

August 23, 2010

EA-10-081
CAL 3-08-004
NMED Nos. 080606, 080613, 080646, 080803, 090079, 090120, and 090244

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
PENALTIES - \$39,000; NRC INSPECTION REPORT NO. 030-34325/2008-030
DEPARTMENT OF VETERANS AFFAIRS

Dear Dr. Petzel:

This letter refers to the inspections conducted by the U.S. Nuclear Regulatory Commission (NRC) between October 8, 2008, and April 24, 2009, with continued NRC in-office review through April 22, 2010. These inspections occurred at 13 Department of Veterans Affairs (VA) facilities with permanent prostate implant brachytherapy programs. The VA facilities (or permittees) operate under the Master Materials License (MML) issued to the VA by the NRC. The purpose of the inspections was to determine whether the problems identified at the Philadelphia VA Medical Center documented in NRC Inspection Report Nos. 030-34325/2008-029(DNMS) and 2009-001(DNMS) also existed at other VA facilities. Throughout the inspections, and specifically during the final exit meeting, conducted by telephone on April 22, 2010, the NRC discussed the circumstances which led to apparent violations occurring, the significance of the issues, and the need for lasting and effective corrective actions. Details regarding the facilities inspected and the apparent violations identified were provided in NRC Reactive Inspection Report No. 030-34325/2008-030(DNMS) dated May 24, 2010.

On June 30, 2010, a Predecisional Enforcement Conference, open to the public, was conducted at the NRC's regional office in Lisle, Illinois, to discuss the apparent violations, their significance, their root causes, and the VA's corrective actions. Representatives from the Veterans Health Administration, the National Radiation Safety Committee (NRSC), and the National Health Physics Program (NHPP) were in attendance. During the conference, your staff discussed the VA's position on the apparent violations and the actions taken by the VA in response to the violations. Your staff disagreed with some of the violation examples and with the NRC's concerns. To better understand the VA's basis for the disagreement, the NRC requested that the VA document the basis for disagreeing with the violations in writing and provide any additional information to support that basis. On July 15, 2010, the VA provided a written response. The VA's response stated that the VA accepted one example of the violation of Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a)(2), and the four examples of the violation of 10 CFR 35.41(b)(2), but felt that the two violations should be combined. The VA accepted the violations of 10 CFR 35.3045(c), 10 CFR 35.3045(d) and 10 CFR 35.67(g); however, the VA only accepted the violation of 10 CFR 35.40(b)(6)(ii) for one of the three facilities in the inspection report.

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, and the circumstances surrounding them are described in detail in the subject inspection report.

Violation A.1 involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that administrations were in accordance with the written directive, contrary to the requirements of 10 CFR 35.41(a)(2) and 10 CFR 35.41(b)(2). This failure resulted in post-treatment verifications not being performed on numerous patients and, in the case of patients at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi, resulted in medical events not being identified in a timely manner. The violation is of significant concern to the NRC because of the similarities to the events at the Philadelphia VA Medical Center, and because the violation was identified to the VA by the NRC after the NHPP had completed its inspections without identifying the issues (the VA subsequently issued their inspection report on July 15, 2010). Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In citing this violation, the NRC considered the information that you presented during the conference. The NRC specifically evaluated each example presented in the NRC inspection report – and in the VA Inspector General (IG) Report in the case of the Cincinnati VA Medical Center in Cincinnati, Ohio – and determined that the cases for the VA Sierra Nevada Health Care System in Reno, Nevada, the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi, and the VA Boston Healthcare System in Boston, Massachusetts, are examples of Violation A.1. Additional examples of the violation of 10 CFR 35.41(a)(2) and 10 CFR 35.41(b)(2) were identified for the VA Boston Healthcare System in Boston, Massachusetts and are discussed below as Violation B.1. Additionally, the NRC determined that the two examples where post-verifications were not accomplished for the VA New York Harbor Healthcare System in Brooklyn, New York, were due to patients not returning despite the Medical Center's efforts to contact them. Therefore, the NRC is not citing these examples. While the Cincinnati VA Medical Center permittee in Cincinnati, Ohio, did not precisely follow its procedures, as identified by the VA IG, the NRC was satisfied that the authorized user's actions – which included use of various modalities including ultrasound imaging, fluoroscopy images during surgery, post-surgery radiographs and computerized tomography (CT) scans, and the activity of the sources – demonstrated with high confidence that the treatment was in accordance with the written directive.

Finally, the NRC evaluated the procedure deficiencies at the remaining 8 VA facilities identified in the inspection report. The NRC determined that, in these cases, the licensee had written, implemented and maintained procedures that contained the minimum requirements listed in 10 CFR 35.41(b)(2) such that there was a high confidence that treatment was in accordance with the written directives. The NRC noted that the VA had implemented a standard procedure across all VA facilities which performed prostate brachytherapy as a corrective action for the Philadelphia VA Medical Center event. Therefore, these facilities are not being cited.

Violation A.2 involved a single instance where the licensee failed to report a medical event, contrary to the requirements of 10 CFR 35.3045(c). Failing to make timely reports of medical events is a concern to the NRC because it impacts the NRC's ability to perform its regulatory function. At the time this event occurred, there had been significant interaction between the NRC and the VA about timely reporting of medical events due to the events at the Philadelphia

VA Medical Center. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$6500¹ is considered for each Severity Level III violation. Because the VA has been the subject of escalated enforcement actions within the last two years², 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 determined that credit would not be warranted for *Identification* in that the NRC identified these violations after the NHPP performed inspections without identifying the issues. Credit would be warranted for *Corrective Action* based on the corrective actions described during the June 30, 2010, Predecisional Enforcement Conference and in your July 15, 2010, letter. Normally, this would result in a base civil penalty of \$6500 for each Severity Level III violation.

Although corrective actions were taken to address the specifics of Violations A.1 and A.2, the NRC remains concerned that the VA has not taken steps to adequately assess or correct the problems the NHPP and the NRSC have had in effectively implementing the VA MML. While failures at the individual VA facilities directly caused the above violations, the root cause was a failure by the NHPP to aggressively and proactively execute its regulatory and permittee oversight functions under the MML in an integrated manner before and after the VA Philadelphia findings were identified. For example, the NHPP was not sufficiently aggressive in ensuring that all VA facilities recognized what constituted a medical event to ensure prompt reporting, and even as the broader implications of the events at the Philadelphia VA Medical Center were being identified by the NRC, NHPP failed to identify that post-treatment verifications were not being performed for long periods of time at other VA facilities.

In addition, the NRSC has failed to provide sufficiently rigorous oversight of the NHPP to ensure thorough and integrated execution of regulatory and oversight functions without NRC intervention. Although both the NHPP and the NRSC have been responsive to NRC inquiries, and although they have assessed the causes of individual non-compliances identified by NRC, they have not adequately assessed whether or how their own processes have contributed to (or failed to prevent) those non-compliances.

Accordingly, based on the VA's particularly poor performance in identifying issues similar to those previously identified at the Philadelphia VA Medical Center at other hospitals, and based on the lack of effective assessment by the NHPP and the NRSC of shortcomings in their own

¹ 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 September 2005 to October 2008, the 2004 adjusted value was used.

² The NRC issued two Severity Level II violations, two Severity Level III violations, and one Severity Level III problem with a proposed civil penalty of \$227,500 on March 17, 2010, to the VA based on actions at the Philadelphia VA Medical Center (EA-09-038). The VA paid the civil penalty on April 8, 2010. The NRC issued two Severity Level III violations with a proposed civil penalty of \$14,000 on June 2, 2010, to the VA based on actions at the San Diego Medical Center (EA-10-023). The VA paid this civil penalty on July 1, 2010.

processes under the MML, the NRC is exercising its authority, under Section VII.A.1.c. of the Enforcement Policy, to use discretion to escalate the civil penalty for each Severity Level III violation. Escalation of the civil penalty is necessary to underscore not only the performance issues at the individual VA facilities, but primarily to highlight the failure of the NHPP to aggressively and proactively execute its regulatory and permittee oversight function, as well as the failure of the NRSC to provide sufficient oversight of the NHPP to ensure proper execution of its regulatory functions without NRC intervention. 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 Penalties (Notice) in the total amount of \$39,000. Issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC plans to meet with the VA to discuss the NRC's expectations for effective implementation of the MML and the associated Letter of Understanding. At that meeting, the NRC expects to communicate its continuing concerns about the performance of NHPP and NRSC as it relates to their oversight of the MML, and will use information VA provides to assess whether further action should be taken. The meeting will be scheduled through separate correspondence, and the NRC will issue a public meeting notice once the date and time for this meeting have been finalized.

In addition to the above, the NRC determined for the VA Boston Healthcare System in Boston, Massachusetts that there were five other cases where the treatment was performed between February and May 2005 that involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that administrations were in accordance with the written directive, contrary to the requirements of 10 CFR 35.41(a)(2) and 10 CFR 35.41(b)(2). These five cases were determined to be outside the Statute of Limitations for civil penalty assessment and, therefore, are not included in the examples cited in the enclosed Notice for violations assessed a civil penalty. However, this Severity Level III violation is cited in the enclosed Notice as Violation B.1., which will not be assessed a civil penalty. The NRC also determined that two violations of lesser significance occurred that will not be assessed a civil penalty. Violation B.2 describes a single instance where a 15-day report did not contain all information required by 10 CFR 35.3045(d). Violation B.3 describes four instances which occurred on a single day where the licensee failed to specify the radionuclide, the treatment site, the number of sources and the total source strength, or the total dose on the written directives prior to the treatment being completed, contrary to the requirements of 10 CFR 35.40(b)(6)(ii). Both of these violations were categorized, in accordance with the NRC Enforcement Policy, at Severity Level IV.

Finally, the NRC chose not to cite a violation of 10 CFR 35.67(g) for the failure of the radiation safety officer at the Cincinnati VA Medical Center in Cincinnati, Ohio, to inventory all unused brachytherapy sources in the waste storage room. The NRC determined that, although this Severity Level IV violation was identified as a result of an NRC inspector question, it has been documented in an NHPP inspection report and corrective actions have been taken. Therefore, the NRC has determined that a separate NRC violation is not necessary.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to 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>. Therefore, 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

Enclosures:

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

cc w/Enclosure 1: 1. Charles Anderson, Chair
National Radiation Safety Committee
2. Gary Williams, Director
National Health Physics Program

Letter to Robert A. Petzel from Mark A. Satorius dated August 23, 2010

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTIES- \$39,000; NRC INSPECTION REPORT NO. 030-34325/2008-030
DEPARTMENT OF VETERANS AFFAIRS

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NOTICE OF VIOLATION

AND

PROPOSED IMPOSITION OF CIVIL PENALTIES

Department of Veterans Affairs
North Little Rock, Arkansas

Docket No. 030-34325
License No. 03-23853-01VA
EA-10-081

During U.S. Nuclear Regulatory Commission (NRC) inspections at permittees from the Department of Veterans Affairs (VA or licensee), conducted from October 8, 2008, to April 24, 2009, with continued NRC in-office review through April 22, 2010, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the Code of Federal Regulations (10 CFR) 2.205. The particular violations and associated civil penalties are set forth below:

A. Violations Assessed a Civil Penalty

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

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, the licensee failed to develop and implement written procedures that addressed verifying that the administration was in accordance with the applicable treatment plan and written directive. As a result, there was not high confidence that the administrations were in accordance with the written directives. Specifically the licensee's procedures at the following facilities either did not address verifying the administration or the licensee did not implement the procedure:

- (a) Between September 29, 2005, and October 12, 2008, at the VA Sierra Nevada Health Care System, Reno, Nevada, the procedure entitled "Procedure For Written Directives" (undated) did not address verifying the administration when the normal verification method was unavailable. As a result, the post-administration dose was not verified for 50 patients who received brachytherapy implants during this period.
- (b) Between May 2007 and February 2008, at the G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi, the procedure entitled "Written Directive Procedures Radiation Therapy" (undated) did not address verifying the administration when the normal verification method was unavailable. As a result, the post-administration dose was not verified for 37 patients who received brachytherapy implants during this period. In

addition, during this period the licensee did not implement the procedure and at least 10 medical events occurred.

- (c) On September 27, 2005, at the VA Boston Healthcare System, Boston, Massachusetts, the licensee failed to generate a graphic dose distribution plan and a dose volume histogram required by the procedure entitled "Brachytherapy Program QMP" (undated) in effect in 2005 for two patients.

This is a Severity Level III violation (Supplement VI).
Civil Penalty – \$19,500

2. 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 a medical event had occurred on September 18, 2008, at the VA New York Harbor Healthcare System, Brooklyn, New York. The licensee had sufficient information, based on the data generated by the patient's post-treatment plan, to make a determination on October 10, 2008, that the dose to the treatment site during a permanent prostate implant was not in accordance with the authorized user's written directive. The licensee notified the NRC Operations Center of the medical event on November 18, 2008, a period greater than one calendar day after October 10, 2008.

This is a Severity Level III violation (Supplement VI).
Civil Penalty – \$19,500

B. Violations Not Assessed a Civil Penalty

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

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, on February 1, March 22, April 26 and May 3, 2005, the licensee failed to develop and implement written procedures that addressed verifying that the administration was in accordance with the applicable treatment plan and written directive. As a result, there was not high confidence that the administrations were in accordance with the written directives. Specifically the licensee, at the Boston Healthcare System, Boston, Massachusetts, failed to generate a graphic dose distribution plan and a dose volume histogram for five

patients on the above dates as required by the procedure entitled "Brachytherapy Program QMP" (undated) in effect in at the time.

This is a Severity Level III violation (Supplement VI).

2. 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 requirement, on December 1, 2008, the licensee did not include all required information in the written report for an event that occurred at the VA New York Harbor Healthcare System, Brooklyn, New York. Specifically, the licensee's written report submitted December 1, 2008, failed to describe why the event occurred and what actions were taken or planned to prevent recurrence. Instead, the written report indicated that "the event occurred because three seeds were placed lower than the prostate region," and that "extreme care is always taken in delivery of needles/seeds. An unusual event occurred and care will be taken to assure it does not recur."

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

3. Title 10 CFR 35.40(b)(6)(ii) states in part that the written directive for manual brachytherapy must specify, after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources and the total source strength and exposure time (or total dose).

Contrary to the above, on December 11, 2007, the licensee, at the VA Sierra Nevada Healthcare System in Reno, Nevada, completed four brachytherapy treatments but failed to specify the radionuclide, the treatment site, the number of sources and the total source strength, or the total dose on the written directives.

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

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: Roy Zimmerman, 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-10-081)" 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: Roy Zimmerman, 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: Roy Zimmerman, 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 penalties. 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

Notice of Violation and
Proposed Imposition of Civil Penalties

-5-

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 23rd day of August 2010

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to 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>. Therefore, 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

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- 1 OGC No Legal Objection received via E-mail from C. Safford on August 16, 2010.
 - 2 FSME concurrence received via E-mail from M. Burgess on August 11, 2010.
 - 3 OE concurrence received via E-mail from R. Summers on August 18, 2010.