

## Enhancing Our Safety Culture by Understanding Recent Mishaps (Part 2): Brachytherapy

Bruce Libby, PhD  
Associate Professor and Chief of  
Clinical Brachytherapy Physics  
University of Virginia Health System

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## Conflicts of Interest

- Royalties from UpToDate.com

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## Learning Objectives

- To review and understand the root causes of brachytherapy medical events
- To review and understand corrective actions that should be in place
- To review and understand the established recommendations for safe delivery of brachytherapy and to foster a culture of safety
- To discuss communication among users, seed vendors, and TPS makers on use of identical terminology to reduce possible sources of errors

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# Recent Work

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# Strategies to Prevent Errors in Brachytherapy: Learning from our Mistakes

R. Lee, MD  
World Congress of Brachytherapy  
Barcelona, May 2012

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Slide 1: Is high safety in Brachytherapy a Result of Advance Techniques and Advance Imaging?

Dimos Baltas, Ph.D., Prof <sup>1,2</sup>

<sup>1</sup>Dept. of Medical Physics & Engineering, Strahlenklinik, Klinikum Offenbach GmbH, 63083 Offenbach, Germany

<sup>2</sup>Nuclear and Particle Physics Section, Physics Department, University of Athens, Panepistimiopolis, Ilisia, 157 01 Athens, Greece

E-mail: [dimos.baltas@klinikum-offenbach.de](mailto:dimos.baltas@klinikum-offenbach.de)

World Congress of Brachytherapy  
Barcelona, May 2012

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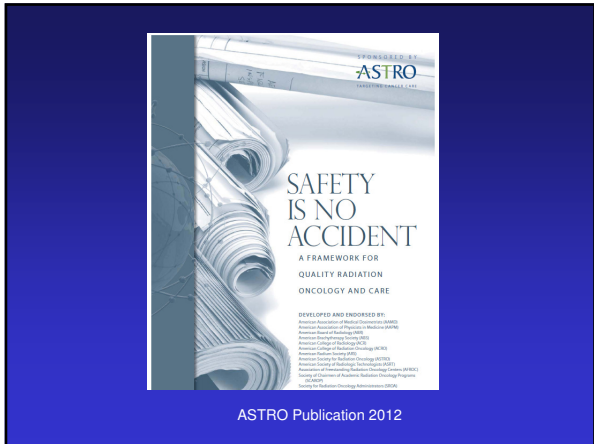
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A 2 Year review of recent NRC events: What errors occur in the modern brachytherapy era  
Susan Richardson  
Practical Radiation Oncology  
Volume 2, Issue 3 (2012)

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Important Quotes to Remember

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“Those who cannot remember the past are condemned to repeat it.” - *George Santayana*



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The Original Soundtrack Collection



“Everything old is new again”

Peter Allen, All That Jazz

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**Britney Spears**  
**OOPS I DID IT AGAIN**

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“Lessons Learned From Investigations of Therapy Misadministration Events”

Lee Ostrum, et al  
IJROBP 34:227-234 (1996)

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7 Events categorized  
(5 brachytherapy)

- Event 1- HDR- wrong data card was used to treat the patient
- Event 3- Manual LDR- wrong sources were used in a Henschke applicator
- Event 5- Manual LDR- source ribbons came out and nurse taped them to the patient's abdomen
- *Event 6- Manual LDR- sources were 0.79 mgRaeq, physicist recorded 0.79 mCi*
- *Event 7- HDR- source broke off inside patient, radiation monitors ignored (Indiana PA event)*

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Direct Causes of Medical Events

- Organizational policies and procedures
- Lack of training and experience
- Lack of supervision
- Decision errors
- Hardware failures (only event 7 was due to hardware failure)

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## Conclusions

- Many medical events occur primarily due to an absence of procedures
- Changes in routine (exacerbated by lack of policies and procedures)
- Hardware failures seldom occur but they can lead to severe consequences!

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## Event 6

- Ir-192 seeds were ordered in mg-Raeq, plan was performed in mCi (pre 1996)
- TG-43 introduces the concept of Air Kerma Strength (U) to replace activity, mg-Raeq (1995, with updates in 2004,2007)

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UVa Clinic, 2009

	Mg-Raeq	mCi	U
Physics Resident 1	1	1.76	7.24
Physics Resident 2	1	1.79	7.21
Junior Physicist	1	1.79	7.23
Senior Physicist*	1	1.79	7.21

\*- asked the mfr for the conversion factors that the mfr used

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From the Manufacturer's Web site  
(July 9, 2012)

"We are the first and only provider of Iridium 192 in nylon ribbons in a wide range of activities from 0.10 to 10 mg Raeq per seed or 0.3 to 30 mg Raeq per centimeter."

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Event 7

- NUREG 1480 "Loss of an Ir-192 source and therapy misadministration at IRCC, Indiana, PA on November 16, 1992"
- Machine error made worse by human error

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Executive summary

- An area radiation monitor in the treatment area was observed in an alarm condition when the source should have been retracted
- Three technologists and the MD were aware of the alarm condition, a room and patient survey was not conducted
- The treatment console reported that the source was "safe"
- The staff claimed to have had experienced difficulties with the area radiation monitor (Primalert) but errors could not be reproduced

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### Hardware Malfunction

- Source broke off inside the patient
- Manufacturer's emergency procedures were to manually retract a stuck source wire
- Breakage was not considered possible by the manufacturer

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### Policies and Procedures Malfunction

- No systematic radiation safety training to the staff
- Manufacturer's emergency procedures did not include radiation safety
- Expectation that the medical director or medical physicist would provide safety training (which was not done)

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### Policies and Procedures Malfunction (cont'd)

- Staff failed to respond to the radiation alarm
- technologist reset the radiation monitor by unplugging it
- no radiation survey with a survey meter was performed
- Patient wound up received a dose of 16000 Gy (prescribed dose was 18 Gy)

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*“The safety culture at IRCC contributed significantly to the event. Technologists routinely ignored the Prim-Alert 10 alarm. Its problems were worked around and not fixed. Technologists did not survey patients, the afterloader, or the treatment room following HDR treatments. No one was sure who was responsible for radiation safety training or the radiation safety program. The authorized user failed to wear a film badge on both occasions when the source was encountered.”*

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### Hooray for physicists

- A second source wire broke on Dec. 7, 1992 in Pittsburgh (same consulting group as Indiana, PA incident)
- The physicist was aware of the previous issue and recognized the problem, with proper intervention

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### Analysis of Treatment Delivery Errors in Brachytherapy Using Formal Risk Analysis

B. Thomadsen, et al  
IJROBP 57:5 (2003)

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Process Trees and Fault Trees were developed  
(TG100)

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Majority of LDR errors

- Wrong sources loaded
- Sources not loaded properly
- Wrong units entered in the treatment planning system
- sources not fixed in applicator (or applicator in patient)
- 75% of treatment errors were during treatment delivery

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HDR errors

- Most common error was a failure to enter the correct treatment distance (default distance was used)
- Other errors included incorrect connection between applicator and treatment channel, incorrect source strength, applicator shift in patient, source drive mechanism

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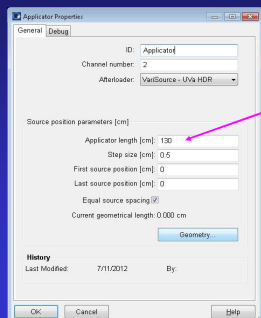
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## BrachyVision Applicator Properties



Default is 130 cm (usually longer than needed)

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## “Interfering Tasks”

- Important in HDR as compared to LDR, because more actions are compressed into a very short duration, and distractions can divert attention long enough to cause a problem
- As IGBT becomes more common, this could be an increased problem

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Image Guided Brachytherapy Suite at the University of Virginia



Anesthesia

Trumph OR couch (w/ carbon fiber insert)

Siemens Somatom CT-on-rails

OR lights

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# Words of Wisdom

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"Your job is stay off the front page of the newspaper"

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### At V.A. Hospital, a Rogue Cancer Unit



The Veterans Affairs Medical Center in Philadelphia.  
By WALT BOGDANICH  
Published June 20, 2009

Medical Knowledge for The New York Times

TWITTER

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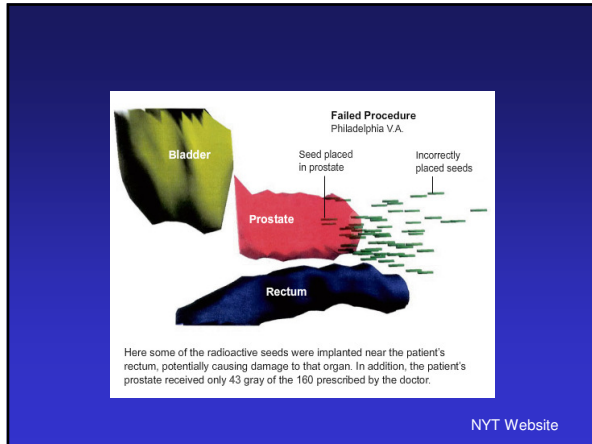
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### NY Times Article

- Most of the seeds, 40 in all, landed in the patient's healthy bladder, not the prostate.
- MD rewrote his surgical plan to match the number of seeds in the prostate
- That was the correct procedure! (10CFR 35-  
"After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose)."

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### NY Times Article (cont'd)

- Botched 92 of 116 cancer treatments over a span of more than six years
- The team continued implants for a year even though the equipment that measured whether patients received the proper radiation dose was broken

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## TG 137 recommendation

*Postimplant dosimetry at the nominal optimal dosimetry time for respective radionuclides.* Because of the existing dose-response data, the postimplant dosimetry for <sup>125</sup>I implants should be performed at 1 month ( $\pm 1$  week) after the procedure. For <sup>103</sup>Pd and <sup>131</sup>Cs, postimplant dosimetry should be performed at their respective nominal optimal times,  $16 \pm 4$  and  $10 \pm 2$  days, respectively.

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**Department of Veterans Affairs  
Office of Inspector General**

### Healthcare Inspection

**Review of Brachytherapy Treatment of  
Prostate Cancer, Philadelphia,  
Pennsylvania and Other VA Medical  
Centers**

<http://www.va.gov/oig/54/reports/VAOIG-09-02815-143.pdf>

Released May 3, 2010

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## VA OIG Report Conclusions

- Wrong seed activity for one case due to pre-printed order form
- No evidence of record falsification
- QMP program deficient
- No post-implant dosimetry for 12 months
- "Clinical Outcomes" within the norm
- Two other VA hospitals were not performing post implant dosimetry
- Criteria for medical event is controversial

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What is a medical event in permanent brachytherapy?

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### 10CFR35

- Wrong Patient
- Wrong Site
- Wrong Isotope
- Wrong Dose

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### ASTRO Working Group Problems in using dose

- Timing of post implant dosimetry
- Imaging modality differences
- Observer variability
- Planning margins may vary
- Planning system uncertainties
- Seed Migration (administration vs. result)

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**ASTRO Recommendation**

☐ Source strength based criterion (>20% of source strength implanted outside PTV) is more appropriate for defining ME in permanent brachytherapy.

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Statement of  
**Danny Song, MD**  
 Associate Professor and Clinical Director  
 Department of Radiation Oncology and Molecular Radiation Sciences  
 Johns Hopkins University School of Medicine  
 On Behalf of the American Society for Radiation Oncology (ASTRO)  
 Before the Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes  
 April 11, 2011

ASTRO Statement  
 ACMUI Meeting  
 April 11, 2011  
 Page 3

selected: c) the observer variability in prostate contouring (both inter-observer and intra-observer); and d) the planning margins used. If the current dose-based medical event definition remains in force, many properly executed implants would be improperly classified as a medical event leading to a detrimental effect on brachytherapy.

**Instead of a rule based on absorbed dose, ASTRO strongly recommends using an activity (i.e., source strength) based rule (>20 percent of source strength implanted outside the treatment site) to define medical events for regulatory purposes.** This is because the total source strength implanted within and around the prostate is under control of the

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**Definition of Medical Event in Permanent Implant Brachytherapy**  
 NRC-April 24, 2012

W. Robert Lee, MD, MS, MEd  
 On behalf of the American Brachytherapy Society (ABS)

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# Process Trees/TG100

- Brachytherapy is well suited to the creation of process trees because we are used to working with checklists

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### Daily QA Check List

Quality Assurance Daily Check on HDR Unit  
Version: IX 5/N 600509

No	Item	DATE (mm/dd/yy)						
1	Current Date & Time on HDR Unit [Correct]							
2	Observed Activity on HDR Unit [Correct] (7%)							
3	Person Verification Test (V) (sec)							
4	Pinpoint (Backup Power Unit Functional)							
5	Tumor Airway (I) (sec)							
6	Over Radiation Indicator [Operable]							
7	Over Switches [Operable] upon dose test							
8	Dose Interchange Button [Operable]							
9	Source Substitution at Console [Operable]							
10	Interchange Button at Console [Operable]							
11	Indicator Locked							
12	Key off at Console							
13	L&V System [Operable]							
14	Key off at Afterloader							
15	Emergency Response Kit (Prevent) Storage, unless removed kit, exp. lat. correct, www. www							
16	Survey Meter [Operable]							
17	Survey Meter [Operable] (Prevent)							
18	Applicable Inspection and length test (13, 4 & 6) (sec)							
19	Device open							
Performed by (initials)								
Returned by Authorized Physician (initials)								
Comments								

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# Eye Plaque Process

- Patient is referred for consult w/ Radiation Oncology, nursing/resident notifies BL of the date of the consult.
- Ophthalmologist office faxes exam result to RadOnc, including tumor diagram.
- After consult, Physics is given diagram of eye w/ tumor location of size.
- (Questions about tumor location and use of notched plaque answered)
- Physics develops plan and communicates w/ Conway office of proposed dates of implant. Plan is done using COMS dose calculation protocol. When calculating dose, make sure the COMS button is showing (not USG).
- (Note: Preplan cannot be finalized without OR dates due to seed activity)
- Preliminary second check is performed to ensure correct calculation protocol and seed assay date.
- Preplan is printed and reviewed/signed by Radiation Oncologist. Written directive signed at this time.
- Seeds are ordered and the confirmation is checked to confirm seed activity, assay date, PO is faxed to EHS. Note: planning system uses U, seed vendor used mCi-make sure that the U to mCi is conversion is correct.
- Seeds received and assayed. Assay is checked.
- Plaque is prepared.
- Assayed value entered into preplan. Tentative on and off times communicated to ophthalmology.
- Plan second check performed.
- OR-plaque is placed, plaque on time entered into preplan.
- From source assay and on time, off time is calculated and communicated to Ophthalmologist office, dosimetry.
- Plaque is removed. Off time entered into plan, final dose is calculated. Final plan is printed. Preplan, written directive, and final plan are scanned into Mosaic.
- Source assay, on time, off time, final entered into physics consult for Radiation Oncologist to sign, copy is sent to Ophthalmologist.

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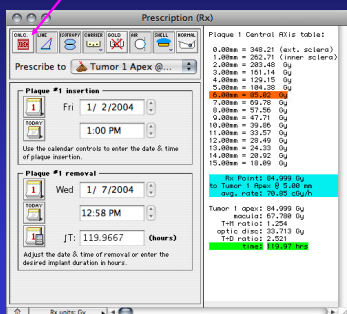
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Easy to overlook changing calculation protocol  
(USC protocol is default, CANNOT change the default to COMS protocol)



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### Other Issues

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### Seed Ordering

Is there a way for physicists, seed vendors, and TPS vendors to speak a common language?

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# BeBig Eye Plaque Software

Inventory index # 17

Isotope name: 1-125 (6711 COMS) Trade name: OncoSeed  
 Mfg. lot number: test (11 chars max) Unique ID: COMS  
 Inventory name: unknown Inventory ID: 06C7BEE171  
 Number of seeds: 8 of 8 Physical length: 4.500 mm  
 Shell opacity: 1.00 Colors: Diameter: 0.800 mm  
 Active length: 3.000 mm

Calibration  
 Source strength: 5.1700 to 5.1700 u Manufacturer's midpoint: 5.26 u  
 Assay date: 4/16/2010 12:00 PM  
 Avg.: 5.170 Available strength: 41.36 of 41.36 u

Cancel OK



# Seed Order Confirmation

UNIVERSITY OF VIRGINIA  
 ENVIRONMENTAL HEALTH & SAFETY OFFICE  
 3908 M. FREDERICKS & VICTOR LEE, ONLY  
 515 EDGEWOOD RD.  
 CHARLOTTESVILLE, VA 22904

UNIVERSITY OF VIRGINIA ENVIRONMENTAL HEALTH & SAFETY OFFICE 3908 M. FREDERICKS & VICTOR LEE, ONLY 515 EDGEWOOD RD. CHARLOTTESVILLE, VA 22904	BRUNNEN LABOR 434-962-6699	BRUNNEN 125I-SEED 01/20/2012	DATE ORDERED 01/04/2012
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\*\*\*\*\*  
 Customer Service FAX No.: 800-897-2382 (24hr. Med.)  
 800-969-7333 (Therapy)

Terms Of Payment:  
 Within 30 days without deduction

MATERIAL	DESCRIPTION	Quantity
6711-03300	125I SEED W/ BAY MARKER 3.750 mCi 24 SA	

Special Instructions:  
 Shipping Date / Assay Date  
 8/7/2012 / 7/7/2012

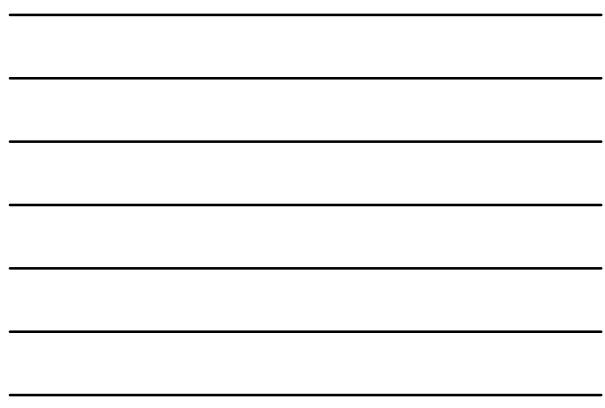
activity in mCi



# Eye Plaque Source Activity

mCi	Air Kerma	mCi	Air Kerma
MEDIAN	MEDIAN	MEDIAN	MEDIAN
1.103	1.401	7.21	9.16
1.197	1.520	7.62	9.53
1.298	1.648	8.49	10.78
1.409	1.789	9.21	11.70
1.529	1.942	10.00	12.70
1.659	2.107	10.85	13.78
<b>1.800</b>	<b>2.286</b>	11.77	14.95
<b>1.953</b>	<b>2.480</b>	12.77	16.22
<b>2.12</b>	<b>2.69</b>	13.86	17.60
<b>2.30</b>	<b>2.92</b>	15.04	19.10
<b>2.49</b>	<b>3.16</b>	16.31	20.71
<b>2.71</b>	<b>3.44</b>	17.70	22.48
<b>2.94</b>	<b>3.73</b>	19.21	24.40
<b>3.19</b>	<b>4.05</b>	20.80	26.40
<b>3.46</b>	<b>4.39</b>	22.60	28.70
<b>3.76</b>	<b>4.76</b>	24.60	31.10
<b>4.07</b>	<b>5.17</b>	26.60	33.80
<b>4.42</b>	<b>5.61</b>	28.90	36.70
<b>4.78</b>	<b>6.08</b>	31.30	39.80
<b>5.20</b>	<b>6.60</b>	34.00	43.20
<b>5.64</b>	<b>7.16</b>	36.90	46.90
<b>6.12</b>	<b>7.77</b>	40.00	50.80
<b>6.65</b>	<b>8.45</b>		

(Inquire for higher activities)



## Seed Registry

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCE  
(AMENDED IN ENTIRETY)

NO: IL-136-S-338-S      DATE: August 13, 2010      PAGE: 1 of 13

**SOURCE TYPE:** Therapeutic Sealed Source

**MODEL:** 6711 (OncoSeed™), 9011 Brachytherapy Source

**DISTRIBUTOR:** Medi-Physics, Inc.  
d/b/a GE Healthcare  
3350 North Ridge Avenue  
Arlington Heights, IL 60004

**MANUFACTURER:** Medi-Physics, Inc.  
d/b/a GE Healthcare  
3350 North Ridge Avenue  
Arlington Heights, IL 60004

Amersham Health  
White Lion Road Amersham  
Buckinghamshire, England HP79LL

**ISOTOPE:** Iodine-125      **MAXIMUM ACTIVITY:** 9.99 GBq (270 millicuries) ↗ activity

(Courtesy Lory Bradley Oncura)

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### Labels for Type A Package

Contents: All nuclides that account for 95% of the contents. Printed as listed in the regulations (e.g., I-125, Tl-201).

**RADIOACTIVE I**  
NET WT: 185 MBq (5 mCi)

**RADIOACTIVE II**  
NET WT: 37 MBq (1 mCi)

**Total Activity:** The primary units must be Bq (i.e., MBq, GBq, Bq, etc.). Ci is acceptable in parentheses but not required (49CFR 172.403(g)(2) and IATA 10.7.3.3.2).

**Tl:** The mrem/hr reading at 1 m rounded **UP** to the nearest tenth.

(Courtesy Lory Bradley Oncura)

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### VariSeed Software

**URGENT MEDICAL DEVICE CORRECTION  
URGENT FIELD SAFETY NOTICE**

**Subject:** Enter the source activity using the correct units of activity.

**Commercial Name of Affected Product:** VariSeed

**Reference / FSCA Identifier:** BT-00011

**Date of Notification:** 2012-01-19

**Type of Action:** Notification

**Details on Affected Devices:** All versions of VariSeed are affected.

**Description of Problem:**  
This letter is to advise you that some VariSeed users have inadvertently entered a source activity in units of air kerma (U) when the actual source activity was specified in millicuries (mCi). This notice describes the issue, the actions you can take to avoid or mitigate the issue, and steps Varian is taking to address the issue.

**Details:**  
VariSeed requires the user to enter the activity of the source that will be implanted into the patient. The activity may be entered in U or mCi.

Comment: \_\_\_\_\_

Activity:  U  mCi ↗ Activity in U or mCi

Fig. 1 Source Activity Input Field

When entering the activity in U, the value is accepted and no further message is displayed.

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**URGENT MEDICAL DEVICE CORRECTION  
URGENT FIELD SAFETY NOTICE**

If the activity is entered as mCi, the following message is shown indicating that VariSeed will show U in the user interface from that point on and notifying the user of the converted value in U.

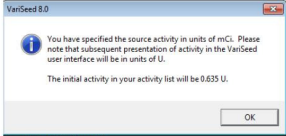


Fig. 2 Activity Pop-Up

We have received several reports of a user mistakenly entering the mCi value in the U field resulting in a patient mistreatment.

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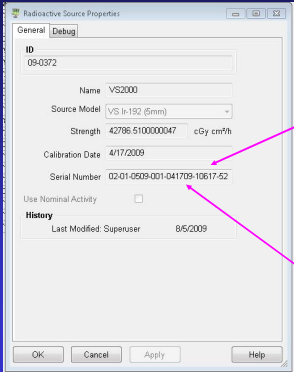
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### BrachyVision Source Properties



Activity (mCi)

Calibration Date

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### Issues with Physicists

- Seed ordering
- Seed returning

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## Seed Ordering Errors

- Incorrect patient name or name does not match order and plan
- Incorrect source model number on plan
- Incorrect quantity of seeds on order form or needle loading plan
- Seed quantities not broken down correctly (preloaded linked vs. preloaded loose)
- Incorrect address
- Incorrect PO #
- Customer marks I-125 and Pd-103 on order forms or enters info in both locations

(courtesy Kurt Maffei, Bard)

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## Even more errors (returns)

- No package return authorization number or FedEx tracking number
- No hospital name, contact number, city or state
- No sales order number
- No Hazardous Goods Declaration or improperly filled out Declaration

(courtesy Kurt Maffei, Bard)

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## Still More Errors (Seed Returns)

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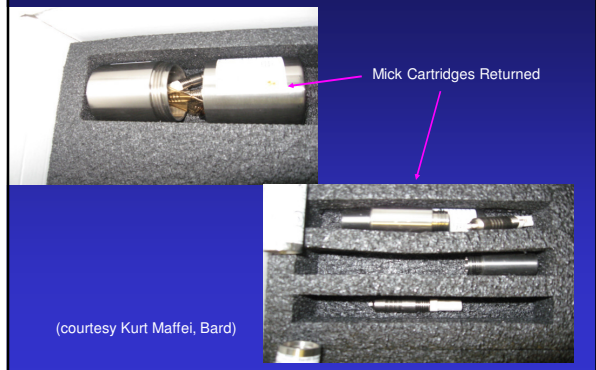
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### The Bad Mick Return



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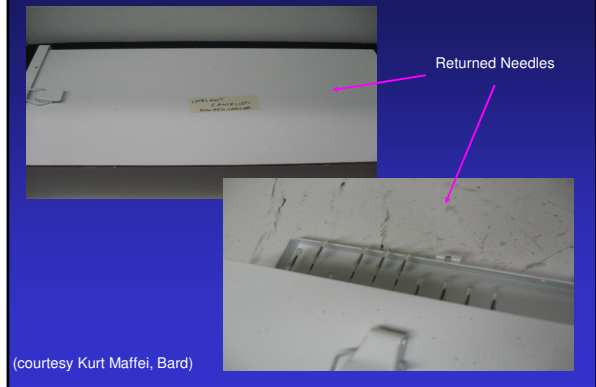
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### Bad Needle Return



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### Bad Linked Seed Return



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Where do we go from here?



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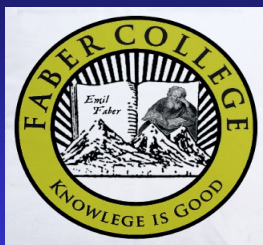
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Reporting of Medical Events

 **U.S.NRC**  
 United States Nuclear Regulatory Commission  
 Protecting People and the Environment

Office of Federal & State Materials & Environmental Management Programs

**LICENSEE NEWSLETTER**

NUREG/BR-0117, No. 12-01 Spring 2012

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0117/>

involving the failure to meet the physical presence requirements of 10 CFR 35.615(f)(2) during high dose radiation treatments. Specifically, on an indeterminate number of occasions on and before April 28, 2011, neither a CRIC authorized user nor a physician under the supervision of an authorized user was physically present during the entire duration of patient treatments involving the high-dose radiation unit.

10 CFR 35.41(a). Specifically, between June 18, 2008, and February 23, 2011, the licensee performed approximately 200 high-dose-rate remote afterloader administrations requiring written directives and failed to develop written procedures to provide high confidence that each administration was in accordance with the written directive.

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For Agreement states are there central repositories of medical events?

(what can manufacturers do to assist in reporting?)

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## Technical Service Bulletins

The screenshot shows the MYVARIAN website interface. The main heading is 'Brachytherapy VariSeed'. Below it is a search bar with the text 'Brachytherapy VariSeed' entered. The search results are displayed in a table with columns for Title, Date, Doc. Type, and Document Number.

Title	Date	Doc. Type	Document Number
Enter the source activity using the correct units of activity	Jan 2012	Safety Notifications	BT-00011
VariSeed 7.0 End of Support Notification Swedish	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification Brazilian Portuguese	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification Spanish	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification Italian	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification German	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification French	Nov 2011	End of Support	
VariSeed 7.0 End of Support Notification English	Nov 2011	End of Support	
Approved 8.0 Instructions for Use	Oct 2010	Manuals	
Increased anisotropy factor at 1 and 2 cm for the Brachytherapy 125 (2010)	Jun 2010	CTBs	CTB-VE-0059
French User Interface Update VariSeed 8.0.1	Apr 2010	CTBs	CTB-VE-0058

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## Conclusions

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- "Greed is good"- Gordon Gekko
- "Fear is good"- Bruce Libby

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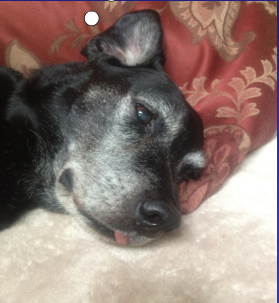
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Walt Bogdanich wants to talk to you about your brachytherapy program

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### Acknowledgements

- W. Robert Lee, MD (Duke University)
- Dimos Baltus, PhD (Germany)
- Lory Bradley (Oncura)
- Kurt Maffei (Bard)

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