Incidents in Radiation Therapy

-

Lessons from the Past

ICTP School on Medical Physics
March 25 – April 5, 2019
Miramare, Trieste

Yakov Pipman, DSc

Once upon a time…

Radiotherapy accidents were so rare and far between…

…that when we learned about one, it happened in a land far away…

And the circumstances were so special and unusual…

So we were surprised and shocked, but surely this could not happen to us, nor in our environment.

Except that …

It was really not so.

There were other cases about which we did not know.

And some were repeats of similar ones,

So, why talk about this now?

Most Medical Physicists worked for many years in the background, almost unheard and unseen.

- But suddenly we became famous!!!

The New York Times FRONT PAGE

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

BY WALT BOGDANICH
JANUARY 24, 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.

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

1 of 4

Scott Jerome-Parks, with his wife, Carmen, was 43 when he died in 2007 from a radiation overdose.

Full report at: https://www.nytimes.com/2010/01/24/health/24radiation.html

THE RADIATION BOOM

They Check the Medical Equipment, but Who Is Checking Up on Them?

By WALT BOGDANICH and KRISTINA REBELO
Published: January 26, 2010

In the eyes of those who hired him, Norman Fenton was a model medical physicist — diligently protecting patients from the hazards of too much medical radiation or too little.

Related

For nearly three decades, Mr. Fenton inspected radiological equipment,

https://www.nytimes.com/2010/01/24/health/24radiation.html

The New York Times

January 24, 2010

Radiation Mistakes: One State's Tally

Even though New York State is the most stringent regulator of radioactive medical devices in the nation, many radiation mistakes go unreported there.

State records analyzed by The New York Times described 621 mistakes from January 2001 to January 2009. On average, there were about two contributing

October 2008 — Prostate Glands Misidentified

Five prostate cancer patients were treated incorrectly after a faulty ultrasound machine misidentified their prostate glands. One patient was irradiated incorrectly on 32 of 38 treatments; another on 19 of 45 treatments. After the ultrasound was repaired, quality checks were performed by the vendor, and not the consulting physics group that was servicing the facility. The therapist warned the oncologist that the treatment position appeared incorrect, but nothing was done about it.

June 2008 — Therapist Mistakes Treatment on Alternate Days

A 63-year-old woman was to undergo two different treatments on alternate days — one to the upper lung and the other to the mediastinum — an area in the chest. But because of a therapist's error, her upper lung received one-tenth the prescribed dose and her mediastinum got 10 times the prescribed dose. The patient died of cancer later in the year. The hospital now requires two radiation therapists to attend whenever a complex treatment plan is being delivered. The therapists must also use a checklist to verify the patient's identity, the type of treatment, the dose and the site to be treated.

December 2007 — Radioactive Seeds Implanted in Wrong Location

A patient's prostate cancer was underdosed by 50 percent — increasing the odds that cancer would recur — because a doctor implanted radioactive seeds in the wrong location. Consequently, the rectum and urethra received more radiation than intended. The radiation oncologist then failed to promptly interpret a post-implant CT scan, which would have revealed the error sooner.

March 2006 — Wrong Patient Receives Treatment

Patient A had just completed treatment for a brain tumor received additional radiation intended for Patient B, who had breast cancer. Patient A did not realize that treatment had been completed when a therapist closed the patient's electronic chart and pulled up the chart for Patient B. A second therapist arrived, saw the breast cancer treatment had not been administered, and mistakenly administered it to the first patient.

March 2007 — Radioactive Seeds Measured Incorrectly

A 31-year-old woman with vaginal cancer was overdosed because of confusion over the method of measuring the strength of radioactive seeds. The operator failed to enter the correct information into the treatment planning software, causing an overdose to her rectum and vagina. The patient faced an increased risk of radiation cystitis, rectal proctitis, and the formation of a fistula between the rectum and the vagina. Neither the physicist nor the radiation oncologist had prepared a treatment plan using iridium-192 — an isotope — in six years.

November 2005 — Wrong Body Part Is Radiated; Computer Is Overridden

A male patient undergoing treatment for chondrosarcoma was radiated using the wrong body marks. Instead of the left chest and upper abdomen as prescribed, the patient's lower abdomen was radiated. The therapist also overrode the computer, which had the correct aiming point, and then failed to record the override on the patient's chart.

October 2005 — Old Photos Result in Wrong Body Part Being Radiated

Instead of the upper spine as prescribed, the patient's esophagus was treated. The therapist used a tattoo from a previous round of treatment to guide the radiation. The computerized set-up notes did not mention that the patient had received earlier radiation therapy, and another system downloaded an older photograph of the esophagus rather than current photographs. Afterward, the hospital introduced measures to solve the software problems and to ensure that second treatment areas were doubly marked. The oncologist did not believe that the mistake harmed the patient.

November 2005 — Therapist Errors Result in Radiation Overdose

A female patient with laryngeal cancer received a 47 percent overdose after a therapist left out the wedges, which modify the beam, for eight treatments. A device that measures radiation produced an unexpected reading, but the therapist did not inform the physicist or the physician. The facility also lacked a written policy for verifying data entered manually into the computer system. Although it was treating 20 to 30 patients a day, a certified medical physicist was present only 20 percent of the time.

September 2005 — Temporary Workers Overdose Patient

A patient with breast cancer received a 50 percent overdose for 10 treatments because a wedge was mistakenly left out. The medical physicist failed to perform the first weekly chart check. The hospital reported that it had a staffing issue at the time of the vent and that temporary workers did not have the same training or competency checks as the permanent staff.

July 2005 — Wrong Patient Is Radiated, Again

A patient received a 22 percent overdose of radiation after he underwent a treatment intended for another patient. Both patients were scheduled to be treated for tumors of the head and neck, and the technologist called up the first patient's treatment plan on the computer system. But since the first patient was unavailable at the scheduled time, the technologist escorted the second patient into the treatment room. The second patient was then treated using the first patient's protocol. After the first treatment was completed, the technologist realized that the wrong protocol was on the computer screen and the treatment was aborted. According to the radiation oncologist, the clinical impact was minimal. But this same facility had also treated the wrong patient in November 2004 and January 2005.

August 2005 — Staff Administers Wrong Radiation Dose

A 72-year-old man with cancer of the esophagus was to receive twice-daily treatments, but instead got only one a day for five days. The facility said the physics, dosimetry and therapy staff all failed to catch the error. After learning of the mistake, the patient refused twice-daily treatments and continued with the one-a-day treatments at a revised dose. A state inspection in November 2005 found staffing problems at the time of the mistake.

The New York Times FRONT PAGE

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

BY WALT BOGDANICH
JANUARY 24, 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

March 2005 — Computer Error Not Spotted

A male patient in his early 40s received three massive overdoses of radiation to his brain stem because a device that shaped and modulated the beam was mistakenly left open. A computer crash meant that vital treatment instructions were not saved. The physicist did not double-check the treatment plan until after the third treatment. The error was clearly displayed on the treatment screen, but two therapists did not notice it. The patient eventually died from the overdose.

Nov 2001: New York State law requires a **license to practice** Medical Physics!

The New York Times — January 24, 2010

Radiation Mistakes: One State's Tally

Even though New York State is the most stringent regulator of radioactive medical devices in the nation, many radiation mistakes go unreported there.

State records analyzed by The New York Times described 621 mistakes from January 2001 to January 2009. On average, there were about two contributing factors for each.

621 RADIATION MISTAKES

Missed all or part of intended target	Wrong dose given	Wrong patient treated	
284	255	50	32 Other (5%)
46% of total	41%	8%	

1,264 CAUSES OF MISTAKES

Quality assurance flawed	Data entry or calculation errors by personnel	Misidentification of patient or treatment location	Blocks, wedges or collimators misused	Patient's physical setup wrong	Treatment plan flawed	Hardware malfunction	Staffing
355	252	174	133	96	77	60	52

Computer, software or digital information transfer malfunction **24**

Override of computer data by personnel **19**

Miscommunication **14**

Unclear/other **8**

Sources: New York State Dept. of Health; Times analysis

THE NEW YORK TIMES

Let’s consider a few common beliefs:

- ❑ Incidents in radiotherapy are very rare
- ❑ The majority of accidents happened long ago
- ❑ Most accidents happen in the developing world
- ❑ Accidents are linked to LOW tech equipment
- ❑ Accidents are linked to HIGH tech equipment

Ohio, USA - 1992

A Special Reprint

THE PLAIN DEALER

OHIO'S LARGEST NEWSPAPER

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

Dangerous medicine, deadly mistakes

P.D./BRYNNE SHAW

...peeled from the face of her 9-year-old son, Dwight.

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.

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.**

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**

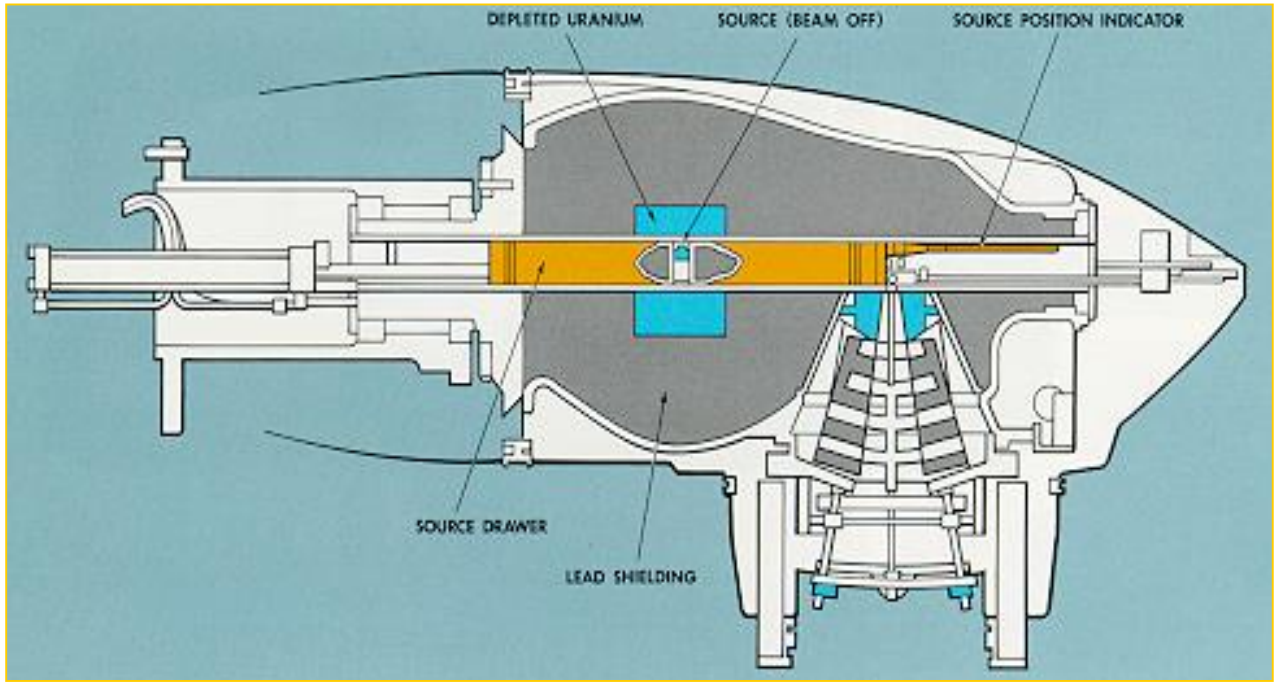
A promise from NRC, hearings before Congress

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.**

A most infamous accident: Riverside, Ohio 1974-1976

Warning for the audience !

The next few slides contain NO scandalous material nor juicy pictures about fancy equipment failures!



Chronology of events at Riverside

September 1974 — Joel C. Axt, a Riverside radiation physicist, begins using the wrong type of graph paper to calculate the strength of the radioactive cobalt used in the hospital's cancer-treatment machine. The error goes undetected until January 1976, resulting in radiation overdoses to more than 400 patients treated with the machine.

March 1975-January 1976 — Physicians and a deputy coroner at Riverside raise concerns in staff meetings about what they say are excessive side effects from radiation treatments. They are assured by administrators that the burns and other problems result from differences in how individual patients tolerate radiation.

Dec. 30, 1975 — Edna Gail Valentine, a 25-year-old elementary school teacher from Columbus, dies of radiation injuries. She is the first of at least 28 Riverside patients to die from the overdose.

Jan. 30, 1976 — Axt notifies hospital staff that patients have been overdosed. He blames the error on an equipment malfunction.

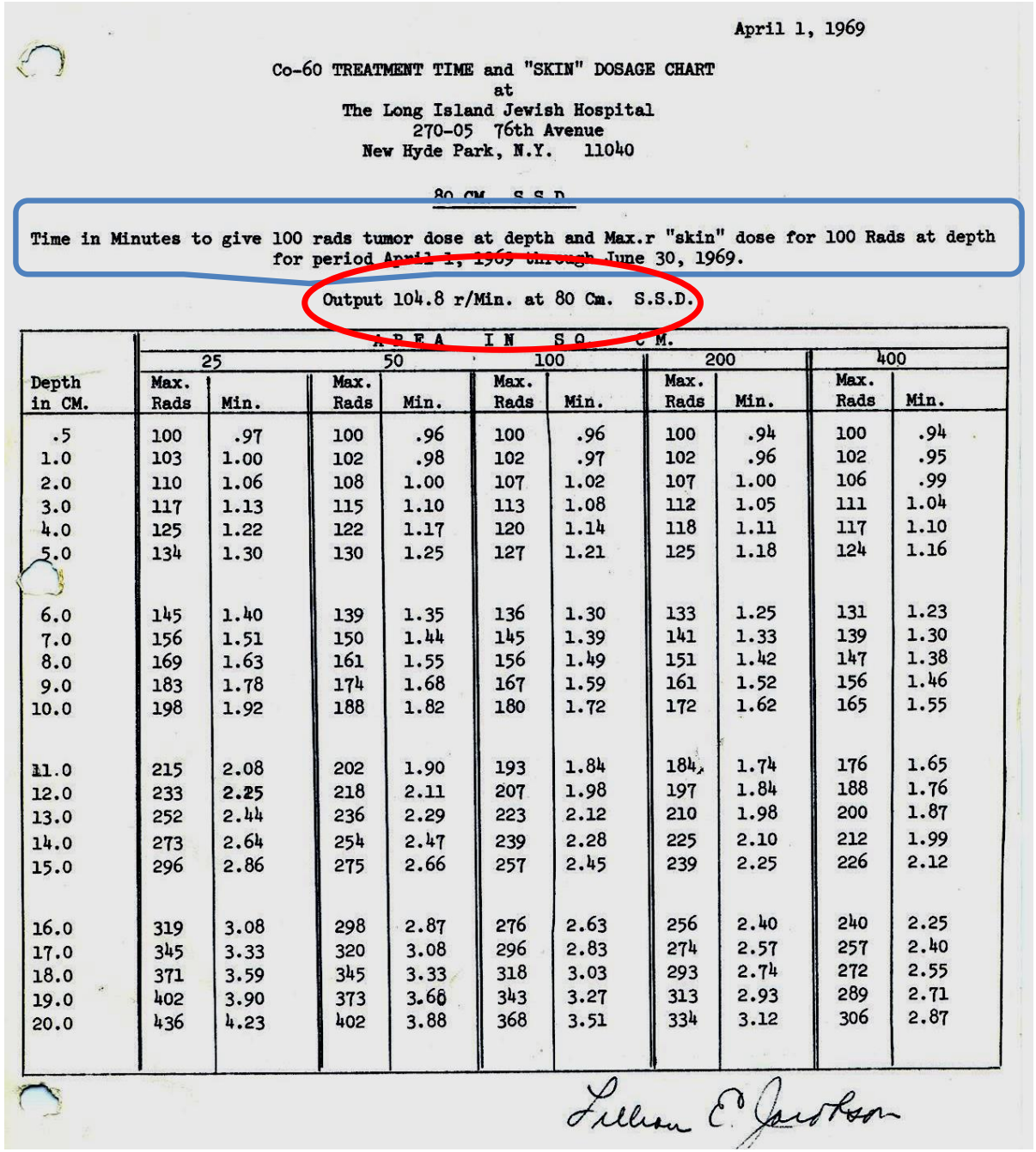
Feb. 18, 1976 — The executive committee of Riverside's Board of Trustees

By his own statement, Callendine is a perfectionist, who often insisted on checking two separate calibration systems against each other when monitoring the output of a cobalt radiation source. "I recognize that anyone can make a medical mistake," he recalls, "so we wanted to minimize this.... When George signs his name, I want to be sure. It's a personal thing."

Notwithstanding Callendine's reputation and long service, Mansfield and others in Riverside's administration had concluded by 1972 that changes had to be made. Because

Typical dosimetric calculation:

Computation of Beam- ON time for a Co-60 treatment



April 1, 1969

Co-60 TREATMENT TIME and "SKIN" DOSAGE CHART
at
The Long Island Jewish Hospital
270-05 76th Avenue
New Hyde Park, N.Y. 11040

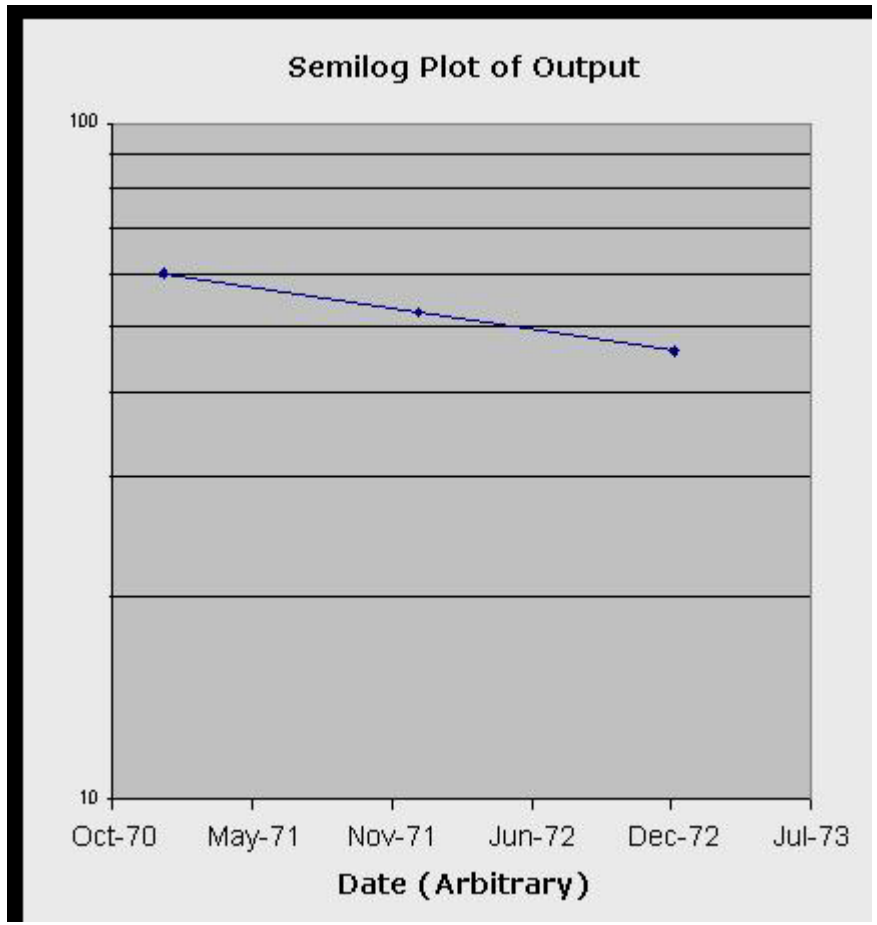
80 CM. S.S.D.

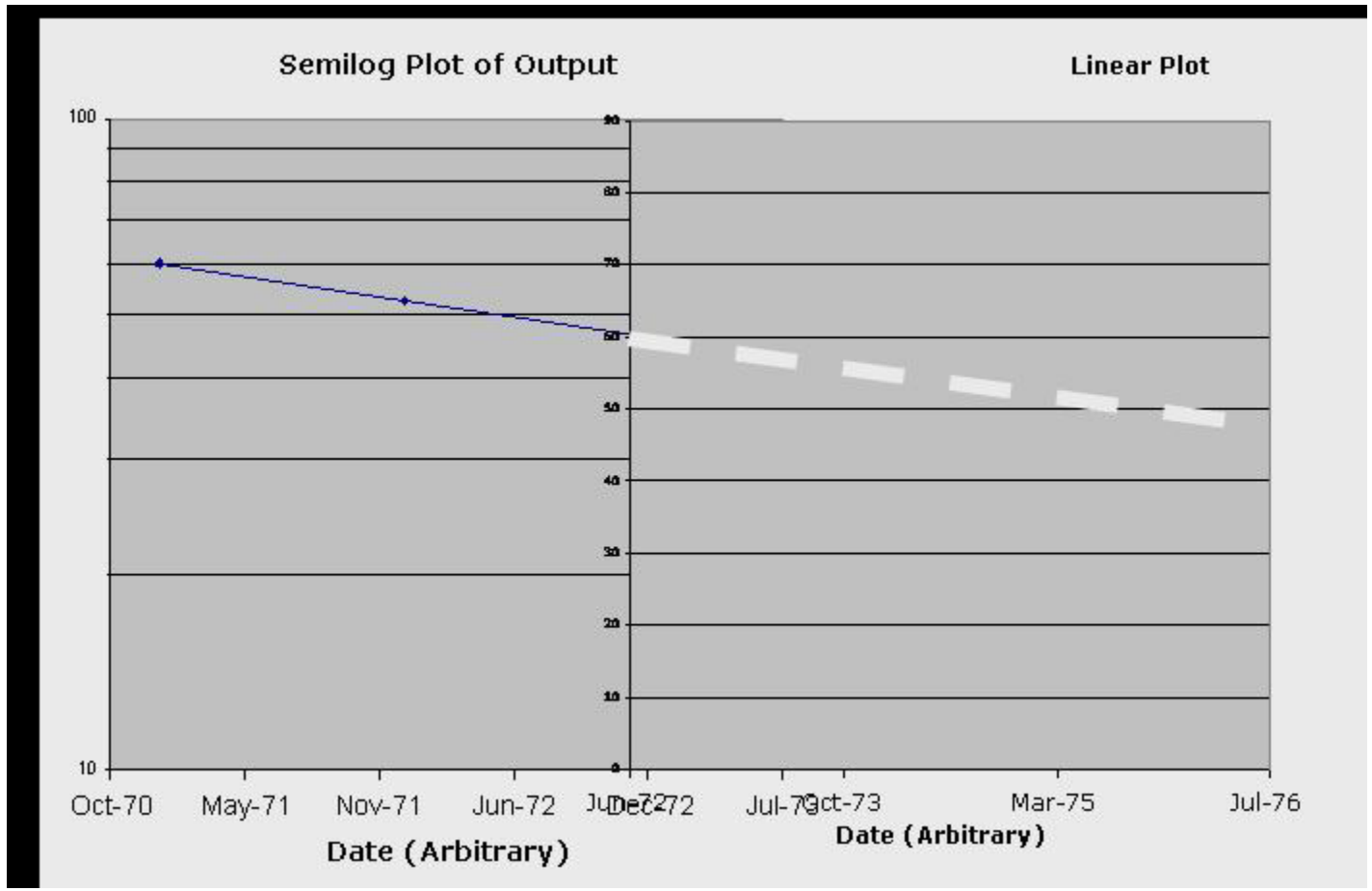
Time in Minutes to give 100 rads tumor dose at depth and Max.r "skin" dose for 100 Rads at depth for period April 1, 1969 through June 30, 1969.

Output 104.8 r/Min. at 80 Cm. S.S.D.

	AREA IN SQ. CM.									
	25		50		100		200		400	
Depth in CM.	Max. Rads	Min.	Max. Rads	Min.	Max. Rads	Min.	Max. Rads	Min.	Max. Rads	Min.
.5	100	.97	100	.96	100	.96	100	.94	100	.94
1.0	103	1.00	102	.98	102	.97	102	.96	102	.95
2.0	110	1.06	108	1.00	107	1.02	107	1.00	106	.99
3.0	117	1.13	115	1.10	113	1.08	112	1.05	111	1.04
4.0	125	1.22	122	1.17	120	1.14	118	1.11	117	1.10
5.0	134	1.30	130	1.25	127	1.21	125	1.18	124	1.16
6.0	145	1.40	139	1.35	136	1.30	133	1.25	131	1.23
7.0	156	1.51	150	1.44	145	1.39	141	1.33	139	1.30
8.0	169	1.63	161	1.55	156	1.49	151	1.42	147	1.38
9.0	183	1.78	174	1.68	167	1.59	161	1.52	156	1.46
10.0	198	1.92	188	1.82	180	1.72	172	1.62	165	1.55
11.0	215	2.08	202	1.90	193	1.84	184	1.74	176	1.65
12.0	233	2.25	218	2.11	207	1.98	197	1.84	188	1.76
13.0	252	2.44	236	2.29	223	2.12	210	1.98	200	1.87
14.0	273	2.64	254	2.47	239	2.28	225	2.10	212	1.99
15.0	296	2.86	275	2.66	257	2.45	239	2.25	226	2.12
16.0	319	3.08	298	2.87	276	2.63	256	2.40	240	2.25
17.0	345	3.33	320	3.08	296	2.83	274	2.57	257	2.40
18.0	371	3.59	345	3.33	318	3.03	293	2.74	272	2.55
19.0	402	3.90	373	3.68	343	3.27	313	2.93	289	2.71
20.0	436	4.23	402	3.88	368	3.51	334	3.12	306	2.87

Lillian E. Jackson


Semilog Plot of Output
100
10
Oct-70
May-71
Nov-71
Jun-72
Dec-72
Jul-73
Date (Arbitrary)


Semilog Plot of Output
Linear Plot
100
10
Oct-70
May-71
Nov-71
Jun-72
Dec-72
Jul-73
Mar-75
Jul-76
Date (Arbitrary)
Date (Arbitrary)

Because both Callendine and his equipment were gone when he arrived, Axt was forced to reconstruct Riverside's radiation physics program almost from scratch. His clinical experience had been limited to a 14-month stint at the University of California Medical Center at San Francisco not enough to qualify for American Board of Radiology certification. Part of his training there involved working with cobalt-60.

often a cobalt-60 source should be calibrated to check its output, but an average recommendation might be once every two or three months. Yet, in the 27 months between his arrival and the discovery of the radiation overdoses in January, 1976, Axt apparently calibrated the source only twice and not at all after May, 1974.

Why did Axt stop making cobalt-60 calibrations? Mainly, he told attorneys who interviewed him at length in June, 1977, he stopped because his time was fully occupied by other, higher-priority projects. Very soon after his arrival at Riverside, Axt was given considerable responsibility for the acquisition, installation and testing of a new linear accelerator—one of the most advanced and complex high-energy nuclear therapy machines available.

At first, because the overdoses were marginal and because therapeutic radiation in *any* dosage almost always produces some unwanted side effects, the overdoses went unnoticed. But by late 1975, the number and intensity of complaints from Riverside's cancer patients and their doctors were increasing.

One patient, Ohio Bell telecommunications specialist Jim Baily, says his cobalt treatments left him "weak as a kitten" and produced "incapacitating diarrhea." After receiving two sets of treatments, estimated later at 26 per cent and 40 per cent overdoses, Baily recalls, "I told Dr. Fahey about these effects and his reply was that they were normal.

Dr. Steven Andresen, a radiation therapist who joined the Riverside staff under Fahey in September, 1975, later told NRC investigators he almost immediately noted more significant patient reactions than he had seen elsewhere. Because the number of such reactions seemed to be increasing, Andresen says, he asked Axt in late January, 1976, when he last "put a meter under" the cobalt-60 teletherapy device to check its output.

When Axt could not give him a specific date for the last calibration, Andresen became concerned and directed him to make one immedi-

expert on the biological effects of radiation, arrives at Riverside to begin an investigation. Saenger immediately appears at a news conference with Riverside officials and praises them for their quick actions and concern for patients.

May 6, 1976 — Axt admits to hospital officials that his error, not an equipment malfunction, caused the overdoses. He also admits falsifying hospital records to cover up his mistake.

Aug. 16, 1976 — NRC releases results of its investigation: 413 patients received radiation overdoses of up to 41%. The agency cites the hospital for three infractions, none of which relate to the overdoses. The hospital is required to correct the violations, but no fine is issued. Dr. Laurence J. Fahey, the radiation oncologist who oversaw the treatments, dies of a heart attack the same day at age 37.

April 19, 1978 — Riverside pathologist and Deputy Coroner Dr. Robert E. Zipf Jr. resigns, saying the hospital pressured him to drop his investigation into the radiation deaths. In a speech at a national coroner's convention, Zipf had said at least 10 people died from radiation overdoses. The NRC never attempted to verify Zipf's finding.

doses. The hospital is required to correct the violations, but no fine is issued. Dr. Laurence J. Fahey, the radiation oncologist who oversaw the treatments, dies of a heart attack the same day at age 37.

-il 19, 1978 — Riverside pathologist

deaths. In a speech at a national coroner's convention, Zipf had said at least 10 people died from radiation overdoses. The NRC never attempted to verify Zipf's finding.

Who were the 28 who died?

More than 400 patients received overdoses of radiation in the mid-1970s during cancer treatments at Riverside Methodist Hospitals in Columbus.

U.S. Nuclear Regulatory Commission officials say only two people died of radiation injuries. A Plain Dealer investigation found 26 other people whose medical records show that radiation overexposure contributed to their deaths. Here are their names:

Baby Girl Valentine, was delivered stillborn Dec. 1, 1975, at 7½ months as a result of radiation overdose administered to her mother.

Edna Gail Valentine, 25, of Columbus. Elementary school teacher and mother of Baby Girl Valentine. Died Dec. 30, 1975.

Ruth T. Howell, 59, of Columbus. Saleswoman. Died March 9, 1976.

Agnes Carro, 48, of Columbus. Bookkeeper and mother of two. Died April 19, 1976.

Margaret E. Baby, 56, of Worthington, O. Retired registered nurse. Died May 11, 1976.

Betty L. Drabek, 55, of Columbus. Homemaker and mother of four. Died May 16, 1976.

U.S. Nuclear Regulatory Commission officials say only two people died of radiation injuries. A Plain Dealer investigation found 26 other people

At Riverside, whose fault was it?

- Axt ? – no question
- …but he got quite an amount of help! Really a team effort!

- Administration hired unqualified staff
- Conflicting priorities on workload – New Linac vs. “routine” work
- Not enough staff to do it all
- There was no external audit
- No peer review or analysis of morbidities
- There was no significant QC program and no attempt to use redundant methods of verifying critical data
- Physician ignored `suspicious’ clinical signs

East Texas Cancer Center, Tyler, Texas

In the summer of 1986, Voyne Ray Cox, 33, and Vernon Kidd, 66, died in separate incidents shortly after receiving lethal overdoses of radiation due to a computer malfunction in the center's Therac 25 linear accelerator. In April 1987, another man, Glen A. Dodd, died at Yakima Valley Memorial Hospital in Yakima, Wash., after that hospital's Therac 25 experienced a similar computer malfunction. Previously, in December 1985, the machine had injured another Yakima Valley patient, Dora Moss, during treatments to treat a cancer in her hip.

In yet another case in June 1985, Katy Yarbrough received a huge overdose from a Therac 25 at the Kennestone Regional Oncology Center in Marietta, Ga. Yarbrough survived but lost the use of her left arm and had to have a mastectomy of the left breast. She died in a car accident in 1990 at age 67.

In March, the House subcommittee on oversight and investigations criticized the U.S. Food and Drug Administration's Center for Devices and Radiological Health, which regulates the manufacturers of radiation-emitting devices such as linear accelerators, for its tardy response to the

The Therac-25 accidents

- June 1985-January 1987
- 6 accidents of massive overdoses.
- Deaths and serious injuries.
- The “worst series of radiation accidents” in the 35-year history of medical accelerators.

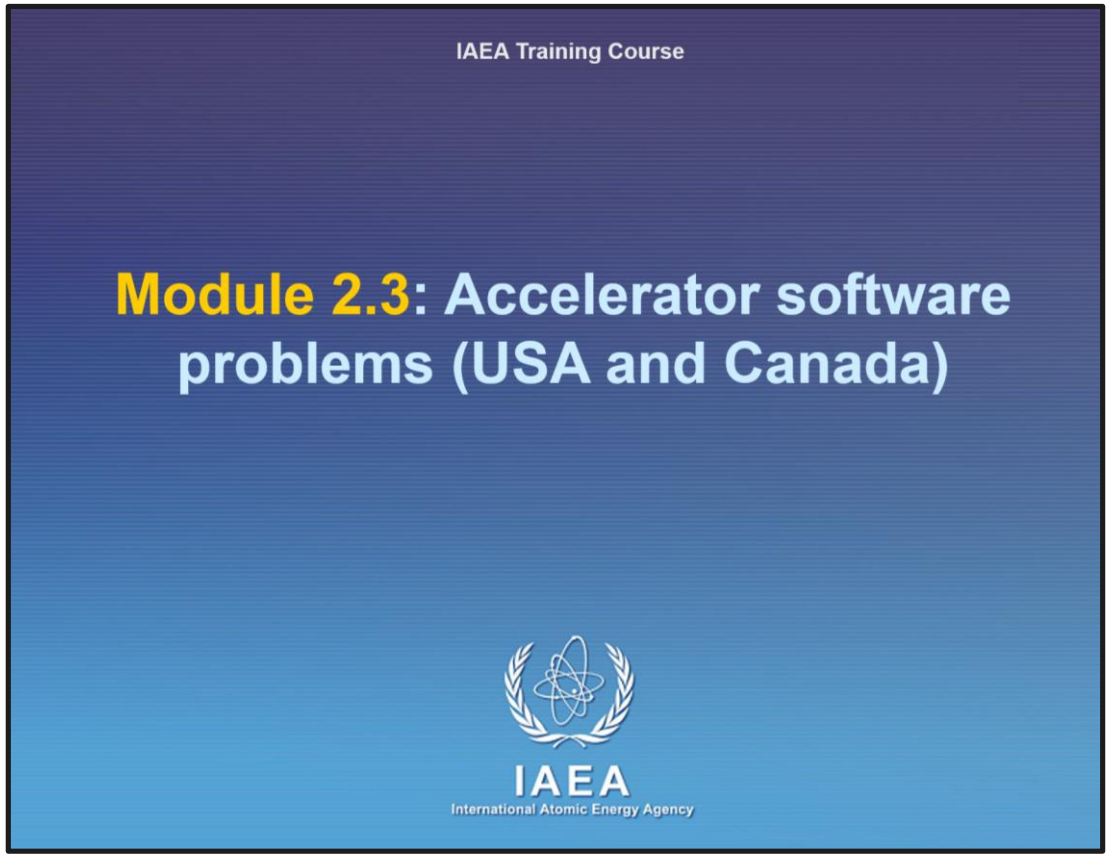
1. Kennestone Center, Marietta,GA
2. Hamilton Cancer center, Ontario
3. Yakima Valley, Washington
4. East Texas Cancer Center, Tyler,TX

(http://rpop.iaea.org)

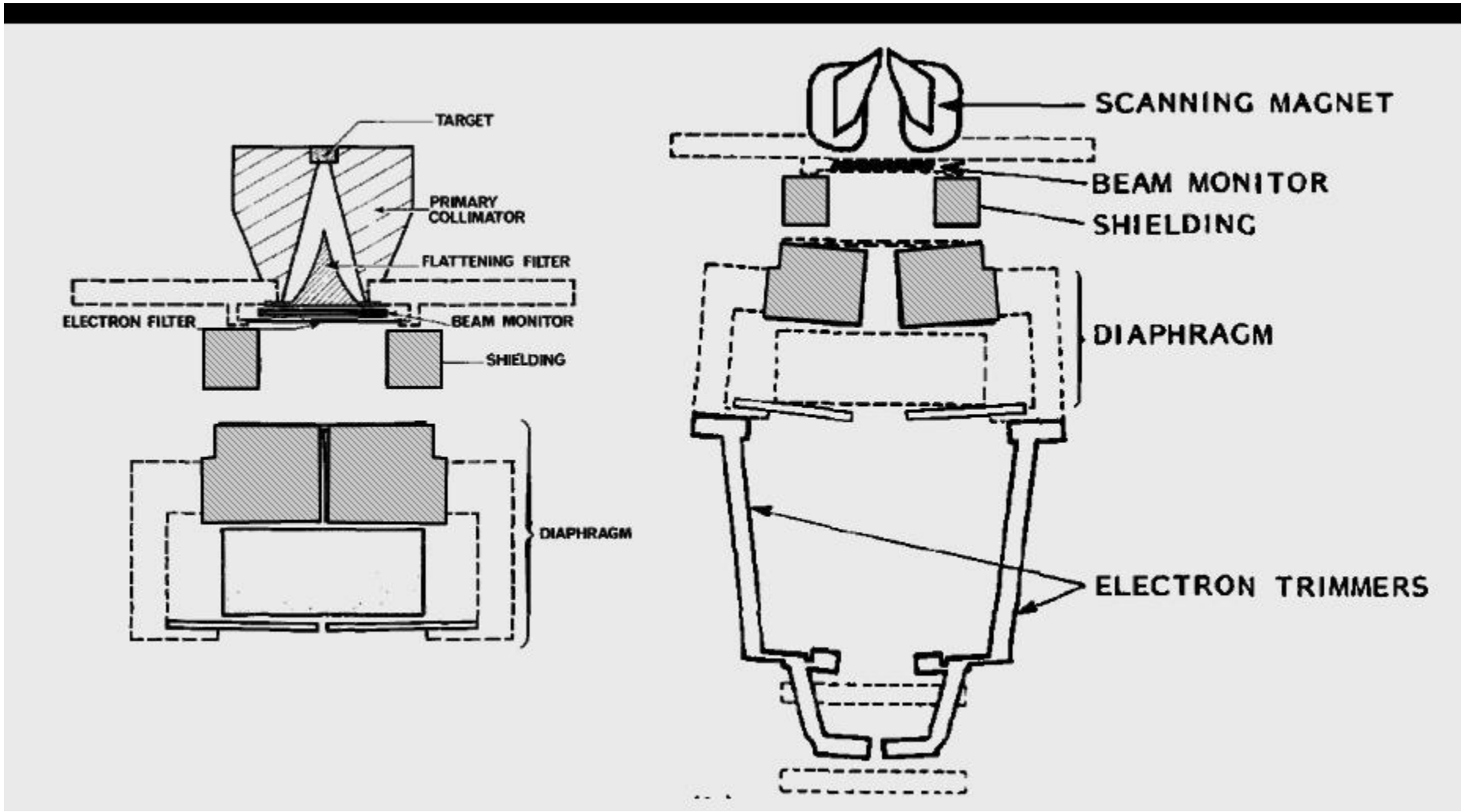
Part 2: Case studies of major accidental exposures in radiotherapy

- Nine major case studies – descriptions of events, discovery of problems, consequences and lessons to learn

- Discussion on some newer case studies (2004-2007)



Photon vs. electron - treatment head

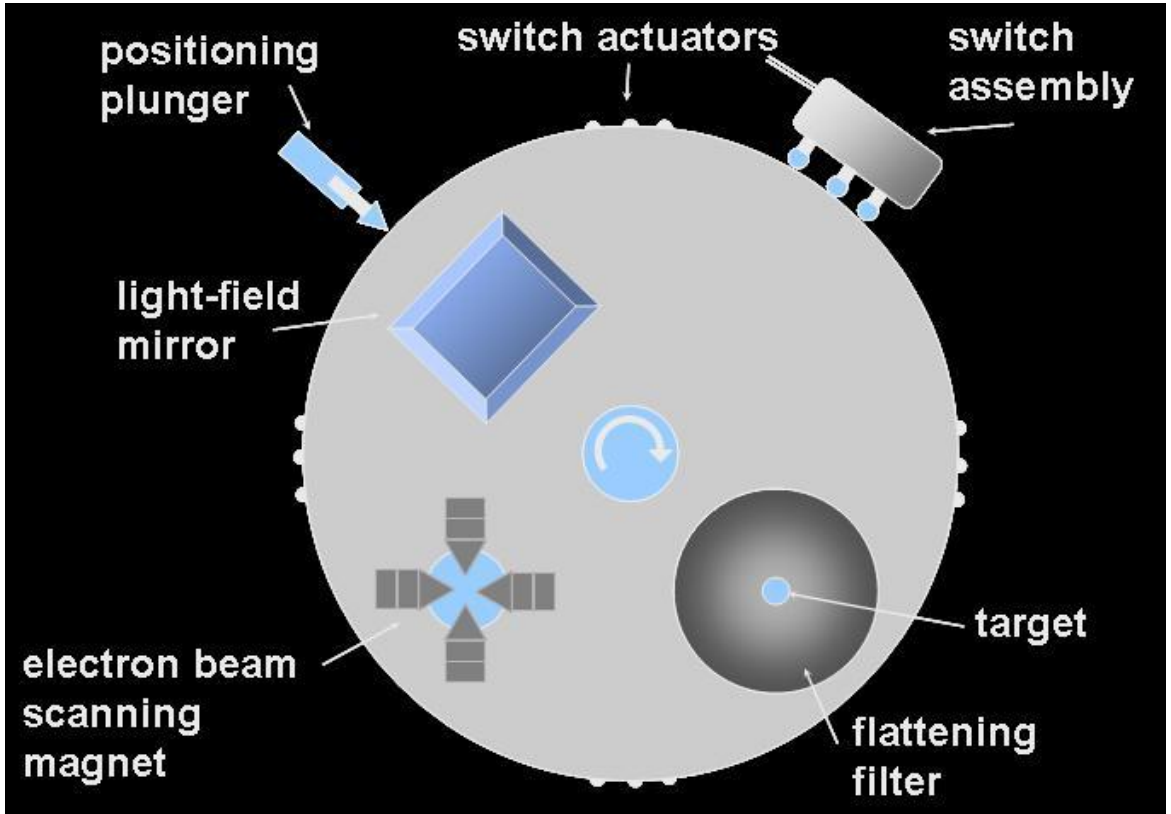


Prevention of accidental exposure in radiotherapy

A combination of technical features

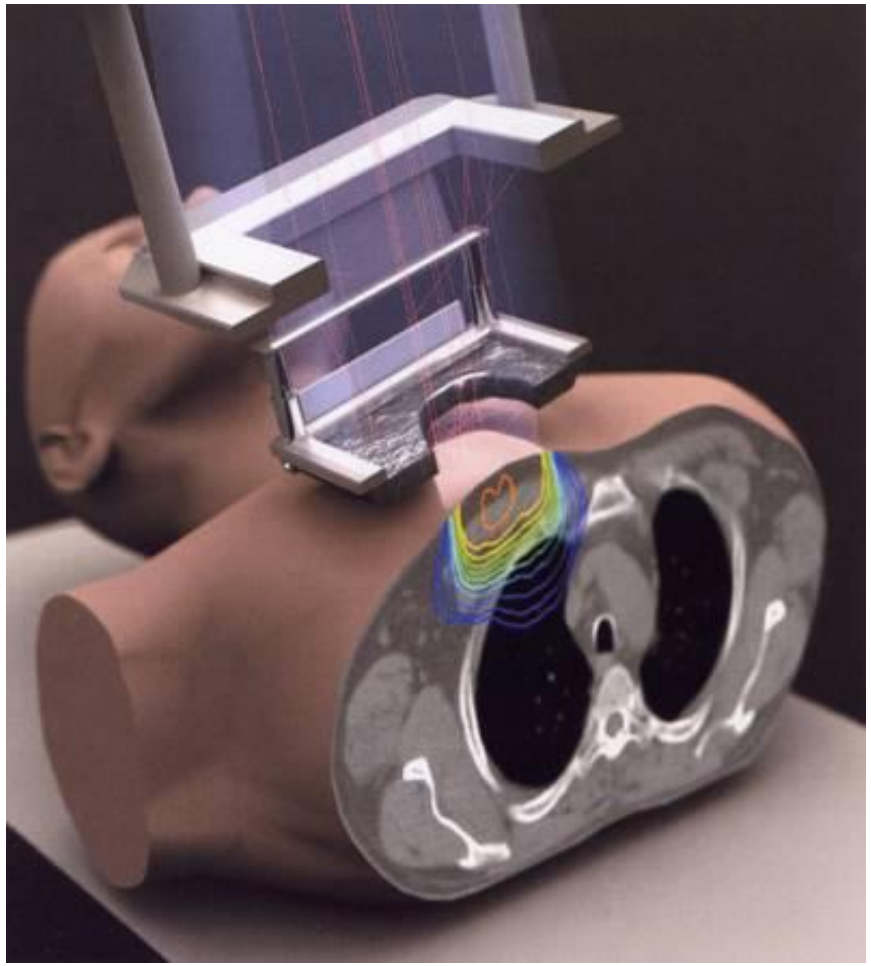
1. The Therac's scanning electron beam mode
   - The electron pencil beam is scanned by two computer controlled electromagnets in two orthogonal directions to cover the treatment field

2. The beam current in the photon mode about 1000 times higher than in e-mode.



1 - Marietta, June 1985

- Approximately 6 months experience with the new machine
- A breast cancer patient treated with 10 MeV electrons commented: You burned me!
- After the radiation session, the treated area felt warm when the technologist checked



Time line of events

The Therac-25 Accidents Timeline

1985

- JUN 3rd: Marietta, Georgia, overdose. Physicist asks AECL if non-scanning e-beam could be delivered and overdose given. AECL's Aswer: Not Possible
- No official report filed since it is not required.
- JUL 26th: Hamilton, Ontario, Canada, overdose. AECL notified and determines a micro-switch failure was the cause.
- OCT - Georgia patient files suit against AECL and hospital.
- DEC - Yakima, Washington. Severe and abnormal skin reaction interpreted as an overdose.

The Therac-25 Accidents Timeline

1986

- FEB 24th: Letter from AECL to Yakima saying overdose was impossible and no other incidents had occurred.
- MAR 21st: Tyler, Texas, overdose. Experienced staff, noticed obscure "Malfunction 54" console message. AECL notified and claims overdose impossible and no other accidents had occurred. Suggests hospital might have an electrical problem.
- APR 7th: Tyler machine put back in service after no electrical problem could be found.
- APR 11th: Second Tyler, TX overdose. AECL again notified. Physicist and Therapist manage to reproduce the error. Software problem found. Dose estimate: More than 4,000 cGy !!

The Therac-25 Accidents Timeline

1986

- MAY 2nd: FDA declares Therac-25 defective. Asks for CAP and proper re-notification of Therac-25 users.
- JUN – DEC: Multiple exchanges between AECL and FDA about corrective action and user notification

1987

- JAN 17th: Second overdose at Yakima.
- FEB - Hamilton clinic investigates first accident and concludes there was an overdose.

The Therac-25 Accidents Timeline

1987

- FEB 10th: FDA sends notice of adverse findings to AECL declaring Therac-25 defective under US law and asking AECL to notify customers that it should not be used for routine therapy. Health Protection Branch of Canada does the same thing. This lasts until August 1987.
- JUL 21st: Fifth (and final) revision of CAP sent to FDA.

1988

- NOV 3rd: Final safety analysis report issued.

Characteristics of the accidents

- Three cases involved carousel rotation prior to treatment (confirmed)
- The accelerator malfunctioned shortly after “beam on”, reporting a malfunction code at the console
  - The codes were cryptic and not recognized by the operator as indicating a serious error
- In several cases, the operator repeated the exposure one or more times
- Following treatment, the patients complained of burning sensations, sometimes accompanied by a feeling of electric shock
- In each case, the patients received doses of between 40 and 250 Gy in a very brief exposure (1-3 seconds)

Summary of causes of accidental exposure

- Manufacturer recycled software
  - Earlier model functioned somewhat differently, so software was not entirely suitable
  - Newer model relied entirely on software for safety, whereas older model had mechanical and electrical interlocks
  - The safety of the newer system was not evaluated as a whole, only the hardware was evaluated since software had been in use for years…
- The manufacturer had no mechanism for investigating and reporting accidents
  - After the first accident, the manufacturer refused to believe the equipment was at fault
  - The FDA was not notified, nor were other users
  - The vendor kept their opinion that this machine was safe

Who was at fault in the Therac -25 accidents?

- AECL? – no question
- …but plenty of "help"! Again a real "team effort"!
- Patient complaints were not investigated immediately by the appropriate staff
- Very atypical clinical outcomes did not trigger an immediate and thorough inquiry
- Three of the four clinics failed to investigate vigorously and immediately some suspicious linac performance. The facilities did not assume the primary responsibility for equipment function and accepted the manufacturer's explanations for quite some time.
- There were no regulations for error reporting
- No communication between institutions or user groups

…a Textbook Case In Engineering, Software design, and Professionalism!

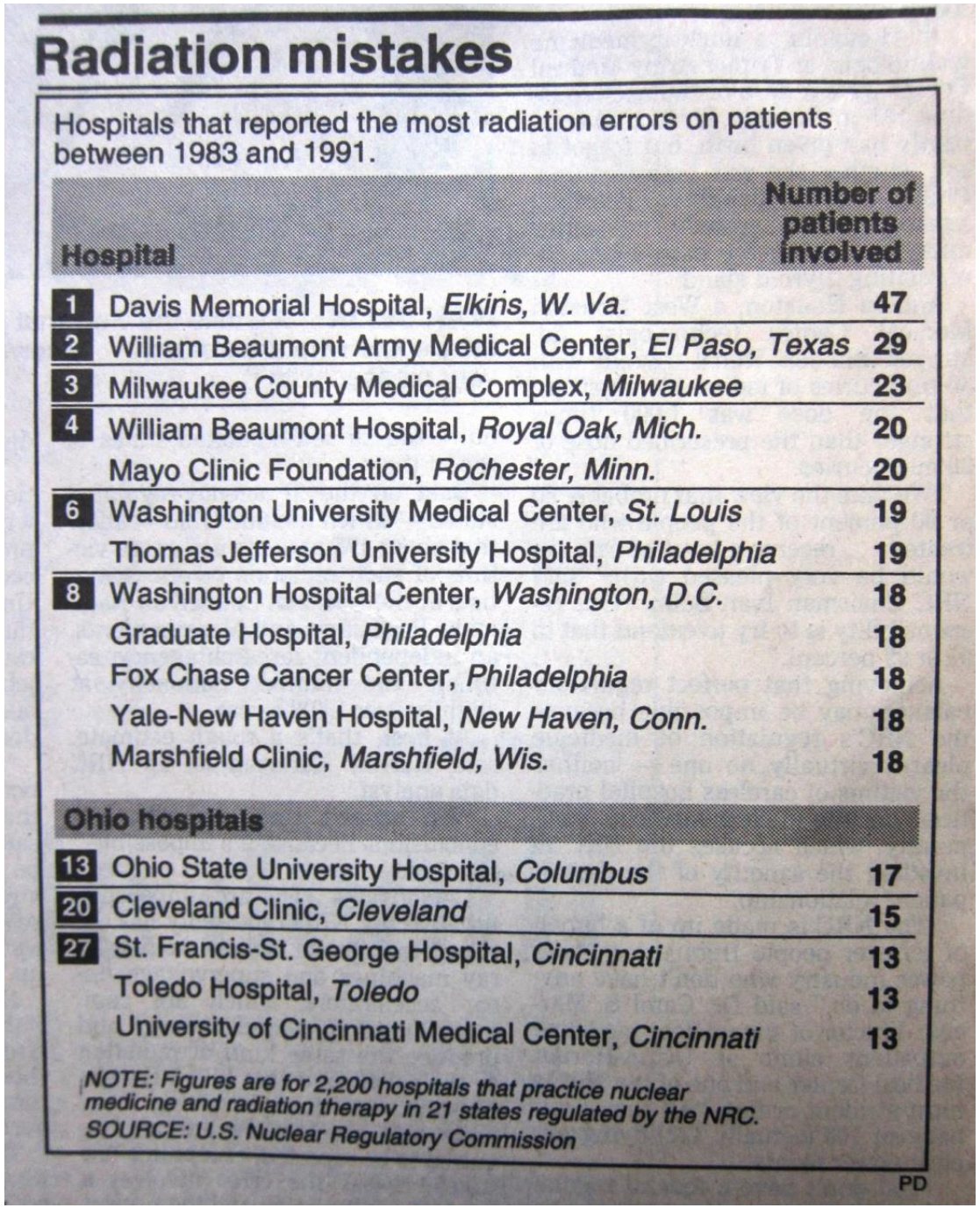
An Investigation of the Therac-25 Accidents

Nancy G. Leveson, University of Washington
Clark S. Turner, University of California, Irvine

Institutions: small and large, rural and academic.

Who reports and who does not?

That list did not include linear accelerator cases, since it is only from the NRC!



Radiation mistakes

Hospitals that reported the most radiation errors on patients between 1983 and 1991.

	Hospital	Number of patients involved
1	Davis Memorial Hospital, *Elkins, W. Va.*	47
2	William Beaumont Army Medical Center, *El Paso, Texas*	29
3	Milwaukee County Medical Complex, *Milwaukee*	23
4	William Beaumont Hospital, *Royal Oak, Mich.*	20
	Mayo Clinic Foundation, *Rochester, Minn.*	20
6	Washington University Medical Center, *St. Louis*	19
	Thomas Jefferson University Hospital, *Philadelphia*	19
8	Washington Hospital Center, *Washington, D.C.*	18
	Graduate Hospital, *Philadelphia*	18
	Fox Chase Cancer Center, *Philadelphia*	18
	Yale-New Haven Hospital, *New Haven, Conn.*	18
	Marshfield Clinic, *Marshfield, Wis.*	18
	Ohio hospitals	
13	Ohio State University Hospital, *Columbus*	17
20	Cleveland Clinic, *Cleveland*	15
27	St. Francis-St. George Hospital, *Cincinnati*	13
	Toledo Hospital, *Toledo*	13
	University of Cincinnati Medical Center, *Cincinnati*	13

NOTE: Figures are for 2,200 hospitals that practice nuclear medicine and radiation therapy in 21 states regulated by the NRC.
SOURCE: U.S. Nuclear Regulatory Commission

PD

Wendling

Davis

Shaw

An extensive effort

Plain Dealer reporters Dave Davis and Ted Wendling traveled from San Francisco to Burgettstown, Pa., and from Washington, D.C., to West Palm Beach, Fla., to gather records and conduct interviews for this series. They interviewed more than 150 people, including doctors, lawyers, government officials and radiation victims. Brynne Shaw photographed the victims and their families.

The reporters gathered more than 10,000 pages of court records, inspection reports and investigative files kept by the U.S. Nuclear Regulatory Commission and numerous state agencies.

They filed more than 100 requests under the federal Freedom of Information Act and state public records laws, including numerous appeals when documents were denied. One of the appeals prompted the NRC to reverse its policy of withholding names of people who have died.

The reporters also used a computer to analyze and search more than 1.5 million NRC records. Olivia Wallace provided research and library assistance. This series was directed by City Editor John Griffith.

How hard was it to investigate these cases?

Commission and numerous state
es.

They filed more than 100 requests under the federal Freedom of Information Act and state public records laws, including numerous appeals when documents were denied. One of the appeals prompted the NRC to reverse its policy of withholding names of people who have died.

The reporters also used a computer to analyze and search more than 1.5 million NRC records. Olivia Wallace provided research and library assistance. This series was directed by City Editor John Griffith.

A gamut of other cases

- Bend, Oregon, 1980's: incorrect T/P correction. 13% overdose
- Spain, 1990: Linac `repair' led to 36MeV e- beam no matter what was programmed. No dosimetry check. 27 patients, 15 deaths
- Costa Rica, 1996: Incorrect Co-60 source calibration. Confusion between 0.30 min and 30 seconds. About 115 patients received 60% higher doses, 17 deaths among them.
- Panama, 2000-01: Unverified change of a procedural detail in Treatment planning . 28 patients received "double their doses" . Eight deaths and many major complications.
- France, 2004: Incorrect MU for dynamic wedge. 23 patients overdosed 20%, 4 deaths
- Glasgow,2006: Incorrect calculation of MU's. Planner thought TPS calculated MU/Gy and not MU/fraction. It didn't! 67% overdose results in death
- UK, 1982-90: incorrect SSD correction (did not know how TPS worked). 1045 patients, 30% underdose, >492 RT failures
- France, 2006-7: large ion chamber used for SRS. 145 overdoses.

A global issue!

http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/AccidentPreventionRadiotherapy.htm

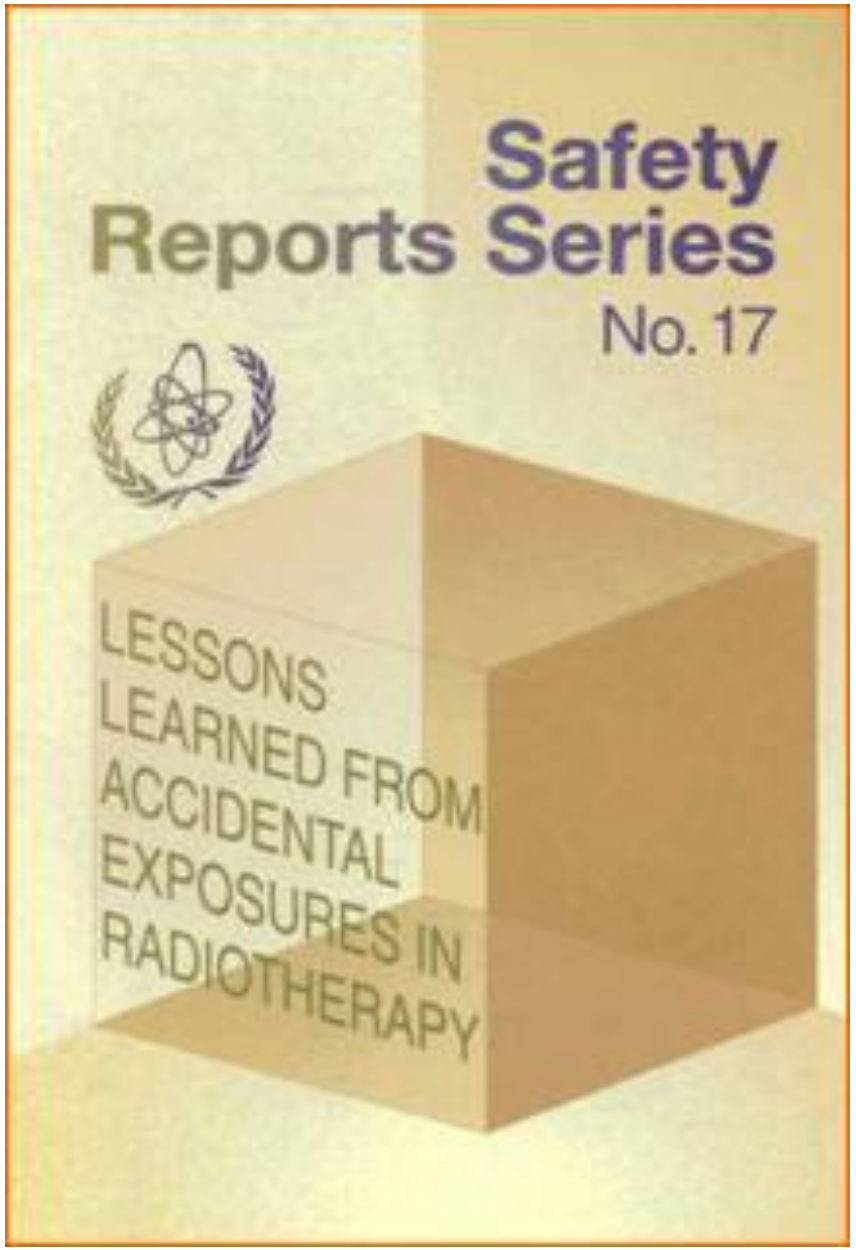
Incidents are a global issue

Table 1. Data on adverse events in health care from several countries

Study	Study focus (date of admissions)	Number of hospital admissions	Number of adverse events	Adverse event rate (%)
USA (New York State) (Harvard Medical Practice Study) (*1,2*)	Acute care hospitals (1984)	30 195	1 133	3.8
USA (Utah-Colorado Study (UTCOS)) (*10*)	Acute care hospitals (1992)	14 565	475	3.2
USA (UTCOS)[1] (*10*)	Acute care hospitals (1992)	14 565	787	5.4
Australia (Quality in Australian Health Care Study (QAHCS)) (*3*)	Acute care hospitals (1992)	14 179	2 353	16.6
Australia (QAHCS)[2] (*10*)	Acute care hospitals (1992)	14 179	1 499	10.6
UK (*4*)	Acute care hospitals (1999-2000)	1 014	119	11.7
Denmark (*12*)	Acute care hospitals (1998)	1 097	176	9.0
New Zealand (*6,7*)	Acute care (1998)	6 579	849	12.9
Canada (*8*)	Acute and community hospitals (2001)	3 720	279	7.5

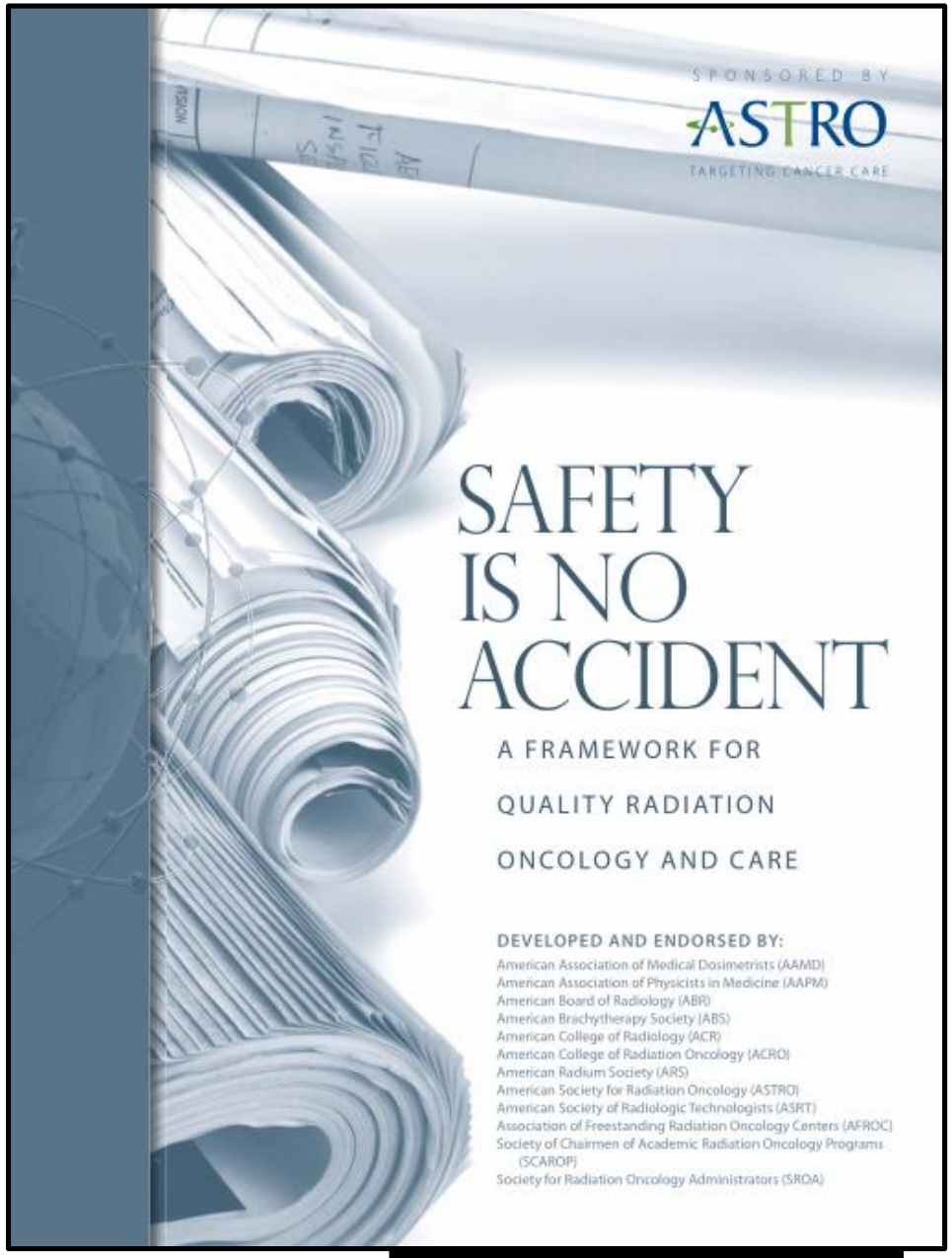
Part 3: Analysis of causes and contributing factors

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



What can we learn?

- Accidents happen
- When they happen there is more than one factor
- Many more ‘almost accident’s than big ones
- Some common factors:
  - Training,
  - Communication, internal and external
  - Barriers,
  - Authority To Question, Or Lack-of
  - Lack Of Redundancies
  - Distractions / Attention
  - Procedural Variations
- Lack of clarity in analysis and reports of what happened



Zietman et al. 2012

Practical Radiation Oncology (2011) 1, 16–21

pro
www.practicalradonc.org

Special Article

Improving patient safety in radiation oncology

William R. Hendee PhD[a], Michael G. Herman PhD[b,*]

[a]*Medical College of Wisconsin, Rochester, Minnesota*
[b]*Department of Radiation Oncology, Mayo Clinic, Rochester, Minnesota*

Received 5 November 2010; accepted 12 November 2010

Abstract Beginning in the 1990s, and emphasized in 2000 with the release of an Institute of Medicine report, health care providers and institutions have dedicated time and resources to reducing errors that impact the safety and well-being of patients. However, in January 2010, the first of a series of articles appeared in *The New York Times* that described errors in radiation oncology that grievously impacted patients. In response, the American Association of Physicists in Medicine and the American Society for Radiation Oncology sponsored a working meeting entitled "Safety in Radiation Therapy: A Call to Action." The meeting attracted 400 attendees, including medical physicists, radiation oncologists, medical dosimetrists, radiation therapists, hospital administrators, regulators, and representatives of equipment manufacturers. The meeting was co-hosted by 14 organizations in the United States and Canada. The meeting yielded 20 recommendations that provided a pathway to reducing errors and improving patient safety in radiation therapy facilities everywhere.

The problem

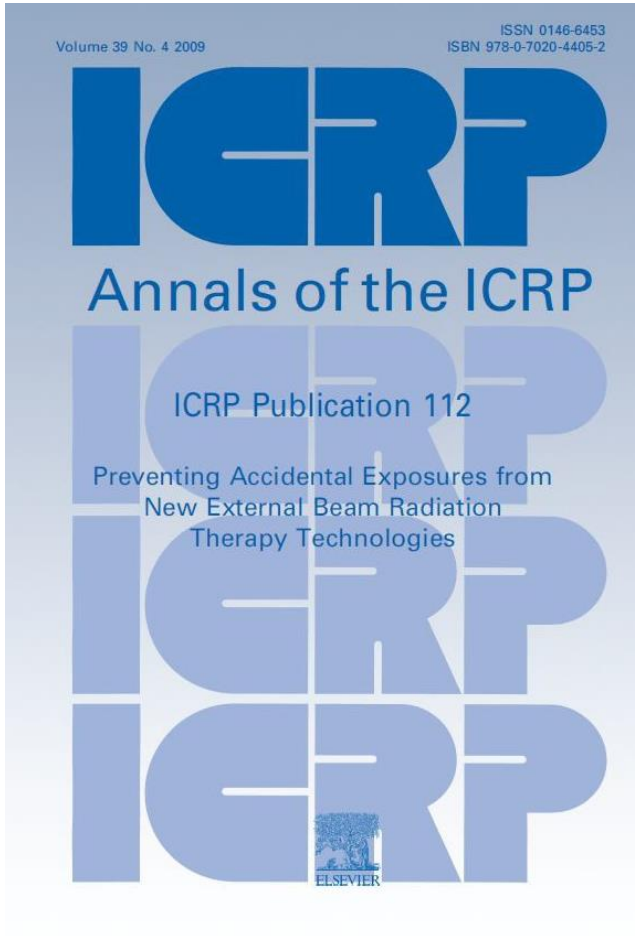
In the early 1990s, articles began to appear in the scientific literature[1,2] describing the frequency of medical mistakes that place patients at risk. Soon thereafter, reports surfaced in the public media regarding medical errors (eg, chemotherapy overdose, wrong-sided surgery, anesthesia error) that caused the death or severe disability of patients. Partly in response to these reports, an international conference was held in 1993 (in Rancho Palos Verdes, CA) to examine the causes and consequences of severe errors in medicine. The conference was hosted by the American Medical Association and had several organizational co-sponsors. This conference spawned the National Patient Safety Foundation[3] and several other initiatives (eg, the Veterans Administration National Patient Safety Partnership) that devoted substantial resources to the identification and mitigation of medical errors. The National Academy of Sciences Institute of Medicine formed the Committee on Quality of Health Care in America that published a seminal report in 2000, entitled "To Err is Human: Building a Safer Health System."[4] This report estimated that between 44,000 and 98,000 patients died in the United States in 1997 as a consequence of medical errors, and it captured the attention of health care providers and public interest groups. For the past decade, programs to reduce medical errors have been established in most of the nation's hospitals and health care organizations.

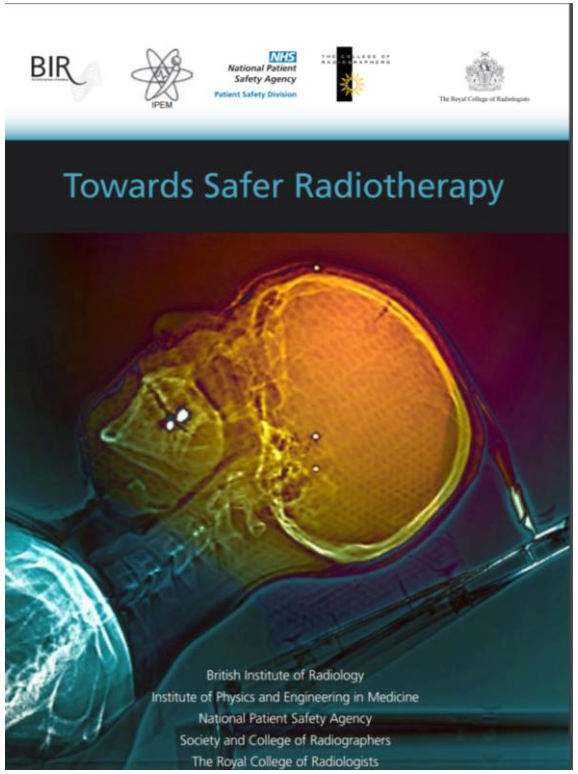
Errors are known to occur in radiation oncology. The treatment of cancer patients with radiation is complicated for several reasons: the complexity of the disease, the sophistication of the technologies employed, the

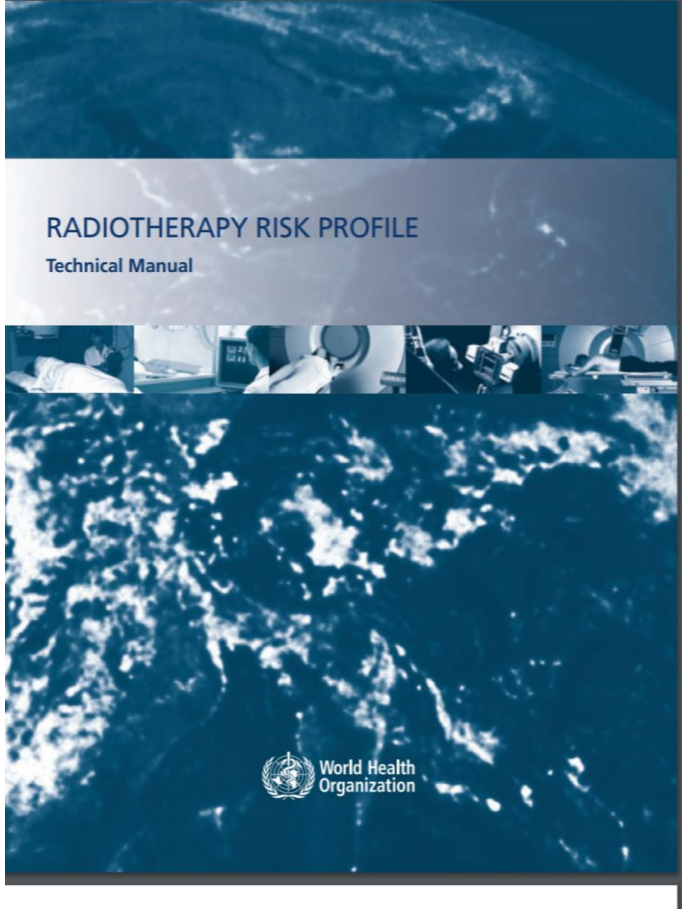
This article is being published simultaneously in the January issue of *Medical Physics*.
Conflicts of interest: None.
*Corresponding author. Department of Radiation Oncology, Mayo Clinic, 200 First St SW, Rochester, MN 55905.
E-mail address: herman.michael@mayo.edu (M.G. Herman).

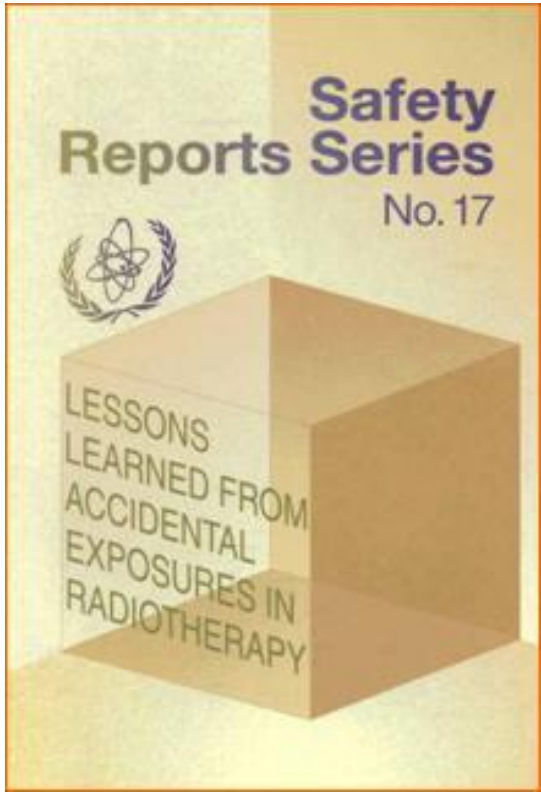
doi:10.1016/j.prro.2010.11.003

Hendee and Herman 2011


Volume 39 No. 4 2009
ISSN 0146-6453
ISBN 978-0-7020-4405-2
ICRP
Annals of the ICRP
ICRP Publication 112
Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies
ELSEVIER


BIR
IPEM
NHS National Patient Safety Agency
Patient Safety Division
The Royal College of Radiologists
Towards Safer Radiotherapy
British Institute of Radiology
Institute of Physics and Engineering in Medicine
National Patient Safety Agency
Society and College of Radiographers
The Royal College of Radiologists


RADIOTHERAPY RISK PROFILE
Technical Manual
World Health Organization


Safety Reports Series
No. 17
LESSONS LEARNED FROM ACCIDENTAL EXPOSURES IN RADIOTHERAPY

What should we do?

Abundant Recommendations

Report	Advice
Towards safer Radiotherapy	*37*
Radiotherapy Risk Profile	*15*
Preventing Accidental …..	*15*
Hendee and Herman	*20*
Hierarchy of Actions	*19*
ASTRO	*6*
TG 100	*5*
Total	**117**

frontiers in ONCOLOGY

REVIEW ARTICLE
published: 28 September 2012
doi: 10.3389/fonc.2012.00129

Recommendations for safer radiotherapy: what's the message?

*Peter Dunscombe**

Education/ Training (7)

Staffing/skills mix(6)

Documentation/SOP (5)

Incident Learning System (5)

Communication/questioning (4)

Check lists (4)

QC and PM (4)

Dosimetric Audit(4)

Accreditation (4)

Minimizing interruptions (3)

Prospective risk assessment (3)

Safety Culture (3)

To be continued…