2009

The New York Times

U.S.

Radiation Overdoses Point Up Dangers of CT Scans

By WALT BOGDANICH
Published: October 15, 2009

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

January 27, 2010

THE RADIATION BOOM

Case Studies: When Medical Radiation Goes Awry

By WALT BOGDANICH

THE RADIATION BOOM

As Technology Surges, Radiation Safeguards Lag

By WALT BOGDANICH
Published: January 26, 2010

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

The New York Times

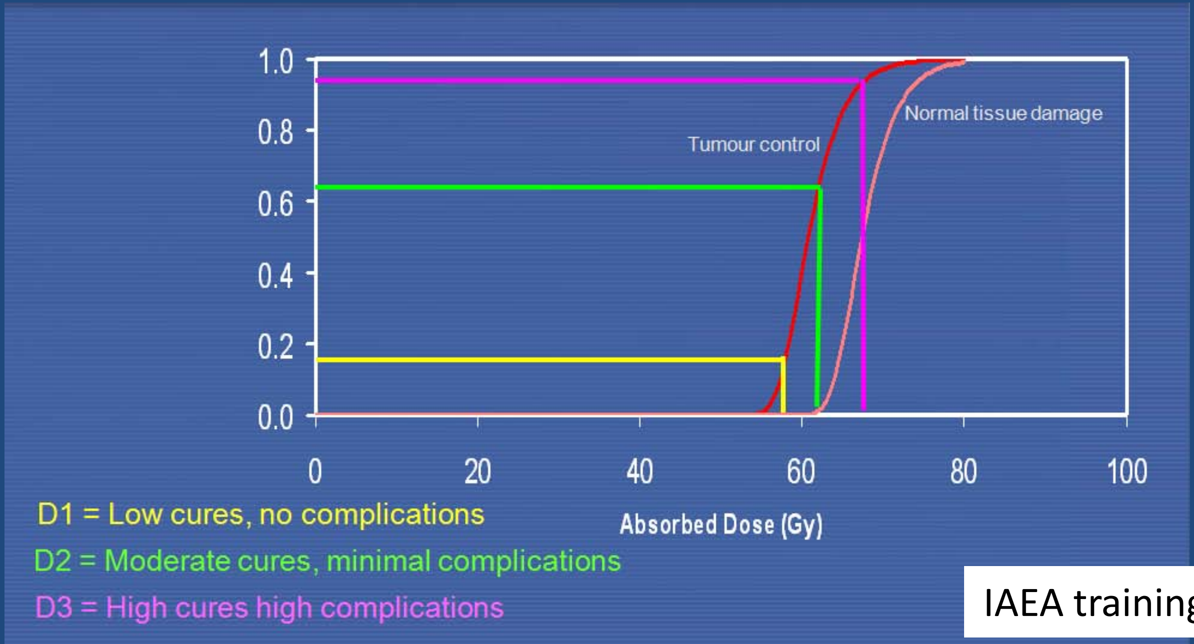
At Hearing on Radiation, Calls for Better Oversight

By WALT BOGDANICH
Published: February 26, 2010

WASHINGTON — A dozen witnesses, including representatives of virtually all of the leading professional groups in medical radiation, told a House subcommittee during a hearing Friday that more needed to be done to make sure that radiation continues to help, not harm, patients.

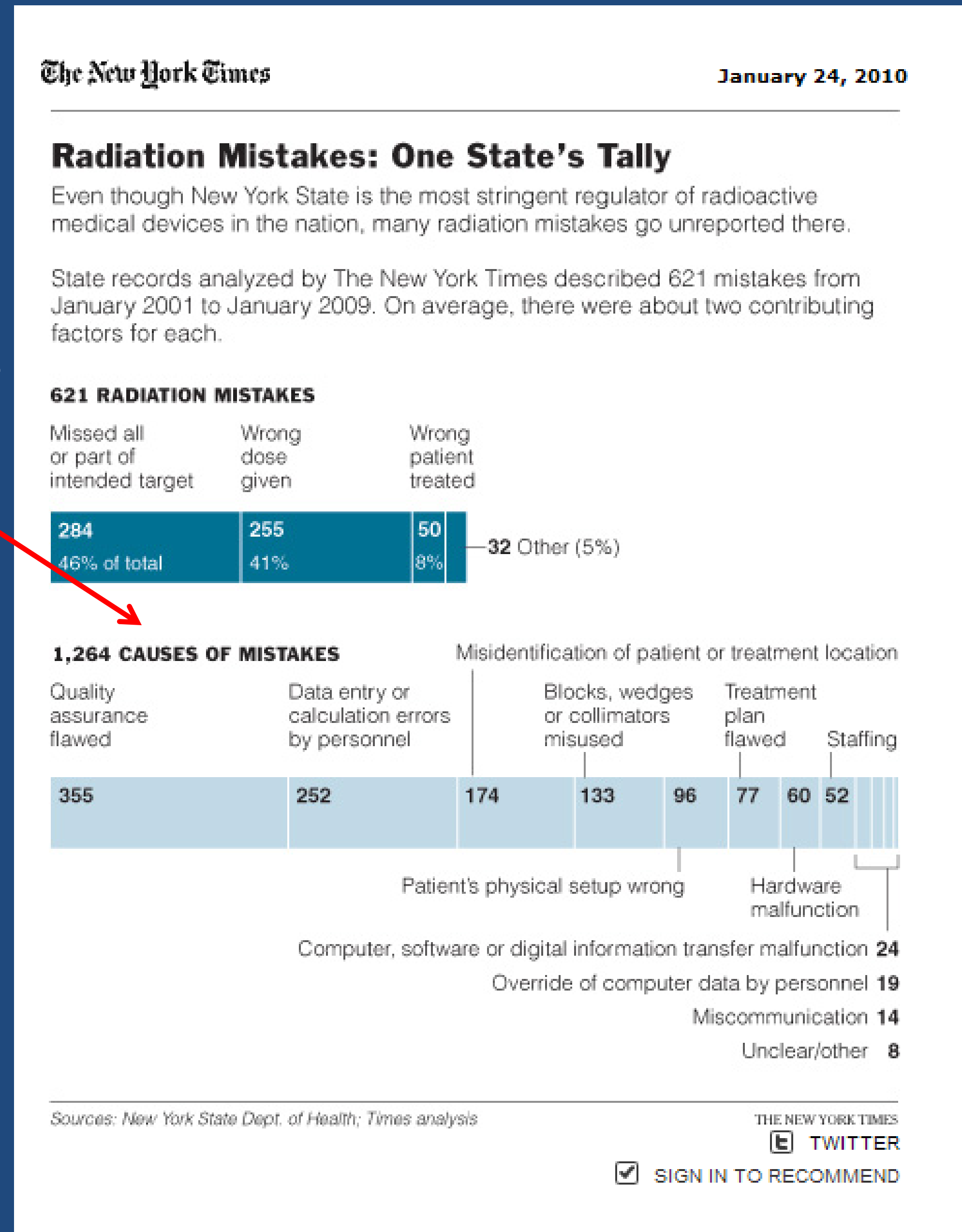
The call for a more standardized, comprehensive method of overseeing medical radiation, both diagnostic and therapeutic, came from radiation oncologists, radiologists, therapists, researchers, medical physicists and equipment manufacturers.

- **Errors/adverse events/accidents in radiotherapy have the potential to be catastrophic in the near term**
  - Unlike situation in diagnostic radiology
  - Focus of the NY Times articles
- Smaller events → different outcomes for nominally identical treatments, 'noise' in outcomes studies
  - Radiological Physics Center (RPC)-funded by NCI for ~ 40 years to provide physics QA for NCI-funded clinical trials



IAEA training slide set

- Traditional medical physics "QA" is good
  - ~ 0.5% error rates
- But it's not enough
- Radiation therapy errors are a team effort!
- Common information sources about problems
  - our departments
  - Gossip
  - Occasional vendor's warnings
- No clear plan of attack, or official information source



These are the ones reported!

The American Association of Physicists in Medicine

Links of Interest

We advance the science, education and professional practice of medical physics

My AAPM
AAPM
Public & Media
International
Medical Physicist
Members
Current & Prospective Students
Meetings
Education
Government Affairs
Publications
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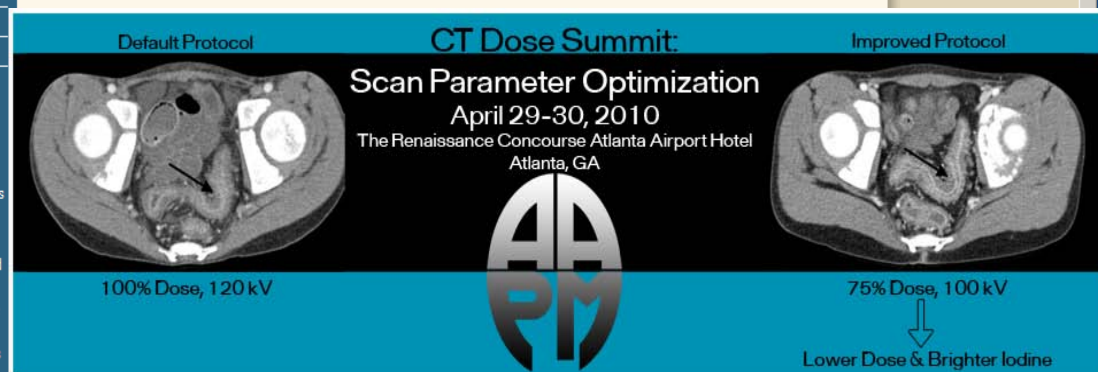
Corporate Affiliates
Links of Interest
Links to Medical Radiation Incident References
Response to Public Radiation Incidents - Links
Radiological Physics Center
Medical Physics & Related Organizations
Medical Physics Resource Page
Electronic Medical Physics World
RadioGraphics
Free Medline Search
Web-based Dosimetry Training Tool - Stanford University
Links of Interest Home
Advertising Opportunities
Logout
CME Gateway

Links to Medical Radiation Incident References

The following links are to documents and educational material in the area of error management and patient safety in radiotherapy. Suggestions for additional links to other relevant information should be made to the Chair of AAPM's Working Group on the Prevention of Errors in Radiation Oncology.

- The ROSIS Database of Incidents
- A Training Slide Set developed by the International Atomic Energy Agency
- Towards Safer Radiotherapy: UK document
- Radiotherapy Risk Profile: World Health Organization document
- Preventing Accidental Exposures....: a draft of ICRP 112
- The Ottawa Orthovoltage Incident: Report of the Expert Panel
- Root Cause Analysis

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
(FDA, MAUDE database)



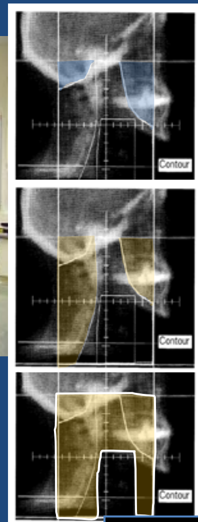
General Information
Program Information
Registration & Housing Information
Travel Information
Contact Us

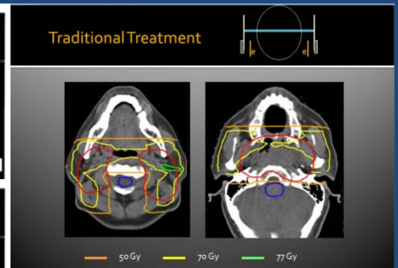
Items of Interest

ON-LINE REGISTRATION

Registration is limited to the first 325 registrants.

Increasing complexity (1985-present)





Field Size	3X3	4X4	6X6	8X8	10X10	12X12	14X14	16X16	18X18	20X20
Sc	0.949	0.958	0.977	0.991	1.000	1.011	1.014	1.017	1.021	1.024
Sp	0.952	0.963	0.981	0.991	1.000	1.005	1.013	1.021	1.026	1.030
TMRs										

Field Size	3X3	4X4	6X6	8X8	10X10	12X12	14X14	16X16	18X18	20X20
Depth=1.4	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
1.5	1.002	1.002	1.001	1.001	1.002	1.002	1.001	1.001	1.001	1.001
2.0	0.996	0.997	0.997	0.997	0.997	0.997	0.997	0.997	0.997	0.997
2.5	0.980	0.982	0.984	0.985	0.987	0.987	0.986	0.987	0.987	0.988
3.0	0.962	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
3.5	0.944									
4.0	0.923									
4.5	0.906									
5.0	0.887									
5.5	0.867									
6.0	0.850									
6.5	0.830									
7.0	0.811									
7.5	0.792									
8.0	0.774									
8.5	0.757									
9.0	0.741									
9.5	0.725									
10.0	0.708									

MU Calculation for X-ray Treatments: Isocentric Technique
Memorial Sloan-Kettering Cancer Center
Department of Radiation Oncology

Patient name____________
Patient MRN__________

Treatment Machine/Room:_______ Treatment Site:____________

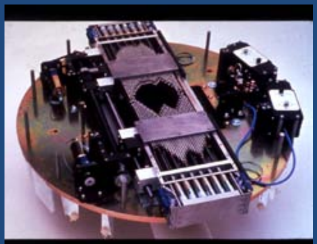
Field Number				
Field Description				
Xray Energy				
Collimator Setting (CS)				
Collimator Equiv. Sq. (CSeq)				
Irradiated Field Equiv. Sq. (FSeq)				
Treatment Depth (d) d= Rx. Depth + Bolus				
Prescribed Dose per Fraction				
÷ Number of Fields				
÷ Ref. Output (10x10,dmax,100 SAD)	1.0 cGy/MU	1.0 cGy/MU	1.0 cGy/MU	1.0 cGy/MU
÷ Sc (CSeq)				
÷ Sp (FSeq)				
÷ TMR (FSeq, d)				
÷ Tray Transmission				
÷ Board and/or Couch Transmission				
Monitor Units				
Calculated By/Date				
Checked By/Date				

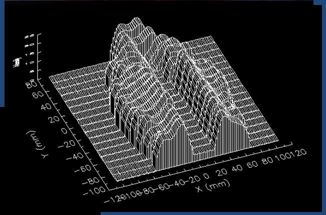
$$MU = \frac{\text{Prescribed Dose}}{\text{Number of Fields} \times \text{Ref. Output} \times Sc \times Sp \times TMR \times \text{Tray Trans.} \times \text{Board and/or Couch Trans.}}$$

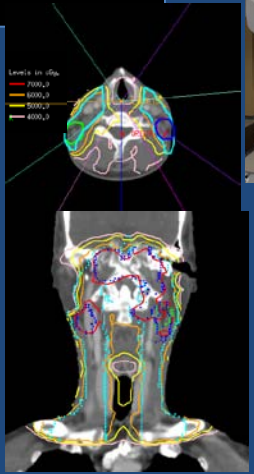
Notes: For open fields, FSeq = CSeq. Treatment Depth is the sum of the prescribed depth in the patient and bolus, if it covers a significant fraction of the field.

THEN

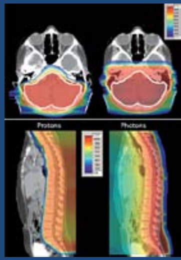
NOW

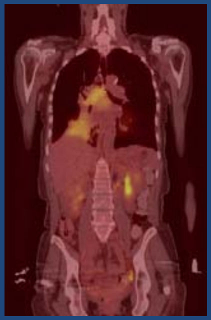


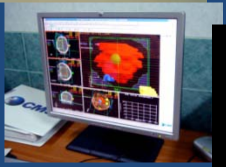




& protons







GTV, CTV, ITV, 4D, OAR, PRV, DVH, NTCP, TCP, EUD

19 field H&N IMRT
3 Dose levels

The new developments are beneficial

- **Multimodality imaging for treatment planning/evaluation**: Better targeting, staging, management
- **Better tumor targeting, normal tissue avoidance:** higher local control and/or lower normal tissue toxicity for same Rx
- **Safe/effective dose escalation:** higher tumor dose for same toxicity- better local control
- **Safe delivery of hypofractionation** (SBRT and SRS)
- **Evidence that high-tech (IMRT) improves outcomes**
  - A random sample
    - **Prostate**: Zelefsky et al, J Urol 179; Kuban et al IJROBP 70
    - **Lung**: Yom et al IJROBP 68
    - **H&N**: Lee et al HeadNeck 29, Graff et al IJROBP 67, Fang et al Cancer 109
    - **Breast**: Donovan et al Radiother Oncol 82, Freedman et al Am J Clin Onc 29
    - **SBRT_Lung**: Timmerman et al JAMA 303
    - **SBRT_Spine**: Sahgal et al, IJROBP 74

But can't just blame complexity

January 27, 2010

THE RADIATION BOOM

Case Studies: When Medical Radiation Goes Awry

By WALT BOGDANICH

"Because New York State is a leader in monitoring radiotherapy and collecting data about errors, The Times decided to examine patterns of accidents there and spent months obtaining and analyzing records. Even though many accident details are confidential under state law, the records described 621 mistakes from 2001 to 2008. While most were minor, causing no immediate injury, they nonetheless illuminate underlying problems. Following are ~~18~~ 17 accidents representing a variety of medical mistakes."

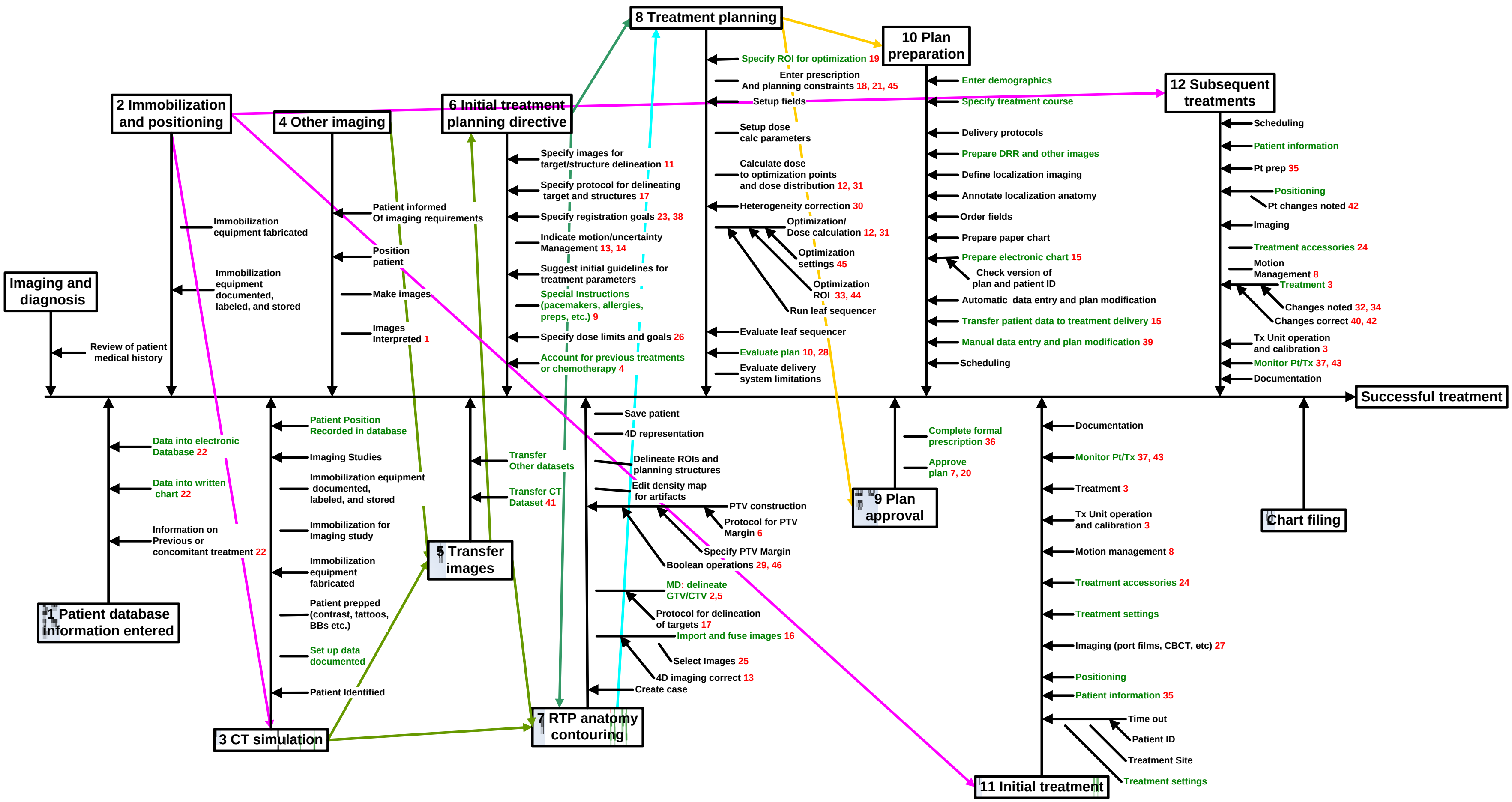
Type	Number
Low Tech	10
High Tech	3
R&V but low tech	2
Brachy	2

- **Low Tech:** dose doubling, other math errors, wrong site, wedges (3 cases)
- **R&V**: wrong patients
- **High tech:** **2** with IMRT

In each case, several factors allowed an initial error or 'failure' to propagate through to treatment

Simple and complex radiotherapy have many steps in common and many similar ways to go wrong

IMRT Treatment Process Tree generated by AAPM's TG100



A systematic error

Radiation Errors Reported in Missouri
By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

Essentially "Low Tech"

• Small field data incorrectly measured when commissioning BrainLAB SRS (ion chamber too large). **Undetected from 2004-2009 when a new physicist attended BrainLAB training**

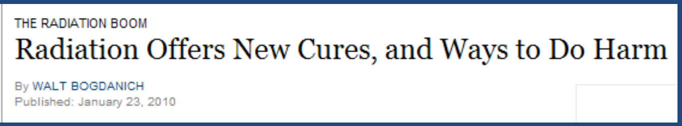
- •Similar error (IAEA slides) in Toulouse, France in 2007; **persisted for 1 yr, detected through a BrainLAB intercomparison study**

• SRS incident with different cause (beam data was incorrectly processed to create TPS data tables) but similar effects; 77 pts, ~50% overdose. **Persisted ~ 1 yr found by an RPC on-site audit**

•**Clinical consequences unclear** - small irradiated volumes, much cranial SRS is palliative (short survival vs time to complication)

•Contributing factors – understanding small field dosimetry, <u>**no independent check/audit**</u> (single physicist project in all 3 cases)

Single-patient high-tech catastrophic incident

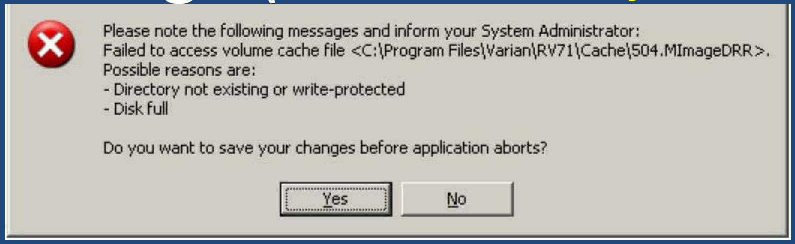

THE RADIATION BOOM
Radiation Offers New Cures, and Ways to Do Harm
By WALT BOGDANICH
Published: January 23, 2010

3 treatments with IMRT MU with open fields

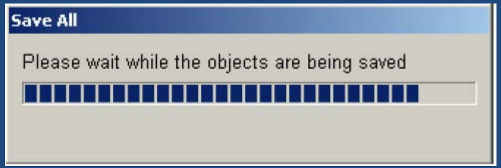
Lethal overdose to H&N patient

- Excellent descriptions in IAEA Training Slide Set #2.10 and in NY Times article
  - Very much a 'team effort'. **CF**="contributing factors"

1. System software 'bug' under rare circumstances (**CF: Vendor, FDA**)
2. MD requested replan for 5th fraction; short time allowed for planning complex case (**CF: culture**)
3. Partial computer crash during TPS - database data transfer, cryptic error message (**CF: vendor, FDA**)



4. Physicist answers ‘yes’–NYTimes: patient was in room (**CF: Physics, culture**)
5. Another cryptic message; physicist persists (IAEA slides) leaving database with fluence data (plan), images but no MLC control point data (**CF: Vendor, FDA, Physics, culture**)



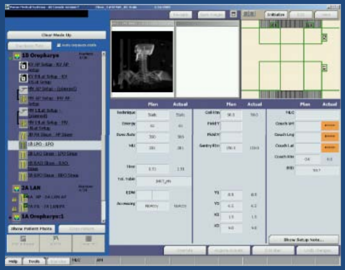
6. **Despite dept policy**, no independent physics review or measurement (**CF: Physics, culture**)

   IAEA: *“According to QA programme, a second physicist should then have reviewed the plan, including an overview of the irradiated area outline, and the MLC shape used.”* Varis/RT Chart or plan itself would have given a cue

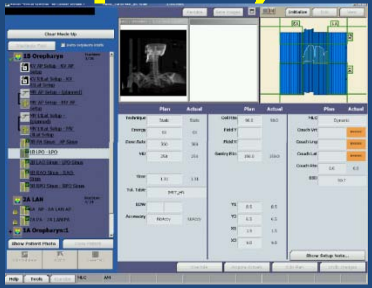
   According to NY Times, simultaneously, *“two therapists were prepping Mr. Jerome-Parks for his procedure, placing a molded mask over his face to immobilize his head.”*

   Patient was treated 2 hrs after planning which (IAEA) “*indicates time pressure*”

7. Console screen displays “open field” rather than moving-leaf cartoon. It is not noticed for three treatments (**CF: therapists, culture**)



vs



8. (NY Times) After 2nd treatment, patient was severely symptomatic. Medical personnel did not associate this with radiation (**CF: culture**)

Lessons to learn

- Do what you should be doing according to your QA program – the error could have been found through verification plan (normal QA procedure at the facility) or independent review
- Be alert when computer crashes or freezes, when the data worked on is safety critical
- Work with awareness at treatment unit, and keep an eye out for unexpected behaviour of machine

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

The other case described in this article was low-tech (perhaps R&V)

A breast cancer patient planned with wedges was treated without them for entire treatment

Missed by all departmental checks

NY Times: Patient received 3.5 x prescribed dose

What can we do- Short term

- Well…..you are here……
- **Доверяй, но проверяй**
- Don’t be pressured into shortcuts.
- Follow your local physics QA program
- Participate in hospital QA program
- Intradepartmental communication
  - Radiation oncologists, other physicists, dosimetrists, therapists
- Keep up with **your department’s** technology
  - Numerous AAPM TG reports (free at AAPM website)
  - Staff inservice for new procedures (learn by teaching)
- Make clear instructions for common procedures easily available to physics and other staff
- Don’t hesitate to question vendors, other physicists, staff, MDs, if you don’t understand.

Longer Term

- Calibrate current QA program against events and near misses in your department and others
  - *Would your QA program catch the incidents described by IAEA? What changes do these incidents suggest?*
- Review dept QA as a group (physics+others)
- Consider more formal analysis by the group. (Process Tree, FMEA, FTA, Root Cause Analysis)
  - This symposium (Galvin, Siochi), application to department at Johns Hopkins (Ford et al IJROBP 74), proceedings of 6/24-25 AAPM/ASTRO safety meeting, TG100 in future

Terminology

- **Incident (IAEA)** *Any unintended event including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety*
- **TG100** separately defines Errors *(failure to carry out action as intended)*, Mistakes *(wrong from the beginning)* and Violations *(intentional quality failures)* and then defines *Event* as "*a situation resulting from a failure with detectable undesirable consequences*"
- **WHO** distinguishes "adverse events" from "near misses"
- **Incidents** can be
  - **Patient-specific** (everything on preceding slide): affects one patient – may be minor or catastrophic
  - **Systematic** (incorrect dose calibration, incorrect data in planning system, persistent bug in planning software, misuse of planning system, poor linac maintenance): affects many patients, may be minor or catastrophic