

RI - DNMS Licensee Event Report Disposition

Licensee: Stamford Hospital

Event Description: Medical Event

License No: 06060970 Docket No: 0300205 MLER-RI: 2013-002

Event Date: 11/21/12 Report Date: 11/21/12 HQ Ops Event #: 48528

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input checked="" type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input checked="" type="checkbox"/>	Other	<u>Retracted Event</u>	

2. REGION I RESPONSE

<input checked="" type="checkbox"/>	Immediate Site Inspection	Inspector/Date	<u>11/19/12</u>
<input type="checkbox"/>	Special Inspection	Inspector/Date	
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report		Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log		Review at Next Inspection
<input type="checkbox"/>	Report Referred To:		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input checked="" type="checkbox"/>	Calculations Adequate
<input checked="" type="checkbox"/>	Cause of Event	<input checked="" type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<p>N/A ↓</p> <input type="checkbox"/> Release w/Exposure > Limits <input type="checkbox"/> Repeated Inadequate Control <input type="checkbox"/> Exposure 5x Limits <input type="checkbox"/> Potential Fatality If any of the above are involved: <input type="checkbox"/> Considered Need for IIT Decision/Made By/Date:	<p>N/A ↓</p> <input type="checkbox"/> Deliberate Misuse w/Exposure > Limits <input type="checkbox"/> Pkgng Failure > 10 rads/hr or Contamination > 1000x Limits <input type="checkbox"/> Large# Indivs w/Exp > Limits or Medical Deterministic Effects <input type="checkbox"/> Unique Circumstances or Safeguards Concerns <input type="checkbox"/> Considered Need for AIT
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5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

N/A ↓

 Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
 Medical Consultant Used-Name of Consultant/Date of Report: _____
 Medical Consultant Determined Event Directly Contributed to Fatality
 Device Failure with Possible Adverse Generic Implications
 HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

Licensee initially reported this as a Medical Event. They later retracted the event after re-evaluating the implant using a source strength & activity evaluation criteria.

Non-Public Inspector Signature: [Signature] Date: 4/26/13
 Public-SUNSI REVIEW COMPLETE Branch Chief Initials: [Signature] Date: 5/9/13



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Affiliate Columbia University-College of Physicians & Surgeons
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A Planetree Hospital

To: U.S. NRC Region I
2100 Renaissance Boulevard
Renaissance Park
King of Prussia, PA 19406

January 23rd, 2013
updated March 10th, 2013

Re: Medical Event Retraction #48528 for Materials License # 08-06697-02

This is a follow up letter for the medical event #48528 reported on November 21st 2012.

- **Stamford Hospital reviewed internal documentation processes (activity based versus dose based) for LDR brachytherapy**
- **We have retracted the medical event after reviewing the patient case and changing our in house reporting procedures**
- **Called in to retract February 4th at 11: 30 EST by Sarah Bull, RSO**

We reported this case as a medical event because it fits the definition under 10CFR 35.9045 Subpart M. In the original plan, the total dose delivered to 90% of the prostate differed from the preplan by 20% or more. However, we submit that by following the NRC Advisory Committee on the Medical Uses of Isotopes definition of medical event for permanent implant brachytherapy to source strength/activity then this case does not constitute a medical event. Our criteria are now more completely formalized in our attached quality management program.

Corrective Action

We have reviewed our LDR brachytherapy program and have decided to move to activity based documentation. We have revised our QMP (enclosed), our written directive (enclosed), and reviewed the other forms and procedures associated with this program.

For the patient in question activity based documentation would mean a difference of <10% since there were 4 seeds missing from the initial implant of 86 palladium 103 seeds with the activity of 2.089U per seed. All seeds were implanted within 1 cm of the defined treatment area. Under our proposed changes to the brachytherapy program that means the patient does not constitute a medical event.

If you have any questions or desire additional information, please contact our RSO Sarah Bull at 203- 276-4036 or 203-417-3986, or via email; SBULL1@stamhealth.org.

Thank you for your time and efforts with our requests.

Respectfully submitted,

Kathy Silard

Executive VP & Chief Operating Officer

Dr Frank Masino


Medical Director Bennett Cancer Center
Authorized User

The Stamford Hospital

Subject: Bennett Cancer Center Radiation Oncology

Policy # _____ **Implemented** January 2013
Reference(s) _____ **Revisions** March 2013
Approval(s)  **Department** Radiation Oncology

Dr Frank Masino
Bennett Cancer Center Medical
Director (AU)


Kathy Silard
Executive Vice President & COO


Sarah Bull
AMP, Chief Physicist, RSO

Purpose

To outline the process for LDR brachytherapy procedure for prostate permanent implants at the Bennett Cancer Center.

Policy (NRC QMP)

Overview

Prior to the permanent implant the LDR prostate patient comes for a pre-implant ultrasound volume study one or two weeks in advance. Once the structures are contoured by the AU then a pre-plan is created using the written directive Attachment A for source strength, type (I-125 or Pd-103), and total prescription. Once the pre-plan is approved by the attending then the seed ordering process, listed under the forms section of this policy, is followed to order the pre loaded needles.

When the sources arrive on site please follow the delivery sheet form to verify order, condition of packaging, and logging them into the hot lab. Prior to the implant the preloaded needles are tested following the example testing sheet included in this policy.

On the day of the implant the needles are logged out of the hot lab and brought to the OR by either the physicist or AU. Once the implant is complete and an x-ray has verified the seed positions and removed or left over seeds are logged back into the hot lab. The vendor will send a courier to pick up the unused and left over seeds from the hot lab

Annually or at the time of an upgrade the entire implant system will be tested by physics according to attachment D. The testing procedure will be reviewed annually to include any changes from the vendor or national/international physics task groups. We have developed a physics checklist that incorporates the patient flow from volume study through post-plan.

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

A Quality Management Program will be established for the Brachytherapy program as a condition of the NRC License, as follows:

1. **Written Directives.** Prior to administration, a written directive will be prepared for any brachytherapy radiation dose in accordance with 10 CFR 35.41. The written directive will be prepared specifically for each patient. It will contain the quantity and activity to be administered and the procedure date. The directive will be signed and dated by an authorized user. **Attachment A** documents the form for Stamford Hospital for the written directive for permanent implants.

A written directive may be revised orally if, because of the patient's condition, a delay in order to provide a written revision would jeopardize the patient's health. Oral revisions will be documented immediately in the patient's record, and revised written directive will be signed and dated by an authorized user within 48 hours of the oral revision.

Revisions to written directives may be made for any brachytherapy procedure, provided that the final revision is dated and signed by an authorized user before completion of the administration of the brachytherapy implant. Any revision must also be documented on the final plans of treatment and signed and dated by the authorized user.

2. **Patient Identification.** Prior to each administration mentioned above, the patient's identity will be verified by more than one method as the individual named in the written directive in accordance with 10 CFR 35.41.

The patient's name will be checked orally (if the patient is unable to speak the oral verification of identity will be confirmed with a relative or guardian), and via hospital ID bracelet, and photograph from the patient's chart. If any portion of documentation is missing, than the minimum requirement of one oral and one written verification of the patient's identity before commencement of treatment. **Attachment B** shows the permanent implant form that will be used to verify the patient's identity before a brachytherapy procedure is administered.

3. **Quality Management.** Before each administration described above, the administration will be reviewed to determine that it complies with the intentions of the authorized user. Someone will undertake this review other than the authorized user, in his or her presence. Unintended deviations from the written directive will be identified and evaluated, and appropriate action will be taken.

Only authorized staff, who has received the necessary radiation safety training, will be permitted to handle brachytherapy sources.

The quantity of activity to be administered will be measured in the dose calibrator before administration, and the quantity cross-checked against the quantity specified in the written directive. On the implant date, the total number of seeds taken from the Source Room will be recorded in the source logbook.

Only the authorized user can administer the brachytherapy dose to the patient. Sources are administered by the authorized user who completes the written directive. The authorized user signs the patient's chart. Authorized personnel will instruct nursing staff.

A permanent logbook is maintained for each brachytherapy radionuclide to document seed activity and total number of seeds ordered, received, actual assay value, removal for implant procedure and number of seeds not used. **Attachment C** shows the forms used for tracking isotopes used in brachytherapy from ordering through implant.

In addition to inventory duties, the radiation oncology authorized physics staff is responsible for providing computerized treatment plans and dose rate calculations for all brachytherapy administrations. Acceptance testing will be completed before a computerized brachytherapy program is used for treatments, or when software or hardware is upgraded or replaced. Please see **Attachment D** for an example of procedures used in the absence of a more rigorous procedure specified by the manufacturer.

All patients receiving brachytherapy treatment will have either orthogonal or stereo shift films, and/or a post-operative CT scan (approximately 4-6 weeks after procedure), to determine the three dimensional location of all radioactive sources. The source locations, as determined from the radiographs and/or CT scan, will be digitized into the treatment planning computer and computer assisted isodose distributions will be generated. As a check on the computer generated plan, a hand calculation will be done from a single source to a point of interest. This check must be within 10% of the computer-generated value.

After the administration described above and after review and check by the physicist of the final treatment plan the final plans of treatment and related calculations will be presented to the authorized user in order to document the actual dose distribution administered to the patient. The dose administration will be reviewed, by the authorized user or their designee, to determine that it is in accordance with the following acceptance criteria:

1. Total Activity and source strength positioning accuracy compared with Written Directive and pre plan
 2. 90% of the target volume covered by more than 80% of the implanted seeds and that 95% of implanted seeds are within 1 cm of the target volume
 3. Normal tissue DVH's reviewed by AU
4. **Quality Management Review.** On an annual basis, a review of the quality management program will be carried out. This review will include:
- a. A review of a representative sample of administrations.
 - b. A review of all medical events to verify compliance with all aspects of the quality management program.
 - c. An evaluation to determine the effectiveness of the quality management program and if required modifications to meet the objectives of the program.
 - d. Recording and retaining for at least three years, in an auditable form, records of the annual review.
5. **Medical events.**
- Any medical event for brachytherapy must be reported to the NRC, the referring physician, and the patient within 24 hours, and evaluated within 15 days. This is moving toward source

strength/positioning as the measurable metric or surrogate for dose. A brachytherapy medical event could be any of the following:

- a. For the treatment site if 20% or more of the implanted seeds are located outside of the intended implant location
- b. For normal tissue structures (e.g. bladder, rectum) the dose to at least 5 contiguous cm³ exceeds 150% of that structures expected absorbed dose based on the approved pre-implant.
- c. The wrong patient treated, and/or treatment site treated, and/or wrong radioisotope used, and/or a leaking sealed source implanted, and/or when wrong activity or source strength differs by more than $\pm 20\%$ as specified by the Written Directive, and/or when 20% or more of the implanted seeds are located outside of the implanted location as specified by the Written Directive, and/or when seeds are implanted directly into the wrong site or body part (i.e. into other (distant from the treatment site) locations).

Unintended deviations from the written directive will be identified and evaluated, and if appropriate actions required by 10 CFR 35.40 and 35.3045 will be preformed.

6. **Records.** We will retain, for a period of at least three years after the date of administration, in auditable form, the written directives described above, and the record of the administration itself.
7. **Changes to QMP.** Changes may be made as approved by the Radiation Safety Committee to the quality management program.



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**Written Directive for Radioactive
Permanent Prostate Seed Implant**

Patient Name _____ ID# _____

Stage _____ Gleason Grade _____

Plan Implant Alone **OR** External Beam
Plus Implant

Implant Isotope I-125 **OR** Pd-103

Pre-Implant Prescription

Seed Activity: _____ mCi

Total # of Seeds: _____

Planned Total Source Strength to Treatment Area: _____

Frank Masino, M.D.

Date: _____

Final Implant Prescription

If changes happen in the OR, then the physician will document changes on the Variseed print out and sign and date.



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**Permanent Prostate Implant
Survey Form**

Patient Information

Name: _____ O.R.# & Floor _____
Oncologist: _____ Total Volume: _____ cc

Implant Information

Loading Date: _____ Time: _____ AM/PM
Radionuclide: _____ # Seeds Ordered _____
Seeds Implanted _____ # Seeds Remaining _____

**Patient Exposure Rates
Measured Unshielded (mR/Hr)**

	Skin Surface	Bedside	3 ft from Bed	6 ft from Bed	Initial & Date
O.R. #:					
Patient Release Room #:					

**Room Survey
Measured Unshielded (mR/Hr)**

All Urine filters/bags scanned YES NO
Bedding, Drapes, Floor, Surgical Instruments scanned YES NO
 o O.R. YES NO
 o One Day Surgery Room YES NO

Survey Instrument

Make:		Model #:	
Serial #:		Calibration Date Due:	
Surveyor:		Physicist:	

**Attachment C – Ordering through Implant
Example Checklist**

Prostate Implant Checklist

Name _____ **MR Number** _____

	1st Checker	2nd Checker
Ultrasound Verification (image transfer)		
Imported correctly		
Number of Slices (volume agreement)		
Prostate Area		
Coordinates/Grid Overlay (ok?)		
Prescription Agreement		
Rx Dose (Gy)		
VariSeed Dose (Gy)		
Plan signed by MD		
Case Information		
Implant Date		
Isotope		
Activity (mCi)		
# of seeds		
# of needles		
Plan Coverage		
Prostate Coverage V100%=		
Prostate Coverage D90%=		
Prostate Coverage V90%=		
Rectal Dose (Rx does not exceed 0.1cc) y/n		
Urethra Dose (under 150%) y/n		
QA		
Certificate Activity		
Measured Activity		
Within 5% y/n		
Needle Loading film check		
VariSeed Printout		
Retraction Page		
Dosimetry		
Needle Loading Page		
DVH Page		
CVA Page		
Miscellaneous		
Nursing Instructions		
Survey Page (bedside shield, linen, extra seeds, etc.)		
Wrist Band		
Hand Calc 2nd Check		
Radiation stickers for chart		
Initials		

Example Ordering Sheet

ORDER INFORMATION

Order Date: _____
 Ordered By (facility contact): _____
 Shipping Notification Email: _____

PO Number: _____
 Contact Phone: _____
 Contact Fax: _____

BILL TO INFORMATION

Facility Customer Number: _____
 Facility Name: _____

SHIP TO INFORMATION

Facility Customer Number: _____
 Facility Name: _____
 ATTN: _____

BRACHYTHERAPY KITS - IMPLANT INFORMATION

Physician Name: _____
 Date of Implant: _____
 Delivery Date to Hospital: _____
 Advantage™ I-125 Theraseed Pd-103 Cesium 131
 Activity Level at Implant Date: _____ mCi $\mu\text{Gy m}^2/\text{hr}$

Patient Name: _____
 Patient Number: _____
 Ordered by: _____
 Physicist Phone #: 203 276 7886

_____ Stranded Seeds	Needles _____	<input type="checkbox"/> Vari-Strand™ (stranded seeds & custom spacing)
_____ Stranded Seeds	Needles _____	<input type="checkbox"/> Standard-Strand™ (stranded seeds & standard spacing)
_____ Loaded Seeds	Needles _____	<input type="checkbox"/> Vari-Load™ (loose seeds & custom spacing)
_____ Loaded Seeds	Needles _____	<input type="checkbox"/> Anchor-Load™ (Loose Anchor Seeds with or w/o spacers)
_____ Loaded Seeds	Needles _____	<input type="checkbox"/> Standard-Load™ (loose seeds & standard spacing)
_____ Seeds in Vial (non-sterile)		<input checked="" type="checkbox"/> Manual Retraction <input type="checkbox"/> Base Line Load
_____ Seeds in Magazines (non-sterile)		
_____ Calibration Seeds (non-sterile)		SeedLock™ Needle: <input checked="" type="checkbox"/> Round Hub <input type="checkbox"/> Square
	Extra Needles _____	
_____ TOTAL SEEDS	TOTAL NEEDLES _____	Trailing Spacers: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Special Instructions (including extra seeds): _____

Example Delivery Sheet

**Radioactive Shipment
Receipt Report**

Company: BrachySciences or Exempt Shipment
BrachySciences

Isotope: I-125 or Pd-103

P.O. #: _____

Survey Date: _____ Survey Time: _____

Surveyor: _____ Survey Instrument: GM Model 14C, Ludlum

SN: _____ Calibration Due: _____

Source Check: CS-137 Background: _____ mR/hr

Condition of Package: _____ Measured Radiation Levels:

_____ Punctured Package Surface _____ mR/hr

_____ Wet _____ Crushed 3 feet from surface _____ mR/hr

Other _____

Do packing slip and contents agree?

- Radionuclide _____ yes _____ no if no . . . _____
- Amount _____ yes _____ no if no . . . _____
- Chemical Form _____ yes _____ no if no . . . _____

Survey Results of Packing and Cartons _____ mR/hr

Disposal of Packing and Cartons after inspection: _____

Average CPM Wipe Test before package disposal: _____

Initials: _____ **Date:** _____

Example Testing Sheet

**Stamford Hospital
Sample Testing of Pd-103 Seeds**

Today's Date _____
 Pt. Ordered For: _____
 Radiation Oncologist: Dr Masino

Implant Date _____
 MRN _____
 NMH PO _____

Seeds Ordered: _____
 10 % of Seeds Ordered 0
 Temperature (°C) _____
 Pressure (mmHg) _____

Assay Date _____
 Activity at Assay _____ mCi
 Temp. Kelvin 273.12 °K
 Time/Reading 120 sec.

	Electrometer Reading (nC)*
Background	0.001
Calibrated Seed	
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
Average	#DIV/0!
Standard Dev.	#DIV/0!

Expected Activity Today 0.000 mCi
 Measured Activity Today #DIV/0! mCi
 Measured/Expected* #DIV/0! %
 Activity on Implant Date 0.000 mCi
 (Manufacturers)

Measured Source Air Kerma Strength

$$S_x = N_x \left(\frac{U}{A} \right) \times E_d \left(\frac{A}{R_{c \text{ ading}}} \right) \times \frac{E_{\text{is. ading}} (R_{c \text{ ading}})}{120 \text{ sec}} \times C_{\text{Temp. Pr. cor}}$$

Temperature/Pressure Conversion

$$C_{\text{Temp. Pr. cor}} = \frac{273.15 + T}{295.15} \times \frac{760}{P}$$

I-125 Calibration Constant** 2.317E+11 U/A
 Air Kerma Strength to Apparent Activity Factor 1.27 U/mCi
 Electrometer Factor = 1.0 nC/Reading
 TP Factor = 0.000
 Electrometer Standard Imaging CDX-2000A #B982934
 Well Chamber Standard Imaging HDR 1000 Plus #A987333

Completed By: _____
 Date: _____
 Physicist: _____
 Date: _____

Attachment D – Variseed QA

LDR VariSeed Brachytherapy Treatment Planning System Upgrade Testing Procedures

The following acceptance testing procedures are designed to evaluate the validity of the machine data tables and image data transfer methods used in the brachytherapy treatment planning system VariSeed from Varian. In addition to performing these tests as part of the initial installation of the source data, they should also be performed whenever any new software (upgrade) or hardware is implemented.

1. Input of treatment planning data – Acquire a patient's data from both CT and Ultrasound

The accuracy of all input data should be verified. Verify orientation, position and scaling of all ultrasound image information. Input data ultrasound or other digital images, manual contours or other data entered via a digitizer. When transferring digital information such as CT images from removable drive, contours or other information may be transferred into the system as part of the image transfer.

2. New Source Data Check

Using the patient just loaded above, run a standard implant plan using a known source and activity. Then change the source to the new seed structure. Save and print each plan separately.

During the initial system installation, the Variseed distributions can either be compared to previous Variseed plans or another reliable planning system. The same isotope activity and treatment parameters (target cc's, etc.) should be used even if the machine data is for a different unit.

3. DVH and CVA Results Test

Also include testing of the archiving abilities of the system.

4. Dosimetry Check - Dose Calculation Verification Dose to Point and Isodose Contours

For two activities of the new source model, verify system calculations (i.e. calculation of dose at a point) for a variety of clinical situations. These calculations should be compared with hand calculations, other known source model or another planning system output whenever possible. Agreement should be within 10%. Again, it is possible to use data from another brachytherapy planning system. In this case agreement should be within 20%.

VARISEED
Upgrade, Source Change and/or Annual
QA Procedure

The functionality of the VARISEED system depends both on the correct transfer and creation of patient data and the correct calculation of data presented to the system. Therefore, there are two main types of tests to perform; data input and calculation results. Remember, temperature affects the speed of sound.

The transfer and input of data can be quickly tested. Create a patient file for each of the image input modalities used with this system. Then create a basic patient plan using all of the sources used for patient implants.

There are three main sections of the software to check for calculation accuracy. The first is dose verification to a point source. Next the isodose contours created need to be checked. Finally, the DVH and CVA results need to be reviewed. Then positional accuracy is tested where consistency is the most important value over a period of time.

VARISEED Dose Calculation Definitions (based on TG43 & TG128)

VARISEED has the ability to calculate the dose via three methods; with the anisotropy constant, with the anisotropy table, or without any anisotropy data.

- Dose Rate (cGy/hr) - $\dot{D}(r) = \frac{\text{dose}}{\text{apptime} / 100}$
- Dose Rate with Anisotropy constant - $\dot{D}(r) = \left(\frac{S_K \Lambda r_0^2}{r^2} \right) g(r) \bar{\phi}_{an}$ Where S_K is the Air Kerma strength, Λ is the dose rate constant, r is the radius, r_0^2 is the reference distance, $g(r)$ is the radial dose function, and ϕ_{an} is the anisotropy constant.
- Dose Rate with Anisotropy Factor Values - $\dot{D}(r) = \left(\frac{S_K \Lambda r_0^2}{r^2} \right) g(r) \phi_{an}(r)$ Where $\phi_{an}(r)$ is the anisotropy factor.
- Dose Rate without Anisotropy Correction - $\dot{D}(r) = \left(\frac{S_K \Lambda r_0^2}{r^2} \right) g(r)$
- Activity calculation - $S_K = \frac{\dot{D}(r) \times r^2 \times 100}{\Lambda \times g(r) \times \bar{\phi}_{an} \times \text{apptime}}$
- Activity calculation using anisotropy factors - $S_K = \frac{\dot{D}(r) \times r^2 \times 100}{\Lambda \times g(r) \times \phi_{an}(r) \times \text{apptime}}$
- Permanent Implants – Application Time = 1.44*24 hours/day*half life

I Verification of Dose from a Point Source

- Create a single point source with an activity of 100 U on a pre-operative plan.
- Use the "Add Dose Point" to a distance that is clearly defined by the "Source Specification" table. Don't forget to check if Anisotropy is used in the calculation.
- Add another source between the original source and the dose calculation point. Check the summed dose to the calculation point for accuracy.

Run the same test for any other sources being used clinically.

II Isodose Contour Verification

- Create a pre-operative plan using CIRS Model 045
 - Images must be Ultrasound images.
 - 0.5 cm distance between images
- Step through phantom until spheres are located.

	Expected (mm)	Measured Ultrasound (mm)	% Difference	Measured Variseed (mm)	% Difference
Small Sphere (4cc)					
Medium Sphere (9 cc)					
Egg shaped sphere (20 cc)					
Top View	44				
Front View					
End View					

- Make sure the anisotropy constants are on.
- Add isodose levels (in Gy) that correspond to the anisotropy constants entered under the source specification. Use the distance 0.5 – 4.5.
- Set activity to 100 U
- Enter a single seed and "Calculate Dose Volume". Make sure the "Automatic Dose Calculation" is turned on. With the "Automatic Dose Calculation" on, Variseed automatically updates the isodose levels.
- Verify the position of the isodose curves to within ± 2 mm of what is expected from the anisotropy constants.
- Verify the calculation by viewing the number of isodose levels on subsequent slices. With isodose levels on the seed plane, the next slice (0.5 cm away) should show one less level. Each succeeding slice away from the seed should show one less isodose level.
- Print "Therapy Visualization" report.

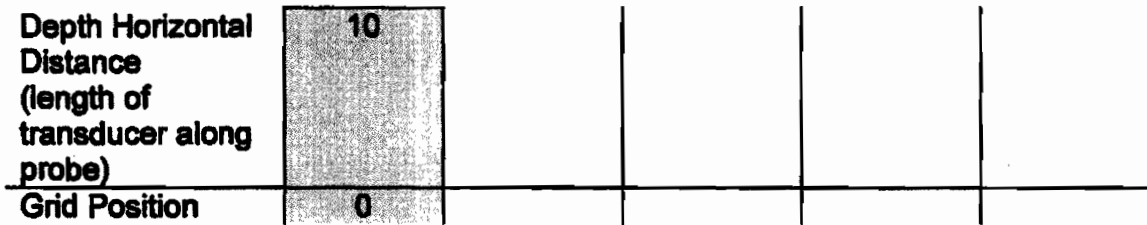
III DVH and CVA Verification

- Create a pre-operative plan
 - Images must be Ultrasound Images.
 - 0.5 cm distance between images
- Outline a 6x6 square on all images. The four corners of the template can be used.
- Select "Dose Calculation" and set the "Dose Matrix Resolution" to 0.5 and the "Dose Matrix Extent" to 80.
 - Turn on the Anisotropic Factor Correction.
- In an image, place a source in the center of the contoured area.
- Select DVH/CVA Settings. Set the Min=0 Gy, the Max=100 Gy, and Increment = 10 Gy.
- Set up a "source activity" (U) to represent each one of the anisotropy levels as shown in the "source specification" data.
- Run the test for each clinical source.

IV Position Verification

- At least once a year weigh your phantom and compare with original weight = 2049 g
 - Tolerance = 1% of original
- Create a pre-operative plan using CIRS Model 045
 - Images must be Ultrasound Images.
 - 0.5 cm distance between images
- Uniformity Test - Ability of the machine to display echoes of same magnitude and depth with equal brightness on the display
 - Align the probe in a spot on the phantom with minimum targets.
 - Freeze the image and obtain a hard copy. Acquire on Variseed.
 - Document comparison.
- "N" Group – asses depth of penetration (maximum depth of sensitivity or visualization)
 - Consists of 0.1 mm diameter parallel wires positioned at 1 cm spacing and shaped like the letter N. Should be dots not lines.
 - Freeze image and measure distance. Record below.

	Expected (mm)	Measured Ultrasound (mm)	% Difference	Measured Variseed (mm)	% Difference
Distance b/w scanning surface and last scatterer	40				
Vertical Distance (Axis of beam)	10				
Horizontal Distance (length of transducer)	10				
Depth Vertical Distance (Axis of beam along probe)	10				



- Make sure Grid is aligned to exterior surface of phantom prior to scanning. Proper alignment is superposition of wires and grid.

V Needle position Verification

- At least once a year weigh your phantom. This is a disposable phantom to be replaced annually.
- Create a pre-operative plan using CIRS Model 053 with grid
 - Images must be Ultrasound images.
 - 0.5 cm distance between images
- Evaluate positioning of needle versus image. Tolerance $\leq 0.5\text{mm}$ deviation

Stamford Health System

Nursing Instructions

patients receiving I-125 or PD-103 permanent prostate implants

Patient Name: _____
Date: _____ Time: _____
Isotope _____ Activity: _____
Patient's Exposure Rate @ 1 meter (mR/hr) _____

NOTE: Wearing a wristband stating that the patient contains radioactive material, does not signify radiation precautions. Please follow instructions that are checked below.

- _____ **No restrictions on time at bedside.**
- _____ **Pregnant personnel are not permitted to attend the patient.**
- _____ **No restrictions on personnel attending the patient.**
- _____ **Foley bag must be saved until checked by RSO or designee.**
- _____ **Wristband on patient's wrist stating that the patient contains radioactive material must be removed upon discharge, defaced and disposed of in normal trash.**
- _____ **Patient's chart will have "Radioactive Materials" label affixed to it. This must be removed, defaced and disposed of in normal trash when patient released.**
- _____ **No restrictions on visitor's outside of normal hospital rules.**
-

**In case of emergency, contact Dr Frank Masino.
After hours please call the hospital operator to have him paged.**

Any questions please do not hesitate to contact the appropriate person below:

Radiation Oncologist	Dr Frank Masino	(203) 276-7886 Pager 135
Radiation Safety Officer	Sarah Bull	(203) 276-7886 or ext 4036 Cell (203) 417-3996
Physics	Carolyn Dicker Patricia Lopez Robert Masino	(203) 276-7886



maryann.abogunde@nrc.gov

Received: Apr 23, 2013 2:22 PM
Expires: May 7, 2013 2:22 PM
From: sbull1@stamhealth.org
To: maryann.abogunde@nrc.gov
Cc:
Subject: RE: Status

Attachments: Stamford Hospital.pdf

This message was sent securely using ZixCorp.

Hi Maryann-

Attached is the permanent prostate implant Written directive form, the signed permanent prostate implant Policy and Procedure (includes updated QMP and other applicable forms), and Nursing instructions. Please let me know if there is anything else you need.

Thank you for all of your knowledge and patience .

All the best /Sarah

Sarah Bull Chief Physician, RSO

The Stamford Hospital /32 Strawberry Hill Court /Stamford, CT 06904

O: (203) 276-4036 /C: (203) 417-3996

SBULL1@StamHealth.org



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Affiliate Columbia University-College of Physicians & Surgeons
Member NewYork-Presbyterian Healthcare System
A Planetree Hospital

REC RG 1 02 08 13 07 15

To: U.S. NRC Region I
2100 Renaissance Boulevard
Renaissance Park
King of Prussia, PA 19406

January 23rd, 2013

Re: Medical Event Retraction #48528 for Materials License # 06-06697-02

This is a follow up letter for the medical event #48528 reported on November 21st 2012.

- Stamford Hospital reviewed internal documentation processes (activity based versus dose based) for LDR brachytherapy
- We have retracted the medical event after reviewing the patient case and changing our in house reporting procedures
- Called in to retract February 4th at 11: 30 EST by Sarah Bull, RSO

We reported this case as a medical event because it fits the definition under 10CFR 35.3045 Subpart M. The total dose delivered differs from the prescribed dose by 20% or more. However, we submit that by following the current proposed NRC changes to the definition of medical event for permanent implant brachytherapy from dose based to source strength/activity then this case does not constitute a medical event.

Corrective Action

We have reviewed our LDR brachytherapy program and have decided to move to activity based documentation. We have revised our QMP (enclosed), our written directive (enclosed), and reviewed the other forms and procedures associated with this program.

For the patient in question activity based documentation would mean a difference of <10% since there were 4 seeds missing from the initial implant of 86 palladium 103 seeds with the activity of 2.069U per seed. All seeds were implanted within 3 cm of the defined treatment area. Under our proposed changes to the brachytherapy program that means the patient does not constitute a medical event.

If you have any questions or desire additional information, please contact our RSO Sarah Bull at 203- 276-4036 or 203-417-3996, or via email; SBULL1@stamhealth.org.

Thank you for your time and efforts with our requests.

Respectfully submitted,

Handwritten signature of Kathy Silard in black ink, written over a horizontal line.

Kathy Silard
Executive VP & Chief Operating Officer

Handwritten signature of Dr. Frank Masino in black ink, written over a horizontal line.

Dr Frank Masino
Medical Director Bennett Cancer Center
Authorized User

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

A Quality Management Program will be established for the Brachytherapy program as a condition of the NRC License, as follows:

1. **Written Directives.** Prior to administration, a written directive will be prepared for any brachytherapy radiation dose in accordance with **10 CFR 35.32 (a) (1) iii**. The written directive will be prepared specifically for each patient. It will contain the quantity and activity to be administered and the procedure date. The directive will be signed and dated by an authorized user. *Attachment A* documents the form for Stamford Hospital for the written directive for permanent implants.

A written directive may be revised orally if, because of the patient's condition, a delay in order to provide a written revision would jeopardize the patient's health. Oral revisions will be documented immediately in the patient's record, and revised written directive will be signed and dated by an authorized user within 48 hours of the oral revision.

If, because of the emergent nature of a patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

Revisions to written directives may be made for any brachytherapy procedure, provided that the final revision is dated and signed by an authorized user before completion of the administration of the brachytherapy implant. Any revision must also be documented on the final plans of treatment and signed and dated by the authorized user.

2. **Patient Identification.** Prior to each administration mentioned above, the patient's identity will be verified by more than one method as the individual named in the written directive in accordance with **10 CFR 35.32 (a) (2)**.

The patient's name will be checked orally (if the patient is unable to speak the oral verification of identity will be confirmed with a relative or guardian), and via hospital ID bracelet, and photograph from the patient's chart. If any portion of documentation is missing, then the minimum requirement of one oral and one written verification of the patient's identity before commencement of treatment. *Attachment B Q. #1* shows the permanent implant form that will be used to verify the patient's identity before a brachytherapy procedure is administered.

3. **Quality Management.** Before each administration described above, the administration will be reviewed to determine that it complies with the intentions of the authorized user. Someone will undertake this review other than the authorized user, in his or her presence. Unintended deviations from the written directive will be identified and evaluated, and appropriate action will be taken.

Only authorized staff, who has received the necessary radiation safety training, will be permitted to handle brachytherapy sources.

The quantity of activity to be administered will be measured in the dose calibrator before administration, and the quantity cross-checked against the quantity specified in the written directive. On the implant date, the total number of seeds taken from the Source Room will be recorded in the source logbook.

Only the authorized user can administer the brachytherapy dose to the patient. Sources are administered by the authorized user who completes the written directive. The authorized user signs the patient's chart. Authorized personnel will instruct nursing staff.

A permanent logbook is maintained for each brachytherapy radionuclide to document seed activity and total number of seeds ordered, received, actual assay value, removal for implant procedure and number of seeds not used. *Attachment C* shows the forms used for tracking isotopes used in brachytherapy from ordering through implant.

In addition to inventory duties, the radiation oncology authorized physics staff is responsible for providing computerized treatment plans and dose rate calculations for all brachytherapy administrations. Acceptance testing will be completed before a computerized brachytherapy program is used for treatments, or when software or hardware is upgraded or replaced. Please see **Attachment D** for an example of procedures used in the absence of a more rigorous procedure specified by the manufacturer.

All patients receiving brachytherapy treatment will have either orthogonal or stereo shift films, and/or a post-operative CT scan, to determine the three dimensional location of all radioactive sources. The source locations, as determined from the radiographs and/or CT scan, will be digitized into the treatment planning computer and computer assisted isodose distributions will be generated. As a check on the computer generated plan, a hand calculation will be done from a single source to a point of interest. This check must be within 10% of the computer-generated value.

After the administration described above and after review and check by the physicist of the final treatment plan the final plans of treatment and related calculations will be presented to the authorized user in order to document the actual dose distribution administered to the patient. The dose administration will be reviewed, by the authorized user or their designee, to determine that it is in accordance with the written directive. The written directive and final treatment plans will be kept in the patient's medical record.

4. **Quality Management Review.** On an annual basis, a review of the quality management program will be carried out. This review will include:
 - a. A review of a representative sample of administrations.
 - b. A review of all recordable events and any misadministration to verify compliance with all aspects of the quality management program.
 - c. An evaluation to determine the effectiveness of the quality management program and if required modifications to meet the objectives of the program.
 - d. Recording and retaining for at least three years, in an auditable form, records of the annual review.

5. **Reportable events.** We will evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:
 - a. Assembling relevant facts, including the root cause analysis.
 - b. Identifying what, if any, corrective action is required to prevent recurrence.
 - c. Retaining a record, in an auditable form, for at least three years, of the relevant facts and what corrective action if any, was taken.

Any misadministration for brachytherapy must be reported to the NRC, the referring physician, and the patient within 24 hours, and evaluated within 15 days. This is moving toward source strength/positioning as the measurable metric or surrogate for dose. A brachytherapy misadministration could be any of the following:

- a. For the treatment site if 20% or more of the implanted seeds are located outside of the intended implant location
- b. For normal tissue structures (e.g. bladder, rectum) the dose to at least 5 contiguous cm³ exceeds 150% of that structures expected absorbed dose based on the approved pre-implant.
- c. The wrong patient treated, and/or treatment site treated, and/or wrong radioisotope used, and/or a leaking sealed source implanted, and/or when wrong activity or source strength differs by more than $\pm 20\%$ as specified by the Written Directive, and/or when 20% or more of the implanted seeds are located outside of the implanted location as specified by the Written Directive, and/or when seeds are implanted directly into the wrong site or body part (i.e. into other (distant from the treatment site) locations).

Unintended deviations from the written directive will be identified and evaluated, and if appropriate actions required by **10 CFR 35.33** will be preformed.

6. **Records.** We will retain, for a period of at least three years after the date of administration, in auditable form, the written directives described above, and the record of the administration itself.
7. **Changes to QMP.** Changes may be made as approved by the Radiation Safety Committee to the quality management program. Changes must be submitted to the NRC within 30 days in accordance with **10 CFR 35.32 (e)**.



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A Planetree Hospital*

Written Directive for Radioactive Permanent Prostate Seed Implant

Patient Name _____ ID# _____

Stage _____ Gleason Grade _____

Plan Implant Alone **OR** External Beam
Plus Implant

Implant isotope I-125 **OR** Pd-103

Pre-Implant Prescription

Seed Activity: _____ mCi

Total # of Seeds: _____

Planned Total Source Strength to Treatment Area: _____

Frank Masino, M.D. Date: _____

Final Implant Prescription

If changes happen in the OR, then the physician will document changes on the Variseed print out and sign and date.