



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

MAR 02 2010

In Reply Refer To: 598/115HP/NLR

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 Medical Center, Minneapolis, Minnesota.

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

Sincerely,

Handwritten signature of Lisa Maloy Offutt in cursive.

Lisa Maloy Offutt
Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 05 2010

6/1

NRC Request for Information (February 16, 2010)
VA Medical Center, Minneapolis, Minnesota

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.

-----Original Message-----

From: Hensch, Thomas

Sent: Monday, February 22, 2010 11:09 AM

To: Williams, Gary E

Cc: Leidholdt, Ed; Huston, Thomas E.; Offutt, Lisa M

Subject: RE: additional information for NRC inspection

The following information is the training portion only. The policies, procedures, and forms will be faxed.

Brachytherapy Training

3/26/08 - OR Nurses - By James Schmitz, CMD

3/27/08 - Ward Nurses - By James Schmitz, CMD

8/27/08 - Radiation Oncology Staff (entire); Radiation Safety - By James Schmitz, CMD

?/?/08 - James Schmitz attended the ASTRO Meeting

1/8-9/09 - Dr. Wang, Dr. Silva, Dr. Qin, PhD (Radiation Oncology), RSO - Attended the VHA Radiation Oncology Practice Standards Meeting

2/11/09 - Radiation Oncology Staff (entire); Radiation Safety - By James Schmitz, CMD

5/7/09 - Dr. Wang, Dr. Qin, Joseph Lynch, James Schmitz, Jane Johnson, Radiation Oncology Resident, Urology Staff Physicians, Urology

Resident; Training on new ultrasound unit - By Julie Hesner, R.T., RDMS of BK Medical Systems Inc.

8/5/09 - OR Nurses - By Thomas Hensch, RSO

10/?/09 - Dr. Wang attended the ASTRO Meeting

1/21&29/10 - Radiation Oncology Staff - By Joseph Lynch, CMD

1/22/10 - Radiation Oncology Staff, RSO - By Joseph Lynch, CMD

1/27/10 - Radiation Oncology Staff, Assistant to the RSO - By Joseph Lynch, CMD

2/4/10 - Urology Staff (Nurses, Physicians, Residents) - By Joseph Lynch, CMD

Scheduled for 3/10 - Radiation Oncology Staff (entire); Radiation Safety - By Thomas Hensch, RSO



VA Medical Center
One Veterans Drive
Minneapolis, MN 55417

To: NHPP

Fax Number: 501-257-1570

From: THOMAS HENSEN

Sender's Number: 612-467-2620

Subject: REQUESTED MATERIAL BY
NRC

Comments: _____

Date: 2/22/10

Time: 11:25 AM

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Attachment I

Minneapolis VA Medical Center
Radiation Safety Office

Radiation Safety Procedures for Permanent Implant Brachytherapy

This document describes radiation safety policies and procedures instituted at the Minneapolis VA Medical Center (MVAMC) for permanent implant brachytherapy treatments. These policies and procedures are designed to comply with NRC Regulations Title 10 Code of Federal Regulations and conditions of the MVAMC NRC Radioactive Materials License. These procedures supplement current radiation safety procedures contained in the Radioactive Materials License application and subsequent amendments.

1. Receipt, Storage and Inventory of Permanent Implant Brachytherapy Seeds

Each shipment of 125I or 103Pd brachytherapy seeds will be monitored upon receipt for radiation levels and radioactive contamination in accordance with 10 CFR 20.1906. Results of package monitoring will be recorded on a MVAMC radioactive material receipt record sheet and maintained on file for review and inspection.

Implant seeds will be stored prior to use in a shielded container in Room SV-13, Building 49, Therapeutic Radiology Service.

2. Radiation Warning Signs

Signs are required whenever radioactive materials are present in accordance with 10 CFR 20.1902.

- A Caution – Radioactive Material sign will be posted at the entrance to the implant seed storage room.
- Caution – Radioactive Material signs will be posted on all entry doors into the implant procedure area. This includes the Operating Room and recovery room where the patient stays post-implant. In the recovery room, the sign will be posted on the patient's bed.

3. Radiation Surveys

A radiation survey will be performed and recorded after each seed shipment is placed in storage to ensure that radiation levels in unrestricted areas outside the storage room do not exceed allowable limits in 10 CFR 20.1301. A radiation survey of the sealed source storage area will be performed at least quarterly.

The following areas will be surveyed with a calibrated survey meter to detect misplaced or lost brachytherapy seeds.

- The loading area after seeds have been loaded and moved to a safe distance.
- The O.R. implant procedure area following insertion to include suction containers, drainage basins, loading/needle storage boxes, floor, table, linens, trash, all needles to insure no seeds have remained in them, catheter bag, instrument and loading tables, and all other areas of the suite which may possibly harbor a stray seed.
- The patient will be surveyed with a radiation measurement instrument (ion chamber) when moved to Post-Anesthesia Recovery to confirm acceptable dose rate around the patient.

4. Release of Patients Following Implant

Permanent implant brachytherapy patients will be released based on the criteria in NRC Regulatory Guide 8.39 dated April 1997. Records of patient release, including dose rate survey results, will be maintained as required by 10CFR 35.75.

Personnel working under the supervision of the Authorized User, as well as nursing personnel and other ancillary personnel involved in the implant procedures will be trained. Training will include requirements of 10 CFR 19.12 as well as instruction in radiation safety precautions for permanent implant procedures, to include:

- Demonstration using a non-radioactive dummy seed, permanent implants seeds, and discussion of how a seed might be released from the patient (urine, wound, etc).
- Precautions in the event of a seed falling out of the patient:
 - Never handle radioactive sources directly with your fingers. Use a long-handle forceps to pick up the seed and return it to a shielded lead container. This container will accompany the patient into surgery and the recovery room.
 - Immediately notify the Radiation Safety Officer or Authorized User if an implant seed is found.
- Use standard Radiation protection principles of time, distance and shielding to keep occupational radiation dose As Low As Reasonable Achievable (ALARA).

Implant patients will be provided with oral and written instructions upon release. Instructions will include radiation safety guidance on methods to keep radiation doses to household members and the public as low as reasonable achievable, and radiation safety precautions in the event a seed is dislodged:

- Do not handle the source directly with your fingers. Use tweezers or other long-handled instrument to pick up the seed and place it in a jar or other closable container. Place the jar in a location away from people, and, at your earliest convenience, bring the closed container with the seed back to the Therapeutic Radiology Service for disposal.

5. Radiation Dosimetry

The Authorized User and other individuals handling implant sources will be issued whole body (film badge or TLD) dosimeters and extremity TLD ring badges. Our NVLAP-accredited Dosimetry supplier will provide dosimetry.

Nursing and other ancillary personnel will be provided Dosimetry for permanent implant procedures if the Radiation Safety Officer determines that they are likely to receive more than 10% of the applicable dose limits in accordance with 10CFR 20.1502.

6. Radioactive Waste Disposal

Unused implant seeds and seeds returned to the Therapeutic Radiology Service will be disposed by the Radiation Safety Officer in accordance with current radioactive waste disposal procedures.

Attachment 2

Minneapolis VA Medical Center
Therapeutic Radiology Service

Quality Management Program for Permanent Implant Brachytherapy

This document describes the quality management program instituted at the Minneapolis VA Medical Center (MVAMC) Therapeutic Radiology Service, for permanent implant brachytherapy treatments. These policies and procedures are designed to comply with 10 CFR Part 35.32.

1. Directives

Written directives signed and dated by an Authorized User are required before administration of any brachytherapy dose. An oral directive may be used only in the event that the delay in obtaining a written directive would jeopardize the patient's health in the opinion of the physician. In the event of use of an oral directive, a written directive must be obtained and placed in the patient's chart within 24 hours.

Before delivery of any brachytherapy dose, the radiation dosimetrist/physicist will check that an Authorized User fills out the written directive section of the brachytherapy form. The individual performing the procedure must sign and date the appropriate section of the form prior to loading.

2. Patient Identification

Prior to delivery of treatment, each patient will be identified by two methods. After patient identification is confirmed by the two methods, the Authorized User will initial the appropriate section of the brachytherapy form.

3. Preliminary verification of brachytherapy pre-plan

Before preparation of sources for a brachytherapy treatment, a pre-implant treatment plan will be reviewed by a dosimetrist/physicist. He/she will initial the appropriate section of the brachytherapy form prior to preparation of the sources.

4. Obtaining guidance for carrying out written directives

Any worker having questions about carrying out a written directive should consult with the Authorized Physician User who created the written directive, rather than continuing a procedure when in doubt.

5. Verification of sources for pre-plan

Two individuals (dosimetrist/physicist or physician) will verify that the radioisotope, number of sources, and source strengths are in agreement with the written directive and the treatment pre-plan prior to implanting. After verification both individuals will initial the brachytherapy form in the appropriate section.

6. Verification of computer generated treatment plans

Upon completion of the computerized treatment plan, and after the Authorized User has checked the dosage calculation /computer plan, a complete dosimetric check of all plans and recorded dosages will be conducted by the physicist/dosimetrist. He/she will confirm that the proper sources, numbers and strengths have been used in the computer plan.

7. CT image verification of source placement

Following the implant procedure, a CT scan will be performed and source placement reconstruction will be used to generate the final treatment plan and total dose calculation.

8. Recording of actual number of sources used

Promptly after insertion of the sources, the Authorized User shall record the actual number of sources implanted on the brachytherapy form and sign the appropriate section.

9. Double check procedure for emergent patients

If the Authorized User determines that performance of the double-check procedure as defined in (6) above will cause an unacceptable delay and jeopardize a patient's health, the verification process may be performed within two working days of completion of the treatment. Reasonable attempt will be made to confirm visually that the dose distribution depicted in the computer plan conforms to the written directive.

When the verification is completed, the appropriate section of the brachytherapy form will be completed and signed by the individual performing the verification.

10. Acceptance testing for computer hardware/software used to generate treatment plans

Acceptance testing will be performed by a physicist for all computer hardware and software prior to use for treatment planning. The acceptance testing will validate the appropriateness of the software/hardware for the needs of the Service and also to verify that a performance matches manufacturer specifications. Additionally, accuracy of data input and output devices and information will be confirmed.

11. Periodic reviews of brachytherapy quality management program

Each patient receiving permanent implant brachytherapy will have a Brachytherapy Quality Management Form filled out. At the conclusion of therapy, the physicist/dosimetrist will perform a final quality management review of the treatment and sign off in the last section of the form. Deviations from accepted procedure will be noted and logged.

Yearly, a review of the Brachytherapy Quality Management Plan will be performed by the physicist/dosimetrist and will include:

- A representative number of brachytherapy cases from the previous 12 months. For each patient case reviewed, a determination will be made whether the radiation administered was in accordance with the written directive, and whether the Quality Management Form for Permanent Implant Brachytherapy was properly completed, including all required signatures and initials.
- For each patient case reviewed, deviations from the written directive and the cause of each deviation will be identified, and the action required to prevent recurrence.

Following each annual review, the Radiation Safety Officer and the Radiation Safety Committee will reevaluate the brachytherapy QM program to determine whether the program is still effective or to identify actions required to make the program more effective.

NEW

Quality Management Form for Prostate Permanent Implant Brachytherapy
Veterans Affairs Medical Center Mpls, MN
Department of Radiation Oncology

This form must be completed and reviewed for prostate permanent implant brachytherapy procedures. The original will be placed in the patient chart and a copy will be filed in the Radiation Oncology Service.

Physician Written Directive

(Fill out prior to implant procedure)

Patient Name: _____ Patient Number: _____

Diagnosis: _____

Treatment Site: _____

Prescription: _____ cGy is planned to be delivered to a minimum target volume with total source strength _____ mCi. Source type:(check one) I-125 Pd-103

Physician: _____ Date: _____

Patient Identification

Double patient ID check required before implant procedure:

(Check each box when verification completed)

Name/Social Security Number:
Birth Date:

Initials: _____ Date: _____

Pre/Post Treatment Verification

A. Pre-Treatment:

1. Dose calculation Verification

a. Patient Data Verification (check each after verification)

<input type="checkbox"/> Volume	<input type="checkbox"/> Source Strength	<input type="checkbox"/> Prescribed Dose	<input type="checkbox"/> Loading Sequence	<input type="checkbox"/> Treatment Site
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b. Calculation Check:

Quality Management Form for Prostate Permanent Implant Brachytherapy
Veterans Affairs Medical Center Mpls, MN
Department of Radiation Oncology

2. Computer- Planned source requirements:

Position																				
Needle#	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
# seeds																				

Position																				
Needle#	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
# seeds																				

Source type: (check one) I-125 Pd-103

Total # seeds: _____

Total seed strength: _____ mCi.

Seed strength verification Complete: (check box if complete) Name: _____ Date: _____

Pre-treatment review by: _____ Date: _____
(Physicist/Dosimetrist or Physician)

COMMENTS:

Number of seeds implanted _____ Date _____

Number of seeds returned to RSO _____

Survey Meter used Model _____ Serial # _____

Survey Meter wand used Model _____ Serial # _____

Survey patient @ 1M <1mR/hr _____ room survey _____

Person doing Survey _____

1 mR/hr or less at one meter for implanted I-125 is U.S.NRC; NUREG-1556; Vol. 9, Rev. 2; Table U.1, Column 2

B. Post-treatment: Complete promptly following implant insertion.

Position																				
Needle#	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
# seeds																				

Position																				
Needle#	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
# seeds																				

Quality Management Form for Prostate Permanent Implant Brachytherapy
Veterans Affairs Medical Center Mpls, MN
Department of Radiation Oncology

Treatment site: _____

Source type: (check one) I-125 Pd-103

Total # seeds: _____

Total seed strength: _____

Planned Dose: _____

Physician: _____ Date: _____

C. Post-Implant CT scan taken: (check box if completed)

QM Form Review

The following items are reviewed for completeness and correctness:
(Check each box after verifying the review)

- Written directive
- Patient ID
- Pre/Post treatment verification
- Dose calculation verification

DEVIATIONS AND ACTIONS NOTED HERE:

Reviewed by: _____ Date: _____
(Dosimetrist/Physicist)

OLD

Quality Management Form for Prostate Permanent Implant Brachytherapy
Veterans Affairs Medical Center Mpls, MN
Department of Radiation Oncology

This form must be completed and reviewed for prostate permanent implant brachytherapy procedures. The original will be placed in the patient chart and a copy will be filed in the Radiation Oncology Service.

Physician Written Directive

(Fill out prior to implant procedure)

Patient Name: _____ Patient Number: _____

Diagnosis: _____

Treatment Site: _____

Prescription: _____ cGy is planned to be delivered to a minimum target volume with total source strength _____ mCi. Source type:(check one) I-125 Pd-103

Physician: _____ Date: _____

Patient Identification

Double patient ID check required before implant procedure:

(Check each box when verification completed)

Name/Social Security Number:

Birth Date:

Initials: _____ Date: _____

Pre/Post Treatment Verification

A. Pre-Treatment:

1. Dose calculation Verification

a. Patient Data Verification (check each after verification)

<input type="checkbox"/> Volume	<input type="checkbox"/> Source Strength	<input type="checkbox"/> Prescribed Dose	<input type="checkbox"/> Loading Sequence	<input type="checkbox"/> Treatment Site
---------------------------------	--	--	---	---

b. Calculation Check:

Quality Management Form for Prostate Permanent Implant Brachytherapy
 Veterans Affairs Medical Center Mpls, MN
 Department of Radiation Oncology

2. Computer- Planned source requirements:

Position																				
Needle#	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
# seeds																				

Position																				
Needle#	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
# seeds																				

Source type: (check one) I-125 Pd-103

Total # seeds: _____

Total seed strength: _____ mCi.

Seed strength verification Complete: (check box if complete) Name: _____ Date: _____

Pre-treatment review by: _____ Date: _____
 (Physicist/Dosimetrist or Physician)

COMMENTS:

B. Post-treatment: *Complete promptly following implant insertion.*

Position																				
Needle#	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
# seeds																				

Position																				
Needle#	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
# seeds																				

Quality Management Form for Prostate Permanent Implant Brachytherapy
Veterans Affairs Medical Center Mpls, MN
Department of Radiation Oncology

Treatment site: _____

Source type: (check one) I-125 Pd-103

Total # seeds: _____

Total seed strength: _____

Planned Dose: _____

Physician: _____ Date: _____

C. Post-Implant CT scan taken: (check box if completed)

QM Form Review

The following items are reviewed for completeness and correctness:
(Check each box after verifying the review)

- Written directive
- Patient ID
- Pre/Post treatment verification
- Dose calculation verification

DEVIATIONS AND ACTIONS NOTED HERE:

Reviewed by: _____ Date: _____
(Dosimetrist/Physicist)

From: Origin ID: LITA (501) 257-1571
 Kelly Mayo
 VHA National Health Physics Pr
 2200 FORT ROOTS DR
 B101 R208D
 NORTH LITTLE ROCK, AR 72114



J10101002220224

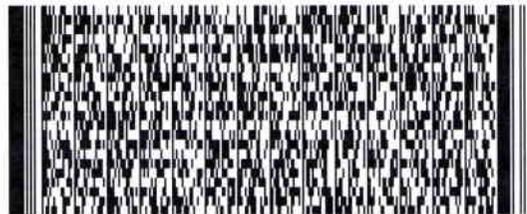
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Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532



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