

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: **JAN 14 2009**

From: Director, VHA National Health Physics Program (NHPP) (115HP/NLR)

Subj: Radiation Safety Program Inspection - Inspection Report 630A4-08-I01

To: Director (630A4/00), VA New York Harbor Healthcare System, Brooklyn New York

1. Edwin M. Leidholdt, Jr., Ph.D., and Paul L. Yurko, M.S., NHPP, performed an announced reactive inspection of the radiation safety program at VA New York Harbor Healthcare System, Brooklyn, New York, on November 20 and December 8-9, 2008, with continuing review through December 17, 2008. The inspection focused on a medical event and the permanent implant brachytherapy program though all elements of a routine core inspection were included.

3. Attachment A is the inspection report and consists of the narrative report with no violations cited. Attachment B is an audit checklist for prostate brachytherapy. Attachment C is a list of recommendations.

4. You are not required to respond to this memorandum.

5. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Yurko at 410-642-2411, extension 6288, if you have any questions about the inspection.


E. Lynn McGuire

Attachments

cc: Chair, National Radiation Safety Committee
Network Director, VISN 3 (10N3)

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 630A4-08-I01
VA New York Harbor Healthcare System, Brooklyn, New York
November 20 – December 17, 2008

1. Introduction

a. Edwin M. Leidholdt, Jr., Ph.D., and Paul L. Yurko, M.S., VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the radiation safety program at VA New York Harbor Healthcare System, Brooklyn, New York. The initial on-site visit was performed by Mr. Yurko on November 20, 2008.

(1) The inspection focus was a possible medical event involving transperineal permanent implant prostate brachytherapy (hereafter referred to as prostate brachytherapy) that occurred on September 18, 2008, and was reported to the NRC Operations Center on November 18, 2008. In addition to the inspection regarding the possible medical event, a routine core inspection of the radiation safety program also was completed.

(2) The possible medical event was discovered during a conference call between members of the NHPP and VA New York Harbor Healthcare System staff on November 17, 2008. The basis for the medical event was an inadequate seed distribution such that the D90 dose (the largest doses covering 90% of the volume of the prostate) was less than 80% of the prescribed dose. The event was reported to NRC on November 18, 2008, and was assigned Event Number 44663. A 15-day report was sent to NRC on December 1, 2008.

(3) The inspectors presented their preliminary findings at meetings with key healthcare system staff on November 20, 2008 and December 9, 2008, including review of apparent violations.

b. Two inspectors performed a second on-site visit to the healthcare system during December 8-9, 2008, to evaluate further the possible medical event and perform a routine core inspection of the radiation safety program.

(1) NRC regulations in 10 CFR 35.3045 define a medical event. The inspectors used this definition as a basis to evaluate the possible medical event.

(2) The inspectors conducted an exit meeting for the second visit on December 9, 2008, and left the inspection open. The inspection was closed on December 17, 2008.

c. NHPP reviewed the possible medical event and agreed with the healthcare system position that the post-plan data supported the definition of a medical event. No further medical events were discovered during the inspection. The identification of a medical event under 10 CFR 35.3045 is not, by itself, a violation of NRC regulations

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2. Scope of inspection

The inspection was risk-informed and performance-based. All items on the inspection plan were completed to include, but were not limited to, the following:

- a. Interviews with healthcare system and contract staff,
- b. Review of records related to the event and radiation safety program,
- c. Tour of facilities and review of equipment involved,
- d. Review of the healthcare system's initial actions regarding the event, including a review of the effectiveness and comprehensiveness of the initial actions to prevent a recurrence,
- e. Review of compliance with other regulatory requirements under 10 CFR 35 for a prostate brachytherapy program,
- f. Evaluation of root or basic causes for the event, and
- g. Comparison of identified deficiencies with other therapy modalities to determine if the event was an isolated occurrence or a programmatic issue.

3. Findings and impressions (background information)

- a. The most recent NRC inspection at the healthcare system, on February 14, 2005, cited no violations. NHPP inspected the healthcare system on November 30 and December 1, 2006, and did not cite any violations.
- b. The healthcare system had not previously reported any medical events involving prostate brachytherapy.
- c. The inspectors gathered information about the history of the prostate brachytherapy program at the healthcare system and the workload.
 - (1) The first prostate brachytherapy procedure was performed on October 1, 1998.
 - (2) During 2005, 15 patient procedures were performed; in 2006, 7 patient procedures were performed; and from January 1 to September 20, 2008, 5 patient procedures have been performed.
- d. The inspectors gathered information about the workflow for prostate brachytherapy procedures.

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(1) The healthcare system obtains either non-sterilized I-125 seeds, in cartridges/magazines for the Mick applicator or sterilized preloaded needles, from a commercial vendor. The seeds in the preloaded needles are stranded.

(2) Within a few weeks before each patient procedure, an authorized user physician obtains transrectal ultrasound (TRUS) images. The images are transferred to a treatment planning system (TPS) for a medical physicist to create a treatment plan to achieve the dose prescribed by the authorized user physician. Creation of this treatment plan requires designation of the prostate boundaries on the images by the physician.

(3) The authorized user physician reviews the treatment plan prepared using the TPS and prepares and signs a written directive. The physician may be assisted by a medical physicist.

(a) Title 10 CFR 35.40 specifies that the part of the written directive completed before an implant procedure must state the treatment site, radionuclide, and dose.

(b) The healthcare system written directive procedures require preparation of a written directive form before each implant. This information includes the radionuclide, treatment site, planned number of seeds, strength per seed, and dose in cGy. The information is transcribed from the treatment plan and needle loading diagrams onto the written directive form.

(4) A medical physicist orders either cartridges/magazines or preloaded needles from the seed vendor.

(5) The seed vendor ships a package to the healthcare system. The package is delivered to the warehouse; the warehouse staff stores the package in a secure area and notifies the medical physics staff. A member of the physics staff takes the package of seeds to Room G-116A in radiation therapy and performs a package receipt survey. The seeds are then stored in Room G-116A until the prostate brachytherapy procedure. A medical physicist uses a well-type ionization chamber and electrometer to verify activity of the single separate calibrated seed in the package or, if preloaded needles are utilized, the vendor is required to provide a certificate of assay of 10% of the seeds in an order.

(6) Seeds are implanted in patients in an operating room under TRUS guidance. Fluoroscopy is used to supplement the TRUS imaging. The team for patient treatments includes an authorized user physician, a medical physicist, a urologist, an anesthesiologist, and nurses.

(7) After the procedure, the patient recovers from the anesthesia in a post-surgical recovery room and is hospitalized overnight. Until recently, CT images were obtained of the patient's pelvic region about 30 days after each procedure. Currently, CT images are obtained on the day of the procedure and again at about 30 days after the procedure. The CT images are transferred to the TPS, an authorized user physician contours the prostate, and a medical physicist creates a post-plan to assess the dose distribution. Indices of the dose distribution to the prostate, including V100 and D90, are calculated and given to the physician. The post-plan is typically created within a day of the post-implant CT scan.

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d. The inspectors confirmed regulatory compliance for the following:

(1) Radiation safety practices and record keeping under 10 CFR 35.404, 35.406, 35.432, and 35.457.

(2) Security of stored sealed sources before and after prostate brachytherapy procedures under 10 CFR 20.1801 and permit conditions.

4. Findings and impressions (regulatory compliance)

a. The inspectors reviewed and evaluated information about the possible medical event that had been reported and overall implementation of the prostate brachytherapy program.

b. The inspectors concluded that, even though there had been a medical event, no violations were identified.

c. The inspectors reviewed and evaluated the entire radiation safety program for the use of byproduct radioactive material and did not identify any violations.

5. Findings and impressions (medical event)

The inspectors collected information regarding the medical event.

a. The implant procedure that was declared a medical event was performed on September 18, 2008. The authorized user physician stated that prior to withdrawing two needles to place seeds in the anterior prostate, he failed to advance the plungers sufficiently, causing the seeds in suture to follow the needles as they were withdrawn. This resulted in three seeds outside the prostate in the perineal tissues caudad to the prostate and three seeds being removed entirely from the patient. The authorized user placed additional seeds in the anterior part of the prostate in an attempt to remedy this circumstance.

b. A post-implant CT study of that patient was performed on October 10, 2008, and a post-plan was created on the same date. The D90 was discovered to be 69% of the prescribed dose. The reason for the low D90 was too few seeds in the anterior prostate.

c. The authorized user physician recommended to the patient a supplemental procedure to implant additional seeds in the anterior prostate. The supplemental procedure was performed on October 30, 2008, and 10 additional seeds were implanted in the patient. Another post-implant CT was performed on the day of the procedure and a post-plan was created on the same day. The D90 was calculated as 90% of the prescribed dose.

d. The RSO mentioned the supplemental procedure to an NHPP program manager on or about October 31, 2008. The NHPP manager requested that the RSO obtain more information about these procedures to determine whether the initial implant met the definition of a medical

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event in 10 CFR 35.3045. A series of meetings and discussions occurred among the RSO and radiation oncology staff at the healthcare system and a series of discussions between the RSO and NHPP staff ensued. A conference call among radiation oncology staff, the RSO, and NHPP staff was scheduled on November 17, 2008, to make a decision whether a medical event had occurred.

e. The medical event was discovered during a conference call between members of the NHPP and healthcare system staff on November 17, 2008. The basis for the medical event was an inadequate seed distribution such that the D90 dose (the largest doses covering 90% of the volume of the prostate) was less than 80% of the prescribed dose. The event was reported to NRC on November 18, 2008, and was assigned Event Number 44663. A 15-day report was sent to NRC on December 1, 2008.

6. Causes of medical event

a. The inspectors performed a causal analysis.

(1) The inspectors identified a root cause as “human engineering, non-fault tolerant system, errors not recoverable,” in that, if an error is made in seed or seed strand placement and the error is promptly identified, the seeds cannot be recovered.

(2) Other causes could not be determined with certainty. However, the authorized user physician stated that prior to withdrawing two needles, he may have failed to advance the plungers sufficiently, causing the seeds to follow the needles as they were withdrawn. If this did indeed occur, a second root cause would be “work direction, preparation, needs improvement,” in that the authorized user physician omitted a step in the motor skills necessary for proper seed placement.

b. The authorized user physician stated corrective actions would include proper preparation to assure all steps are completed in proper sequence for proper placement of seeds.

c. The error in seed placement was an isolated and infrequent event.

7. Notice of violation

The inspectors did not identify any violations.

8. Persons contacted

John J. Donnellan Jr., Director
Martina Parauda, Associate Director
Michael Simberkoff, M.D., Chief of Staff
David Schwartz, M.D., Authorized User Physician
Howard Banner, M.D., Chief of Nuclear Medicine Service, and Authorized User Physician
Alka Mokadam, M.S., Therapy Physicist

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Esfadiar Sarfaraz, Ph.D., Radiation Safety Officer
Edward Siclari, Assistant Radiation Safety Officer

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**New York Harbor Healthcare System, Brooklyn, New York
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The audit checklist should be used to determine overall status for the seed implant program and to ensure compliance with specific regulatory requirements and best clinical practices. The issues or categories to evaluate and review are in the six major sections below.

1. Handling and security of sealed sources

a. Radioactive material package receipt surveys and records (10 CFR 20.1906).

Packages are delivered to the warehouse and kept in a secure area. Packages are delivered to the warehouse only during normal working hours. Most packages are labeled as Excepted Package, Limited Quantity, but occasionally packages are labeled as Radioactive – White I. When a package is delivered, the warehouse staff promptly contacts radiation oncology. A member of medical physics staff takes the package to Room G-116A in radiation oncology and performs a receipt survey. Received packages are surveyed per 10 CFR 20.1906 within 3 hours of package receipt. Practices appear to conform to NRC regulations.

b. Security requirements (10 CFR 20.1801 and 20.1802) and two delay methods if stored.

All I-125 seeds are kept in a locked cabinet in the radiation therapy hot lab Room G-116A. The room is locked when unattended. Security of seeds appears to conform to NRC regulations and permit requirements.

c. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).

Seed inventory records are filled out upon receipt of seeds and after each treatment. Also a separate record was kept when they were returned to the manufacturer. Until recently, all information required by 10 CFR 35.406 and 35.2406 was not on a single form. During the most recent visit, the RSO presented a form that would contain all information required by 10 CFR 35.406 and 35.2406.

d. Physical inventory (10 CFR 35.67(g)).

Every quarter the medical physicist and RSO perform an inventory of the seeds in storage. The NHPP inspectors recommended changes to the forms to enable better tracking of seeds.

e. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

Seeds are disposed by returning them to the vendor. Seeds are returned no more than 3 months after receipt. There is a single vial of Pd-103 seeds that has been stored for several years. The NHPP inspectors recommended survey and disposal of these seeds.

2. Preparations for seed implant procedures

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

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- a. Written procedures and checklists (10 CFR 35.40 and 35.41).

The facility has written procedures, called "The Quality Management Program," that appear to comply to 10 CFR 35.40 and 35.41. Every quarter, the RSO reviews the patients' records according to a checklist and the QMP procedures. However, the QMP does not specifically require post-implant dosimetry for prostate seed implants and does not require the calculation of the D90. The NHPP inspectors recommended making the procedures more specific regarding post-implant dose analysis.

- b. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).

Conform to NRC regulations. A second check of the treatment plan is performed by a physicist or dosimetrist other than the one who prepared the plan. A nomogram from Memorial Sloan Kettering is used to verify that the total planned activity to be implanted is approximately correct for the volume of the prostate.

- c. Pre-implant imaging (volume study), how long before implant?

Done by trans-rectal ultrasound (TRUS), usually within 1 month prior to an implant.

- d. Pre-plan preparation. Who contours the prostate and other organs?

The authorized user physician outlines the prostate, urethra, and rectal wall. The authorized user then generates a request to prepare a pre-implant plan specifying the intended radionuclide and dose to the prostate. A dosimetrist or a physicist then determines the average dimension of the prostate and uses a nomogram to estimate the total activity required and the number of seeds needed, depending on the activity of the seeds. Philips Pinnacle3 treatment planning system is then used to prepare a pre-plan. The pre-plan is accepted if the following criteria are met: 100% of the prostate is covered by 90% dose line, less than 50% of the prostate receives 150% of the dose, less than 20% of prostate receives 200% of the dose, urethra receives less than 140% of the dose, and less than 1cc of rectum receives 100% of the dose. The authorized user may accept a plan that does not exactly meet all the above criteria but meets most of them per his/her clinical judgment.

- e. Written directive, pre-implant part preparation, including prescribed dose.

Appears to conform to NRC regulations.

- f. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).

VHA National Health Physics Program Inspection Record

Inspection report number: 630A4-08-I01

Permit number: 31-02892-03

Permittee (name and address):

VA New York Harbor Healthcare System
800 Polly Place
Brooklyn, New York 11209

Locations of use being inspected: Same as above

Permittee contact (name and telephone number): Esfandiar Sarfaraz, Ph.D., 718-836-6600, x6285

Permit priority: 2

Permit program code: 2120/3620/2230

Date of last inspection: November 30 - December 1, 2006

Date of this inspection: November 20 and December 8-9, 2008, with continuing review through December 17, 2008

Type of inspection: (X) Announced () Unannounced
() Initial (X) Routine () Special

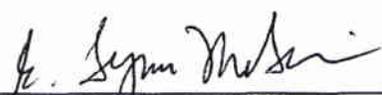
Next inspection date: December 2010 (normal, unless modified by NHPP inspection algorithm)

Summary of findings/actions:

- (X) No violations (NHPP inspection report issued)
- () Severity Level IV and/or non-cited violations (NHPP Form 591 issued)
- () Severity Level IV and/or non-cited violations (NHPP inspection report and Form 591 issued)
- () Severity Level I, II, or III violations (NHPP inspection report and NOV issued)
- () Follow-up on previous violations

Inspector(s): 
Paul L. Yurko

Date: December 23, 2008

Approved: 
E. Lynn McGuire, NHPP Director

Date: 1/15/09

VHA National Health Physics Program Inspection Record

PART I - PERMIT, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No. 90, October 2007, renewed the permit.
Amendment No. 91, January 2008, deleted an authorized user.
Amendment No. 92, March 2008, added a medical physicist.
Amendment No. 93, August 2008, added an authorized user

2. INSPECTION AND ENFORCEMENT HISTORY:

Last NRC inspection: February 14, 2005, no violations.

Last NHPP inspection: November 30 - December 1, 2006, no violations.

No enforcement history.

3. INCIDENT/EVENT HISTORY:

None in permit files or NMED initial permit.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

VA New York Harbor Healthcare System, Brooklyn Campus, conducts a radiation safety program under a VHA limited-scope permit for medical and research uses, with a high-dose-rate (HDR) remote-afterloading brachytherapy device. The inspection focus was a possible medical event involving prostate brachytherapy that occurred on September 18, 2007, was discovered November 17, 2008, and was reported to the NRC Operations Center on November 18, 2008. In addition, the inspectors performed a routine core inspection of the entire radiation safety program.

The Radiation Safety Officer (RSO) is Esfandiar Sarfaraz, Ph.D. The Radiation Safety Committee (RSC) meets quarterly. The RSC membership and activity was commensurate with the scope of the permit. The RSC reports to the Environment of Care committee quarterly.

2. INSPECTION SCOPE AND NRC INSPECTION PROCEDURES USED:

The inspector followed a pre-approved inspection plan. The inspection focus was risked-informed and performance-based. The inspection consisted of an examination of the rooms and equipment of the Nuclear Medicine, Research, and Radiation Oncology Services, review of radiation safety manuals and procedures, and interviews with medical staff. All items on the inspection plan were completed. The inspectors observed nuclear medicine, research, and radiation oncology staff work routines and conducted interviews with the staff. Specific written records were reviewed back to NHPP's last routine inspection. NRC inspection procedures used for this inspection were IP 87134, IP 8712, and NRC Management Directive 8.10. Specific records reviewed included post-plan data for the last 30 seed implant brachytherapy procedures, RSC minutes for 2007 and 2008, written directives for I-131 liquid therapies performed in 2008, and HDR treatments performed in 2008.

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3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Spot-check measurements were taken in research and nuclear medicine. No contamination was found. The instrument used was a Ludlum Model 2401-P last calibrated September 30, 2008.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations were identified.

5. PERSONNEL CONTACTED:

John J. Donnellan, Jr., Director ^{1,2}
Michael Simberkoff, M.D., Chief of Staff ^{1,2}
Martina Parauda, Associate Director ^{1,2}
Esfadiar Sarfaraz, Ph.D., Radiation Safety Officer ^{1,2,3}
Howard Banner, M.D., Chief, Nuclear Medicine Service ^{1,2,3}
Alka Mokadam, M.S., Medical Physicist ^{1,2,3}
David Schwartz, M.D., Authorized User ^{1,2,3}

1. Individual(s) present at entrance meeting
2. Individual(s) present at exit meeting
3. Individual(s) present or participating in inspection discussions