



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3900 Woodland Avenue
Philadelphia PA 19104

NOV 21 2008

In Reply Refer To:

E. Lynn McGuire
Director
National Health Physics Program (115HP/NLR)
Bldg 101, Room 208E
2200 Fort Roots Drive
North Little Rock, AR 72114

RE: Reply to Notice of Violation
Inspection Report 642-08-I02

Dear Mr. McGuire:

Thank you for granting the extension for our reply to the Notice of Violation contained in your October 16, 2008 Inspection Report.

In response to the "Required Actions" listed in the Notice of Violation, this letter confirms the Medical Center instituted prompt action to correct identified violations and implemented corrective actions to prevent a recurrence. Also, as stipulated, the attached written response includes the required descriptions for each violation

Please do not hesitate to contact our Radiation Safety Officer, Mary Moore, at (215) 823-6009 if additional information is needed.

Sincerely,


RICHARD S. CITRON-FACHE
Medical Center Director

Enclosure

cc: M. O'Shea Caplan
S. Gallerizzo
M. Heyworth, M.D.
C. Heidt, R.N.
P. Yagnik, M.D.
J. Maslow, M.D.
A. Maity, M.D.
M. Moore, RSO

Philadelphia VA Medical Center
November 21, 2008
Response
To
Notice of Violation (NOV)
Issued October 16, 2008
By
National Health Physics Program
Inspection Report Number 642-08-102
VHA Permit Number 37-00062-07

The following is submitted in compliance with the 30 day response time specified in the October 16, 2008 Notice of Violation and the November 21, 2008 extension issued by VACO NHPP for the brachytherapy program at the Philadelphia VA Medical Center.

1) Required Actions

- A) The medical Center must take prompt action to correct the violations listed in the NOV and ensure the violations do not recur.*

Response

As soon as the Medical Center discovered the possibility that additional patients may have been under dosed, it voluntarily and independently placed the prostate brachytherapy program on-hold effective on June 11, 2008. The program currently remains closed with no foreseeable timeline for reactivation. Patients scheduled to have procedures were transferred to other hospitals and the Medical Center incurred all costs.

In order to determine if any other patients were under-dosed, the Medical Center immediately initiated a comprehensive and thorough review of every prostate brachytherapy patient's treatment. The Medical Center contacted every patient by phone and informed each patient of the on-going investigation into prostate dose issues through a registered mailing. Additionally, the Medical Center issued a press release to news media within and around VISN 4, and worked with and gave detailed briefings to appropriate congressional offices and local Veteran Service Organizations (VSO's). The purpose of these efforts was to inform all patients treated at the medical center of our efforts and ensure that all patients received adequate follow-up.

Based on the initial review of treatments, patients identified as at risk of being under-dosed were contacted and asked to obtain current CT scans. These were necessary to complete the evaluation and identification of any patient who may have received dose deviations of 20% or more. The Medical Center contacted external experts to provide independent evaluations of patient treatments. The Medical Center arranged to send patients identified as needing a second implant to a leading prostate brachytherapy implant center. Subsequent notifications to all brachytherapy patients included the

Medical Center's apology and information about their legal rights , including information regarding tort claims.

Corrective Actions taken to correct the violations listed in the NOV and to ensure the violations do not recur are addressed below in individual responses to Violations a, b, c and d.

B) Other actions are listed below under specific violations.

a. *The Medical Center must submit a written statement to NHPP within 30 days of the date of this October 16, 2008 NOV.*

Response:

This report fulfills this requirement

2) Violations

The 4 violations are listed separately and are addressed in the order in which they appear in the October 16, 2008 NOV.

The following are described in the Medical Center's response for each violation:

- a) Basic cause or causes for the violations or agreement with the basic causes identified in the inspection report narrative, or if contested, the basis for disputing the violation or severity level.
- b) Corrective steps already taken
- c) Corrective steps which will be taken
- d) Date full compliance will be achieved

D) Violation – “a”

“Written Procedures for Written Directives:

Title 10 CFR 35.41 requires for any administrations requiring a written directive, that written procedures be developed, implemented, and maintained to provide a high confidence that each administration is in accordance with the written directive.

Violations:

Contrary to the above, for a brachytherapy procedure performed on May 5, 2008, and many other brachytherapy procedures performed since February 25, 2002 the permittee did not have adequate written procedures to provide a high confidence that each administration was in accordance with the written procedure.

1) The written directives prescribed doses of 160 Gy but many brachytherapy procedures resulted in inadequate seed distributions that produced, or will produce, D90 doses as less than 128 Gy.

2) Clinical staff (i.e. physician authorized users and medical physicists) for brachytherapy procedures did not receive training about regulatory requirements to identify and report medical events. “

Response to Violation “a” (1)

The Medical Center concurs that many brachytherapy procedures resulted in prostate doses lower than the prescribed dose. The adequacy of the doses delivered is being evaluated by independent prostate brachytherapy experts.

The **basic cause** for this deficiency relates to ineffective policies and procedures to address, ensure and verify that the dose patients receive from a brachytherapy procedure conforms to the dose specified on the Written Directive. Medical Center Memorandum (MCM) 11-17 “Sealed Source Radiotherapy” (1999), and revised 2002, 2005, and 2008 (renamed as MCM-00-76) did not address comparison of post-implantation CT scans and post-treatment plans to determine compliance with the Written Directive and the pre-treatment plan. MCM 11-17 and its later revision as MCM 00-76 also did not require the review to take place within a proscribed time period.

A second basic cause is that both the Medical Center and Regulatory bodies were deficient in ensuring that such policies and procedures in use at the time of commencement of the brachytherapy program and subsequently adequately addressed these points. The Medical Center did not include post-treatment comparison and evaluation when the 1999 version of MCM 11-17 was revised in 2002 and again in 2005. In addition, the NRC conducted a Special Inspection of the brachytherapy program in July 2003, after the 9th implantation procedure and determined that the policies and procedures in place were sufficient and adequate.

Corrective actions implemented for Violation "a" (1)

Corrective Actions taken to ensure high confidence that each administration is in accordance with the Written Directive are as follows:

1. PVAMC MCM 00-76 Sealed Source Radiotherapy policy (formerly MCM 11-17) was amended and approved at the July 2, 2008 and Nov 12, 2008 Radiation Safety Committee meetings to include requirement for
 - a. comparison and evaluation of both treatment plans and associated calculations with the Written Directive,
 - b. that no implant procedures will proceed if the treatment planning computer is unable to produce pre or post-treatment plans, and
 - c. that all deviations that exceed 10% of the prescribed dose or dose fraction are immediately reported to the RSO and QM staff.
2. On May 30, 2008 the RSO and Radiation Safety and Radiation Oncology staffs developed a procedure to ensure pre-treatment plans and Written Directives are compared and evaluated by the AU physician and brachytherapy AMP before seed order requests are delivered to RSO staff for processing. A "Comparison of WD and TP Completed" stamp will be used and initialed by both the AU and AMP. This will inform RSO staff that the comparison has been completed and approved by both the AU and AMP.
3. On July 2, 2008, PVAMC Radiation Safety Committee also initiated the requirement of radiation safety training for all new employees in Services using radiation in addition to the radiation safety training they received during New Employee Orientation Training.
4. On July 2, 2008, PVAMC Radiation Safety Committee also mandated the requirement for a 1 week window between receipt of the post-implant CT and completing the post treatment plan and dose comparison with the Written Directive. Also required is cessation of treatments if pre and post-treatment dose evaluations are not possible.
5. Prior to the June 2, 2008 implant, RSO staff instituted routine double review of all requests received from Radiation Therapy for brachytherapy sources as standard operating procedure. Two physicists in the Radiation Safety Office reviewed and compared the Needle Loading Form, the pre-treatment plan and the Written Directive.
6. The Medical Center instituted a peer-review system for Radiation Oncology Service as a whole to include weekly chart rounds. These began in July, 2008. Quality data from Radiation Therapy is being reported to the Quality Council quarterly.

Response to Violation "a" (2)

Clinical staff (i.e. physician authorized users and medical physicists) for brachytherapy procedures did not receive training about regulatory requirements to identify and report medical events. "

The Medical Center concurs that the Authorized User Physicians (AU) for prostate brachytherapy and the Authorized Medical Physicists (AMP) did not receive formal training from PVAMC staff about regulatory requirements to identify and report medical events when they started to work at PVAMC.

The **basic cause** for not providing initial training is the hospital followed NRC guidance and regulations that stipulate that training is not required for experienced AU physicians and AMPs.

NRC guidance in the 2002 Federal Register report, and regulation 10 CFR 35.57 stipulate additional on-site training is not required for Authorized User Physicians (AU) and Authorized Medical Physicists (AMP)

- 1) **Federal Register, Vol. 67, No. 79, Wednesday, April 24, 2002/ Rules and Regulations page 20281, Section 35.14 Notifications, NRC Response to Issue 3: Is it Necessary To Name an AMP on a License:**

" The NRC believes that the requirements for naming an AMP and AU in the license should be the same. In order to be considered an AMP, the individual must meet the training and experience qualifications in [Part] 35.51. If the individual is certified by a board whose certification process has been recognized by NRC, the Licensee may allow that individual to begin work immediately and notify us within 30day that the individual has begun work...."

The NRC's response in the 4-24-02 Federal Register also clarifies that AU and AMP are both supervisors and therefore are not subject to the training requirements of 10 CFR Part 19

- 3) **Title 10 CFR 35.57: "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist"**

reaffirms the use of prior training, experience and board certification as adequate criteria to determine if additional training is needed, and stipulates

A) For AMPs - compliance with the training requirements of Part 35.50, 35.51, or 35.55, respectively is not needed if the AMP was listed on a NRC license prior to October 24, 2002 or between October 24, 2002 and April 29, 2005

- 1) In compliance with 10 CFR 35.57 (a) (1), the primary prostate brachytherapy AMP was first approved by PVAMC on 3-12-02

- 2) In compliance with 10 CFR 35.57 (a) (2) the second AMP was approved by PVAMC on September 16, 2003.
- 3) In compliance with 10 CFR 35.57 (a) (2) the third AMP was approved and listed as an AMP on NRC License No. 37-07722-04 from January 2005 through August 2006, and on the University of Pennsylvania NRC License from August, 2006 to present. He was approved by PVAMC RSC January 9, 2008

B) For physicians listed on a license “ before October 24, 2002, need not comply with the training requirements of Subparts D through H of this part.

- 1) In compliance with 10 CFE 35.57 (b)(1), the primary prostate brachytherapy AU physician was approved by PVAMC Radiation Safety Committee (RSC) on February 3, 2000 .
- 2) In compliance with 10 CFR 35.57 (b)(1), the second brachytherapy AU physician was approved by PVAMC RSC on August 2, 2001. He was also approved on Hospital of the University of Pennsylvania’s NRC license for at least 10 years at the time of his approval by PVAMC.

Prior to employment, all AU physicians and AMPs involved in the brachytherapy program presented verification of NRC approved board certifications and documentation of training and experience and NRC license(s) numbers on which they were listed. These credentials were verified and approved by the Radiation Safety Committee prior to performance of duties.

PVAMC Radiation Safety Committee, patient safety staff, and HUP Radiation Oncology staff developed a Radiation Therapy Service Dose Deviation Reporting policy finalized in February 2002. This document clearly identifies medical events and the immediate notification procedures required.

During the development of the Medical Center’s prostate brachytherapy program, and especially during the events in 2003 and 2005, discussions among the current AUs, AMPs and Medical Center Radiation Safety Officer clearly demonstrated the AUs and AMPs were knowledgeable about medical events. This is also demonstrated in emails on file in the Radiation Safety Office.

Corrective actions implemented for Violation “a” (2)

- 1) On May 30, 2008 the RSO reviewed Written Directive form and Medical Event regulations with Radiation Oncology AU physicians and AMPs.
- 2) Additional training was provided on August 15 and September 8 and 11, 2008: RSO staff gave Radiation Oncology staff a radiation safety training information packet and

2 tests that addressed NRC regulations for Written Directives, Medical Events and how to identify medical events. Both brachytherapy and external beam treatments were included. On August 5, 2008, RSO staff provided training about Written Directives and Medical Events for Nuclear Medicine staff. This training has been continued to date for new employees, trainees and contractors in both services.

- 3) On July 2, 2008, PVAMC Radiation Safety Committee also initiated the requirement of radiation safety training that includes the definition of a medical event for new employees in Services using radiation in addition to the radiation safety training they receive during New Employee Orientation Training.

Date compliance will be achieved for Violations "a" (1 and 2)

The program is considered to be in compliance at this point. If however, it is decided that the brachytherapy program is to be re-instituted that the medical center will request external review (internal VA and regulatory body) to ensure that proposed policies and procedures are deemed sufficient.

II) Violation – “b “

10 CFR 35.41 (b) requires for any administration requiring a written directive that written procedures be developed, implemented, and maintained to provide high confidence that each administration is per the written directive; specifically the written procedures must include verifying the administration is in accordance with the treatment plan and written directive and checking computer-generated dose calculations.

Violation:

Contrary to the above, for a brachytherapy procedure performed on May 5, 2008, and many other brachytherapy procedures performed since February 5, 2002, the permittee did not have adequate procedures to provide a high confidence that each administration was in accordance with the written directive. Specifically, permittee written procedures for permanent implants in Medical Center memorandum 00-76 do not address verification that the administration is per the treatment plan and written directive and checking the computer generated dose calculations.

Response to Violation “ b”

The Medical Center concurs that PVAMC Policy MCM 00-76 (2005) does not specify that Post-Treatment plans and calculations must be compared to the Written Directive. It also does not address when the Post-Treatment plan has to be completed to permit timely comparison with the Written Directive. It only addresses pre-treatment plan comparison with the Written Directive.

*PVAMC Policy MCM 00-76 (2005), Section B, Permanent Implants state
#3) “Radiation Therapy Physicist will prepare the treatment plan and related calculations to ensure compliance with the Written Directive. ...”*

The **basic cause** underlying the violation is that that procedures outlined in PVAMC Medical Center Memorandum MCM 00-76 (2005 version) were insufficient to address post-implantation evaluation procedures. The lack of clarity in the MCM 00-76, and its precursor MCM 11-77, reflects, and is in concordance with regulation 10 CFR 35.41.

The **second basic cause** was lack of local Quality Management oversight of the prostate brachytherapy program

The **third basic cause** is that all oversight reviews of the Medical Center’s policies and procedures related to brachytherapy program did not detect or identify deficiencies.

Corrective actions taken for Violation “b”

MCM 00-76 was revised and approved by the RSC in July and November 2008 to include the following:

- a) NRC regulations 10 CFR 35.41 and 10 CFR 35.3045

- b) verification of the post-treatment plan comparison with the Written Directive
- c) implant procedures will not proceed if there is no ability to produce pre-treatment or post-treatment plans

Date compliance will be achieved

The program is considered to be in compliance at this point. If however, it is decided that the brachytherapy program is to be re-instituted that the medical center will request external review (internal VA and regulatory body) to ensure that proposed policies and procedures are deemed sufficient.

Violation "c"

10 CFR 35.40 requires a written directive for low-dose rate brachytherapy, after implantation, but before completion of the procedure, to specify the radionuclide, treatment site, number of sources, and total source strength or total dose.

Violation:

Contrary to the above, for a brachytherapy procedure performed on May 5, 2008 the written directive did not document, after implantation, the required information.

Response to Violation "c"

The Medical Center concurs the AU physician did not complete the Written Directive after completing the implant as required by both 10 CFR 35.40 and PVAMC policy MCM 00-76 (2005), page 6, #13

"Radiation Therapy physician and physicist shall complete the Written Directive (Appendix B) at the end of the treatment and prior to leaving the treatment room. If events during treatment necessitate changing the planned treatment, the Radiation Therapy Physician must revise the Written Directive before the end of the procedure."

Investigation into the cause of this violation found it was an oversight by the physician and was a one-time event both for this physician and for the medical center as a whole.

Corrective actions taken for Violation "c"

Following the NHPP May 28 and 29, 2008 Reactive Inspection, the RSO met with the AU physician and reviewed the regulations requiring completion of the Written Directive at the end of the procedure and prior to leaving the treatment room with the AU physician to prevent it from happening again.

On May 30, 2008 RSO met with AU physicians and AMPs to review regulations, PVAMC reporting requirements and answer any questions.

Date compliance will be achieved

The program is considered to be in compliance at this point. If however, it is decided that the brachytherapy program is to be re-instituted that the medical center will request external review (internal VA and regulatory body) to ensure that proposed policies and procedures are deemed sufficient.

Violation "d"

10 CFR 35.3045 requires a permittee to notify NRC (through NHPP) not later than the next calendar day after discovery of a medical event meeting the criteria in 10 CFR 30.3045(a)(1) and (a)(3), and send a written report within 15 days after discovery.

Violation:

Contrary to the above, as of June 4, 2008, the permittee had not reported, either by telephone or in writing, many medical events that occurred between February 25, 2002 and May 5, 2008. Specifically, brachytherapy procedures were performed in which prescribed doses were 160 Gy but D90 doses were evaluated as less than 128 Gy, and the permittee did not discover and report the medical events.

Response to Violation "d"

The Medical Center does not concur that it failed to comply with 10 CFR 35.3045. This regulation specifically stipulates reporting after discovery.

As noted in the NHPP Notice of Violation, dated 16 October 2008, PVAMC had not discovered medical events prior to May 15, 2008 except for the possible one reported in 2003 and the possible one reported in 2005. As noted in this NOV report, PVAMC called to report the suspicion of a possible medical event on May 12, 2008. And then PVAMC called NHPP on May 15, 2008, the day the May 5th patient dose was confirmed as less than 128Gray, to inform NHPP of the discovery. This reporting pattern is consistent with PVAMC's history of reporting suspected as well as confirmed violations within the 24-hour requirement.

As a result of the May 15, 2008 discovery, a retrospective review was initiated which lead to the discovery of additional cases. As additional medical events were identified and confirmed, NHPP was notified within a few hours of each subsequent discovery which enabled NHPP to notify the NRC within the 24 hour deadline. Also, 15-day reports were provided to NHPP in a timely manner. As such, a violation of 10CFR 35.3045 does not apply.

Procedures were in place to identify and report any suspected medical events. The compliance with, and effectiveness of, those procedures and policies, or lack of, are addressed in response to Violation "b". As such, a violation of 10CFR 35.3045 does not apply.

Corrective actions taken for Violation "d"

- 1) A self-initiated review of every prostate brachytherapy implant procedure began in June 2008 following the discovery of additional possible medical events among the NHPP recommended review of 20 additional implant procedures.

- 2) To ensure that employees know the definition of a medical event and how to recognize one, PVAMC RSC mandated that radiation safety training include these topics and be provided before new employees in Radiation Oncology and Nuclear Medicine begin employment and that such training be documented.
- 3) RSO staff included and reinforced PVAMC Open Door policy for reporting concerns and suspected violations during the above documented training conducted in August 2008
- 4) PVAMC's contract with the Hospital of the University of Pennsylvania for Radiation Oncology Services is being revised to realign medical physicists and dosimetrists under PVAMC Radiation Safety Officer to ensure proper communication channels for supervision and for reporting possible medical events in the future.
- 5) Medical Center peer review and post-treatment evaluations are being conducted and reported to the PVAMC Quality Council.

Date compliance achieved for Violation "d"

PVAMC has maintained its compliance with 10CFR35.3045 and will continue that compliance as an on-going commitment.

In August 2008, radiation safety training as described above was provided to current employees, trainees, and contractors in Radiation Oncology and Nuclear Medicine. It is an ongoing process and has been provided to new staff in these two services subsequently.

Date compliance will be achieved for Violation "d"

As of this date, PVAMC's contract with the Hospital of the University of Pennsylvania for Radiation Oncology Services is being revised and will be sent to the University of Pennsylvania Radiation Oncology Department by December 15, 2008 for their input and concurrence.