DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

In Reply Refer To: 598/115HP/NLR

MAR 23 2010

Cassandra F. Frazier
Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Ms Frazier:

Per your request for information regarding the prostate seed implant program, I am enclosing documents from the VA Sierra Nevada Health Care System, Reno, Nevada.

Please contact Gary E. Williams at 501-257-1572, if you have any questions or comments.

Sincerely,

Lisa Maloy Offutt

Lisa Maloy Offutt
Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 25 2010

GW 3/3/10

NRC Request for Information (February 16, 2010)
VA Sierra Nevada Health Care System, Reno, Nevada

1. Provide copies of policies and procedures for prostate implants to include the following:

a. Copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program with the effective date indicated.

b. Copies of policies and procedures that were revised after the on-site NRC inspection or in response to NHPP recommendations with the effective date indicated.

2. Provide copies of any training records for calendar years 2007, 2008, and 2009 for medical physicists, dosimetrists, physician authorized users, and radiation safety staff involved in prostate implants.

NRC Request for Information (February 16, 2010)
VA Sierra Nevada Health Care System, Reno, Nevada

1. Provide copies of policies and procedures for prostate implants to include the following:

   a. Copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program with the effective date indicated.
      - **Documents 1a thru 23a were in place.**

   b. Copies of policies and procedures that were revised after the on-site NRC inspection or in response to NHPP recommendations with the effective date indicated.
      - **Documents noted 1b thru 7b developed by Radiation Safety Officer after on-site NRC.**

2. Provide copies of any training records for calendar years 2007, 2008, and 2009 for medical physicists, dosimetrists, physician authorized users, and radiation safety staff involved in prostate implants.
      - **Documents 1 thru 8 submitted as note of training.**

If you have further questions, please call Fran White at (775) 328-1264

RADIATION ONCOLOGY ASSOCIATES

VA MEDICAL CENTER

QUALITY MANAGEMENT PROGRAM
I-125 or Pd-103 SEED THERAPY
WRITTEN DIRECTIVE
TREATMENT PLAN

R.D. Miercort, M.D. G.E. Campbell, M.D. B. L. Hummer, M.D.
Jennifer Sutton, M.D. Jonathan S. Tay, M.D.

DATE:

PATIENT NAME:

RADIOACTIVE MATERIAL: **I-125 (STM 1251) [NIST 99] BARD**

TREATMENT SITE: **PROSTATE**

mCi/seed

PRESCRIPTION: Gy

NUMBER OF SEEDS:

TOTAL SOURCE STRENGTH: mCi

Signed: _____ Date: _____

PATIENT IDENTIFICATION (USE TWO METHODS)

Patient Name	Birthdate
Social Security Number	Address
Signature	ID Bracelet
ID Card	Other _____

Administered by: _____ Date: _____

WASTE DISPOSAL - ROOM SURVEY

CONDUCTED BY: _____ Date: _____

TOTAL NUMBER OF SOURCES IMPLANTED: _____

NOTE:

Operating Room: Patient Name: _____
Patient ID #:

Pre-Procedure

_____ Identify Patient by two means of ID: Name - ID Bracelet - ID Card - SS Number
Signature - Birth Date - Address
_____ Verify Written Directive
_____ Verify the Correct Number and Batch of Seeds (if possible)

Ensure the following are in the Operating Room:
_____ 1) Lead Container for Loose Seeds
_____ 2) Tweezers
_____ 3) Survey Meter for Room
_____ 4) Survey Meter for Patients
_____ 5) Pre-loaded Seeds
_____ 6) Written Directives Part I and II
_____ 7) Physicians' Radiation Badges
_____ 8) Ultra-sound Pictures from Volume Study

Post-Procedure (10 CFR 35.2404)

_____ Survey People in Operating Room (linens, trash, etc.)

_____ Survey Patient – IMPORTANT: Patient Survey must show **less than 1 mR/hr at 1 meter**. If greater than 1 mR/hr, immediately call Radiation Safety Officer and Do Not release the patient from the hospital until approved by the RSO. See 10 CFR 35.75.

_____ Survey Operating Room
Note Total Number of Loose Seeds Recovered: _____

_____ Complete the following (Part II of Written Directive):

1) Radionuclide _____

2) Treatment Site _____

3) Number of Sources _____

4) Total Source Strength _____

5) Exposure Time PERMANENT

_____
Signature of Authorized User Physician

_____
Date

Prostate Seed Implant Patient Checklist

This checklist is to ensure all procedures conform to the Nuclear Regulatory Commission's requirements for prostate seed implants and handling of associated radioactive materials.

Please check the following when completed: Patient Name _____
_____ Patient Name/ID # on this and next pages Patient ID #: _____
_____ Volume Study
_____ Treatment Plan
_____ Approval of Treatment Plan by Authorized User Physician (Signed and Dated)
_____ Seeds Ordered

Part I of Written Directive Includes (10 CFR 35.41)**:**
_____ Patient Name
_____ Second Form of Identification
_____ Treatment Site
_____ Radionuclide
_____ Dose
_____ Signed by Authorized User Physician
_____ Dated by Authorized User Physician
* Retain a copy of this Written Directive in accordance with 10 CFR 35.2040. Note: If, because of an emergent nature of a patient's condition, an oral directive is acceptable if followed by a written directive within 48 hours of the oral directive (10 CFR 35.40).

Arrival of Seeds:
1) Date of Arrival: _____

2) Time of Arrival: _____

3) Received By: _____ Department: _____

4) Survey of Package to be completed within 3 working hours (i.e. hours between 8:00 am and 5:00 pm) of delivery.
Survey Time: _____Survey Date:_____

Through measurements or manufacture documentation, complete the following:
1) Source Activity: _____
2) Correct the source activity determined above for physical decay at intervals consistent with 1 percent physical decay: _____ for procedure date _____.
3) Do the source positions within the applicators agree with the Needle Loading Report? _____

Seed Location Log

User	Date & Time	Transfer From	Transfer To	# of seeds trans.

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VA MEDICAL CENTER
PROSTATE IMPLANT BRACHYTHERAPY PROGRAM
PROSTATE IMPLANT SEED ORDER FORM

FAX (888) 383-3839

DATE:

SUPPLIER

PATIENT

IMPLANT DATE:

DESIRED DELIVERY DATE:

RADIOACTIVE MATERIAL:

ACTIVITY/SEED ON PI DATE: mCi

ASSAY DATE:

ASSAY ACTIVITY: mCi
U/seed

PRESCRIBED DOSE (Gy):

NUMBER OF PRESCRIBED SEEDS:

NUMBER OF XTRA SEEDS:

TOTAL SEEDS:

PERSON PLACING ORDER: _____

PERSON TAKING ORDER: _____

CONFIRMATION NUMBER: _____

PHYSICIST SPECIFYING SEED ORDER: _____

AUTHORIZATION BY PHYSICIAN: _____

Phone Numbers: VA FAX 775-328-1796
VA Phone 775-328-1288 Carl

PLEASE INCLUDE THE CALIBRATION SEED ON EACH AUTORADIOGRAPH FOR QA PURPOSES.
THE CALIBRATION SEED SHOULD BE LOADED IN A NEEDLE WITH SPACERS AT EACH END.
THANK YOU

Ship to Address:

VA Medical Center
1000 Locust Street
Reno, NV 89520

Attn: Nuclear Medicine Department

Procedure for Written Directives

The following procedure for Written Directives must be followed to satisfy the requirements of 10 NRC 35.40 and 35.41.

1) At least two types of patient identification must be examined in the operating room directly prior to the surgical procedure.

Acceptable forms of identification:
- Patient Name
- ID Bracelet
- ID Card
- Social Security Number
- Signature
- Birth Date
- Address

2) To ensure successful treatment, the administration must be in accordance with the treatment plan and the Written Directive. Therefore:

- The treatment plan shall be approved (signed and dated) by the Authorized User Physician.
- The patient shall be properly identified prior to the surgical procedure using two methods.
- The patient name, treatment site, radionuclide, dose, and correct number of seeds shall be documented in the Written Directive which is to be signed and dated by the Authorized User Physician.
- The needle number, retraction depth, hole location, and number of seeds shall be read aloud by someone other than the physician during the procedure.

3) Manual and computer-generated dose calculations shall be verified to ensure accuracy for therapy-related computer systems and software to satisfy the requirements of NRC 35.457. These acceptance tests must include verification of:

- The source-specific input parameters required by the dose calculation algorithm.
- The accuracy of dose, dwell time, and treatment time calculations at representative points.
- The accuracy of isodose plots and graphic displays
- The accuracy of the software used to determine sealed source positions from radiographic images.

4) Be aware of NRC 35.3045 describing what constitutes a Medical Event and the procedure to follow if such an event occurs.

5) A copy of the procedures will be retained by the Veterans Affairs Medical Center as required under paragraph (a) in accordance with NRC 35.2041.

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December 19, 2008

VHA Standard Procedure - - Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy

1. VHA facilities that perform permanent implant prostate brachytherapy must prepare and complete a written directive for each patient treatment. NRC has regulatory requirements for written directives. This standard procedure provides specific guidelines to be followed by VHA facilities.

2. Current regulatory information is available on the NRC Website at the following address.

http://www.nrc.gov/materials/miau/med-use-toolkit.html

3. NRC defines a written directive, in 10 CFR 35.2, as:

> Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

4. For permanent implant prostate brachytherapy, the NRC requirements for a written directive, in 10 CFR 35.40, are:

> 1. A written directive must be dated and signed by an authorized user before the administration any therapeutic dose of radiation from byproduct material.
>
> 2. The written directive must contain the patient or human research subject's name and the following information:
>
> (a) Before implantation: treatment site, the radionuclide, and dose; and
>
> (b) 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).
>
> 3. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.
>
> (a) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

5. NRC requirements to retain a copy of the written directive are in 10 CFR 35.2040 as follows:

> A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

6. VHA facilities must comply with NRC requirements. In addition, VHA facilities must follow these additional guidelines for prostate brachytherapy procedures.

a. Ensure initial and periodic training for prostate brachytherapy programs includes the requirements in this standard procedure and is provided to, as a minimum, physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff.

December 19, 2008

VHA Standard Procedure - - Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy

b. Complete and document quarterly audits of written directives to ensure NRC and VHA requirements have been meet.

c. Use the standard procedure for training for medical events as criteria to evaluate written directives and to determine if a medical event has occurred.

d. For the pre-implant portion of the written directive, provide the following information per 10 CFR 35.40: treatment site, the radionuclide, and dose.

e. For the post-implant part of the written directive, provide the following information per 10 CFR 35.40: radionuclide, treatment site, number of sources, total source strength, and the word "permanent."

f. At the bottom of the written directive, after the post-implant part, or on a separate review worksheet for written directives. (If possible, the reviewing medical physicist should be a reviewer other than the medical physicist who prepared the treatment plan.)

(1) Name, date, and signature for medical physicist review to determine if a medical event occurred.

(2) Name, date, and signature for Radiation Safety Officer review to determine if a medical event occurred.

Documents re: Brachytherapy Program

VA Sierra Health Care System-Reno
Quality Management Program
Brachytherapy Program

Protocol for Lost Radioactive Seed in the Operating Room.

Radioactive Seed Flow at VA Hospital, Reno.

Records of Patient Release.

Unused Brachytherapy Seeds Returned to OR.

OR Personnel

Brachy Patient Log

Seed Receiving Log

Seed Transfer and Location Log

Unused Seeds Log

10 CFR 20.1906 Procedures for receiving and opening packages

10 CFR 35. 67 Requirements for possession of sealed sources and brachytherapy sources.

10 CFR 35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources.

10 CFR 35. 3045 Report and notification of a medical event.

10 CFR 35.2092 Records of decay-in-storage.

10 CFR 35.61 Calibration of survey instruments.

10 CFR 35.40 Written Directives

10 CFR 35.2040 Records of Written Directives .

10 CFR 35.41 Procedures for administrations requiring a written directive.

10 CFR 35.457 Therapy related computer systems.

10 CFR 35.432 Calibration measurements of brachytherapy sources.

10 CFR 35.404 Surveys after source implant and removal.

10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

10 CFR 35.406 Brachytherapy sources accountability.

10 CFR 35.400 Use of sources for manual brachytherapy.

10 CFR 35.432 Calibration measurements of brachytherapy sources.

VHA Standard Procedure
--- Training
--- Training for Medical Events
--- Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy.
--- Clinical Requirements

Radioactive Seeds Delivered to Medical Center
for use in Brachytherapy procedure.

Seeds are received the day previous to their being used in the OR.

FedEx delivers most often ~11am

Typically, within 5 minutes of receiving the boxes containing the seeds, the receipt of the boxes is recorded and boxes are taken to the Nuclear Medicine department.

The seeds are given to the NM tech to be placed in the NM hot lab. They are never left unattended. If the NM tech is not present, the department manager is located or some other person who has access to hot lab is located so the seeds are made secure.

In the NM depart the NM tech logs in the boxes and surveys the boxes for radiation. He then records, for each patient, the patient name and the number of seeds delivered for that patient. Occasionally this documentation is completed by the RSO.

In the NM department after the seeds are logged in, the RSO checks the seeds information against patient information for each group of seeds. He removes the shielded seed containers from the boxes and places them in a locked drawer in NM to await uses early the next morning.

It is a priority for receiving personnel to see that the seeds are delivered to NM dept as soon as possible.
They understand the importance of the seeds being brought to NM quickly, as the seeds are to be used early the following morning and must be readied for use by NM personnel, the RSO and Brachytherapy physicist.

Richard O Barlow Ph.D.
ABR Certified Physicist

January 2008

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RADIOACTIVE SEEDS SHIPMENT RECEIVING REPORT

Nuclear Medicine Department

Date:	Time:	By:
#1 Patient Name		
#2 Patient Name		
#3 Patient Name		
#4 Patient Name		
Manufacturer:		

	Nuclide:	# of seeds	Activity/seed	Total Activity
Pt #1			mCi	mCi
Pt #2				
Pt #3				
Pt #4				

External Survey Radiation Seed Container			
Biodex Model 14C S/N 121194			
	BKG	Surface	1 meter
#1			
#2			
#3			
#4			

Robert O Brubow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Procedure for opening boxes containing seeds:

1. Inspect each package for damage. Do not accept if damaged.
2. Survey the package BKG, surface, and 1 meter.

3. Open the box.

4. Inside will be an envelope containing:
   Autoradiographs of the needles showing the placement of the seeds and spacers within each needle.
   Documentation of seed strength.
   Documentation of where each needles is to be positioned in the "needle box".

5. Inside the box will also be a metal box.
   In this inner metal box will be a leaded sleeve with the preloaded STERILE package of needles.
   Each sterile package within the sleeve also contains leaded sheets to protect personnel from the seeds radiation until loaded into the needle box.

6. Either
   a.) The leaded sleeve will be transported to the O.R. where the needles with seeds are loaded into the sterile needle box.
   or
   b.) The needles with seeds will be loaded into the sterile needle box before transferring the needle box to the O.R.

Richard O Barlow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Protocol for Lost Radioactive Seed in the Operating Room

During the Brachytherapy seed implantation procedure in which radioactive seeds are involved, the following protocol will be adhered to:

1) There will always be the Radiation Safety Officer or a representative of the RSO involved in the Brachytherapy procedure.

   a. This person may be a physicist, Nuclear Medicine technologist or trained nursing staff.
   b. A Scintillation Detector, lead container and forceps should be available in the operating room in the eventuality of a lost or dropped seed.
   c. The person designated above shall have training in the handling of radioactive materials. No person who has not had training shall handle radioactive material in the operating room.

2) In case of a lost radioactive seed, the procedure is as follows:

   a. Once a seed has been determined to be missing or gone astray, the RSO or representative will request that no one leave the operating room, and that everyone remain in place.
   b. The RSO or representative will then begin surveying the room with the scintillation detector beginning with the location of the last known location of the missing seed. The surveyor will sweep the room in a circular fashion, covering all instrument trays, trashcan, linen, and other equipment. Personnel within the OR will be asked to lift their feet and raise their arms to shoulder level so that the surveyor can scan each person for the lost seed.
   c. No one is allowed to leave the OR until the RSO or representative has thoroughly surveyed his or her body from head to feet.
   d. The survey continues until the missing seed is found or all possibilities have been exhausted.
   e. All personnel are now permitted to leave the room.

3) Once a seed is found, it should only be picked up using forceps or other utensil capable of holding the radioactive seed without crushing it. It should then be placed into the lead container for return to storage in the Nuclear Medicine Department.

4) If the seed is not found, the Radiation Safety Officer and NHPP are to be notified immediately.

Richard O Brusow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

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Unused Seeds Transferred from OR to NM for Decay

Date	Patient	# of seeds	Total Seeds this date
			_____
			_____
			_____
			_____
			_____

Richard O Barlow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Radiation Survey Instruments

There are two radiation survey instruments used in the Brachy program.

Unit: Ludlum
Type: Scintillation, Model #: 3, Serial #: 209042, DET M # 44-3, DET S # PR213493

This instrument is used for monitoring in the OR.
Personnel and area are surveyed at the end of the implant procedure for seed accountability.

Unit: Victoreen
Type: Ionization Chamber, Model #: 451B-RYR, Serial #: 611

The unit is used for the purpose of determining if a patient may be released from the hospital based on measured dose rate.
NUREG-1556, U.1.2

Both meters are calibrated yearly using Cesium 137 as a standard source of radiation. The output is traceable to the National Institute of Standards and Technology.

Richard D Brusow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Release of Patients Administered Radioactive Material

The licensee may authorize the release of patients who have been administered implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5rem).

Either one of the following Release Criteria will be used to determine when the patient shall be released.

Release criteria based on Administrative Activity. (ref b, U.1.1)

Release criteria based on Measured Dose Rate. (ref b, U.1.2)

Robert D Bursow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

References:
a) 10CFR35.75
b) NUREG-1556, Vol. 9, Appendix U

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Record of Patient Release

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

Patient	Release Date	Release Criteria	By
Measurement/Calculations done by			

NUREG-1556 Vol. 9, Rev.1 Release Criteria
U.1.1 Release of Patient based on Administered Activity
U.1.2 Release of Patient based on Measured Dose Rate
10 CFR 35.75

Richard D Baslow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Unused Brachytherapy Seeds Returned from OR
and Stored in Nuclear Medicine Department Hot Lab

Date	Patient	# of seeds	Activity/seed (mCi)	Total Activity (mCi)	By (initial)

Richard O Barlow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Seed Transfer and Location Log

Date	Patient	Time	Nuclide	# of seeds	Total Activity	Transfer From	Transfer To	initial

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SURVEY INSTRUMENT CALIBRATION

DATE: December 5, 2009

FACILITY: VA Medical Center
Nuclear Medicine
CONTACT: Richard Breslow

Most recent - Instrument Calibration Document

UNIT:	Ludlum
TYPE:	Scintilation
MODEL #:	3
SERIAL #:	209042
DET M#:	44-3
DET S#:	PR213493

This instrument was calibrated using Cesium 137 as a standard source of radiation. The output is traceable to the National Institute of Standards and Technology. For ionization chambers, no correction was made for temperature and pressure. GM saturatio

CALIBRATION SOURCE CHARACTERISTICS

JLS CALIBRATOR MODEL 28-6 S/N 10304
Ref. Date: 11-Nov-98 Strength: 176.57 mR/hr @ 100cm

INSTRUMENT CHECKS

Battery Check: OK
Check Source: NO CHECK SOURCE

CALIBRATION GEOMETRY

Unit perpendicular to source line of sight.

COMMENTS:

Refer to the enclosed graph for 10% accuracy.

Signed: David K. Chamberlain

David K. Chamberlain
Physicist

V

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SURVEY INSTRUMENT CALIBRATION

DATE: December 5, 2009

FACILITY: Reno VA Hospital
Reno, Nv
CONTACT: Richard Breslow

UNIT:	Victoreen
TYPE:	Ionization Chamber
MODEL #:	451B-RYR
SERIAL #:	611
DET M#:	NA
DET S#:	NA

This instrument was calibrated using Cesium 137 as a standard source of radiation. The output is traceable to the National Institute of Standards and Technology. For ionization chambers, no correction was made for temperature and pressure. GM saturation conditions may occur in fields greater than 100 mR/hr. The results of this calibration are indicated on the attached graph. Data points were determined on all scales and cross checked when possible for consistency.

CALIBRATION SOURCE CHARACTERISTICS

JLS CALIBRATOR MODEL 28-6 S/N 10304
Ref. Date: 11-Nov-98 Strength: 176.57 mR/hr @ 100cm

INSTRUMENT CHECKS

Battery Check: OK
Check Source: 0.31 mR/hr

CALIBRATION GEOMETRY

Unit perpendicular to source line of sight.

PANCAKE CHAMBER DPM/CPM CONVERSION:

Using a standard Co-57 source the cpm to dpm conversion was determined to be:

NA dpm/cpm

COMMENTS:

This ionization chamber is excellent for general relative measurements. Use the enclosed graph to achieve 10% accuracy.

Signed: David K. Chamberlain

David K. Chamberlain
Physicist

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Documents re: Brachytherapy Program

VA Sierra Health Care System-Reno
Quality Management Program
Brachytherapy Program

Protocol for Lost Radioactive Seed in the Operating Room.

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Records of Patient Release.

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Brachy Patient Log

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10 CFR 35. 67 Requirements for possession of sealed sources and brachytherapy sources.

10 CFR 35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources.

10 CFR 35. 3045 Report and notification of a medical event.

10 CFR 35.2092 Records of decay-in-storage.

10 CFR 35.61 Calibration of survey instruments.

10 CFR 35.40 Written Directives

10 CFR 35.2040 Records of Written Directives .

10 CFR 35.41 Procedures for administrations requiring a written directive.

10 CFR 35.457 Therapy related computer systems.

10 CFR 35.432 Calibration measurements of brachytherapy sources.

10 CFR 35.404 Surveys after source implant and removal.

10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

10 CFR 35.406 Brachytherapy sources accountability.

10 CFR 35.400 Use of sources for manual brachytherapy.

10 CFR 35.432 Calibration measurements of brachytherapy sources.

VHA Standard Procedure
--- Training
--- Training for Medical Events
--- Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy.
--- Clinical Requirements

VA SIERRA HEALTH CARE SYSTEM

Quality Management Program

BRACHYTHERAPY

Overview:

This outpatient procedure uses radioactive seeds permanently implanted into the prostate to deliver a dose of radiation directly to the tumor. The physician, together with the medical physicist and using ultrasound images of the prostate, plan the most effective placement of the seeds. In the operating room, live ultrasound and fluoroscopic imaging are used to guide the placement of the seeds into the prostate. The seeds, about the size of a grain of rice are implanted through thin needles causing little or no discomfort.

The implant procedure is a complicated process, is carried out in the operating room and requires the cooperation of a radiation oncologist, a medical physicist, a radiation safety officer and typically an urologist. Also, anesthesiologists, nurses and x-ray department personnel are an important part of the team.

Objective:

The goal of the brachytherapy prostate seed implant procedure is to achieve a specified dose to the prostate, as uniformly as possible, while avoiding excessive doses to nearby radiosensitive organs.

Authority:

The regulations and guidelines of the US Nuclear Regulatory Commission (NRC), the conditions of the VA's Master Materials License (MML) and the VHA Permit No. 27-15192-01 issued to VA Sierra Health Care System must be followed.

The Brachytherapy Program is governed by regulations set forth in various parts of Title 10 of the Code of Federal Regulations:
10 CFR 35.40, 35.41 and 35.2040 (written directives), 35.75 (patient release), 35.400 (sources that may be used, 35.404 (surveys after source implantation), 35.406 (source accountability), 35.432 (calibration of sources), 35. 457 (testing of treatment planning computer system).

The radiation oncologist is the physician authorized user (AU) listed in VHA Permit No. 27-15192-01.
Likewise the Radiation Safety Officer is listed in this permit.
The RSO will be responsible for ensuring that requirements of Title 10 of the Code of Federal Regulations are adhered to. The RSO shall maintain as necessary, records of inventory, radioactive waste disposal, storage, transfers of radioactive materials, patient release, personnel dosimetry and surveys performed on OR facilities and personnel.

There will always be the Radiation Safety Officer or a representative of the RSO in the O.R. during the seed implant procedure.

Policies and Procedures for the Use of Brachytherapy Sources

A. Prior to administration of any dose from a Brachytherapy source, a "Written Directive" will be dated and signed by an "Authorized User". A "written directive " is here defined as an order, in writing, for a specific patient, dated and signed by an "Authorized User" prior to the administration of a brachytherapy dose and contains the following information:

- Patient Name
- Patient Identification Number
- Brachytherapy source/isotope
- Dose, number of sources/total strength
- Area of implantation/treatment sight

A "written directive" may be revised by the Authorized User, but the revision(s) must be recorded and signed prior to the administration of the implanting of any seeds.

Except in an emergency situation, as defined in subsection D, no personnel shall administer any brachytherapy source in the absence of a signed "written directive" with the above essentials.

B. Prior to administration, the patient's identity MUST be verified as the patient named in the "written directive". Verification MUST be by **two** of the following methods:

- Requesting and confirming name from patient.
- Requesting from patient and confirming DOB or SS#
- Signature of patient
- Picture ID card
- ID Bracelet

C. Ensure each administration is in accordance with the "written directive".

The brachytherapy dose and treatment site shall be confirmed prior to administration of the dose to verify its agreement with the treatment plan and the "written directive". A check of the computer generated dose calculations shall have been made before the patient is treated. This check shall be made by one of the following methods:
A second person reviews the plans, a nomogram is used to verify that the activity to be implanted and the number of seeds is approximately correct for a prostate of a specific volume.

Documentation of seed strength verification shall be kept in the appropriate records.

D. Oral Directives are permissible under the following conditions (10CRF35.40(a)(1)):

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

E. In the event of a "Medical Event", as described in 10 CFR 35.3045, the Authorized User and the RSO will be notified immediately. They will take suitable action. Reports will be filed as required.

F. Policies for personnel involved in Brachytherapy procedures.
All O.R. and Recovery Room personnel involved in the brachytherapy procedures will receive training as appropriate.
The instruction will include:

- Demonstration using a dummy seed and ribbon of seeds and discussion of how a seed may be released from the patient (urine).
- Precautions in the event of seeds dislodging.
- Immediately call the RSO if a misplaced seed/ribbon is found.
- Use standard radiation protection principles of Time, Distance and Shielding.
- Employees will be issued appropriate Dosimetry badges.

G. Radiation Surveys:

- Areas where the procedure was carried out including any medical instruments and devices will be surveyed with an appropriate survey instrument to identify areas that may harbor a stray seed or seed ribbon.
- All seeds brought into the O.R. prior to the procedure, shall be accounted for, i.e. their number shall equal the sum of the seeds placed in the patient plus the seeds, if any, returned to the Nuclear Medicine hot lab.

Patient Release from Hospital:

Patients shall be released from the hospital based on measured dose rate. (NUREG-1556, U.1.2)

Patient Release Instructions:

The Authorized User will provide to the Implant Patients oral instructions. Written instructions will be provided to the patient when appropriate. Instructions may include radiation safety guidance for keeping radiation dose to household members minimal and radiation precautions in the event of a dislodged seed.

Annual Audit:

An audit of the Brachytherapy Program shall be conducted by the RSO periodically and a written summery report filed annually.
The audit checklist will include all applicable sections of the NHPP document Transperineal Permanent Implant Prostate Brachytherapy--- Audit Checklist.

Medical Event:

If an event is identified as a "Medical Event", the Authorized User physician and Radiation Safety Officer shall be notified immediately. The appropriate response shall take place as soon as possible.
(10 CFR 3045, 10 CFR 30.6)

6b

MEDICAL EVENTS

A medical event is patient circumstances that are within the NRC definition in 10 CFR 35.3045

For prostate brachytherapy procedures, the figure of merit to identify a medical event during the post treatment dose analysis is D90.

D90 is the dose received by 90% of the target volume as delineated on post implant CT.

The post implant dose analysis produces the D90. The D90 is the figure of merit for determining whether the prescribed dose was achieved. The D90 must exceed 80% or the prescribed dose in the written directive or a medical event has occurred.

A medical event may also result from an overly large dose to tissue outside the prostate or from an implanted leaking seed.

Physician authorized users, medical physicists and dosimetrists who are involved in the prostate brachytherapy procedures shall be made aware of patient circumstances that might be a medical event and the requirement to report those circumstances to the RSO promptly.

In the event of the possible occurrence of a medical event NHPP shall be contacted by the RSO as soon as possible about any patient circumstances that might be a medical event.

Normal business hours for Central Time Zone 501-257-1571

After normal business hours for Central Time Zone 800-815-1016

The RSO and physician authorized user and NHPP shall have contact cellular telephone numbers so contact can occur during a medical event situation.

7b

VA Sierra Health Care System

VHA Standard Procedure—Training

Training Topics by RSO for personnel in O.R. and the Recovery room.

1. Concepts of ALARA, time, distance and shielding.
2. Proper use of dosimetry, Occupational dose limits.
3. Source accountability.
4. Radiation surveys after completion of implant procedure.
   a) Implements used in procedure
   b) O.R. Personnel
5. Emergency procedures—lost/misplaced seeds/damaged or leaking seeds, damaged/leaking seed implanted in patient.
6. Patient release criteria. Regulations allow the patient to be released from the hospital if the exposure rate at one meter from the patient is less than one mrem/hr at one meter.

(A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).)

Richard O Barlow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

TRAINING

RE: 10 CFR 35.27 Supervision

10 CFR 35.27 requires that persons involved with the brachytherapy program at VASNHCSR be supervised in numerous procedures relating to the program.

Nuclear Medicine personnel who receive, monitor, log-in and secure the seeds used in the program have been instructed by the RSO in these procedures and the necessity of following proper radiation protection measures. That they do so has been observed by the RSO.

Nurses in the OR have had an inservice by the RSO covering the important topics in radiation protection.

Persons in the room where the brachy procedure occurs have been instructed by the RSO as to the procedure of their being scanned before they leave the OR and to the course of action followed in the event of an unaccountable seed. That they follow these procedures has been observed by the RSO.

The medical personnel and the medical physicist actively involved in the implantation of the radioactive seeds have had no direct supervision by VA personnel. The RSO is aware that the medical physicist has attended numerous continuous education brachytherapy training programs.

Direct observation of the medical personnel and the medical physicist by the RSO before, during and after each of the 71 procedures performed demonstrates that any expressed supervision would not result in any modification in the program.

Robert O Brusbow Ph.D.

ABR Certified Physicist

Radiation Safety Officer

3/4/2010

VA Sierra Health Care System-Reno

Radiation Safety Officer
Year End Report 2005

Activities not previous carried out that have occurred during the preceding year that relate to Radiation Safety and the use of Radioactive Materials.

The Brachytherapy program commenced operation. The procedure involves implantation of radioactive iodine seeds in the prostate of the patient. The first patients underwent this procedure on September 8, 2005. A total of 11 patients underwent the procedure through December 22, 2005. All 11 procedures went according to plans. Personnel in the O.R. closely involved with the procedure wore personal radiation dose monitors. None of these radiation dose monitors indicated any radiation exposure above background. All personnel were instructed as to the practice that everyone is to be monitored with a radiation detector before leaving the O.R. In the event a radioactive iodine seed is not accounted for after the procedure ends, i.e., it has not been implanted in the patient or remains with the unused seed inventory, no one will leave the O.R. until all seeds are accounted for. No problems relating to radiation safety occurred.
All I-125 seeds not placed in patients were returned to the Nuclear Medicine department "hot lab". These seeds shall be kept secure for decay in storage.
This waste is held for 10 half-lives. If activity is then at background level, the waste is disposed as ordinary hospital waste.

Documentation of the arrival if the iodine seeds at the Nuclear Medicine department, the storage of the seeds, and the transportation of the seed to and from the O.R. from Nuclear Medicine department are kept in logs in the Nuclear Medicine department. Also recorded is documentation of dosimetry measurements of patients before they are released from the medical center and the disposal of unused seeds.

Richard O Barlow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

VA Sierra Health Care System-Reno

Radiation Safety Officer
Year End Report 2006

Radiation Safety meetings were held in the Medical Imaging department on February 23, May 18, and September 21, 2006. The meetings were held to discuss topics relevant to radiation safety at the Reno VA and the progress of the VA's brachytherapy program.

The following persons were in attendance.
Lenore Amante, M.D.[1] ,Chair, Radiation Safety Committee
Richard Breslow, Ph.D., Radiation Safety Officer [1]
Jonathan S. Tay, M.D.[2], Authorized User I-125 [1]
Trevor Burris, M.S., Brachytherapy Physicist
Carl Montoya, Nuclear Medicine technologist

At each of these meetings:

Richard Breslow, Ph.D., Radiation Safety Officer said the Radiation Safety program, following accepted guidelines, NRC regulations and requirements of VHA Permit No. 27-15192-01, operates in a manner that all radiation doses are As Low as Reasonably Achievable, i.e. ALARA and no problems have been reported.
Jonathan S. Tay, M.D. indicated, that everything relating to the seed implant program is going smoothly.
Trevor Burris, M.S., was in agreement with Dr. Tay.
Carl Montoya, NM technologist, said that there had been no problems relating to Radiation Safety in the Nuclear Medicine department.

1 VHA Permit No. 27-15192-01
2 via e-mail May 18

Submitted by:

Richard O Breslow Ph.D.
ABR Certified Physicist

Radiation Safety Officer

Brachytherapy program

The Brachytherapy program, having begun on September 8, 2005, has continually operated efficiently and without incident with approximately 3 patients per month undergoing the procedure. All procedures have proceeded as planned.

Personnel in the O.R. closely involved with the procedure wear personal radiation dose monitors. None of these radiation dose monitors indicated any radiation exposure above background. All personnel were instructed as to the practice that everyone is to be monitored with a radiation detector before leaving the O.R. In the event a radioactive iodine seed is not accounted for after the procedure ends, i.e., it has not been implanted in the patient or remains with the unused seed inventory, no one leaves the O.R. until all seeds are accounted for. No problems relating to radiation safety have occurred.

All I-125 seeds not placed in patients were returned to the Nuclear Medicine department "hot lab". This radioactive "waste" is kept secure for decay in storage for a minimum of 10 half-lives ($T_{1/2}$ = 60 days) at which time the activity is measured to insure it is at background level. The waste will then be disposed as ordinary hospital waste.

Documentation of the arrival of the iodine seeds at the Nuclear Medicine department, the storage of the seeds, and the transportation of the seeds to the O.R. from Nuclear Medicine department and the return of unused seeds to the Nuclear Medicine department are kept in Nuclear Medicine department logs. Also documented are the dosimetry measurements of patients before they are released from the medical center.

VA Sierra Health Care System-Reno

Radiation Safety Officer
Year End Report 2007

Radiation Safety meetings/discussions were held in the Medical Imaging department on May 11, and October 15, 2007. The meetings were held to discuss topics relevant to radiation safety at the Reno VA and the progress of the VA's brachytherapy program. In addition, each month when seed implants are performed, discussions are carried out, as needed, between the Radiation Safety Officer and those involved in the procedure.

The following persons generally are in attendance or communicated their input.
Lenore Amante, M.D.[1] ,Chair, Radiation Safety Committee
Richard Breslow, Ph.D., Radiation Safety Officer [1]
Jonathan S. Tay, M.D.[2], Authorized User I-125 [1]
David Chamberlain, M.S.[2], Brachytherapy Physicist
Lynn Smith, Nuclear Medicine technologist
Carl Montoya, Nuclear Medicine technologist

Richard Breslow, Ph.D., Radiation Safety Officer said the Radiation Safety program, following accepted guidelines, NRC regulations and requirements of VHA Permit No. 27-15192-01, operates in a manner that all radiation doses are As Low as Reasonably Achievable, i.e. ALARA and no problems have been reported.
Jonathan S. Tay, M.D. indicated, that everything relating to the seed implant program is going smoothly.
David Chamberlain, M.S., was in agreement with Dr. Tay.
Carl Montoya, NM technologist, said that there had been no problems relating to Radiation Safety in the Nuclear Medicine department.

1 VHA Permit No. 27-15192-01
2 via e-mail May 18

Submitted by:

Richard O Breslow Ph.D.
ABR Certified Physicist

Radiation Safety Officer
December 2007

Brachytherapy program

The Brachytherapy program, having begun on September 8, 2005, has continually operated efficiently and without incident with 3 or 4 patients per month undergoing the procedure. All procedures have proceeded as planned. All personnel in the O.R. involved with the procedure continue to perform commendably. Personnel wear lead aprons, thyroid shields and personal radiation dose monitors. None of these radiation dose monitors indicated any radiation exposure above background. All personnel are monitored with a radiation detector before leaving the O.R. All iodine seeds brought to the O.R. before any implant procedure began were accounted for. All I-125 seeds not placed in patients were returned to the Nuclear Medicine department "hot lab". This radioactive "waste" is kept secure for decay in storage for a minimum of 10 half-lives ($T_{1/2}$ = 60 days) at which time the activity is measured to insure it is at background level. The waste will then be disposed as ordinary hospital waste. All refuse from the procedure is monitored before disposal. No problems relating to radiation safety have occurred.

Documentation of the arrival of the iodine seeds at the Nuclear Medicine department, the storage of the seeds, and the transportation of the seeds to the O.R. from Nuclear Medicine department and the return of unused seeds to the Nuclear Medicine department are kept in Nuclear Medicine department logs. Also documented are the dosimetry measurements of patients before they are released from the medical center.

VA Sierra Health Care System-Reno

Richard Breslow, Ph.D.
Radiation Safety Officer
2008 Year End Report

Radiation Safety Committee meetings were held in the Medical Imaging department on 5/8, 6/12, 10/8 and 12/15/2008. The meetings were held to discuss topics relevant to radiation safety at the Reno VA.

Additionally, each month when Brachytherapy procedures were performed, discussions are carried out, as needed, between the Radiation Safety Officer and those involved in this seed implant procedure.

The Radiation Safety program, following accepted guidelines, NRC regulations and requirements of VHA Permit No. 27-15192-01, operates in such a manner that all radiation doses to all personnel are "As Low as Reasonably Achievable", i.e. ALARA.

Richard O Breslow Ph.D.

ABR Certified Physicist

Radiation Safety Officer

Brachytherapy program

VHA Permit No. 27-15192-01

The Brachytherapy program begun on September 8, 2005, was stopped in March due to lack of personnel. Since that time a quality assurance problem was found with the program. This quality assurance problem is being addressed and in no way involved or was a question of radiation safety.

Up until the program was halted all operating room personnel involved with the procedure continued to perform commendably. No problems relating to radiation safety had occurred.

All radioactive iodine seeds that were transferred from the NM department to the OR, placed in patients or returned to the Nuclear Medicine department "hot lab" unused, were accounted for. Those seeds returned to the hot lab are stored in secure shielded containers until their activity is at background level, at which time they will be discarded.

Documentation of the location of the iodine seeds from their arrival at the hospital to there placement in patients or returned to the hot lab are kept in Nuclear Medicine department logs. Also documented are the dosimetry measurements of patients before they are released from the medical center.

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Kelly Mayo
VHA National Health Physics Pr
2200 FORT ROOTS DR
B101 R208D
NORTH LITTLE ROCK, AR 72114

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Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

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