Brachytherapy Physics:
Everything you Need to Know
and
Controversial Issues

Robin Miller
Radiation Oncology Services, Inc

Bruce Thomadsen
University of Wisconsin-Madison

Disclaimer

- The presenters have no conflicts to declare.
- Images of commercial devices have been supplied by vendors or taken by the presenters, but do not imply endorsement of any particular equipment.

Prostate Brachytherapy

Learning Objectives Prostate Brachytherapy

- Review the isotopes in vogue, prescription ranges, and common clinical characteristics for LDR and HDR
- Compare and contrast LDR vs HDR
- Review radiation safety and release criteria

What is Brachytherapy?

Brachytherapy can be
low dose rate or **high dose rate**
permanent or temporary

What is **LDR** (low dose rate) brachytherapy?

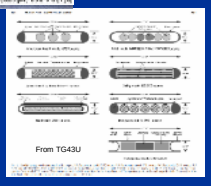
- Per ICRU report #38 LDR is in the range of 0.4 to 2.0 Gy/hr (think DAYS)

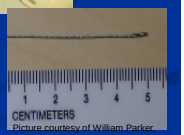
What is **HDR** (high dose rate) brachytherapy?

- Per ICRU report #38 is a dose rate greater than 12 Gy/hr (think MINUTES)

There is also **MDR** (medium dose rate) that falls between 2 to 12 Gy per hour (think HOURS)

LDR vs HDR





Picture courtesy of William Parker, McGill University

Common Sources:

I-125, Pd-103, Cs-131

Ir-192

Prostate Brachytherapy

HDR **LDR**

What do LDR and HDR patient selection criteria have in common?

-typically early stage
-Gleason score 2-10
-Obstructive urinary symptoms contraindication
-prior TURP is a challenge
-no distant metastasis

HDR

AMERICAN BRACHYTHERAPY SOCIETY
PROSTATE HIGH-DOSE RATE TASK GROUP
I-Chow Hsu, MD, Yoshiya Yamada MD, Eric Vigneault MD, Jean Pouliot, PhD
August, 2008

Patient Selection Criteria:

Monotherapy:
Clinical T1b-T2b and Gleason score ≤ 7 and PSA ≤ 10 ng/mL

Boost:
Patients with high risk features such as T3-T4, Gleason score 7-10, and/or PSA > 10 ng/mL
Selected patients with "bulky" T1-2b tumor (inadequate information exists to clearly define bulky tumor based on DRE, TRUS, percentage positive biopsies)

Prescription Doses:

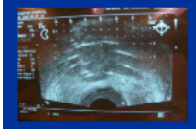
Monotherapy
10.5 Gy x 3
8.5-9.5 Gy x 4
6.0-7.5 Gy x 6

Boost
15 Gy x 1 (with 36-40 Gy XRT)
9.5-10.5 Gy x 2 (with 40-50 Gy XRT)
5.5-7.5 Gy x 3 (with 40-50 Gy XRT)
4.0-6.0 Gy x 4 (with 36-50 Gy XRT)

The 1st HDR Fx should be delivered on the day of the catheter placement.

If multiple Fxs are delivered, consecutive Fxs should be delivered within 24 hours after the 1st Tx, but no less than 6 hours between Txs.

Prostate Brachytherapy HDR



Under U/S guidance, typically 12-20 flexible needles are inserted into the prostate

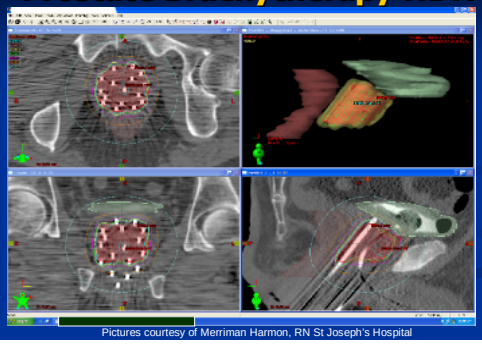
Can use a C-arm to assist with visualization

Patient must have a treatment planning CT

Volume implant technique, "goodness of plan" similar to that of a seed implant

Pictures courtesy of Merriman Harmon, RN St Joseph's Hospital

Prostate Brachytherapy HDR



Pictures courtesy of Merriman Harmon, RN St Joseph's Hospital

LDR: Comparing Isotopes

Isotope	T 1/2 (days)	(median) Energy (KeV)	90% Dose delivered (days)	Dose	
				Implant Alone	Boost *
^{125}I	~60	28	204	145	100-110
^{103}Pd	~17	22	58	120 or 125	90-100
^{131}Cs	~10	29	33	115	85

*Boost: (not necessarily prior) XRT 40 - 45 Gy

M J Rivard et al. ABS recommends no change for prostate implant dose prescriptions Using iodine-125 or palladium-103. *Brachytherapy*, 6: 34-37, 2007.

What makes it a Good Plan?

- Seattle Prostate Institute Criteria **pre-plan**
  - Modified uniform loading
  - V100: 98-100%
  - V150: I-125 30-40%
    Pd-103 40-50%
  - V200: 10-20%
  - Uretha max: 100-125% (definitely <150%)
  - Rectum point: <80%
  - Margin: 3-5 mm

Seattle Prostate Institute, Class notes, 2002

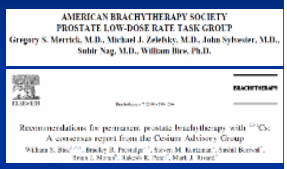
The perfect post plan

Suggested Post Implant Dosimetry Targets

Prostate
- I-125 D_{90} >140 Gy
- Pd-103 D_{90} >125 Gy
- Cs-131 D_{90} > 115 Gy
- Boosts D_{90} > reference dose

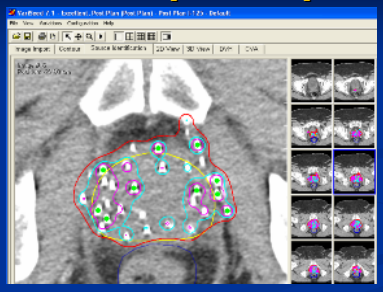
Urethra
- D90 <180 Gy
- V150 <60% reference dose

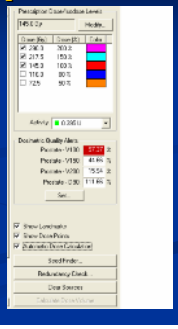
Rectum
- Dose to > 1cm length of the anterior mucosal wall < reference dose
- Max dose to the anterior mucosal wall < 120% of reference dose


AMERICAN BRACHYTHERAPY SOCIETY
PROSTATE LOW-DOSE RATE TASK GROUP
Gregory S. Merrick, M.D., Michael J. Zelefsky, M.D., John Sylvester, M.D., Subir Nag, M.D., William Bice, Ph.D.

Brachytherapy Physics, Joint AAPM/ABS Brachytherapy Summer School 2nd Ed, 2005 Chapter 31, Bice

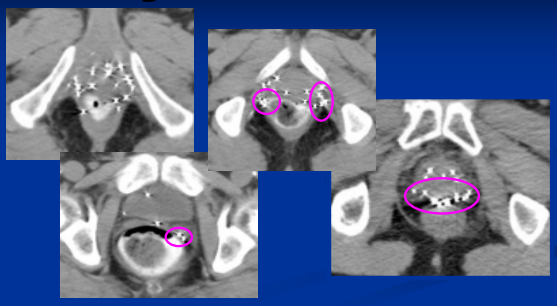
The perfect post plan





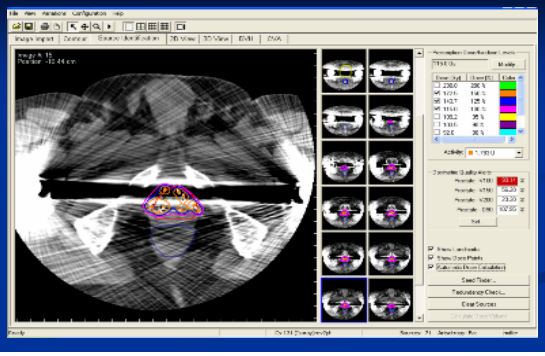
Courtesy of Michael Sitter, President PDS

Seeds gone wild……

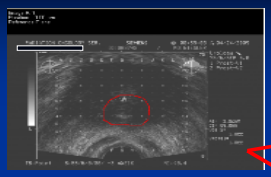


Pictures courtesy of Merriman Harmon, RN St Joseph's Hospital

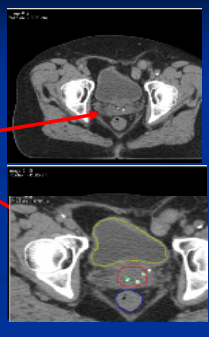
Post Plan Challenges



Post Plan Challenges



?



Leg position is different between pre-plan U/S and post plan CT

Where's the base?

Prostate Brachytherapy Question:

All of the following are equivalent treatment prescription ranges for either LDR or HDR prostate treatment except?

20% 1. 145 Gy using ^{125}I

20% 2. 125 Gy using ^{103}Pd

20% 3. 115 Gy using ^{131}Cs

20% 4. 2 implants, typically one or two weeks apart, of 6 to 9.5 Gy in 2 or 3 fractions

20% 5. 110 Gy using 169Ytterbium

10

Prostate Brachytherapy question:

All of the following are equivalent treatment prescription ranges for either LDR or HDR prostate treatment except:

1. 145 Gy using ^{125}I
2. 125 Gy using ^{103}Pd
3. 115 Gy using ^{131}Cs
4. 2 implants, typically one or two weeks apart, of 6 to 9.5 Gy in 2 or 3 fractions
5. 110 Gy using ^{169}Ytterbium

Prostate Brachytherapy question:

References

- American Brachytherapy Society recommends no change for prostate permanent implant dose prescriptions using iodine-125 or palladium-103. Mark J. Rivard1, Wayne M. Butler, Phillip M. Devlin, John K. Hayes Jr., Robert A. Hearn, Eugene P. Lief, Ali S. Meigooni, Gregory S. Merrick, Jeffrey F. Williamson. Brachytherapy 6(2007) 34-37
- Recommendations for permanent prostate brachytherapy with 131Cs:A consensus report from the Cesium Advisory Group. William S. Bice, Bradley R. Prestidge, Steven M. Kurtzman, Sushil Beriwal, Brian J. Moran, Rakesh R. Patel, Mark J. Rivard. Brachytherapy 7(2008) 290-296
- HDR Brachytherapy for Prostate, Zoubir Ouhbib. Brachytherapy Physics, 2nd Ed, Joint AAPM/ABS Summer School, chapter 32
- Modern Advances in Prostate Brachytherapy, Eugene Lief. Brachytherapy Physics, 2nd Ed, Joint AAPM/ABS Summer School, chapter 3

Radiation Safety and release criteria

- Release criteria are based on exposure to the general public
- Where to measure @ 1 meter?
- What meter are you using?

Release Dose Calculation

NUREG -1556 vol 9 (2005) supersedes reg guide 8.35

You can release based on activity or dose rate (appendix U)

for I-125 it is 1 mrem/hr @ 1 meter

The maximum release dose rate for Cs 131 is not tabulated in NUREG – 1556

The maximum release dose rate can be calculated from the formalism in stated in NUREG -1556

When calculated it is 6 mrem/hr

Resources

http://www.americanbrachytherapy.org/resources/HDRTaskGroup.pdf

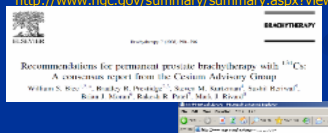
http://www.americanbrachytherapy.org/resources/prostate_lowdoserateteskgroup.pdf

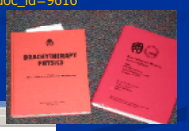
NUREG -1556 vol 9 (2005)

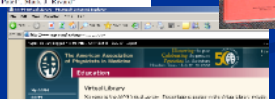
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/nureg-1556-9.pdf

http://www.rtog.org/members/protocols/0232/0232.pdf

http://www.ngc.gov/summary/summary.aspx?view_id=1&doc_id=9616







Electronic Brachytherapy

Electronic Brachytherapy

- Brachytherapy using an x-ray generator instead of a radioactive source.
- At the moment, all of the units operator between 30 and 50 kVp.
- Why do users what this?
  - More control?
  - Less regulation?

Available Units

Currently, there are two devices on the market:

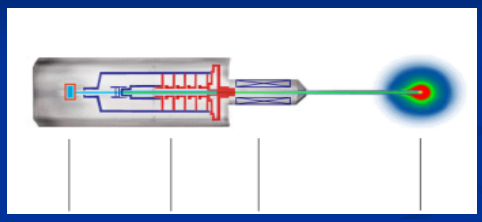
- The INTRABEAM, from Carl Zeiss, a stationary beam model used mostly for intraoperative applications;
- The Axxent system, from Xoft, a stepping-source device, mostly to replace conventional HDR units.

Carl Zeiss IntraBeam

- A balanced, mobile stand to allow for six degrees of freedom using electromagnetic clutches and breaking systems to ensure safe and accurate delivery of the probe to the target.
- The IINTRABEAM may be rolled into any O.R. suite and no special room shielding is required.

The INTRABEAM - X Ray Source

Soft' X-rays Produced Inside Tumor or Tumor Cavity



Internal Radiation Monitor (IRM) detects radiation emitted back along the beam and is the primary monitor of patient dose delivery.

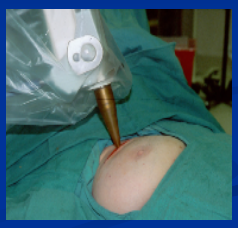
X-ray Tube, Cathode Gun & Accelerator Section – 50 kV max

Beam Deflectors precess electron beam around central axis of probe tip creating a spherical pattern.

Electron Beam strikes gold target generating x-rays at probe tip.

INTRABEAM Applicators

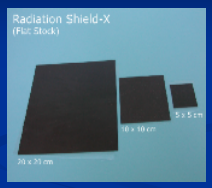
Spherical Applicator Set Ranges from 1.5 to 5.0 cm diameters are available.



Patient Shielding

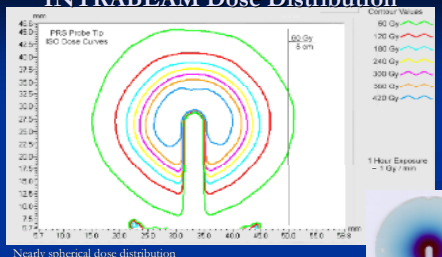
Sterile Shields and Drapes

- Radiation shields are devices to protect tissue from unwanted radiation exposure.
- Shields are designed to be used with the spherical applicators
- They are provided as sterile, single use items.
- Shielding material is also available as flat stock.



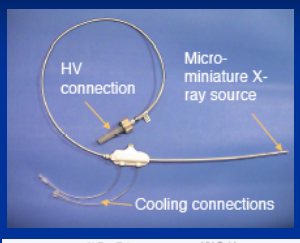
Shielding:
93% attenuation at 1cm depth, 3 cm applicator

INTRABEAM Dose Distribution



- Nearly spherical dose distribution
- Low energy high dose rate
- High dose at center, steep fall-off approximately $1/r^3$
- For intra-cavity or surface applications, applicators may be used

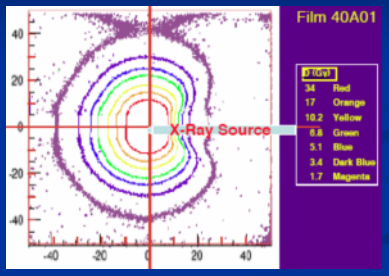
Xoft Axxent System



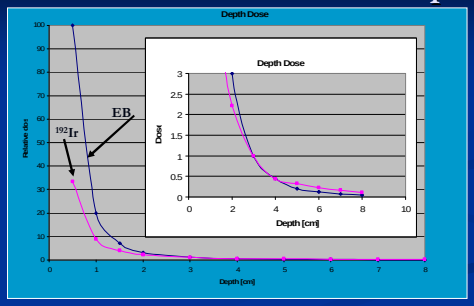
Miniature X-ray source inserted into a flexible, cooling catheter
- High vacuum x-ray tube
- 50 kV operating potential
- Output: ~1 Gy/m @ 1 cm
- Water cooled
- Fully disposable device

Control Unit

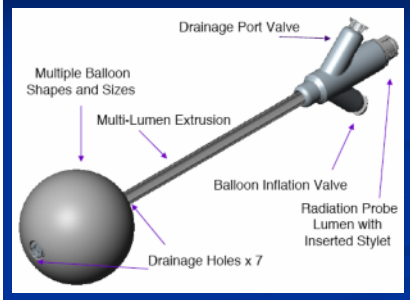
Dose Distribution Pattern



Dose as a Function of Depth



Axxent® Balloon Applicator



Applicators for Breast, vagina and skin

Slide courtesy of Xoft

Axxent Vaginal Applicator Set

4 Vaginal Applicators – *20 mm, 25 mm, 30 mm, 35 mm*

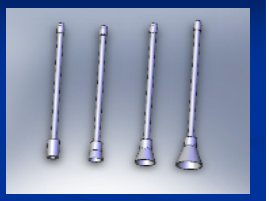
4 Source Channels

Reusable for 100 treatment fractions or 100 sterilization cycles

Slide courtesy of Xoft

Applicator Selection

- Applicator development of 10mm, 20mm, 35mm, 50 mm
- Stainless Steel:
  - Easy to sterilize
  - Applicator Cone and Source Channel (shown with V-Groove SC)
  - Flattening Filter integrated in Cone
  - Single use cover for applicator cone



Slide courtesy of Xoft

Comparisons with Sources for Breast Brachytherapy

- Electronic Brachytherapy dose is higher near the source but lower far.
- The lower energy give *some* sparing of skin and pectoralis, but does not give quite as much dose beyond the prescription.
- Room shielding is not required.
- Inhomogeneities will produce a greater effect.

Electronic Brachytherapy Dosimetry Question: When treating breast with 50 kVp x rays, compared to ^{192}Ir, which is true?

20% 1. The dose at the surface of an intracavitary applicator will be higher.

20% 2. The dose beyond the prescription point will be higher.

20% 3. The dose uniformity on the surface of the applicator will be less uniform.

20% 4. Tissue inhomogeneities will perturb the dose distribution less.

20% 5. The dose should be prescribed at 0.5 cm instead of 1 cm.

10

Electronic Brachytherapy Dosimetry Question: When treating breast with 50 kVp x rays, compared to ^{192}Ir, which is true?

1. The dose at the surface of an intracavitary applicator will be higher.
2. The dose beyond the prescription point will be higher.
3. The dose uniformity on the surface of the applicator will be less uniform.
4. Tissue inhomogeneities will perturb the dose distribution less.
5. The dose should be prescribed at 0.5 cm instead of 1 cm.

Electronic Brachytherapy Dosimetry Reference

RK Das, B Thomadsen. The Physics of Breast Brachytherapy. In D Wazer, D Arthur, F Vincini, eds. *Accelerated Partial Breast Irradiation, 2nd.* (Springer-Verlag, Berlin 2009).

Electronic Brachytherapy RBE Question: Given that breast brachytherapy treatments using ^{192}Ir use fractions of 3.4 Gy, treatments using 50kVp x rays might use which dose per fraction?

20% 1. 1.3 Gy, using an RBE of 3

20% 2. 2.8 Gy, using an RBE of 1.2

20% 3. 3.5 Gy, since the doses or the two are equally effective

20% 4. 4.1 Gy, using an RBE of 1.2

20% 5. 10.2 Gy, using an RBE of 3

10

RBE

- Relative Biological Effectiveness is a function of beam energy.
  - Usually relative to 200 or 250 kVp or ^{60}Co
  - For ^{125}Ir and ^{103}Pd, values run about 1.6 to 2.5
- RBE is a function of dose and depth: maybe running from 1.38 near the source to 1.24 2 cm away.

More RBE Variables

- RBE depends on the end-point.
  - Cancer cell response, normal tissue damage, α/β
  - Generally, RBE increases with α/β
  - Not a lot of real information on this
- RBE depends on dose/fraction (Fowler, Dale and Rusch): RBR from 1.78 for 1 Gy to 1.13 for 20 Gy, α/β =3
- RBE depends on dose rate (Fowler, Dale and Rusch): RBR from 1.79 for 2.5 Gy/h to 1.16 for 50 Gy/h, α/β =3

Electronic Brachytherapy RBE Question: Given that breast brachytherapy treatments using ^{192}Ir use fractions of 3.4 Gy, treatments using 50kVp x rays might use which dose per fraction?

20% 1. 1.3 Gy, using an RBE of 3

20% 2. 2.8 Gy, using an RBE of 1.2

20% 3. 3.5 Gy, since the doses or the two are equally effective

20% 4. 4.1 Gy, using an RBE of 1.2

20% 5. 10.2 Gy, using an RBE of 3

Electronic Brachytherapy RBE Question: Given that breast brachytherapy treatments using ^{192}Ir use fractions of 3.4 Gy, treatments using 50kVp x rays might use which dose per fraction?

1. 1.3 Gy, using an RBE of 3
2. 2.8 Gy, using an RBE of 1.2
3. 3.5 Gy, since the doses or the two are equally effective
4. 4.1 Gy, using an RBE of 1.2
5. 10.2 Gy, using an RBE of 3

References on RBE

- J. Fowler, R.G. Dale, T. Rusch, "Variation of RBE with Dose and Dose Rate for a Miniature Electronic Brachytherapy Source," Poster presented at the American Association of Physicists in Medicine (AAPM) meeting, (2004), available at http://www.xoftinc.com/images/pdf/posters/Poster_7.pdf (accessed January 27, 2009).
- Zellmer DL, Gillin MT, Wilson JF. Microdosimetric single event spectra of Ytterbium-169 compared with commonly used brachytherapy sources and teletherapy beams. Int J Radiat Oncol Biol Phys. 1992;23(3):627-32.
- Wuu CS, Kliauga P, Zaider M, Amols HI. Microdosimetric evaluation of relative biological effectiveness for 103Pd, 125I, 241Am, and 192Ir brachytherapy sources Int J Radiat Oncol Biol Phys. 1996 Oct 1;36(3):689-97.
- Brenner DJ, Leu CS, Beatty JF, Shefer RE. Clinical relative biological effectiveness of low-energy x-rays emitted by miniature x-ray devices. Phys Med Biol. 1999 Feb;44(2):323-33.

Breast Brachytherapy

Learning Objectives Breast Brachytherapy

- Review the current treatment options for breast brachytherapy
  - Balloon & hybrid devices (Mammosite, Contura, Savi)
  - Interstitial HDR
  - Accuboost
- Review the advantages and disadvantages of the current treatment options

Breast Brachytherapy Treatment planning question:

Using a comparison between partial breast irradiation techniques utilizing CT based 3D dose volume analysis, PTV coverage is superior with which technique:

20% 1. a balloon device, such as mammosite

20% 2. interstitial HDR

20% 3. 3D conformal radiation therapy

20% 4. there is no difference between techniques

20% 5. the balloon & interstitial HDR showed superiority over 3D conformal radiation therapy

Breast Brachytherapy Treatment planning question:

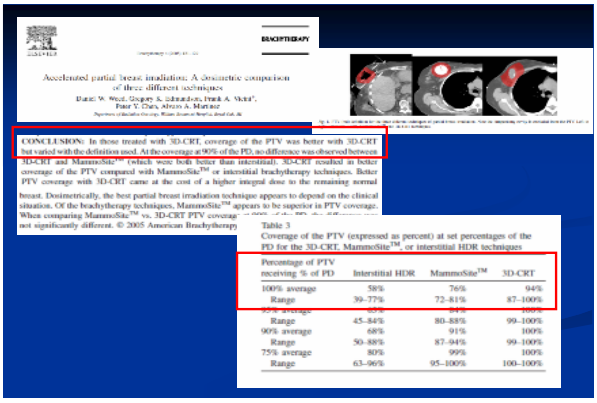
Using a comparison between partial breast irradiation techniques utilizing CT based 3D dose volume analysis, PTV coverage is superior with which technique:

1. a balloon device, such as mammosite
2. interstitial HDR
3. 3D conformal radiation therapy
4. there is no difference between techniques
5. the balloon & interstitial HDR showed superiority over 3D conformal radiation therapy

Breast Brachytherapy Treatment planning question:

Reference

- Accelerated partial breast irradiation: A dosimetric comparison of three different techniques. Daniel Weed, Gregory Edmundson, Frank Vicini, Peter Chen, Alvaro Martinez. Brachytherapy, volume 4 #2, 2005 pp121-129
- Mammosite & PBI: rethinking one size fits all breast irradiation after lumpectomy. Julia White. Brachytherapy, volume 4, #3, 2005 pp183-185



BRACHYTHERAPY

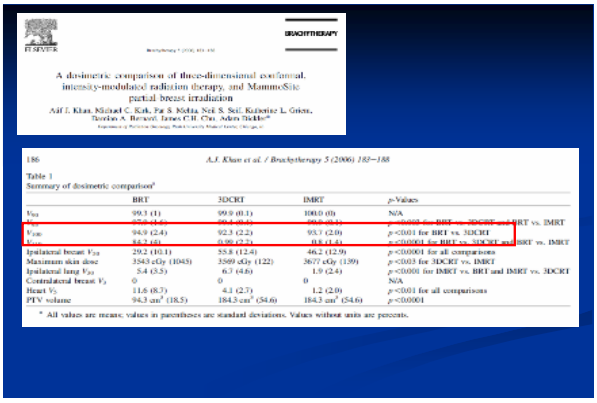
Accelerated partial breast irradiation: A dosimetric comparison of three different techniques

Daniel W. Weed, Gregory A. Edmundson, Frank A. Vicini*, Peter Y. Chen, Alvaro A. Martinez

CONCLUSION: In those treated with 3D-CRT, coverage of the PTV was better with 3D-CRT but varied with the definition used. At the coverage at 90% of the PD, no difference was observed between 3D-CRT and MammoSite™ (which were both better than interstitial). 3D-CRT resulted in better coverage of the PTV compared with MammoSite™ or interstitial brachytherapy techniques. Better PTV coverage with 3D-CRT came at the cost of a higher integral dose to the remaining normal breast. Dosimetrically, the best partial breast irradiation technique appears to depend on the clinical situation. Of the brachytherapy techniques, MammoSite™ appears to be superior in PTV coverage. When comparing MammoSite™ vs. 3D-CRT PTV coverage [illegible] not significantly different. © 2005 American Brachytherapy

Table 3
Coverage of the PTV (expressed as percent) at set percentages of the PD for the 3D-CRT, MammoSite™, or interstitial HDR techniques

Percentage of PTV receiving % of PD	Interstitial HDR	MammoSite™	3D-CRT
100% average	58%	76%	94%
Range	39–77%	72–81%	87–100%
95% average	65%	84%	100%
Range	45–84%	80–88%	99–100%
90% average	68%	91%	100%
Range	50–88%	87–94%	99–100%
75% average	80%	99%	100%
Range	63–96%	95–100%	100–100%



BRACHYTHERAPY

A dosimetric comparison of three-dimensional conformal, intensity-modulated radiation therapy, and MammoSite partial breast irradiation

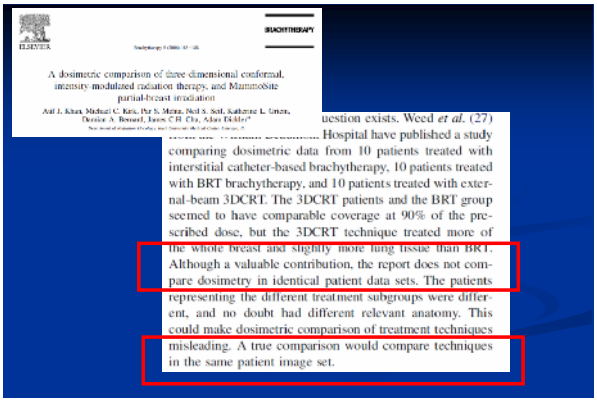
Atif J. Khan, Michael C. Kirk, Par S. Mehta, Neil S. Seif, Katherine L. Griem, Thorlton A. Bernard, James C.H. Chu, Adam Dicker*

186 A.J. Khan et al. / Brachytherapy 5 (2006) 182–188

Table 1
Summary of dosimetric comparison*

	BRT	3DCRT	IMRT	p-Values
V_{100}	99.3 (1)	99.9 (0.1)	100.0 (0)	N/A
V_{95}	95.9 (3.4)	99.4 (0.4)	99.8 (0.1)	p <0.001 for BRT vs. 3DCRT and IMRT vs. IMRT
V_{100}	94.9 (2.4)	92.3 (2.2)	93.7 (2.0)	p <0.001 for BRT vs. 3DCRT
V_{90}	84.7 (4)	0.99 (7.2)	0.8 (1.4)	p <0.0001 for BRT vs. 3DCRT and IMRT vs. IMRT
Ipsilateral breast V_{50}	29.2 (10.1)	55.8 (12.4)	46.2 (12.9)	p <0.0001 for all comparisons
Maximum skin dose	3543 cGy (1045)	3569 cGy (122)	3677 cGy (139)	p <0.003 for 3DCRT vs. IMRT
Ipsilateral lung V_{20}	5.4 (3.5)	6.3 (4.6)	1.9 (2.4)	p <0.001 for IMRT vs. BRT and IMRT vs. 3DCRT
Contralateral breast V_5	0	0	0	N/A
Heart V_5	11.6 (8.7)	4.1 (2.7)	1.2 (2.0)	p <0.01 for all comparisons
PTV volume	94.3 cm³ (18.5)	184.3 cm³ (54.6)	184.3 cm³ (54.6)	p <0.0001

* All values are means; values in parentheses are standard deviations. Values without units are percents.



BRACHYTHERAPY

A dosimetric comparison of three-dimensional conformal, intensity-modulated radiation therapy, and MammoSite partial-breast irradiation

uestion exists. Weed *et al.* (27) Hospital have published a study comparing dosimetric data from 10 patients treated with interstitial catheter-based brachytherapy, 10 patients treated with BRT brachytherapy, and 10 patients treated with external-beam 3DCRT. The 3DCRT patients and the BRT group seemed to have comparable coverage at 90% of the prescribed dose, but the 3DCRT technique treated more of the whole breast and slightly more lung tissue than BRT. Although a valuable contribution, the report does not compare dosimetry in identical patient data sets. The patients representing the different treatment subgroups were different, and no doubt had different relevant anatomy. This could make dosimetric comparison of treatment techniques misleading. A true comparison would compare techniques in the same patient image set.

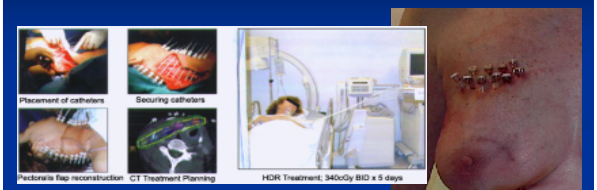
Breast Brachytherapy Interstitial

Interstitial Radium Brachytrapy for Breast Cancer, 1917

Radiotherapy for breast carcer, London Hospital. c.1917

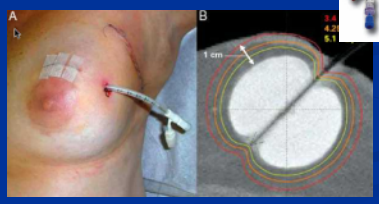
http://radonc.wikidot.com/other-references

Breast Brachytherapy Interstitial



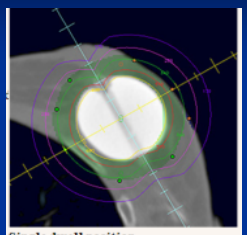
Pictures courtesy of William Parker, McGill University

MammoSite

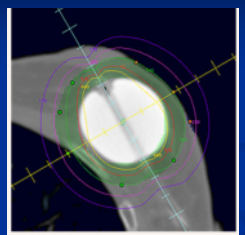


https://www.beaumonthospitals.com/radiation-therapy-breast-cancer-treatment

MammoSite



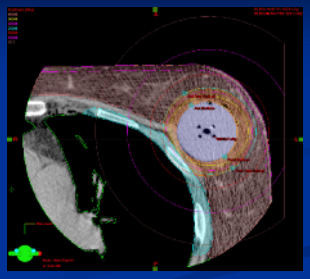
Single dwell position



Multiple dwell positions

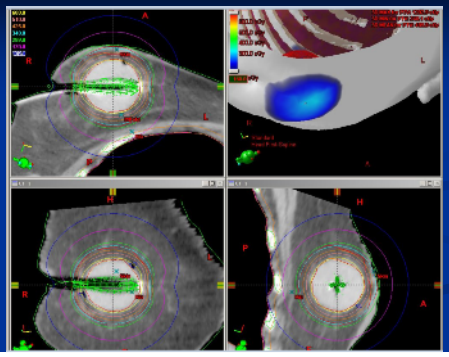
http://radonc.usc.edu/USCRadOnc/Downloadable/PalmOS/MammoSite.html

Contura



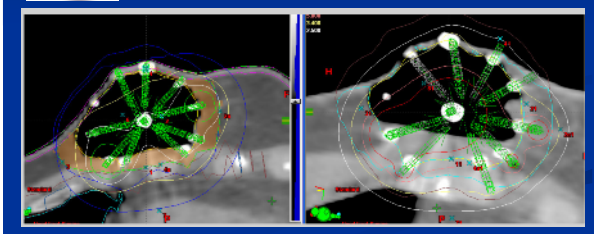
Courtesy of Scott Dodd, ROS, Cobb

Contura



Courtesy of Keith Pope, Wellstar Kennestone Hospital, GA

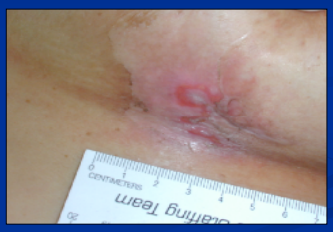
Savi



Picture courtesy of Rebecca Kitchens, Aurora BayCare Medical Center, WI

Treatment Planning: Balloon to Skin Spacing

Skin reaction due to minimal skin spacing



Picture courtesy of Jeff Dorton, Hologic

Comparison of Techniques

Balloon brachytherapy (intra-cavitary)

- single entry point, requires less skill
- various sizes and shapes available (circular, elliptical)
- performed in the surgeons office, patient convenience
- many patients treated
- simpler dosimetry (easier? Because of library or template plans)

Interstitial brachytherapy

- technically more challenging
- shape of cavity unimportant
- excellent dose conformation

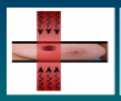
What is AccuBoost?

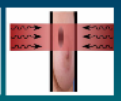
- Novel technique for partial breast irradiation
  - non-invasive
  - immobilization
  - image-guidance
- Tungsten alloy applicators
- Utilizes HDR ^{192}Ir source
- Clinical applications
  - tumor bed boost
  - APBI being explored

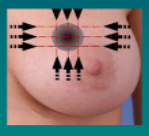
Slide courtesy of Shirin Sioshansi, M.D.

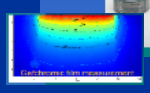
Challenge of AccuBoost Dosimetry

- Composite DVH
  - TPS cannot model applicator collimation
  - tissue deformation









Slide courtesy of Shirin Sioshansi, M.D.

Resources

AMERICAN BRACHYTHERAPY SOCIETY
BREAST BRACHYTHERAPY TASK GROUP
Martin Keisch, M.D., Douglas Arthur, M.D., Rakesh Patel, M.D., Mark Rivard, PhD., Frank Vicini, M.D.
February, 2007

http://www.rtog.org/members/protocols/0413/0413.pdf

STRETCH

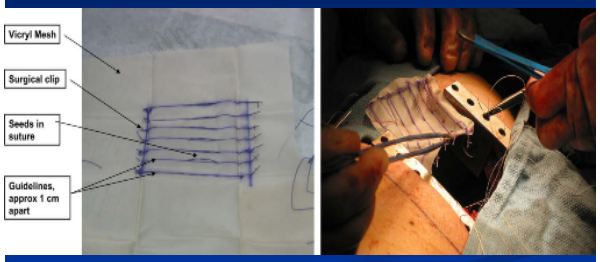
Some New Brachytherapy Applications

Some New Brachytherapy Applications

Intraoperative lung

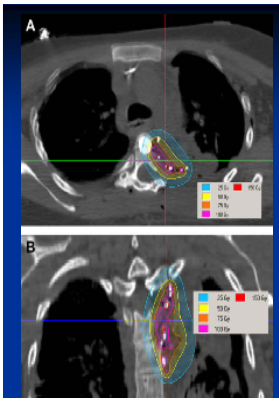
- Intended to reduce recurrences
- Permanent implants of ^{125}I sources (or possibly the like) in suture, sewn into mesh

Intraoperative lung



From Stewart et al. *Brachytherapy* 2009

Intraoperative lung



- Dose is 100 Gy at 5 mm from the mesh,
- Sort of.
- A problem is that the implant geometry may be perfect at the time of placement,
- But then the surgeon closes the patient…

Intraoperative Interstitial Lung Brachytherapy Question : Which is true?

20% 1. The dose delivered is 100 Gy to the center of the plane 0.5 cm from the sources.

20% 2. The dose follows the Manchester system.

20% 3. Because the treatment is intraoperative in an open patient, it is more like an intracavitary treatment than interstitial.

20% 4. Because the implant is permanent, the 100 Gy dose is equivalent to and actual 100 Gy of external beam.

20% 5. The homogeneity of the dose distribution will likely be lower than most common interstitial treatments.

10

Intraoperative Interstitial Lung Brachytherapy Question : Which is true?

1. The dose delivered is 100 Gy to the center of the plane 0.5 cm from the sources.
2. The dose follows the Manchester system.
3. Because the treatment is intraoperative in an open patient, it is more like an intracavitary treatment than interstitial.
4. Because the implant is permanent, the 100 Gy dose is equivalent to and actual 100 Gy of external beam.
5. The homogeneity of the dose distribution will likely be lower than most common interstitial treatments.

Intraoperative Interstitial Lung Brachytherapy - Reference

Intraoperative seed placement for thoracic malignancy-A review of technique, indications, and published literature. AJ Stewart1, S Mutyala, CL Holloway, YL Colson, PM Devlin. Brachytherapy 8 (2009) 63-69

Some New Brachytherapy Applications

Macular Degeneration

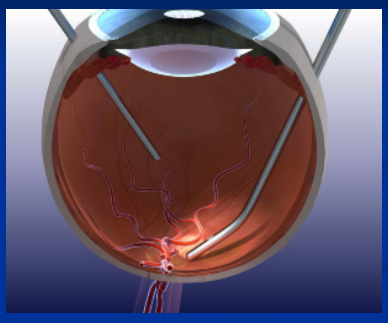
- Concept: radiation inhibits the proliferation of blood vessels.
- Seems to work better then the anti-VEGF that is the current standard.
- Dose used in current protocol is 24 Gy to the foveola, 2.5 mm from the source.
- Toxicity not seen in animals until 123 Gy

Some New Brachytherapy Applications

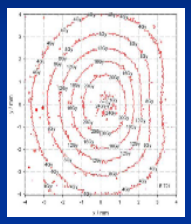
Macular Degeneration

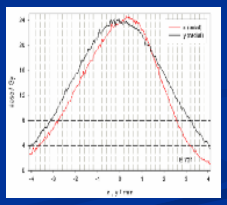
- The treatment uses ^{90}Sr in a hand-held device.
- The treatment is delivered by a retinal surgeon, who holds it in place.
- The procedure is performed in the OR, with ports placed in the eye ball: 1 for the source and 1 for viewing.

Device Placement



Epipen Dose distribution





Errors & Reporting

Learning Objectives Errors & Reporting

- Review the concept of Medical Event
- Review the steps to analyze a treatment variance utilizing a Root Cause Analysis

You've discovered a deviation now what?

- Do you know where the policy or procedure that covers this lives?
- Is this a medical event? *This is tricky*
- What is your chain of command?
  - Inform the attending physician & RSO
  - Inform the Medical Director
  - Hospital Management/Risk Management
  - Referring physician
    - Patient/Patient's family
- *Possibly* the responsible regulatory agency (the State or the NRC)

Is it a "Medical" Event?

From http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/risks-assoc-medical-events.pdf

For all medical uses of NRC-licensed radioactive materials, a "medical event" occurs if ***BOTH*** of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose[1] administered differs from the prescribed dose by at least 20 (too high or too low)
- the wrong radioactive drug is administered
- the radioactive drug is administered by the wrong route
- the dose is administered to the wrong individual
- the patient receives a dose to a part of the body other than the intended treatment site that exceeds by 50 percent or more the dose expected by proper administration of the prescription
- a sealed source used in the treatment leaks;

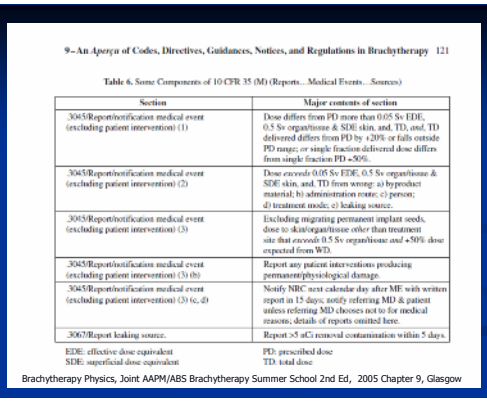
AND

[1] The word "dose" refers to administered total radiation dose or radioactive drug dosage.

What is the "AND" part?

AND

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.



9 – An *Aperçu* of Codes, Directives, Guidances, Notices, and Regulations in Brachytherapy 121

Table 6. Some Components of 10 CFR 35 (M) (Reports…Medical Events…Sources)

Section	Major contents of section
3045/Report/notification medical event (excluding patient intervention) (1)	Dose differs from PD more than 0.05 Sv EDE, 0.5 Sv organ/tissue & SDE skin, and, TD, *and*, TD delivered differs from PD by +20% or falls outside PD range; *or* single fraction delivered dose differs from single fraction PD +50%.
3045/Report/notification medical event (excluding patient intervention) (2)	Dose *exceeds* 0.05 Sv EDE, 0.5 Sv organ/tissue & SDE skin, and, TD from wrong: a) byproduct material; b) administration route; c) person; d) treatment mode; e) leaking source.
3045/Report/notification medical event (excluding patient intervention) (3)	Excluding migrating permanent implant seeds, dose to skin/organ/tissue *other* than treatment site that *exceeds* 0.5 Sv organ/tissue *and* +50% dose expected from WD.
3045/Report/notification medical event (excluding patient intervention) (3) (b)	Report any patient interventions producing permanent/physiological damage.
3045/Report/notification medical event (excluding patient intervention) (3) (c, d)	Notify NRC next calendar day after ME with written report in 15 days; notify referring MD & patient unless referring MD chooses not to for medical reasons; details of reports omitted here.
3067/Report leaking source.	Report >5 nCi removal contamination within 5 days.

EDE: effective dose equivalent
SDE: superficial dose equivalent
PD: prescribed dose
TD: total dose

Brachytherapy Physics, Joint AAPM/ABS Brachytherapy Summer School 2nd Ed, 2005 Chapter 9, Glasgow

Is it a "Medical Event"?

From **http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/risks-assoc-medical-events.pdf**

A "Medical Event" does not necessarily result in harm to the patient.

The NRC requires a report of medical event because it indicates:

Potential technical or QA problems

A dose error $\geq$ 20 percent may indicate treatment delivery problems

There is no scientific basis to conclude that such an error necessarily results in harm to the patient.

Is it a "Medical Event"?

The NRC has very clear guidelines how to report a medical event

See:
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html

Is it a "Medical Event"?

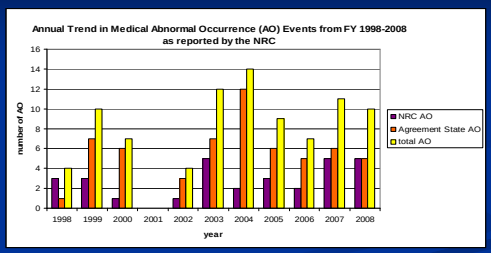
AGREEMENT STATE REPORT - MEDICAL EVENT INVOLVING AN UNDERDOSAGE TO THE PROSTATE

"Ohio Department of Health (ODH) Bureau of Radiation Protection (BRP) was notified of a medical event that occurred at <<CENTER NAME & ADDRESS>>, Ohio license # XXXX at 12:30 PM 05/12/2009. The patient received a permanent implant of 64 I-125 seeds on 5-11-09. The total activity implanted was 28.422 mCi. (.444mCi/seed). The prescribed dose to the prostate was 144.0 Gy. The post-plan CT was evaluated 5-12-09 and determined that the prostate volume receiving the prescribed dose was 47% (i.e. V100%=47%) resulting in a 53 percent under dose of the prescribed dose. The patient and physician have been notified. ODH BRP will continue to evaluate this event. The licensee has initiated an internal evaluation."

A Medical Event may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

http://www.nrc.gov/reading-rm/doc-collections/event-status/event/2009/20090520en.html

Reported Medical Events



Data taken from http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2009/secy2009-0052/enclosure1.pdf
Definition of AO: http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2009/secy2009-0052/enclosure1.pdf

Errors & Reporting question:

Under NRC 10 part 35 all of the following are medical events for the administration of brachytherapy if they occur ***AND*** the difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201 EXCEPT??

20% 1. Any radiation delivered involving the wrong patient

20% 2. Any radiation delivered involving the wrong treatment site

20% 3. Any radiation delivered involving the wrong radioisotope

20% 4. The calculated dose differs from the prescribed dose by more than 10%

20% 5. One or more temporary implants not removed upon completion of the procedure

Errors & Reporting question:

Under NRC 10 part 35 all of the following are medical events for the administration of brachytherapy if they occur ***AND*** the difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201 EXCEPT??

1. Any radiation delivered involving the wrong patient
2. Any radiation delivered involving the wrong treatment site
3. Any radiation delivered involving the wrong radioisotope
4. The calculated dose differs from the prescribed dose by more than 10%
5. One or more temporary implants not removed upon completion of the procedure

Errors & Reporting question:

Reference

NRC 10CFR35 subpart M

http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html

Point/Counter Point: The Current NRC Definitions of Therapy Misadministration are Vague, do not Reflect the Norms of Clinical Practice, and Should be Rewritten. Howard Amols, Jeffrey Williamson. Medical Physics, vol 31 issue 4 pp 691-694 April 2004

Root Cause Analysis (RCA)

- What is an RCA?
- RCA is a retrospective approach to error analysis
  - Provides a process focused framework for analysis
  - Attempts to identify contributing factors and all causes
- RCA has its foundations in industrial psychology and human factors engineering
- In 1997, the joint commission mandated the use of RCA in the investigation of sentinel events in accredited hospitals

Root Cause Analysis (RCA)

When two planes nearly collide, they call it a "near miss". It's a **NEAR HIT**.

A collision is a "near miss".

BOOM! "Look, they nearly missed!"

George Carlin, The Absurd Way We use Language
www.georgecarlin.com

Root Cause Analysis (RCA)

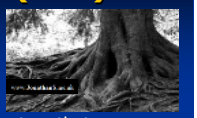
An RCA is designed to answer **3** basic questions

1. What happened?
2. Why did it happen?
3. What can be done to prevent it from happening again?

Root Cause Analysis (RCA)

- What happened?
  - This is the INVESTIGATION phase, a factual representation of the incident
    - Structured interviews, document review and/or observation to create a timeline of events
  - Ignore (for now) what should have happened
  - If critical evidence is not available or was destroyed in the process, consider using secondary sources BUT use plausible scenarios; test the theory to confirm or deny the explanation.

Root Cause Analysis (RCA)



- Why did it happen?
  - This is the ANALYSIS phase
  - Analyze what happened and also the system that allowed it to happen
    - Was the process correct but inadequately followed? Was the process flawed? Did the process create or contribute to the event?
  - Do not be lured into finding ways to fix what happened at this point
  - The final result should be a finite set of causes for the event that explain why it was inevitable

Root Cause Analysis (RCA)

- Why did it happen?
  - There are categories of factors that can influence clinical practice
    - Institutional or Regulatory Factors
      - Corporate Culture or Communication Barriers
    - Organizational or Management Factors
      - Is the information needed available?
    - Work Environment
      - Environmental Factors (physical environment), Equipment Performance
    - Human Factors (Staff Factors, Team Factors or Patient Characteristics)
      - Staff qualifications/competencies, staff training, staffing levels

Root Cause Analysis (RCA)

- What can be done to prevent it from happening again?
  - This is the DECISION phase
  - Develop recommendations that identify *what* should be learned and *what* needs to be done
    - Beware of being overly complicated
    - There may be several competing options: evaluate based on a structured decision analysis for simplicity, effectiveness, longevity, cost, etc
  - Consider the consequences for each recommendation
    - Have you induced new latent conditions or weaknesses to the system?

Root Cause Analysis (RCA)

Garbage in = Garbage out

"Insanity: doing the same thing over and over again and expecting different results" *attributed* to Einstein

RCA resources

http://www.bill-wilson.net/b34.html
http://www.jointcommission.org/SentinelEvents
http://www.ahrq.gov/clinic/ptsafety/chap5.htm
Effectiveness and Efficiency of Root Cause Analysis in Medicine, Wu et al, JAMA vol.299 No.6, February 13, 2008
NRC regulations on medical uses of radioactive material, Title 10 Code of Federal Regulations Part 35
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/
Reporting requirements for medical events, 10 CFR 35.3045
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html
NRC's annual dose limits, 10 CFR 20.1201
http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-1201.html
http://www.va.gov/ncps/TIPS/Docs/TIPS_MayJune09.pdf
http://www.plant-maintenance.com/articles/Getting_Root_Cause_Analysis_to_Work_for_You.pdf

Some Brachytherapy QA Issues

Some Brachytherapy QA Issues

Assay of Sources Loaded in Needles in Sterilized Packages

- Purchasing implant needles with the sources already loaded is convenient and time saving.
- Autoradiography can show the presences of sources and the correct loading pattern.
- The problem is how to check the source strength.

Assay of Sources Loaded in Needles in Sterilized Packages

The AAPM Low-energy Brachytherapy Source Calibration Working Group recommendations

- The facility radiotherapy physicist still maintains the responsibility to assure that the source strengths are correct, regardless if the vendor calibrates sources.
- For Sterile source assembles,
  - ≥10% of the assemblies by sterile insert in a well-chamber or by "quantitative image analysis," or
  - Order and assay 5% or 5 (whichever is fewer) additional loose sources (check if from same batch.)

Quantitative Film Analysis

You just cannot take the film darkening to be directly proportional to source strength because:

- The distance from the sources to the receptor is not uniform due to cheap packaging;
- Each dark spot received contributions from many sources.

Assay of Sources Loaded in Needles in Sterilized Packages

The AAPM Low-energy Brachytherapy Source Calibration Working Group recommendations

- For stranded source assembles,
  - ≥10% of the strands or 2 (whichever is larger) by sterile insert in a well-chamber, or
  - Order and assay 5% or 5 (whichever is fewer) additional loose sources (check if from same batch.)

Assay of Sources Loaded in Needles in Sterilized Packages

The AAPM Low-energy Brachytherapy Source Calibration Working Group recommendations

Actions to take

- $\Delta S_k \leq 3\%$, enjoy!
- $3\% < \Delta S_k \leq 5\%$, investigate discrepancy or increase sample size.
- $\Delta S_k > 5\%$, contact manufacturer; if in OR, discuss with RO whether to use the average (vendor and measured) or measured.

Assay of Sources Loaded in Needles in Sterilized Packages Question : Which is true?

20% 1. The vendors assume the responsibility for the source strength used for patients.

20% 2. The facility physicist is to measure at least 10% of the assemblies or loose sources or 5% additional sources.

20% 3. If the measured source strength differs from the vendor's specified source strength by >5%, use the vendor's value.

20% 4. The source strength is easily measured using the autoradiograph.

20% 5. Agreement within 5% is very rare.

10

Assay of Sources Loaded in Needles in Sterilized Packages Question : Which is true?

1. The vendors assume the responsibility for the source strength used for patients.
2. <u>The facility physicist is to measure at least 10% of the assemblies or loose sources =5%.</u>
3. If the measured source strength differs from the vendor's specified source strength by >5%, use the vendor's value.
4. The source strength is easily measured using the autoradiograph.
5. Agreement within 5% is very rare.

Assay of Sources Loaded in Needles in Sterilized Packages: Reference

WM. Butler, WS. Bice, Jr., LA. DeWerd, JM. Hevezi, MS HuqGS. Ibbott, JR. Palta, MJ. Rivard, JP. Seuntjens, BR. Thomadsen. Third-party brachytherapy source calibrations and physicist responsibilities: Report of the AAPM Low Energy Brachytherapy Source Calibration Working Group. Med Phys 35: 3860-3865, 2008