Patient Safety and Radiation Accidents

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San Diego Gamma Knife Center
RTUVT University, South Bend, IN
The American radiation therapy community changed on January 23, 2010

The Radiation Boom

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
New York Times

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.
Scott Jerome-Parks was diagnosed with base of tongue tumor in Dec. 2004. Treated at St. Vincent’s Hospital in New York with IMRT (120 leaf MLC) in March 2005. Plan revision after 4 fractions. Varian treatment planning computer seized up, physicist saved changes. Received 2 fractions, in “agonizing pain”, received a third fraction, then physicist made measurement of new field: MLC’s found to be wide open (parked).

Each fraction reported as 7 times the prescribed dose, to his entire head and neck. Patient deteriorated, required constant care, died in February, 2007.


ASTRO and AAPM issued statements in response to these stories

A congressional hearing was held in Washington, D.C. on February 10, 2010. Several AAPM and ASTRO members testified
Plan as delivered (courtesy G.W. Sherouse)
How safe is “safe”?

The German philosopher Johann Goethe once said “I never heard of a crime I could not have committed”

What about accidents? I always ask myself when I hear another accident report “Could I have let that happen? Would I have prevented it from happening?”

A safety culture is necessary to comprehensively build in safeguards and safety checks at all levels along the way from simulation to treatment

Every one of us may be “the last chance” to prevent an error
Part 1) Training and Staffing

- Since 1991 the “ACR Blue Book” has been the reference which radiation therapy departments referred to for recommended staffing levels
- It is now more than 20 years old, hopelessly outdated
- We no longer use Cerrobend blocks, with targets sketched in grease pencil on a simulator film, 2D treatment planning, four field box for prostates
RADIATION ONCOLOGY
IN
INTEGRATED CANCER MANAGEMENT

REPORT OF THE INTER-SOCIETY COUNCIL
FOR RADIATION ONCOLOGY

Sponsored by the:

American Association of Physicists in Medicine
American College of Medical Physics
American College of Radiology
American Radium Society
American Society for Therapeutic Radiology and Oncology
North American Hyperthermia Group
Radiation Research Society
Radiological Society of North America
Society of Chairmen of Academic Radiation Oncology Programs

DECEMBER 1991
1980s: cerrobend blocks w 2D plans
1986-1990: Conformal therapy
2000: Intensity Modulated Radiation Therapy
Has the increased complexity of treatment adversely affected our ability to ensure patient safety?
Anthony Zietman, M.D. Massachusetts General, ASTRO President

Dr. Zietman gave an ASTRO Presidential Address at annual meeting in San Diego October 31, 2010: “The Siren Song of New Technology”
Odysseus knew how to avoid hazards!

- The hero lashed himself to the mast so he could not steer his ship onto the rocks when he heard the “song of the Sirens”
- The rest of the crew had ear muffs!
- **Do we do the same thing?** How many cardiac surgery centers does one community need? How many proton therapy centers? (there will soon be two in Oklahoma City)
- Union Tribune published a state study: hospitals who do the **most heart surgery** have the **lowest death rates**.
- It takes a lot of practice to be proficient.
- Should small centers do very advanced techniques if they only do them a few times per year?
New “Blue Book” (actually white)

- Joint project of 12 radiological societies including AAPM, ASRT, ASTRO, ACR and MDCB
- Has a title: “SAFETY IS NO ACCIDENT”
- These staffing levels reflect both patient volume AND the complexity of treatments
- IGRT, radiosurgery, brachytherapy, 4D CT and other complex procedures require far more staff time to carry out than simpler procedures
- Are you a community center or a teaching hospital?
Signatories:

AAMD
AAPM
ABR
ABS
ACR
ACRO
ARS
ASTRO
ASRT
AFROC
SCAROP
SROA
TABLE VIII-1
MINIMUM PERSONNEL REQUIREMENTS FOR CLINICAL RADIATION THERAPY

<table>
<thead>
<tr>
<th>Category</th>
<th>Staffing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist-in-Chief</td>
<td>One per program</td>
</tr>
<tr>
<td>Staff Radiation Oncologist</td>
<td>One additional for each 200–250 patients treated annually. No more than 25-30 patients under treatment by a single physician.</td>
</tr>
<tr>
<td>Radiation Physicist</td>
<td>One per center for up to 400 patients annually. Additional in ratio of 1 per 400 patients treated annually</td>
</tr>
<tr>
<td>Treatment Planning Staff</td>
<td></td>
</tr>
<tr>
<td>Dosimetrist or Physics Assistant</td>
<td>One per 300 patients treated annually</td>
</tr>
<tr>
<td>Physics Technologist (Mold Room)</td>
<td>One per 600 patients treated annually</td>
</tr>
<tr>
<td>Radiation Therapy Technologist</td>
<td></td>
</tr>
<tr>
<td>Supervisor</td>
<td>One per center</td>
</tr>
<tr>
<td>Staff (Treatment)</td>
<td>2 per megavoltage unit up to 25 patients treated daily per unit 4 per megavoltage unit up to 50 patients treated daily per unit</td>
</tr>
<tr>
<td>Staff (Simulation)</td>
<td>2 for every 500 patients simulated annually</td>
</tr>
<tr>
<td>Staff (Brachytherapy)</td>
<td>As needed</td>
</tr>
</tbody>
</table>
## Table 2.3. Clinical Personnel Requirements

<table>
<thead>
<tr>
<th>Clinical FTE</th>
<th>Approximate Max No. of Patients Treated per FTE, per Year*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>250</td>
</tr>
<tr>
<td>Physicist</td>
<td>250</td>
</tr>
<tr>
<td>Dosimetrist</td>
<td>250</td>
</tr>
<tr>
<td>Radiation Therapist</td>
<td>90</td>
</tr>
<tr>
<td>Nurse</td>
<td>250</td>
</tr>
<tr>
<td>Tx machine</td>
<td>300*</td>
</tr>
</tbody>
</table>

*This number may be higher or lower depending upon the complexity of patients treated by an individual physician.

**It is recommended that a minimum of two qualified individuals be present for any external beam patient treatment. To provide this coverage, the ratio of the total number of radiation therapists employed at a facility to the number of treatment machines is typically in the range of 3 or 4 to 1, which also allows coverage of simulation equipment.
### Spreadsheet for Physicists and Dosimetrists

<table>
<thead>
<tr>
<th>Services - Number of Units or Licenses</th>
<th># of systems</th>
<th>Relative FTE Factor</th>
<th>Required FTE</th>
<th>Required Total FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Physician</td>
<td>Dosimetrist</td>
<td>Physician</td>
</tr>
<tr>
<td>Multi energy Accelerators</td>
<td>4</td>
<td>0.25</td>
<td>0.05</td>
<td>1</td>
</tr>
<tr>
<td>Single energy accelerators</td>
<td>0</td>
<td>0.08</td>
<td>0.01</td>
<td>0</td>
</tr>
<tr>
<td>Tumor therapy, CyberKnife, GammaKnife</td>
<td>1</td>
<td>0.3</td>
<td>0.03</td>
<td>0.3</td>
</tr>
<tr>
<td>Cobalt Units, IMRT, PACS, EMR &amp; Contouring</td>
<td>0</td>
<td>0.08</td>
<td>0.03</td>
<td>0</td>
</tr>
<tr>
<td>Orthotargets and Superficial units</td>
<td>0</td>
<td>0.02</td>
<td>0.01</td>
<td>0</td>
</tr>
<tr>
<td>Manual brachytherapy; LDR Seed Implants</td>
<td>1</td>
<td>0.2</td>
<td>0.03</td>
<td>0.2</td>
</tr>
<tr>
<td>HDR brachytherapy</td>
<td>1</td>
<td>0.2</td>
<td>0.02</td>
<td>0.2</td>
</tr>
<tr>
<td>Simulator, CT- Simulator, PET, MRI Fusion</td>
<td>1</td>
<td>0.05</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>Computer planning system (per 10 workstations)</td>
<td>1</td>
<td>0.05</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>HDR planning system</td>
<td>1</td>
<td>0.2</td>
<td>0.01</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td>2.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Annual # of Patients undergoing Procedures</th>
<th># of patients</th>
<th></th>
<th>Physician</th>
<th>Dosimetrist</th>
<th>Physician</th>
<th>Dosimetrist</th>
<th>Physician</th>
<th>Dosimetrist</th>
<th>Physician</th>
<th>Dosimetrist</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Beam RT with 3D planning</td>
<td>500</td>
<td>0.0003</td>
<td>0.003</td>
<td>0.15</td>
<td>1.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Beam RT with conventional planning</td>
<td>200</td>
<td>0.0002</td>
<td>0.002</td>
<td>0.04</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sealed source Brachytherapy (LDR &amp; HDR)</td>
<td>100</td>
<td>0.0008</td>
<td>0.008</td>
<td>0.8</td>
<td>0.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsealed source therapy</td>
<td>25</td>
<td>0.0008</td>
<td>0.008</td>
<td>0.2</td>
<td>0.125</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMRT/IGRT, SRS, TBI, SBRT</td>
<td>400</td>
<td>0.0008</td>
<td>0.008</td>
<td>3.2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td>4.39</td>
<td>4.33</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated Total (Phys &amp; Dosim) FTE Effort</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Education &amp; Training (FTE)</td>
<td>0.1</td>
<td>0.667</td>
<td>0.333</td>
<td>0.0667</td>
<td>0.0333</td>
</tr>
<tr>
<td>Generation of Internal Reports (FTE)</td>
<td>0.1</td>
<td>0.667</td>
<td>0.333</td>
<td>0.0667</td>
<td>0.0333</td>
</tr>
<tr>
<td>Committees &amp; Meetings; Inc. Rad. Safety (FTE)</td>
<td>0.1</td>
<td>0.667</td>
<td>0.333</td>
<td>0.0667</td>
<td>0.0333</td>
</tr>
<tr>
<td>Administration and Management (FTE)</td>
<td>0.5</td>
<td>0.667</td>
<td>0.333</td>
<td>0.3335</td>
<td>0.1665</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.53</td>
<td>0.27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>6.92</td>
<td>4.92</td>
</tr>
</tbody>
</table>
Staff needed: FTE factor times number of systems AND number of patients AND nonclinical effort
Minimum educational and certification requirements

- **Licensure** in a profession is a sign of both maturity and the importance the public places on the work performed.
- Physicians, attorneys, engineers, architects, contractors and even hairdressers are licensed. *Why aren’t medical physicists licensed? (licenses are required in only four states)*
- California Assembly and Senate passed a **licensure bill for medical physicists in 1992**: vetoed by Governor Pete Wilson. Said “it would cost hospitals too much money”!!!
- Only Texas, Hawaii, New York and Florida require licenses for medical physicists
Licensure for Medical Physicists
CARE (Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act) of 2013

- Bill requires each state to license medical physicists, medical dosimetrists, radiation therapists and radiological technologists within 6 months or face cutoff of Medicare funding.
- Costs absolutely nothing! Professionals pay for all costs thru their own accreditation and licensing.
- Up to 100 sponsors of both parties. Died in committee for the last 11 years.
- Currently listed as HR 1146. Given a 4% chance of passage by this Congress.
What about continuing education and training?

- Medical physicists are subject to the American Board of Radiology (since 1949)
- A ten year **Maintenance of Certification** program is now mandatory for all medical physicists (and physicians) certified by ABR after 1995
- Some employers allow time off for mandatory continuing education, some help defray travel and registration costs. Some don’t!
- No one enters a 30 to 40 year career knowing everything they will need to know at the end of their career.
- Radiation oncology is one of the fastest changing fields in medicine.
Part 2) Quality Control and Quality Assurance

- **Quality control**: the operational techniques and activities that sustain the quality of a product or service
- **Quality assurance**: a program for systematic evaluation of a product or service
- **Continuous quality improvement**: a focus on objective data to improve performance
- **Accident**: an unplanned event that results in loss, including human injury or loss of life
- **Six Sigma Certification** (pioneered by Jack Welch at General Electric); implies 3.4 defects per 1 million opportunities
Quality Control for Treatment and Imaging Devices

- QC begins with the physicist doing acceptance testing: does the new machine perform according to its specifications? Does it meet AAPM standards?
- AAPM has nearly 200 AAPM Reports online (all available to anyone) and nearly 100 more Task Groups at work. Most of these reports deal with QA, QC and/or acceptance testing

www.aapm.org/pubs/reports/
Written protocols, policy and procedure

- Writing such documents is onerous! No one likes them. Forces one or more people to think very carefully about goals, objectives and methods: readers are bored!
- Written documents are USELESS by themselves. They have to be practical and staff has to be familiar with them.
- Need continuous training and re-training.
- How do you “break in” a new member of the team?
- Physicians and physicists in many places (e.g., Gamma Knife) are required to be “proctored” for first five cases.
Checklists

- Are **checklists** useful? Necessary? Infallible?
- Aircraft accidents provide useful instruction: A commercial jet crashed immediately after takeoff in Detroit. Flaps were in the wrong position. Cockpit voice recorder demonstrated crew working thru checklist in a distracted way: missed one critical step.
- **Over-reliance** on checklists can be fatal, but checklists can help you avoid leaving something out.
- San Diego Gamma Knife Center is now required to do a “**surgical timeout**” for each patient.
Gamma Knife Timeout

- **Correct patient:**
  two patient identifiers
- **Correct procedure**
- **Correct side of brain** (ask patient) and/or patient marking
- **Correct prescription** (dose and isodose line)
- **Supine vs. prone** (all supine now)
- **Written directive signed**
AAPM: “We remain committed to identifying and implementing improvements in patient safety in order to enable us to continue to offer high quality, safe and effective radiation treatments for every patient in the fight against cancer.”

ASTRO: Launched “Target Safely” campaign in January, 2010. Have you heard of it?

ASTRO: “Patient safety is of the utmost concern to radiation oncologists and safety considerations are woven into all aspects of clinical practice. The field of radiation oncology is complex and rapidly evolving, and the safe delivery of radiation therapy requires the coordinated efforts of the entire radiation oncology team.”
“SAFETY IS NO ACCIDENT”: The need for a culture of safety

• “Modern radiation therapy is complex and rapidly evolving. The safe delivery of radiation therapy requires the concerted and coordinated efforts of many individuals with varied responsibilities.”

• “An excessive workload can lead to errors. Conversely, light workloads can also be a problem since a certain level is needed to maintain “situational awareness”. (Experience?)

• “Systems that facilitate clear, unambiguous and efficient communication between all team members are critical.”

• “Clinical practice is complex, often mired in administrative and historically-derived procedures. Efficiency impacts quality and safety. Harried workers are more prone to error.”
From Dick Fraass, Cedars-Sinai Los Angeles (physicist contributor to SAFETY IS NO ACCIDENT):

“Given all the bad things that can happen, we must do much more QA!”

NO!

- We must evaluate risks, processes, failure modes
- We must better prioritize our safety/QA efforts
- We must spend our efforts on the most frequent, severe and risky problems, not just the ones amenable to QA
- Perhaps we should concentrate more on systematic errors? Are a bigger fraction of our errors now systematic?
No fault problem reporting

- US passenger airlines negotiated with Federal Aviation Administration and pilots unions
- Came up with a “no fault” reporting system
- Pilots can now report “near misses” without fear of retaliation
- Black boxes record dozens of in-flight parameters
- Memory of black boxes uploaded periodically to FAA computers which “re-fly” each passenger flight looking for adverse conditions

RESULT: BETTER PASSENGER SAFETY!!
“The normalization of deviance in healthcare delivery”

- Paper by John Banja, Center for Ethics, Emory University
- “Many serious medical adversities result from violations of recognized standards of practice. Over time, even egregious violations of standards of practice may become “normalized”.
- How many of us have been advised to use a “work-around” because software or hardware does not work the way it is supposed to?
Part 4) Human Factors

- **Nancy Leveson**, Massachusetts Institute of Technology Professor of Aeronautics and Astronautics and Engineering Systems: Consultant to Boeing, NASA space shuttle catastrophe investigations, and the Presidential Commission on Deepwater Horizon (Gulf of Mexico oil spill)
- Author of new book “Engineering a Better World”
- Safety must be “built in” from the start! Can’t be “added on” later
- MUST CONSIDER HUMANS as part of design process
To understand and prevent accidents, must consider system as a whole

And so these men of Hindustan
Disputed loud and long,
Each in his own opinion
Exceeding stiff and strong,
Though each was partly in the right
And all were in the wrong.

John Godfrey Saxe (1816-1887)
Why do accidents occur?

Facts about Accidents
• Almost never have single causes
  – “Root cause seduction”
  – Accidents are complex processes
• Usually involve flaws in
  – Engineered equipment
  – Operator behavior
  – Management decision making
  – Safety culture
  – Regulatory oversight
Human Error as a Cause
• ALL accidents are caused by “human error” (except “acts of God,” like hurricanes)
• Almost always there is:
  – Operator “error”
  – Flawed management decision making
  – Flaws in the physical design of equipment
  – Safety culture problems
  – Regulatory deficiencies

Cop-out!!
Hindsight Bias

- Almost impossible to go back and understand how world looked to somebody not having knowledge of outcome
  - Oversimplify causality because can start from outcome and reason backward to presumed or plausible “causes”
  - Overestimate likelihood of the outcome and people’s ability to foresee it because already know outcome
  - Overrate rule or procedure “violations”
  - Misjudge prominence or relevance of data presented to people at the time
  - Match outcomes with actions that went before it: if outcome bad, actions leading to it must have been bad too (missed opportunities, bad assessments, wrong decisions, and misperceptions)
Hindsight
Should Have Went In And Asked How To Spell It...
Example Accidents from Chemical Plants

Operator told to fix pump 7.

a. Note reversal of trip–reset positions

b. Another Inconsistency
Old vs. new assumptions

Accidents are caused by **chains of directly related events**. We can understand accidents by looking at the chains of events leading to the loss.

Accidents are **complex processes involving the entire socio-technical system**. Traditional event-chain models cannot describe the process adequately.
Old vs. New Assumptions

Most accidents are caused by operator error. Rewarding safe behavior and punishing unsafe behavior will eliminate or reduce accidents significantly.

Operator error is a product of the environment in which it occurs. To reduce operator “error” we must change the environment in which the operator works.
Old vs. New Assumptions

Major accidents occur from the chance **simultaneous occurrence of random events**.

**Systems tend to migrate toward states of higher risk.** Such migration is predictable and can be prevented by appropriate system design or detected during operations using leading indicators of increasing risk. *(e.g., Space Shuttle)*
Old vs. New Assumptions

Assigning blame is necessary to learn from and prevent accidents or incidents.

Blame is the enemy of safety. Focus should be on understanding how the system behavior as a whole contributed to the loss and not on who or what to blame for it.
Ever feel like this?

Fumbling for his recline button Ted unwittingly instigates a disaster
A few “seminal events” have changed the course of radiation therapy.

Each of these events brought greater awareness to the community about potential lethal risks from radiation therapy.

Surgeons learn that some procedures will result in death, but this is a hard lesson in radiation oncology (M and M conferences).

Initial reaction: public fear

Later reaction: responsible change
To Err is Human: Building a Safer Healthcare System

- Published by National Institute of Medicine in 2000
- **44,000 to 98,000 deaths per year** in U.S. due to medical errors
- **8th** leading cause of death in U.S.
- $17 to 29 Billion annual cost
- 2% of all hospital admissions
- Adds $4700 to each admission
- Report updated March, 2013. Number of hospital deaths declined 8% between 2000 and 2010
Free from International Atomic Energy Authority web site:

www.ieaa.org
3.2. EXTERNAL BEAM THERAPY

3.2.1. Events related to equipment, thus affecting many patients

Accidents related to problems with equipment, such as calibration of the beam output, involve all patients treated with the beam until the problem is discovered. The most important events were those resulting in an error in the determination of dose rate, and therefore wrong irradiation times for patients treated under these conditions. In the three worst cases, 115, 207 and 426 patients were involved, with dose deviations of up to 60% and many deaths. In addition, there were two major accidents related to maintenance of accelerators, one of them involving 27 patients (several of whom died as a direct result of radiation exposure).
On 5 December 2001 three US Special Forces soldiers (ages 19, 19 and 21) were killed and many others were injured by “friendly fire” when a 2000 lb guided bomb dropped from a B-52 was targeted precisely to their location at a battalion command post.

The Washington Post, Mar 24, 2002
The airstrike coordinates were called in based on readings of a Precision Lightweight GPS Receiver (PLGR).

The operator calculated and recorded the target coordinates, preparing to relay to the incoming B-52.

Then the battery died.

When it comes back on after its battery is replaced the PLGR defaults to displaying its own current location.

The Washington Post, Mar 24, 2002
[...] the official said the incident shows that the Air Force and Army have a serious training problem that needs to be corrected. "We need to know how our equipment works; when the battery is changed, it defaults to his own location," the official said. "We've got to make sure our people understand this."

The Washington Post, Mar 24, 2002

Question: Why would you ever want to call in an airstrike on your own position?
Case 1) The **Riverside Methodist** Hospital Cobalt-60 overdose accident

- Took place in Columbus, OH in 1974-76. New physicist (not adequately trained) failed to calibrate Co-60 unit. Put decay curves on linear (not semi-logarithmic) graph paper.
- By end of 2 years patients were being overdosed about **45% each day!** 476 patients involved
- New radiation oncologist (seeing many adverse reactions) asked when was last time physicist had measured output (he had not).
- Physicist tried at first to cover up incident, even faked data in log book. (Leroy Humphries of M.D. Anderson discovered error)
Riverside Hospital aftermath

- 62 patients with “severe complications”, as many as 10 died of overdoses.
- Lawsuits went on for many years, bankrupted insurance carrier. Radiation oncologist died of heart attack afterward at age 37!
- Many years later an analysis of the overdoses was published in IJROBP (Lionel Cohen, 1995)
- Incident resulted in new federal law: All cobalt-60 units (and most linacs) must have monthly spot check by medical physicist.
- Hospital must have an ion chamber and electrometer calibrated by an ADCL within the last 2 years.
Case 2) AECL Therac-25 “malfunction 54”

- One of the earliest computer controlled linear accelerators. Only four in United States.
- **Tyler, TX March 21 and April 12, 1986:** A patient reported “electric shock” to his head. AECL denied that there had been any problem reports.
- Electrician examined linac, found nothing wrong.
- Incident happened again: **physicist Fritz Hager** quietly, patiently asked therapist to reproduce error. He then measured and found appallingly large dose to patient (**several thousand cGy**) in a few seconds before error shut off. Patient quickly suffered pain in neck and shoulder, paralysis and **died five months later**.
- Physicists called each other, gradually became aware of malfunctions.
Investigation of AECL incidents

- Professor Nancy Leveson (then at UC Irvine, now at MIT) investigated. Extensively reported in journals and in her seminal book “Safeware”.
- Computer world shocked that a software error had killed people!
- AECL stonewalled investigation all the way to Canadian Supreme Court, then declared bankruptcy. Came out of bankruptcy as Theratronics.
- Very limited liability payout, no charges filed.
- See article in References.
Case 3) Evanston Hospital Radiosurgery Accidents: “A pinpoint beam strays invisibly...” Dec. 28, 2010

- Three women were treated for trigeminal neuralgia on a Varian linac with Brainlab circular cone beam collimators in March, 2009.
- Trigeminal neuralgia is a syndrome causing intractable pain of cranial nerve V (innervating the face).
- Treatment is typically 80 to 85Gy at 100% in a single dose with a beam diameter of 4 to 5 millimeters. More than 33,000 patients have been treated with the Leksell Gamma Knife for this condition (over 650 at San Diego Gamma Knife Center) with good to excellent pain relief. The condition is not fatal.
- Something went dreadfully wrong that day, though no one knew it for some time. Marci Faber had vomiting, a burning throat, weight loss and hair loss. Did not connect it to her treatment. Another patient had irregular heartbeat, weakness and changes in mental status. Third patient hospitalized for 4 days because of nausea, vomiting and dehydration.
- Physicist finally noted a setup error just before a fourth patient was to be treated. (May have been multiple causes for these 3 incidents)
What happened? NY Times Java illustration
Normal Trigeminal neuralgia Gamma Knife Treatment
Patient follow-up

- By time of publication of New York Times article (21 months later), two patients were dead of complications, Marci Faber was in a nursing home, comatose. She subsequently died.
- Brainlab collimators were (apparently) not interlocked with Varian linear accelerator. (Legal point of contention)
- Jaw position should have been $X \text{ by } X\text{cm}^2$: it was much wider. Large volume of the brain received 80 Gy. How did it happen?
- Attachment plate blocked light field: no projected light field was visible. No possibility of port films or OBI imaging.
- Three deaths from one single error (or multiple errors)
- *I am now an expert witness in this case.*
Case 5) French doctors and medical physicist convicted of manslaughter

Doctors on trial in case of radiation overdoses

Shanghai Daily News September 25, 2012

TWO doctors and a radiophysicist went on trial yesterday on manslaughter charges arising from radiation overdoses given to nearly 450 cancer patients in a French hospital.

At least seven people died as a result of overdoses administered to patients at the Jean Monnet hospital in Epinal in northeastern France between 2001 and 2006.

At least 24 people treated between May 2004 and August 2005 received 20 percent more radiation than they should have had due to a calibration error.

The official report of IRSN (French regulatory agency) also noted up to 6 Gray delivered per prostate patient by imaging alone!!
Background

• When the EDW (soft wedges) were introduced:
  • The independent MU check in use could not be used anymore (unless modified)
  • The diodes used for independent dose check could not be correctly interpreted anymore
What happened?

• Treatment planning with EDW (soft wedges) started
  • Not all the treatment planners did understand the interface to the planning system
  • Some selected the planning for mechanical wedge when intending dynamic wedge
  • Instead they should have selected Enhanced Dynamic Wedge…
    • …which would have let the correct planning tool appear
What happened?

• When planning was finished and the isodose distribution approved
  • …the parameters were manually transferred to the treatment unit
  • Manually transferred MU’s would have been calculated for mechanical wedges and would be much greater than what is needed for giving the same dose with dynamic wedges
Lessons to Learn

Ensure that staff
- Understand the properties and limitations of the equipment they are using
- Are properly trained in safety critical procedures

Include in the Quality Assurance Program
- Formal procedures for verifying new technologies and procedures before implementation
- Independent MU checking of ALL treatment plans
- In vivo dosimetry

Make sure the clinic has a system in place for
- Investigation and reporting of accidents
- Patient management and follow up, including communication to patients

Instructions should be in a language that is understood
Postscript to accident in Epinal

• Going through the records, two further episodes were reported subsequently

• Reported in Feb 2007:
  
  In the time period 2001-2006, portal imaging was used repeatedly without taking into account the added dose (estimated to have been +8% of total) for 412 patients under medical survey. Up to 6 Gray per patient.

Reported in July 2007:

In the time period 1989-2000, use of an in-house TPS not updated after change in treatment technique, might have led to 300 patients receiving up to 7% added dose.
Late information from IRSN

- Dose escalation (up to 78 Gy) for prostate patients was criticized (very aggressive)
- Ignored up to 6 Gy per patient from imaging doses
- Very shoddy treatment planning, poor sparing of rectum and bladder
- Patients not informed of risks of high dose treatment (effectively up to 84 Gy)
- IRSN advocated better training and quality assurance
French doctors and radiologist jailed for radiation overdoses

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.
Case 5) First proton therapy overdose reported

- Rinecker Proton Therapy Center (RPTC), Munich, Germany
- Overdose reported to patient treated last summer.
- Press reports indicate the prostate cancer patient after 15 daily treatments mistakenly received a daily dose of **63Gy** instead of 3Gy!
- The patient has severe problems (blood in the urine) and cannot sit
- Incident was blamed on “human error” and two employees were fired.
- Additional software installed to prevent this problem from happening again.
Other radiation incidents and accidents

- **Bend, OR**: mis-calibrated barometer, many patients over-treated (high altitude, mistakenly corrected to sea level)
- **Springfield, MO**: mis-calibrated small diameter circular collimators: 86 patients over-treated
- **Tampa Bay, FL**: physicist accidentally changes cobalt-60 calibration file: 20 patients over-treated
- **Exeter, England**: new cobalt-60 teletherapy source mis-calibrated initially, 117 patients over-treated
- **Zaragoza, Spain**: local physicist attempts to repair linac: dozens of patients over-exposed, some killed
- **Detroit, MI**: 5 HDR patients treated with 130cm catheter instead of 100cm catheter. Received “sham irradiation”
“In my profession, there is very little room for error and no room for unqualified personnel,” said Dr. Steve Goetsch, a medical physicist in California who runs training programs in the field.
Conclusions

- We are all in this together.
- We must create a “safety culture”.
- Blame is useless: all problems must be freely reported in a blame-free environment.
- Human engineering is a better approach than “punishing the guilty”.
- Complexity does not necessarily cause problems.
- The only foolish question is the one you don’t ask!
References

- IAEA Safety Report Series No. 17 “Lessons Learned from Accidental Exposures in Radiation Therapy”
“Those who cannot remember the past are condemned to repeat it.”

George Santayana, philosopher
Save the date:

Midwinter Symposium
Sheraton Universal Hotel, Starview Room

January 24, 2014

Up to 8 hours ASRT and MDCB credits
Advance registration REQUIRED
Includes breakfast and lunch