



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

JUL 15 2010

Steven A. Reynolds
Director, 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; EA-10-081; CAL 3-08-004

Dear Mr. Reynolds:

This letter is in follow-up to the pre-decisional enforcement conference that was held on June 30, 2010. I am enclosing detailed responses for the apparent violations, concerns, and potential violations that were outlined in your "extent of condition" inspection report dated May 24, 2010. In addition, I am enclosing a list of ongoing and future actions for overall implementation of the master materials license.

In this letter, as requested, I will not provide a comprehensive review of the extensive efforts the Veterans Health Administration (VHA) has taken to evaluate possible medical events for prostate seed implants in the VHA facilities and VHA plans to implement corrective actions. These efforts were initiated promptly after medical events were discovered at VA Medical Center, Philadelphia, in 2008.

I would like to emphasize however that, as a result of continuous improvement initiatives, VHA has established clinical standards and procedures that are among the most rigorous in the health care industry. Additionally, the National Health Physics Program has implemented a detailed audit checklist for annual inspections at the VHA facilities performing prostate seed implants.

For your consideration and review, I am providing four enclosures. The first enclosure has a response for the apparent violations. The second enclosure has a response for the concerns. The third enclosure has a response for the potential violations. The last enclosure has a list of ongoing and future actions.

The Under Secretary for Health, as the named licensed official, understands and mandates vigorous oversight to assure the safe use of radioactive materials. The Under Secretary has stressed to the Chair, National Radiation Safety Committee, and to me as the Director, National Health Physics Program, a very high expectation for health and safety for use of radioactive materials and for achieving regulatory compliance.

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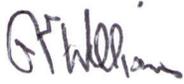
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As a final point, our internal review of circumstances for prostate seed implants and how to improve VHA oversight and regulatory compliance identifies a very specific need for a more detailed agreement identifying effective and efficient methods of communication among the NRC, National Health Physics Program, National Radiation Safety Committee, and VHA facilities.

I invite NRC to join with us in developing closer communication so that expectations for regulatory compliance and master materials license implementation are understood and met.

Please contact me if you have any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Williams".

Gary E. Williams
Director, National Health Physics Program

Enclosures: as stated

Enclosure 1 - Response for Apparent Violations

1. Apparent violation related to lack of adequate written procedures.

a. The apparent violation is accepted but with clarification below for most examples of the apparent violation. VHA does not agree that the regulations have the prescriptive requirements stated in the NRC inspection report.

(1) NRC regulations in 10 CFR 35.41(b) require the written procedures for written directives address “verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.” NRC regulations do not explicitly require written procedures to “specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified...”

(2) As regulatory guidance, NRC NUREG-1556, Volume 9, Rev. 2, Appendix S, provides a model written procedure for written directives. The document states:

“This model provides acceptable procedures for administrations that require written directives (WDs). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.”

For sealed therapeutic sources, the NRC’s model procedure discusses verification, but only in the context of checks and calculations performed before source administration. The NRC’s model procedure does not mention post-implant imaging, the time-frame for such imaging, the methods to calculate post-implant dose quantities, or specific criteria for evaluating doses from permanent prostate seed brachytherapy.

(3) VHA concludes that a lack of these specific items in the written procedures should not be cited as a violation of NRC regulations.

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(4) The NRC inspection report acknowledges that most of the 11 VHA facilities had established and implemented appropriate criteria, methods, and time-frames, but not necessarily in writing.

b. This apparent violation is based on examples identified for 11 facilities. For the examples, VHA agrees with the one example for G.V. (Sonny) Montgomery VA Medical Center, Jackson but disagrees with the other 10 examples.

c. The root cause summary in response to the CAL states the causes for medical events and regulatory violations are related to procedures and training. A contributing factor for not identifying this apparent violation in the previous regulatory inspections is "procedures, wrong, less than adequate." Also, a contributing factor was "training, no training, task not analyzed" in that the training for regulatory inspectors did not include review of post treatment dose analysis.

d. The primary corrective action was to suspend patient treatments using prostate seed implants at the only active facility (G.V. (Sonny) Montgomery VA Medical Center, Jackson) not completing post treatment dose analyses. At the other active facilities, the primary corrective action was to implement the VHA standard procedures and perform periodic internal self-audits. Before any patient treatments may resume at an inactive facility, the facility must complete the VHA restart process, implement the VHA standard procedures, and be approved by VHA senior leadership. VHA notes that the NRC has generally agreed that adequate corrective actions for the apparent violation were incorporated into the VHA standard procedures. However, pending outcomes for this NRC inspection report, VHA plans to review the VHA standard procedures to determine if any additions or corrections are appropriate.

e. VHA notes the proposed rulemaking for 10 CFR 35 appears to recognize the lack of previous understanding by licensees on the extent of requirements to prescribe in the written procedures and in training for facility staff. The proposed new requirements in

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10 CFR 35 reflect a language correction to make regulatory requirements more explicit as indicated below.

(1) Addition of a requirement that licensees provide and document training regarding requirements for reporting a medical event to individuals who participate in procedures requiring a written directive.

(2) Addition of a requirement that, for permanent implant brachytherapy, a licensee must assess the dose to the treatment site and sites other than the treatment site that are identified in the pre-implant written directive using published protocols accepted by nationally recognized professional organizations within 60 days from when the patient leaves the post-treatment recovery area.

2. Apparent violation related to verification of patient treatment.

a. The apparent violation is accepted for facility circumstances that are described in the NRC inspection report. However, VHA disagrees with the violation being cited separately from the apparent violation related to lack of adequate written procedures.

b. This apparent violation is based on examples identified for four facilities. Since the violation is based on lack of adequate written procedures which is also identified as an apparent violation for the same facilities, this apparent violation should not be cited as a separate violation in the NRC inspection report.

(1) VHA concludes a violation is appropriate only for the underlying violation for lack of adequate written procedures.

(2) A historical review of NRC inspection reports identifies several examples where the NRC practice was to incorporate deficiencies for 10 CFR 35.41(b) into the violation of 10 CFR 35.41(a) related to lack of adequate procedures.

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c. The description of root or basic causes in the root cause analysis prepared for the CAL addresses causes for medical events and regulatory deficiencies.

(1) The root causes for VHA program deficiencies were often related to procedures and training.

(2) A contributing factor for not identifying lack of post treatment dose analysis in the previous regulatory inspections is "procedures, wrong, less than adequate."

(3) A second contributing factor was "training, no training, task not analyzed" in that training for regulatory inspectors did not include review for post treatment dose analysis.

d. The primary corrective actions were to complete dose verification for the patient treatments with adequate post-implant imaging, to suspend future patient treatments using prostate seed implants (G.V. (Sonny) Montgomery VA Medical Center, Jackson), and to implement VHA standard procedures (VA Boston Healthcare System, Boston and VA New York Harbor Healthcare System, Brooklyn). Before patient treatments may resume at suspended or inactive facilities, each facility must complete the VHA restart process and implement the VHA standard procedures.

e. VHA notes the proposed rulemaking for 10 CFR 35 appears to recognize the lack of previous understanding by licensees on the extent of requirements to prescribe in the written procedures and in training for facility staff. See paragraph 2e above.

3. Apparent violation related to reporting a medical event.

a. The apparent violation is accepted.

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b. The facility interpretation about when a patient treatment should be considered to have been completed was a reasonable interpretation of NRC regulations under these circumstances and was consistent with a focus to patient care.

c. The root cause for the violation is "procedure, wrong, needs improvement" in that additional details for determining when a medical event had occurred needed to be in the facility written procedures.

d. As corrective actions, the facility revised written procedures for the prostate seed implant program to implement VHA standard procedures and performed training of staff on the revised procedures. The facility confirmed revisions were implemented in April 2009. NHPP inspected the facility in December 2009 and verified implementation of the revised procedures.

4. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at G.V. (Sonny) Montgomery VA Medical Center, Jackson, is accepted since this facility had a significant number of medical events.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes these root causes for the apparent violation: "procedure, wrong, needs improvement" and "management system, policies or standards, accountability needs improvement."

c. The primary corrective action was to suspend patient treatments using prostate seed implants. Before patient treatments at the facility can resume, the facility will be required to complete the VHA restart process and implement VHA standard procedures. The facility terminated prostate seed implant procedures and currently does not have any plans to resume the implants.

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5. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Medical Center, Minneapolis, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, the facility's written procedures in place at the time of the NRC inspection included a document titled "Quality Management Program for Permanent Implant Brachytherapy." This document specified that both post-implant CT imaging and post-implant dose analysis were to be performed.

(1) Section 7 of that document is titled "CT image verification of source placement" states: "Following the implant procedure, a CT scan will be performed and source placement reconstruction will be used to generate a final treatment plan and total dose calculation." Although the timing of CT imaging was not explicitly stated in the procedures, the facility's usual practice, as documented in the NRC inspection report, was to complete post-implant CT imaging 1 to 2 days after the implant.

(2) Section 11 of that document states, "Each patient receiving permanent implant brachytherapy will have a Brachytherapy Quality Management Form filled out. At the conclusion of the therapy, the physicist/dosimetrist will perform a final quality management review of the treatment and sign off in the last section of the form. Deviations from accepted procedure will be noted and logged."

(3) The Brachytherapy Quality Management Form in use at the time of NRC's inspection includes a box in the post-implant section of the form to indicate if a post-implant CT image was completed. The form also included check boxes in the final review section to indicate whether "Pre/Post Treatment Verification" and "Dose Calculation Verification" were completed.

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c. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement.

d. The primary corrective actions were implementation of VHA standard procedures and completion of periodic internal audits.

6. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Puget Sound Health Care System, Seattle, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, Section 9 of the procedure referenced in the NRC inspection report states:

"Following the implant procedure, a CT scan will be performed and source placement reconstruction will be used to generate the final treatment plan and total dose calculation."

c. The normal protocol followed by the facility, both now and at the time of the NRC inspection, was to perform CT imaging and post-plan dosimetry evaluations the same day as seed implantation. In fact, the radiation oncology department has a dedicated CT scanner a short distance from where the implants are performed.

d. VHA notes that over 1,500 successful seed implant procedures have been performed by this facility in the last five years (VA OIG Report No. 09-02815-143, May 3, 2010, p. 56, Fig. C) with no medical events. From a performance-based perspective, the facility's record supports the conclusion that procedures used by the facility resulted in "high confidence" each administration was per the written directive.

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e. NRC attributes root causes to failure of previous inspectors and the permittee to recognize that the written procedures did not include certain required aspects of the brachytherapy procedure in adequate detail. A more appropriate root cause for such a violation is "procedures, wrong, need improvement."

f. As corrective actions, the facility revised the written procedures for the prostate seed implant program to implement the VHA standard procedures and performed training of staff on the revised procedures. The facility notified NHPP that the revised procedures were implemented in April 2009. NHPP inspected the facility in November 2009 and verified implementation of the revised procedures.

7. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Sierra Nevada Health Care System, Reno, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. In addition to statements in the NRC inspection report about root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

c. The prostate seed implant program was inactive at the time the apparent violation was identified. The primary corrective action, from the VHA perspective, was to develop standard procedures for prostate seed implants. Before any patient treatments may resume, the facility will be required to complete the restart process and implement VHA standard procedures.

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8. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at Samuel S. Stratton VA Medical Center, Albany, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, the NRC is referred to the documents for the facility which were transmitted to NRC in an NHPP letter dated March 1, 2010.

(1) Page 11 of that transmittal provides the written medical event criteria established for the facility's seed implant program at the time of the NRC inspection. The written criteria for the treatment site state that the "D90 value must be greater than 80%".

(2) Page 27 of that transmittal is from the facility's written radiation safety procedures for prostate seed implants in place at the time of the NRC inspection. The section titled "Post Plan" specifies the time-frame for performing follow-up imaging and post plans specific to the physician performing the implant.

c. NRC attributes root causes to failure of previous inspectors and the permittee to recognize that the written procedures did not include certain required aspects of the brachytherapy procedure in adequate detail. A more appropriate root cause for such an apparent violation is "procedures, wrong, needs improvement."

d. As corrective actions, the facility revised the written procedures for the prostate seed implant program to implement the VHA standard procedures and performed training of staff on the revised procedures. The facility notified NHPP that revised procedures were implemented in March 2009. NHPP inspected the facility in August 2009 and verified implementation of the revised procedures.

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9. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA New York Harbor Healthcare System, Brooklyn, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. While the facility's usual practices included the completion of imaging and post treatment dose analysis, the procedures did not have an explicit listing of these practices, as stated in the NRC inspection report.

c. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

d. The primary corrective actions were implementation of VHA standard procedures and completion of periodic internal audits.

10. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Boston Healthcare System, Boston, is not accepted based on VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events. In addition, if the apparent violation is specific to implementation of procedures, then this example of an apparent violation appears to be redundant to the other apparent violation related to the completion of post treatment dose analysis.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

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c. The primary corrective actions were implementation of VHA standard procedures and completion of periodic internal audits. The facility revised the written procedures for the prostate seed implant program to implement the VHA standard procedures and performed training of staff on the revised procedures. The facility notified NHPP that revised procedures were implemented in April 2009. NHPP inspected the facility in August 2009 and verified implementation of the revised procedures.

11. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Medical Center, Washington, DC, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

c. The primary corrective action was to suspend patient treatments using prostate seed implants. Before patient treatments can resume, this facility will be required to complete the restart process and implement VHA standard procedures.

12. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Greater Los Angeles Healthcare System, Los Angeles, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, the NRC report did not appear to consider a facility written procedure entitled "Quality Management Program - Radiation Therapy

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Permanent Seed Prostate Brachytherapy,” dated 2005. The stated purpose of this document, as written in Section I. Purpose, “is to provide high confidence that byproduct material will be administered as directed by the authorized user(s)...” This document required CT post plans to be performed and subsequently reviewed by a medical physicist. In addition, the procedure required at least annual reviews of the prostate brachytherapy program which included reviewing of each case and comparing the results to the medical event criteria.

c. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

d. The primary corrective action was to implement VHA standard procedures.

13. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Medical Center, San Francisco, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, the facility written procedure titled “Brachytherapy Quality Management Form for 125I Prostate Brachytherapy Procedures using Pre-loaded System,” which was in effect at the time of the NRC inspection, appears to have much of the information which the NRC inspection report states is missing.

(1) “Section 7. Radiation Oncologist Post Implantation Information...Review dose indices including D90, V100, and rectal dose index, and evaluate seeds significantly outside the intended treatment volume....Compare the results to the prescribed dose to determine if a medical event occurred, including whether the D90 is less than 80% of the prescription dose (10 CFR 35.3045(a)(1)(i)).”

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(2) "Section 9. Post-QM Form Review by the RSO after final Post Patient CT Evaluation.... I have reviewed the D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT and the Post report...Reviewed the dose indices including D90, V100, and rectal dose index, and evaluated seeds significantly outside the intended treatment volume...I have compared the results to the prescribed dose to determine if a medical event occurred, including whether the D90 is less than 80% of the prescription dose (10 CFR 35.3045(a)(1)(i))."

Additional sections in the procedure provide information on medical event reporting.

c. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

d. The facility had already implemented VHA standard procedures at the time of the NRC inspection, and the written procedures generally had the prescriptive requirements in the NRC inspection report that were stated to be missing.

14. Example of apparent violation related to lack of adequate written procedures.

a. This example of an apparent violation at VA Medical Center, Durham, is not accepted based on the VHA disagreement with the basis for the violation and the lack of adverse outcomes such as a significant number of medical events.

b. As additional information, the NRC inspection report does not appear to consider all written procedures related to the seed implant program, which were in place at the time of NRC's onsite inspection in April 2009. Specifically, the NRC is referred to the documents for Durham which were transmitted to NRC in an NHPP letter dated February 25, 2010.

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c. Page 13 of that transmittal is a facility procedure titled, "Review of Implant Quality," which is dated September 16, 2008. Paragraph two of this procedure states:

"A dosimetric goal is to achieve D90 80% of the Rx dose... If $D90 < 80\%$ 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. D90 will be recalculated."

" If $D90 \geq 80\%$ of Rx, no further analysis is required. If D90 is still $< 80\%$, the CT scan will be repeated 6 weeks after the implant date and D90 will be recalculated. If D90 is $\geq 80\%$, no further analysis is required. If D90 is $< 80\%$, a medical event will be declared."

d. VHA concludes that this written procedure addressed both the "criteria for evaluating the dose to the treatment site" and "the method and time-frame the dose to the treatment site was verified".

e. NRC attributes root causes to failure of previous inspectors and the permittee to recognize that the written procedures did not include certain required aspects of the brachytherapy procedure in adequate detail. VHA considers the root cause for such a violation to be "procedure, wrong, needs improvement."

f. As required by VHA, the facility revised the written procedures for the prostate seed implant program to implement the VHA standard procedures and performed training on the revised procedures for staff involved in prostate seed implant program. The facility notified NHPP that the revised procedures were implemented in April 2009.

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15. Example of an apparent violation related to verification of patient treatment.

a. This example of an apparent violation at G.V. (Sonny) Montgomery VA Medical Center, Jackson, is accepted since multiple medical events were reported for this facility and post-implant dose analysis was significantly delayed for many patients.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes these root causes for the apparent violation: "procedure, wrong, needs improvement" and "management system, policies or standards, accountability needs improvement."

c. The primary corrective actions were to complete dose verification analysis for past treatments with adequate post-implant imaging and to suspend patient treatments using prostate seed implants. Before patient treatments may resume, the facility must complete the VHA restart process and implement VHA standard procedures.

16. Example of an apparent violation related to verification of patient treatment.

a. This example of an apparent violation at VA Sierra Nevada Health Care System, Reno, is accepted since post-implant dose analysis was significantly delayed at this facility.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes these root causes for the apparent violation: "procedure, wrong, needs improvement" and "management system, policies or standards, accountability needs improvement."

c. The prostate seed implant program was inactive at the time the apparent violation was identified. The primary corrective action, if patient treatments are to resume in the

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future, is for the facility to complete the VHA restart process and implement the VHA standard procedures.

17. Example of an apparent violation related to verification of patient treatment.

a. This example of an apparent violation at VA New York Harbor Healthcare System, Brooklyn, is accepted since the post-implant dose analysis was significantly delayed or unable to be performed by normal methods for a small number of patients treated in 2007 at this facility.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for such a violation: "procedure, wrong, needs improvement."

c. The primary corrective actions were to complete dose verification for any past treatments with adequate and available post-implant imaging, implement VHA standard procedures, and complete periodic internal audits.

18. Example of an apparent violation related to verification of patient treatment.

a. This example of an apparent violation at VA Boston Healthcare System, Boston, is accepted since post-implant dose analysis was significantly delayed or unable to be performed by normal methods for some patients at this facility in 2005.

b. In addition to the statements in the NRC inspection report about the root causes, VHA notes this root cause for the apparent violation: "procedure, wrong, needs improvement."

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c. The primary corrective actions were to complete dose verification for any past treatments with adequate and available post-implant imaging, implement VHA standard procedures, and complete periodic internal audits.

19. Root causes and corrective actions.

a. The root cause summary prepared in response to the CAL addresses causes for the medical events and regulatory violations that are related to procedures and training. Other causes specific to the potential violations are discussed above or in the NRC and NHPP inspection reports.

b. The primary corrective actions were to suspend patient treatments using prostate seed implants and/or to implement VHA standard procedures. VHA notes that NRC has generally agreed that corrective actions for the apparent violations were incorporated into VHA standard procedures. However, pending outcomes for this NRC report, VHA plans to review the standard procedures to determine if any additions or corrections are appropriate to ensure the prescriptive requirements being established in this report are addressed in facility level written procedures.

Acronyms

CAL	Nuclear Regulatory Commission Confirmatory Action Letter
CFR	Code of Federal Regulations
MML	Master Materials License
NHPP	National Health Physics Program
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
RSO	Radiation Safety Officer
VHA	Veterans Health Administration

Enclosure 2 - Response for Concerns

1. Concerns related to National Radiation Safety Committee (NRSC) oversight.

a. The concerns related to NRSC oversight are accepted ; however, VHA wants to work with NRC to improve communications related to any NRC requests to individual facilities to enhance the ability of NRSC and NHPP to provide technical guidance and support. Such improved communications should minimize potential misunderstandings related to NRC data or information requirements.

b. NRSC functions as a senior level committee to provide oversight for the NHPP and functions under a committee charter and delegation of authority.

(1) NHPP completes day-to-day actions under NRSC aegis and interacts frequently with the committee chair, alternate chairs, and national program directors for nuclear medicine and radiation oncology. The interactions include group meetings, conference calls, and e-mail updates.

(2) NRSC holds quarterly meetings for NHPP to provide summary updates about significant program results and includes agenda items for security, status of the master materials license, and results for core performance indicators. Unresolved issues are assigned a tracking number and tracked to completion. Advance meeting handouts are used to help streamline meeting discussions by providing detailed information for review in advance.

(3) NRSC establishes working groups for more detailed reviews. These include a working group each year to review program assessment results and working groups to review allegation circumstances. For medical events related to prostate seed implants, a working group was initiated in August 2008. This working group included the chair, two alternate chairs, physician authorized users, and a medical physicist. The working group has been provided more than 100 updates since August 2008.

Enclosure 2 - Response for Concerns

(4) NRSC reviews and approves (or disapproves) escalated enforcement citations by NHPP. NHPP provides an update to the NRSC chair before escalated enforcement citations are issued and resolves any questions or comments with the chair before the inspection report is signed.

(5) NRSC does not normally direct specific corrective actions an individual facility takes in response to medical events and program deficiencies but rather through the inspection process tracks the effectiveness of corrective actions and, if necessary, provides the facility feedback or requires additional corrective actions to be completed.

(6) For future significant programmatic weakness, NRSC plans to evaluate facility capacity for corrective actions from the perspective of program oversight, technical expertise, and staffing to determine if detailed intervention is appropriate by either the NRSC or NHPP. As needed, NRSC will make appropriate recommendations to the Under Secretary for Health related to the direct decision-making, staff assignments, and allocation of resources that are not normally addressed by NRSC. NRSC also has the option to use enforcement tools such as to issue an order or Confirmatory Action Letter.

c. For the Philadelphia data request from NRC, NRSC was not aware of a regulatory basis for the data that was requested and was not tracking submission of data for the NRC other than updates for 15-day written reports.

(1) NRSC has a role to monitor the adequacy of a facility response to a regulatory request but not to interfere with the interactions between the facility and NRC.

(2) At the exit briefing for the NRC visit in June 2009, a milestone was established with NRC by NHPP and the facility to provide revised data by August 7, 2009. This milestone was achieved.

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(3) Approximately one month after the data submission, Philadelphia staff became aware of possible errors in the dose calculations. The error was based on incorrect identification of seeds in the calculation process. NHPP immediately informed NRC and a milestone to resubmit the data was set for October 19, 2009. This milestone was achieved.

(4) The expected interactions among NRC, facility staff, and NHPP are an issue to be clarified and require a higher level of communications between NRC and NHPP.

d. Circa January 2009, Michael P. Hagan, M.D., Ph.D., was appointed as Director, National Radiation Oncology Program. Dr. Hagan, in this new position, was approved as a NRSC member. As an authorized user at a VHA facility performing prostate seed implants and a clinical expert, Dr. Hagan provided guidelines to NRSC, NHPP, and all VHA facilities performing prostate seed implants. Dr. Hagan provided subject matter expertise to Philadelphia for the data submissions to NRC.

e. NRSC actions for the medical events related to prostate seed implants included, but were not limited to, the following.

(1) Initial on-site audits for current seed implant programs. These were initiated in August 2008 and completed in January 2009 as reactive inspections under the NRC Confirmatory Action Letter. These initial audits were followed by NHPP being tasked by NRSC to complete annual inspections for prostate seed implants.

(2) Development of an audit checklist for NHPP and facility use in evaluating the prostate seed implant programs.

(3) Establishment of a NRSC Working Group for oversight. NHPP provided frequent updates to the working group about inspection results, medical events, NRC initiatives,

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and corrective actions. The working group has committee members and other subject matter experts such as a medical physicist expert in prostate brachytherapy.

(4) Assigning a NRSC tracking item. The medical events for prostate seed implant were discussed in detail at the meeting on August 6, 2008, with updates provided at quarterly meetings since that date under the tracking item.

(5) Approving CAL related procedures, criteria, and root cause analysis. These included approval for standard procedures for prostate seed implants, prostate seed implant program start and restart criteria, program suspend criteria, and a root cause analysis for medical events.

(6) Approving escalated enforcement for Philadelphia. The enforcement action was approved on November 13, 2008, and represented prompt response to the Philadelphia circumstances.

(7) Completing other actions such as endorsing recommendations from a "Blue Ribbon Panel" of medical experts for revised medical event criteria for a target-site metric based on dose by activity rather than dose by D90. The activity metric is yet to be implemented by VHA.

2. Concerns related to NHPP inspection process.

a. The concerns are not accepted. Clarifying comments are provided below.

b. VHA acknowledges NHPP inspections missed opportunities to identify medical events and program deficiencies during earlier routine inspections at VHA facilities. NHPP had a focus to compliance with specific regulatory requirements and did not evaluate results for post treatment dose analysis.

Enclosure 2 - Response for Concerns

c. VHA did self-identify the medical events at Philadelphia and other VHA facilities based on retrospective reviews of previously completed prostate seed implants.

d. The NRC precedent for regulatory citations for written procedures has generally been not to cite violations for inadequate written procedures unless a medical event had occurred. Many VHA facilities for which the NRC inspection report identified apparent violations or examples of apparent violations have not reported medical events since the index case at Philadelphia was identified in May 2008.

e. VHA notes root causes for NHPP inspection results to be inadequate inspection procedures. The NHPP inspection procedures did not require inspectors specifically to review post treatment dose analysis results or evaluate written procedures.

f. Corrective actions already taken include:

(1) Development and use of a detailed audit checklist by NHPP for inspections of prostate seed implant programs. The checklist was first used during August 2008 and has been revised frequently to incorporate NRC feedback. The most recent revision is dated February 12, 2010.

(2) Development and implementation of VHA standard procedures for prostate seed implants requiring post treatment dose analysis.

(3) Completion of a national radiation oncology conference for VHA facilities in early January 2009 that included attendance by both facility staff and NHPP inspectors.

g. Future corrective actions include revisions to NHPP inspection procedures and the audit checklist to incorporate:

(1) Revisions to NRC inspection procedures,

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(2) Results from NRC “lessons learned” related to prostate seed implant inspections and licensing actions by NRC,

(3) Observations by NRC during accompaniments for NHPP inspections, and

(4) Observations by NHPP during accompaniments for NRC inspections such as the NRC feedback to NHPP during a facility inspection during June 9-11, 2010.

3. Concerns related to NHPP enforcement process.

a. The concerns are not accepted except for the concern about the severity level of the NHPP violation cited for Philadelphia.

b. VHA does agree that the NHPP inspection report which cited a Severity Level III violation should have cited the violation at Severity Level II to be consistent with NRC Enforcement Policy.

c. NHPP developed an enforcement worksheet to complete before issuing escalated enforcement actions. The worksheet is used to document review of NRC enforcement actions and policy, past inspection results for both NRC and NHPP, and NRSC SOP #3 to establish a basis for the enforcement decision.

d. NHPP provides an update to the NRSC chair before escalated enforcement citations are issued and resolves any questions or comments with the chair before the inspection report is signed. NRSC reviews and approves (or disapproves) escalated enforcement citations by NHPP at quarterly meetings.

e. For a facility response to an inspection, VHA requires agreement with corrective actions and future actions but does not specifically demand that a facility agree with the regulatory violations.

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(1) NRC regulations do not specifically require agreement with inspection results by the facility that was inspected.

(2) An overly restrictive approach to a possible facility response is likely to result in a chilling effect on the facility and might preclude meaningful feedback from the facility.

(3) The authority delegated to NRSC and NHPP is more than sufficient to require specific corrective actions.

4. Concerns related to NHPP technical assistance request process.

a. The concerns are not accepted.

b. VHA facilities had the option to request NHPP assistance in different formats such as telephone calls, e-mail, and formal correspondence since even before the master materials license was issued.

c. The NHPP Intranet Web site has included a button for facilities to use to submit an e-mail question or request. The message group for this e-mail included the NHPP Director and Administrative Officer, among others, to ensure requests are screened and responded to expeditiously.

d. During November 2009, NHPP redesigned the homepage for the Intranet Web site to provide a clearer and more detailed set of options for facilities to use to submit a technical or other question by e-mail. The message group for any technical questions includes the NHPP Director. This homepage includes links to various NHPP resources and the NRC Web site.

e. *NHPP Scatterings* (July/August 2010) that was issued on July 8, 2010, has an article to restate methods for facilities to request technical assistance.

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f. The NRC inspection report outlines the NHPP methods to respond to a request for technical assistance.

g. When the NHPP mission became more focused to regulatory compliance and with issuing of the master materials license, VHA established a Radiation Safety Center for Inquiry (RSCI) as an educational and consultative resource.

(1) RSCI is staffed by eight facility Radiation Safety Officers who have demonstrated their expertise in health physics at their respective facilities and volunteered to provide assistance to other VHA facilities.

(2) The RSCI volunteers are geographically dispersed and are prepared to answer questions about radiation safety and regulatory compliance.

(3) RSCI provides assistance by telephone calls and e-mail. RSCI meets quarterly to discuss a broad spectrum of issues in radiation safety, regulatory compliance, best practices and address questions raised by the field.

(4) Recently RSCI has assisted the National Program Director, Nuclear Medicine Service, in selecting topics for presentation/discussion for web-based RSO education conferences. The first of these conferences focused on the prescriptive reporting requirements for Radiation Safety Committees that was followed by RSCI members responding to radiation safety and regulatory compliance questions from field-based Radiation Safety Officers.

h. The National Program Director, Nuclear Medicine Service, office is an additional resource in radiation safety for VHA facilities. The office has an Intranet Web page for facilities to use to obtain information and updates at the following address.

<http://vaww1.va.gov/nuclearmedicineservice/page.cfm?pg=95>

Enclosure 2 - Response for Concerns

i. For the Philadelphia questions related to prostate seed implants and evaluation of medical events, any delay in NHPP response was related to the complexity of the issue and not to a lack of a procedural process for requesting technical assistance.

5. Concerns related to NHPP involvement with connectivity issues.

a. The concerns are not accepted.

b. VHA completed a review to identify information technology system vulnerabilities that might have contributed to discontinuation of brachytherapy post-treatment activities at VHA facilities and to recommend solutions. This review was initiated in November 2008 and completed in December 2008 as an early effort to evaluate possible connectivity issues.

(1) The review included an on-site visit to Philadelphia and data collection from other facilities including Jackson and Reno.

(2) The review concluded that the reported loss of connectivity was not a principal cause for lack of post treatment dose analysis at any of the facilities that were reviewed.

(3) The review did identify vulnerabilities that contributed to delays in the correction of information technology-related problems such as network connectivity.

c. NHPP identified connectivity issues at Jackson in a telephone call with a medical physicist at the facility in mid-September 2008, before NRC was on-site in October 2008.

(1) NHPP promptly contacted the facility Chief of Staff with a resulting agreement that the facility was to suspend prostate seed implant treatments.

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(2) NHPP monitored facility efforts to complete post treatment dose analysis.

d. NHPP identified connectivity issues at Reno in October 2008, when the prostate seed implant program was inactive and before NRC was on-site in January 2009.

(1) NHPP promptly notified the facility executive management and requested details on the scope of the deficiency.

(2) NHPP monitored facility efforts to complete post treatment dose analysis.

e. VHA understands the significance of a facility completing post treatment dose analysis and the facility responsibility either to complete the dose analysis or cease patient treatments until regulatory compliance can be achieved.

f. VHA does not agree that NHPP has a specific role to resolve day-to-day program challenges at the facility level. Rather, NHPP, as does NRC, has a regulatory oversight role and uses an outcome based inspection approach to identify unacceptable results such as failure to complete post treatment dose analysis, to verify actions are promptly taken to correct the deficiency, and to confirm the actions are effective.

g. VHA notes that NHPP inspections before August 2008 did not have an adequate focus to post treatment dose analysis. A review of outcomes related to post treatment dose analysis would likely have identified connectivity issues at an earlier date.

h. The NHPP audit checklist that was established in August 2008 required a more detailed review of prostate seed implant programs and post treatment dose analysis. The checklist has been updated to include review for implementation of VHA standard procedures.

Enclosure 2 - Response for Concerns

i. The previously reported connectivity issues at VHA facilities have been resolved and post treatment dose analysis is routinely completed.

6. Concerns related to completion of actions for Confirmatory Action Letter (CAL).

a. The concerns are not accepted.

b. The inspections required under the CAL were for “active seed programs.” For Jackson, the prostate seed implant program was suspended circa September 18, 2008, which was before the NHPP commitments to NRC in a letter dated October 12, 2008, and before the date the CAL was issued on October 14, 2008.

c. NHPP did complete an on-site reactive inspection at Jackson on October 8-10, 2008, and a return visit on June 28-29, 2010. VHA agrees that this inspection should be completed as soon as possible.

d. The NHPP inspection has remained open to provide an opportunity to complete an external review of the previous prostate seed implant treatments to determine if any additional medical events should be reported. The prostate seed implant program has remained suspended and restart is not expected.

e. After the NRSC meeting in August 2008, NHPP developed a schedule for on-site visits at each prostate seed implant program.

(1) These site visits were initiated in August 2008 and three were completed before the CAL was issued.

(2) NHPP used a newly developed audit checklist at each facility to ensure that the full range of prostate seed implant issues were evaluated. The audit checklist was used

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at the other NHPP visits to prostate seed implant programs after the CAL. These other visits were termed reactive inspections to be consistent with the wording in the CAL.

(3) NHPP provided updates to NRC on results for inspections required under the CAL and used the initial site visit results which were completed before the CAL was issued to document completion of CAL requirements.

Enclosure 3 - Response for Potential Violations

1. Potential violation related to semi-annual inventories.

a. The potential violation is accepted.

b. This violation occurred at VA Medical Center, Cincinnati, and was first identified by NHPP during a reactive inspection in October 2008. NHPP identified the violation to the NRC inspector who was observing the NHPP inspection.

c. NHPP completed a second on-site visit to the medical center in July 2009 and confirmed corrective actions for the violation.

d. The cause for the violation was misunderstanding by the Radiation Safety Officer about whether seeds in storage for decay should be considered as radioactive waste or as sealed sources required to be inventoried per 10 CFR 35.67(g).

2. Potential violation related to information in a 15-day written report.

a. The potential violation is accepted.

b. This violation occurred at VA New York Harbor Healthcare System, Brooklyn, and was identified by NRC during a reactive inspection in February 2009.

c. The cause for the medical event was likely related to "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.

(1) An alternate possible cause or contributing factor was that the "work direction, preparation, needs improvement," in that the authorized user physician omitted a step in the motor skills necessary for proper seed placement.

Enclosure 3 - Response for Potential Violations

(2) The authorized user physician identified corrective actions to ensure preparation for the procedures such that all steps are completed in proper sequence for placement of seeds addresses both of the root causes.

d. The 15-day written report indicated that incorrect seed placement had occurred for which a specific causal factor was not identified. The causes above are judgments by the NHPP inspectors but are not clearly established.

e. Rather than the NRC statement about root causes as being lack of familiarity, the VHA concluded the physician was reluctant to identify a root cause that did not appear to be valid based on his clinical and regulatory review of what had occurred during the patient treatment.

3. Example of potential violation related to failure to record dose on written directives.

a. The potential violation is accepted.

b. This violation occurred at VA Sierra Nevada Health Care System, Reno, and was first identified by NRC during a reactive inspection in January 2009. NHPP identified a similar violation during an inspection in May 2010.

c. The cause for the violation was failure to follow health care system procedures by the physician authorized user.

d. The prostate seed implant program at this health care system is currently inactive and must undergo a restart process and implementation of VHA standard procedures to begin patient treatments. The restart process will confirm the corrective actions for the violation.

Enclosure 3 - Response for Potential Violations

4. Example of potential violation related to failure to record dose on written directives.

a. The potential violation is not accepted.

b. The potential violation occurred at Samuel S. Stratton VA Medical Center, Albany, and was identified by NRC during a reactive inspection in February 2009.

c. The NRC report states "...some Written Directives that did not include a record of the total dose after implantation, but before completion of the procedure."

d. 10 CFR 35.40(b)(6)(ii) states "that after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources and total source strength and exposure time (or total dose)."

e. The medical center included the isotope, source strength, treatment site, number of sources and total strength (total activity) and asserts that dose to the prostate cannot be determined at this point in the patient procedure. In addition, the exposure time was specified by the terminology "permanent" in the written directive.

f. VHA agrees with the medical center interpretation that records and methods used were compliant with 10 CFR 35.40(b)(6)(ii).

5. Root causes and corrective actions.

a. The description of root or basic causes in the VHA root cause analysis addresses the general causes which are related to procedures and training.

b. The required actions and steps for implementation of VHA standard procedures are adequate and sufficient to address the potential violations.

Enclosure 4 - VHA Future Actions for Master Materials License

Current and ongoing

1. Continued implementation of VHA standard procedures and annual inspections at prostate seed implant programs with adjusted procedures and inspection frequencies as approved by NRSC and warranted by inspection results with updates to procedures and methods within 60 days after significant programmatic findings.
2. Dissemination of regulatory program information by e-mail user groups, newsletters, frequently asked questions, and conference calls to user and management groups with availability of technical assistance for inquiries from facilities. Include conference calls using Radiation Safety Center for Inquiry and national program directors for radiation oncology, nuclear medicine, and diagnostics.
3. Reviewing facility level focus to a safety conscious work environment during routine inspections to ensure current NRC guidelines are followed and monitoring development of NRC policy statement on safety culture for incorporation into facility level programs.
4. Continued comprehensive NRSC oversight for any significant programmatic issues.
 - a. Identify significant issues using core performance indicators and evaluate results for possible trends or generic issues to include appropriate actions required to prevent recurrence and to monitor effectiveness of the actions.
 - b. Identify issues for incorporation into the committee tracking matrix, track those issues to resolution, and validate effectiveness of resolution.
 - c. Review significant issues for corrective actions for VHA-wide implementation.
 - d. Use NRSC member expertise, especially national program directors for radiation oncology and nuclear medicine, to provide technical guidelines and assistance.

Enclosure 4 - VHA Future Actions for Master Materials License

e. Evaluate facility capacity for corrective actions, for significant program issues, from the perspective of program oversight, technical expertise, and staffing to determine if detailed intervention is appropriate by either the NHPP, NRSC, or national program directors.

f. Increase committee member participation and discussions at quarterly meetings to include technical and update presentations by working group members, subject matter experts, and other committee members.

5. Updates to the NHPP generic inspection plan to include current issues such as the executive management oversight, possible undue reliance on affiliates or consultants, and continuous RSO coverage.

6. Continued focus to security during inspections and emphasis for NHPP support of the facilities under the current NRC order for increased controls for larger activity sealed sources.

Situational, circumstances specific

7. Revisions or adjustments to VHA standard procedures, training, and verification of implementation for any future changes for 10 CFR 35.

8. Completion of start or restart process for any facilities that might initiate or restart a prostate seed implant program.

9. Use of NHPP enforcement worksheet to document basis for future violations cited as escalated enforcement.

10. Benchmarking to NRC revisions to inspection procedures related to prostate seed implant programs and other programmatic changes or revisions by NRC.

Enclosure 4 - VHA Future Actions for Master Materials License

11. Benchmarking to NRC observations during accompaniments for NHPP inspectors and observations during NHPP accompaniments for NRC inspectors with revisions to methods, procedures, or training, if needed.

Target date July 15, 2010

12. Implementation of prescriptive requirements for the facility level Radiation Safety Committees to increase documentation, timeliness, and executive management review of committee results.

Target date October 1, 2010

13. Seeking agreement with NRC for adjustments to coordination and communication with NRSC and NHPP during NRC ongoing facility level inspections.

Target date December 1, 2010

14. Review of NHPP resources to determine adequacy to complete requirements for the implementation of the master materials license and to provide technical guidance and consultation when requested by facilities.

Target date May 2011 (or 90 days after NRC policy statement issued)

15. Development of implementation strategy for NRC policy statement on safety culture and support for facility level implementation.

Target date October 2011 (or within timeframe specified by rulemaking)

16. Implementation of 10 CFR Part 37 when issued.

Enclosure 4 - VHA Future Actions for Master Materials License

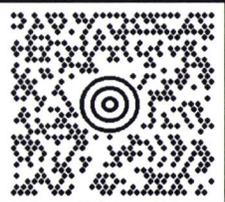
Acronyms

CFR	Code of Federal Regulations
NHPP	National Health Physics Program
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
VHA	Veterans Health Administration

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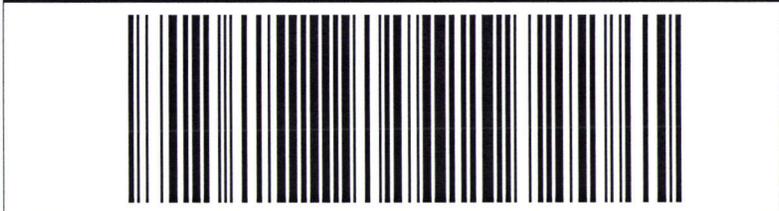
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