Safety and Quality Assurance Aspects in Stereotactic Radiosurgery & Stereotactic Body Radiation Therapy

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Therapy Symposium - Safety and QA for SRS/SBRT

2011 JOINT AAPM/COMP MEETING · JULY 31 - AUGUST 4 · VANCOUVER

UT SOUTHWESTERN MEDICAL CENTER

RTOG 0236

Stereotactic Body Radiation Therapy for Inoperable Early Stage Lung Cancer

Robert Timmerman, MD
Rebecca Paulus, BS
James Galvin, PhD
Jeffrey Michalski, MD
William Straube, PhD
Jeffrey Bradley, MD
Achilles Fakiris, MD
Andrea Bezjak, MD
Gregory Videtic, MD
David Johnstone, MD
Jack Fowler, PhD
Elizabeth Gore, MD
Hak Choy, MD

Context Patients with early stage but medically inoperable lung cancer have a poor rate of primary tumor control (30%-40%) and a high rate of mortality (3-year survival, 20%-35%) with current management.

Objective To evaluate the toxicity and efficacy of stereotactic body radiation therapy in a high-risk population of patients with early stage but medically inoperable lung cancer.

Design, Setting, and Patients Phase 2 North American multicenter study of patients aged 18 years or older with biopsy-proven peripheral T1-T2N0M0 non–small cell tumors (measuring <5 cm in diameter) and medical conditions precluding surgical treatment. The prescription dose was 18 Gy per fraction × 3 fractions (54 Gy total) with entire treatment lasting between 1½ and 2 weeks. The study opened May 26, 2004, and closed October 13, 2006; data were analyzed through August 31, 2009.

Main Outcome Measures The primary end point was 2-year actuarial primary tumor control; secondary end points were disease-free survival (ie, primary tumor, involved lobe, regional, and disseminated recurrence), treatment-related toxicity, and overall survival.

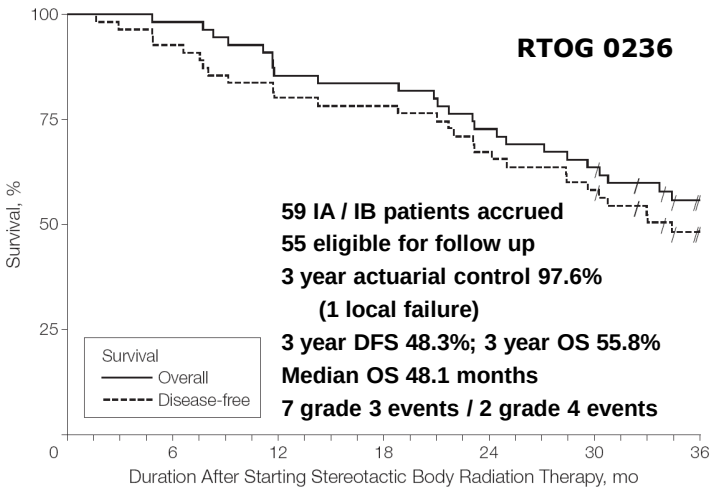
Results A total of 59 patients accrued, of which 55 were evaluable (44 patients with T1 tumors and 11 patients with T2 tumors) with a median follow-up of 34.4 months (range, 4.8-49.9 months). Only 1 patient had a primary tumor failure; the estimated 3-year primary tumor control rate was 97.6% (95% confidence interval [CI], 84.3%-99.7%). Three patients had recurrence within the involved lobe; the 3-year primary tumor and involved lobe (local) control rate was 90.6% (95% CI, 76.0%-96.5%). Two patients experienced regional failure; the local-regional control rate was 87.2% (95% CI, 71.0%-94.7%). Eleven patients experienced disseminated recurrence; the 3-year rate of disseminated failure was 22.1% (95% CI, 12.3%-37.8%). The rates for disease-free survival and overall survival at 3 years were 48.3% (95% CI, 34.4%-60.8%) and 55.8% (95% CI, 41.6%-67.9%), respectively. The median overall survival was 48.1 months (95% CI, 29.6 months to not reached). Protocol-specified treatment-related grade 3 adverse events were reported in 7 patients (12.7%; 95% CI, 9.6%-15.8%); grade 4 adverse events were reported in 2 patients (3.6%; 95% CI, 2.7%-4.5%). No grade 5 adverse events were reported.

Conclusion Patients with inoperable non–small cell lung cancer who received stereotactic body radiation therapy had a survival rate of 55.8% at 3 years, high rates of local tumor control, and moderate treatment-related morbidity.

WHILE ANATOMICAL RESECTION is the standard treatment for early stage lung cancer, some patients cannot tolerate surgery due to comorbidities such as emphysema and heart disease. These patients are deemed medically inoperable and are generally offered conventional radiotherapy (most commonly given during 20-30 outpatient treatments) or observed without specific cancer therapy. Outcomes are not ideal with either approach. Conventional radiotherapy fails to durably control the primary lung tumor in 60% to 70% of patients.[1-3] More than half of patients

JAMA. 2010;303(11):1070-1076 www.jama.com

Timmerman et al, JAMA, 2010



Timmerman et al, JAMA, 2010

ARTICLE IN PRESS
Int. J. Radiation Oncology Biol. Phys., Vol. ■, No. ■, pp. 1–7, 2010

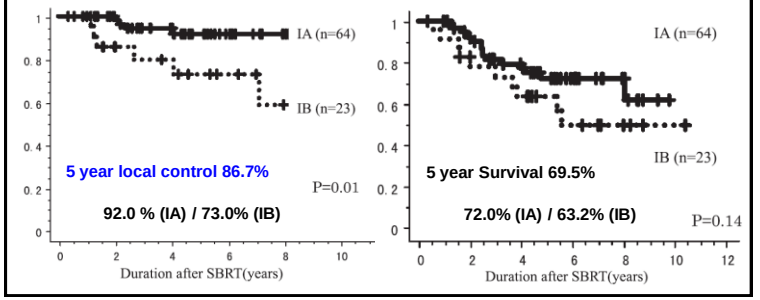
0360-3016/$–see front matter

ELSEVIER

CLINICAL INVESTIGATION

STEREOTACTIC BODY RADIOTHERAPY (SBRT) FOR OPERABLE STAGE I NON–SMALL-CELL LUNG CANCER: CAN SBRT BE COMPARABLE TO SURGERY?

HIROSHI ONISHI, M.D.,* HIROKI SHIRATO, M.D.,† YASUSHI NAGATA, M.D.,‡ MASAHIRO HIRAOKA, M.D.,§ MASAHARU FUJINO, M.D.,†* KOTARO GOMI, M.D.,§ KATSUYUKI KARASAWA, M.D.,¶ KAZUSHIGE HAYAKAWA, M.D.,# YUZURU NIIBE, M.D.,# YOSHIHIRO TAKAI, M.D.,** TOMOKI KIMURA, M.D.,†† ATSUYA TAKEDA, M.D.,‡‡ ATSUSHI OUCHI, M.D.,§§ MASATO HAREYAMA, M.D.,|| MASAKI KOKUBO, M.D.,¶¶ TAKUYO KOZUKA, M.D.,## TAKURO ARIMOTO, M.D.,*** RYUSUKE HARA, M.D.,††† JUN ITAMI, M.D.,‡‡‡ AND TSUTOMU ARAKI, M.D.*



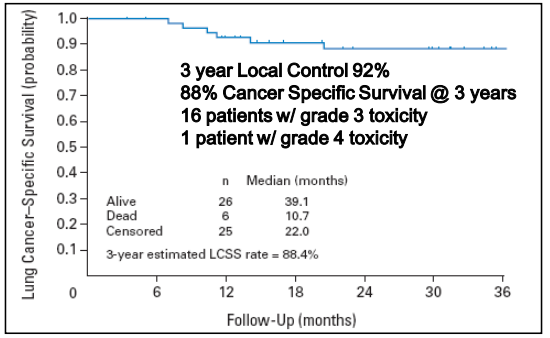
VOLUME 27 · NUMBER 10 · APRIL 1 2009

JOURNAL OF CLINICAL ONCOLOGY | ORIGINAL REPORT

Outcome in a Prospective Phase II Trial of Medically Inoperable Stage I Non–Small-Cell Lung Cancer Patients Treated With Stereotactic Body Radiotherapy

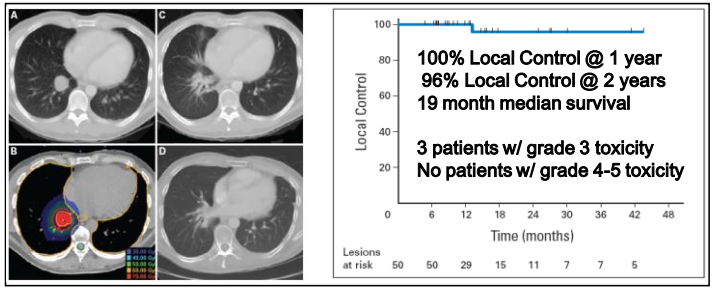
Pia Baumann, Jan Nyman, Morten Hoyer, Berit Wennberg, Giovanna Gagliardi, Ingmar Lax, Ninni Drugge, Lars Ekberg, Signe Friesland, Karl-Axel Johansson, Jo-Åsmund Lund, Elisabeth Morhed, Kristina Nilsson, Nina Levin, Merete Paludan, Christer Sederholm, Anders Traberg, Lena Wittgren, and Rolf Lewensohn

57 NSCLC patients 45 Gy in 3 fractions



38 patients with 63 lesions
48 – 60 Gy in 3 fractions

SBRT for Lung Mets

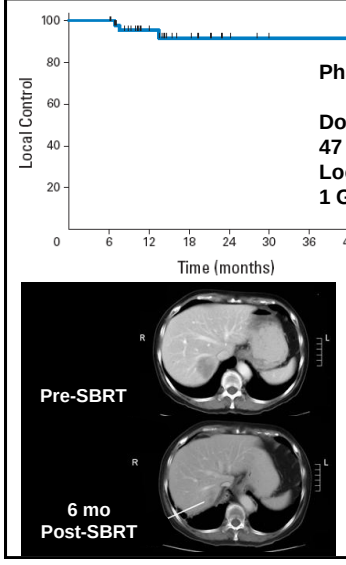


VOLUME 27 · NUMBER 10 · APRIL 1 2009

JOURNAL OF CLINICAL ONCOLOGY | ORIGINAL REPORT

Multi-Institutional Phase I/II Trial of Stereotactic Body Radiation Therapy for Lung Metastases

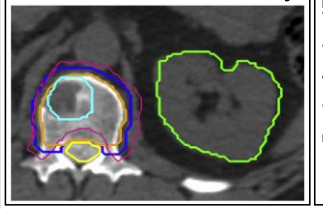
Kyle E. Rusthoven, Brian D. Kavanagh, Stuart H. Burri, Changhu Chen, Higinia Cardenes, Mark A. Chidel, Thomas J. Pugh, Madeleine Kane, Laurie E. Gaspar, and Tracey E. Schefter

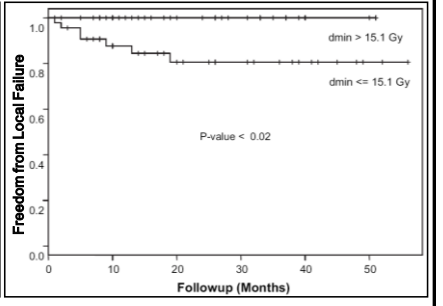


Rustoven et al, JCO, 2009

Dose Response to Spine SRS

91 lesions in 79 patients
Prescribed 18-24 Gy
Cord constrained to14 Gy





Int. J. Radiation Oncology Biol. Phys., Vol. 77, No. 4, pp. 1282–1287, 2010

0360-3016/$–see front matter

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CORRELATION OF LOCAL FAILURE WITH MEASURES OF DOSE INSUFFICIENCY IN THE HIGH-DOSE SINGLE-FRACTION TREATMENT OF BONY METASTASES

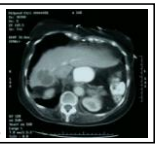
D. MICHAEL LOVELOCK, PH.D.,* ZHIGANG ZHANG, PH.D.,† ANDREW JACKSON, PH.D.,* JENNIFER KEAM, M.D.,‡ JUSTIN BEKELMAN, M.D.,§ MARK BILSKY, M.D.,‖ ERIC LIS, M.D.,¶ AND YOSHIYA YAMADA, M.D.†

But with any aggressive approach, there may be complications

Three treatment-related deaths following SBRT for primary liver cancer

3 x 15 Gy for 57 cc tumor
3 x 10 Gy for 293 cc tumor
1 x 30 Gy for a "large" tumor

Blomgren et al, Acta Oncol. 34:861-70, 1995



VOLUME 24 · NUMBER 30 · OCTOBER 20 2006

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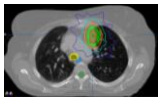

Excessive Toxicity When Treating Central Tumors in a Phase II Study of Stereotactic Body Radiation Therapy for Medically Inoperable Early-Stage Lung Cancer

Robert Timmerman, Ronald McGarry, Constantin Yiannoutsos, Lech Papiez, Kathy Tudor, Jill DeLuca, Marvene Ewing, Ramzi Abdulrahman, Colleen DesRosiers, Mark Williams, and James Fletcher

Int. J. Radiation Oncology Biol. Phys., Vol. 77, No. 2, pp. 548–553, 2010
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0360-3016/$–see front matter

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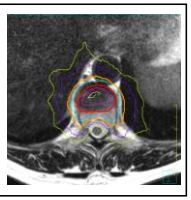
CLINICAL INVESTIGATION — **Spinal Cord**

SPINAL CORD TOLERANCE FOR STEREOTACTIC BODY RADIOTHERAPY

Arjun Sahgal, M.D.,* Ljiun Ma, Ph.D.,† Iris Gibbs, M.D.,† Peter C. Gerszten, M.D.,‡,§ Sam Ryu, M.D.,‖ Scott Soltys, M.D.,† Vivian Weinberg, Ph.D.,¶ Shun Wong, M.D.,‖ Eric Chang, M.D.,†† Jack Fowler, D.Sc., Ph.D.,‡‡ and David A. Larson, M.D., Ph.D.†

We report 5 cases of radiation-induced myelopathy (RM) that occurred following spine SBRT



And there is a significant burden on practitioners to minimize errors

Ours is not the only field to have had highly public errors

In 1997, between 44,000 and 98,000 patients died as a result of medical errors
- To Err is Human: Building a Safer Health System, Institute of Medicine

Los Angeles Times | ARTICLE COLLECTIONS

← Back to Original Article

Wrong patient got kidney at

University Hospital shut down its kidney transplant program last month after realizing the error. The hospital said transplants may resume as early as Friday.

February 18, 2011 | By Alan Zarembo and Lisa Girion, Los Angeles Times

University Hospital halted kidney transplants last month after a kidney was accidentally transplanted into the wrong patient, according to a spokesman for the program that coordinates organ transplants in Los Angeles.

The patient who received the wrong kidney escaped harm, apparently because the kidney happened to be an acceptable match, said Bryan Stewart, spokesman for the program, OneLegacy, which was notified of the error by the hospital.

The hospital, which performs about two transplants a week, confirmed in a statement that it had voluntarily halted transplants Jan. 29 after a "process error" was discovered. The hospital did not detail the nature of the error and declined to answer questions. It said no patients were harmed.

Most recent analyses suggest the situation has not improved significantly

The Washington Post
NATIONAL

The Pain of Wrong Site Surgery

By Sandra G. Boodman, Published: June 20

When the president of the Joint Commission, the Chicago-based group that accredits the nation's hospitals, unveiled mandatory rules to prevent operations on the wrong patient or body part, he did not mince words.

"This is not quite 'Dick and Jane,' but it's pretty close," surgeon Dennis O'Leary declared in a 2004 interview about the "universal protocol" to prevent wrong-site surgery. These rules require preoperative verification of important details, marking of the surgical site and a timeout to confirm everything just before the procedure starts.

38 Comments Weigh In | Corrections?

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(Richard Price/GETTY IMAGES) - Surgeon holding scalpel, close-up, low angle view (gel effect)

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Mistakes such as amputating the wrong leg, performing the wrong operation or removing a kidney from the wrong patient can often be prevented by what O'Leary called "very simple stuff": ensuring that an X-ray isn't flipped and that the right patient is on the table, for example. Such errors are considered so egregious and avoidable that they are classified as "never events" because they should never happen.

But seven years later, some researchers and patient safety experts say the problem of wrong-site surgery has not improved and may be getting worse, although spotty reporting makes conclusions difficult. Based on state data, Joint Commission officials estimate that wrong-site surgery occurs 40 times a week in U.S. hospitals and clinics. Last year 93 cases were reported to the accrediting organization, compared with 49 in 2004. Reporting to the commission is voluntary and confidential – to encourage doctors and hospitals to come forward and to make improvements, officials say. About half the states, including Virginia, do not require reporting. In two states that track and intensively study these errors, 48 cases were reported in Minnesota last year, up from 44 in 2009; Pennsylvania has averaged about 64 cases for the past few years.

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Medical Mistake: Surgeon Operates on the Wrong Eye of a 4-Year-Old Boy

Surgeon Operates on Boy's Wrong Eye

WORLD NEWS

By MICHAEL MURRAY
April 19, 2011

Jesse Matlock went to a doctor today to find out if he suffered any permanent damage when a surgeon performed corrective surgery on the wrong eye and then, without consulting the boy's parents, quickly operated on the correct eye.

"Right now we're in the dark about what this will be like in the future," Tasha Gaul, mother of 4-year-old Jesse, told ABC news. The doctor they saw today told her they will have to wait 5 weeks for his eyes to completely heal before they can determine if there has been any permanent damage.

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Though radiation errors are extremely rare, they are drawing increasing attention…..

health DEVICES

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2011

Reprinted from Volume 39 Issue 11
November 2010

ECRI Institute
The Discipline of Science. The Integrity of Independence.

1. Radiation Overdose and Other Dose Errors during Radiation Therapy
2. Alarm Hazards
3. Cross-Contamination from Flexible Endoscopes
4. The High Radiation Dose of CT Scans
5. Data Loss, System Incompatibilities, and Other Health IT Complications
6. Luer Misconnections
7. Oversedation during Use of PCA Infusion Pumps
8. Needlesticks and Other Sharps Injuries
9. Surgical Fires
10. Defibrillator Failures in Emergency Resuscitation Attempts

…. and much more can and must be done to prevent radiation errors

For many of us, the awareness began with this series of articles

The New York Times — Health

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Enlarge This Image

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember

Well
Tara Parker-Pope on Health

When Radiation Treatment Turns Deadly
January 23, 2010

The New York Times — U.S.

Fatal Radiation

But accidents and the publicity surrounding them are nothing new

A Special Reprint

THE PLAIN DEALER

OHIO'S LARGEST NEWSPAPER

FIRST OF A SERIES **LETHAL DOSES** RADIATION THAT KILLS

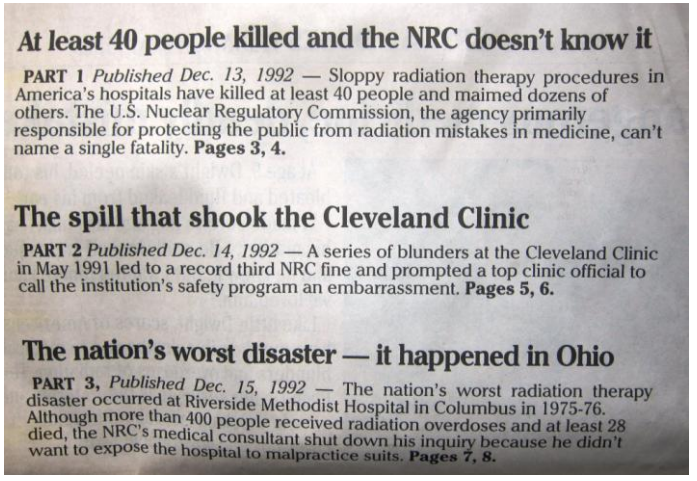
Dangerous medicine, deadly mistakes

At age 9, Dwight's skin peeled, his tongue bloated and fluid leaked from his ear.

"I made sure to hug and kiss him," says his mother. "He really looked grotesque and he knew it, but I wanted him to know we loved him."

Like little Dwight, scores of Americans have met horrible deaths due to medical blunders and overdoses of radiation. This Plain Dealer series tells their stories and unveils shocking facts about hospital cover-ups and government laxity.

Courtesy Yakov Pipman



At least 40 people killed and the NRC doesn't know it

PART 1 *Published Dec. 13, 1992* — Sloppy radiation therapy procedures in America's hospitals have killed at least 40 people and maimed dozens of others. The U.S. Nuclear Regulatory Commission, the agency primarily responsible for protecting the public from radiation mistakes in medicine, can't name a single fatality. **Pages 3, 4.**

The spill that shook the Cleveland Clinic

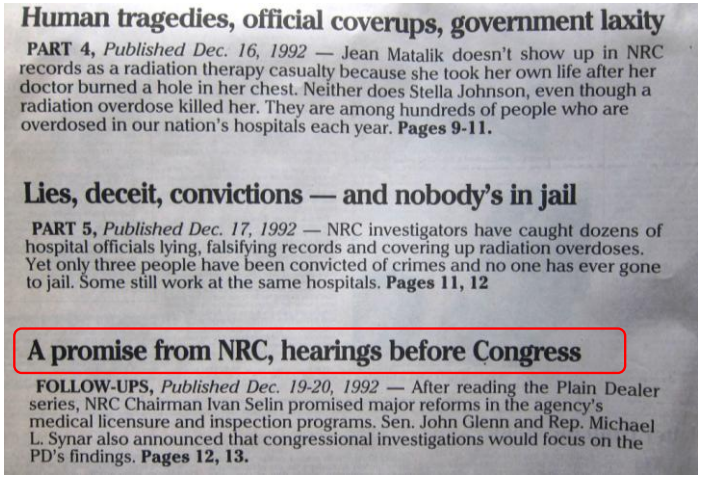
PART 2 *Published Dec. 14, 1992* — A series of blunders at the Cleveland Clinic in May 1991 led to a record third NRC fine and prompted a top clinic official to call the institution's safety program an embarrassment. **Pages 5, 6.**

The nation's worst disaster — it happened in Ohio

PART 3, *Published Dec. 15, 1992* — The nation's worst radiation therapy disaster occurred at Riverside Methodist Hospital in Columbus in 1975-76. Although more than 400 people received radiation overdoses and at least 28 died, the NRC's medical consultant shut down his inquiry because he didn't want to expose the hospital to malpractice suits. **Pages 7, 8.**

Courtesy Yakov Pipman

and the reaction should be predictable ……



Human tragedies, official coverups, government laxity

PART 4, *Published Dec. 16, 1992* — Jean Matalik doesn't show up in NRC records as a radiation therapy casualty because she took her own life after her doctor burned a hole in her chest. Neither does Stella Johnson, even though a radiation overdose killed her. They are among hundreds of people who are overdosed in our nation's hospitals each year. **Pages 9-11.**

Lies, deceit, convictions — and nobody's in jail

PART 5, *Published Dec. 17, 1992* — NRC investigators have caught dozens of hospital officials lying, falsifying records and covering up radiation overdoses. Yet only three people have been convicted of crimes and no one has ever gone to jail. Some still work at the same hospitals. **Pages 11, 12**

A promise from NRC, hearings before Congress

FOLLOW-UPS, *Published Dec. 19-20, 1992* — After reading the Plain Dealer series, NRC Chairman Ivan Selin promised major reforms in the agency's medical licensure and inspection programs. Sen. John Glenn and Rep. Michael L. Synar also announced that congressional investigations would focus on the PD's findings. **Pages 12, 13.**

Courtesy Yakov Pipman

RADIATION IN MEDICINE

A NEED FOR REGULATORY REFORM

Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission

Kate-Louise D. Gottfried and Gary Penn, Editors

Division of Health Care Services
INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1996

Several responses to congressional hearings

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INDUSTRY NEWS MARCH 1, 2010

Congressional hearing: More oversight needed for medical radiation procedures

During testimony before a committee of the House of Representatives Friday, stakeholders from the medical imaging and radiation oncology communities extolled the life-saving virtues and safety of medical imaging procedures, but also agreed that more needs to be done to regulate the profession and protect patient safety.

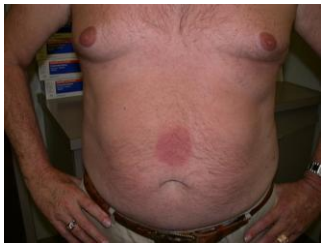
"Image-guided medical procedures have replaced more invasive surgical options for many patients, while improving outcomes and reducing hospitalization and recovery times," E. Stephen Amis, Jr., MD, told the House Energy and Commerce Health Subcommittee. "Furthermore, clinical trials and experience have demonstrated the benefits of radiation therapy in curing cancer, extending life, and alleviating pain and suffering for over one million patients each year."

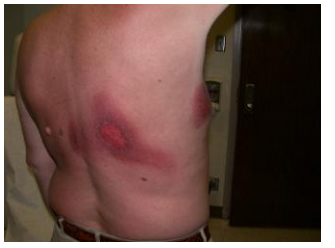
Amis, former chair of the Board of Chancellors of the American College of Radiology (ACR), also told the subcommittee that a recent series of articles in the New York Times laying out several tragic cases of medical imaging radiation errors, was a reminder that the use of medical radiation has risks as well.

"As a profession, we can and must do a better job of preventing such errors – not only to ensure all patients get the best quality of care we can provide, but also to maintain the confidence of the public who rely on our care," Amis said.

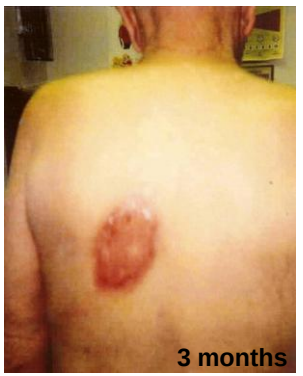
Contents

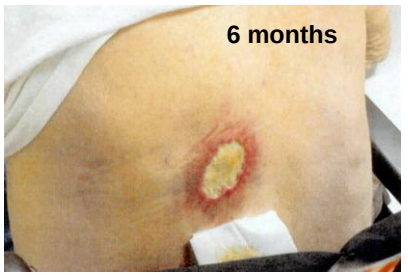
Errors in SRS / SBRT

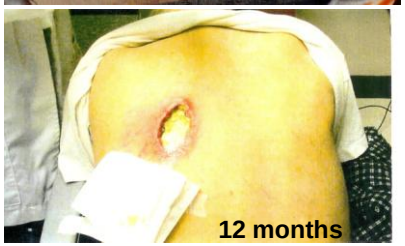




Errors in SRS / SBRT







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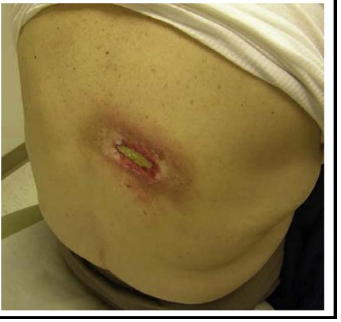
0360-3016/08/$–see front matter

doi:10.1016/j.ijrobp.2008.08.036

RAPID COMMUNICATION

ACUTE SKIN TOXICITY FOLLOWING STEREOTACTIC BODY RADIATION THERAPY FOR STAGE I NON–SMALL-CELL LUNG CANCER: WHO'S AT RISK?

Bradford S. Hoppe, M.D.,* Benjamin Laser, M.D.,* Alex V. Kowalski, B.A.,†
Sandra C. Fontenla, B.A.,† Elizabeth Pena-Greenberg, R.N.,* Ellen D. Yorke, Ph.D.,†
D. Michael Lovelock, Ph.D.,† Margie A. Hunt, M.S.,† and Kenneth E. Rosenzweig, M.D.*



Who caught it, and what could have been done to prevent it?

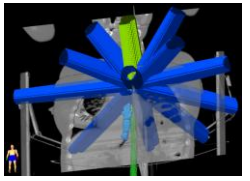
Patients "caught" it

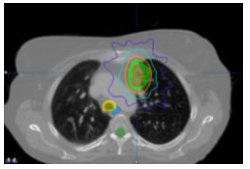
Better training on SRS principles –
Many beams from many directions!

Carefully evaluate plans

Develop dose constraints – understand normal tissue tolerance

Follow nationally accepted guidelines
e.g., RTOG compactness criteria (PTV + 2 cm)





Systematic Use of Dose Constraints

Serial Tissue	Volume (mL)	Volume Max (Gy)	Max Point Dose (Gy)	Endpoint (≥Grade 3)
SINGLE-FRACTION TREATMENT				
Optic pathway	<0.2	8	10	Neuritis
Cochlea			12	Hearing loss
Brainstem	<1	10	15	Cranial neuropathy
Spinal cord	<0.25	10	14	Myelitis
	<1.2	7		
Cauda equina	<5	14	16	Neuritis
Sacral plexus	<3	14.4	16	Neuropathy
Esophagus*	<5	14.5	19	Stenosis/fistula
Ipsilateral brachial plexus	<3	14.4	16	Neuropathy
Heart/pericardium	<15	16	22	Pericarditis
Great vessels	<10	31	37	Aneurysm
Trachea and ipsilateral bronchus*	<4	8.8	22	Stenosis/fistula
Skin	<10	14.4	16	Ulceration
Stomach	<10	13	16	Ulceration/fistula
Duodenum*	<5	8.8	16	Ulceration
Jejunum/ileum*	<5	9.8	19	Enteritis/obstruction
Colon*	<20	11	22	Colitis/fistula
Rectum*	<20	11	22	Proctitis/fistula
Bladder wall	<15	8.7	22	Cystitis/fistula
Penile bulb	<3	14	34	Impotence
Femoral heads (right and left)	<10	14		Necrosis
Renal hilum/vascular trunk	<2/3 volume	10.6		Malignant hypertension
Parallel Tissue	**Critical Volume (mL)**	**Critical Volume Dose Max (Gy)**		**Endpoint (≥Grade 3)**
Lung (right and left)	1,500	7		Basic lung function
Lung (right and left)	1,000	7.4		Pneumonitis
Liver	700	9.1		Basic liver function
Renal cortex (right and left)	200	8.4		Basic renal function

Timmerman et al, Sem Rad Onc, 2008

Systematic Use of Dose Constraints

Serial Tissue	Volume (mL)	Volume Max (Gy)	Max Point Dose (Gy)	Endpoint (≥Grade 3)
THREE-FRACTION TREATMENT				
Optic pathway	<0.2	15 (5 Gy/fx)	19.5 (6.5 Gy/fx)	Neuritis
Cochlea			20 (6.67 Gy/fx)	Hearing loss
Brainstem	<1	18 (6 Gy/fx)	23 (7.67 Gy/fx)	Cranial neuropathy
Spinal cord	<0.25	18 (6 Gy/fx)	22 (7.33 Gy/fx)	Myelitis
	<1.2	11.1 (3.7 Gy/fx)		
Cauda equina	<5	21.9 (7.3 Gy/fx)	24 (8 Gy/fx)	Neuritis
Sacral plexus	<3	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	Neuropathy
Esophagus*	<5	21 (7 Gy/fx)	27 (9 Gy/fx)	Stenosis/fistula
Ipsilateral brachial plexus	<3	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	Neuropathy
Heart/pericardium	<15	24 (8 Gy/fx)	30 (10 Gy/fx)	Pericarditis
Great vessels	<10	39 (13 Gy/fx)	45 (15 Gy/fx)	Aneurysm
Trachea and ipsilateral bronchus*	<4	15 (5 Gy/fx)	30 (10 Gy/fx)	Stenosis/fistula
Skin	<10	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	Ulceration
Stomach	<10	21 (7 Gy/fx)	24 (8 Gy/fx)	Ulceration/fistula
Duodenum*	<5	15 (5 Gy/fx)	24 (8 Gy/fx)	Ulceration
Jejunum/ileum*	<5	16.2 (5.4 Gy/fx)	27 (9 Gy/fx)	Enteritis/obstruction
Colon*	<20	20.4 (6.8 Gy/fx)	30 (10 Gy/fx)	Colitis/fistula
Rectum*	<20	20.4 (6.8 Gy/fx)	30 (10 Gy/fx)	Proctitis/fistula
Bladder wall	<15	15 (5 Gy/fx)	30 (10 Gy/fx)	Cystitis/fistula
Penile bulb	<3	21.9 (7.3 Gy/fx)	42 (14 Gy/fx)	Impotence
Femoral heads (right and left)	<10	21.9 (7.3 Gy/fx)		Necrosis
Renal hilum/vascular trunk	<2/3 volume	18.6 (6.2 Gy/fx)		Malignant hypertension
Parallel Tissue	**Critical Volume (mL)**	**Critical Volume Dose Max (Gy)**		**Endpoint (≥Grade 3)**
Lung (right and left)	1,500	10.5 (3.5 Gy/fx)		Basic lung function
Lung (right and left)	1,000	11.4 (3.8 Gy/fx)		Pneumonitis
Liver	700	17.1 (5.7 Gy/fx)		Basic liver function
Renal cortex (right and left)	200	14.4 (4.8 Gy/fx)		Basic renal function

Timmerman et al, Sem Rad Onc, 2008

Systematic Use of Dose Constraints

Serial Tissue	Volume (mL)	Volume Max (Gy)	Max Point Dose (Gy)	Endpoint (≥Grade 3)
FIVE-FRACTION TREATMENT				
Optic pathway	<0.2	20 (4 Gy/fx)	25 (5 Gy/fx)	Neuritis
Cochlea			27.5 (5.5 Gy/fx)	Hearing loss
Brainstem	<1	26 (5.2 Gy/fx)	31 (6.2 Gy/fx)	Cranial neuropathy
Spinal cord	<0.25	22.5 (4.5 Gy/fx)	30 (6 Gy/fx)	Myelitis
	<1.2	13.5 (2.7 Gy/fx)		
Cauda equina	<5	30 (6 Gy/fx)	34 (6.4 Gy/fx)	Neuritis
Sacral plexus	<3	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuropathy
Esophagus*	<5	27.5 (5.5 Gy/fx)	35 (7 Gy/fx)	Stenosis/fistula
Ipsilateral brachial plexus	<3	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuropathy
Heart/pericardium	<15	32 (6.4 Gy/fx)	38 (7.6 Gy/fx)	Pericarditis
Great vessels	<10	47 (9.4 Gy/fx)	53 (10.6 Gy/fx)	Aneurysm
Trachea and ipsilateral bronchus*	<4	18 (3.6 Gy/fx)	38 (7.6 Gy/fx)	Stenosis/fistula
Skin	<10	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Ulceration
Stomach	<10	28 (5.6 Gy/fx)	32 (6.4 Gy/fx)	Ulceration/fistula
Duodenum*	<5	18 (3.6 Gy/fx)	32 (6.4 Gy/fx)	Ulceration
Jejunum/ileum*	<5	19.5 (3.9 Gy/fx)	35 (7 Gy/fx)	enteritis/obstruction
Colon*	<20	25 (5 Gy/fx)	38 (7.6 Gy/fx)	colitis/fistula
Rectum*	<20	25 (5 Gy/fx)	38 (7.6 Gy/fx)	proctitis/fistula
Bladder wall	<15	18.3 (3.65 Gy/fx)	38 (7.6 Gy/fx)	cystitis/fistula
Penile bulb	<3	30 (6 Gy/fx)	50 (10 Gy/fx)	Impotence
Femoral heads (right and left)	<10	30 (6 Gy/fx)		Necrosis
Renal hilum/vascular trunk	<2/3 volume	23 (4.6 Gy/fx)		Malignant hypertension
Parallel Tissue	**Critical Volume (mL)**	**Critical Volume Dose Max (Gy)**		**Endpoint (≥Grade 3)**
Lung (right and left)	1,500	12.5 (2.5 Gy/fx)		Basic lung function
Lung (right and left)	1000	13.5 (2.7 Gy/fx)		Pneumonitis
Liver	700	21 (4.2 Gy/fx)		Basic liver function
Renal cortex (right and left)	200	17.5 (3.5 Gy/fx)		Basic renal function

*Avoid circumferential irradiation.

Timmerman et al, Sem Rad Onc, 2008

St Petersburg Times Tampa Bay

Patients exposed to high radiation levels

A machine's programming error caused the problem at Tampa's H. Lee Moffitt Cancer Center & Research Institute for 10 months.

April 1, 2005

Errors in SRS / SBRT

UT SOUTHWESTERN MEDICAL CENTER AT DALLAS
MONCRIEF RADIATION ONCOLOGY CENTER

A TG-51 Photon Calibration

Date: 6-Mar-11

2a Ion Chamber:

Manufacturer & model	PTW 31013
Serial #	1100
$N_{D,w}$[Gy/C]	9.524E+07
Cavity inner radius	0.275 cm

2b Electrometer:

Manufacturer & model	CNMC N502
Serial #	31919A
Scale	1.00E-08
P_{elec}	0.996 Gy/Rdg

3 Measurement conditions:

SSD	100 cm
Field size	10 x 10 cm
MU	100

4 Beam Quality:

a. 6 MV
Measure $PDD(10)_x$ 66.20 %

b. 10 MV
Measure $PDD(10)_{Pb}$ with 1 mm lead foil at distance of 30 ± 1 cm from the water surface. N/A

If Pb distance = 30 cm:
$PDD(10)_x = [0.9116 + 0.00264*PDD(10)_{Pb}]*PDD(10)_{Pb}$ N/A

5 Determination of k_Q:

Chamber model used to get k_Q: PTW 31013

6 MV $PDD(10)_x$ 66.20 %
(Table 1 or figure 4) k_Q 0.992

10 MV $PDD(10)_x$ 73.20 %
(Table 1 or figure 4) k_Q 0.98026

6 Temperature/Pressure Correction:

Temperature	21.2 ° C
Pressure	751.2 mmHg
P_{TP}	1.009

7 & 8 Polarity & P_{ion}

Energy	Polarity	M_1 [C]	M_2 [C]	M_3 [C]	M_{avg} [C]	P_{pol}	P_{ion}
6 MV	+ 300 V	0.693	0.693	0.693	0.693	0.998	1.002
	- 300 V	0.695	0.696	0.696	0.696		
	- 150 V	0.694	0.694	0.694	0.694		
10 MV	+ 300 V	0.766	0.766	0.766	0.766	0.998	1.003
	- 300 V	0.769	0.769	0.769	0.769		
	- 150 V	0.767	0.767	0.767	0.767		

9 Corrected ion chamber reading:

$M=P_{ion}P_{TP}P_{elec}P_{pol}M_{raw}$

6 MV M 6.995E-09 C
10 MV M 7.733E-09 C

10 Dose to water per MU at d_{max}:

$D_w=M k_Q N_{D,w} PDD(10)_x$

6 MV D_w(10 cm) 0.995 cGy
10 MV D_w(10 cm) 1.003 cGy

St Petersburg Times Tampa Bay

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A machine's programming error caused the problem at Tampa's H. Lee Moffitt Cancer Center & Research Institute for 10 months.

What Happened?

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	- 300 V	0.769	0.769	0.769	0.769		
	- 150 V	0.767	0.767	0.767	0.767		

"Basically, they were supposed to have a second physicist independently verify the calibrations of the first physicist," said Bill Passetti, the bureau's chief. "It looks like the second verification wasn't performed, which is a violation of the facility's protocol and procedures."

St Petersburg Times Tampa Bay

Patients exposed to high radiation levels

A machine's programming error caused the problem at Tampa's H. Lee Moffitt Cancer Center & Research Institute for 10 months.

Who caught it, and what could have been done to prevent it?

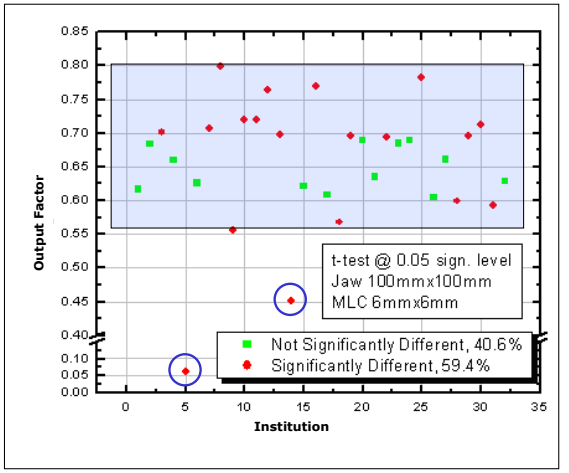
RPC caught it, but not until after 77 patients had been treated

Don't rely on Excel – perform hand calcs

Perform independent checks

Use mailed dosimetry service as part of commissioning, before patients are treated

Accurate measurement of small field output factors has challenged many physicists



wnn world nuclear news

[Dosimetric stereotactic radiosurgical accident: Study of 33 patients treated for brain metastases.]

Neurochirurgie. 56(5):368-73, 2010

Borius PY, Debono B, Latorzeff I, Lotterie JA, Plas JY, Cassol E, Bousquet P, Loubes F, Duthil P, Durand A, Caire F, Redon A, Berry I, Sabatier J, Lazorthes Y.

Front Page
ENERGY & ENVIRONMENT
NEW NUCLEAR
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WASTE & RECYCLING
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The INES rating system
Significant events in history
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This information service is assisted by
WNA WNU

33 patients with 57 brain mets
Mean volume: 3.2 cc [0.04 – 14.07]
Mean prescribed dose: 20 Gy [10 – 23]
Mean delivered dose: 31.5 Gy [13 – 52]
Mean overdose: 61.2% [5.6 – 226.8]
Local control: 80.7%
No morbidity observed

RADIOPROTECTION - VOL. 43 - N° 5 (2008)

The French radiation accident experience: emerging concepts in radiation burn and ARS therapies and in brain radiopathology

P. Gourmelon[a], E. Bey[b], T. De Revel[b], Y. Lazorthes[c], J.A. Lotteries[c] and J.-J. Lataillade[d]

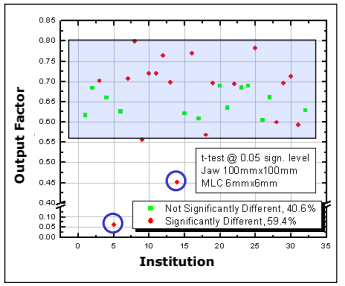
32 unilateral ACN patients
31% 12 month actuarial rate of trigeminal neuropathy

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

S. Derreumaux*, C. Etard, C. Huet, F. Trompier, I. Clairand, J-F. Bottollier-Depois, B. Aubert and P. Gourmelon

Institut de Radioprotection et de Sûreté Nucléaire, Direction de la Radioprotection de l'Homme, IRSN, BP 17. F-92262 Fontenay-aux-Roses Cedex. France

Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135



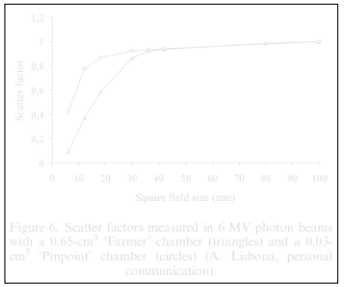


Figure 6. Scatter factors measured in 6 MV photon beams with a 0.65-cm³ 'Farmer' chamber (triangles) and a 0.03-cm³ 'Pinpoint' chamber (circles) (A. Lisbona, personal communication).

wnn world nuclear news NUCLEAR EVENT REPORTS
Front Page Dose deviation during stereotactic radiosurgery treatments
18th June 2007

Who caught it, and what could have been done to prevent it?

Vendor caught it, but not until after 145 patients had been treated

Better training on small field dosimetric methods

Compare beam data with colleagues

Perform comprehensive commissioning including dosimetric verification of TP calculations

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THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO
Published: December 28, 2010

SRS treatment for a benign tumor

Overdoses ranging from 25 to 100%

Patient developed facial spasms, balance and memory problems

The New York Times

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ

Who caught it, and what could have been done to prevent it?

New physicist caught it, after attending vendor training, but not until after 152 patients had been treated

Better training on small field dosimetric methods

Compare beam data with colleagues

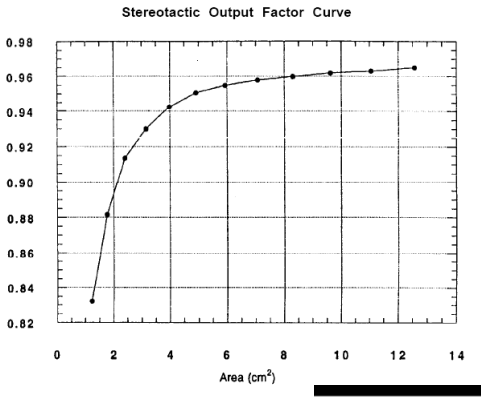
Perform comprehensive commissioning including dosimetric verification of TP calculations

Accurate measurement of small field output factors has challenged many physicists

Unnamed U.S. Institution, July, 2010

Cone size (mm)	Original Output Factor	Re-measured Output Factor
4.0	0.312	0.699
7.5	0.610	0.797
10.0	0.741	0.835
12.5	0.823	0.871
15.0	0.862	0.890
17.5	0.888	0.904
20.0	0.903	0.913
25.0	0.920	0.930
30.0	0.928	0.940

There was ample opportunity to avoid these errors



AAPM REPORT NO. 54
STEREOTACTIC RADIOSURGERY
June 1995

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

S. Derreumaux*, C. Etard, C. Huet, F. Trompier, I. Clairand, J-F. Bottollier-Depois, B. Aubert and P. Gourmelon
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Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135

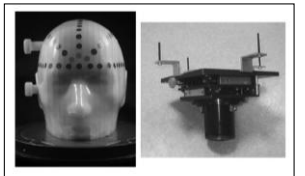


Figure 2. Stereotactic radiotherapy treatment delivery with successive beam entrance positions as a function of accelerator and table rotation angles (left). The plate used in the centre (Case 2) to hold the cylindrical additional collimator (right).

Errors in SRS / SBRT

Single fraction SRS for AVM, November, 2004

Prescription dose not reported; plan/treatment used multiple isocenters, with collimators from 10 - 30 mm

Jaws set to 40 x 40 cm² instead of 40 x 40 mm². Physicist told therapist "40 x 40"

Some areas of normal brain received in more than dose to intended target

Severe complications: "fibrosis and oseo-tracheal fistula that required surgical operation." Patient died several days later as a result of a "brutal haemorrhage."

Errors in SRS / SBRT

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO
Published: December 29, 2010

The initial accident report offered few details, except to say that an unidentified hospital had administered radiation overdoses to three patients during identical medical procedures.

Marci Faber is nearly comatose after a treatment mistake.

The Radiation Boom

Missing the Target

Articles in this series examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.

Previous Articles in the Series »

Multimedia

Interactive Graphic

Making a Complex Machine Even More Complex

It was not until many months later that the full import of what had happened in the hospital last year began to surface in urgent nationwide warnings, which advised doctors to be extra vigilant when using a particular device that delivers high-intensity, pinpoint radiation to vulnerable parts of the body.

Marci Faber was one of the three patients. She had gone to Evanston Hospital in Illinois seeking treatment for pain emanating from a nerve deep inside her head. Today, she is in a nursing home, nearly comatose, unable to speak, eat or walk, leaving her husband to care for their three young daughters.

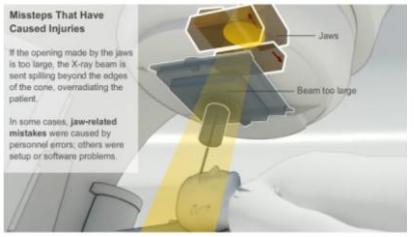
Two other patients were overdosed before the hospital realized that the device, a linear accelerator, had inexplicably allowed radiation to spill outside a heavy metal cone attachment that was supposed to channel the beam to a specific spot in the brain. One month later, the same accident happened at another hospital.

The treatment Ms. Faber received, stereotactic radiosurgery, or SRS, is one of the fastest-growing radiation therapies, a technological innovation designed to target tiny tumors and other anomalies affecting the brain or spinal cord, while minimizing damage to surrounding tissue.

Missteps That Have Caused Injuries

If the opening made by the jaws is too large, the X-ray beam is sent spilling beyond the edges of the cone, overradiating the patient.

In some cases, **jaw-related mistakes** were caused by personnel errors; others were setup or software problems.



Then, in what seemed like a blink of an eye, she disintegrated. “Four weeks later, she was like a vegetable,” Mr. Kagan said. “It was mind-boggling to see one person who was not elderly deteriorate that quickly.” Now, she can only blink her eyes and lightly squeeze her husband’s hand. “It is very hard on the kids,” Mr. Faber said. “It has been hard on me but really nothing compared to what Marci is going through.” Doctors who deal with her type of radiation injury say the prognosis for any meaningful recovery is poor.

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO
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Who caught it, and what could have been done to prevent it?

Patients / staff “caught” it

Better communication

Use of checklists

Machine Interlocks

Perform comprehensive, end-to-end commissioning of overall process, including R/V system

Vendor Response

BrainLAB

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Kapellenstraße 12 · 85622 Feldkirchen · Germany
phone: +49 89 99 15 68 -0
fax: +49 89 99 15 68 -33
brainlab.com

SUPPLEMENTAL COMMUNICATION

Subject:	Stereotactic Radiosurgery/Radiotherapy Treatments using Conical Collimators in combination with Novalis
Product Reference:	Novalis (excluding all Novalis Tx systems)
Date of Notification:	February 1, 2010
Individual Notifying:	Markus Hofmann, MDR & Vigilance Manager
BrainLAB Identifier:	09-06-29.BVA.2 (II)
Type of Action:	Supplemental Communication

This Supplemental Communication is intended for Novalis users and supplements BrainLAB's Field Safety Notice "09-06-29.BVA.2" dated August 12, 2009 ("Field Safety Notice"), which addressed jaw settings and safety checks when using conical collimators.

In order to assist the customer in implementing the recommendations in the Field Safety Notice, a mandatory software modification that limits the field size to a maximum of 4x4cm² when the conical collimators are inserted will be provided. This modification will be installed at no cost to the Novalis user and will include the necessary changes to product labeling to reflect this reduced maximum field size when using conical collimators. There are no other changes to features or performance in this software modification.

This Supplemental Communication does not alter or amend the Field Safety Notice. Users are strongly advised to be familiar with and implement the Field Safety recommendations to enhance safe and effective use of conical collimators.

One of BrainLAB's authorized service providers will install the update. Accordingly, you will be directly contacted by a service representative within the next six weeks to schedule the update. If you require further clarification, please contact MDR & Vigilance Manager Markus Hofmann.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by
E-mail: support@brainlab.com
Fax: BrainLAB AG +49 89 99 15 68 33
Address: BrainLAB AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

Thank you for paying attention to this information.

February 1, 2010

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medical systems

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fax: 650 315 4489
email: ros.helpdesk@varian.com
www.varian.com

URGENT MEDICAL DEVICE CORRECTION

Subject:	**Warning about the use of Conical Collimator Accessories for Stereotactic Radiosurgery Treatments**
Reference:	C-series Clinac®, Trilogy™ and Novalis Tx™ used for SRS treatments
Affected Serial Numbers:	see attached list
File Reference:	CP-01891
Date of Notification:	October 8, 2009

We are writing to advise you about a risk that exists when using conical collimator accessories with C-Series Clinacs for Stereotactic Radiosurgery (SRS) treatments.

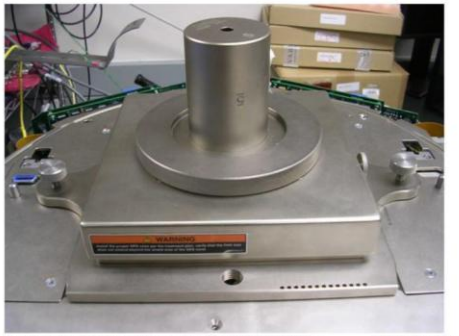
These machines have no mechanism for verifying that:

1. The conical collimator mount accessory is installed.
2. The conical collimator is installed in the cone mount.
3. The correct size conical collimator is inserted in the cone mount.
4. The primary collimator ("jaw size" or "field size") on the Clinac is set correctly to a size safely within the outside diameter of the conical collimator in use.

Anomaly:

Varian has become aware of incidents in which SRS treatments have taken place with the intended conical collimator accessory not inserted at all, or with the conical collimator accessory correctly mounted, but with a primary collimator field size setting which exceeds the outside diameter of that conical collimator. In the case of the incorrect field size, unintended radiation is delivered to the patient outside the outer edge of the cone.

The following Figure 1 depicts the **correct** way for the field size to be configured with a cone:



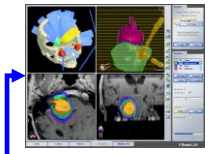
One vendor’s solution

Figure 2: Recommended rear decal location for conical collimator

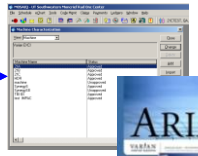
Bill Of Materials

-08	-07	-06	-05	-04	-03	-02	-01	Part Number	Description
-	-	-	-	-	-	-	2	100050083-01	Label Warning (English)
-	-	-	-	-	-	2	-	100050083-02	Label Warning (Chinese)
-	-	-	-	-	2	-	-	100050083-03	Label Warning (French)
-	-	-	-	2	-	-	-	100050083-04	Label Warning (Italian)
-	-	-	2	-	-	-	-	100050083-05	Label Warning (Swedish)
-	-	2	-	-	-	-	-	100050083-06	Label Warning (Spanish)
-	2	-	-	-	-	-	-	100050083-07	Label Warning (Japanese)
2	-	-	-	-	-	-	-	100050083-08	Label Warning (German)

Do all of your commissioning in clinical mode, and through your Verify/Record system



Planning



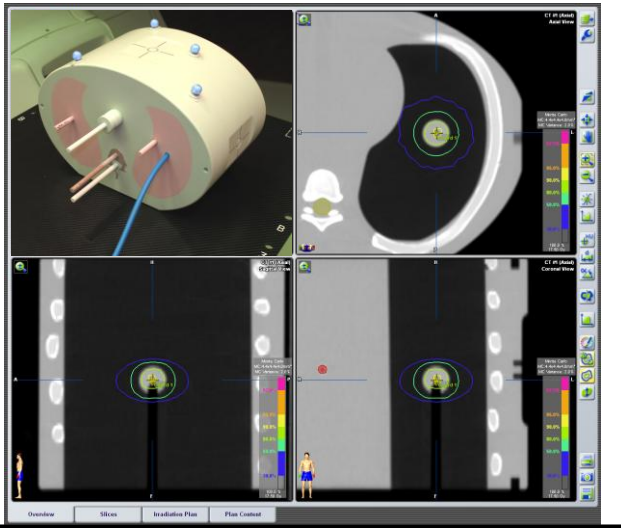
R/V

A verify/record system can help to minimize errors….

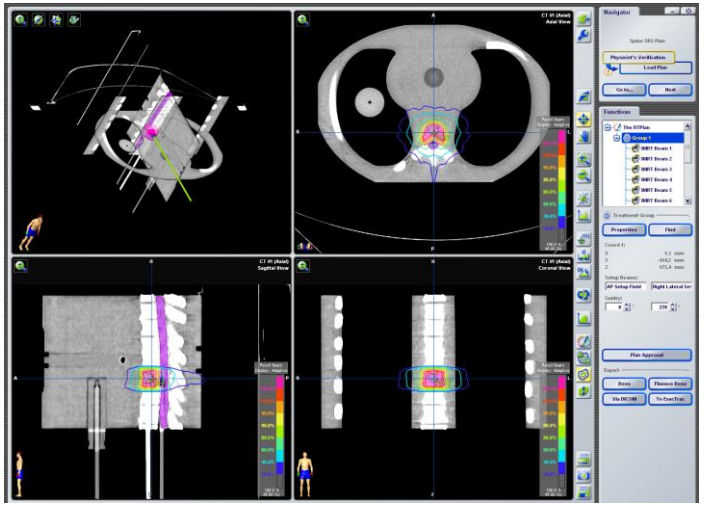
….as long as it is configured properly

Tx Unit

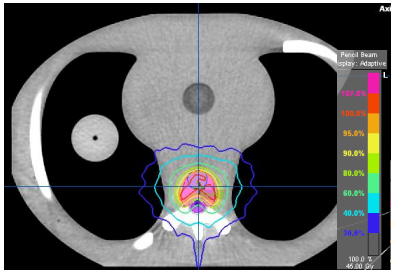
End-to-end, image guided dosimetric assessment

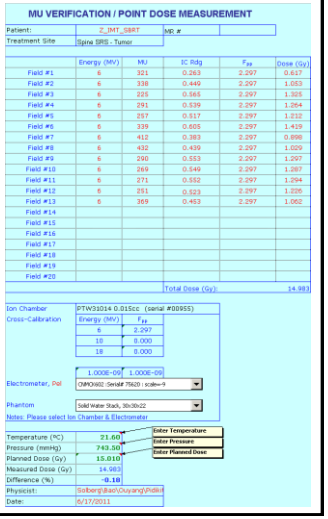


End-to-end, image guided dosimetric assessment

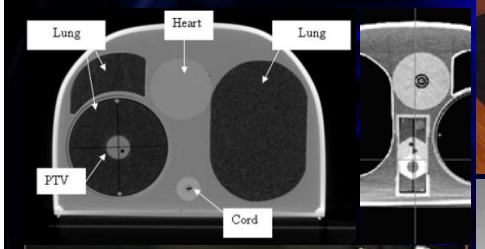


End-to-end, image guided dosimetric assessment





SRS/SBRT programs should be subject to independent review

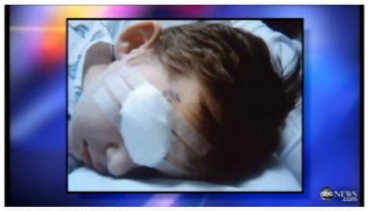


RPC Radiological Physics Center
Excellence through Quality Assurance

Wrong site errors in SRS/SBRT

abcNEWS/U.S.

Medical Mistake: Surgeon Operates on the Wrong Eye of a 4-Year-Old Boy



Surgeon Operates on Boy's Wrong Eye

WORLD NEWS

Jesse Matlock went to a doctor today to find out if he suffered any permanent damage when a surgeon performed corrective surgery on the wrong eye and then, without consulting the boy's parents, quickly operated on the correct eye.

"Right now we're in the dark about what this will be like in the future," Tasha Gaul, mother of 4-year-old Jesse, told ABC news. The doctor they saw today told her they will have to wait 5 weeks for his eyes to completely heal before they can determine if there has been any permanent damage.

U.S.NRC

About NRC | Nuclear Reactors | Nuclear Materials | Radioactive Waste | Nuclear Security | Public Meetings & Involvement

Event Description	Treatment Implication
Patient orientation entered incorrectly at MR Scanner	Wrong location treated
Fiducial box not seated properly during CT imaging	Wrong location treated
Malfunction of automatic positioning mechanism following re-initialization	Wrong location treated
Right trigeminal nerve targeted instead of left	Wrong location treated
Facial nerve targeted instead of trigeminal nerve	Wrong location treated
Mistake in setting isocenter coordinates	Wrong location treated
Head not secured to stereotactic device (2 events)	Wrong location treated
Selected collimators did not match planned	Wrong dose/distribution delivered
Physician mistakenly typed 28 Gy instead of 18 Gy into planning system	Wrong dose delivered
Physicist calculated prescription to 50% isodose instead of 40%	Wrong dose delivered
Microphone dislodged, causing stereotactic device to break	Treatment halted after 2 of 5 fractions
Couch moved during treatment	None; personnel interrupted treatment

A written checklist system can help minimize errors

Trigeminal Neuralgia Treatment Time Out

This form is to be signed at the treatment console
Physician, Physicist, ExacTrac Therapist and Treating Therapist all present
Treatment cannot be initiated until all parties agree on treatment and sign this form

Affix Patient Label Here — DRAFT DRAFT DRAFT DRAFT

Date:

Time:

Circle One

Treatment side verbally confirmed with patient	Treat Therapist	L	R
Treatment side visually confirmed by physicist (lasers)	Physicist	L	R
Treatment side conformed with patient records	Physician	L	R

Patient on treatment matches 4DTC (ARIA) patient

☐ Treat Therapist ☐ Physician

Patient on Exactrac matches 4DTC (ARIA) patient

☐ Treat Therapist ☐ E-T Therapist ☐ Physicist ☐ Physician

Jaw Size 4cm x 4cm (Linac Control Console)

☐ Treat Therapist ☐ E-T Therapist ☐ Physicist ☐ Physician

UCLA Radiation Oncology - Radiosurgery Check List

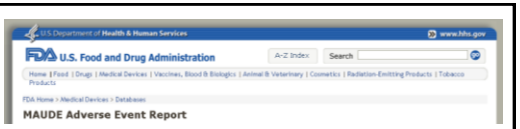
Patient Name: _____ Patient ID #: _____ Date: _____

Step	*Isocenter Operations*	*Isocenter 1*	*Isocenter 2*	*Isocenter 3*	*Isocenter 4*	*Isocenter 5*	*Isocenter 6*
1	Arrange sheet and pad on couch.						
2	Set the couch to 0 & coll to 90.						
3	Take photos of patient (3).						
4a	Set backup jaws to 4.0 x 4.0cm. (2 initials & size).	/	/	/	/	/	/
4b	Install the cone. (2 initials & size).	/	/	/	/	/	/
5	Position isocenter templates on positioning box. 2 init.						
6	Enable linac switches 1, 2, and 4. Unlock microadjusters/table locks.						
7	Fit ring onto patient head frame.						
8	Attach large bolts (2) onto ring.						
9	Assist patient onto couch.						
10	Secure frame to couch mount. Tighten large bolts.						
11	Attach small bolts (2) onto ring.						
12	Secure patient to couch w/ strap.						
13	Attach positioning box to the frame.						
14	Positon positioning box to the isocenter.						
15	Tighten Lat & Long table locks and disable linac switches 1,2,4.						
16	Use microadjusters, reposition box to isocenter, lock microadjusters.						
17	Review of fields by physician.						

Other Sources of Information

MAUDE is voluntary

Other Errors



VARIAN MEDICAL SYSTEMS, INC. VARIAN / ZMED STEREOTACTIC RADIOSURGERY Back to Search Results

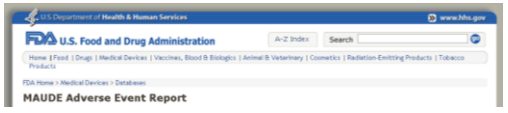
Event Type Injury
Event Description

An stereotactic radiosurgery patient at (b)(6) radiation oncology in (b)(6) was given treatment without the ficonfl device that limits the radiation beam to a relatively small -approximately 14 to 20mm- circular beam. The patient received a portion of her treatment with a 5cm by 5cm square beam before the error was recognized and the treatment stopped. The medical device used for the stereotactic radiosurgery treatment was sold by varian. The device was originally developed by (b)(4), a company that varian now owns. The device lacks a safety interlock which would prevent treatment without the circular beam limiting cone being in place. This is a glaring deficiency in the product design. Varian linear accelerators have many interlock safety systems. It's very odd, and in my opinion irresponsible, that varian would market a system without a basic, simple safety interlock when that system is designed to give a very high radiation dose in one treatment. This error occurred several years ago. (b)(6) radiation oncology has not treated very many stereotactic patients, so the patient's name should be relatively easy to find.

Search Alerts/Recalls

Circular collimator left off

Other Errors



VARIAN MEDICAL SYSTEMS CL-NOVALIS TX LINEAR ACCELERATOR Back to Search Results

Event Date 05/10/2010
Event Type Death **Patient Outcome** Death;
Manufacturer Narrative

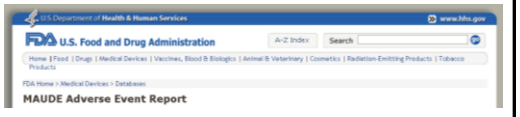
On (b) (6) 2010, the patient's mother informed varian that her daughter had passed away, and declined to provide any further information, including the dates of treatment, on advice from her lawyers. No other details of the event have been reported to varian. Additional follow-up to this mdr is expected upon completion of the investigation.

Event Description

Patient's mother called with an allegation that her daughter had been mistreated with a novalis tx. On (b) (6) 2010, varian received a call from a patient's mother with an allegation that her daughter had been mistreated with a novalis tx. The patient had radiosurgery on a novalis tx at (b) (6) in (b) (6). The doctors informed the patient's mother that the radiation, "went into an area that it wasn't supposed to go to, beyond the area that they targeted. " in addition, the patient's mother was calling for information about recalls on the novalis tx machine during 2009 and 2010. She said the staff at (b) (6) told her that the machine was subject to a recall, and when she asked the facility staff for details, they referred her to the manufacturer. (b) (6).

Search Alerts/Recalls

Other Sources of Information



ELEKTA INSTRUMENT AB LEKSELL GAMMA KNIFE RADIATION THERAPY Back to Search Results

Catalog Number ARC 904121
Event Date 08/09/2010
Event Type Injury **Patient Outcome** Required Intervention;
Manufacturer Narrative

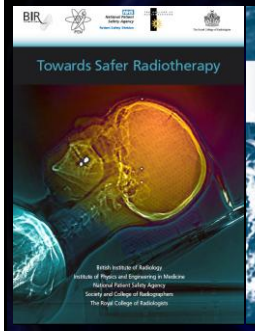
The customer will upgrade to counter-scale to increase accuracy of the system.

Event Description

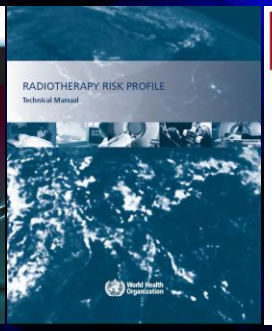
Leksell stereotactic neurology system was installed in 2008, (b)(6). From the beginning, the accuracy was not correct according to the (b)(6) target coordinates. By experience, the system shows 1, 5 mm wrong in x and 0,5-0,7 mm in y. The doctor manually adjusts the coordinates accordingly and then comes to correct position for implantation of dbs electrode - this is confirmed by post operative mr-images. No mistreatment but potential for mistreatment due to the incorrect settings.

Search Alerts/Recalls

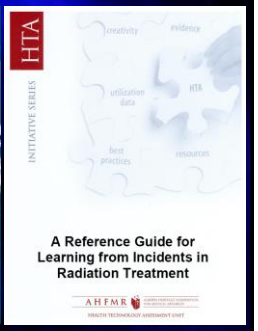
Efforts to Improve Safety



Royal College of Radiologists, 2008



World Health Organization, 2008



Alberta Heritage Foundation, 2006

Many European countries have legislatively-mandated reporting of radiation incidents

Radiation Oncology Safety Information System

Funded by ESTRO, began in 2001

Voluntary, anonymous, web-based reporting system

~20 countries participating, ~700 incidents reported

Courtesy Peter Dunscombe

www.rosis.info

Efforts to Improve Safety

BILL NUMBER: SB 1237 CHAPTERED
BILL TEXT

CHAPTER 521
FILED WITH SECRETARY OF STATE SEPTEMBER 29, 2010
APPROVED BY GOVERNOR SEPTEMBER 29, 2010
PASSED THE SENATE AUGUST 30, 2010
PASSED THE ASSEMBLY AUGUST 26, 2010
AMENDED IN ASSEMBLY AUGUST 20, 2010
AMENDED IN ASSEMBLY JUNE 23, 2010
AMENDED IN SENATE APRIL 28, 2010

INTRODUCED BY Senator Padilla
(Coauthor: Senator Alquist)

FEBRUARY 19, 2010

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

Must provide dose form every CT scan by 2012 (and must be accurate within 20%, verified annually by a medical physicist)

Must credential all CT facilities by 2013

New reporting requirements for radiotherapy misadministrations

Recent U.S. Efforts

ASTRO
TARGETING CANCER CARE
About ASTRO
Meetings and Education
Membership
American Society for Radiation Oncology

TABLE II. ASTRO six point action plan.

ASTRO six point action plan
Creation of an anonymous national database for event reporting
Enhance and accelerate the ASTRO/ACR Practice Accreditation Program
Expand education and training programs to include intensive focus on quality and safety
Develop tools for cancer patients to use in discussions with radiation oncologists
Accelerate development of the IHE-RO (Integrated Health Enterprise—Radiation Oncology) program
Advocate for passage of the CARE (Consistency, Accountability, Responsibility, Excellence in Medical Imaging and Radiation Therapy) act

Hendee WR, Herman MG. Improving patient safety in radiation oncology. Med Phys 38(1): 78-82, 2011

Efforts to Improve Safety

Online self-assessment module on QA (90 minutes)

Recent U.S. Efforts

American Society for Radiation Oncology

Series of 5 safety white papers

IMRT
IGRT
SRS/SBRT
HDR
Peer Review

Written by 8 "experts"
Reviewed by 8 independent "experts"
Endorsed by AAPM, ACR, AAMD, ASRT
Reviewed by AANS, MITA, public

Recent U.S. Efforts

American Society for Radiation Oncology

SRS/SBRT White Paper

SRS/SBRT as a well thought out program, not an addition/afterthought
Team approach, plan ahead

SRS/SBRT specific training

SRS/SBRT expertise/competence, including personnel certification
Follow nationally accepted standards, clinical and physics

SRS/SBRT accreditation / credentialing

Adequate resources:
Time, equipment, personnel
Quality management system, including reporting and ongoing quality improvement, and peer review
Physician and physicist supervision for each procedure

Practice Accreditation Programs – should be MANDATORY

And, specific accreditation programs for specialized programs such as SBRT should be developed, and required

Board certification is a minimum requirement for physicists

"Finally, it may be time to acknowledge that some radiotherapy procedures, including perhaps SRS and SBRT, share more in common with other specialized medical procedures (e.g., heart or liver transplants), and should perhaps be performed only by highly experienced personnel at recognized centers of excellence."

Vendor Responsibility

There must be dialogue and communication between equipment manufacturers and end-users on the approaches, system design, QA methodology, and clinical implementation of SRS and SBRT. The vendors need to understand the needs and requirements of the clinicians, medical physicists, radiotherapists relative to the systems and processes of SRS and SBRT. With such understanding they must exert all the necessary efforts to incorporate features and safeguards to assure efficacious and safe operation of their products. By the same token, the end-users need to work with the manufacturers in developing commissioning, safety and quality assurance tools, programs and procedures for SRS and SBRT systems.

Vendor Responsibility

Vendors must provide additional opportunities for specialized training, emphasizing implementation, clinical and quality assurance in addition to technical aspects, and the home institution must make available resources and time for such training. It is not adequate to train users on the basic aspects of system operation if the systems are sold and used for specialized purposes such as SRS and SBRT.

Vendors must do more to emphasize all QA aspects, not only equipment QA, but process QA. SRS / SBRT systems consist of multiple components, and vendors must ensure and demonstrate full mechanical, electronic and information connectivity of these components. In situations where components or subsystems come from more than one manufacturer, it is the responsibilities of the manufacturers to collaboratively demonstrate compatibility of the various subsystems, and their safe operation when used in combination.

Vendor Responsibility

Finally, while a turn-key approach to the use of complex clinical systems is appealing in terms of procedural simplicity, inadequate understanding of the internal workings of such complex systems by the end-users is of concern. Rather, vendors should take an "all-inclusive" approach of safe equipment design, understanding the need for QA equipment and procedures, and emphasizing commissioning, safety and quality assurance requirements and procedures.

SBRT has the potential to completely change the practice of radiation oncology and management of cancer

Doing so requires a systematic approach to clinical practice and technology

complete diligence on the part of both physicians and physicists

and adherence of a culture of safety on the part of all stakeholders

Thank you