DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: OCT 26 2009

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

Subj: Radiation Safety Program Inspection - Inspection Report 539-09-I02

To: Director (539/00), VA Medical Center, Cincinnati, Ohio

1. We performed an announced inspection at your facility on June 30 - July 1, 2009, to assess your readiness to resume permanent implant prostate brachytherapy. The inspection was closed on October 22, 2009, when we received documentation of acceptance testing of your treatment planning system. The scope of the inspection included compliance with the applicable Nuclear Regulatory Commission (NRC) regulations and commitments in the NRC Confirmatory Action Letter dated October 14, 2008.

2. The inspection report is attached and consists of an NHPP Form 591 with no violations cited and a prostate brachytherapy checklist completed during this inspection.

3. We conclude you have implemented all requirements under our purview for the resumption of prostate brachytherapy procedures. We will make a recommendation to the National Radiation Safety Committee and Director, National Radiation Oncology Program (DRO) about restart.

4. If the restart is approved, we will provide you written authorization to restart and also notify NRC. The DRO will provide to you guidelines for initial clinical reviews and proctoring of patient treatments.

5. Thank you for the courtesy and cooperation extended during the inspection. Please contact Edwin M. Leidholdt, Jr., Ph.D., at 707-562-8374 if you have questions about the inspection.

GE Williams

Gary E. Williams

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 10 (10N10)
Director, VHA National Radiation Oncology Program

NHPP FORM 591
(1-2009)

VHA National Health Physics Program

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. PERMITTEE/PERMIT NUMBER:	2. LOCATION(S) INSPECTED:
VA Medical Center Cincinnati, Ohio 34-00799-03	3200 Vine Street Cincinnati, Ohio 45220
3. INSPECTION DATES: June 30–October 22, 2009	4. INSPECTION REPORT NUMBER: 539-09-I02

PERMITTEE:
The inspection was an examination of activities under your permit as they relate to radiation safety and compliance with Nuclear Regulatory Commission rules and regulations and your permit conditions. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and performance-based observations by the inspector. The inspection findings are as follows:

☒ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of Nuclear Regulatory Commission requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting per 10 CFR 19.11. The violations and corrective actions are as follows:

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made per 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand no further written response to the VHA National Health Physics Program will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
PERMITTEE			
NHPP INSPECTOR	Edwin M. Leidholdt, Jr., Ph.D.	Edwin M. Leidholdt, Jr.	October 22, 2009

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist
(VA Medical Center, Cincinnati, Ohio - June 30 – October 22, 2009)

1. Handling and security of sealed sources

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

      Packages of seeds are received at the warehouse. The current vendor, Core Oncology, ships them as excepted packages, limited quantity. The warehouse staff promptly delivers them to nuclear medicine, where package receipt surveys are performed. These appear to comply with NRC regulations.

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

      Appears to comply with NRC regulations and conditions of the facility's VHA permit.

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

      The checklist completed in October 2008 stated, "These appear to substantially conform to NRC regulations. Recommend that the RSO compare the records with 10 CFR 35.3045 and modify for full conformance."

      The revised form reviewed during this restart inspection appears to comply with NRC regulations and conditions of the facility's VHA permit.

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

      The checklist completed in October 2008 stated, "The only seeds kept at the medical center sufficiently long to require physical inventories pursuant to NRC regulations and the medical center's VHA permit are seeds stored for decay. These are not being included in inventories of sealed sources. This is an apparent violation of NRC regulations."

      Most unused seeds will be returned to the vendor. The only seeds kept at the medical center sufficiently long to require physical inventories pursuant to NRC regulations and the medical center's VHA permit are seeds stored for decay for specific reasons, mentioned in the next item, that hinder return to the vendor. These are now being included in inventories of sealed sources.

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

      Most unused seeds are shipped back to the vendor. Currently, these unused seeds are contained in cartridges for the Mentor Isoloader. However, a few seeds, such as those excreted by a patient or stuck in needles, are stored for decay. The methods of source disposal appear to conform to NRC regulations.

2. Preparations for seed implant procedures

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

Appears to conform to NRC regulations.

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

Appears to conform to NRC regulations.

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

Pre-implant imaging is performed by transrectal ultrasound (TRUS) 2 days before each implant.

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

Pre-plans are prepared by a physicist or possibly a dosimetrist using the Varian VariSeed treatment planning system (TPS). The medical center has just purchased a VariSeed system; prior to program suspension, a VariSeed system at the Barrett Cancer Center was used. Dr. Redmond contours the prostate and other organs.

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

Signed by the authorized user physician in the procedure room prior to implantation of any seeds. Appears to conform to NRC regulations.

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

Usually performed by a nuclear medicine technologist who is called to the procedure room at the end of each procedure. May be performed by a medical physicist. Surveys and records appear to conform to NRC regulations.

g. Patient release procedures, surveys, and records (10 CFR 35.75 and 35.2075).

Patient release procedures are to perform a measurement of the exposure rate from the patient, typically with the patient standing, at a distance of 1 meter. In the past, a Victoreen Model 498 survey meter, equipped with a Model 493-50 GM probe, was used. A Ludlum survey meter with a thin-window pancake GM probe has been purchased for such surveys. The methods and records appear to conform to NRC regulations.

h. Patient release measurements after source implantation with a survey meter capable of accurately measuring energy emitted or a method to correct measurements for energy response.

Patient release measurements will be made with a survey meter calibrated for the energy of the I-125 photons or the measurement will be modified to account for the energy response of the survey instrument.

i. Patient instructions (10 CFR 35.75).

Written instructions are given to each patient. The written instructions were reviewed. Appears to conform to NRC regulations and good health physics practices.

j. Calibration measurements of sources (10 CFR 35.432).

For calibration of the strengths of the seeds, the facility primarily relies upon calibration of the seeds by the vendor. However, the Mentor Isoloader performs checks of the seed strengths. No other checks of seed strengths are performed. This appears to conform to NRC regulations.

k. Acceptance testing of treatment planning system (10 CFR 35.457).

A Varian VariSeed TPS was purchased by the medical center and was received in August or September 2009. Acceptance testing and commissioning were performed by Michael Lamba, Ph.D., DABR. The Core Oncology Model 125SL seed was commissioned. A report of the acceptance testing and commissioning, dated October 22, 2009, was received by e-mail on October 22, 2009. The acceptance testing and commissioning appears to meet the requirements of NRC regulations.

l. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer to TPS).

The facility has a CIRS Model 045 phantom. The medical physicist has implemented a QA program for the TRUS systems that substantially conforms to TG 128. The testing of transfer of TRUS and CT images to the TPS were performed as part of the acceptance testing and commissioning of the TPS as described in the previous item.

m. Requirements for a medical event or other incident circumstances including after-hours recall or notifications (10 CFR 35.3045).

Interviews with the RSO, primary medical physicist, and authorized user physician indicated they are aware of regulatory requirements. There were adequate preparations for contacting them outside normal working hours in case of an incident.

n. Radiation Safety Committee approval of physician authorized users (broad-scope) or named on the permit (limited-scope).

Authorized user physicians are named on the permit for 35.400 uses. Dr. Grisell is leaving and should be removed from the permit.

o. Procedures to evaluate for possible leaking seeds and follow-up actions.

The RSO has implemented procedures for this contingency.

p. Training (i.e., initial and periodic) for authorized user physicians, medical physicists, and other staff.

Training complies with NRC regulations and VHA standard procedures.

q. Usual type of anesthesia.

General or epidural.

r. Prescribed dose for each radionuclide used.

For I-125, 145 gray will be prescribed when brachytherapy using I-125 seeds is used as monotherapy., In the past, 160 gray had been prescribed.

s. How are images (TRUS, radiographs, and CT) used for prostate brachytherapy stored (e.g., film, PACS, server in radiation oncology), are back-up copies maintained, how long are the images retained?

CT images will be stored on PACS, on the VariSeed™ hard drive, and another device or media. TRUS images will be stored on the TRUS, VariSeed™, and on a recordable media.

t. Do any issues with digital information transfer hinder the preparation of pre- and post-plans?

In October 2009, the medical physicist Michael Lamba, Ph.D., tested image transfer from the TRUS and CT system at the medical center to the new VariSeed™ TPS. Transfer of digital images from the CT to VariSeed™ was achieved, and transfer of images from the TRUS to VariSeed™ was achieved by screen capture. According to Dr. Lamba, the images obtained by screen capture are adequate for clinical work. Nonetheless, according to Dr. Lamba, it would be preferable to achieve digital transfer of the TRUS images.

3. Performance-based interviews and observations

a. Authorized user physicians.

There are three authorized user physicians named on the VHA permit for 35.400 uses. However, all prostate implants have been performed by Kevin Redmond, M.D., a radiation oncologist who is employed by the University of Cincinnati Physicians, which serves the Barrett Cancer Center of University Hospital.

Based on performance-based interviews, the authorized user physician currently has adequate and sufficient knowledge of NRC requirements regarding written directives.

b. Medical physicists and dosimetrists.

Michael Lamba, Ph.D., has assumed the role of primary physicist for the prostate brachytherapy program. Howard Elson, Ph.D., will serve as back-up physicist. Both are employees of the University of Cincinnati. Based on performance-based interviews, Dr. Lamba has adequate and sufficient knowledge of regulatory requirements.

c. Other physicians including urologists and/or residents.

Radiation oncology residents commonly participate in the procedures. Urologists do not, except when requested to perform a cystoscopy in response to seeds in the bladder. Neither was interviewed.

d. Radiation Safety Officer.

Chris Rauf, CNMT
Based on performance-based interviews, the RSO has adequate and sufficient knowledge of regulatory requirements.

e. Support staff.

Nuclear medicine technologists perform package receipt surveys, load seeds into needles for implantation, perform surveys for misplaced seeds after each procedure, and perform patient release surveys. Based on performance-based interview of one technologist in October 2008, they have adequate and sufficient knowledge of regulatory requirements.

f. Person completing internal audit.

Not applicable at this time. The program has been suspended for over a year and internal audits are not being performed of the prostate brachytherapy program.

4. Performance-based tours and observations

   a. Radiation oncology areas.

      The medical center does not have a Radiation Oncology Service or section. The only radiation oncology areas are at the Barrett Cancer Center at the University of Cincinnati Hospital. The only actions performed there have been the preparation of pre-plans and post-plans using TPS. In the future, treatment planning will be mostly performed at the medical center instead of the Barrett Cancer Center.

   b. Package receipt areas.

      Warehouse and nuclear medicine. Based on a performance-based tour in October 2008, these areas did not have any deficiencies or deviations from regulatory requirements.

   c. Seed implant preparation areas.

      In nuclear medicine. Based on a performance-based tour in October 2008, these areas did not have any deficiencies or deviations from regulatory requirements.

   d. Seed storage areas.

      In nuclear medicine. Based on a performance-based tour in October 2008, these areas did not have any deficiencies or deviations from regulatory requirements.

5. Evaluation of patient treatment results

   a. Methods and procedures to determine if all seeds were implanted properly.

      At the end of each procedure, the authorized user reviews a PA fluoroscopic image and uses the TRUS to image the prostate in the transverse and sagittal planes. He also reviews the CT images later.

   b. Fluoroscopy used to supplement TRUS during procedure (yes or no).

      No.

   c. Confirm radiograph acquired after implant to verify seed placement.

      Yes, PA image acquired using C-Arm fluoroscope.

   d. Written directive, post-implant part: when completed and how.

      Completed in OR after each procedure.

e. Post-implant CT scans: when completed?

Current plan is to attempt to complete these on the day of the implant.

f. Post-plans: when completed, who draws the contours of the prostate and other organs, are the seed locations found by software manually corrected, how to verify complies with written directive. Are any indices of rectal dose calculated?

The goal will be to complete the initial post-plans before the patient leaves the medical center, which is typically the day after an implant procedure. The authorized user physician contours the prostate and other organs. Seed locations will be manually corrected. The R100 will be calculated.

g. Review of treatment results to dose criteria D90.

The written procedures require the V100 and D90 to be calculated. The authorized user physician, the medical physicist, and RSO will review these indices of dose coverage.

h. Review of treatment results to V100 criteria.

The written procedures require the V100 and D90 to be calculated. The authorized user physician, medical physicist, and RSO will review these indices of dose coverage.

i. Clinical quality assurance, including peer review.

William Barrett, M.D., performs peer review of Dr. Redmond's implants.

6. Workload data

a. Method of implantation (preloaded needles, Mick applicator, needles loaded at facility).

Needles are loaded in nuclear medicine using the Mentor Isoloader.

b. Date of program inception.

September 1998.

c. Number of patients implanted per year.

2007 – 129
2008 – 66
2009 – none to date

d. Radionuclides (I-125, Pd-103, Cs-131) and seed models currently in use.

I-125 only, Core Oncology 125SL

7. Implementation of Standard Procedures for Training (including for medical events)

a. Periodicity of training and how completed.

Initial training in the VHA standard procedures was conducted by discussion led by Dr. Lamba and Mr. Rauf. Participants included two authorized user physicians and two medical physicists. Nuclear medicine technologists and surgical staff were trained by discussion led by the RSO.

b. Review of training records.

Training records are sufficient to document initial training as described above.

c. Methods used to evaluate effectiveness of training.

Not documented, but the RSO stated the method was group and one-on-one discussions.

d. Groups receiving training and evaluation of training topics used for each group.

Groups of staff receiving training were authorized user physicians, RSO, medical physicists, and nuclear medicine technologists. The training topics included the VHA standard procedures, with an emphasis on medical event identification and reporting, and NRC regulatory requirements.

e. Focus to the key topics of safety culture, reporting concerns or issues through chain of command, use of dose as metric for medical events, roles, and responsibilities for seed implant team members, avoiding undue reliance on contractors, consultants, or affiliated universities, and identifying and reporting medical events.

Specifically addressed in training of authorized user physicians, RSO, and medical physicists. Should be added to training of nuclear medicine technologists and surgical staff.

8. Implementation of Standard Procedure for Written Directives

a. Review of written procedures and forms for written directives.

Written procedures and forms for written directives conform to the standard procedure.

b. Review of completed written directives including results of quarterly audits.

Not applicable. Program is inactive and no implants have been performed since the inspection in October 2008.

9. Implementation of Standard Procedure for Clinical Requirements

a. Review of written procedures and forms to incorporate clinical requirements.

Written procedures and forms incorporate clinical requirements from standard procedures.

b. Review of completed records that incorporate clinical requirements.

Not applicable. Program is inactive and no implants have been performed since the inspection in October 2008.

10. Overall evaluation of program implementation and oversight

a. Compliance with regulatory requirements.

The program appears to be ready to comply with regulatory requirements.

b. Implementation of VHA standard procedures.

The permittee has implemented the VHA standard procedures.

c. Avoiding undue reliance on consultants, contractors, and affiliated universities.

The authorized user physicians and the medical physicists are contractors. However, there appears to be adequate oversight over these contractors.

d. Focus to a safety culture and willingness to report safety concerns or issues.

The members of the implant team and the radiation safety office, in interviews, indicated understanding of and support for a safety culture.

e. Oversight by executive management, Radiation Safety Committee, and Radiation Safety Officer.

The RSO, Radiation Safety Committee, and executive management appear to be prepared to provide effective oversight.

f. Understanding of roles and responsibilities by different seed implant team members.

Yes.

g. Adequate and sufficient training and allotted time to achieve regulatory compliance.

Yes.

11. Personnel Contacted

Linda Smith, Medical Center Director [1,2]
Sidney R. Steinberg, M.D., Chief of Staff [1,2]
Chris Rauf, RT(N), CNMT, RSO, and Chief Nuclear Medicine Technologist [1,2,3]
Kevin Redmond, M.D., Radiation Oncologist, Barrett Cancer Center, University of Cincinnati, and Authorized User Physician [1,2,3]
Michael Lamba, Ph.D., Therapeutic Radiological Physicist, University of Cincinnati Medical Center [3]
Howard R. Elson, Ph.D., Therapeutic Radiological Physicist, University of Cincinnati [1,2,3]

1. Individual(s) present at entrance meeting on June 30, 2009
2. Individual(s) present at exit meeting on July 1, 2009
3. Individual(s) present or participating in inspection discussions