Taking Responsibility for Safety

George W. Sherouse, PhD, DABR, PMP, FAAPM
Landauer Medical Physics

User's guide to this talk…

This presentation includes both formal, press-reported and backchannel accounts of actual radiation treatment accidents.

Facts are illusive once patients are harmed.

Watch for "it appears..,"

Safety in Radiation Oncology: A short history

THE RADIATION BOOM

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

For his last Christmas, Scott Jerome-Parks rested his feet in buckets of sand his friends had sent from a childhood beach. More Photos »

The Radiation Boom

When Treatment Goes Awry

This is the first in a series of articles that will examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.

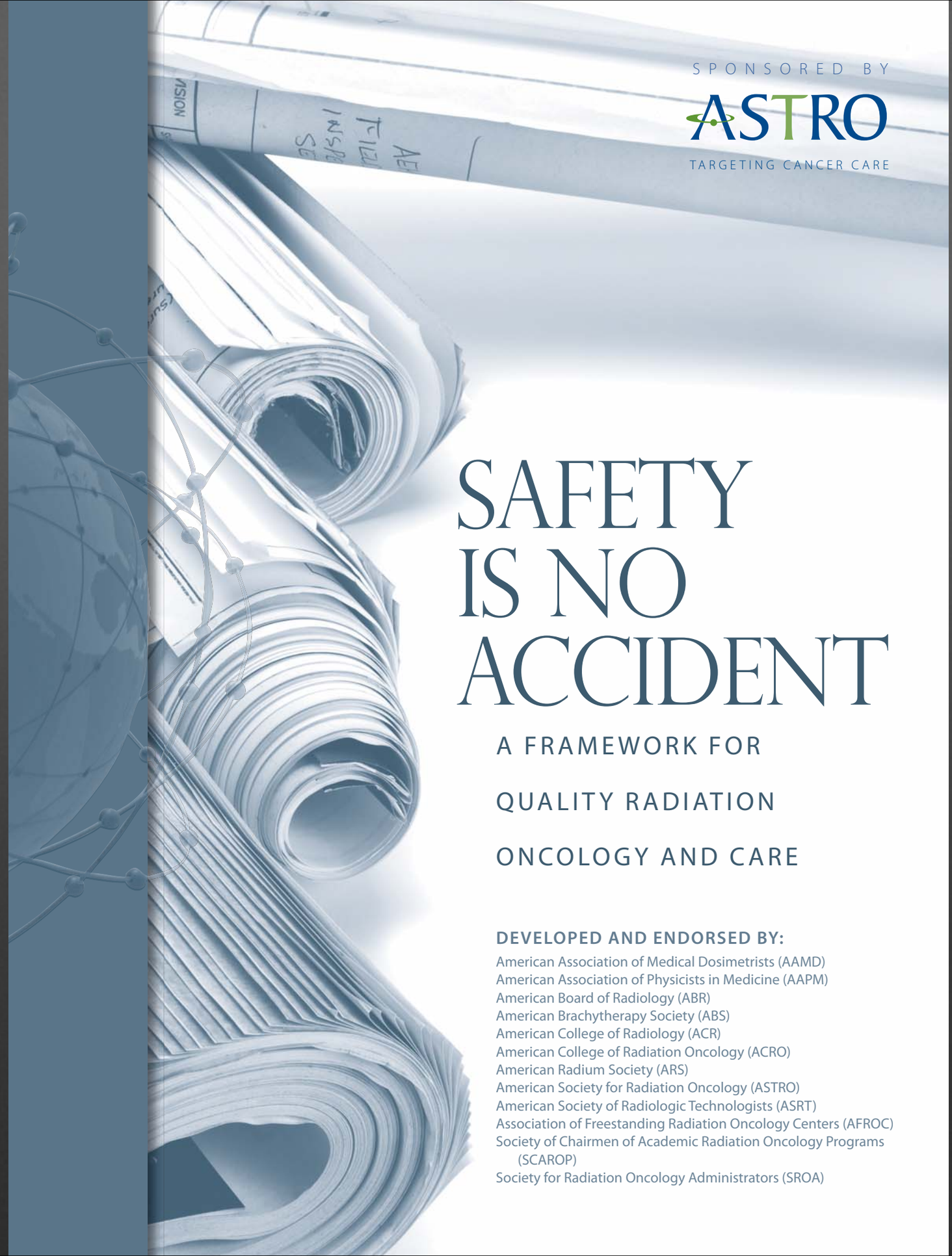
Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days.

Soon after the accident, at St. Vincent's Hospital in Manhattan, state health officials cautioned hospitals to be extra careful with linear accelerators, machines that generate beams of high-energy radiation.

But on the day of the warning, at the State University of New York Downstate Medical Center in Brooklyn, a 32-year-old breast cancer patient named Alexandra Jn-Charles



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ASTRO

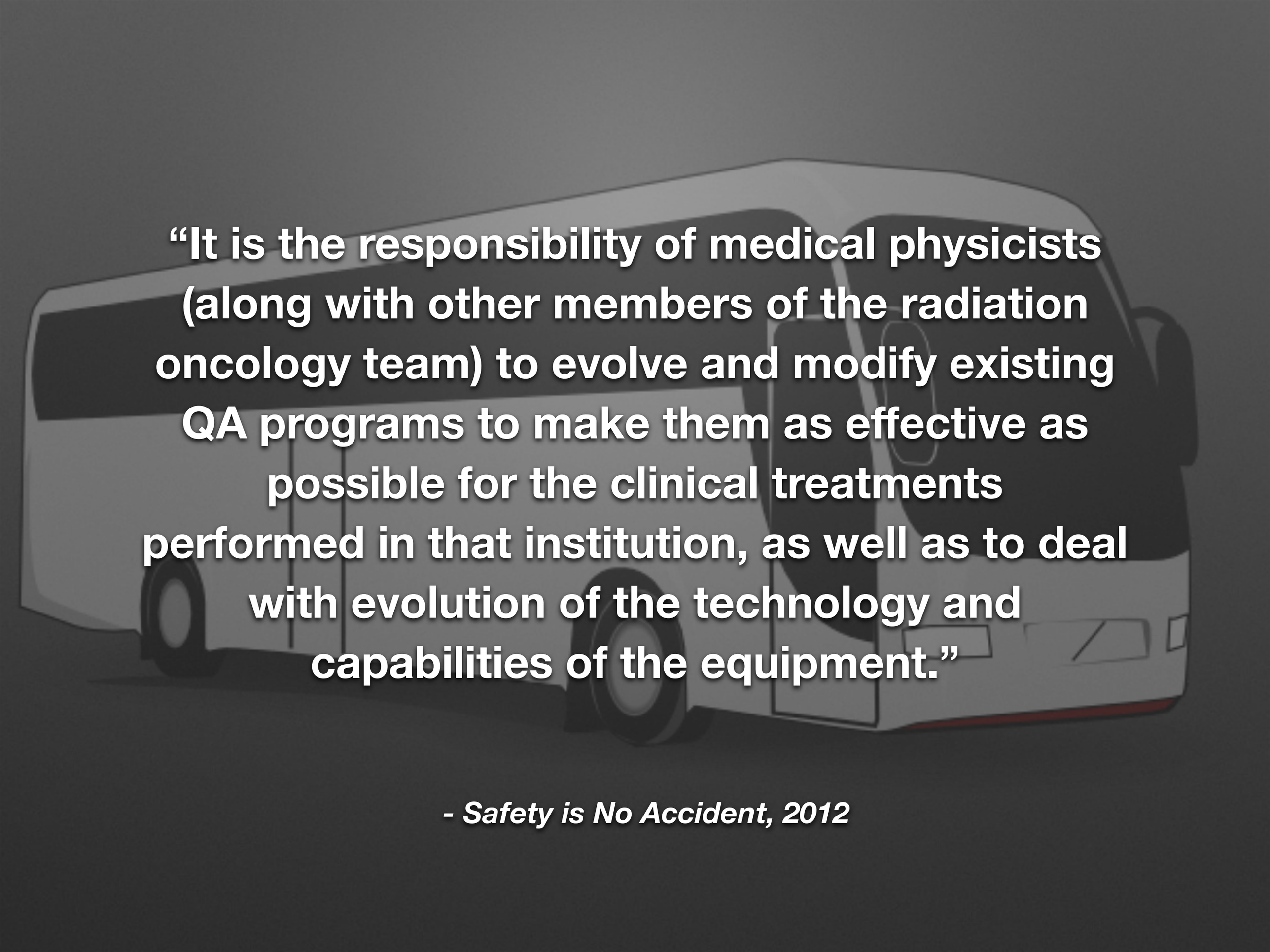
TARGETING CANCER CARE

SAFETY IS NO ACCIDENT

A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY AND CARE

DEVELOPED AND ENDORSED BY:

American Association of Medical Dosimetrists (AAMD)
American Association of Physicists in Medicine (AAPM)
American Board of Radiology (ABR)
American Brachytherapy Society (ABS)
American College of Radiology (ACR)
American College of Radiation Oncology (ACRO)
American Radium Society (ARS)
American Society for Radiation Oncology (ASTRO)
American Society of Radiologic Technologists (ASRT)
Association of Freestanding Radiation Oncology Centers (AFROC)
Society of Chairmen of Academic Radiation Oncology Programs (SCAROP)
Society for Radiation Oncology Administrators (SROA)



“It is the responsibility of medical physicists (along with other members of the radiation oncology team) to evolve and modify existing QA programs to make them as effective as possible for the clinical treatments performed in that institution, as well as to deal with evolution of the technology and capabilities of the equipment.”

- Safety is No Accident, 2012

APPLICATION OF RISK ANALYSIS METHODS TO RADIATION THERAPY QUALITY MANAGEMENT

M. Saiful Huq
Department of Radiation Oncology, University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania

Benedick A. Fraass
Department of Radiation Oncology, University of Michigan Medical Center, Ann Arbor, MI

Peter B. Dunscombe
Department of Oncology, University of Calgary, Calgary, Alberta

John P. Gibbons, Jr.
Department of Medical Physics, Mary Bird Perkins Cancer Center, Baton Rouge, Louisiana

Geoffrey S. Ibbott
Radiological Physics Center, UT MD Anderson Cancer Center, Houston, Texas

Arno J. Mundt
Department of Radiation Oncology, University of California San Diego, San Diego, California

Sasa Mutic
Department of Radiation Oncology, Mallinckrodt Institute of Radiology, Saint Louis, Missouri

Jatinder R. Palta
Department of Radiation Oncology, University of Florida, Gainesville, Florida

Frank Rath
Department of Engineering Professional Development, University of Wisconsin, Madison, Wisconsin

Bruce R. Thomadsen
Department of Medical Physics, University of Wisconsin, Madison, Wisconsin

2013 AAPM Summer School

Quality and Safety in Radiotherapy: Learning the New Approaches in TG 100 and Beyond

June 16 - 20 • Colorado College • Colorado Springs, Colorado

Welcome!

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A “systems analytic” approach to preventing hazards from causing accidents is almost certainly more appropriate than FMEA for clinical process engineering.

But that’s a different lecture.

By the way…

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- Radiotherapy, like many extreme medical interventions, involves selectively *killing* parts of a person while leaving other parts intact. The *purpose* is to do harm.

- An accident takes a far more catastrophic failure of a safe delivery machine than of a harm-doing machine.

What physicists do for safety in the New Epoch…

- Process maps
- Failure mode analysis
- Hazard mitigation, process re-engineering
- Education, training, documentation, endless meetings
- Audit
- Rinse, repeat

And then…

012

HART CHECK - NEW CHART

Date		Primary	Boost 1	Boost 2	Boost 3	Boost 4	Boost 5
	Date						
6/5/12	Consent Form						
	Prescription - Completed & Signed						
	Calc Sheet - Signed by Docs & Physics Checked						
	Chart Info:						
	a. Fields #'s						
	b. Field Site						
	c. Treatment Plan/Energy Check						
	d. Field Size						
	e. Wedges Type & Orientation						
	f. MLC/Blocks						
	g. Cone Size/Cutout						
	h. MU						
	i. Bolus						
	j. Tumor Dose						
	k. Special Instructions & Photos						
	l. Set Up Instructions						
	m. MLC Instructions						
	n. SSDs						
	o. Gantry/Collimator/Floor Angles						
	Check MLC & Field Against Films						
	First Physics Check						
	Diagnosis						
RTT							

MESaq

Riverside Hospital 1974-1976

http://www.columbusmonthly.com/content/stories/2010/08/the-riverside-radiation-tragedy.html

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- Hospital replaced a physics contractor of 15 years, George Callendine, PhD with a salaried employee, Joel Axt (30 y.o.), who came straight out of 14 months training at UCSF.

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- Axt started at $20,000 in Oct 1973. He was the hospital RSO and sole physicist for RadOnc, Dx and NM, reporting to Medical Director of RadOnc.

http://www.columbusmonthly.com/content/stories/2010/08/the-riverside-radiation-tragedy.html

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- The error was compounded in Sept 1974 when Axt switched paper and transferred the same line from 6 squares/division to 5 squares/division.

Riverside Hospital 1974-1976

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- “… before the overdoses were discovered, the hospital had for some time been considering hiring another physicist to assist Axt. But Axt, who by all accounts was a quiet, unaggressive man, apparently did not push for the new position, and nothing was done…”

Riverside Hospital 1974-1976

Percent Overdose vs Month Treated and Patients Started During 2-Month Intervals

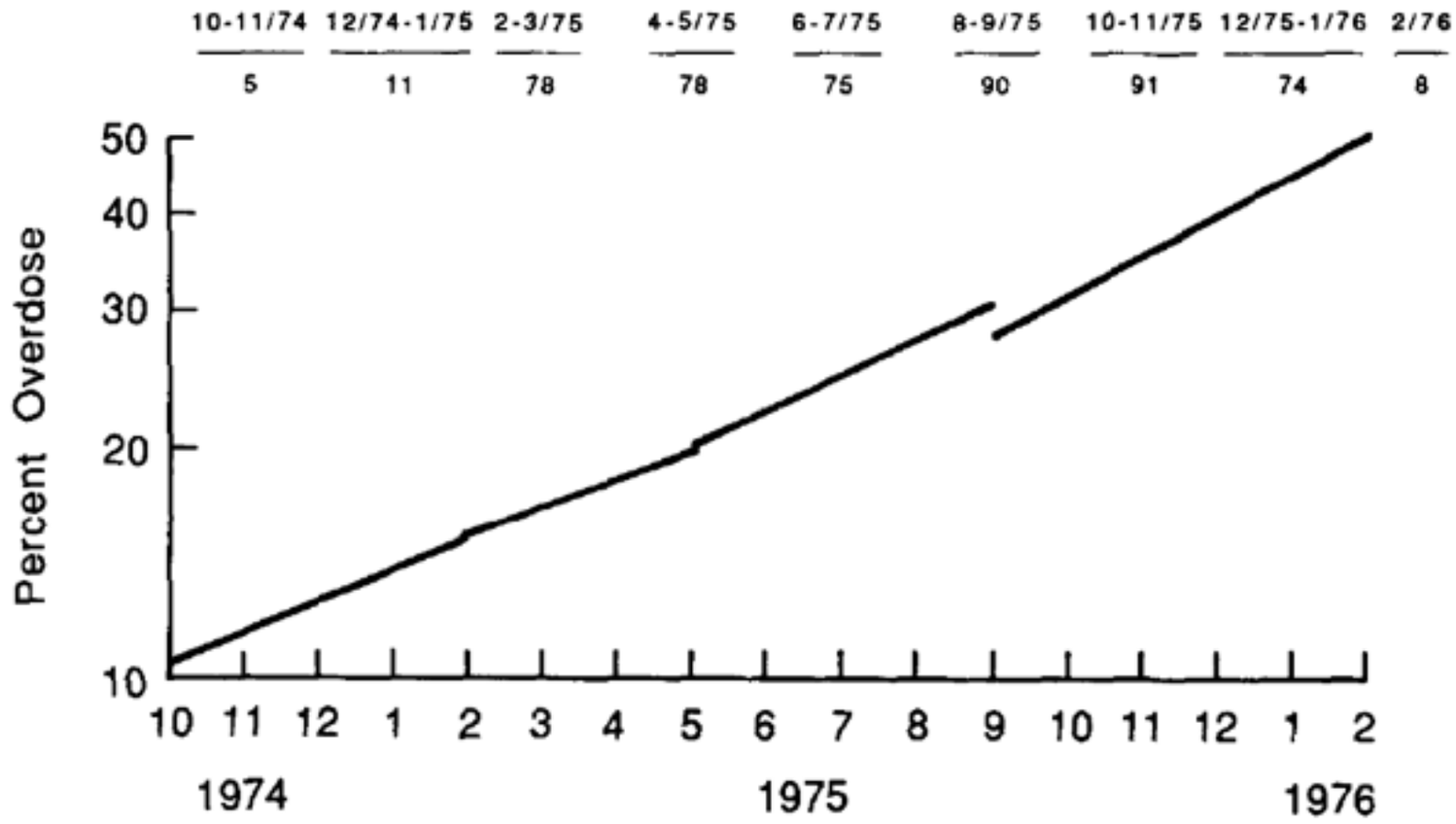

Fig. 1. Progressive overdosage with time between October 1974 and February 1976.

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- 426 patients received significant overdoses, 57% (243) died within the first year.

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Regarding physics practice:

- A fresh grad with limited training should never have been working solo.

Riverside Hospital 1974-1976

Regarding physics practice:

- A fresh grad with limited training should never have been working solo.
- No bucks were saved.

Northside Hospital 2009

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- BrainLAB had chosen to use a "soft" interlock - that is to rely on the R&V system to interlock collimator setting.

- It appears that the software was configured properly as to jaw setting, and the R&V had the right value, but a fault prevented beam-on.

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- It appears that the exact same procedure was followed for the two subsequent patients.

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In summary, it appears that the physicist:

- Responded to “patient on the table” with a quick fix
- Made a grossly incorrect adjustment of the treatment parameters, apparently with no expertise in the technique.
- Undermined the typical chain of QA checks.
- Did not follow-up on correctness of solution and instead instituted it as SOP with no independent review. One patient injury error became three.

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

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

Enlarge This Image

Marci Faber is nearly comatose after a treatment mistake.

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

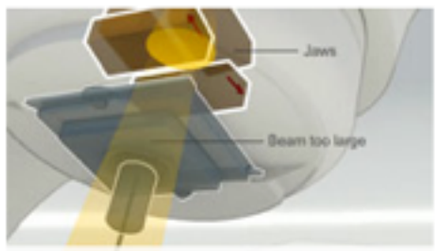
The Radiation Boom

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

France, 2004

- A similar incident occurred in France in 2004.
- “The accidental exposure was due to a oral mis-communication between the physicist and the operator regarding data on the collimator aperture: the physicist gave the instruction ‘40 40’ (meaning 40 mm) and the operator set the aperture to 40 cm by 40 cm.”

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

Dallas, Texas 2012

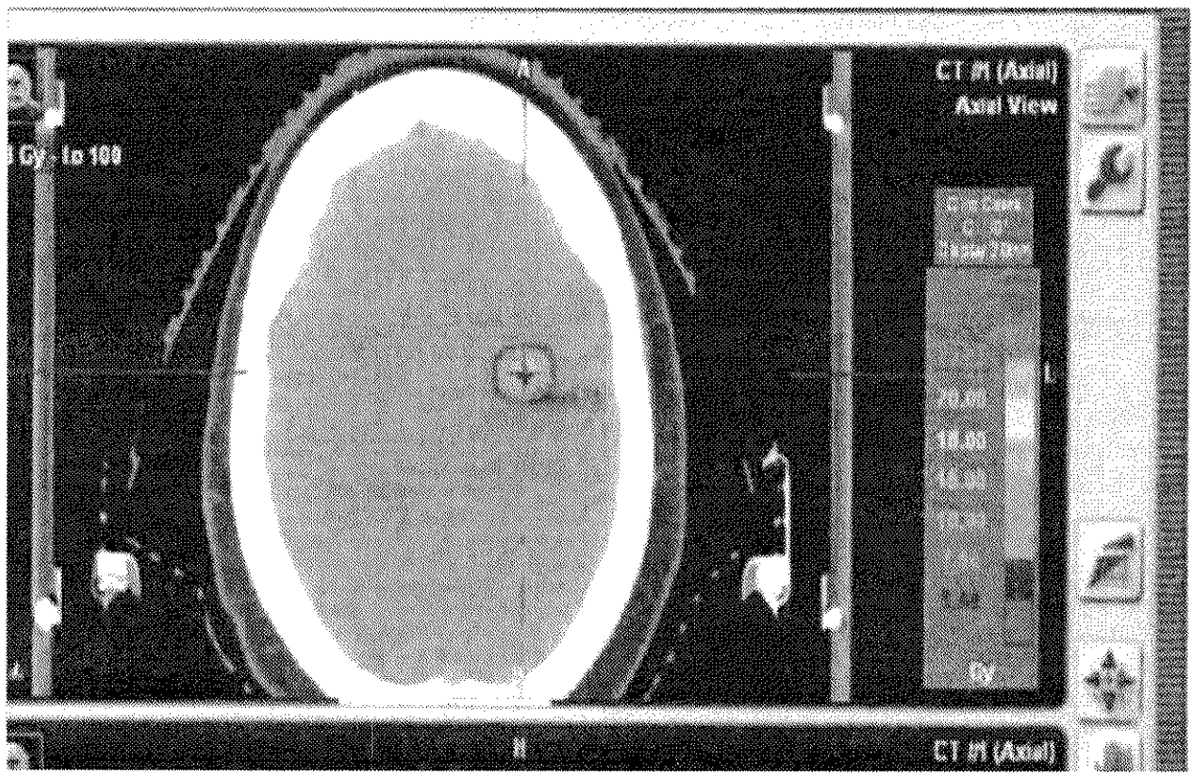
Dallas, Texas 2012

An SRS patient was treated with (apparently) the correct backing jaw setting, but no cone in place.

Texas SRS Incident

- Intended treatment area was < one cubic centimeter
- Actual treatment area was > 100 cubic centimeters
- Impact to patient

Intended treatment area



Actual treatment area

Dallas, Texas 2012

012

HART CHECK - NEW CHART

Date		Primary	Boost 1	Boost 2	Boost 3	Boost 4	Boost 5
	Date						
6/5/12	Consent Form						
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	d. Field Size						
	e. Wedges Type & Orientation						
	f. MLC/Blocks						
	g. Cone Size/Cutout						
	h. MU						
	i. Bolus						
	j. Tumor Dose						
	k. Special Instructions & Photos						
	l. Set Up Instructions						
	m. MLC Instructions						
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	o. Gantry/Collimator/Floor Angles						
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RTT							

Messag

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- State initiated a round of facility surveys and fined others with the same equipment.

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- Was the physicist physically present, if not why not?

St. Vincent's Hospital 2005

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- March 15, 16: Second and third fractions of new plan are delivered.
- evening of March 16: QA measurements of new plan are performed. Physicist discovers that the MLC has been fully retracted for all fields.

In February 2007 Scott Jerome-Parks died “after two terrible years of extreme disability” to complications of an unintended dose of 39 Gy in 3 fractions to much of his head and neck. He was 43 years old.

obituary in The Sun Herald, Feb 9, 2007

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Regarding physics practice:

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- Why was it considered acceptable to delivery 3 fractions of highly modulated IMRT before performing any physics QA?

- What is the physicist's proper role in establishing QA procedure?

An undisclosed location

IAEA Safety Reports Series, No. 17, Lessons Learned from Accidental Exposures in Radiotherapy

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- An independent audit revealed a difference of 15% between the two sets of gear, and hence between facilities.

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- It’s noteworthy that he got the “clinical correction factor” exactly right (in round numbers).

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  - It appears did not have an adequately clinical involvement in the practices.

Philadelphia VAMC 2002-2008

At V.A. Hospital, a Rogue Cancer Unit

Jessica Kourkounis for The New York Times

The Veterans Affairs Medical Center in Philadelphia.

By WALT BOGDANICH
Published: June 20, 2009

For patients with prostate cancer, it is a common surgical procedure: a doctor implants dozens of radioactive seeds to attack the disease. But when Dr. Gary D. Kao treated one patient at the veterans' hospital in Philadelphia, his aim was more than a little off.

Philadelphia VAMC

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- Gary Kao, MD PhD (Hopkins 1988, U Penn 1998) performed the bulk of the implants under contract to the VAMC from U Penn. He has since “voluntarily” given up privileges at U Penn and devoted his full attention to his molecular biology research.

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Philadelphia VAMC

http://www.nytimes.com/2009/06/30/health/30veterans.html

Philadelphia VAMC

Dr. Kao said later in testimony to a Congressional panel that he was never instructed on what constitutes a reportable, potential mistake, and that at no point did he ever try to cover up implants the nuclear commission said were faulty.

http://www.nytimes.com/2009/06/30/health/30veterans.html

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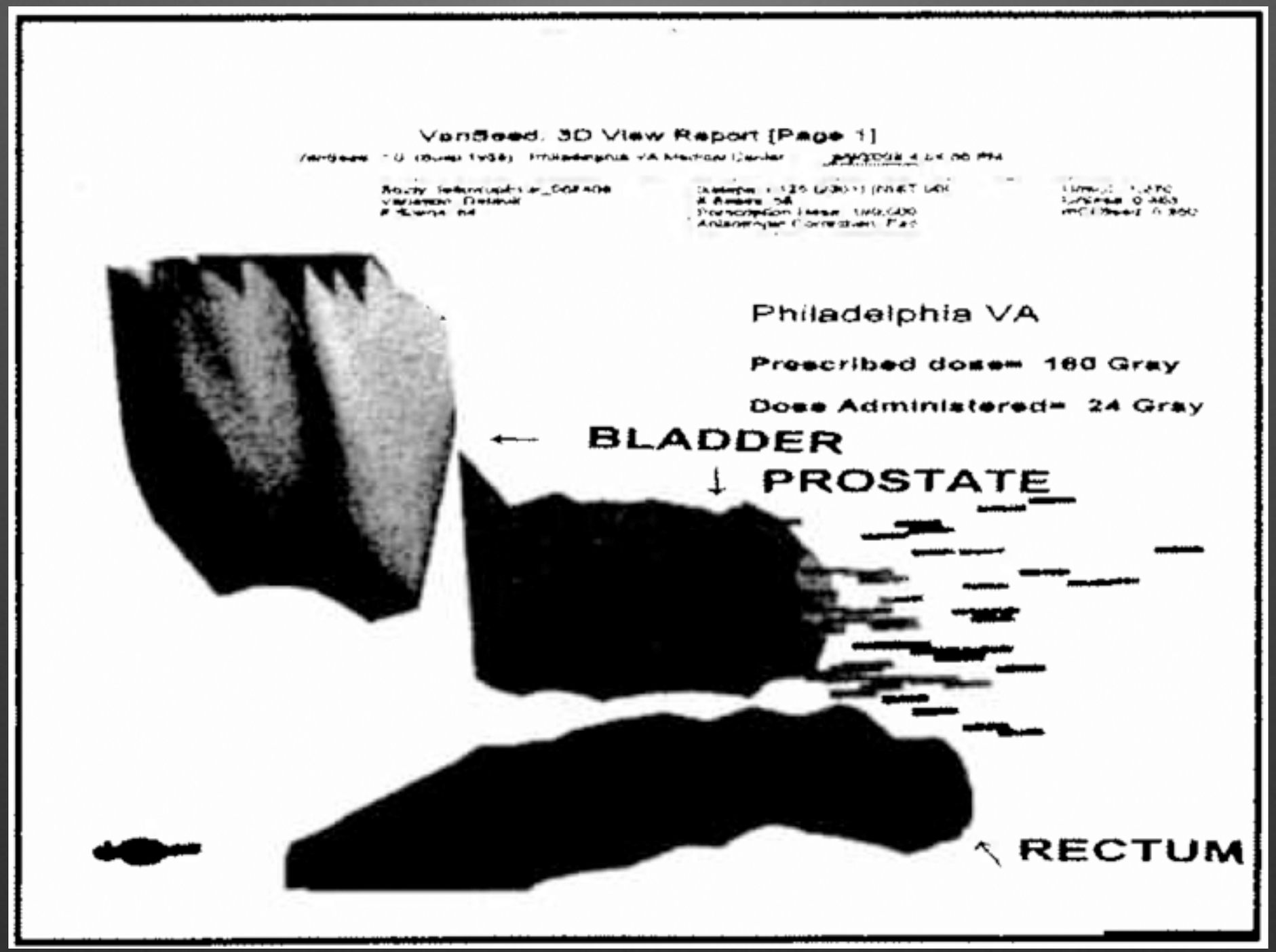
The one 2008 case with the wrong seed strength was a Medical Event - Dr. Kao was not aware of the error at the time of the implant so did not have the opportunity to revise the Written Directive. The NRC attention is what finally triggered an internal investigation.

Philadelphia VAMC



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- One title leaps out:

"Hood ornament" or "V-10 engine"? Myths and realities regarding physician-scientists in academic radiation oncology departments.

Kao GD, McKenna WG.
J Am Coll Radiol. 2004 Aug;1(8):539-44.

“[...] assigning excessive clinical coverage duties to a physician-scientist risks jeopardizing his or her research efforts [...]”

– Kao and McKenna

Philadelphia VAMC

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In testimony to a Congressional panel, despite repeated promptings from the panel, Dr. Kao declined to offer any apology to the patients and families who had come to the hearing.

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- How was it not the role of the UPenn physicists to close the quality feedback loo?

Others

Miscalibrated SRS LINAC at Moffitt Cancer Center in 2004-2005, 77 patients received 150% of prescribed dose. Physicist unwittingly used a tampered spreadsheet. Error was revealed by an RPC audit.

From the NY Times article: “There are clearly places that don’t avail themselves of the [RPC’s] service, even though it is well known and very affordable,” [the RPC Director] said. “I guess they don’t want someone else checking them for some reason.”

http://www.nytimes.com/2010/01/27/us/27radiation.html

Others

http://www.nytimes.com/2010/02/25/us/25radiation.html?_r=0 and S. Derreumaux, Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135

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CoxHealth in Springfield, MO 2004-2009, 74 patients received overdoses of as much as 50% in small cone SRS treatments. Senior physicist used a Farmer chamber to measure cone factors. It appears that warnings from BrainLAB about outlier data were not followed up at initial commissioning.

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In a very similar error, in a French center between April 2006 and April 2007, 145 patients received significant overdose. Maximum overdose was 200% (of intended?).

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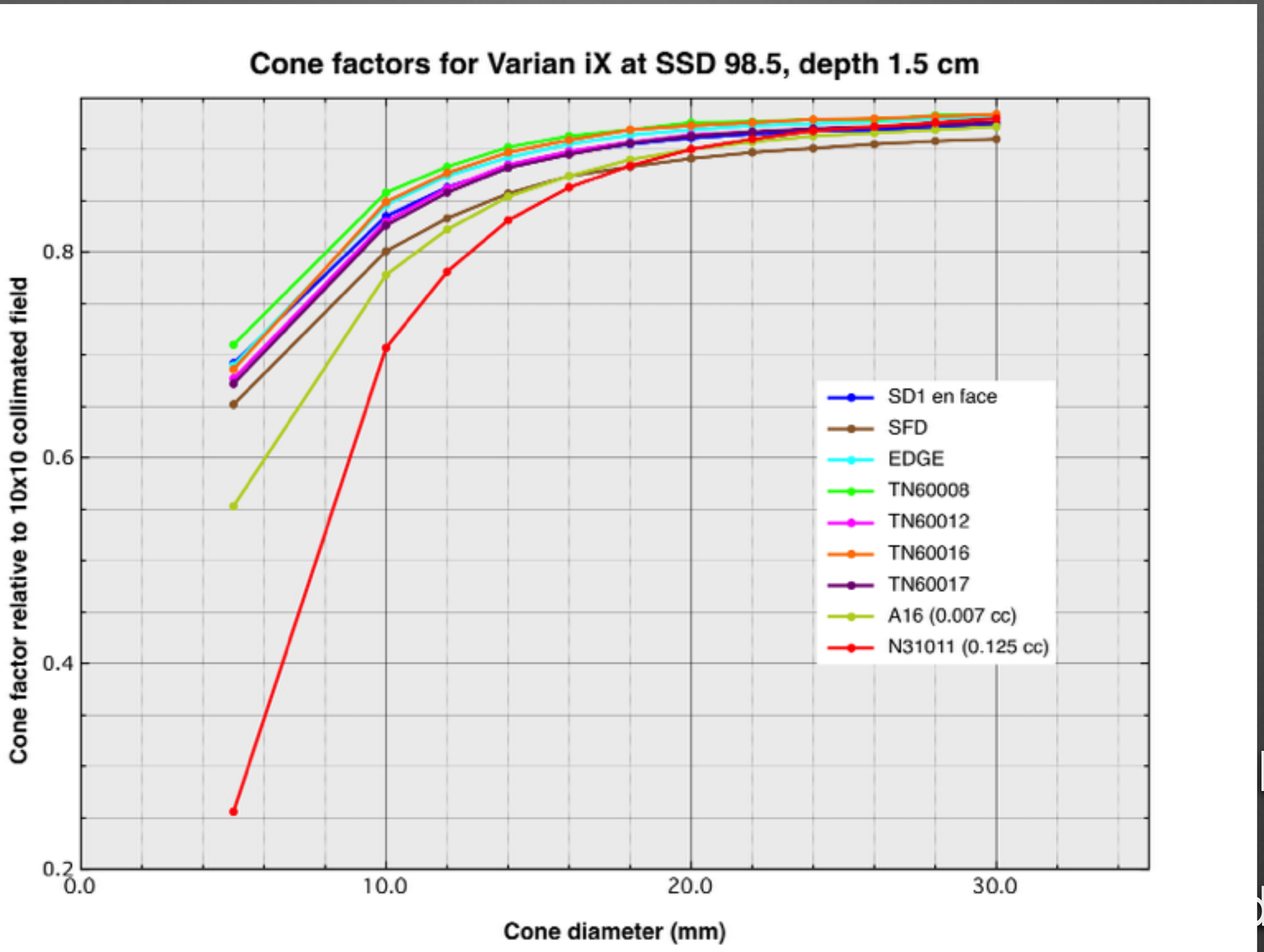

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Others

30 Jan 2013

Two doctors and a radiologist have been sentenced to 18 months in prison for their role in radiation overdoses that killed at least 12 people in France and left dozens seriously ill.

Overdoses were given to nearly 450 cancer patients at the Jean Monnet hospital in Epinal in northeastern France between 2001 and 2006. It is the most serious incident of its kind France has known.

The doctors and the radiologist, who have all denied the charges, had been charged with manslaughter, failure to help people in danger and destroying evidence.

http://www.telegraph.co.uk/news/worldnews/europe/france/9837803/French-doctors-and-radiologist-jailed-for-radiation-overdoses.html

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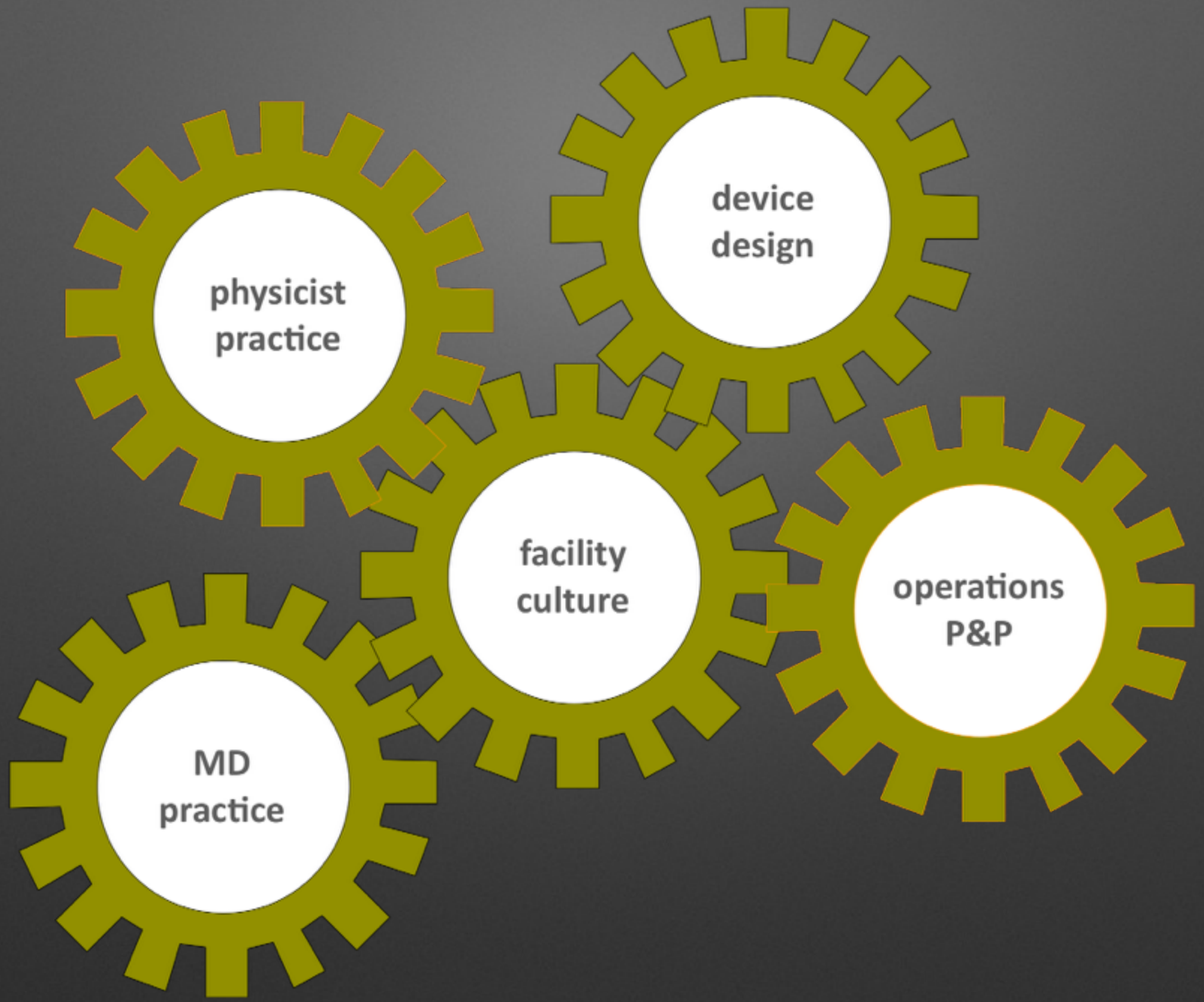
physicist
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- The hospital payment includes support for physics services.
- If adequate physics professional time is not funded from that revenue, then clearly “*Hospital finances come first.*”

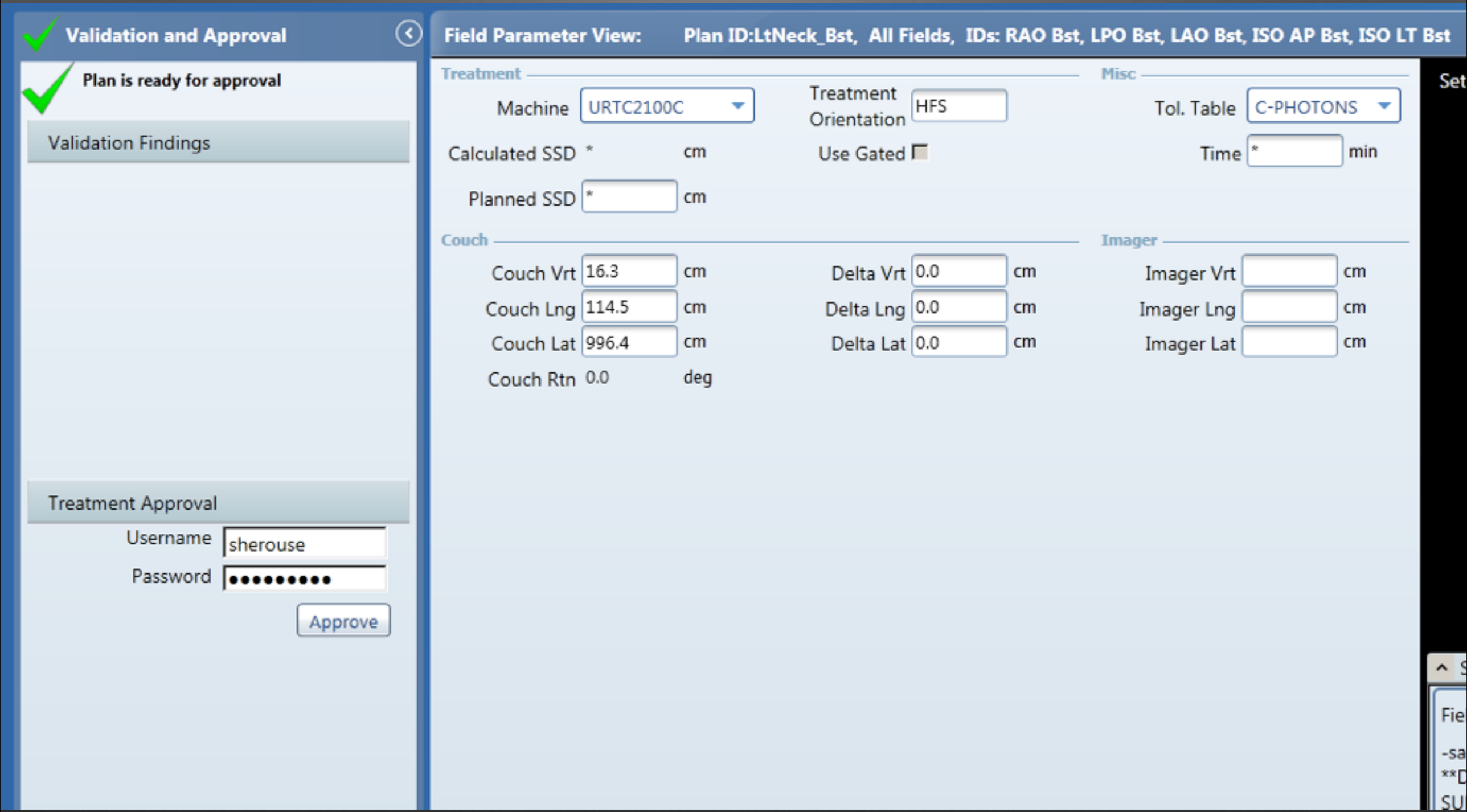
Reminder: Riverside Hospital 1974-1976

- By the time the error was discovered Axt was working 12-13 hours per day, 7 days a week on a difficult LINAC installation.

- “… before the overdoses were discovered, the hospital had for some time been considering hiring another physicist to assist Axt. But Axt, who by all accounts was a quiet, unaggressive man, apparently did not push for the new position, and nothing was done…”

http://www.columbusmonthly.com/content/stories/2010/08/the-riverside-radiation-tragedy.html

What does this mean?



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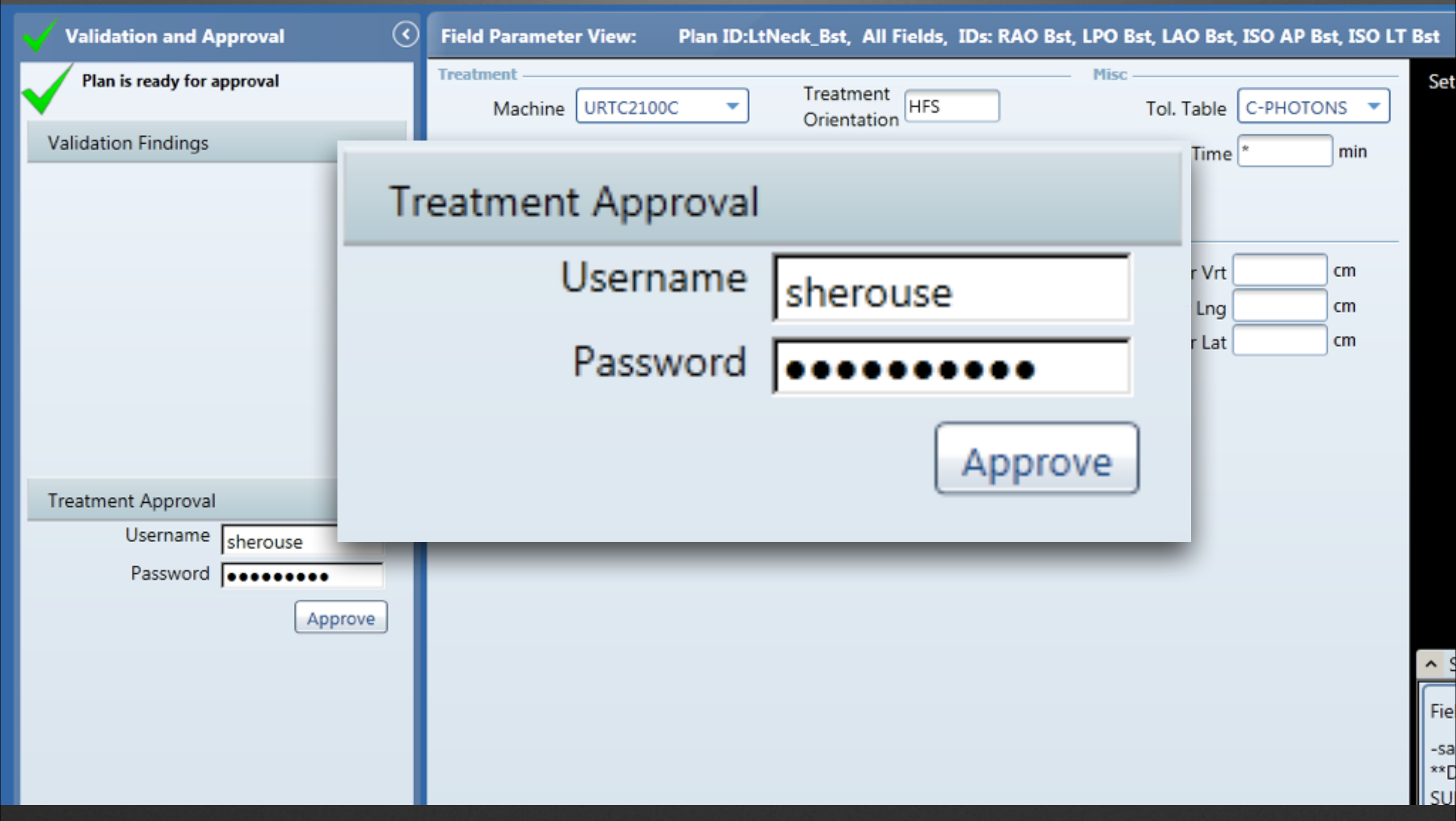

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