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
Radiation Offers New Cures, and Ways to Do Harm

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.

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...
SAFETY IS NO ACCIDENT
A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY AND CARE

DEVELOPED AND ENDORSED BY:
American Association of Medical Dosimetrist (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

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

Bruce R. Thomadson
Department of Medical Physics, University of Wisconsin, Madison, Wisconsin
Welcome!
Welcome!
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...
By the way...

- Radiotherapy is not air travel.
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- Airlines transport objects, including people. Their *raison d’être* is to do no damage to the objects they transport in the course of delivering them on a schedule.
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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.
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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...
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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.

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Riverside Hospital 1974-1976
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• Callendine had performed regular calibrations but also used semi-log graph paper to decay the activity of the cobalt unit. Axt instead used the same straight line transferred onto linear paper.

• The error was compounded in Sept 1974 when Axt switched paper and transferred the same line from 6 squares/division to 5 squares/division.
By the time the error was discovered Axt was working 12-13 hours per day, 7 days a week on a difficult LINAC installation.
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…”
Fig. 1. Progressive overdosage with time between October 1974 and February 1976.
Riverside Hospital 1974-1976
By January, 1976, when the problem was finally discovered, the overdoses were as high as 40 percent.
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• Axt claimed that he had been calibrating regularly with a defective detector and falsified backdated calibration reports.

• 426 patients received significant overdoses, 57% (243) died within the first year.
Riverside Hospital 1974-1976
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Regarding physics practice:

- A fresh grad with limited training should never have been working solo.
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- No bucks were saved.
Northside Hospital 2009
• Backing collimator was set too large (10x10?) for SRS cone and spill-over dose irradiated a large volume of a patient’s head to large single-fraction dose. The patient’s disease had not been life-threatening.
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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.
Northside Hospital 2009

- The “physicist of the day” was called to the machine to address the treatment stop.
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It appears that the exact same procedure was followed for the two subsequent patients.
Northside Hospital 2009
In summary, it appears that the physicist:

- Responded to “patient on the table” with a quick fix
Northside Hospital 2009

In summary, it appears that the physicist:

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- 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.
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.

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.
France, 2004

- A similar incident occurred in France in 2004.

- “The accidental exposure was due to an oral miscommunication 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.”

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
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Primary Boost 1 | Boost 2 | Boost 3 | Boost 4 | Boost 5

HART CHECK - NEW CHART
Dallas, Texas 2012
Dallas, Texas 2012

• State investigation found that the facility had not had required interlocks and “operators failed to follow written procedures.” Vendors sold equipment without required interlocks.
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• State initiated a round of facility surveys and fined others with the same equipment.
Dallas, Texas 2012
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Regarding physics practice:

• Should physicist have known equipment was in violation of regulations?
Dallas, Texas 2012

Regarding physics practice:

• Should physicist have known equipment was in violation of regulations?

• Should physicist have accepted equipment without interlocks?
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Regarding physics practice:

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- What was physicist’s role in developing procedure? While design is inadequate, the vendor’s operating procedure and subsequent bulletins clearly state the hazard.
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Regarding physics practice:

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• Was the physicist physically present, if not why not?
St. Vincent’s Hospital 2005
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- IMRT treatment to oropharynx delivered routinely March 8, 9, 10 and 11 of 2005
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• March 14: A new optimization is performed during which several software failures occur, new plan is approved, exported to Aria, and treated at 12:57.
St. Vincent’s Hospital 2005

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• March 15, 16: Second and third fractions of new plan are delivered.
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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
Regarding physics practice:

- One presumes that the revised plan was not checked by a QMP prior to treatment.
St. Vincent’s Hospital 2005

Regarding physics practice:

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• One presumes that the “3 day rule” was part of the SOP of the facility.
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- Why was it considered acceptable to delivery 3 fractions of highly modulated IMRT before performing any physics QA?
Regarding physics practice:

• One presumes that the revised plan was not checked by a QMP prior to treatment.

• One presumes that the “3 day rule” was part of the SOP of the facility.

• Why was it considered acceptable to deliver 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
An undisclosed location

• Three affiliated hospitals were staffed by 3 radiation oncologists and 2 physicists.
An undisclosed location

- Three affiliated hospitals were staffed by 3 radiation oncologists and 2 physicists.

- The system owned two independent sets of calibration gear which were normally assigned to a specific facility. The instruments were never intercompared.
An undisclosed location

• Three affiliated hospitals were staffed by 3 radiation oncologists and 2 physicists.

• The system owned two independent sets of calibration gear which were normally assigned to a specific facility. The instruments were never intercompared.

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

- One of the radiation oncologists who rotated between facilities had noted a significant difference in acute response between the two centers and had adapted by prescribing different doses between facilities, for instance 70 Gy at one facility for prostate and 60 Gy at the other.
An undisclosed location

- One of the radiation oncologists who rotated between facilities had noted a significant difference in acute response between the two centers and had adapted by prescribing different doses between facilities, for instance 70 Gy at one facility for prostate and 60 Gy at the other.

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

- Regarding physics practice:
  - Failed to crosscheck gear.
An undisclosed location

- Regarding physics practice:
  - Failed to crosscheck gear.
  - Perhaps inadequate external audit (RPC/RDS).
An undisclosed location

• Regarding physics practice:
  • Failed to crosscheck gear.
  • Perhaps inadequate external audit (RPC/RDS).
  • Should they have noticed the difference in prescription and pursued it?
An undisclosed location

- Regarding physics practice:
  - Failed to crosscheck gear.
  - Perhaps inadequate external audit (RPC/RDS).
  - Should they have noticed the difference in prescription and pursued it?
  - It appears did not have an adequately clinical involvement in the practices.
At V.A. Hospital, a Rogue Cancer Unit

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.
A Medical Event in 2008 in which seeds of the wrong strength (20% low) were ordered and implanted was discovered a few days after the implant by unnamed personnel and reported by the VAMC to NRC.
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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.
• In a February 2003 case 40 of 74 seeds (40!!!!) were retrieved from the bladder intra-operatively by the urologist.
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No NRC citation, no foul. This case apparently did not trigger process improvement.
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.
Philadelphia VAMC
In an October 2005 case 45 of 90 seeds (45!!!!) were retrieved from the bladder intra-operatively by the urologist and 2 more in the patient room.

The written directive was revised by Dr. Kao at the end of that procedure (45 seeds, D90 = 47 Gy). So that was not a Medical Event.

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- No NRC citation, no foul. This case apparently did not trigger process improvement.
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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- A MEDLINE search on GD Kao turns up 48 articles published 1991-2008, only a few of which in the 90s are clinical.
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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.

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

— Kao and McKenna
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.
Philadelphia VAMC
Regarding physics practice:

- Testimony revealed that physicists had significant concerns but did not raise them for fear of retribution.
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Regarding physics practice:

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• How was it not the role of the UPenn physicists to close the quality feedback loop?
Miscoalibrated 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.”

Others

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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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.

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• The physician and the hospital are paid *per patient*. 
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“The patient comes first.” fallacy

- The physician and the hospital are paid *per patient*.
- The hospital payment includes support for physics services.
The "The patient comes first." fallacy

- The physician and the hospital are paid *per patient*.
- 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."*
• 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…”
What does this mean?
The safety and integrity of the clinical medical physics practice is the professional responsibility of the Medical Physicist.
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