Medical events in radiotherapy

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2013 Summer School, Colorado Springs, CO

Objectives

- To review the definition of a medical event
- To present and discuss actual cases of medical events
- Identify the source of errors
- To review tools for errors reduction

Disclosures

- Consultant for Nucletron and Theragenics

Headlines in the past few years

Anthony Zeitman MD
ASTRO Past President

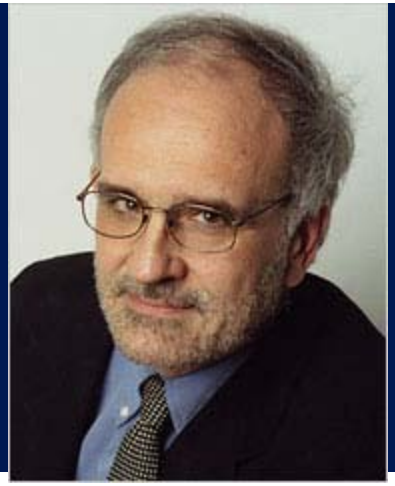
On radiation advancements: *"… For the last decade, wonderful new devices have been* ***coming at us faster*** *than many centers could absorb them. Some centers were* ***understaffed, underprepared,*** *and* ***didn't have the dosimetry support or radiologic technologist training needed*** *for all this new technology to work as it should every time".*

May 16 2011: Walt Bogdanich of *The New York Times*

"Hospitals want more patients, and as soon as a new gee-whiz medical device comes out that is some live-saving device, every hospital wants to get them as quickly as possible, and sometimes they move too quickly," he says.

"They buy them, they install them, they don't spend the kind of money necessary to properly train the staff and to develop the kind of protocols necessary to ensure that mistakes ... are minimized — and that wasn't happening."

NY Times stories



THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH; SIMON AKAM, ANDREW LEHREN, DAN LIEBERMAN, KRISTINA REBELO and REBECCA R. RUIZ CONTRIBUTED REPORTING.

While new technology saves the lives of countless cancer patients, errors can lead to unspeakable pain and death.

January 24, 2010

THE RADIATION BOOM

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

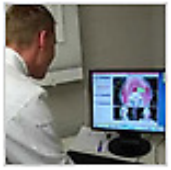
By WALT BOGDANICH and KRISTINA REBELO; ROB HARRIS CONTRIBUTED REPORTING.

Loose regulation of medical physicists has allowed problems to enter a part of the process meant to make health care safer.

January 27, 2010

THE RADIATION BOOM

As Technology Surges, Radiation Safeguards Lag



By WALT BOGDANICH; REPORTING WAS CONTRIBUTED BY SIMON AKAM, RENEE FELTZ, ANDREW LEHREN, KRISTINA REBELO and REBECCA R. RUIZ.

While new treatments are more accurate, errors in software and operation are more difficult to detect.

January 27, 2010

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ

CoxHealth in Springfield, Mo., said 76 patients over five years were overdosed because powerful new equipment had been set up incorrectly.

February 25, 2010

Medical Group Urges New Rules on Radiation

By WALT BOGDANICH

The American Society for Radiation Oncology issued a six-point plan that it said would improve safety and quality and reduce the chances of errors in medical radiation.

February 5, 2010

The Radiation Boom — Stereotactic Radiosurgery Overdoses Harm Patients

By WALT BOGDANICH and KRISTINA REBELO

A fast-growing form of radiation therapy injures patients when its pinpoint beam is allowed to spread too far.

December 29, 2010

New York City Hospital

January 24, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

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

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

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

Soon after the accident, at St. Vincent's Hospital in Manhattan, state health officials cautioned hospitals to be extra careful with

Missouri case

Top 10 health technology hazards for 2011 (ECRI Institute)

1) Radiation overdose and dose errors during radiation therapy
2) Alarm hazards
3) Cross-contamination for flexible endoscopes
4) High radiation dose of CT scans
5) Data loss, system incompatibilities, and other health IT complications

ECRI: Emergency Care Research Institute

These unfortunate outcomes could have happened to the best of us…
No one is immune!!

HDR case: written directives 5.5 Gy x 3.
First fraction: 7.5 Gy (36%); fraction 2 & 3 5.5 Gy each.
Total delivered dose =18.5 Gy vs. Intended dose=16.5 Gy (12% difference).
How would you classify this case?

20%	1. Medical event
20%	2. Possible medical event
20%	3. Not a medical event
20%	4. Not enough information
20%	5. Modify prescription, case closed

Answer

C- Not a medical event

NRC

Total dose delivered differs from the prescribed dose by 20 % or more.

The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

Data on reportable events

- Online database of ***reported*** events at www.nrc.gov
- Period 2000-2012
- Data not consistent, sometimes incomplete or lacking details
- Categories: HDR, LDR prostate, Pharmaceuticals (Y-90, I-131), others

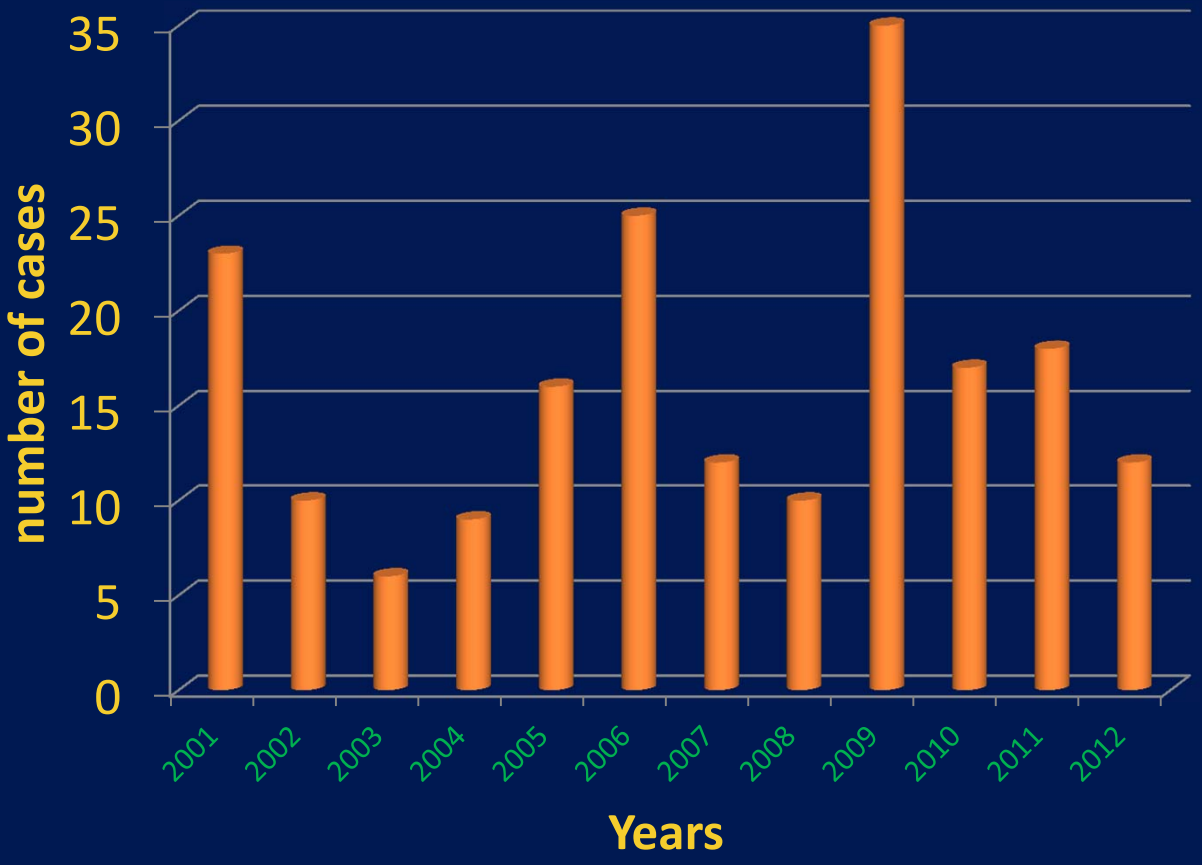
Reportable events

- Types: underdose, overdose, missing target, unintended area, wrong patient, wrong isotope etc…
- Magnitude: small to significant, mm to cm
- Impact: minor, unknown to adverse effects
- Source of errors: human, equipment (software, hardware), training, communication
- Types: LDR, HDR, Gamma Knife, radiopharmaceutical, others.

Data over 12 years

- Total of reported events: 1089
- Related to Radiation Therapy: 975
- Involve patients and personnel: 856

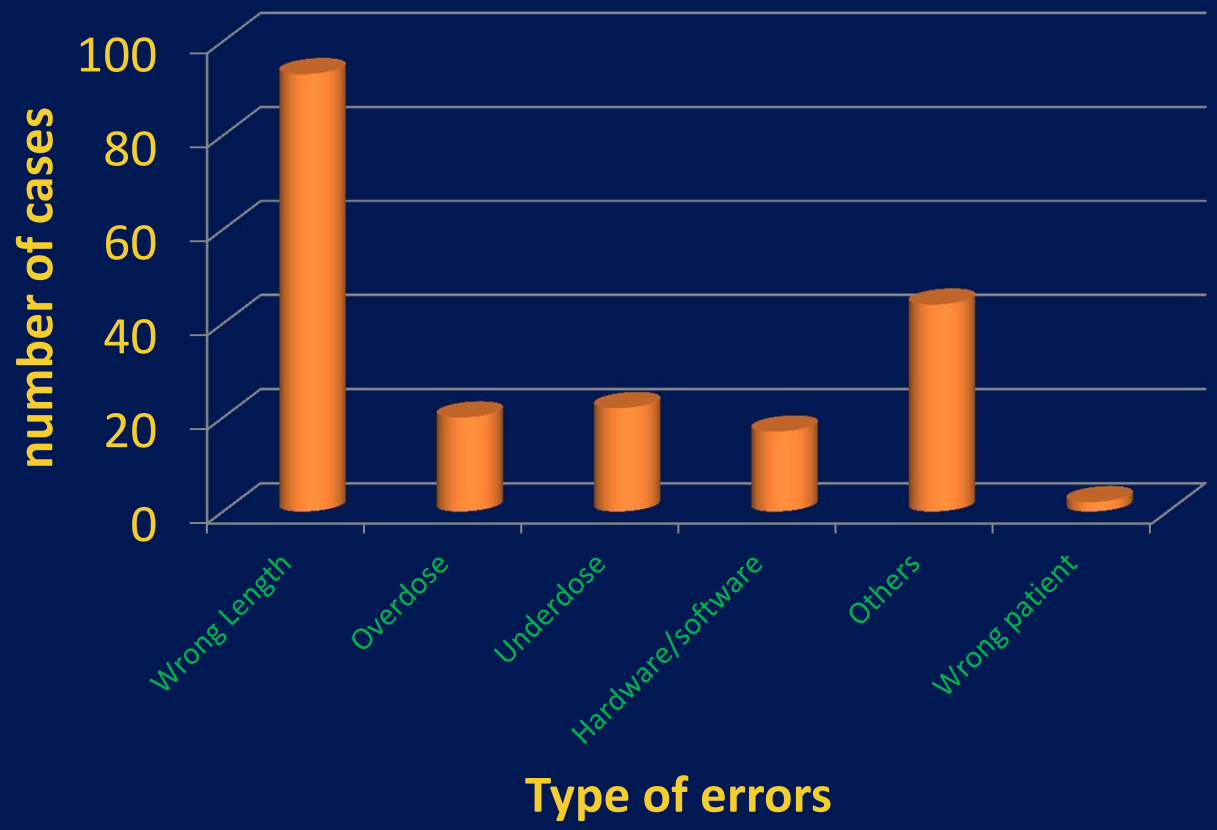
HDR cases vs. years



Years	# cases
2000	5
2001	23
2002	10
2003	6
2004	9
2005	16
2006	25
2007	12
2008	10
2009	35
2010	17
2011	18
2012	12

Total= 198

HDR procedures

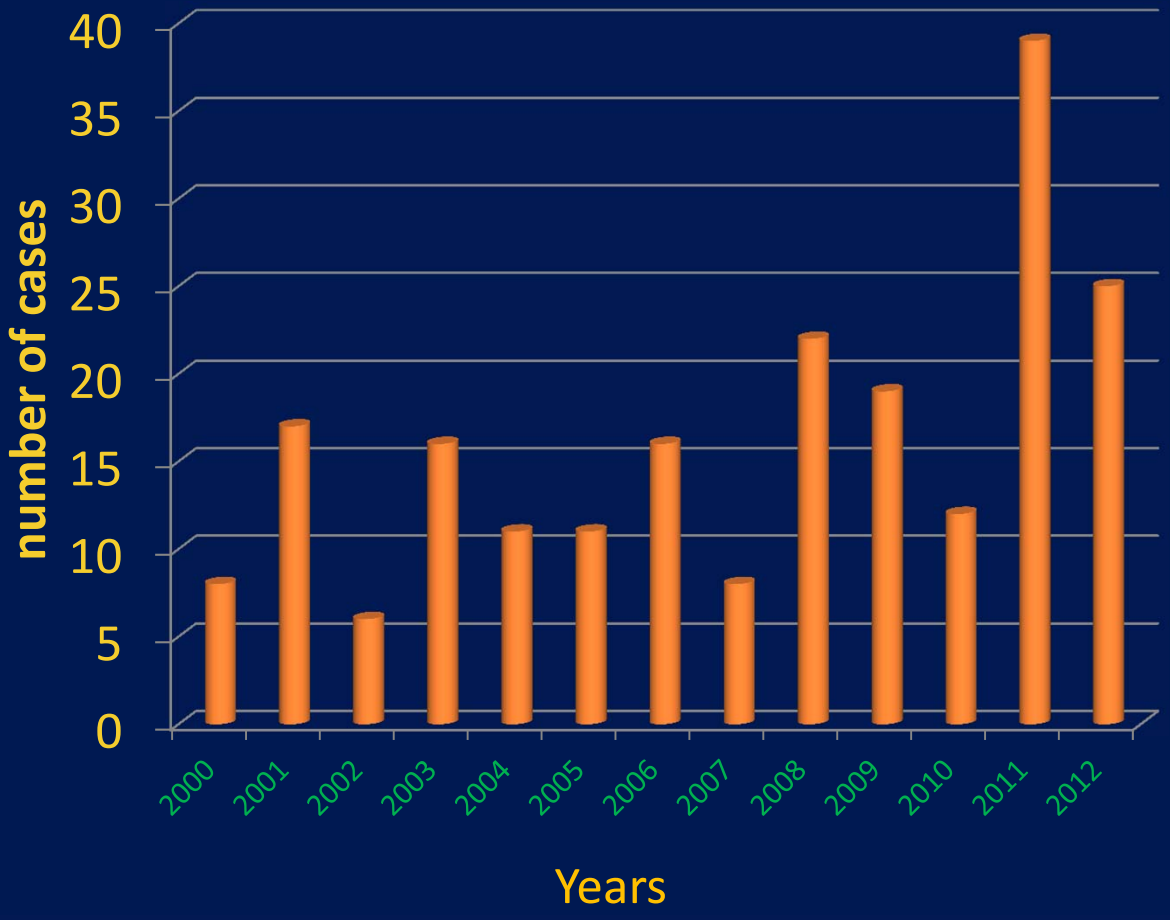


Years	# cases
Wrong Length	93
Overdose	20
Underdose	22
Hardware/ software	17
Others	44
Wrong patient	2

Total= 198

Others: source stuck, personnel exposure

Pharmaceutical Procedures

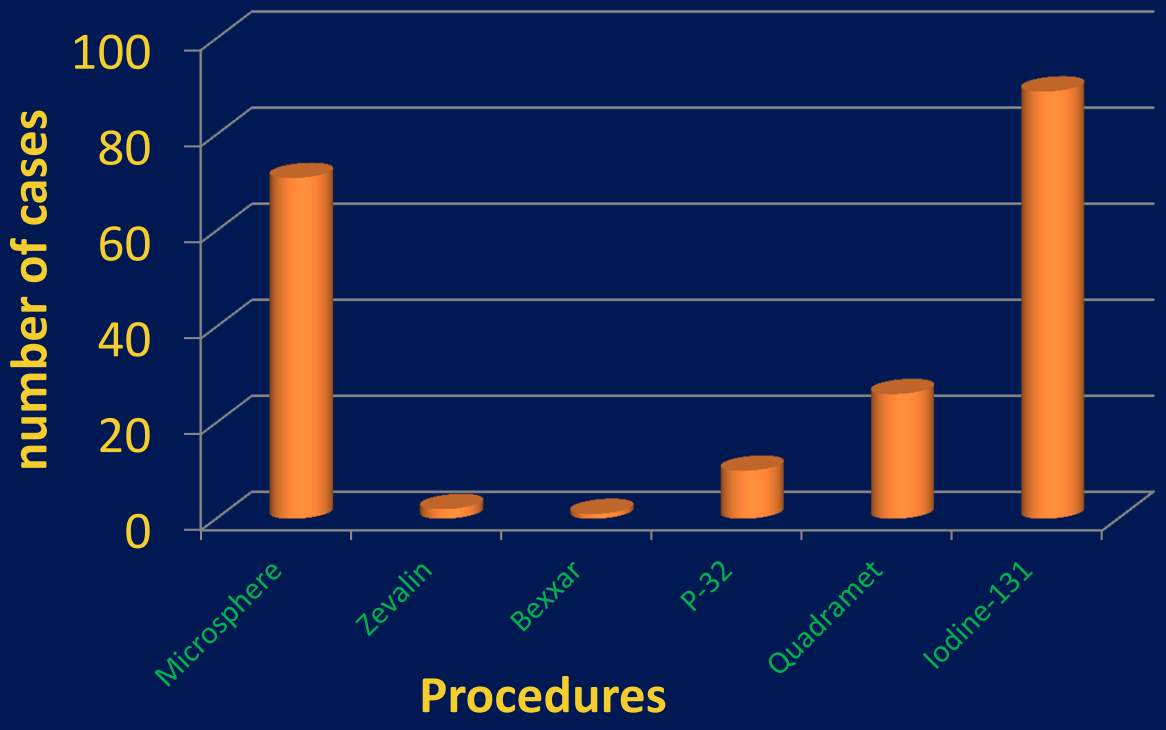


Years	# cases
2000	8
2001	17
2002	6
2003	16
2004	11
2005	11
2006	16
2007	8
2008	22
2009	19
2010	12
2011	39
2012	25

Total= 210

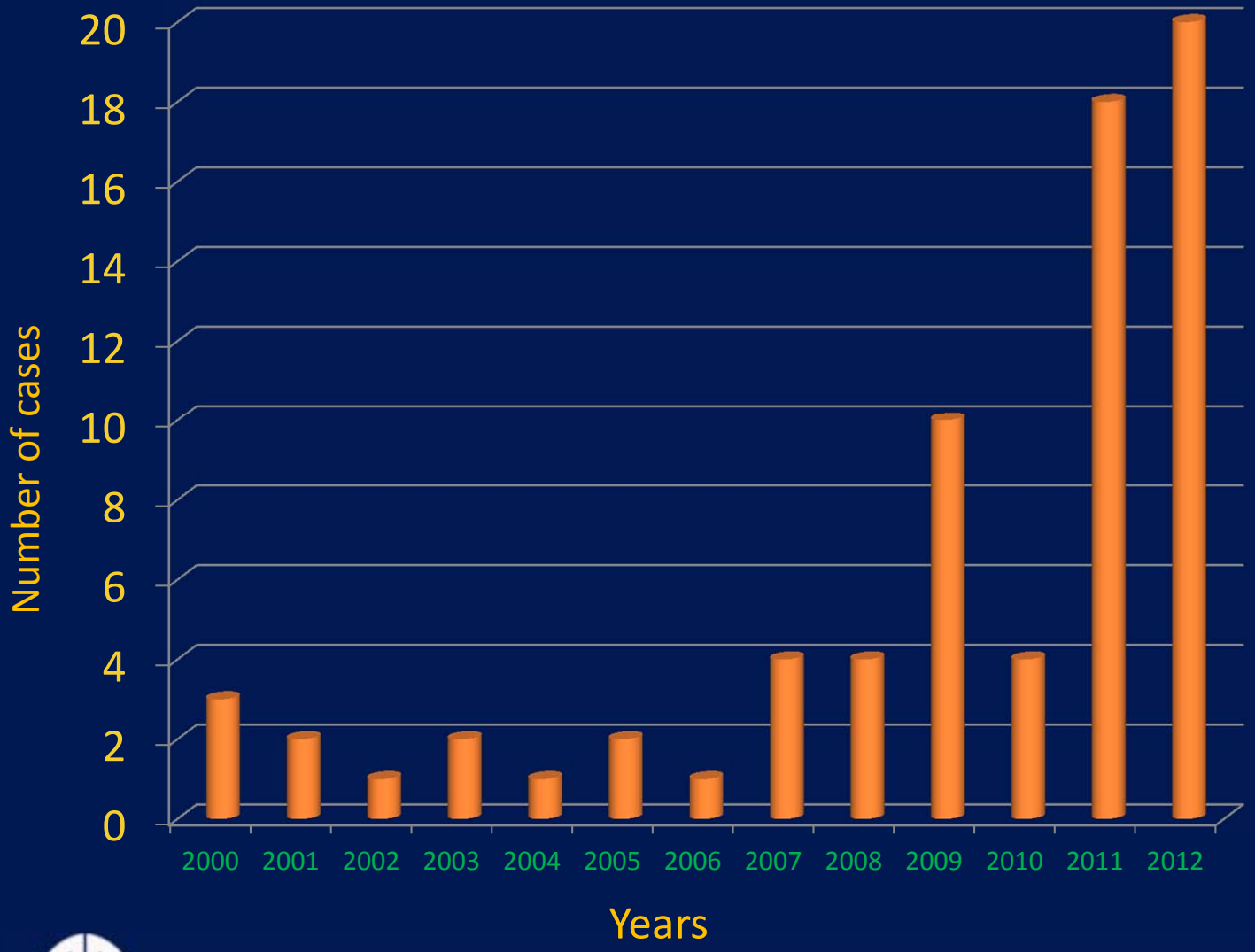
Pharmaceuticals (Therapeutic)

Years	# cases
Microsphere	71
Zevalin	2
Bexxar	1
P-32	10
Quadramet	26
Iodine-131	89



Total= 199 (210)

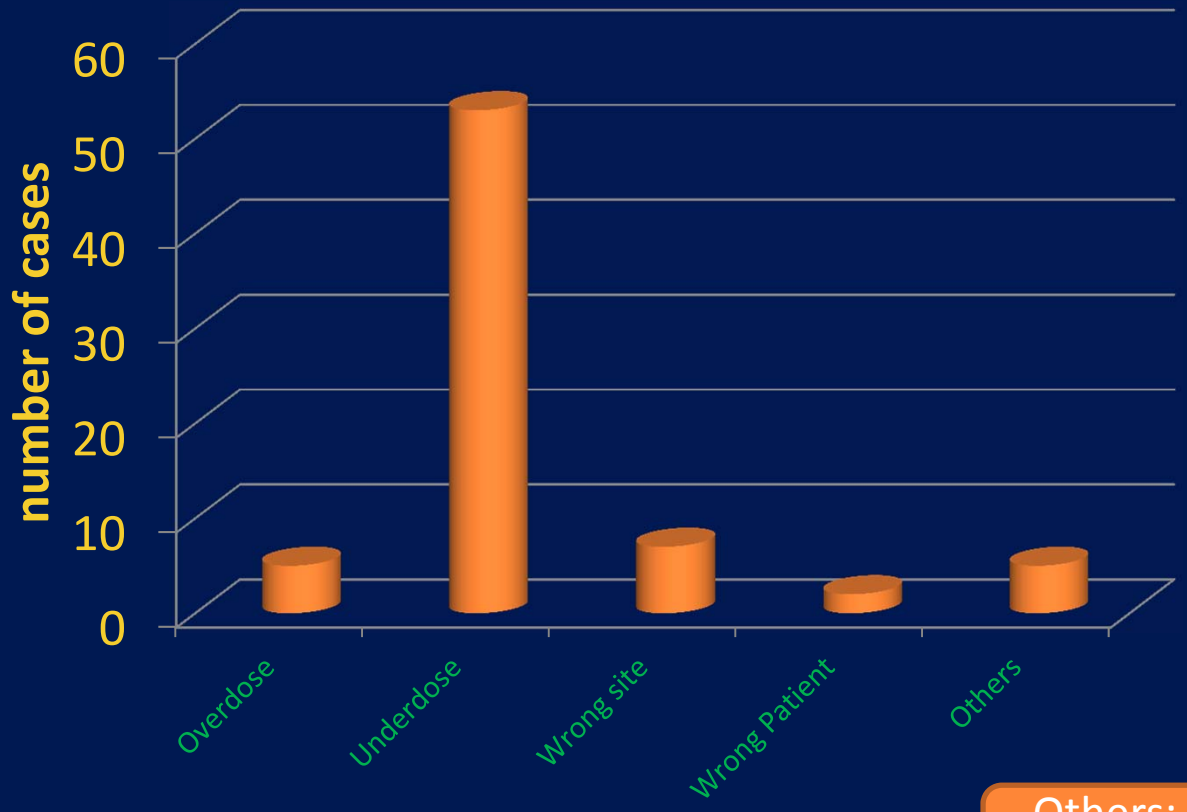
Microspheres



Years	# cases
2000	3
2001	2
2002	1
2003	2
2004	1
2005	2
2006	1
2007	4
2008	4
2009	10
2010	4
2011	18
2012	20

Total= 72

Microspheres

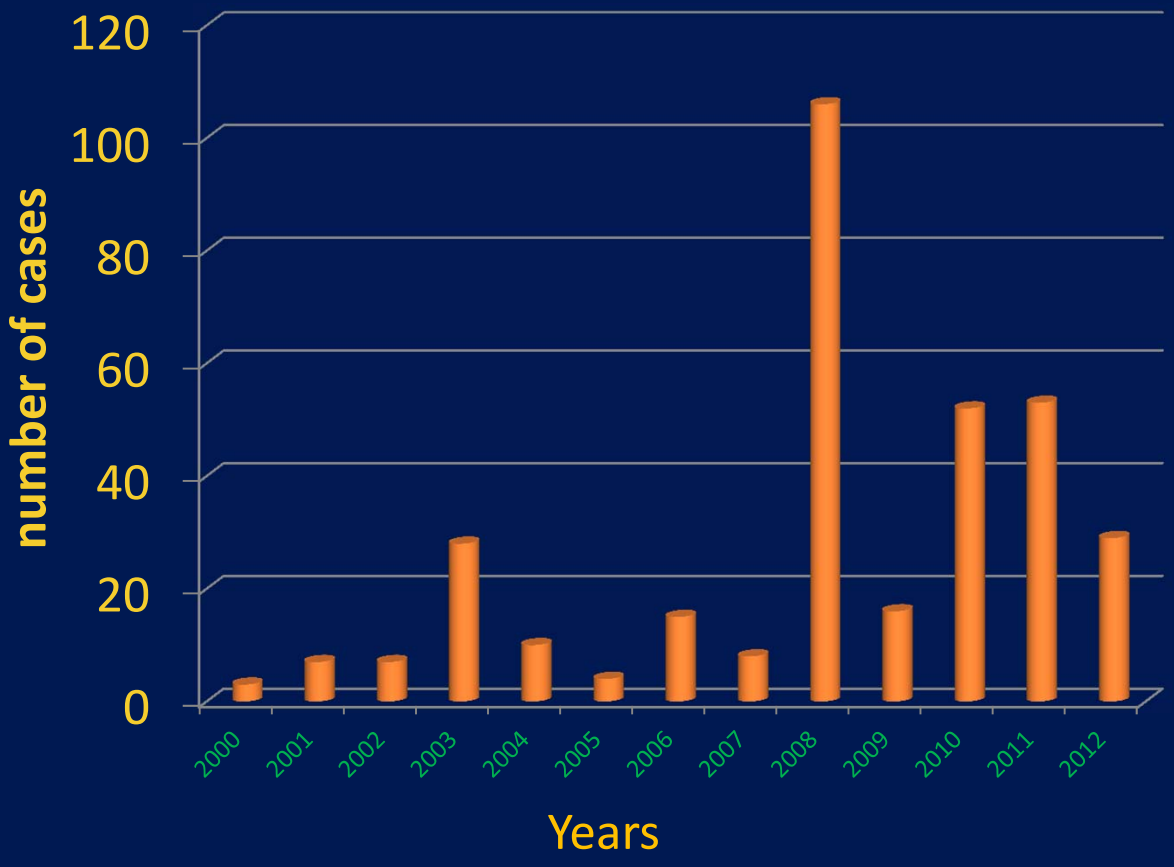


Years	# cases
Overdose	5
Underdose	53
Wrong site	7
Wrong Patient	2
Others	5

Total= 72

Others: spill, exposure to staff, no patient instruction etc…

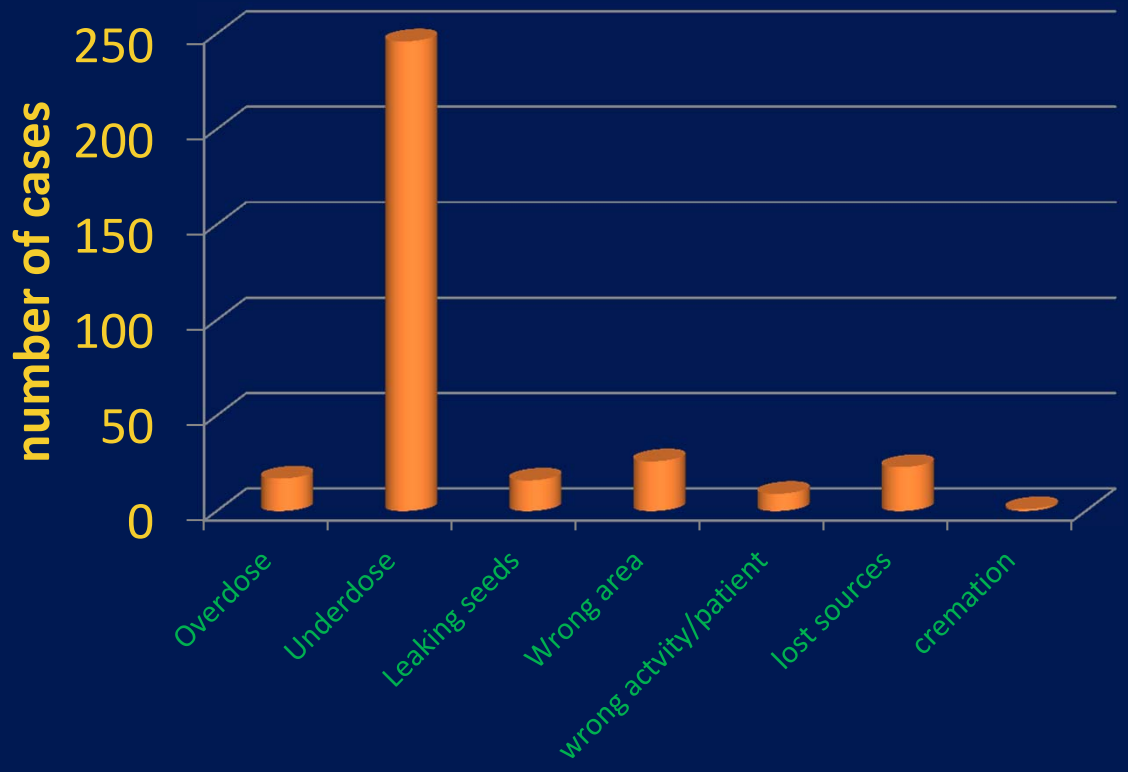
LDR Prostate



Years	# cases
2000	3
2001	7
2002	7
2003	28
2004	10
2005	4
2006	15
2007	8
2008	106
2009	16
2010	52
2011	53
2012	29

Total= 338

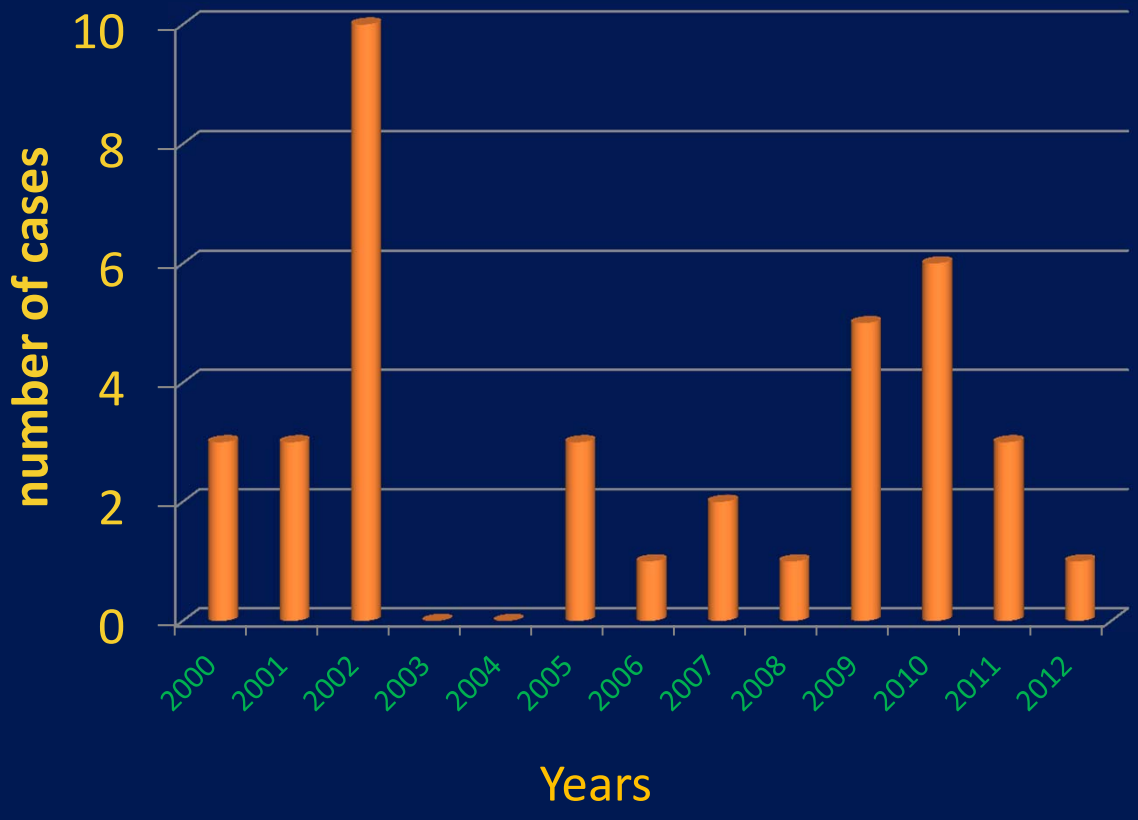
LDR Prostate



Years	# cases
Overdose	17
Underdose	246
Leaking seeds	16
Wrong area	26
wrong actvity/patient	9
lost sources	23
cremation	1

Total= 338

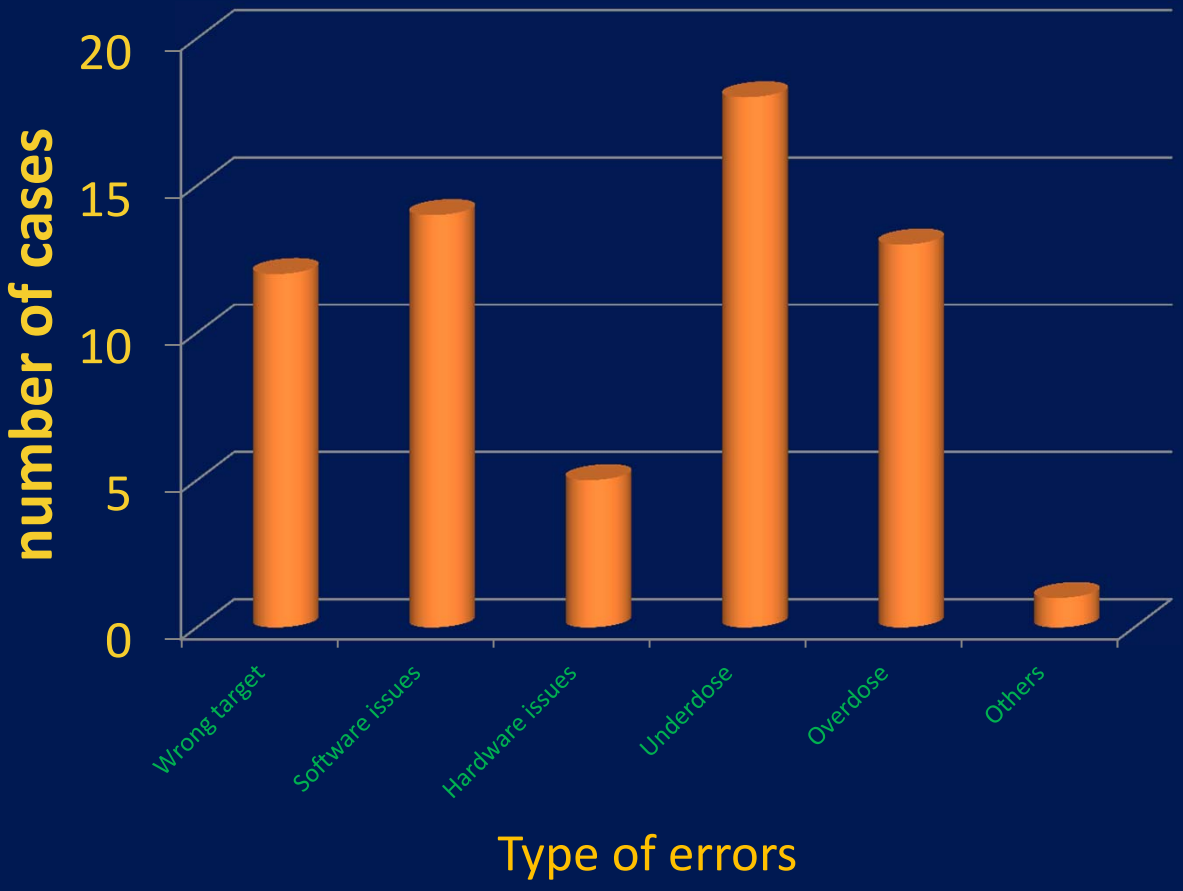
Gamma Knife



Years	# cases
2000	3
2001	3
2002	10
2003	0
2004	0
2005	3
2006	1
2007	2
2008	1
2009	5
2010	6
2011	3
2012	1

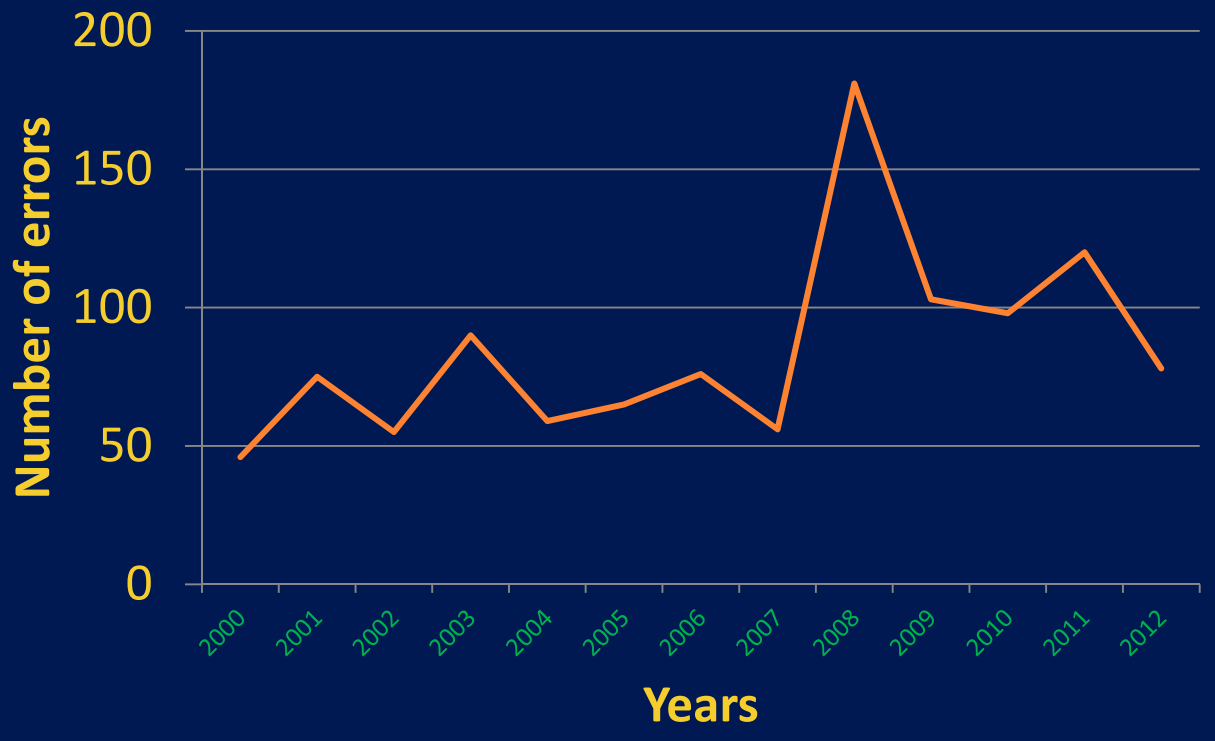
Total= 38

Gamma Knife



Years	# cases
Wrong target	12
Software issues	14
Hardware issues	5
Underdose	18
Overdose	13
Others	1

Reportable events vs. Time



2000	46
2001	75
2002	55
2003	90
2004	59
2005	65
2006	76
2007	56
2008	181
2009	103
2010	98
2011	120
2012	78

Improvement since 2008.
We must be doing something right !!

What are we doing right?

- Talking about it at every opportunity (meetings), white papers, improved communication, awareness, news media etc…
- Is this a temporary improvement till we have a new complex modality prone to errors?
- Is it perhaps that we have decreased (for now) doing certain procedures (Prostate LDR, IVB etc…)!

Findings from data

- LDR, as expected, prostate most common error: 40% (overall); worst reported in 2008 (31%); underdose: 78%
- HDR: 19 % (overall); wrong length use 47%
- GK: 4 % (overall); software issues (22%)
- Others: 2003 IVB reported events
- Underdose (All modalities combined): 82%
- Pharmaceuticals 24.5 %; microspheres Y-90 65% with 74% underdose
- Procedures over the years: significant spike in 2008; numbers affected by new regulations, news media (retro studies)
- decrease since 2008

Why errors are happening?

- Increased complexity of advancing technology => more opportunities for errors
- Technology evolving rapidly (upgrades)
- Lack of Knowledge/education/information, inexperience
- Poor communication
- Time shortage/fatigue
- Equipment failure/poor feedback from system
- Poor instructions/procedures (manufacturers, within)
- Wrong person doing the wrong task
- Lack of proper equipment
- Inattention/distraction
- Relying on computers too much

Why errors are happening (Cont'd) ?

- Poor organizational safety culture (pro-active one)
- Poor morale
- Poor supervision/checking
- Misperceptions of hazards
- False belief that bad outcomes won't happen to us
- Emotional state (anger, stress etc…)
- Power factor/hostile environment

Looking into the future?

Will things improve in the future?

Perhaps: better tools, better awareness, lessons learned etc…

Perhaps not: decrease in reimbursement, reduction in FTE's, more things to do with less manpower.

Solutions: could we be looking at specialized centers for certain complex procedures?

Lessons learned

- Errors are inevitable and no one is immune
- Investigate, question more and assume less.
- Look for errors
- More errors with procedures involving two specialties
- As technology evolved, new errors replaced old ones
- Regulations will always be here; rules might change from time to time and policies might affect those numbers↑↓

Lessons learned: (Cont'd)

- Still dealing with basic errors: wrong patient/wrong dose
- Current approach : evaluate items after a problem occurred
- Better approach: investigate processes and applications for potential problems in a continuous way (part of quality improvement program)
- Are we rushing (Not well prepared or trained) to the implementation of new technologies?

Issue with the current reporting system

- Reporting is a good start but without additional concrete goals will not help reducing errors (same error at different institutions).
- Report should have a specific format: the source(s) of error, conditions, and implemented solutions to assist others.
- Information should be available in an efficient and rapid way to avoid similar ones from happening elsewhere.
- Perhaps “near misses” should be available to others to avoid an actual one.

How to minimize errors

- System for testing both pass and fail situations
- Reward staff discovering potential errors
- Improve training and communication
- Make these errors available to users as soon as possible.
- Users 'meeting or a quarterly WebEx to discuss errors related to a new technology and solutions and/or improvements
- Events should be used as an opportunity for a refresher training and risk audit
- Will events be part of CMS payments in the future?

  more events ➔ less payment ➔better Q.I

Possible consequences from a medical event

- Could have a devastating effect on patients/family and change someone's life
- Increase staff job-related stress and cause significant emotional distress

HDR case# 1: procedures, checklist, training or distraction?

Case: MammoSite
Therapist connected transfer tube to HDR unit
Transfer tube not connected to the balloon but to connector. No one checked the connection.
Treatment completed since MammoSite connector has a closed end.
No interlock
Source stuck out 38 cm from the patient left leg

HDR case# 2: communication and checklist?

DOSE TO NON-RADIATION WORKER DURING MEDICAL TREATMENT

Case: HDR prostate
All transfer tubes connected
Staff exited the room
Treatment started as planned
1.8 minutes after the start, anesthesiologist technician was observed exiting the treatment room
The staff physicist completed the patient treatment and then conducted a review of the circumstances of the event.
The anesthesiologist technician was unaware that the treatment was beginning and was crouched down and not visible when the rest of the staff left the treatment room.
His calculated exposure is believed to be approximately 5.6 mR

Prostate implant with 42 seeds (I-125).
The patient died two weeks later.
The family would like to cremate the patient.
What are the options available to the family?

20%	1. Cremate 20 months after implant
20%	2. Cremate the next day
20%	3. Cremate if reading at 1 m≤0.5 mR/hr
20%	4. Get approval from NRC/State
20%	5. Cremate after 6 months

Answer: 1

This is an EPA issue.

Journal of Applied Clinical Medical Physics, Volume2, Number 3, Summer 2001 pp 174-177

LDR Case: Prostate seed case, cremation

Procedures and checklist (written patient safety information)?

Patient had a an Iodine-125 prostate implant 89 seeds with total Activity 33.84 mCi at Hospital A

Patient admitted at hospital B on May 26 2006 and died

Body release to funeral home May 30 2006 and cremated (31 mCi)

Remains boxed up and buried May 31 2006

Hospital B unaware of seed implant

Physics perform a survey at the funeral home June 6:

Background was noted at approximately 0.4 mr/hr

Readings of approximately 3.0 mr/hr were noted at the entrance to the retort

A filter in the air exhaust system was noted to be reading approximately 1.0 mr/hr so it was removed for decay and ultimate disposal by hospital B.

"It appears that most retorts operate at 1600 degrees Fahrenheit, or more, and the titanium capsule would melt a few hundred degrees lower than that.

The manufacturer confirmed that all seeds had most likely been melted and would not be recovered whole.

The crematorium out of service for a period of time (cleaning and decontamination.). scheduled to happen 8 June 2006.

Good and informative report !!

A. Event description

On Tuesday, June 8, 2004 at 2:25 p.m., a patient was scheduled for an I-131 thyroid uptake with an oral dose between 5 and 20 microcurie. Instead, the patient was administered 915 microcurie (34 MBq), which resulted in an absorbed dose of 2675 rad to the thyroid (assuming a 55% radioactive iodine uptake) and 81 rad effective dose equivalent…

B. Why the Event Occurred

The root cause was determined to be the lack of an adequate double check of the I-131 uptake dose prior to administration...

C. The Effect on the Patient

The absorbed dose to the thyroid was 2675 rad (assuming a 55% radioactive iodine uptake) and the effective dose equivalent was 81 rad. …The patient is not expected to have any adverse effects.

Good and informative report !!(Cont'd

D. What improvements are Needed to Prevent Recurrence

A new pipette will be used... The computer will be re-programmed to accept uptake dose activity (ie., 5 - 20 microcurie) rather than volume. The radiopharmacy staff have been trained…The nuclear medicine technologist will be retrained in… Both the Radiopharmacy technologist and the nuclear medicine technologist will review the dose units (i.e., microcurie, millicurie, MBq) and pass a test.

E. Actions Taken to Prevent Recurrence

1. A new pipette will be used for each I-131 uptake patient dose…
2. The computer will be re-programmed to accept uptake dose activity…
3. The nuclear medicine technologist will be retrained in…
4. Both the Radiopharmacy technologist and the nuclear medicine technologist will review the dose units…

Emergency response case
Good one to learn from !

AGREEMENT STATE REPORT - IRIDIUM 192 SOURCE FAILED TO RETRACT

"At about 9:30 a.m. on 09-08-03, an Ir-192 source (4.6 Ci [Curie]) failed to retract following a patient treatment. The source became stuck in the transfer tube. The physicist started his stopwatch, entered the room and attempted to manually retract the source. Manual retract failed. The physicist called the physician, who was waiting outside the room. The physician entered the room and disconnected the apparatus from the patient and dropped the transfer tube into a lead pig. The physicist and physician moved the patient out of the room. The physicist stopped the watch and it showed that 2 minutes had elapsed. The physicist surveyed the patient and obtained no measurement above background. The physicist re-entered the room and performed a radiation survey, and found the hot spot along the transfer tube to be in the pig. The pig measured 10 mR [millirem] /hr at 3 feet. The room was locked and posted until arrival of the manufacturer's representative, who also was unable to make the source retract. The manufacturer's representative placed the transfer tube into a shipping container and shipped it back to the manufacturer for further investigation. Doses to the patient, physicist and physician were estimated as follows: patient skin dose (10cm from source for 2 minutes) = 9 rem; physicist for 2 minutes = 45 mrem [millirem]; physician 125 mrem [millirem] whole body and 15 rem extremity."

Conclusions

- Radiation treatments can be safe, beneficial and effective when used properly.
- Safety should be in the mind of everyone involved (staff and industry)
- Implement at a slow pace and more important safely
- Annual evaluation of the program