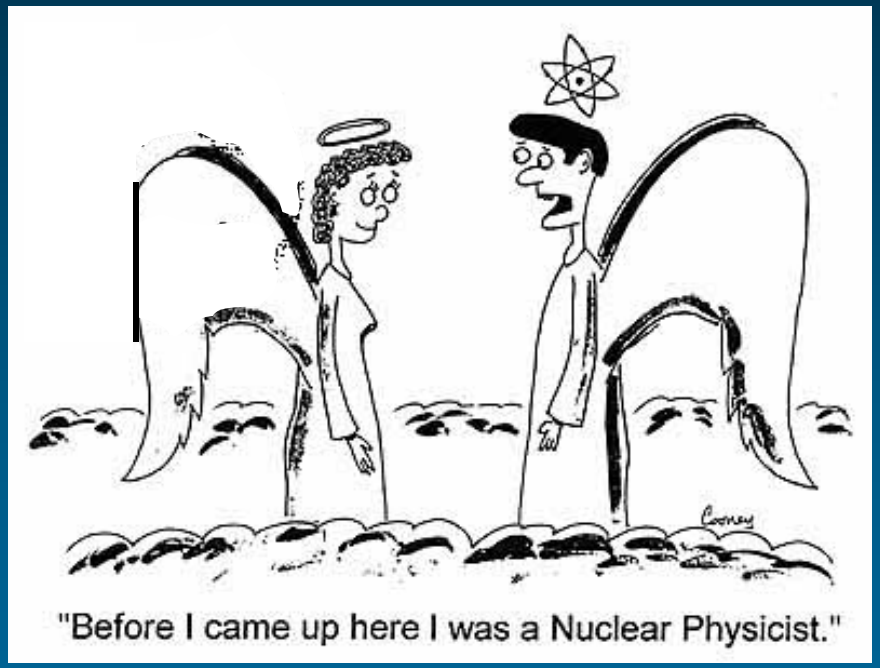
Medical Events: Radioactive Materials and Machine-Generated Radiation

Lynne Fairobent
Manager of Legislative and Regulatory Affairs
American Association of Physicists in Medicine
Texas Radiation Regulatory Conference
September 2, 2010

Career Experience

- Regulatory
  - Nuclear Regulatory Commission
  - Department of Energy
- Consulting
  - Science Applications International Corporation, Inc.
  - Lamb Associates, Inc.
  - Advanced Technology and Laboratories, Inc.
  - The Environmental Company, Inc.
- Association/Non-Profit
  - Nuclear Energy Institute
  - National Council on Radiation Protections and Measurements
  - American College of Radiology
  - AAPM
- Member Advisory Board School of Health Sciences – Purdue University
- Member of the Annual Review Team for DOE/NNSA on US medical isotope production capability



Current Regulatory Status

- 37 Comprehensive Agreement State Radiation Protection Programs
- 11 Medical Radiation Device Programs
  - Share responsibility with the Nuclear Regulatory Commission – 13 non-agreement states
- 2 states with no identified radiation protection program

Current Regulatory Requirements

- Physicians are licensed as practitioners in all states
- Medical Physicists are licensed in TX, FL, and NY and certified in HI
- Radiation Therapists are certified/licensed in 33 states: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming
- Medical Dosimetrists have no specific license required but many are RTTs

Texas and Florida's Program

By the Numbers

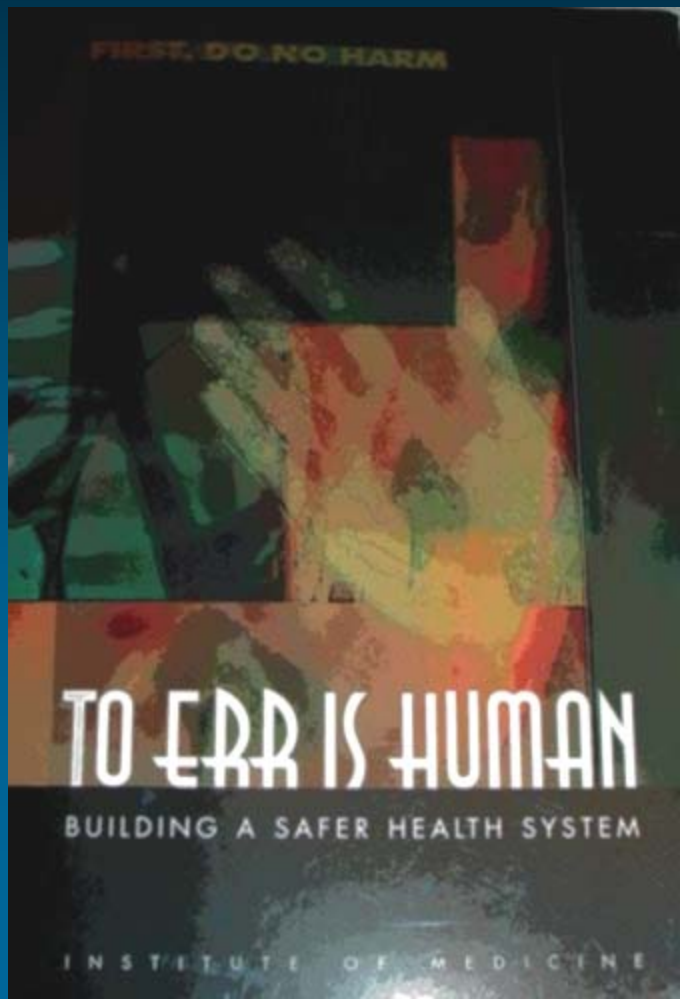
TX	FL	Category
45	45	Years as an agreement state
~2,000	1,741	Radioactive materials licenses
125	99	High Dose Rate devices
8	5	Gamma Stereotatic radiosurgery devices
34	35	Nuclear pharmacies
2	1	Proton therapy units
18,989	17,548	X-ray facilities
183	220	Medical accelerator facilities
160	331	Accelerators in use
26,000	1,526	Certified radiation therapists
545	447	Licensed Medical Physicists*
11	13	Reported medical events
* Some may be licensed in more than one subfield and licensed in both TX and FL		

The National/International Focus

- Past 2 decades → focus on medical errors and healthcare quality (adverse incidents, studies by US and European government-supported groups).
- Result: increased concern with verifying the quality of healthcare delivery and healthcare professionals' competence.

The Institute of Medicine

- In 2000, the National Academy of Science-sponsored Institute of Medicine published its first book in a series on healthcare quality, titled “To err is human”.



The Institute of Medicine

- Concluded that ≈98,000 patients die each year as a result of medical errors.
- Two key recommendations:
  1. Standardize procedures
  2. Regularly validate professional competence.

The Institute of Medicine Report

"Recommendation 7.2:

Performance standards and expectations for health professionals **should focus greater attention on patient safety.**

Health professional licensing bodies should:

(1) Implement periodic reexamination and relicensing of doctors, nurses and other key providers, based on both competence and knowledge of safety procedures, and

(2) Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action."

Technology = Safety ??

IRSN
INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

25 January 2008 / Paris

Sylvie Derreumaux, IRSN

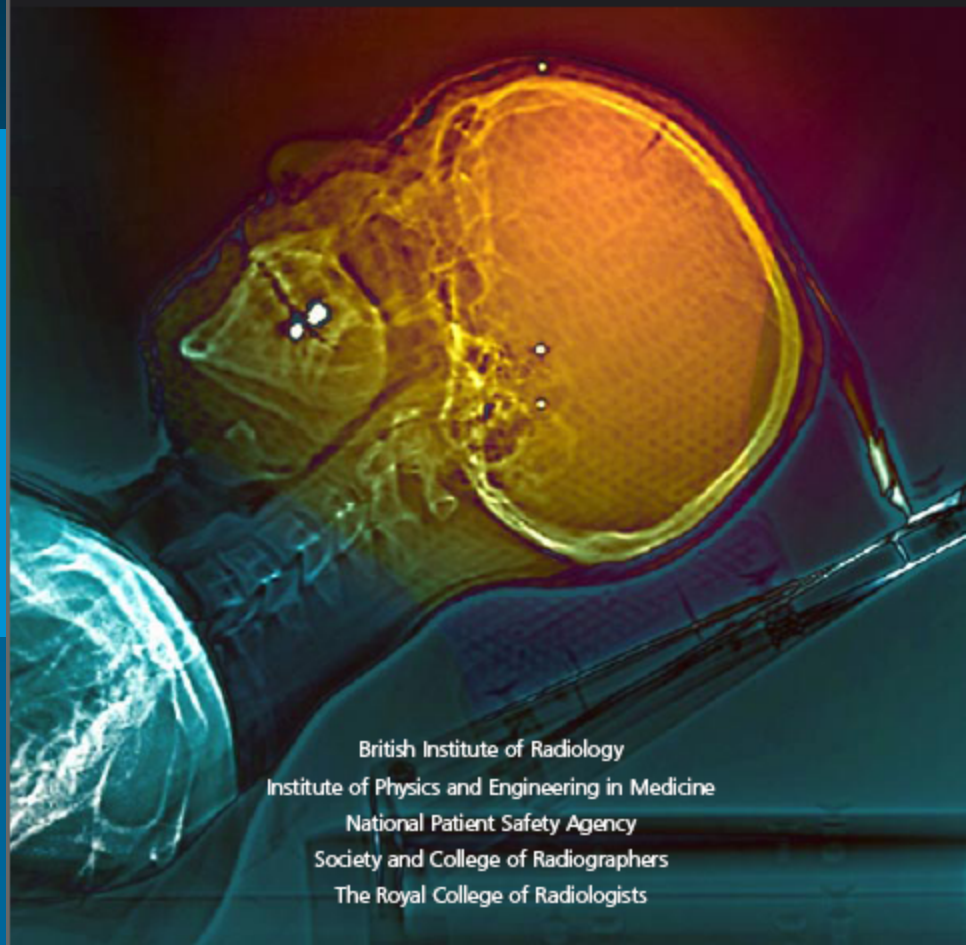
BIR

IPEM

NHS National Patient Safety Agency
Patient Safety Division

The Royal College of Radiologists

Towards Safer Radiotherapy



British Institute of Radiology
Institute of Physics and Engineering in Medicine
National Patient Safety Agency
Society and College of Radiographers
The Royal College of Radiologists

Famous New Technology Failure

- **TITANIC**

Human ERROR, many assumptions, few mitigations of hazards, WARNINGS IGNORED

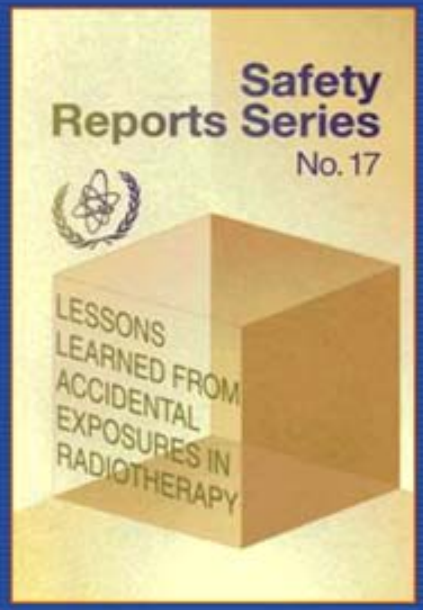
- **http://www.bbc.co.uk/dna/h2g2/A457067**

"Captain Smith ordered the ship to travel at high speed through the night, in spite of the one ice warning he had been confirmed to receive, and the other posted by Lightoller in the chart room. In fact, ice warnings were being received during the whole trip, for a total of 21 in all, only seven of which were received after the radio went down."

The IAEA

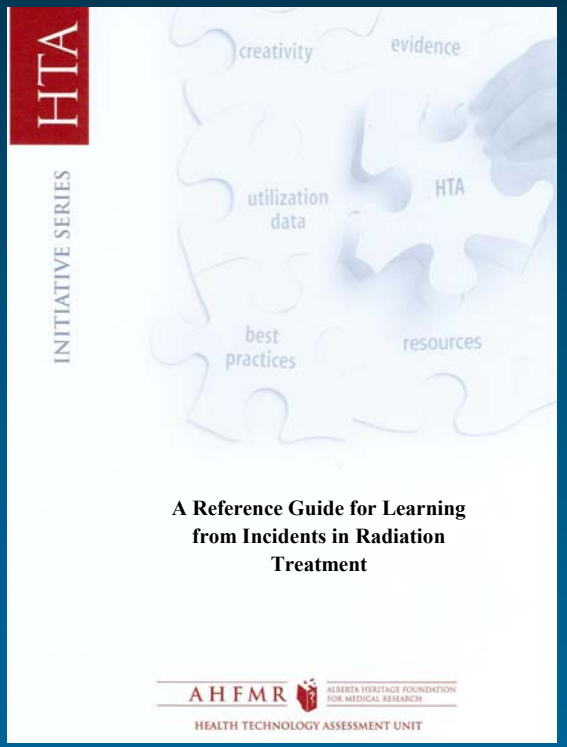
Part 3: Analysis of causes and contributing factors

- Analysis of a collection of other incidents and accidental exposures
- The role of "near misses"
- Are there recurring themes or patterns in the "lessons learned"?



Canada

- Focus on learning from incidents *and potential incidents* – taxonomy to categorize incidents for analysis.



Media Influence

New York Times

Medical Group Urges New Rules on Radiation
By WALT BOGDANICH
...for Radiation Oncology issued a six-point plan that it sa...

At Hearing on Radiation, Co...
By WALT BOGDANICH
A dozen witnesses told a Ho...
patients.
February 27, 2010

...EW LEHREN, KRISTINA REBELO and
...ct.
...ans Affairs Medical

F.D.A. Toughens Process for Radiation Equipment
By WALT BOGDANICH
The agency is taking steps to reduce overdoses after reviewing 1,000 error reports over the last 10 years.
April 9, 2010

They Check the ...
By WALT BO...

...werful new e...

V.A. Is Fined Over Errors in ...
By WALT BOGDANICH
The Nuclear Regulatory Commission cited an "unprecedented ...
Center in treating prostate cancer patients.
March 18, 2010

...one to assure that radiation continues to help, not harm,
...make health care safer.

...issouri

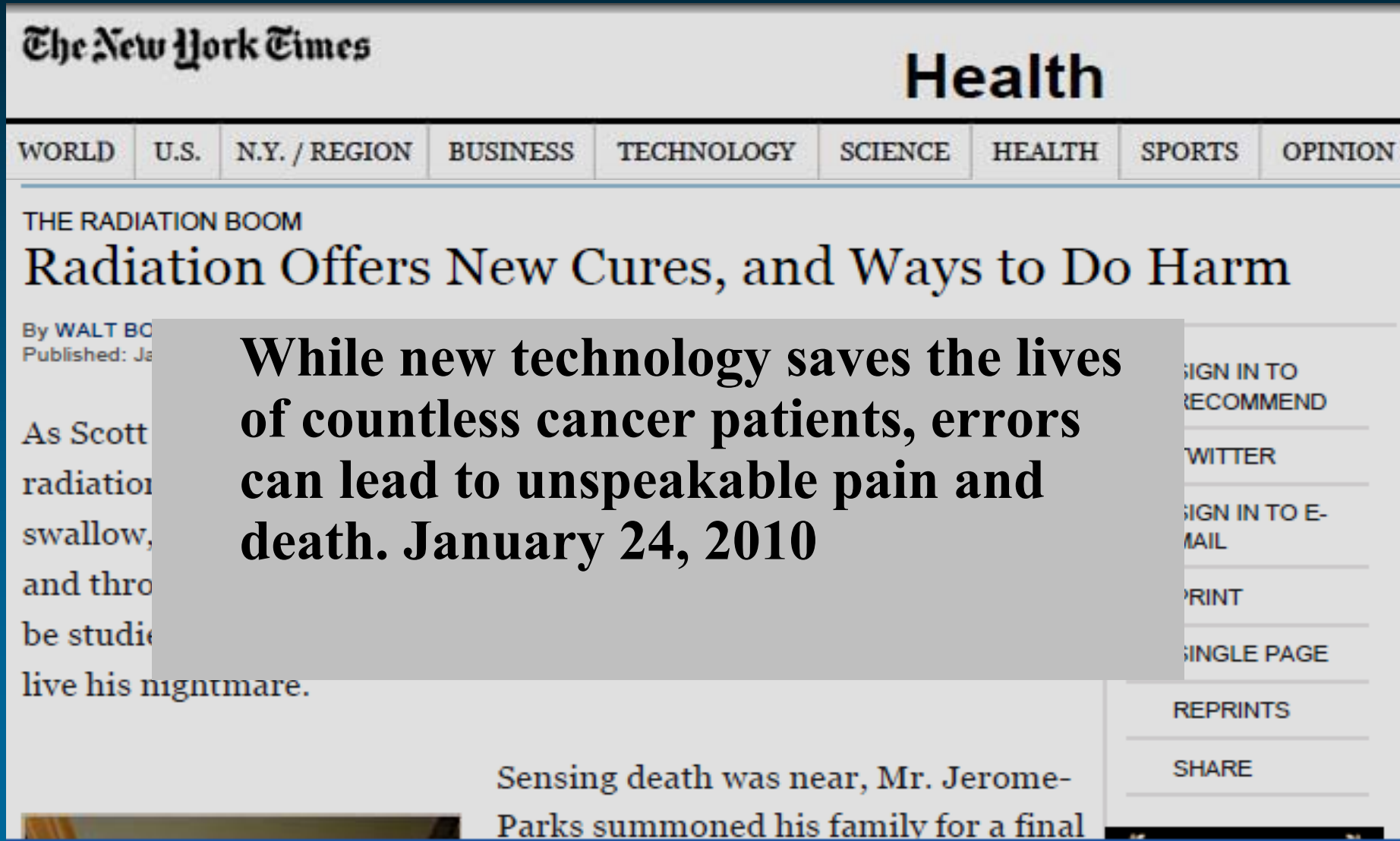
...Question of Supervision
...REBECCA R. RUIZ
...ugating billing practices at a Florida cancer center, a case that points up oversight concerns.

Radiation Erro...
By WALT BOGDANICH and ...
CoxHealth in Springfield, Mo., ...
incorrectly.
February 25, 2010

...ears were ...

F... ...rease Oversight of Medical Radiation
By ... ...GDANICH and REBECCA R. RUIZ; KRISTINA REBELO CONTRIBUTED REPORTING.
The ...gency said it would move to more stringently regulate the most potent sources, including CT scans.
February 10, 2010

Increased Media Focus



The New York Times

Health

WORLD | U.S. | N.Y. / REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH | SPORTS | OPINION

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BO
Published: Ja

As Scott
radiatio
swallow,
and thro
be studi
live his nightmare.

While new technology saves the lives of countless cancer patients, errors can lead to unspeakable pain and death. January 24, 2010

SIGN IN TO RECOMMEND

TWITTER

SIGN IN TO E-MAIL

PRINT

SINGLE PAGE

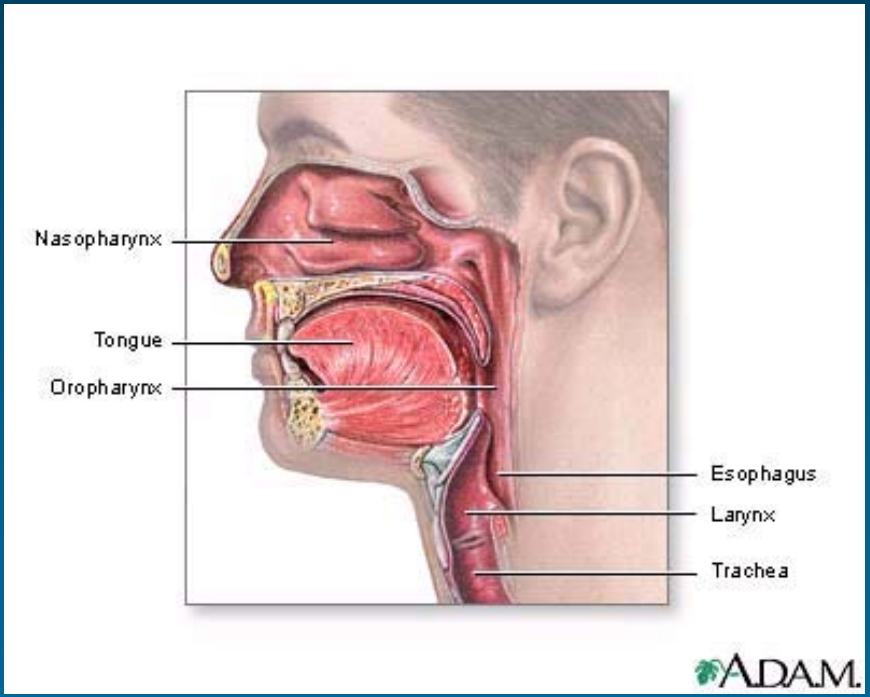
REPRINTS

SHARE

Sensing death was near, Mr. Jerome-Parks summoned his family for a final

A radiotherapy accident in the U.S.A.

- Background (March 2005)
- A patient is due to be treated with IMRT for head and neck cancer (oropharynx)



What happened?

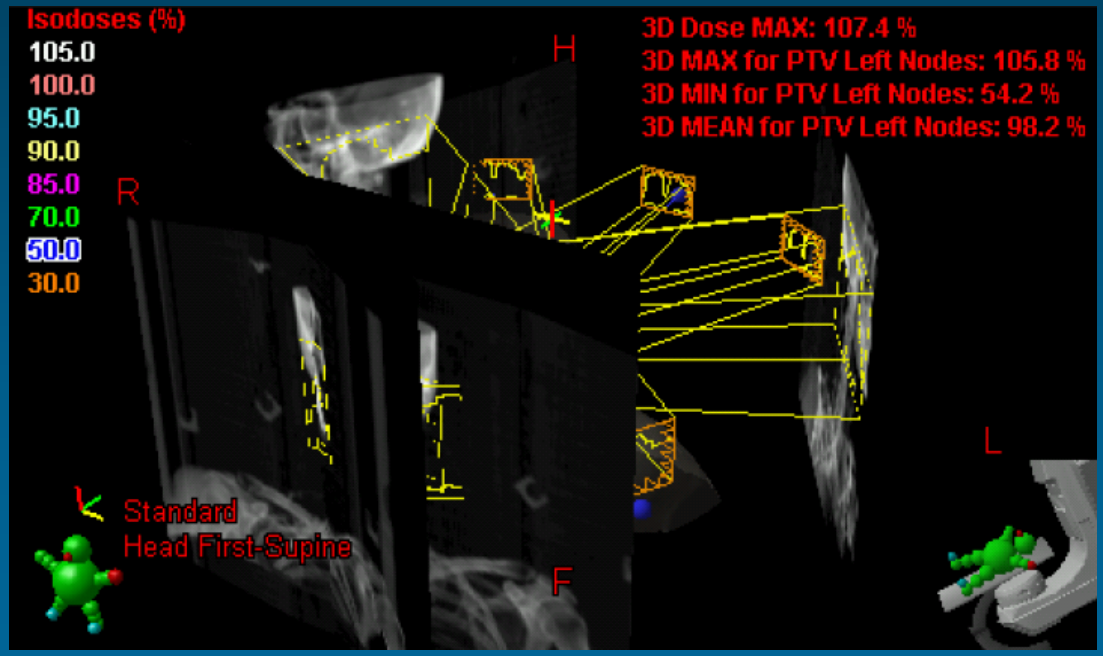
- **March 4 – 7, 2005**
- **IMRT plan is prepared. Verification plan is created in TPS. Portal Dosimetry (with EPID) confirms correctness.**

Example of an EPID (Electronic Portal Imaging Device) (Picture: P.Munro)

What happened?

- March 8, 2005

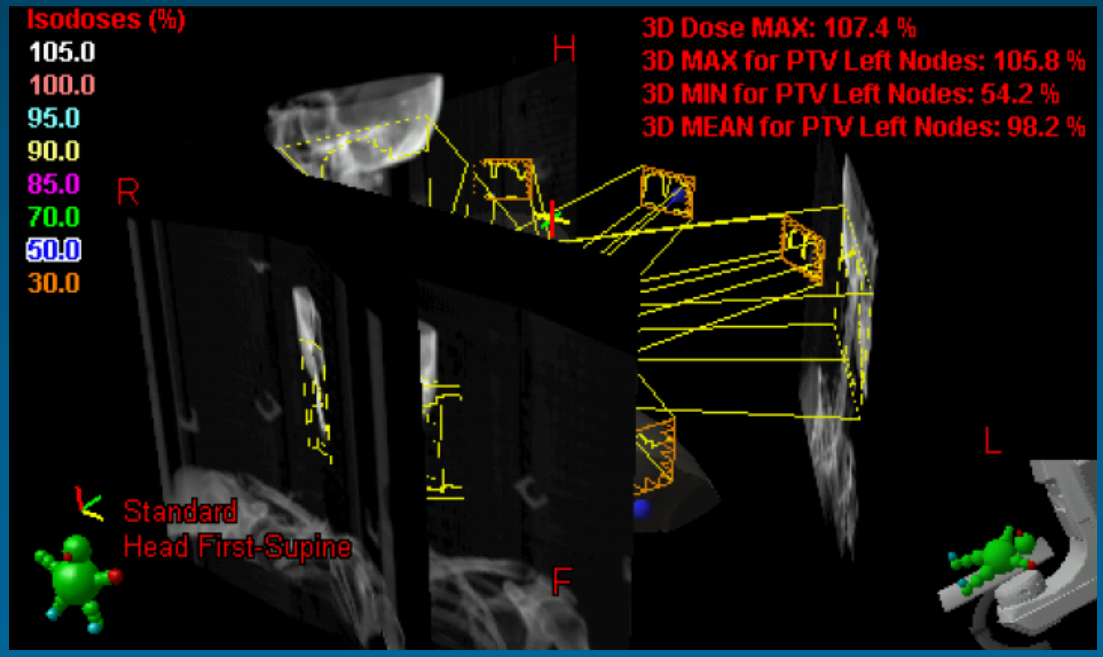
- Patient begins treatment fraction #1, which is delivered correctly.



"Model view" of treatment plan (Picture: VMS)

What happened?

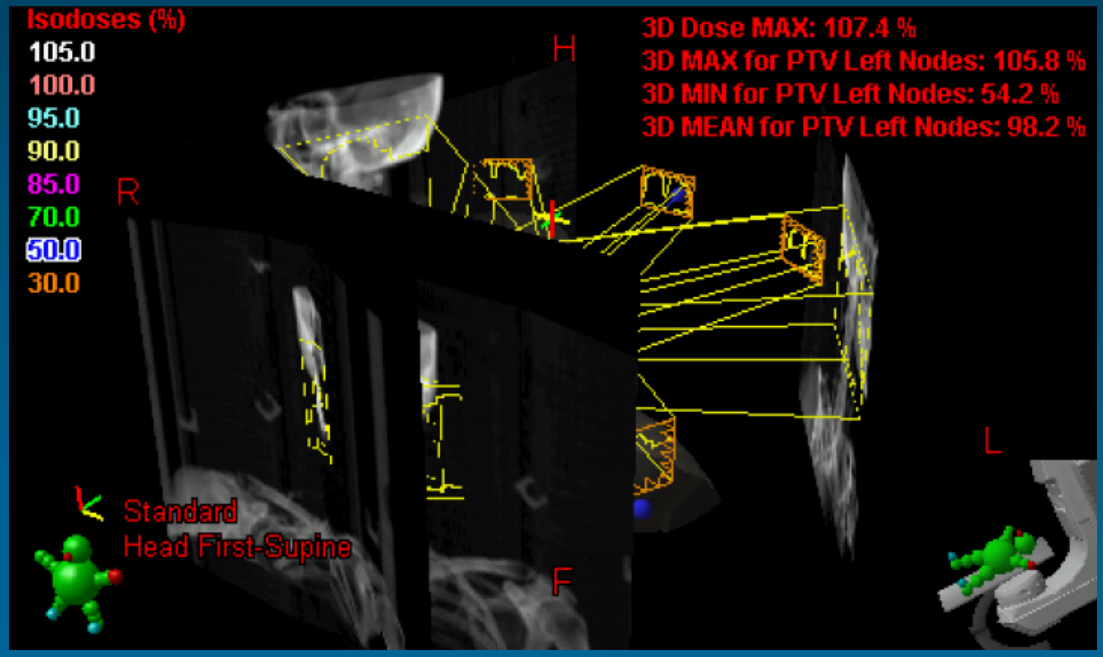
- March 9 – 11, 2005
- Fractions #2, 3 and 4 are also delivered correctly. Verification images for kV imaging system created and added to plan.



"Model view" of treatment plan (Picture: VMS)

What happened?

- March 11, 2005
- Physician reviews case and wants modified dose distribution. Plan is copied and saved to DB.



"Model view" of treatment plan (Picture: VMS)

What happened?

- March 14, 2005
- Re-optimization work on new plan starts.
- Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved to DB.
- Final calculations are started, where MLC motion control points for IMRT are generated. Normal completion.

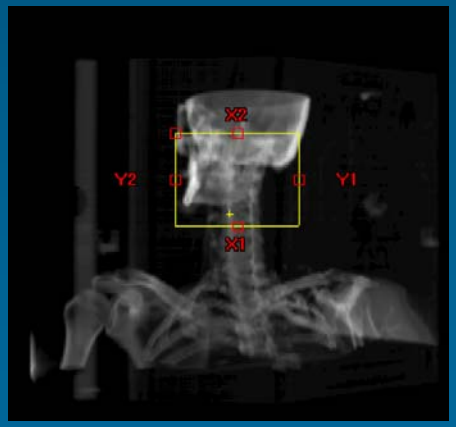
Multi Leaf Collimator (MLC)

What happened?

- March 14, 2005, 11 a.m.

- "Save all" is started. All new and modified data should be saved to DB.
- In this process, data is sent to holding area on server, and not saved permanently until ALL data elements have been received.
- In this case, data to be saved included: (1) actual fluence data, (2) DRR and (3) MLC control points

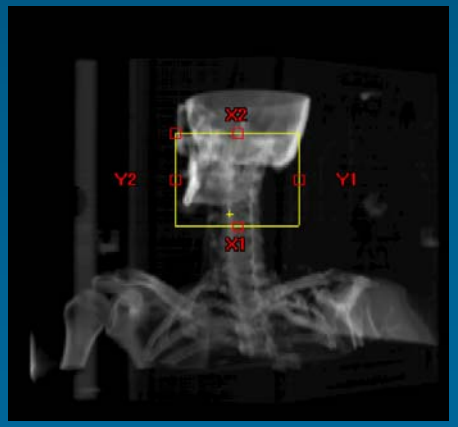
A Digitally Reconstructed Radiograph (DRR) of the patient



What happened?

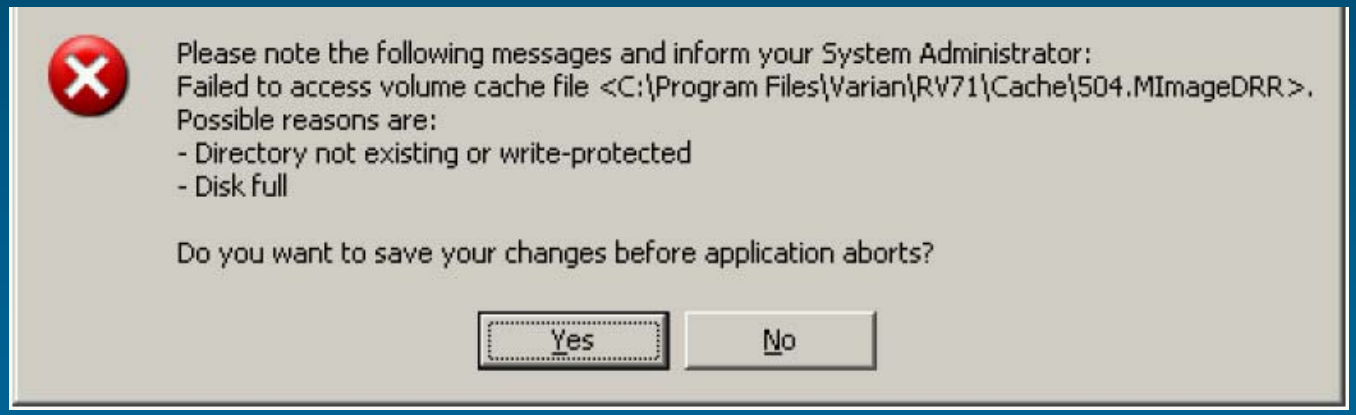
- March 14, 2005, 11 a.m.
- The actual fluence data is saved normally.
- Next in line is DRR. The “Save all” process continues with this, but is not completed.
- Saving of MLC control point data would be after DRR, but will not start because of the above.

A Digitally Reconstructed Radiograph (DRR) of the patient



What happened?

- March 14, 2005, 11 a.m.
- An error message is displayed.
- The user presses “Yes”, which begins a second, separate, save transaction.
- MLC control point data is moved to the holding area.

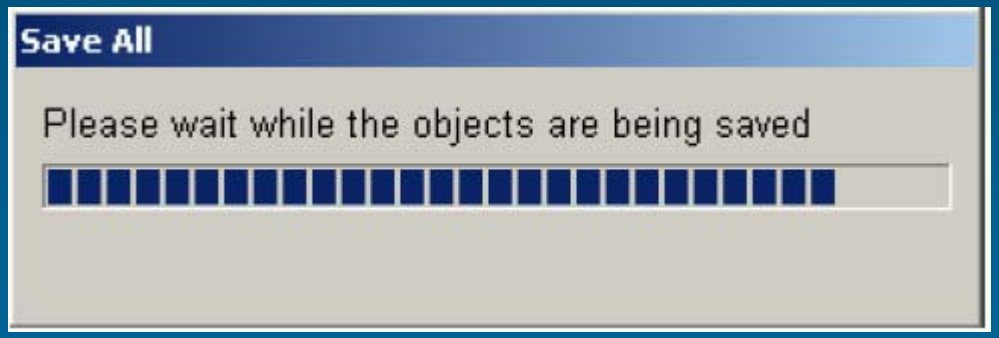


The transaction error message displayed.

What happened?

- March 14, 2005, 11 a.m.

- The DRR is, however, still locked into the faulty first attempt to save.
- This means the second save won't be able to complete.
- The software would have appeared to be frozen.



The frozen state of the second "Save All" progress indication.

What happened?

- March 14, 2005, 11 a.m.

- User then terminates TPS software manually, probably with Ctrl-Alt-Del or Windows Task Manager.

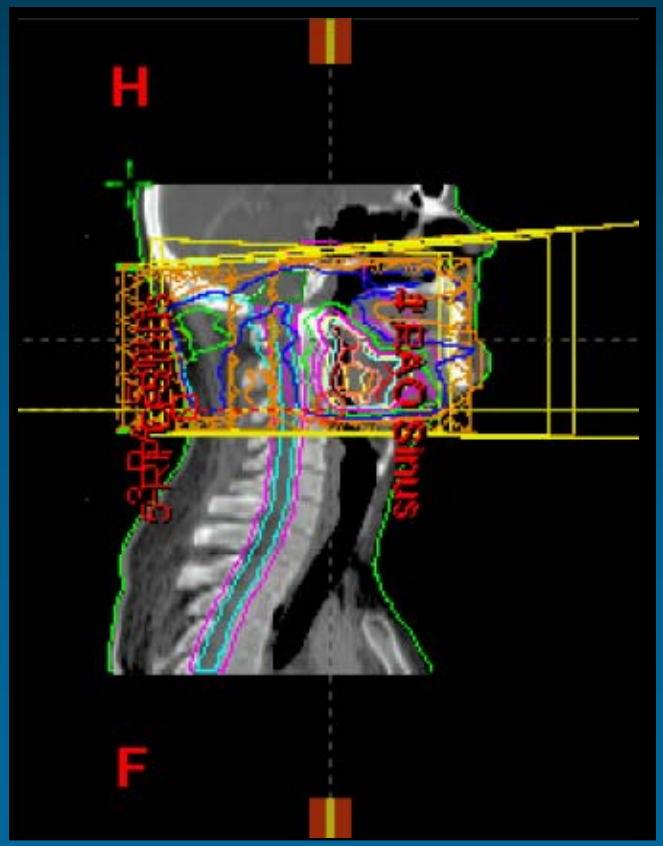
- At manual termination, the DB performs “roll-back” to return data in the holding area to its last known valid state.

- The treatment plan now contains (1) actual fluence data; (2) not the full DRR; (3) no MLC control point data.

Ctrl-Alt-Del

What happened?

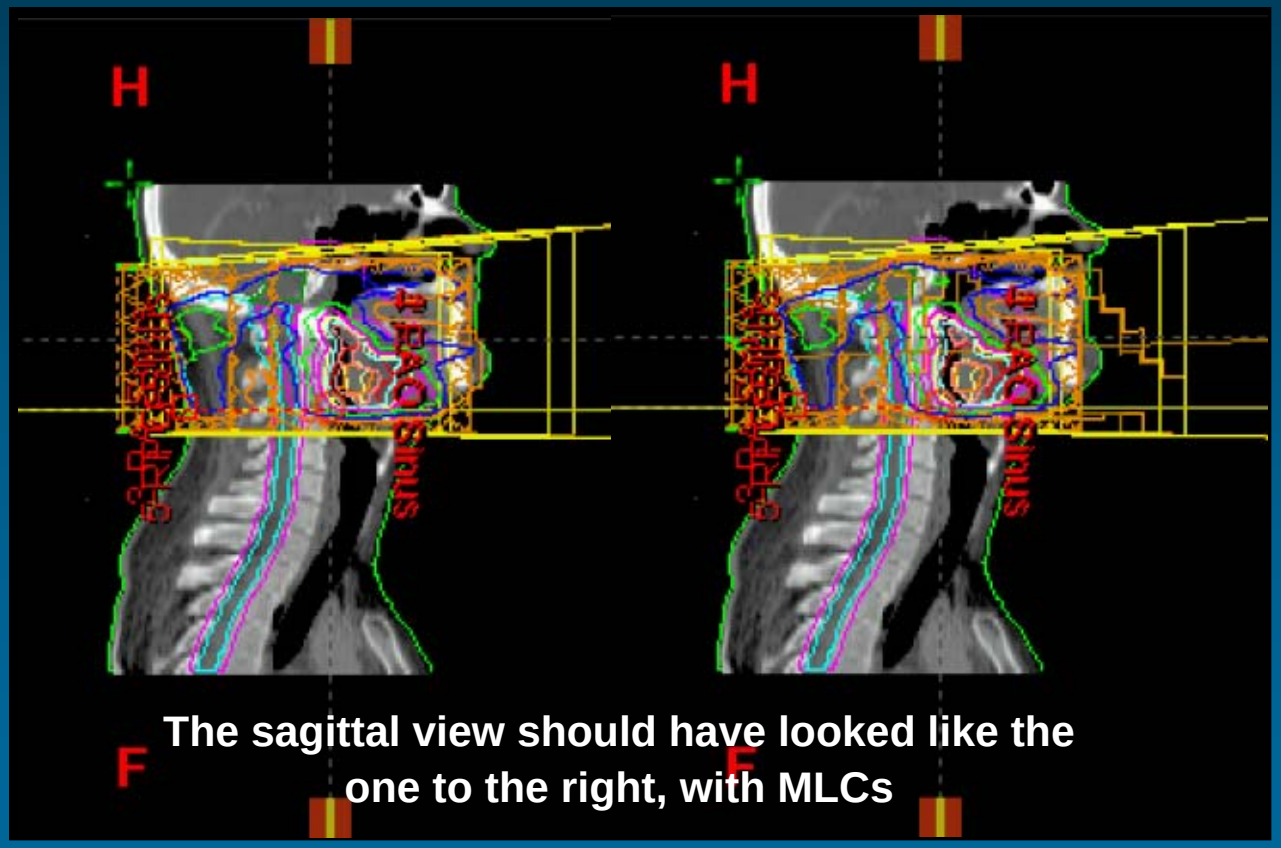
- March 14, 2005, 11 a.m.
- Within 12 s, another workstation is used to open the patients plan. The planner would have seen this:



Valid fluences were already saved. Calculation of dose distribution is now done by the planner and saved. MLC control point data is not required for calculation of dose distribution.

What happened?

- March 14, 2005, 11 a.m.
- No control point data is included in the plan.



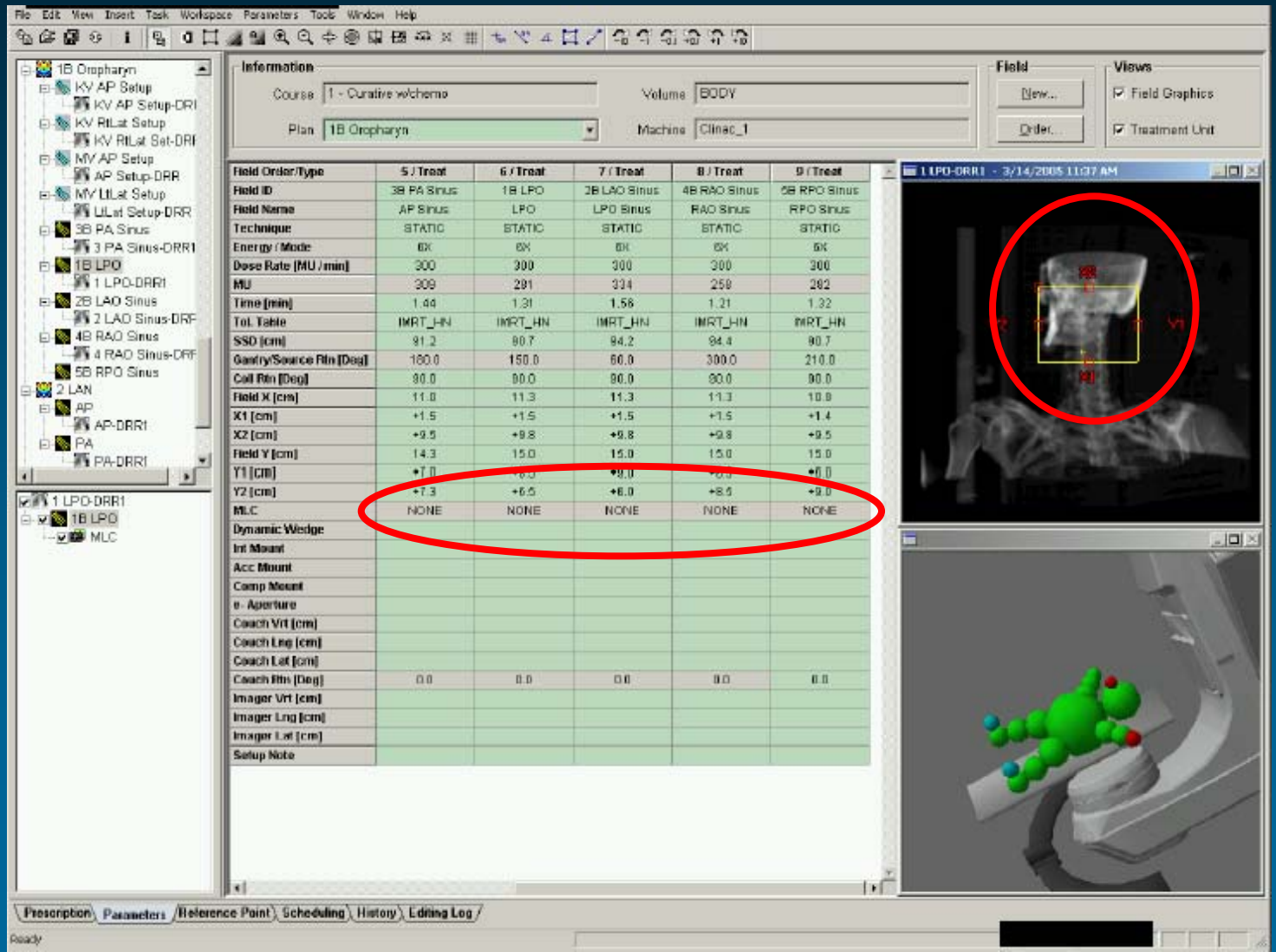
The sagittal view should have looked like the one to the right, with MLCs

What happened?

- March 14, 2005
- No verification plan is generated or used for checking purposes, prior to treatment (should be done according to clinics QA programme).
- Plan is subsequently prepared for treatment – after several computer crashes.
- Plan is also approved by a physician.
- According to QA programme, a second physicist should then review the plan, including overview of the irradiated area outline, and MLC shape used.

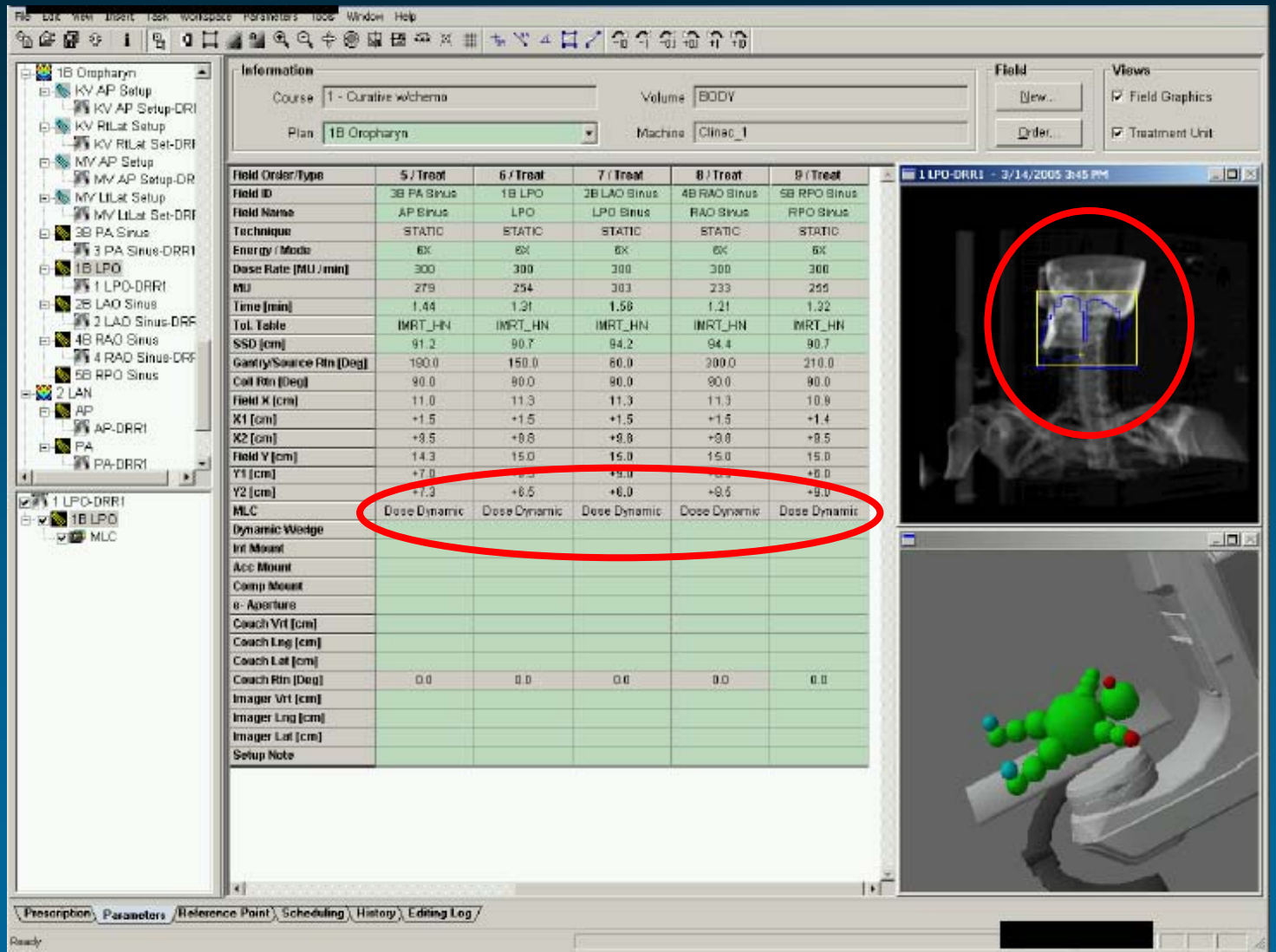
What happened?

- **<u>Would</u> have been seen on verification:**



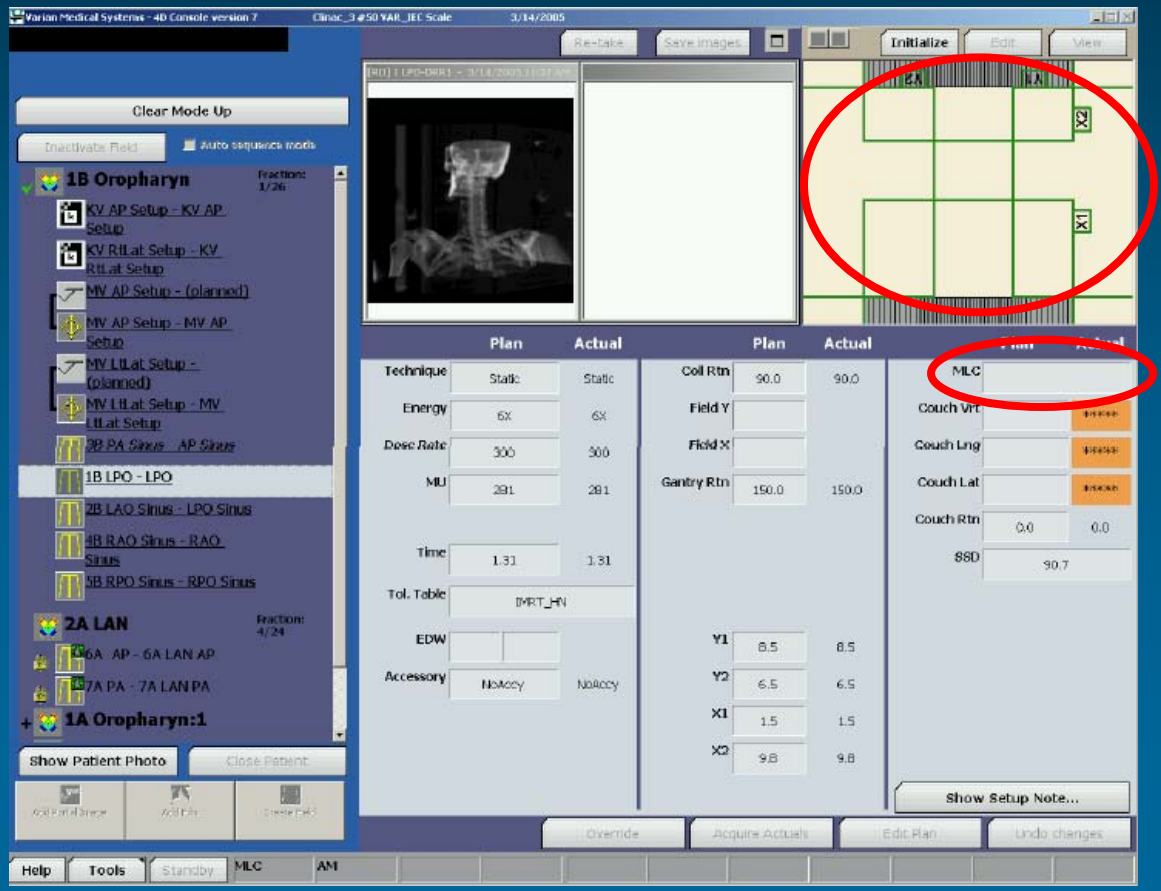
What happened?

- **<u>Should</u> have been seen on verification:**



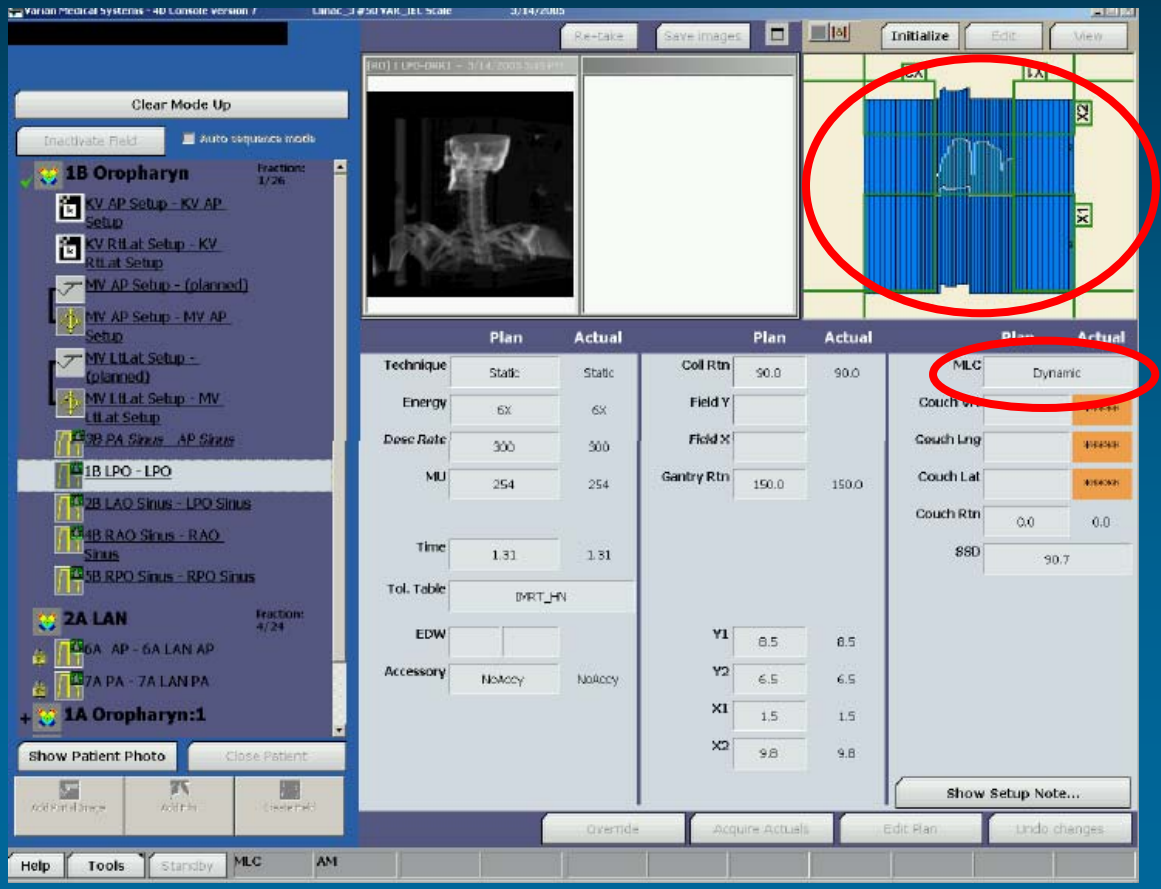
What happened?

- March 14, 2005, 1 p.m.
- The patient is treated. The console screen would indicate that MLC is not used during treatment:



What happened?

- March 14, 2005, 1 p.m.
- Expected display:



Discovery of Accident

- March 15 – 16, 2005

- The patient is treated without MLCs for three fractions.
- On March 16, a verification plan is created and run on the treatment machine. The operator notices the absence of MLCs.
- A second verification plan is created and run with the same result.
- The patient plan is loaded and run, with the same result.

Impact of Accident

The patient received 13 Gy per fraction for three fractions, *i.e.*, 39 Gy in 3 fractions.

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.
- Ensure compliance with procedures, not only for the initial treatment plan but also for treatment modifications
- 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

References

- [Treatment Facility] Incident Evaluation Summary, CP-2005-049 VMS. 1-12 (2005)
- ORH Information Notice 2005-01. Office of Radiological Health, NYC Department of Health and Mental Hygiene (2005)
- Medical Radiation: A Plan Goes Wrong, The New York Times, 24 Jan 2010
- Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies (ICRP Report 112), International Commission on Radiological Protection. Ann ICRP. 2009 Aug;39(4):

Recent NY Times Articles

- THEY CHECK THE MEDICAL EQUIPMENT, BUT WHO IS CHECKING UP ON THEM?

- **Loose regulation of medical physicists has allowed problems to enter a part of the process meant to make health care safer. January 27, 2010.**

Increased media focus

THE PLATFORM

03.05.2010 7:44 am

Inadequate regulation puts patients at risk

By Editorial Board

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St Louis Today:

Rural Missouri

It's the kind of thing that never should happen but did. Seventy-six patients treated for head and neck tumors. On average, they got 50 percent more radiation than had been prescribed.

The problems at CoxHealth began in 2004 and continued unnoticed until September. Sophisticated equipment

There was no independent check of the calibration, and no state or federal regulation requires it. And there are who administer the treatment to be certified.

That certification is an option instead of a requirement "is really silly," said Dr. Eric Klein, a professor of radiatic

Americans get most radiation from medical scans

BY MARILYNN MARCHIONE • THE ASSOCIATED PRESS • JUNE 13, 2010

1 | 2 Next Page

We fret about airport scanners, power lines, cell phones and even microwaves. It's true that we get too much radiation. But it's not from those sources - it's from too many medical tests.

Americans get the most medical radiation in the world, even more than folks in other rich countries. The U.S. accounts for half of the most advanced procedures that use radiation, and the average American's dose has grown sixfold over the last couple of decades.

Dr. Steven Birnbaum works a CT scanner with a patient at Southern New Hampshire Medical Center in Nashua, N.H. Malpractice lawsuit fears for missed heart attacks, burst appendices are one of many reasons patients in the U.S. receive so many scans. (Jim Cole/The Associated Press)

Mad River Hospital, Arcata, CA (Jan 2008)

- 23 months old
- Fell out of bed, unable to move head
- C1-C4 CT
- 151 scans at same level over 68 minutes
- Erythema in few hours
- "I think it was just a rogue act of insanity"

Dosimetry

- 5.3 Gy to the brain
- 5.3 Gy to the salivary glands
- 7.3 Gy to the skin
- 1.54 Gy to the lenses of both eyes
  - Cataracts likely in 3-8 years
- Analysis of the child's lymphocytes found he sustained substantial chromosomal damage

Mad River Hospital fined $25,000

Full story: Eureka Times Standard

The California Department of Public Health announced today that Mad River Hospital has been assessed with a $25,000 administrative penalty from the state of California after a determination was made that the ...

Settlement reached in radiation overdose case; fines dismissed against Mad River Community Hospital

John Driscoll/The Times-Standard
Posted: 05/22/2010 01:30:26 AM PDT

A settlement in a civil suit lodged by the family of a 2-year-old boy allegedly exposed to an overdose of radiation durir a test at Mad River Community Hospital in 2008 was filed in Humboldt County Superior Court on Friday.

The details of the settlement between the family and Mad River Community Hospital are confidential. But the case has drawn the attention of the health care community, and a number of changes in how radiation is used are under consideration.

Carrie and Padre Roth and their son Jacoby filed the suit after Raven Knickerbocker, a state-licensed radiology technician, allegedly administered a 65-minute Computerized Axial Tomography, or C-T, scan to Jacoby in January 2008 after he fell out of his bed and injured his neck.

The suit claimed that Knickerbocker committed 151 medical batteries in the form of 151 scans during the test, exceeding the amount of radiation that should have been administered for the child, who was 23 months old and 28 pounds at the time.

FDA CT Perfusion Warning

CT brain perfusion overexposures

The Center for Devices and Radiological Health (CDRH) issued an alert in regards to high dose levels used in head CT perfusion studies at a hospital in Southern California(1). Over 200 patients apparently received excess radiation during these time-lapse (repeated) CT studies of the head. Subsequently, similar incidents have been identified at two other hospitals in Southern California and potentially in other locations as well. Early investigations of these incidents revealed a misunderstanding of some of the automated dose selection features on the scanner, and this led to an estimated 8 fold increase in radiation to the patient. This was discovered when a number of the patients experienced some temporary hair loss (epilation) and skin reddening (erythema).

This incident apparently resulted from a lack of adequate training of CT technologists, and perhaps an overreliance on the use of preselected CT protocols. There is no

FDA CT Perfusion Warning

- Issued 10/8/2009
- “FDA has become aware of radiation overexposures during perfusion CT imaging to aid in the diagnosis and treatment of stroke.
- Over an 18-month period, 206 patients at a particular facility received radiation doses that were approximately eight times the expected level. Instead of receiving the expected dose of 0.5 Gy (maximum) to the head, these patients received 3-4 Gy. In some cases, this excessive dose resulted in hair loss and erythema. The facility has notified all patients who received the overexposure and provided resources for additional information.

FDA CT Perfusion Warning

- While this event involved a single kind of diagnostic test at one facility, the magnitude of these overdoses and their impact on the affected patients were significant. This situation may reflect more widespread problems with CT quality assurance programs and may not be isolated to this particular facility or this imaging procedure (CT brain perfusion). If patient doses are higher than the expected level, but not high enough to produce obvious signs of radiation injury, the problem may go undetected and unreported, putting patients at increased risk for long-term radiation effects."

CT Perfusion

- **Day 37 after 1st CTP: four CTA/CTP and two DSA exams in 2 weeks**
- **120 kV, 100 mAs, and 50 rotations**

Ref: Eur Radiol (2005) 15:41–46

Causes

- Lack of technologist training
- Lack of understanding of advanced scanner features
- Ignoring scanner feedback
  - Yellow flag when mA automatically adjusted
  - Dose displayed on screen (possibly turned off)
- Poor understanding of patient dose

Prostate Brachytherapy Errors

- March 17, 2010
- Veterans Affairs Medical Center, Philadelphia (PVAMC) retained the services of consulting radiation oncology physicians and medical physics from Hospitals of the University of Pennsylvania for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc.
- 114 patients treated from February 2002 thru May 2008

DVA Medical Event Criteria

- Phase I: ± 20% of prescribed dose
- Phase II: Rectum – dose to 1.33cc volume exceeds 150% of pre-treatment plan dose

  External Tissue – 5 or more seeds located beyond 1cm exterior, and inferior, to the surface of prostate

  Bladder – 3 or more seeds located in bladder wall

Procedure-Specific QA: A Cautionary Tale


The New York Times

Health

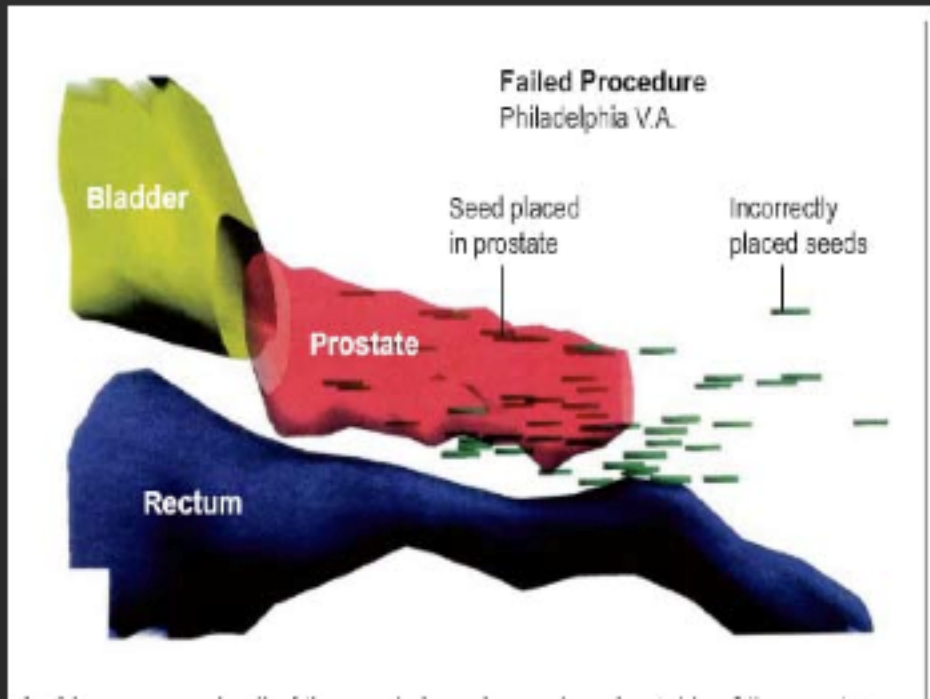
Search Health

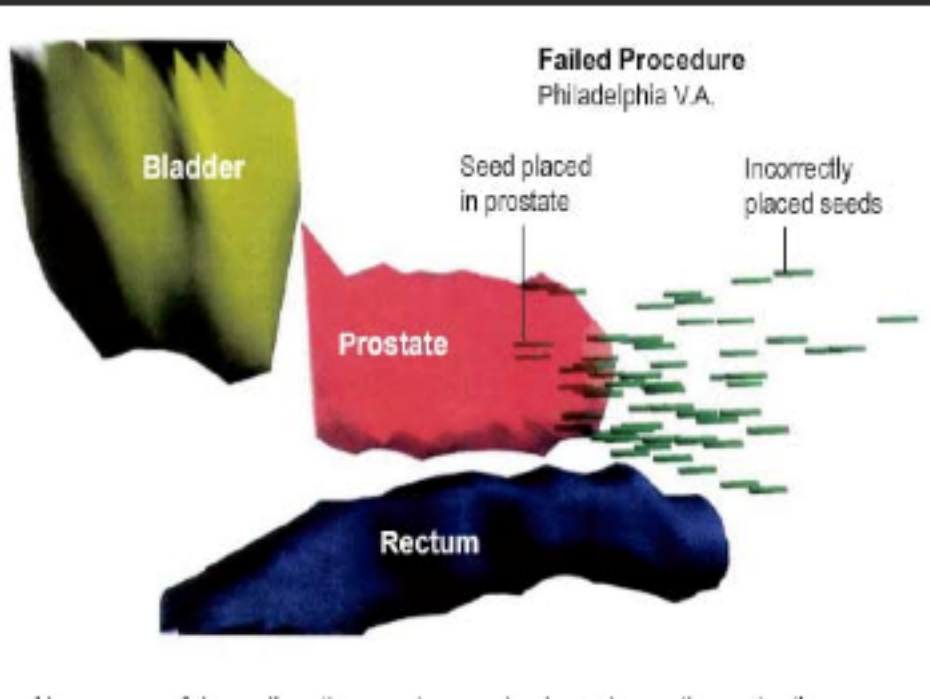
At V.A. Hospital, a Rogue Cancer Unit

Well

New York Times: 21 June 2009

- 97 of 116 procedures were medical events, many were wrong site
  - Failures of process rather than devices
  - QA is a team effort: focus on key physician as well as technical steps

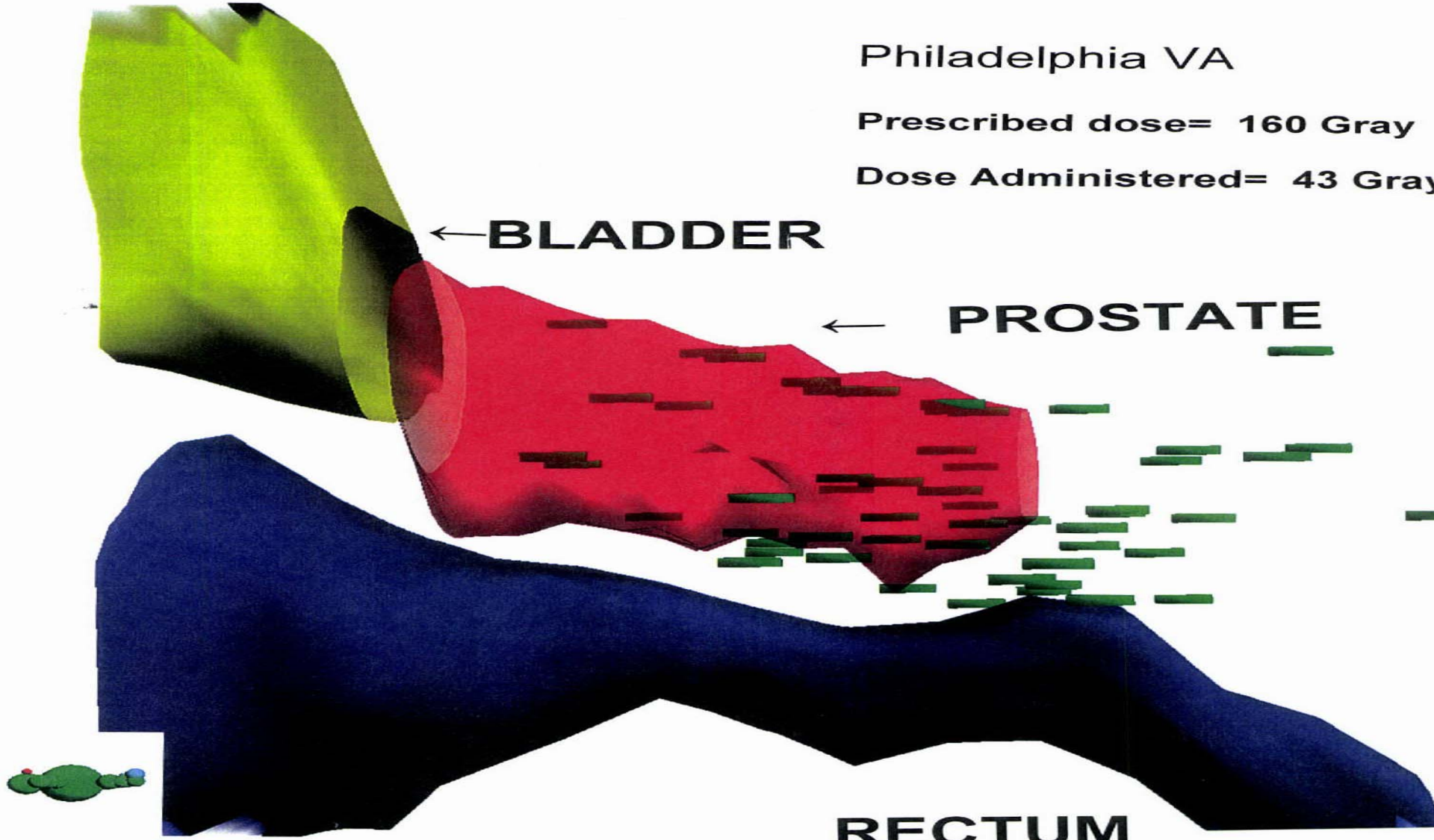




VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · · 9/9/2008 4:47:17 PM

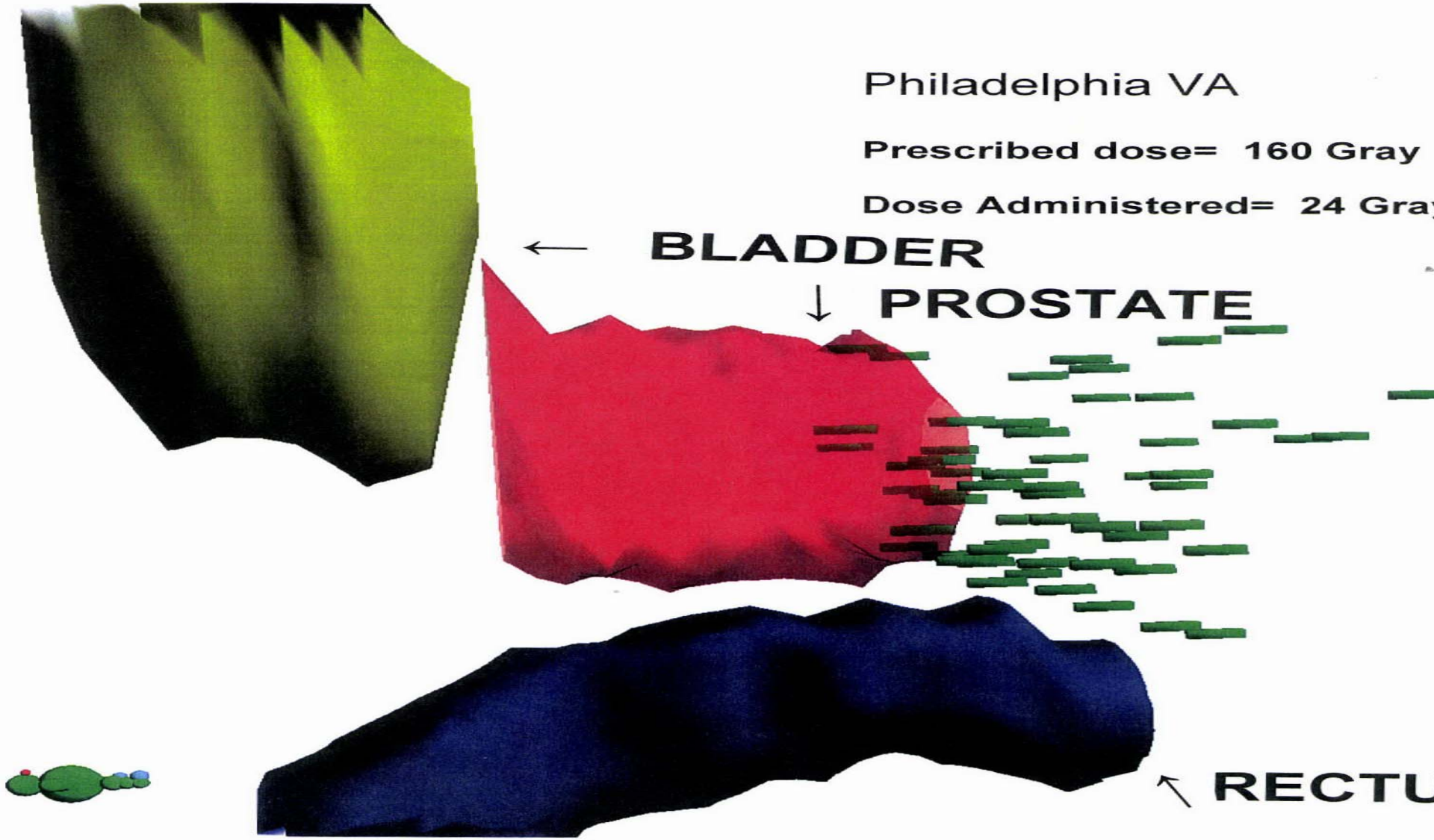
Study: followupEval_061108 Variation: Default # Scans: 29	Isotope: I-125 (2301) [NIST 00] # Seeds: 54 Prescription Dose: 160.000 Anisotropic Correction: 0.982	U/mCi: 1.270 U/Seed: 0.483 mCi/Seed: 0.38



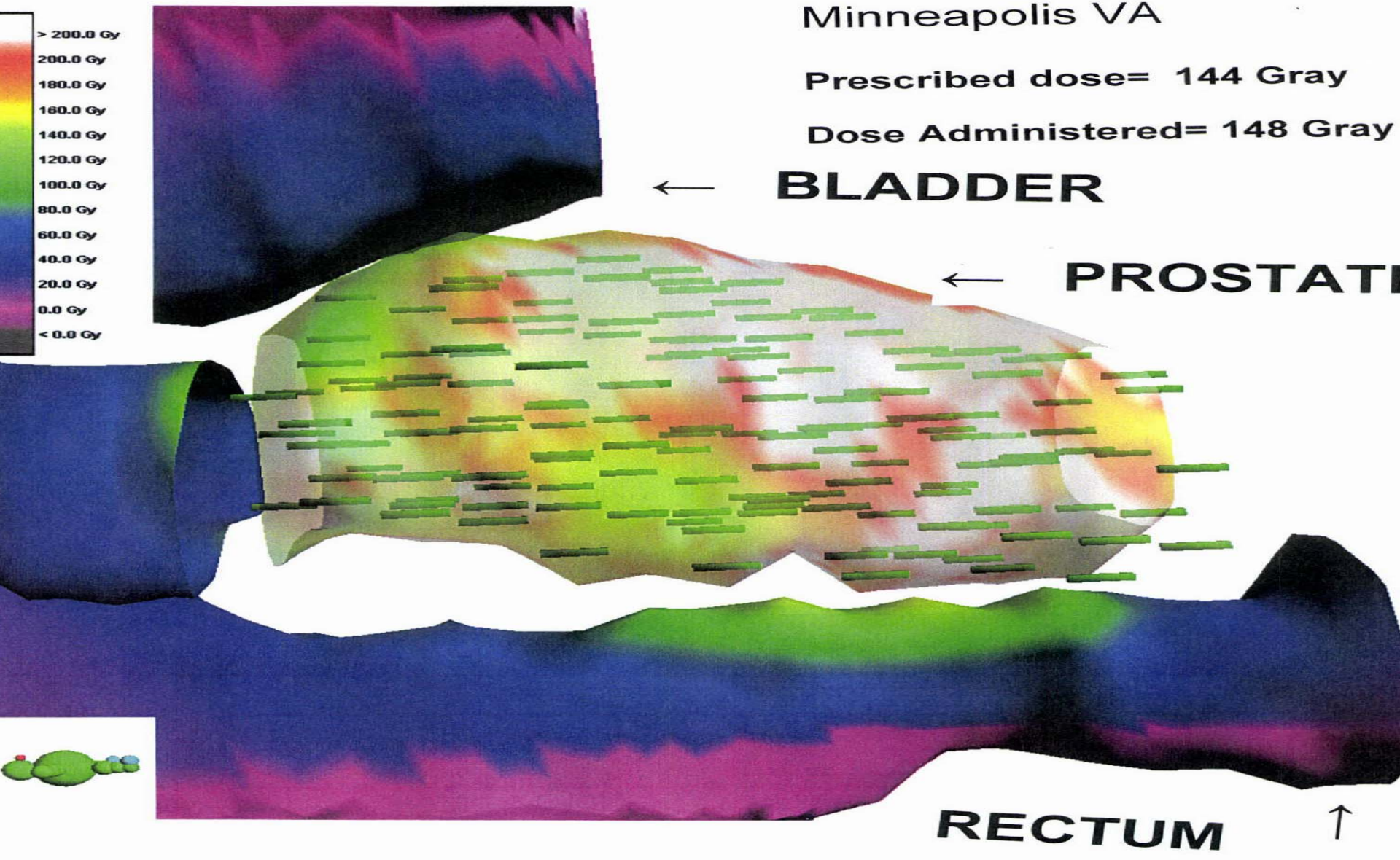
VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · · 9/9/2008 4:54:55 PM

Study: followupEval_062408 Variation: Default # Scans: 54	Isotope: I-125 (2301) [NIST 00] # Seeds: 58 Prescription Dose: 160.000 Anisotropic Correction: Fac	U/mCi: 1.270 U/Seed: 0.483 mCi/Seed: 0.38



	Study: **POST PLAN** Variation: **Default** Images: **37**	Source: **I-125 (IAI-125A) [NIST 00]** Comment: Sources: **152** Anisotropy: **Function (Line Model)** Source Activity: **0.394 U [0.310 mCi]**
Procedure Date: **7/2/2008**	Prescription Dose: **144.0 Gy**	Total Activity: **59.888 U [47.156 mCi]**



Series of Events

- Prostate cases use either 0.380 mCi or 0.509 mCi seeds (default in electronic Written Directive (WD) system is 0.380)
- Patient undergoing prostate brachytherapy received a dose <80% of prescribed. Treatment plan called for seeds of 0.509 mCi
- Written directive called for seeds of 0.380 mCi
- Seeds of 0.380 mCi were ordered, received, and implanted
  - NRC noted that Radiation Safety did not note the discrepancy of activity received and activity on the WD
- NRC noted that the medical physicist who assayed a seed did not note the discrepancy of activity received and activity on the WD.

Series of Events

- The discrepancy was discovered on May 12 and the RSO was notified
- The RSO determined that it was not a medical event
- A post-treatment plan on May 15 showed the dose to be 47% of prescribed
- A medical event was reported on May 16 by the VA's National Health Physics Program to NRC

Investigation Report

An NRC medical consultant noted (p3):

1. seed placement was erratic and not consistent with current medical standards and
2. erratic seed placement led to high radiation doses to the rectum, bladder or perineum.

NRC apparent violations (p13-15) – Failure to:

1. develop adequate written procedures to assure prostate implant was as written directive stated;
2. develop procedures to that outline methods to verify that the treatment was according to the written directive;
3. train supervised staff on identifying medical events and what to do if there is one;
4. train unsupervised staff on identifying medical events and what to do if there is one;
5. record total dose on the written directive; and
6. provide required information to NRC in a 15d report.

In both cases, they were developed but not followed.

Investigation Report

ABI-identified root cause (p17):

1. the licensee's contractors (physicians and physicists) accepted a substandard approach to brachy treatments and allowed the system to fail when post-implant dosimetry was performed and low doses were identified, but took no action.

ABI-identified indirect root causes (p17):

1. lack of safety culture shown by the medical physicist not presenting the AU with information showing the D90 dose was low;
2. assumptions that others were doing the required safety checks;
3. the AUs belief that implant quality was acceptable since he wasn't hearing about complications from his patients;
4. no reviews of the program by the head of RO
5. no statistical reviews of the program by radiation safety; and
6. no QMP reviews

Lack of Safety Culture

The NRC determined "*lack of a safety culture*" because the two medical physicists indicated they had concerns about one of the physicians and how he practiced, but they did not raise these concerns to the RSO, the RSC or management.

NRC Fines VA - $227,500

Fine against VA Hospital Is Second Largest in NRC History

March 21, 2010. By Gordon Gibb

SHARE

Philadelphia, PA: On St. Patrick's Day the Nuclear Regulatory Commission (NRC) hit the Philadelphia VA Medical Center with $227,500 in penalties—one of the largest fines ever levied against a medical institution. While **VA hospital malpractice** was not alleged, the errors that triggered the large fine could very well be of interest to VA medical malpractice lawyers.

According to a story published on 3/17/10 in the New York Times, federal investigators found that the hospital misplaced radioactive seeds in 97 out of 116 procedures involving patients with prostate cancer between 2002 and 2008.

The report cited the number of radiation errors as "unprecedented."

"The lack of management oversight, the lack of safety culture to ensure patients are treated safely, the potential consequences to the veterans who came to this facility and the sheer number of medical events, show the gravity of these violations," said Mark Satorius, a regional administrator for the commission.

The NRC regulates the use of nuclear isotopes in medical treatment. The commission rarely issues fines exceeding several thousands of dollars over errors involving nuclear radiation. The largest fine ever ever levied was 15 years ago and totaled $280,000.

Not Over Yet – NRC Proposes Additional $39,000 Against DVA

08/23/2010

NRC PROPOSES $39,000 FINE AGAINST DEPARTMENT OF VETERANS AFFAIRS FOR VIOLATIONS OF NRC REQUIREMENTS

The Nuclear Regulatory Commission has proposed a civil penalty of $39,000 against the Department of Veterans Affairs (DVA) for two violations of NRC regulations. The NRC identified that the DVA failed to recognize that problems with prostate brachytherapy programs existed at other VA facilities after similar problems were previously cited at the Philadelphia VA Medical Center's program.

"These violations should have been identified by the DVA during their own independent inspections of the VA facilities," said NRC Region III Regional Administrator Mark Satorius. "We expect the DVA to ensure all facilities with prostate brachytherapy programs not only fully understand and follow NRC regulations but also rigorously implement their oversight role to ensure medical procedures with nuclear materials are delivered safely to patients."

NRC PRESS RELEASE

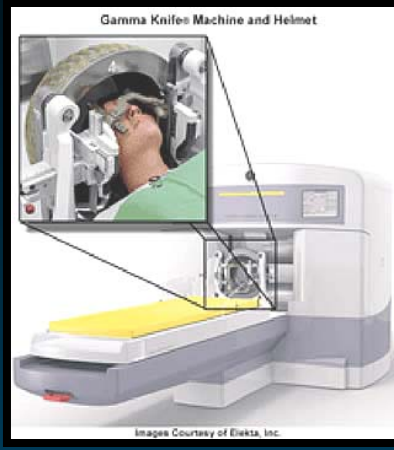
The violations are associated with the DVA's failure to develop and implement written procedures across all VA brachytherapy programs to verify the administrations of nuclear material according to the patients' treatment plan and written directive; as well as a failure to notify the NRC no later than the next day after the discovery of a medical event. The DVA has taken corrective actions to fix these two violations.

The NRC also determined that the DVA had not taken steps to fix the larger problems with the DVA's regulatory oversight organizations. The NRC concluded the VA National Radiation Safety Committee (NRSC) and the VA National Health Physics Program (NHPP) had not taken steps internally to aggressively assess their regulatory and oversight functions and performance.

- **DVA has 30 days to respond.**

http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU_ADAMS%5EPBNTAD01&ID=102350262

FL - Medical Errors
Radioactive Materials



- October 2002
- Gamma Stereotactic Radiosurgery Device
- 10 patients involved
- Dose received was 60% greater than prescribed
- Calibration date changed during the replacement of an external printer by service personnel

FL - Medical Errors
Radioactive Materials

- Prescribed dose range from 1,220 cGy to 2,400 cGy to the target
- Actual dose range 1,920 cGy to 3,840 cGy
- Identified as an Abnormal Occurrence
- Noncompliant issue:
  - Failure to follow the written directive
  - Failure to follow the licensees quality management program

Medical Errors Radioactive Materials Florida's Response

- Facility notified BRC October 31, 2002
- Nov 1, 2002 BRC contacted other licensees with similar equipment to request verification of output (Ringdown)
- Facility agreed to cease operations
- On-site investigation conducted Nov 3-5, 2002
- BRC notified NRC and NRC State Agreement Officer
- Independent Medical Physicists reviewed the device, policy and procedures
- Licensee performed device calibration and revised decayed correction for treatment planning system
- Facility agreed to daily output checks to verify the output
- Reviewed investigation and licensees written report

Medical Errors Radioactive Materials Florida's Response

- Submitted an investigation report to the licensees
- Completed report to NMED 3/24/2003
- Abnormal Report to Congress 5/24/2004

State agency fines Hopkins $370,000 on radiation issues

By Kelly Brewington | **kelly.brewington@baltsun.com**

March 20, 2010

Topics

Johns Hopkins Hospital
Johns Hopkins University
Punishment

See more topics »

The Maryland Department of the Environment announced Friday that it fined the **Johns Hopkins University** and **Johns Hopkins Hospital** $370,000 - the largest such penalty ever paid by Hopkins - after finding problems related to how the university and hospital handled radiation materials, maintained radiation machines and administered radiation to one patient.

Global Safety Impact

~ 1M Radiation Therapy (RT) courses yearly in US (IMV Report – 2007)

Event Type	Event per million RT courses*
Any	~ 10,000 – 20,000
Errors w/ significant clinical consequences	~1,000 – 10,000
Errors w/ serious clinical consequences	~ 5 -10
Lots of caveats (e.g., under-dosing, under-reporting)	

- Most events ≠ serious injury
- RT safe, but could/should always be safer
- **No event should be tolerated**

* Munro – BJR 2007

Increased regulation likely:

http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm

The New York Times

February 10, 2010

F.D.A. to Increase Oversight of Medical Radiation

By WALT BOGDANICH and REBECCA R. RUIZ

The federal Food and Drug Administration said Tuesday that it would take steps to more stringently regulate three of the most potent forms of medical radiation, including increasingly popular CT scans, some of which deliver the radiation equivalent of 400 chest X-rays.

With the announcement, the F.D.A. puts its regulatory muscle behind a growing movement to make life-saving medical radiation — both diagnostic and therapeutic — safer.

Last week, the leading radiation oncology association called for enhanced safety measures. And a Congressional committee was set to hear testimony Wednesday on the weak oversight of medical radiation, but the hearing was canceled because of bad weather.

FDA Initiative Scope

- High-dose medical imaging procedures
  - Computed tomography
  - Interventional fluoroscopy
  - Nuclear medicine
- Promote Safe Use of Medical Imaging Devices
- Support Informed Clinical Decision Making
- Increase Patient Awareness

Congressional Focus

Last Fall

U.S. SENATE COMMITTEE ON VETERANS' AFFAIRS

Home | About | Legislation | Newsroom | Hearings | Issues | Resources | Contact Us

Hearing

Philadelphia VA Medical Center's Terminated Cancer Treatment Program

UNITED STATES SENATE
COMMITTEE OF VETERANS' AFFAIRS

Field Hearing on Philadelphia VA Terminated Cancer Treatment Program

June 29, 2009, 10:00 AM

Philadelphia VA Medical Center

Click Here to Listen to Part 1 of the Hearing

Click Here to Listen to Part 2 of the Hearing

Videos

View the committee's latest hearings or videos

Calendar

View the committee's latest events and hearings

Congressional Focus

American Association of Physicists in Medicine

Statement of Michael G. Herman, Ph.D., FAAPM, FACMP
On Behalf of the American Association of Physicists in Medicine (AAPM)
Before the Subcommittee on Health of the House
Committee on Energy and Commerce
February 26, 2010

Chairman Pallone, Ranking member Deal and members of this distingui
morning and thank you for the opportunity to testify today on Medical I
Issues.

It is my pleasure to be here representing the American Association of Pl
generally as the AAPM. AAPM is a scientific and professional organiz

AAPM Testifies Before Congress

- *As many of you know, there have been a number of recent articles in the press related to tragic errors in radiation therapy. This combined with the recent publicity on CT perfusion dose problems has prompted Congress to call a hearing entitled "Medical Radiation: an Overview of the Issues". AAPM, along with ASTRO, ACR, ASRT and MITA have been asked to testify to help guide direction for improving patient safety in the medical use of radiation. We sincerely believe that working together with all stakeholders that we can improve safety and quality in the medical use of radiation.*

Mike Herman, AAPM President

Congressional Hearing Transcript

- http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1910:medical-radiation-an-overview-of-the-issues&catid=132:subcommittee-on-health&Itemid=72

AAPM Statement

- In summary, the AAPM believes that patient safety in the use of medical radiation will be increased through: consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. We must also learn from our mistakes by collecting and evaluating them at the national level. AAPM has been working directly and in cooperation with other stakeholders for years on some of these issues and we are saddened that some people are injured during what should be beneficial procedures. We believe that more effort on all seven areas of focus, by all of us, working cooperatively, will continue to make the use of medical radiation safer and more effective for the people that need it.

The Medical Radiation Process Overview

Roles of Team members, Manufacturers, Regulatory agencies

key | Activity | Manufacturer | Medical Team | Regulator

At Manufacturer

Equipment/Technology Development	Product Mgr Engineers Physicist	Physicist
Equipment/Technology Manufacture	Manufacturer	Regulator

At Medical Institution
New Process/ Procedure Implementation

Concept Plan Commission Quality Control	Physician Physicist Therapist Dosimetrist

At Medical Institution
New Equipment Implementation

Selection/Purchase	Manufacturer	Medical Team	
Installation/Acceptance Test	Manufacturer	Physicist	
Commissioning & Calibrate	Regulations NRC + States for Radioactive Materials ---- X-Ray Equipment - Varies widely by State	Physicist	2nd Physicist
Establish and perform QA		Physicist	Therapist
Maintenance/Upgrades	Manufacturer	Physicist	

At Medical Institution
Patient Specific Procedure

Patient Referred for Medical Radiation — Referring Physician

Diagnostic Imaging

Registration	Desk	
Image Preparation	Technologist	
Radiologic Imaging Procedure	Technologist	Physician
Images Interpreted	Physician	
Patient Related Dose/QA	Physicist	

Regulations
Some Federal (MQSA)
Other Varies widely by State

Therapy Needed — **Surgery, Medical Oncology, Interventional Radiology/Cardiology**

Radiation Therapy

Consultation	Physician	
Simulation	Physician, Therapist Dosimetrist, Physicist	
Dosimetric Planning	Physician, Dosimetrist, Physicist	
Treatment Verification/QA	Therapist, Physicist Dosimetrist	
Treatment Delivery	Therapist	(Physician, Physicist)
Follow Up	Physician	

Regulations
Limited, varies widely by State
Federal only NRC for materials

Congressional Hearings

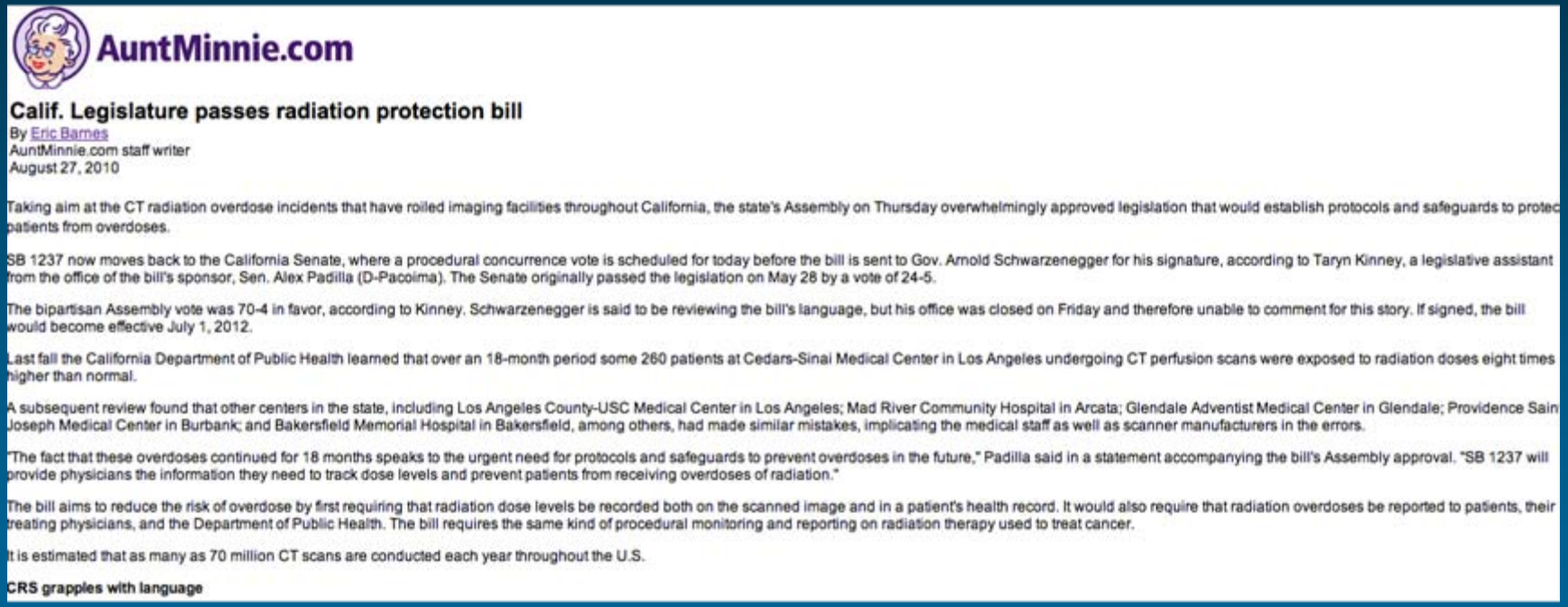
- Recommendations included:
  - Expanding federally mandated accreditation requirements to include all clinical settings (diagnostic and therapeutic)
  - Federally mandated CT dose index registry
  - National database for reporting linear accelerator errors
  - Enhanced adoption of electronic medical records
  - Legislation to enforce patient safety
  - Increased funding for NCI and the Radiological Physics Center

Congressional Hearings

- Recommendations included (continued)
  - Federal mandate for board certification of medical physics and uniform licensing requirements
  - Passage of the CARE Act, which requires minimum educational and credentialing standards for technical staff
  - Rigorous minimum standards for accrediting clinical practices
  - Mandatory public, anonymous reporting of radiation therapy “near misses”
  - Development of radiation dose reference levels

Legislation

CA Legislature Passes Radiation Protection Bill



AuntMinnie.com

Calif. Legislature passes radiation protection bill

By Eric Barnes
AuntMinnie.com staff writer
August 27, 2010

Taking aim at the CT radiation overdose incidents that have roiled imaging facilities throughout California, the state's Assembly on Thursday overwhelmingly approved legislation that would establish protocols and safeguards to protec patients from overdoses.

SB 1237 now moves back to the California Senate, where a procedural concurrence vote is scheduled for today before the bill is sent to Gov. Arnold Schwarzenegger for his signature, according to Taryn Kinney, a legislative assistant from the office of the bill's sponsor, Sen. Alex Padilla (D-Pacoima). The Senate originally passed the legislation on May 28 by a vote of 24-5.

The bipartisan Assembly vote was 70-4 in favor, according to Kinney. Schwarzenegger is said to be reviewing the bill's language, but his office was closed on Friday and therefore unable to comment for this story. If signed, the bill would become effective July 1, 2012.

Last fall the California Department of Public Health learned that over an 18-month period some 260 patients at Cedars-Sinai Medical Center in Los Angeles undergoing CT perfusion scans were exposed to radiation doses eight times higher than normal.

A subsequent review found that other centers in the state, including Los Angeles County-USC Medical Center in Los Angeles; Mad River Community Hospital in Arcata; Glendale Adventist Medical Center in Glendale; Providence Sain Joseph Medical Center in Burbank; and Bakersfield Memorial Hospital in Bakersfield, among others, had made similar mistakes, implicating the medical staff as well as scanner manufacturers in the errors.

"The fact that these overdoses continued for 18 months speaks to the urgent need for protocols and safeguards to prevent overdoses in the future," Padilla said in a statement accompanying the bill's Assembly approval. "SB 1237 will provide physicians the information they need to track dose levels and prevent patients from receiving overdoses of radiation."

The bill aims to reduce the risk of overdose by first requiring that radiation dose levels be recorded both on the scanned image and in a patient's health record. It would also require that radiation overdoses be reported to patients, their treating physicians, and the Department of Public Health. The bill requires the same kind of procedural monitoring and reporting on radiation therapy used to treat cancer.

It is estimated that as many as 70 million CT scans are conducted each year throughout the U.S.

CRS grapples with language

USA TODAY

Report: Thyroid cancer radiation a public threat

Updated 5h 10m ago

By Steve Sternberg, USA TODAY

By H. Darr Beiser, USA TODAY

In October 2007, Holly Russell-Milstein, then 29, rented a townhouse where she could recover from radiation from her thyroid cancer away from her husband and daughters. She stocked up on magazines and bottled water, and wrapped the TV remote in a plastic bag she can throw away when she leaves to avoid spreading the radiation in the Baltimore home.

A Nuclear Regulatory Commission rule allowing hospitals to discharge radioactive thyroid cancer patients to their homes and hotels poses a public health threat, a congressional report says today.

The report, released by Rep. Edward Markey, D-Mass., chairman of the House Subcommittee on Energy and the Environment, which oversees the commission, also found that insurers routinely use the rule to deny hospital care even to patients whom doctors say may pose a radiation risk to others. Patients are often discharged to recover in self-imposed isolation.

FORUM: Living with Cancer

ARCHIVES: It kills thyroid cancer, but is radiation safe?

"The United States simply cannot play radioactive roulette and gamble with public health and safety," Markey says.

Radioactive iodine is a proven cancer fighter, with a five-year survival rate of 97%. The thyroid is the only body organ that uses iodine. Radioactive iodine kills any thyroid cancer cells that surgery might have missed. But radiation also poses a cancer risk, especially to children. Thyroid cancer patients give off radioactive iodine in urine, sweat and saliva for several days; traces may remain in the body for as long as two weeks.

In 1997, the NRC "weakened" its patient-release regulations from the global standard requiring hospitalization for patients whose bodies contain 30 millicuries or more of radioactive iodine to one that allows outpatient treatment, the report says. The report says the NRC repeatedly rebuffed efforts to get the agency to adopt stricter standards.

In August, the Ninth Circuit Court of Appeals rejected a petition by thyroid cancer survivor Peter Crane, a former NRC lawyer, to force a change. The court ruled that he "lacked standing to bring the case" because he is not undergoing treatment, the report says.

"I'm gratified that the committee is paying attention to this," Crane said. "Patients are going home in this country with 200 millicuries of radiation in their system. In Germany, they would be hospitalized with 8 millicuries. This isn't an academic matter, it's

Recent USA Today Article

March 17, 2010.

NRC's Patient Release Rule

- Questions 10 CFR § 35.75
- In 2005 Peter Crane filed a Petition for Rulemaking questioning the regulation
- Most in the medical community requested NRC deny the Petition
- NRC denied the Petition but this did not end Mr. Cane's concerns

Rep. Markey – Patient Release

RADIOACTIVE ROULETTE:

How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety

A report by the Staff of Edward J. Markey (D-MA)
Chairman, Subcommittee on Energy and Environment
Energy and Commerce Committee
U.S. House of Representatives
March 18, 2010

EMBARGOED UNTIL THURSDAY MARCH 18, 2010
12:01 AM

1

CARE Bill

- CARE stands for:
  - *Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2010*

Members of the Alliance for Quality Medical Imaging and Radiation Therapy

- American Association of Medical Assistants
- American Association of Medical Dosimetrists
- American Association of Physicists in Medicine
- American College of Medical Physics
- American Society of Radiologic Technologists
- American Society of Echocardiography
- Association of Educators in Imaging and Radiologic Sciences
- Association of Vascular and Interventional Radiographers
- Cardiovascular Credentialing International
- Joint Review Committee on Education in Cardiovascular Technology
- Joint Review Committee on Education in Diagnostic Medical Sonography
- Joint Review Committee on Education in Radiologic Technology
- Joint Review Committee on Education Programs in Nuclear Medicine Technology
- Nuclear Medicine Technology Certification Board
- Medical Dosimetrist Certification Board
- Nuclear Medicine Technology Certification Board
- Section for Magnetic Resonance Technologists of International Society of Magnetic Resonance in Medicine
- Society of Nuclear Medicine-Technologist Section
- Society for Radiation Oncology Administrators
- Society for Vascular Ultrasound
- Society of Diagnostic Medical Sonography
- Society of Invasive Cardiovascular Professionals

The Alliance

- Consulting Organizations:
- American College of Radiology
- American Healthcare Radiology Administrators
- American Society for Therapeutic Radiation and Oncology
- Conference of Radiation Control Program Directors

- Other Supporters
- American Cancer Society
- American Organization of Nurse Executives
- American Osteopathic College of Radiology
- Cancer Research Foundation of America
- Help Disabled War Veterans/Help Hospitalized Veterans
- International Society of Radiographers and Radiological Technologists
- National Coalition of Cancer Survivorship
- Medical Imaging Consultants, Inc.
- Philips Medical Systems, Inc.

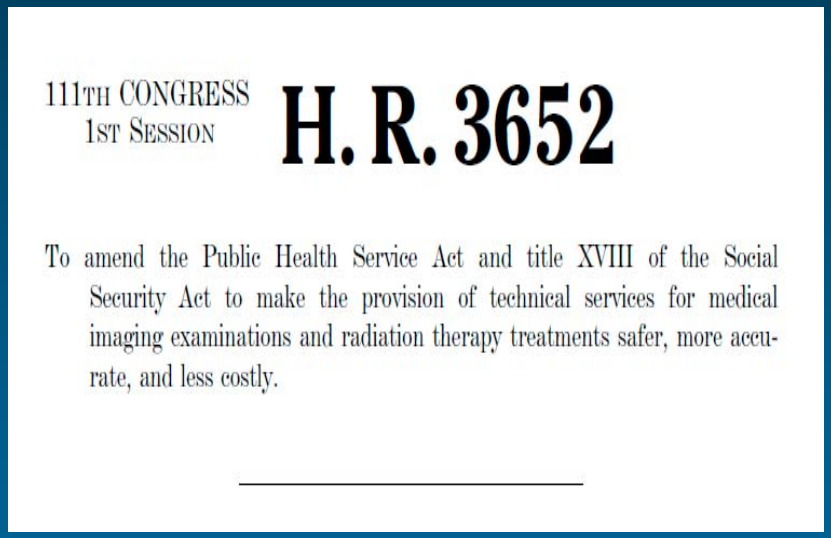
Brief Legislative History – The 110th Congress

- House introduced H.R. 583 – Rep. Doyle [PA-14]
  - 150 co-sponsors (including sponsor)*
    - 97 Democrats
    - 53 Republicans
- Senate introduced S. 1042 – Sen. Enzi [WY]
  - 26 co-sponsors (including sponsor)*
    - 8 Democrats
    - 17 Republicans
    - 2 Independents
- Both Bills were identical!

(*As of October 24, 2008)

111th Congress

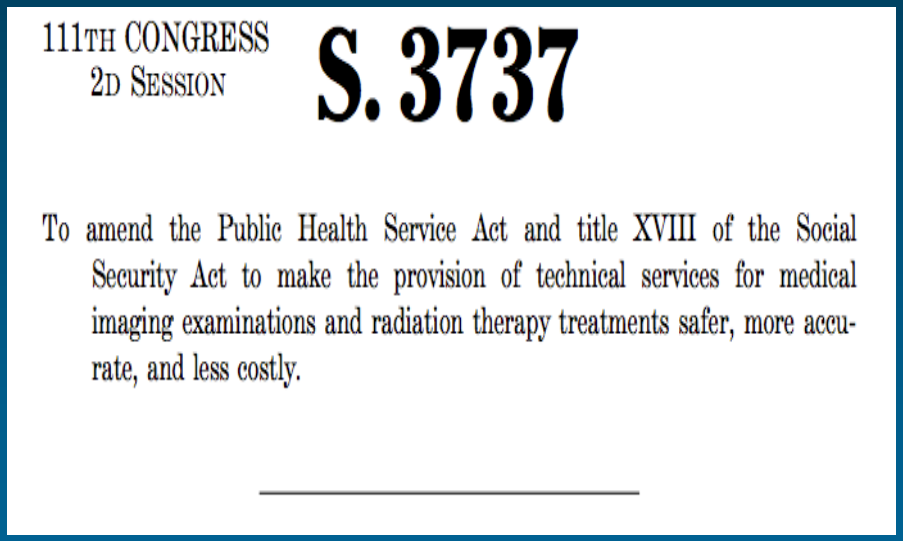
- **To amend the Public Health Service Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.**



111TH CONGRESS
1ST SESSION

H. R. 3652

To amend the Public Health Service Act and title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.



111TH CONGRESS
2D SESSION

S. 3737

To amend the Public Health Service Act and title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

Current Status – The 111th Congress

- Introduced by Rep. John Barrow, [GA-12] on September 25, 2009
- Referred to the House Ways & Means and Energy & Commerce committees.
- Minor adjustments to tie enforcement more closely to Medicare.
- Currently has 116 Cosponsors
- http://www.thomas.gov/cgi-bin/query/z?c111:H.R.3652:

Senate Status

- Senators Enzi, [WY] and Harkin [IA] introduced bill 8/5/2010
- Language is slightly different that H.R. 3652
  - Removes exclusion for MIPPA
  - Tightens dates for enactment
  - Discussions with Rep. Barrow, sponsor of H.R. 3652 indicate he is willing to accept the changes when it comes to the floor of the House for a vote.

CARE Act

- Excludes physicians, physician assistants and nurse practioners
- Does not mandate licensure but does not preclude licensure
- Requires Secretary of HHS to work with expert advisers to develop standards (e.g., regulations)

The CARE Bill will:

- Set uniform standards for personnel performing medical imaging and radiation therapy services paid for by all health programs under the jurisdiction of HHS.

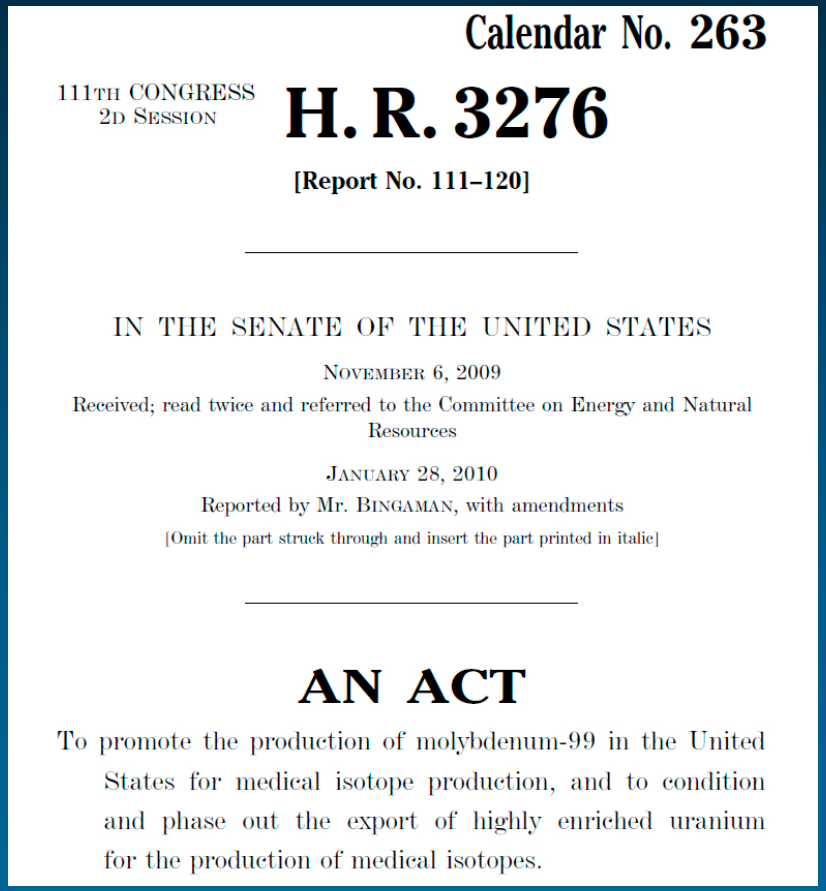
- Direct the Secretary to update federal certification standards for persons performing medical imaging, planning and delivering radiation therapy treatments.

The CARE Bill will:

- Recognize state licensure standards that meet or exceed the federal standard.
- Require HHS to examine each state's existing licensure program to ensure it meets the federal standard.
- Direct HHS to ensure that no later than 3 years after the date of enactment of the legislation, all programs under HHS jurisdiction adhere to the standards including payment for medical imaging or radiation therapy procedures.

American Medical Isotopes Production Act of 2010

American Medical Isotopes Production Act of 2010



Calendar No. 263

111TH CONGRESS
2D SESSION

H. R. 3276

[Report No. 111–120]

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2009

Received; read twice and referred to the Committee on Energy and Natural Resources

JANUARY 28, 2010

Reported by Mr. BINGAMAN, with amendments

[Omit the part struck through and insert the part printed in italic]

AN ACT

To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

- **Rep. Edward Markey, [MA-7]**
- **Passed House**
- **Pending in the Senate**

- **To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.**

Grassroots

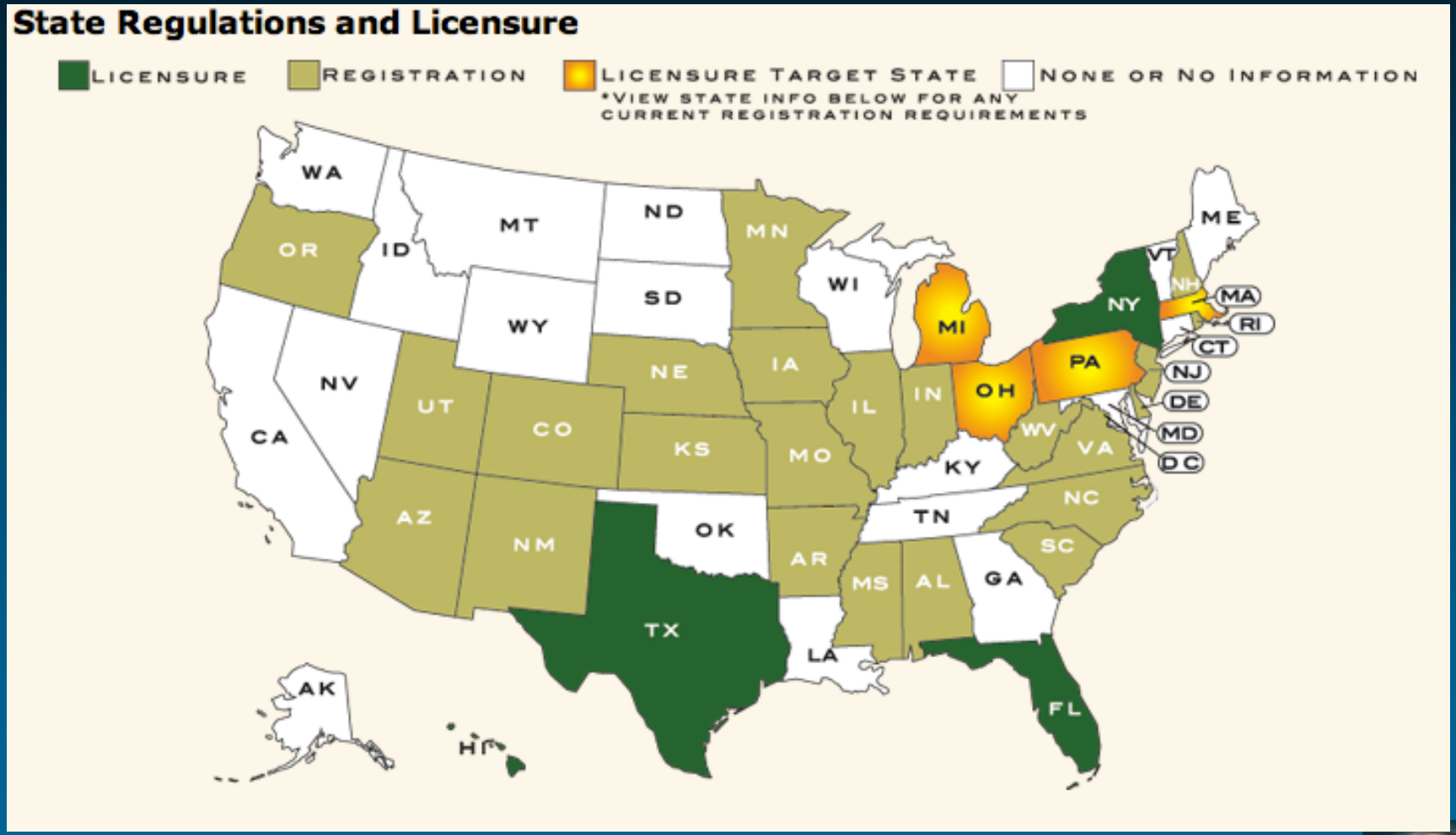
- Grassroots advocacy means promoting the profession's interests and issues by communicating with elected officials or regulators in an effective and efficient manner.

Developing Regulations

Rule Language

Implementation and Interpretation

State Regulations



- **Link: http://www.aapm.org/government_affairs/licensure/default.asp**

Texas Link

TEXAS	
Licensure Categories:	Diagnostic Radiological Physicist, Therapeutic Radiological Physicist, Medical Nuclear Radiological Physicist, Medical Health Radiological Physicist
Fee Schedule:	Examination Fees - $1200 First Specialty, $600 Additional Specialty License Fees - $140 Initial Specialty, $50 Additional Specialty Renewal Fees - $125/One Year First Specialty, $250/Two year First Specialty
Term Valid:	Two Year
Board Certification Required:	No
State Radiation Information Page:	**view State Radiation Information Page**
Documentation & Forms:	**view Documentation & Forms website**
Contact(s):	Richard A. Ratliff, P.E., L.M.P., Chief Bureau of Radiation Control Department of State Health Services Division for Regulatory Services P.O. Box 149347-Mail Code 2835 Austin, TX 78714-9347 Phone: 512/834-6679 Fax: 512/834-6708 Email: richard.ratliff@dshs.state.tx.us

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www.imagegently.org

Founding Partners

- The Society for Pediatric Radiology
- American Association of Physicists in Medicine
- American College of Radiology
- American Society of Radiologic Technologists

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The Alliance for Radiation Safety in Pediatric Imaging

Tests/Procedures | What Can I Do? | Resources | FAQ | International Resources

Let's *image gently* when we care for kids! The *image gently* Campaign is an initiative of the Alliance for Radiation Safety in Pediatric Imaging. The campaign goal is to change practice by increasing awareness of the opportunities to lower radiation dose in the imaging of children.

IMAGE GENTLY AND CT SCANS

One size does not fit all...

There's no question: CT helps us save kids' lives.

But, when we image, radiation matters!

- Children are more sensitive to radiation.
- What we do now lasts their lifetimes.

So, when we image, let's image gently: More is often not better.

When CT is the right thing to do:

- Child size the kVp and mA
- One scan (single phase) is often enough
- Scan only the indicated area

Resources | Parents | Protocols

CT - RESOURCES

- **Online Education Modules for Technologists**
  - **Module 1:** Enhancing Radiation Protection in Computed Tomography for Children
  - **Module 2:** Enhancing Radiation Protection in Computed Tomography for Children
  - **Module 3:** Enhancing Radiation Protection in Computed Tomography for Children
- **For Radiologists:** ***Image Gently*** **Web-based** Practice Quality Improvement Program
- Alternatives to CT
- ASRT White Paper - Computed Tomography in the 21st century: Changing Practice for Medical Imaging and Radiation Therapy Professionals
- RadiologyQuality.com - This site provides ABR-certified practice quality improvement projects to fulfill Maintenance of Certification Part IV requirements.
- From the Pediatric Emergency Physician community: ALARA: is there a cause for alarm? Reducing radiation risks from computed tomography scanning in children - *Current Opinion in Pediatrics*, July 2008
- FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients - November 2, 2001
- Education
- "Medical Radiation in Children" Powerpoint Presentation
- Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers - from NCI and SPR

Publications

- Peer-reviewed
- Trade Press
- Reports
  - AAPM - The Measurement, Reporting, and Management of Radiation Dose in CT - January 2008
- Popular Press

External Links

What Parents Should Know

about Medical Radiation Safety

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What Parents Should Know About CT Scans for Children:

Medical Radiation Safety

What is an X-ray?

X-rays are invisible beams of ionizing radiation that pass through the body and are altered by different tissues to create 2-dimensional images of many organs.

What is a CT scan?

CT scans use x-rays generated from a source that is rotated around the body to create 3-dimensional pictures of the body. CT studies can provide critical information for the care of your child, but obtaining the images results in more radiation exposure for the study than a single X-ray.

How much radiation is used in these exams?

We all are exposed to small amounts of radiation daily from soil, rocks, building materials, air, water, and cosmic radiation. This is called naturally occurring background radiation. The radiation used in X-rays and CT scans has been compared to background radiation we are exposed to daily. This comparison may be helpful in understanding relative radiation doses to the patient.

Radiation source	Days background radiation
Background	1 day
Chest X-ray (single)	1 day
Head CT	up to 8 months
Abdominal CT	up to 20 months

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Not Just CT!

- **Step Lightly** - Interventional Radiology

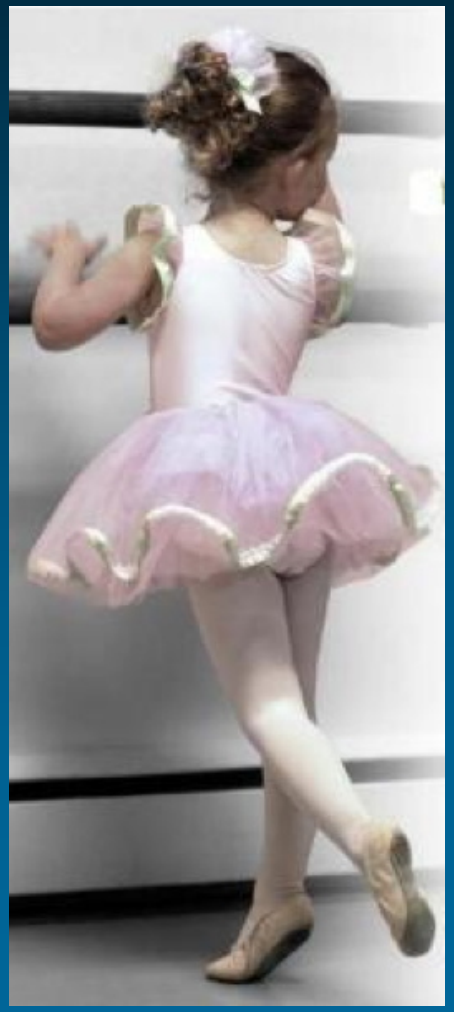

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Image gently...

Step Lightly

Interventional radiology helps us save kids' lives!

But, when we treat patients, radiation matters!

Children are more sensitive to radiation.

What we do now lasts their lifetimes

Treat kids with care:

Step lightly on the fluoroscopy pedal.

Stop and child-size the technique.

Consider ultrasound or, when applicable, MRI guidance.

What is IR? | Parents | Resources | Protocols

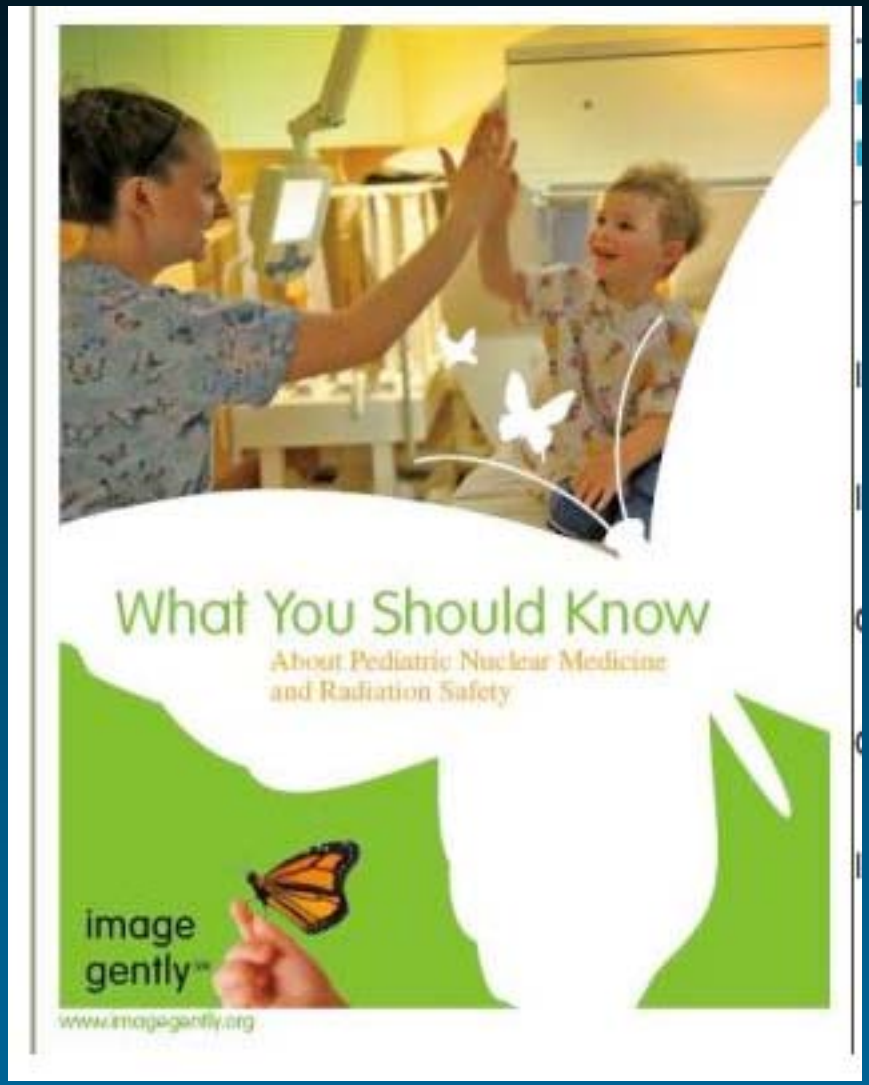

Image Gently and Nuclear Medicine

One size does not fit all...

There's no question: Nuclear Medicine helps us save kids' lives. But, when we image, radiation matters!

Children are more sensitive to radiation. What we do now lasts their lifetimes. So, when we image, let's image gently: More is often not better.

Image Gently is a valuable tool for all to use

One Definition of Quality Care

Care that is safe, timely, patient- centered, efficient and equitable

- **IOM 2001**

Another Definition of Quality

Doing the right thing, at the right time, in the right way, for the right person – and having the best possible results

- **AHRQ 2001**

FDA Initiative: Reducing Unnecessary Medical Imaging Exposure

- Each patient should get the right exam, at the right time, with the right dose
  - Exam justification
  - Ensure that only medically necessary examinations are performed
  - Dose optimization
    - Minimize the individual's exposure to radiation for each exam while maintaining image quality

Ref: CDR Sean M. Boyd, MPH, USPHSU.S. Food and Drug Administration Center for Devices and Radiological Health

Summary

- Everyone is becoming more concerned about patient dose and safety
  - Patients
  - Parents
  - Health Care Professionals
  - Regulators
  - Industry
- Several high profile mistakes have raised the stakes

The Path Forward

- Congress is drafting a bill to include an event reporting database
- The Foundation for the National Institutes of Health in conjunction with the FDA are holding a by invite roundtable to discuss event reporting
- The Alliance is pushing for the passage of the CARE Act – H.R. 3652 and S. 3737

The Path Forward

- AAPM is working with Conference of Radiation Control Program Directors to establish a National Registry of Qualified Medical Physicists (QMP) and to require that any practicing medical physics meet the definition of a QMP

- Efforts are underway to make accreditation of all imaging and therapy facilities mandatory

- The bottom line:

  We all must act to reduce patient dose and improve patient care when and where we can!

Acknowledgements

- Mary Fox
- Douglas Pfeiffer
- Per Halvorsen
- Debbie Gilley

- Questions?????????