LESSONS LEARNED FROM INCIDENTS IN RADIATION THERAPY

ICTP SChool On MEdical PHysics For RAdiation THerapy

DOsimetry And TReatment PLanning For BAsic And ADvanced APplications

13 - 24 April 2015

Miramare, Trieste, Italy

YAKOV PIPMAN, D.SC.

CHAIR- INTERNATIONAL EDUCATIONAL ACTIVITIES COMMITTEE-AAPM

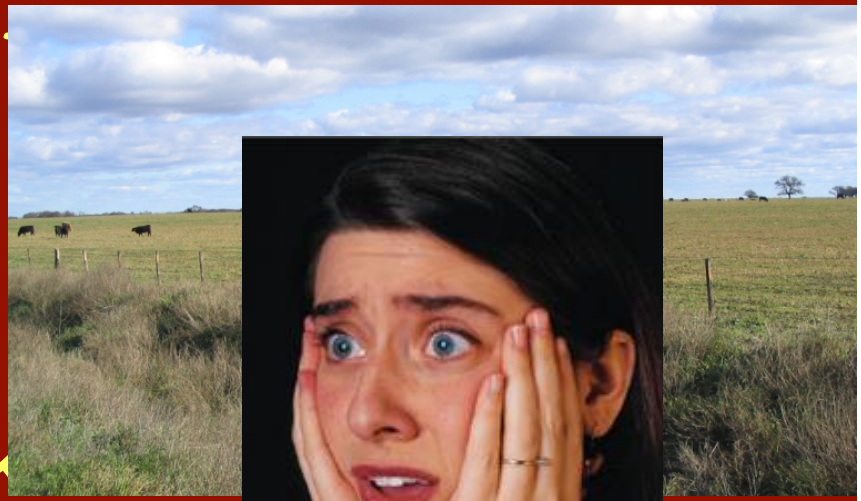
Did you?

- I heard that…
- I would like to learn to…
- We have to improve…
- Our clinic is about to start doing…
- We need to prepare to…
- I never made an error but I worry that…
- Our (Medical Director/ Chief of/Safety Officer, …) warned us that if … ever happened…
- We were told that…

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 shock but surely this could not happen to us, nor in our environment.

Except that …

It was really not so.

There were quite a few 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 RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

BY WALT BOGDANICH
JANUARY 24, 2010

1 of 4

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

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

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,

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

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JANUARY 24, 2010

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Pa

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.

April 2005 — 27 Days of Radiation Overdoses

A 32-year-old breast cancer patient received 27 days of radiation overdoses — each three times the prescribed amount, because a wedge had been left out. The patient had to undergo multiple surgeries to close a wound caused by the overdose. The physics staff failed to notice the mistake during their weekly checks of treatment records. The therapists failed to notice that during treatment, their computer screen clearly showed the wedge missing.

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.

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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	Computer, software or digital information transfer malfunction	Override of computer data by personnel	Miscommunication	Unclear/other
355	252	174	133	96	77	60	52	24	19	14	8

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

THE NEW YORK TIMES

Let's consider a few common beliefs:

Accidents in radiotherapy are very rare

The majority of accidents happened long ago and/or in the developing world

Accidents are linked to equipment of low/high technology

1992 USA

A Special Reprint

THE PLAIN DEALER

OHIO'S LARGEST NEWSPAPER

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

Dangerous medicine, deadly mistakes

PD/BRYNNE SHAW

...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

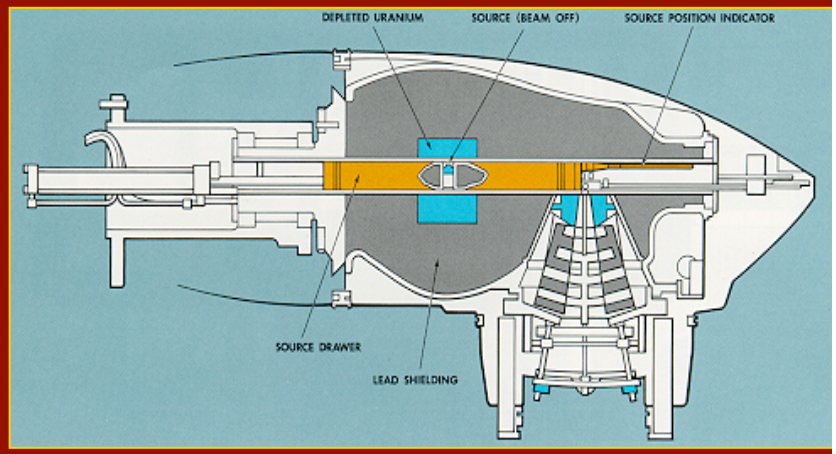
PART 5, *Published Dec. 17, 1992* — NRC investigators have caught dozens of hospital officials lying, falsifying records and covering up radiation overdoses. Yet only three people have been convicted of crimes and no one has ever gone to jail. Some still work at the same hospitals. **Pages 11, 12**

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

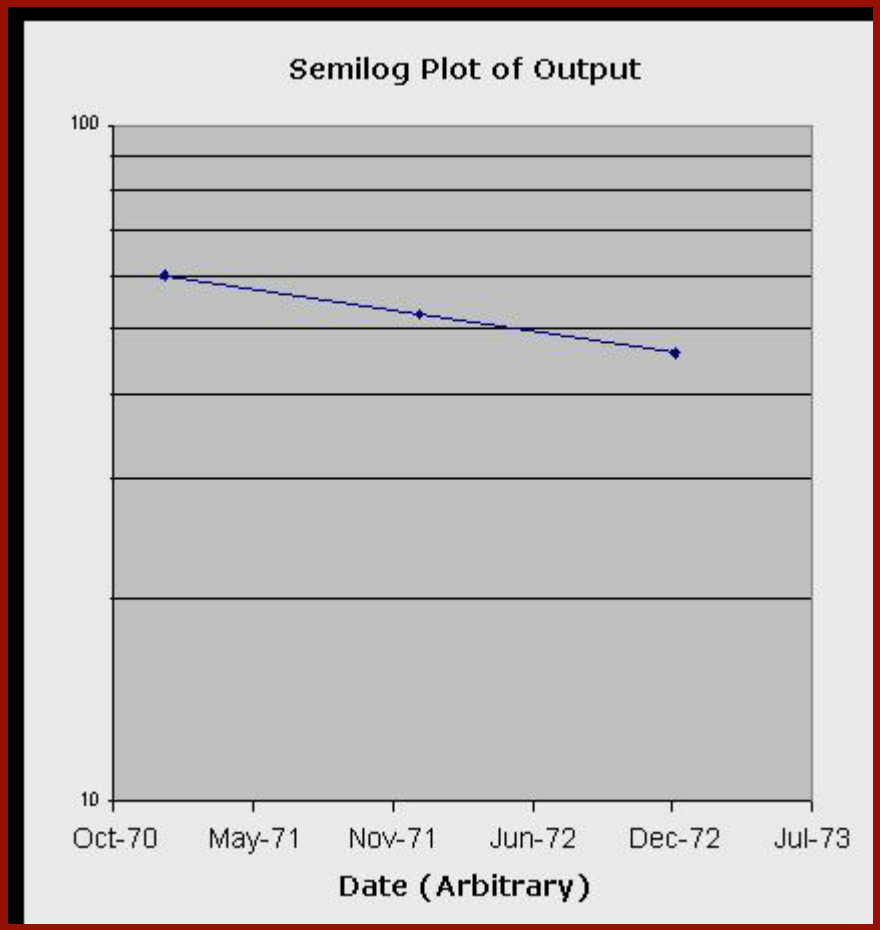
80 CM. S.S.D.

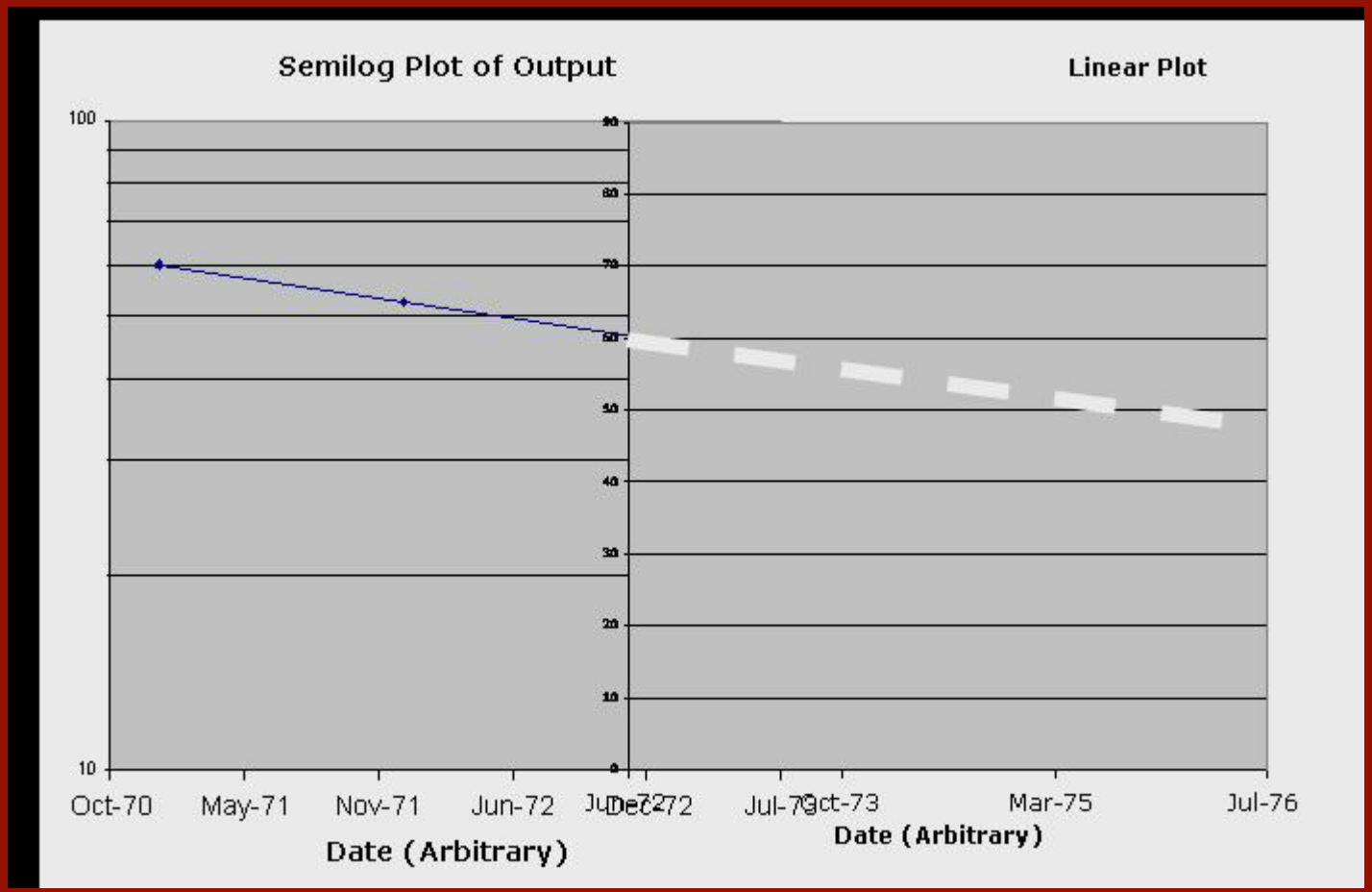
Time in Minutes to give 100 rads tumor dose at depth and Max.r "skin" dose for 100 Rads at depth for period April 1, 1969 through June 30, 1969.

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.

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April 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

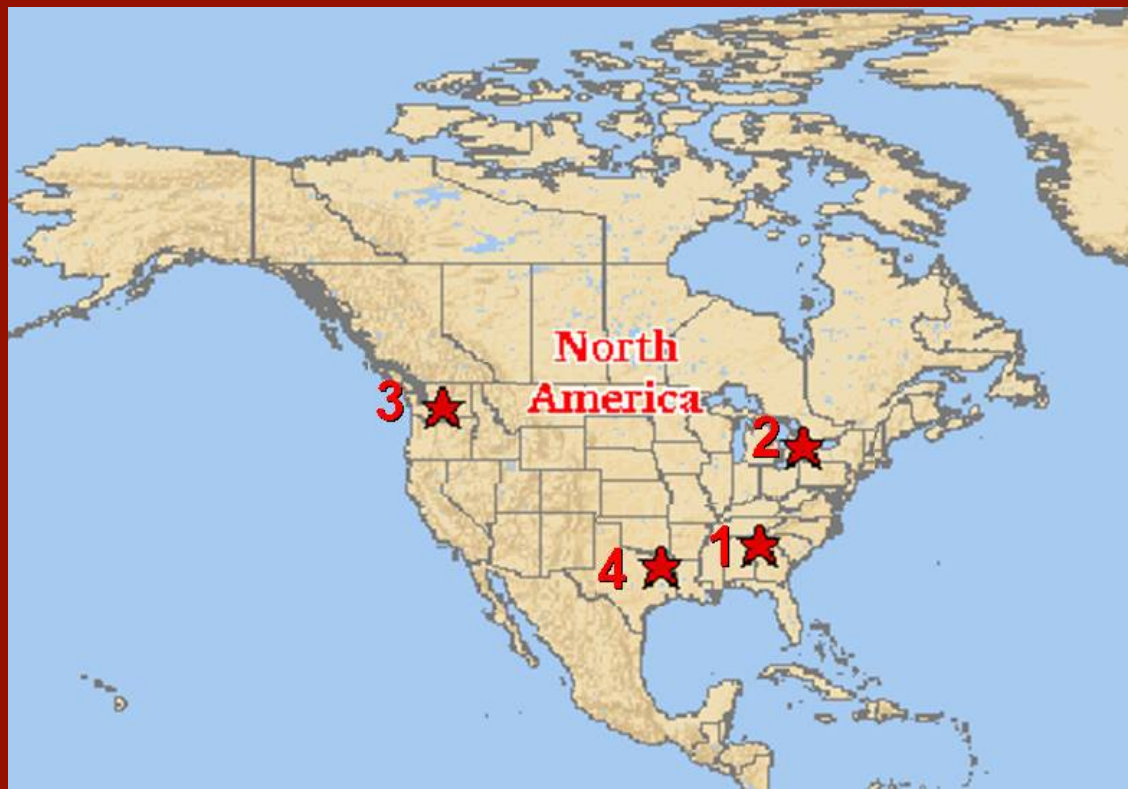
- June 1985-January 1987
- 6 accidents of massive overdoses.
- Deaths and serious injuries.
- The “worst series of radiation accidents” in the 35-year history of medical accelerators.

1. Kennestone Center, Marietta, Georgia

2. Hamilton Cancer center, Ontario

3. Yakima Valley, Washington

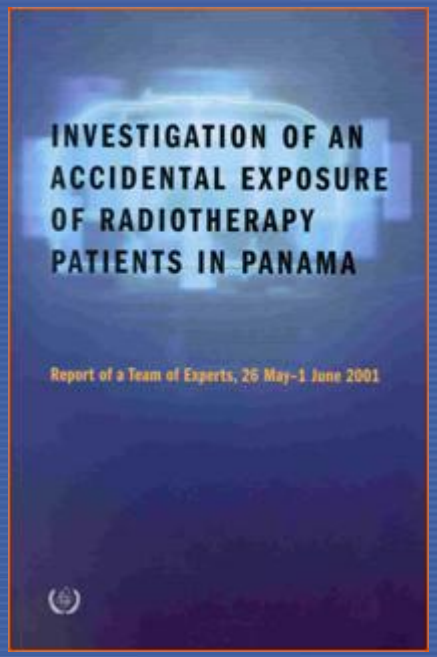
4. East Texas Cancer Center, Tyler, Texas



(http://rpop.iaea.org)

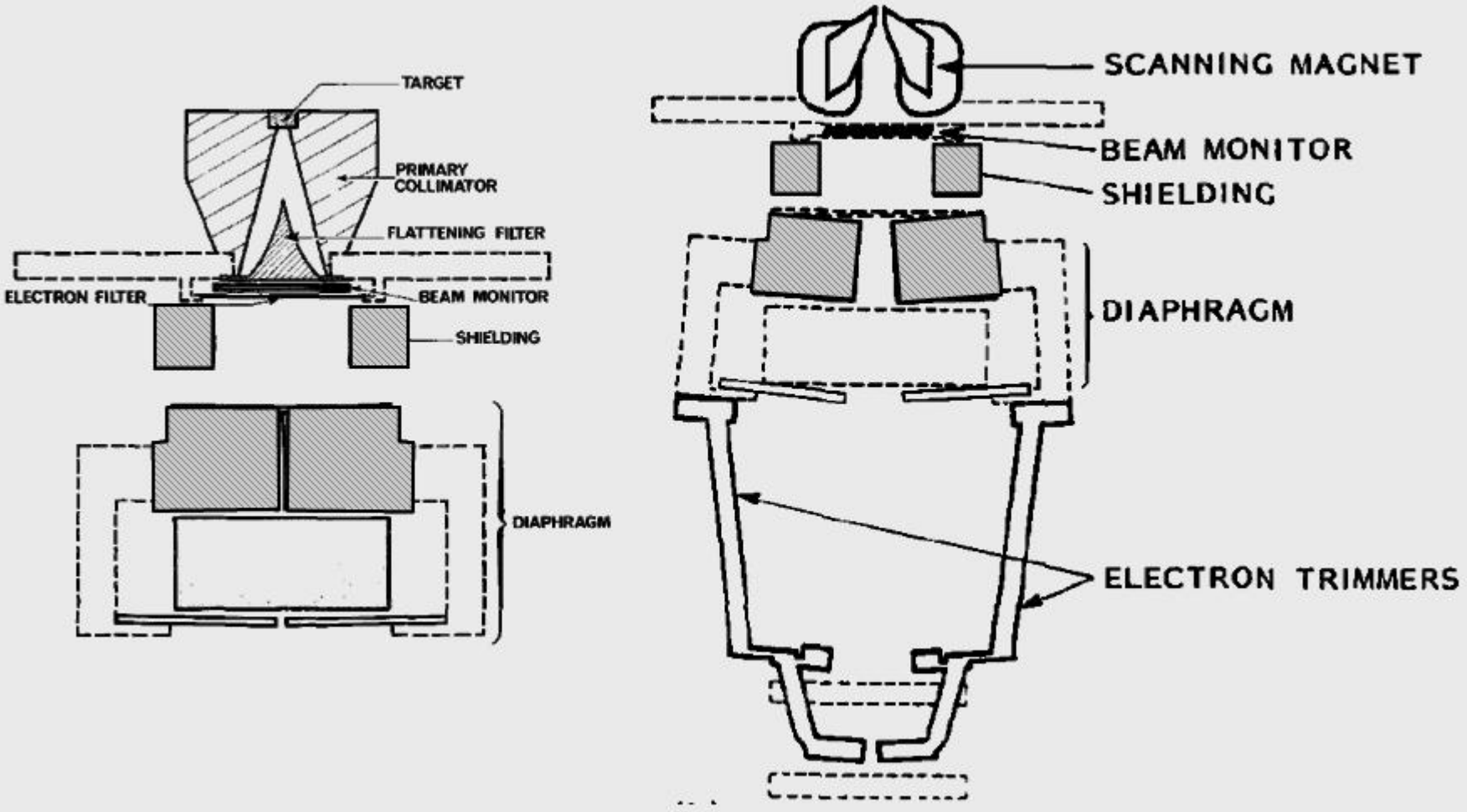
Part 2: Case studies of major accidental exposures in radiotherapy

- Nine major case studies – descriptions of events, discovery of problems, consequences and lessons to learn
- Discussion on some newer case studies (2004-2007)



Module 2.3: Accelerator software problems (USA and Canada)

Photon vs. electron treatment head

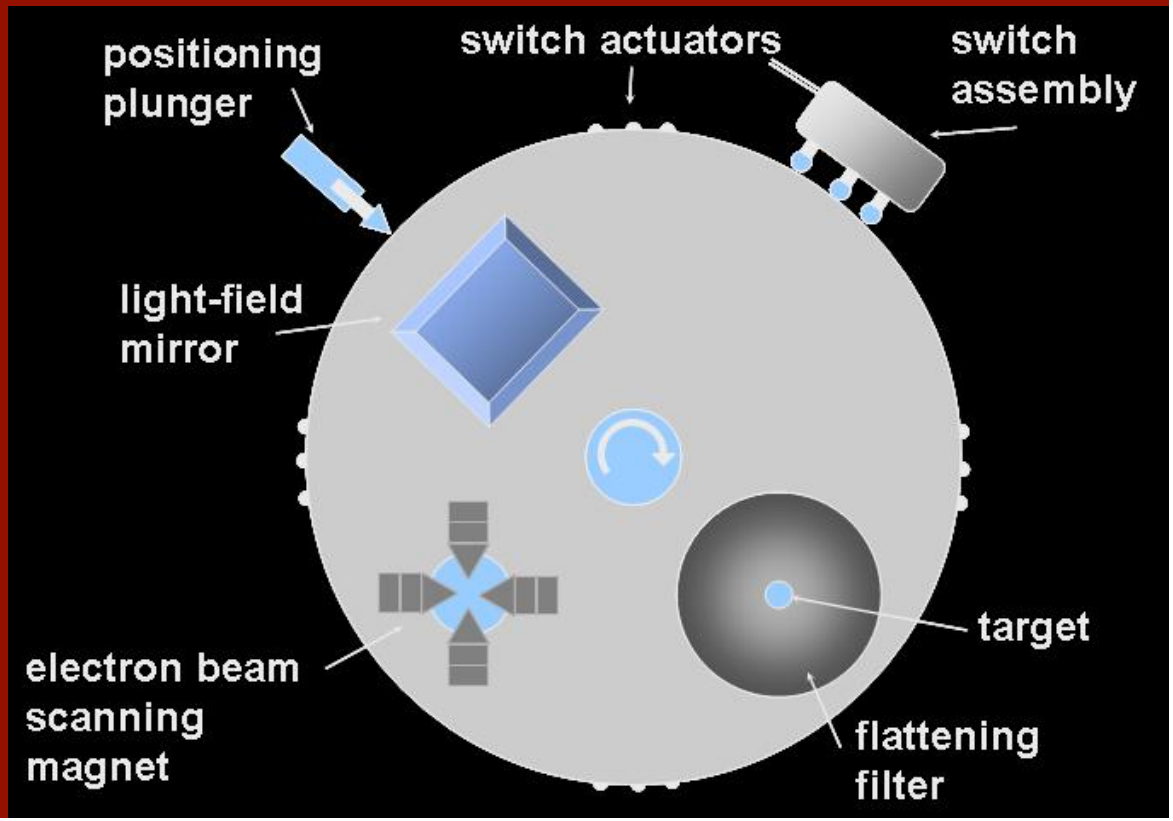


From O'Brien 1985

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

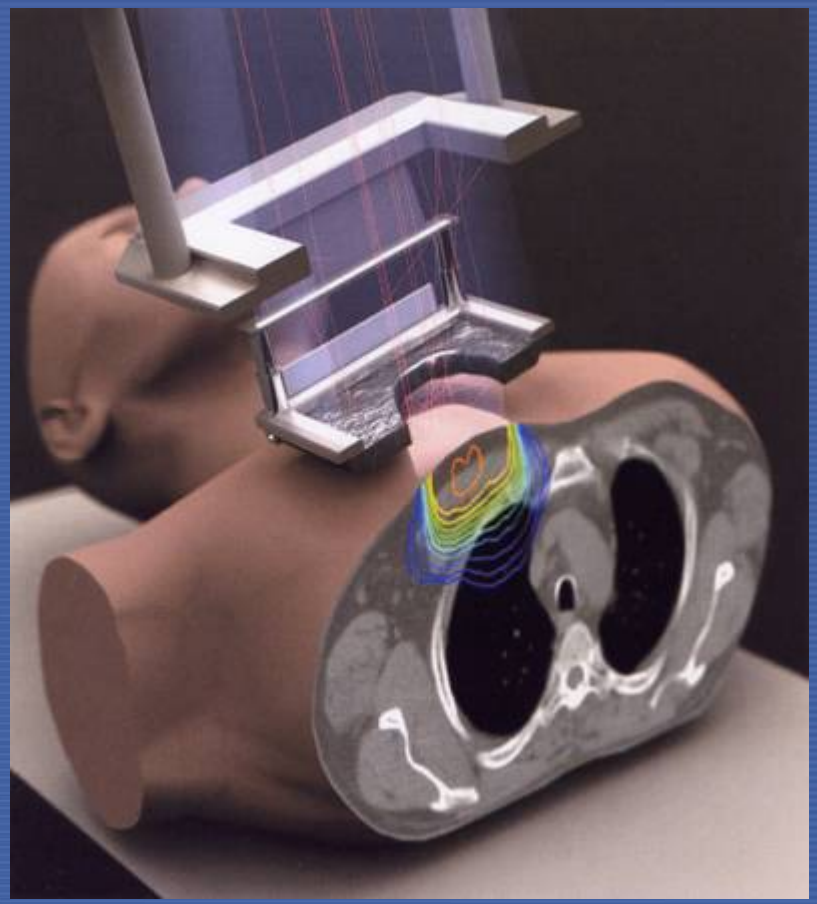
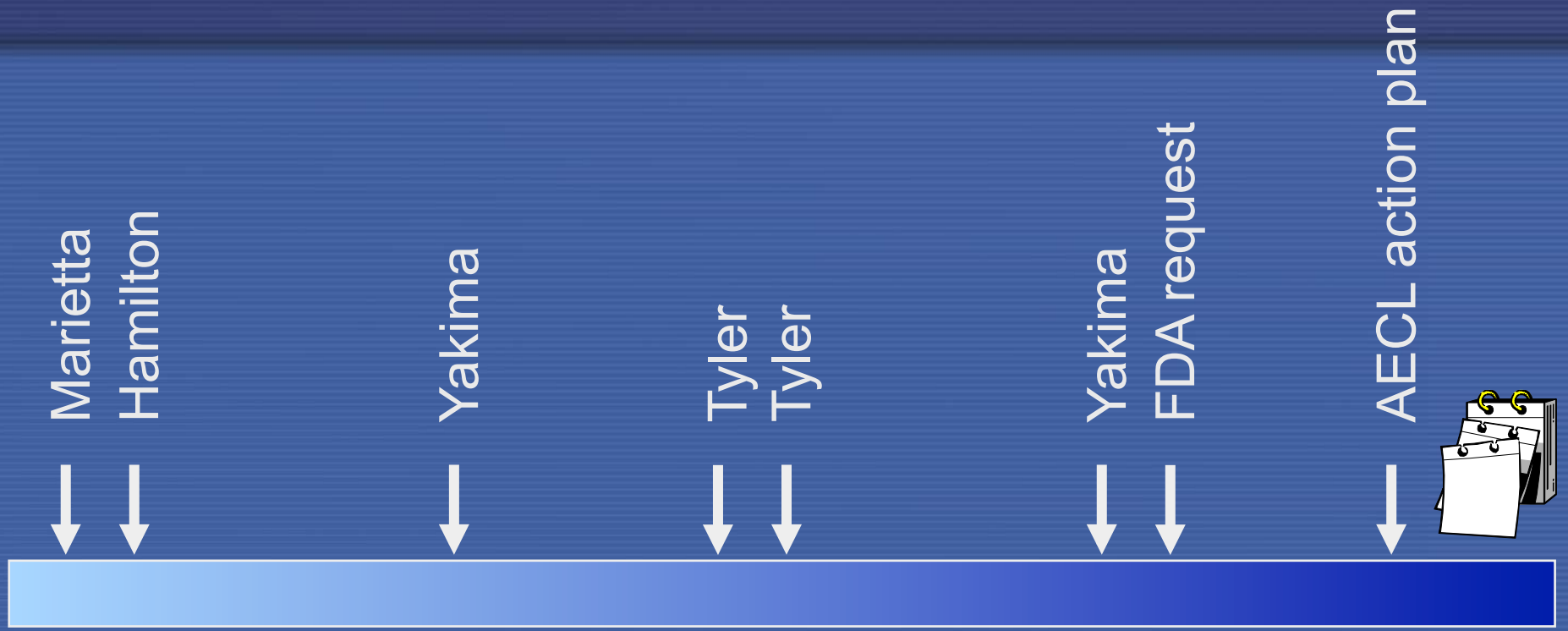


Illustration of chest treatment with electrons (Nucletron)

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 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 they got 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

Maryland releases files amid outcry

By KEITH C. EPSTEIN and TED WENDLING
PLAIN DEALER REPORTERS

BALTIMORE

After four years, Maryland officials finally began shedding light on a rural hospital's dark secret: For 13 months, ignoring complaints of skin reactions and other problems, the hospital had continued to expose cancer patients to excessive radiation.

"Nothing to worry about," Dr. Cynthia A. Brown, a radiotherapist at Sacred Heart Hospital in Cumberland, had responded when Ann Morgan, the chief technologist, repeatedly brought up the subject beginning in November 1987, according to a consultant's 1988 report made public yesterday.

Noticing skin problems in patients, Morgan suspected overdoses of cobalt-60 radiation.

But Brown never checked her work, and Morgan turned out to be right. By the time the hospital quietly notified state authorities in October 1988, 20 patients had died. None knew they had been among 33 men and women who had been exposed to 75% overdoses of radiation.

Two months later, doctors still hadn't notified some patients and families.

While the elderly patients, who were undergoing treatment for brain cancer, already were very sick, the conditions and pain of some worsened after the overdoses.

The hospital's own consultant concluded their lives had been cut "sus-

cancer patients to excessive radiation.

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versity of Virginia radiologist Dr. William Constable implied hospital employees should have detected the problem sooner.

Technicians had noticed severe crusting of patients' skin and discharges from their ears. "A reasonably alert radiotherapist," the consultant wrote, "would have requested a physicist to review the treatment."

Another expert, Johns Hopkins Hospital oncologist Dr. Stanley Order, noted new symptoms, unrelated to brain cancer, in an "ample number of patients" — notably skin reactions over the scalp and ears, and sometimes temporary deafness.

These symptoms "were not appreciated by Dr. Brown as evidence that clearly something was abnormal. A simple check . . . would have yielded the proper results."

What Brown would have found, experts conclude in the documents, is that the doses of cobalt-60 were wrong because she had been relying on an outdated computer program an oncologist had failed to replace.

SEE RELEASES/Page 14

Maryland rel

FROM/PAGE 13

A consultant hired by state officials, Dr. Peter R. Almond, asserted in his report that, especially with the warning signs from patients, Brown should have double-checked her charts.

"Could and should the situation have been avoided?" he wrote. "Unquestionably, yes."

State records show that Brown surrendered her license to practice medicine in Maryland on Feb. 23, 1990. She now lives in Buthell, Wash., and could not be reached for comment.

Among the patients was a man who bled into his tumor and became comatose. "In this case," concluded Order, "one could relate the high . . . dose to the rapid demise of this patient."

A woman, whose condition had seemed to improve before radiation, deteriorated rapidly. She seemed confused and unable to think, though her tumor had not regrown.

Errors

The Plain Dealer reviewed nearly 4,000 radiation mistakes reported by hospitals to state and federal officials in the last eight years. The newspaper examined 200 cases in detail, including:

University of Wisconsin Hospital and Clinics, Madison

In 1986, Lois Nelson's digestive tract was severely burned during radiation treatments for bladder cancer. The trauma was too much for her husband, Robert, who committed suicide. Nelson died in December 1991.

In a separate incident, an unqualified technologist was left alone with a patient who was undergoing cancer treatment when the machine began to beep. The technologist didn't know whether the beeping indicated a malfunction or the end of the treatment. It turned out that the beeping meant the treatment was over.

And in yet another incident, a patient being treated for nasal cancer received a radiation overdose when a technologist picked up the treatment chart for another patient and entered the information into the cancer-treatment machine's computer.

In a 1990 investigation, the NRC found numerous violations of federal regulations, including a failure to double-check treatment times for 35 patients and instances where patients undergoing radiation therapy were left alone without trained operators present. The NRC fined the hospital $7,500.

West Houston Medical Center, Houston

Shi-Jen Wen received 1,000 times more radioactive iodine-131 than she should have in May 1988 because substitute technologist Shirley DeFoe didn't know the difference between microcuries and millicuries, a difference of 1,000. As a result, Wen's thyroid gland was destroyed.

"I cannot undo what harm has been done," DeFoe wrote in an anguished account of the accident. ". . . I thank God that the patient is still alive."

The state investigated the mistake, but issued no fine.

St. Mary's Medical Center, Gary and Hobart, Ind.; Porter Memorial Hospital, Valparaiso, Ind.

In 1990, the NRC suspended the two St. Mary's hospitals from providing so-called brachytherapy treatments — involving surgical implants of radioactive sources — after discovering that patient treatment plans were not being used.

In 69 patient files reviewed by the NRC, no radiation prescription could be found for 57 of the patients. This meant it was impossible to determine whether patients had received underdoses, overdoses or the proper amount of radiation.

Some of the treatments were performed without perscriptions by radiation oncologist Dr. Koppolu P. Sarma, who is still director of radiation oncology at St. Mary's and practices at Porter.

No fine was issued. The NRC gave both hospitals permission earlier this year to begin doing the procedures again after they revamped their programs.

Desert Samaritan Hospital and Health Center, Mesa, Ariz.

In November 1989, homemaker Deborah Lane mistakenly received 100 millicuries, instead of 100 microcuries, of radioactive iodine-131 for a thyroid scan. The overdose, equal to 1,000 times more radiation than her doctor had prescribed, was

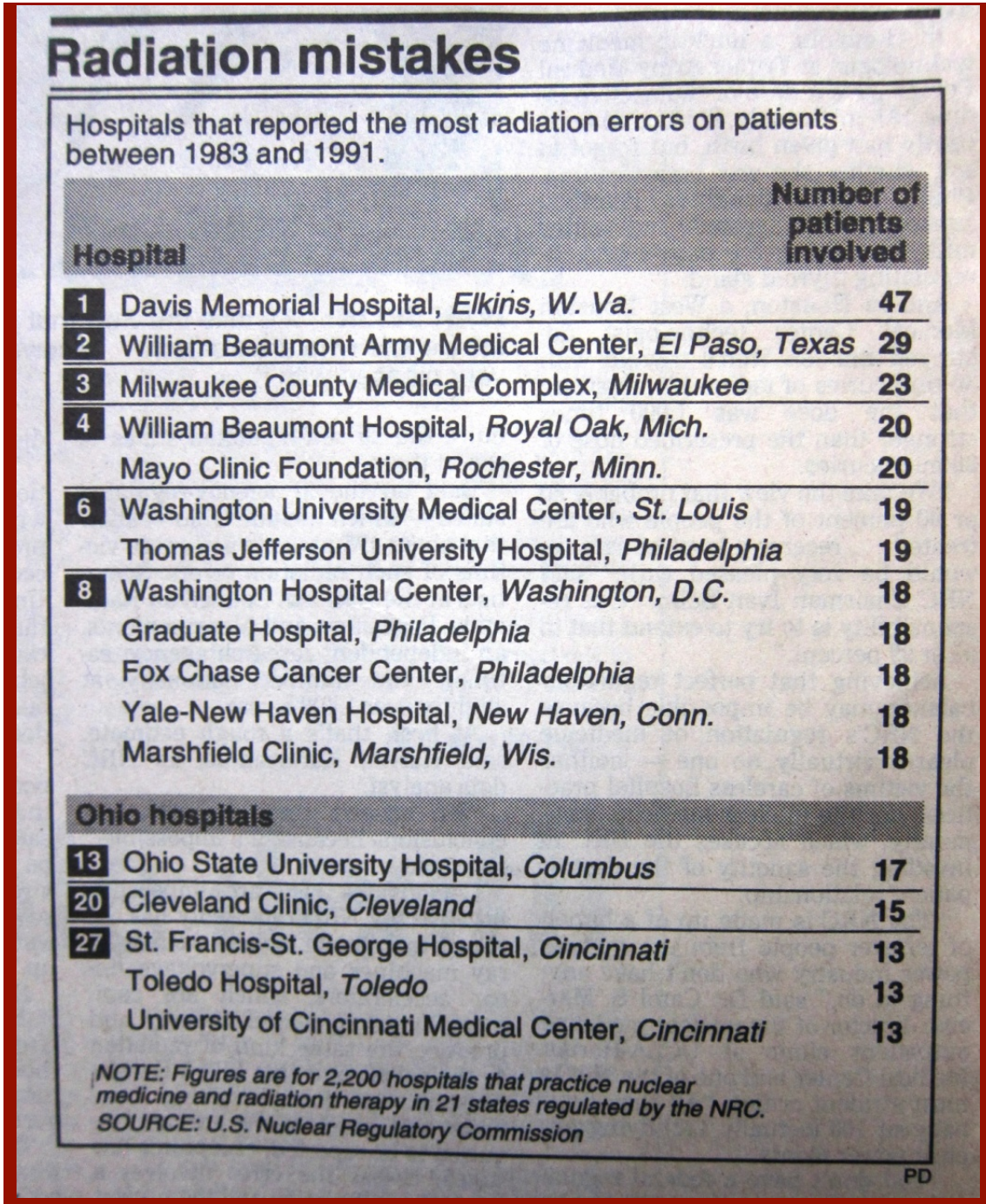
quent investigation, Herskovic pro-
vided "incomplete and inaccurate" information about the incident, according to NRC records.

Herskovic, who is still director of radiation oncology at the hospital, was replaced as radiation safety officer. The NRC also ordered that he be removed from St. Joseph's radiation safety committee for three years.

The NRC fined the hospital $10,250 in 1991. The case also was referred to the Justice Department, which declined to prosecute.

In another incident, a 52-year-old man who was to undergo radiation treatments to his head and neck in November 1991 mistakenly received a large dose to his eye.

The accident occurred because the patient didn't speak English, so the doctor had the man simply point to the area of his body that was to be treated.



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

Institutions: small and large, rural and academic.

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Who reports and who does not?

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This list did not include linear accelerators cases, since it is only from the NRC!

Wendling Davis Shaw

An extensiv

Plain Dealer reporters
Wendling traveled from Sa
gettstown, Pa., and from
West Palm Beach, Fla., to
conduct interviews for thi
viewed more than 150 peop
lawyers, government offici
tims. Brynne Shaw photo
and their families.

The reporters gathered
pages of court records, ins
investigative files kept by t
ulatory Commission and n
cies.

They filed more than 10
federal Freedom of Inform
public records laws, inclu
peals when documents wer
appeals prompted the NRC
of withholding names of pe

The reporters also used a
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 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

World Health Organization

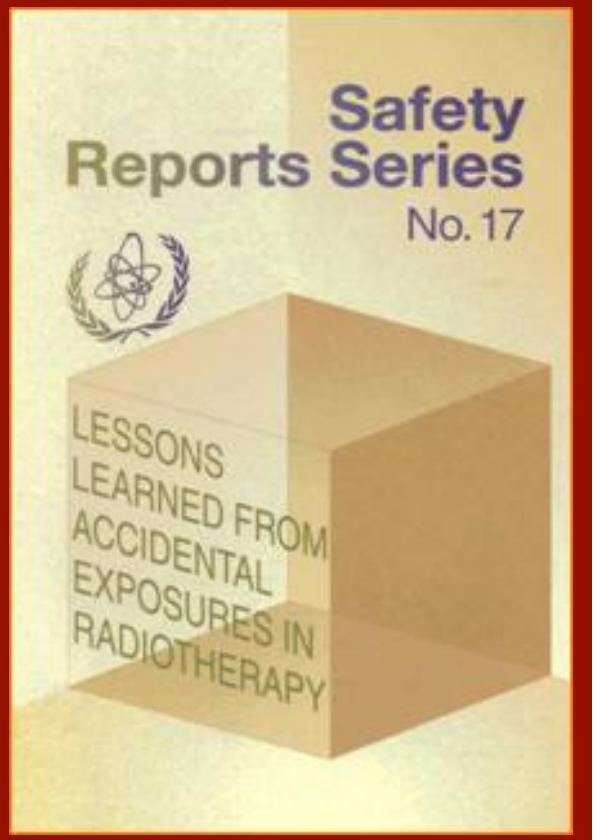
Incidents are a global issue

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 did we learn?

- Accidents happen
- When they happen there is more than one factor
- Many more ‘almost accident’s than big ones
- 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

Coming soon to this theater…

What can we do about all these?