



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

FEB 25 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 Medical Center, Durham, North Carolina.

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

Sincerely,

A handwritten signature in cursive script that reads "Lisa Maloy Offutt".

Lisa Maloy Offutt
Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 01 2010

GW

NRC Request for Information (February 16, 2010)
VA Medical Center, Durham, North Carolina

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.
3. Indicate the current status for the prostate implant program (i.e., active or inactive).
4. For the medical event discovered on February 25, 2005, provide the following:
 - a. Number of seeds implanted into the "fatty tissue" (i.e., perineum)
 - b. Dose to "fatty tissue" (i.e., perineum)
5. For the medical event discovered on January 15, 2009, provide the following:
 - a. D90 determined by Day 1 CT imaging
 - b. Dose to perineum
6. Indicate any time period during which connectivity issues occurred and state the number of patient treatments impacted by connectivity issues. Describe how any connectivity issues were resolved.

NRC Request for Information (February 16, 2010)
VA Medical Center, Durham, North Carolina

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.

Attached. Effective dates are on the footers.

- 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.

Dr. Oleson's permit was amended to require submittal of and approval by the Radiation Safety Committee of standard operating procedures based on the NHPP model procedures before the next implant is performed. The implant program has been inactive since February 2009.

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.

Attached. Training was given in 2007 and 2008 by the RSO to the physician AU and the medical physicist. The dosimetrist played no role in our prostate implants and was not trained. Training was not given in 2009 as the program went inactive in February. Training will be given before the program becomes active again.

3. Indicate the current status for the prostate implant program (i.e., active or inactive).

Inactive since February 2009

4. For the medical event discovered on February 25, 2005, provide the following:

- a. Number of seeds implanted into the "fatty tissue" (i.e., perineum)

59 or 60, as described in the Medical Event Report.

- b. Dose to "fatty tissue" (i.e., perineum)

We are awaiting guidance from the Chief, VHA Radiation Oncology on a method of calculating this dose.

5. For the medical event discovered on January 15, 2009, provide the following:

a. D90 determined by Day 1 CT imaging

62.3%

b. Dose to perineum

We are awaiting guidance from the Chief, VHA Radiation Oncology on a method of calculating this dose.

6. Indicate any time period during which connectivity issues occurred and state the number of patient treatments impacted by connectivity issues. Describe how any connectivity issues were resolved.

There have been no connectivity issues that impacted patient treatments.



Walter Furr
Radiation Protection Manager

February 23, 2010

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

From: Furr, Walter L. (Buddy) DURVAMC

Sent: Tuesday, February 23, 2010 9:39 AM

To: Williams, Gary E

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

Subject: RE: additional information for NRC inspection

Please find my response attached as four files, Durham1, Durham2, Durham3, and Durham4. Please let me know if you have any questions.

Walter Furr

Radiation Protections Manager

Durham VAMC

919-416-5851

**Written Directives Procedures
Durham Veterans Affairs Medical Center**

Purpose: To provide high confidence that radioactive material or the radiation therefrom is administered as directed by the authorized user.

Objectives: That, for any brachytherapy, radiopharmaceutical therapy, or administration of I125 or I131 over 30 microcuries:

An Authorized User must date and sign a written directive prior to the administration of any dose or dosage.

Prior to administering a dose or dosage, the patient's identity will be positively verified as the individual named in the written directive by two methods (i.e. examining the patient's ID bracelet, hospital ID card, driver's license, or social security card). Asking or calling the patient's name does not constitute positive patient identity verification.

The specific details of the administration will be verified, including the dose or dosage, in accordance with the written directive or treatment plan. All components of the written directive (radionuclide, dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the written directive.

Manual and computer generated dose calculations will be independently verified.

Review Process: The Radiation Safety Officer shall review these procedures periodically, including:

Evaluations of all applicable patient administrations and medical events. For radiopharmaceutical therapy, the RSO will conduct the evaluation. A determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive or treatment plan, as applicable. For each patient case reviewed, deviations from the written directive, the cause of each deviation, and the action required to prevent recurrence will be identified.

Evaluations of the above reviews to ensure the effectiveness of the procedures for administrations requiring a written directive.

General If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive or revision to a written directive would jeopardize the patient's health, an oral directive or revision will be acceptable, provided it is documented immediately in the patient's record and a written directive or revised written directive is signed and dated within 24 hours.

Upon discovery of a medical event, the Radiation Safety Officer will, no later than the next calendar day, notify by telephone the VHA National Health Physics Program (NHPP), and within 15 days submit a written report to the NHPP. The referring physician and the patient will also be notified, as required by 10 CFR 35.3045

Radiopharmaceutical Therapy Procedure

1. HANDLING INSTRUCTIONS

I-131

All vials of I-131 should be opened in a fume hood prior to administration to a patient to allow for escape of vapor from the vial. The activity of each dosage shall be measured in a dose calibrator and verified to be within 10% of the prescribed dosage.

The dose rate on the outside of the vial shield may be high. Adequate precautions must be taken when transporting sources.

Sr-89 / Sm-153 / P-32

Sr-89, Sm-153, and P-32 shall be ordered as unit doses, in syringes, using the calibration specified by the provider, corrected for radioactive decay from the date and time of calibration. The calculation shall be independently verified by two individuals and compared prior to administration.

If delivery of a unit dose is not available, a NIST-traceable calibration source of the prescribed radionuclide, in a syringe similar to that to be used for the administration, will be used to calibrate the dose calibrator prior to assaying the dose.

2. HOSPITAL ROUTINE

Prior to administering a dosage, the patient's identity will be positively verified as the individual named in the written directive by two methods. For example, examination of the patient's ID bracelet, hospital ID card, or driver's license.

A negative serum beta HCG pregnancy test must be documented for all potentially pregnant females treated therapeutically with radiopharmaceuticals, or administered any radioiodine.

Minor Therapies

Minor therapies are procedures where the patient is released from the Medical Center immediately after administration of the radiopharmaceutical. Minor therapies are performed in the Nuclear Medicine hot lab.

Major Therapies

Major therapies are procedures where the patient is confined to the hospital to prevent radiation exposure to others. A patient receiving a major therapy must be admitted a private room with bathroom. The room must be approved by the Radiation Safety Officer, taking into consideration the potential radiation levels in all adjacent areas.

The patient must remain hospitalized until the Radiation Safety Officer or his designee determines that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts. The tables and methods of calculating doses to other individuals described in NUREG 1556, Vol. 9 will be used. Before being discharged the patient will be advised how to keep exposures to others as low as reasonably achievable.

Radiopharmaceutical Written Directive & Checklist

Date: _____ Procedure: _____ Tech: _____

Patient: _____ SSN: _____ Sex: _____

COMPLETE THE FOLLOWING CHECKLIST BEFORE ADMINISTERING DOSE

Patient ID verified by (circle two): hospital ID bracelet
hospital ID card
driver's license
social security card

Dose was vented under fume hood _____

WRITTEN DIRECTIVE

Radiopharmaceutical (circle one) NaI-131 Capsule (oral) NaI-131 Liquid (oral)
P-32 Ionic Phosphate (IV) Sr-89 Strontium Chloride (IV)
I-131 MIBG (IV) Sm-153 Lexidronam (IV)

Assayed dose*: _____ millicuries. Time assayed _____. Name _____

Prescribed dose: _____ millicuries *I¹³¹ assayed in Capintec CRC 30BC, SN 31033

PHYSICIAN'S SIGNATURE _____ Date _____

COMPLETE THE FOLLOWING CHECKLIST AFTER ADMINISTERING DOSE:

_____/____/____ Date / Time Administered. Administered by _____.

____ Vial assayed after procedure: _____ microcuries. Name _____

____ Dosage calculation by: Name _____ Name _____.

____ Patient was given oral and written instruction on actions recommended to minimize doses to other individuals

Brachytherapy Procedure

A. General

1. The identity of the patient will be positively verified by two methods before administering any brachytherapy dose. For example, examination of the patient's arm bracelet, hospital ID, or driver's license. The method(s) of verification will be documented on the Procedure Checklist.
2. Workers will be instructed to seek guidance if they do not understand how to carry out the written directive and not to continue with the procedure if there are any doubts concerning the order.
3. Any individual removing sources from the storage room will log the sources out on the appropriate Brachytherapy Logbook. The sources must be logged in on the same form when returned.
4. The source carrier will be attended continuously by Radiation Oncology personnel from the time it leaves Radiation Oncology until the implant is completed and residual sources are returned to the storage room.
5. The authorized medical physicist and the authorized user, or a qualified physician under the direct supervision of an authorized user must verify the radioisotope, number of sources, source strengths, and loading sequence of the sources before the implant.
6. All manual and computer generated dose calculations will be independently verified.
7. Acceptance testing will be performed and documented by the authorized medical physicist on each treatment planning or dose calculating computer program used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for patient dose calculations.
8. A quarterly review of all brachytherapy cases will be conducted by an authorized medical physicist. If feasible, the persons conducting the review will not review their own work. If this is not possible, two people will work together as a team to conduct the review of that work. Any unintended deviation from the written directive will be identified and evaluated, and appropriate action taken. Results of the review will be reported to the RSO.
9. Radiation Safety or Medical Physics personnel will measure and record the radiation level one meter from the patient immediately after the implant.
10. A Procedure Checklist will be completed and maintained in the Brachytherapy Notebook. for each patient receiving a brachytherapy procedure
11. Prior to the administration of any brachytherapy dose, the authorized user will sign and date a written directive naming the radionuclide, the treatment site, and the dose. Before the end of the procedure, the number of sources, the individual source strengths, the total source strength and the time of treatment will be added.
12. Copies of the written directive are put in the patient's Radiation Oncology Chart, the Hospital Chart, and the Brachytherapy Notebook.

B. Permanent Iodine-125 Brachytherapy

1. The written directive is comprised of the signed and dated preplan and brachytherapy flowsheet.
2. If the Foley bulb cannot be positively identified in the sagittal view during the volume study, a radiological image will be used to verify the correct location of the tip of the needles before the initial seeds are implanted. .
3. Prior to the administration of any permanent brachytherapy dose, the authorized user will sign and date a written directive naming the radionuclide, the treatment site, and the dose.
4. After insertion of the sources, the authorized user will promptly record the radionuclide, the treatment site, the number of sources implanted, the total source strength, and sign and date the record.
5. Radiographic or CT imaging of brachytherapy sources in place will be used to verify the position of the sources and to calculate the brachytherapy dose.
6. Radiation Safety personnel will survey the OR, the PACU, and the patient's room, before each room is released for unrestricted use.

C. Temporary Iridium-192 Brachytherapy

1. The written directive is placed on the appended Temporary Brachytherapy Record.
2. The authorized user will check the computer printout to verify that the correct data for the implant was used in the calculation. An authorized medical physicist will check all manual dose calculations done by the dosimetrist.
3. Dose calculations will be checked prior to completion of the brachytherapy dose unless the authorized user determines that this would jeopardize the patient's medical condition. In this instance, the checks will be performed within two working days of completion of the brachytherapy dose.
4. When non-radioactive "dummy" sources are used to verify the position of the radioactive sources, orthogonal films will be taken before inserting the actual radioactive sources for temporary brachytherapy implants.
5. The loading sequence of the sources will be recorded on an "Individual Brachytherapy Sheet" and signed by the authorized user. This is put in the patient's Radiation Oncology Chart and the Hospital Chart and a copy is also kept in the Brachytherapy Notebook.
6. Radiation Safety personnel will survey the patient after the sources are removed, to verify that there is no residual radioactivity.

DURHAM VA MEDICAL CENTER TEMPORARY BRACHYTHERAPY RECORD

Prior to implant:	Patient : _____	Implant site: _____
Rx	SSN: _____	Prescribed dose: _____ Gy
Radionuclide: Ir-192	_____	_____
	Staff Physician's Signature	Date
After implant, but before completion of procedure:	_____ mCi Ir-192 in _____ seeds @ _____ mCi/seed for _____ hours	_____
	Staff Physician's Signature	Date

Review of Implant Quality

1. Implant cases along with post-op dosimetry. Results will be presented at the weekly or monthly chart rounds and this will constitute peer review of the case. The monthly chart rounds are attended by attending and resident physicians from Duke University Medical Center.
2. Implant quality evaluation
 - a. A dosimetric goal is to achieve $D_{90} \geq 80\%$ of the Rx dose (e.g., 145 Gy for I-125).
 - b. If $D_{90} < 80\%$ on the post-op dosimetry based on the 24 hour CT scan, the physician and physicist will review the prostate contouring and adjust as necessary for accuracy.
 - c. D_{90} will be recalculated,
If $D_{90} \geq 80\%$ of Rx, no further analysis is required.
If D_{90} is still $< 80\%$, the CT scan will be repeated 6 weeks after the implant date and D_{90} will be recalculated.
If D_{90} is $\geq 80\%$, no further analysis is required.
If D_{90} is $< 80\%$, a medical event will be declared.
 - d. Following declaration of a medical event, the possibility of a small field hypo-fractionated external beam boost to the under-dosed area to bring the equivalent D_{90} to $\geq 80\%$ will be investigated and offered to the patient. Alternatively, the possibility of a supplemental implant boost will be considered and offered to the patient as judged appropriate.
3. Other Good Implant Indicators to watch
 - a. Bladder: $V_{150} = 0$
 - b. Rectum: $V_{150} = 0$, $V_{100} < 2.5$ mL

Radiation Oncology
VA Medical Center, Durham, NC
Permanent Prostate Seed Implant Procedure

I. Volume Study

The procedure takes place in the RadOnc clinic, by the radiation oncologist, with assistance of radonc nurse, typically 2 weeks before the implant date.

The ultra-sound images from the volume study are delivered to Physics for treatment planning, in both photo and electronic format on a floppy disk.

II. Pre-Treatment Planning

The ultra-sound images are imported to Variseed for treatment planning. The preplan guidelines are:

- Peripheral loading of needles and seeds
- The isodose is donut shaped: hot in the periphery, cold (but more than 100%) in central region of the prostate.
- Isodose line of 100% covers the prostate with a margin of more than 3 mm.
- Isodose line of 150% does not touch the urethra and the rectum
- Avoid needles directly anterior to the urethra.
- Needle/sources are placed no closer than 5 mm from rectal wall and urethra.
- The pre-plan is reviewed by the radiation oncologist and signed.

III. Seed Ordering and Receiving

The seed order is placed by the physicist and received by the Radiation Safety Office typically 2 days before the implant date.

The physicist double-checks the package, including: integrity of the sterile seal, seed position checking film, length of loading (against treatment plan loading), seed model/make, seed strength (against third party assay and treatment planning value), loading diagram for all needles.

IV. Implantation

The radiation oncologist performs the implantation.

The physicist brings seeds to the OR and directs implantation according to the pre-plan.

At least one radiograph is taken at end of implantation to confirm seeds are in the right place and for a seed count. Sometimes extra radiographs are taken during procedure to confirm positions of the needle placement.

During and after the procedure, Radiation Safety performs radiation survey.

When the patient is sent to Recovery, Radiation Safety gives radiation safety instructions to the Recovery staff.

The patient is discharged with Discharge Instructions.

V. CT for Post-Op Dosimetry

Due to logistical reasons, the patients typically stay in the hospital overnight. Before they are discharged the following day, Post-op CT is obtained in Radiation Oncology for post-op dosimetry.

The post-op CT is imported to Variseed to evaluate the quality of the implant, according to the implant quality criteria.

More followup dosimetric evaluations may be ordered according to the Quality Management Program. The radiation oncologist performs the prostate contouring.

Radiation Safety & Written Directive Procedures
Radiation Oncology

Date: 1/9/07

Name (PRINT)

James R. Olson

Simon Zou

HANJUN SONG

Signature

James R. Olson

Simon Zou

H. Song

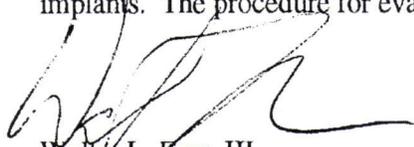
WFO
By: WALTER FOUR

**Department of
Veterans Affairs**

Memorandum

Date: September 23, 2008
From: Radiation Safety Officer (11R)
Subj: Training for Prostate Implant Procedures
To: Training File

Today I trained Drs. James Oleson and Haijun Song in the written directive procedures for prostate implants. The procedure for evaluation for Medical Events was included in the training.



Walter L. Furr, III
Radiation Safety Officer

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



J10101082050224

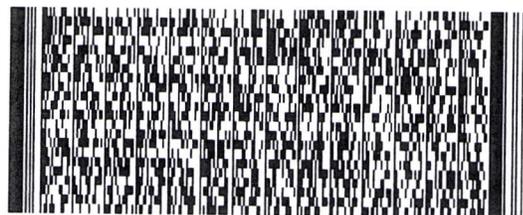
Ship Date: 25FEB10
ActWgt: 0.2 LB
CAD: 5250401/INET3010

Delivery Address Bar Code



SHIP TO: (501) 257-1571 **BILL SENDER**
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

Ref #
Invoice #
PO #
Dept #



TRK# 7984 2521 6707
0201

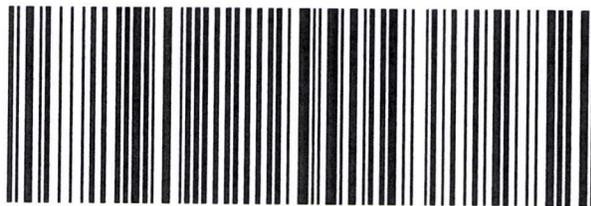
FRI - 26 FEB A1
STANDARD OVERNIGHT

60532

XH ENLA

IL-US

ORD



505G2/C733/5FE8

After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.