March 17, 2010

EA-09-038

Robert A. Petzel, M. D.,
Under Secretary for Health
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY – $227,500; NRC INSPECTION REPORT NOS. 030-34325/2008-029 AND 2009-001(DNMS) – DEPARMENT OF VETERANS AFFAIRS MEDICAL CENTER, PHILADELPHIA, PA

Dear Dr. Petzel:

This letter refers to the inspections conducted on July 23 to 25 and September 9 to 12, 2008, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through February 9, 2009, and subsequent inspections conducted on June 22 to 26, August 27 to 28 and October 14 to 16, 2009, at the Department of Veterans Affairs (DVA), Philadelphia Veterans Affairs Medical Center (PVAMC or permittee). The purpose of the inspections was to review the facts, circumstances, root and contributing causes, and proposed corrective actions regarding numerous medical events, which occurred between February 25, 2002, and June 5, 2008, and to determine whether activities authorized at PVMAC, as a permittee under the Master Materials License (MML) issued to the DVA by the NRC, were conducted safely and in accordance with NRC requirements. Throughout the inspection, and specifically during the final exit meeting, conducted by telephone on November 2, 2009, the NRC discussed the circumstances of the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions. Details regarding the apparent violations were provided in NRC Inspection Report Nos. 030-34325/2008-029(DNMS) dated March 30, 2009, and 030-34325/2009-001(DNMS) dated November 17, 2009.

On December 17, 2009, a Predecisional Enforcement Conference was conducted at the NRC's headquarters office in Rockville, Maryland, to discuss the apparent violations, their significance, their root causes, and the DVA's corrective actions. Representatives from the National Radiation Safety Committee, the DVA, the National Health Physics Program (NHPP), and the permittee were in attendance. During the conference, the DVA conference attendees informed the NRC that the DVA did not agree with and did not accept seven of the eight apparent violations. The NRC requested that the DVA document the basis for disagreeing with the violations and provide any additional information to support that basis. On January 14, 2010, the DVA provided a written response (ML100150326). This response stated that after further consideration, the DVA accepted all of the apparent violations; however, the DVA requested consideration of additional information provided in the response. The NRC has considered the additional information as described below.

Based on the information developed during the inspections and the information that was provided during and following the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection reports.

The NRC considered the information presented by the DVA during the conference as to the number of medical events that occurred. This information was also documented in the January 14, 2010, letter. On January 28, 2010, the DVA submitted a proposal to retract approximately three-fourths of the reported medical events based on a review performed by an external panel. The NRC has reviewed the January 28, 2010, letter and the criteria applied by the DVA for determining whether a medical event occurred, and has determined that the criteria applied by the DVA do not conform to the current regulatory definition of a medical event in Title 10 of the Code of Federal Regulations (10 CFR) 35.2, which references 10 CFR 35.3045(a) or (b). If the DVA desires to deviate from the NRC's regulations, it must file an exemption request pursuant to the requirements of 10 CFR 35.19. Alternatively, if the DVA wishes to request the Commission to change the definition of a medical event, the DVA may file a petition for rulemaking pursuant to 10 CFR 2.802. Accordingly, based on current NRC regulations and requirements, the staff rejects your position regarding medical event retraction as described in the January 28, 2010, letter.

The DVA reported that 97 medical events occurred at PVAMC from February 2002 through May 2008. The NRC determined that most of the medical events are examples of a failure to comply with 10 CFR 35.41(a)(2). Because some of the medical events occurred outside of the statute of limitations applicable to NRC enforcement actions, not all were considered for a civil penalty[1]. Accordingly, the medical events are cited in two separate violations (Violation A.1 and Violation B.1) to differentiate those that may be assessed a civil penalty from those that are not subject to a civil penalty. Those medical events not subject to NRC civil penalties are cited in Violation B.1, while the remaining majority of medical events, for which a civil penalty was considered, are cited in Violation A.1.

In regard to both Violations A.1 and B.1, the NRC determined that the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive, contrary to the requirements of 10 CFR 35.41(a)(2). The NRC determined that a substantial programmatic breakdown had occurred in the PVAMC prostate implant brachytherapy program. The violations are of significant concern to the NRC because of the number of the medical events, the potential consequences to the veterans who came to the PVAMC for treatment, the lack of management oversight, and the lack of a safety culture to ensure adequate administration of radioactive

[1] Title 28 of U.S. Code, Section 2462, "Time for Commencing Proceedings," applies to NRC enforcement actions and requires, in part, that the NRC propose any civil penalty within five years of the date of the violation. In a letter dated October 22, 2009, the NRC requested DVA waive the five-year statute of limitations for civil penalties applicable to violations occurring on dates that had not already been barred from civil penalty consideration. In its letter dated November 6, 2009, the DVA agreed to the waiver. The combined effect of the statute and the DVA's waiver was to bar the NRC from proposing a civil penalty for violations that occurred prior to November 5, 2004.

material to patients. The NRC determined that one of the causes of the substantial programmatic breakdown was a culture where poor decisions were not challenged and both employees and contractors assumed that the responsibility for a safe and adequate program belonged elsewhere. Therefore, the NRC categorized each of these violations, in accordance with the NRC Enforcement Policy, at Severity Level II.

Violation A.2 in the enclosed Notice involved at least 16 instances where post-treatment verification was delayed (and in some cases not done) because the licensee did not have procedures that provided alternate methods for post-treatment verification when the normal verification method was unavailable. For the majority of 2007, the permittee's staff was aware of an existing interface problem that prevented normal transfer of the computerized tomography images taken the day after treatment to the treatment planning computer. As a result of that problem, the PVAMC staff, including contract staff, either did not perform, or delayed performing, verifications to ensure that treatments occurred as planned. Even after the interface problem was resolved, verifications were not done in a timely manner. In the end, post-treatment verifications were not performed for seven patients, because the patient computerized tomography files could not be recovered. The failure to perform verifications in a timely manner also represented a substantial programmatic breakdown in the PVAMC prostate implant brachytherapy program. This violation is also of significant concern to the NRC because the PVAMC staff was aware of the interface problems and delayed taking steps to correct them, or to implement an alternative method, while continuing to perform brachytherapy implants. Therefore, the NRC categorized this violation, in accordance with the NRC Enforcement Policy, at Severity Level II.

Violation A.3 involved a single failure where the wrong dose seeds were ordered and implanted, leading to a medical event. The licensee's procedures did not address verification that the treatment plan agreed with the written directive. This violation is of concern to the NRC because it was indicative of a programmatic weakness in the way that seeds were ordered and verified prior to implanting that resulted in a medical event. Therefore, the NRC categorized this violation at Severity Level III. In its January 14, 2010, letter, the DVA requested that the NRC consider combining Violations A.2 and A.3, because both involved violations of 10 CFR 35.41(b)(2). Consistent with its Enforcement Policy, the NRC will normally consider combining similar violations into a single problem when the violations stem from the same root cause. In this case, however, the NRC determined that although the underlying cause for all the violations was a systematic lack of safety culture at the PVAMC, the principal root causes for Violation A.2 and Violation A.3 were different: the principal root cause of Violation A.2 appeared to be a sense of complacency on the part of PVAMC staff and contractors that there was no urgency to repair the computer interface problem, whereas the principal root cause of Violation A.3 appeared to be a failure on the part of multiple individuals to detect that the radioactive seeds specified in a pre-treatment plan differed from the activity of radioactive seeds routinely ordered for brachytherapy procedures at the PVAMC facility.

Violations A.4 and A.5 involved lack of training for one of the authorized users and for the three physicists involved in the brachytherapy program. The NRC noted that during the December 17, 2009, Predecisional Enforcement Conference, the DVA stated that training had been provided. The NRC explicitly requested at the conference for the DVA to provide to the NRC the evidence to support this claim; however, no new documents were submitted to the NRC with the January 14, 2010 letter. While stating that the PVAMC had identified some

limited training documentation for various staff but that the DVA was not offering those records as adequate and sufficient objective evidence that training was completed as normally expected for a radiation safety program, your staff continued to state that additional training documents had been discovered beyond those submitted to the NRC on March 17, 2009, and would be available to the NRC, if requested. As the NRC had made a specific request during the conference and no documents were provided, the NRC concluded that this violation was valid. The NRC also determined that, although involving two different requirements, 10 CFR 35.27(a)(1) and 10 CFR 19.12(a)(4), it was appropriate to group these violations as a single Severity Level III problem, because the NRC deemed the lack of training to be attributable to a single root cause regarding lack of oversight of contractor staff. The lack of training is of concern to the NRC because it contributed to PVAMC staff and contractors not recognizing or reporting medical events.

Violation A.6 involved the failure to notify the NRC by the next calendar day after discovery of a medical event, as required by 10 CFR 35.3045(c). As stated in Inspection Report No. 030-34325/2009-001(DNMS), the NRC has determined that there was sufficient information available to the permittee at the completion of the prostate treatments to make a determination that a medical event occurred. The NRC determined that the root cause of the failure to report appeared to be a lack of contractor staff understanding of their reporting chain combined with a lack of oversight by PVAMC personnel. The failure to report the events is of concern to the NRC because it delayed the NRC's ability to respond to the medical events in a timely fashion. Therefore, this violation was categorized at Severity Level III.

The NRC also determined that two violations of lesser significance occurred. Violation B.2 describes a single instance where a written directive was not completed, contrary to the requirements of 10 CFR 35.40(b)(6)(ii). Because this was an isolated occurrence and because the lack of signatures did not affect the results for this particular case, the NRC categorized this violation at Severity Level IV. Finally, Violation B.3 describes incomplete 15-day reports being provided to the NRC, contrary to the requirements of 10 CFR 30.9(a). Although the incomplete information was material to the NRC, a more significant sanction was not warranted because the information did not significantly alter actions the NRC would have taken at the time if the information was complete and did not impact the NRC's ability to perform independent inspections or other aspects of its regulatory process. Therefore, this violation was also categorized, in accordance with the NRC Enforcement Policy, at Severity Level IV. Both these violations are being cited because they were identified by the NRC. The NRC noted that the January 14, 2010, letter from the DVA did not agree that these violations constituted escalated enforcement. The NRC took the information provided by the DVA into its assessment of the significance of these two violations and agreed that escalated enforcement was not warranted.

As documented above, numerous root and contributing causes were identified by the NRC for many of these violations. The NRC independently assessed the overall root cause of the violations and determined that there was a lack of management oversight and a lack of a safety culture at the PVAMC. Specifically, there was inadequate management oversight of the prostate brachytherapy program by the Radiation Safety Officer and the Radiation Safety Committee. The authorized users, medical physicists, and radiation safety staff accepted a substandard approach to brachytherapy treatments, which resulted in poor implant techniques,

a patient dose assessment process that lacked rigor and formality, a failure to communicate concerns about the implants, a misperception that safety checks were performed by other team members, and an overall system that did not demonstrate a commitment to safety.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $10,400 is considered for each Severity Level II violation and of $6,500 for each Severity Level III violation. Because some of the violations were assessed at Severity Level II, and because this was not the first escalated enforcement action for the DVA within the last two years,[2] the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The NRC recognizes that the PVAMC identified the event where the wrong dose seeds were ordered and implanted and that the NHPP immediately began an investigation which led to 97 medical events being reported. Further, the NHPP issued an inspection report on October 16, 2008, which identified violations against many of the same requirements as the NRC is citing. However, the NRC determined that credit was not warranted for *Identification* because substantial intercession by the NRC was necessary to ensure that all the medical events were adequately reviewed and assessed and that the substantial programmatic concerns were identified and corrected. The NRC determined that the corrective actions taken by the DVA were sufficient to meet regulatory requirements and thus warrant *Corrective Action* credit. As an immediate corrective action, the DVA suspended the PVAMC prostate brachytherapy program on June 11, 2008, and ordered an external review be performed. The DVA took numerous corrective actions to assess the potential extent of these issues throughout the DVA facilities and to prevent recurrence of the violations, as outlined in Inspection Report Nos. 030-34325/2008-029(DNMS) and 030-34325/2009-001(DNMS).

The NRC has the authority, under Section VII.A.1.c. of the Enforcement Policy, to use discretion to either escalate or mitigate the civil penalty. In this case, the NRC determined that escalation of the civil penalty was warranted due to the PVAMC's particularly poor performance over the course of multiple years, which led to a significant number of medical events occurring, without being identified, reported or corrected. Therefore, after consultation with the Director of the Office of Enforcement, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $227,500. This civil penalty is assessed based on the maximum civil penalty allowed by statute[3] for Severity Level II violations ($104,000 each) and the base civil penalty for SL III violations ($6,500 each). In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

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[2] The NRC issued a SL III violation with proposed civil penalty of $6500 on April 10, 2009, to the DVA based on actions at the Iowa City Medical Center (EA-08-353). The NRC imposed the civil penalty in an Order dated August 14, 2009.

[3] The statutory maximum of civil penalties to be imposed is described in the Enforcement Policy and is based on the period in time over which the violations occurred. This amount is periodically adjusted for inflation. The Enforcement Policy was last adjusted for inflation on November 28, 2008. The previous adjustment occurred on October 26, 2004. As the time period for the violations cited in the violations assessed a civil penalty was from November 2004 to May 2008, the 2004 adjusted values are used.

You are required to respond to the enclosed Notice and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you should provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/.

Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 37-00062-07

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/Enclosure 1:
1. State of Pennsylvania
2. Gary Williams, Interim Director, National Health Physics Program
3. Richard Citron, Medical Center Director - VA Philadelphia Medical Center

Letter to Robert A. Petzel from Mark A. Satorius dated March 17, 2010

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $227,500; NRC INSPECTION REPORT NOS. 030-34325/2008-029 AND 2009-001(DNMS) – DEPARMENT OF VETERANS AFFAIRS MEDICAL CENTER, PHILADELPHIA, PA

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NOTICE OF VIOLATION

AND

PROPOSED IMPOSITION OF CIVIL PENALTY

Department of Veterans Affairs
North Little Rock, Arkansas

Docket No. 030-34325
License No. 03-23853-01VA
EA-09-038

During U.S. Nuclear Regulatory Commission (NRC) inspections at the Department of Veterans Affairs (licensee), Philadelphia Veterans Affairs Medical Center, conducted on July 23 to 25 and September 9 to 12, 2008, with continued NRC in-office review through February 9, 2009, and inspections conducted on June 22 to 26, August 27 to 28 and October 14 to 16, 2009, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. Violations Assessed a Civil Penalty

1. Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a)(2) requires that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

   Contrary to the above, between November 6, 2004, and May 12, 2008, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, Procedure MCM 00-76, "Sealed Source Radiotherapy," dated March 8, 2006, which was previously issued as Procedure MCM 11-17, "Sealed Source Radiotherapy," on October 3, 2002, did not require that the dose to the treatment site be verified to ensure that the administered dose was in accordance with the written directive. This resulted in at least 54 prostate brachytherapy treatments being administered where the administered dose was not in accordance with the written directive.

   This is a Severity Level II violation (Supplement VI)
   Civil Penalty - $104,000

2. Title 10 CFR 35.41(b)(2), requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

   Contrary to the above, between November 2006 and December 2007, the licensee's procedure did not address verifying that the administration was in accordance with the applicable treatment plan and written directive. Specifically, Procedure MCM 00-76, titled "Sealed Source Radiotherapy," dated March 8, 2006, did not address alternate

methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. This resulted in the licensee administering at least 16 prostate brachytherapy treatments from November 2006 through December 2007 without performing post-treatment verifications until December 2007 or January 2008.

This is a Severity Level II violation (Supplement VI)
Civil Penalty - $104,000

3. Title 10 CFR.41(b)(2) requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

   Contrary to the above, on May 5, 2008, the licensee's procedures did not address verifying that the administration was in accordance with the applicable treatment plan and written directive. Specifically, Procedure MCM 00-76, titled "Sealed Source Radiotherapy," dated March 8, 2006, did not address reviewing both the applicable treatment plan and the written directive. This resulted in the licensee failing to identify that the treatment plan for a brachytherapy treatment administered on May 5, 2008, differed from the written directive, resulting in the wrong dose seeds being ordered and implanted.

   This is a Severity Level III violation (Supplement VI)
   Civil Penalty - $6,500

4. Title 10 CFR 35.27(a)(1) requires, in part, that in addition to the requirements in 10 CFR 19.12, the licensee instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of 10 CFR Part 35, and license conditions with respect to the use of byproduct material.

   Contrary to the above, from November 2004 to September 2008, two medical physicists, who were supervised individuals, were not instructed on the requirements for identifying and reporting a medical event as required by 10 CFR 35.2 and 10 CFR 35.3045.

5. Title 10 CFR 19.12(a)(4) requires, in part, that all individuals who are likely to receive in a year an occupational dose in excess of 100 millirem, be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses.

   Contrary to the above, from November 2004 to September 2008, an authorized user physician who received an occupational dose in excess of 100 millirem in each year from 2005 to 2008, was not instructed on his responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations.

   Violations 4 and 5 constitute a Severity Level III problem (Supplement VI)
   Civil Penalty - $6,500

6. Title 10 CFR 35.3045(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.

   Contrary to the above, the licensee failed to report by telephone to the NRC Operations Center no later than the next calendar day when they had information that medical events had occurred between November 15, 2004, through May 12, 2008.

   This is a Severity Level III violation (Supplement VI)
   Civil Penalty - $6,500

Total civil penalty - $227,500.

B. Violations Not Assessed a Civil Penalty

1. Title 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

   Contrary to the above, between February 25, 2002, and November 6, 2004, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, Procedure MCM 11-17, "Sealed Source Radiotherapy," dated October 3, 2002, with previous revision dated December 2, 1999, did not require that the dose to the treatment site be verified to ensure that the administered dose was in accordance with the written directive. This resulted in at least 20 prostate brachytherapy treatments being administered where the administered dose was not in accordance with the written directive.

   This is a Severity Level II violation (Supplement VI)
   (Civil penalty not assessed due to the statute of limitations)

2. Title 10 CFR 35.40(b)(6)(ii) requires, in part, that the written directive specify, 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).

   Contrary to the above, a written directive dated May 5, 2008, did not contain the following information after implementation but before completion of the procedure: the radionuclide, treatment site, number of sources and total dose. Specifically, the procedure was completed on May 5 and the written directive did not specify the number of source seeds implanted or either the total source strength and exposure time or the total dose until May 28, 2008.

   This is a Severity Level IV violation (Supplement VI)

3. Title 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.
   Title 10 CFR 35.3045(d) requires, in part, that a licensee submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a medical event. It further requires that the written report include: (1) why the event occurred; (2) the effect, if any, on the individual(s) who received the administration; and (3) what actions, if any, have been taken or planned to prevent recurrence.

   Contrary to the above, written reports submitted to the NRC on June 21, July 8, July 15, 21, 22, 30, 31, and August 4 and 7, 2008, did not describe: (1) why the event occurred; (2) the effect on the individuals who received the administration; and (3) what actions were taken or planned to prevent recurrence. Specifically, for these three areas, the reports indicated that the cause was still under investigation, the effects were still under investigation and that the program was suspended until long-term actions to prevent recurrence could be determined. This incomplete information was material to the NRC because it affected the NRC's ability to timely determine the significance of the events and the adequacy of the licensee's corrective actions.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, the Department of Veterans Administration (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; (EA-09-038)" and should include for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation if admitted, and if denied, the basis for denying the validity of the violation; (3) the corrective steps that have been taken and the results achieved; (4) the corrective steps that will be taken; and (5) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an order or a Demand for Information requiring you to explain why your license should not be modified, suspended, or revoked or why the NRC should not take other action as may be proper. Consideration may be given to extending the response time for good cause shown.

Within the same time provided for the response required under 10 CFR 2.201, you may pay the cumulative amount of the civil penalties proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a Statement of Payment of Civil Penalty, indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should you fail to answer within 30 days of the date of this Notice, the NRC will issue an Order imposing the civil penalty. Should you elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole

or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the response should address the factors addressed in Section VI.C.2, "Civil Penalty Assessment," of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. Your attention is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to Payment of Civil Penalties, and Answer to a Notice of Violation, may be combined and should be addressed to: Roy Zimmerman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to Mark Satorius, Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532.

Because your responses will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, they should not include any personal privacy or proprietary information. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 17th day of March 2010

You are required to respond to the enclosed Notice and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you should provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/

Sincerely,
/RA/
Mark A. Satorius
Regional Administrator

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 37-00062-07

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/Enclosure 1:
1. State of Pennsylvania
2. Gary Williams, Interim Director, National Health Physics Program
3. Richard Citron, Medical Center Director VA Philadelphia Medical Center

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OFFICE	RIII	RIII	D:OE	D: FSME	D:OGC
NAME	Lougheed	Pelke	Zimmerman[1]	Miller[2]	Safford[3]
DATE	03/12/10	03/12/10	03/12/10	03/02/10	03/12/10
OFFICE	RIII	RIII	RIII	RIII	
NAME	Reynolds	Heck	Orth	Satorius	
DATE	03/15/10	03/15/10	03/16/10	03/17/10	

OFFICIAL RECORD COPY

1 OE concurrence received via E-mail from S. Woods on March 12, 2010.
2 FSME concurrence received via E-mail from D. White on March 2, 2010, with follow-up on March 10, 2010.
3 OGC No Legal Objection received via E-mail with follow-up from C. Safford on March 12, 2010.