

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

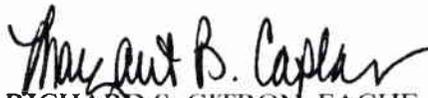
Date: December 29, 2008

From: Director, (642/00), VA Medical Center, Philadelphia, Pennsylvania

Subj: Response to VHA National Health Physics Program Inspection Report 642-08-102

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

1. Per our telephone discussion on December 12, 2008, I rescind my previous response to the inspection report and substitute the following response.
2. I have reviewed and accept the inspection report findings, observations, and violations as cited in the report. I agree with the description of root and basic causes including those referenced in the Administrative Board of Investigation report. I understand and embrace the requirement to focus on a safety culture, to increase management oversight, and to avoid undue reliance on affiliates or outside consultants.
3. I commit to strengthening the radiation safety program and ensure current and future uses of radioactive materials achieve regulatory compliance. I am attaching details for corrective actions for the former seed implant program. We look forward to your return visit to evaluate medical event reporting and to discuss any specific details of the corrective actions, as needed.
4. Please contact me if you have any questions or comments.


RICHARD S. CITRON, FACHE
Medical Center Director

cc: Chair, VHA National Radiation Safety Committee
Network Director, VISN 4 (10N04)

Response to National Health Physics Program Inspection Report Number 642-08-I02
VA Medical Center, Philadelphia, Pennsylvania

1. This attachment has specific details to respond to National Health Physics Program Inspection Report Number 642-08-I02.

2. The VA Medical Center, Philadelphia Pennsylvania (PVAMC), takes very seriously the violations cited in the inspection report and is committed to substantially improving regulatory compliance for the use of radioactive materials. PVAMC recognizes the numerous deficiencies that occurred in the seed implant program and is completing corrective actions for appropriate clinical follow-up for impacted patients and to achieve regulatory compliance. PVAMC has evaluated each case individually and is addressing treatment issues for all patients that have received seeds as part of prostate brachytherapy implants.

3. Violation a: Lack of adequate written procedures to provide high confidence that each administration was per the written directive.

a. PVAMC accepts the violation as cited and the description of root or basic causes in the inspection report. PVAMC notes basic causes related to inadequate and ineffective policies and procedures, a lack of internal and external program reviews, and a lack of training.

b. PVAMC completed the following corrective actions.

(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 staff 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 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.

(4) 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.

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(5) 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.

(6) On May 30, 2008 the RSO reviewed Written Directive form and Medical Event regulations with Radiation Oncology AU physicians and MPs.

(7) 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 for new employees, trainees and contractors in both services.

(8) 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.

4. Violation *b*: Lack of adequate written procedures, specifically to include verifying the administration is per the treatment plan and written directive, and checking computer-generated dose calculations.

a. PVAMC accepts the violation as cited and the description of root or basic causes in the inspection report. PVAMC notes basic causes related to inadequate and ineffective policies and procedures, and a lack of effective program reviews.

b. PVAMC completed the following corrective actions. MCM 00-76 was revised and approved by the RSC in July and November 2008 to include the following:

(1) NRC regulations 10 CFR 35.41 and 10 CFR 35.3045

(2) Verification of the post-treatment plan comparison with the Written Directive

(3) Implant procedures will not proceed if there is no ability to produce pre-treatment or post-treatment plans

5. Violation *c*: Failure to complete a written directive correctly for a seed implant procedure on May 5, 2008.

a. PVAMC accepts the violation as cited and the description of root or basic causes in the inspection report.

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b. PVAMC completed the following corrective actions. 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.

6. Violation *d*: Failure to notify and report medical events.

a. PVAMC accepts the violation as cited and the description of root or basic causes in the inspection report.

b. PVAMC completed the following corrective actions.

(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.

7. The overall status for corrective actions is based on the following specific information and the current suspension for the seed implant program.

a. PVAMC does not currently plan to restart the seed implant program but will comply with the VHA restart criteria if a restart is deemed feasible in the future.

b. PVAMC will continue to evaluate other uses of radioactive materials that might be impacted by the basic causes identified in the inspection report or Administrative Board of Investigation

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and take corrective actions. Specific corrective actions will be addressed for a focus to a safety culture, management oversight, and undue reliance on affiliates or outside consults.

c. Specific status of corrective actions for each violation is noted below.

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

As part of the corrective action for this violation, the medical center has developed a system of continuing education of radiation oncology staff. Additionally, the radiation oncology program has instituted an internal QA program as part of their weekly review to ensure that communication between team members is optimal and that safety and treatment concerns are voiced and discussed.

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

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

(4) 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. PVAMC considers that it is currently in compliance with 10 CFR 35.3045 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.