June 2, 2010

EA-10-023
NMED NO. 090748

Mr. Gary Williams, M.S., Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES – $14,000; NRC INSPECTION REPORT NO. 030-34325/2009-002 DEPARTMENT OF VETERANS AFFAIRS SAN DIEGO HEALTHCARE SYSTEM, SAN DIEGO, CALIFORNIA

Dear Mr. Williams:

This letter refers to the inspection conducted on November 2 and 3, 2009, at the Department of Veterans Affairs (DVA) San Diego Healthcare System (VASDHS, permittee), with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through February 3, 2010. The purpose of the inspection was to review the circumstances surrounding a reported medical event involving a therapeutic dose of sodium iodide iodine-131 (I-131) that was administered to a patient through a gastrostomy feeding tube (g-tube) on September 21, 2009. The medical event was the direct result of the administration of the majority of the I-131 dose into the wrong port of the g-tube, which resulted in an underdose to the patient's thyroid and an unintended dose to the patient's stomach. Throughout the inspection, and specifically during the final exit meeting, conducted on February 3, 2010, 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 No. 030-34325/2009-002 dated March 5, 2010.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. In a letter dated March 29, 2010, you provided a response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated March 29, 2010, the NRC has determined that two 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 report.

On September 26, 2009, you notified the NRC of a medical event involving a patient treatment of approximately 200 millicuries (mCi) of I-131. The permittee administered a dose of 187 mCi on September 21, 2009, through the patient's g-tube. The patient's g-tube had three

ports: (1) a medication port that allowed for the introduction of medications into the patient's stomach; (2) a feeding port which allowed for the introduction of nutrients into the patient's stomach; and (3) a balloon port which was a sealed compartment which allowed for the positioning of the g-tube. Both the medication and the feeding ports provided a pathway for substances to enter the patient's digestive system; however, the balloon port did not. The authorized user (AU), the chief nuclear medicine technologist and a senior nuclear medicine technologist were present for the administration. The senior technologist intended to administer the dose through the "medication" port of the g-tube. However, the orientation of the patient's g-tube obstructed the view of the markings on the ports. Further, the medication port stopper was closed and the balloon port was open, leading the technologist to believe that the balloon port was the medication port. As the technologist attempted to inject the dose in what he thought was the "medication" port he noted backpressure on the syringe and aborted the process. The technologist mistakenly did not believe any material was administered into the g-tube at this time.

The team agreed to administer the dose through the feeding port, but the syringe did not fit the coupling of the feeding port or 3-way stopcock extension. The senior technologist transferred the contents of the syringe into an irrigation syringe and administered the contents through the feeding port of the patient's g-tube.

Daily radiation surveys of the patient over the next two days indicated radiation levels which were higher than expected. The radiation levels were consistent with physical decay of the I-131 rather than biological elimination. On September 23, 2009, the AU ordered patient imaging. The images showed uptake in the patient's head and neck areas, as expected, but also showed a "hot spot" in the patient's abdominal area. On September 24, 2009, additional radiation surveys still showed higher-than-expected readings.

On September 25, 2009, the patient was transferred to the interventional radiology suite for removal of the g-tube. The senior nuclear medicine technologist informed members of the interventional radiology staff that this was a "hot" patient and to place all waste from this patient's procedure in a biohazard waste bag. However, no instruction on radiation safety precautions such as contamination control and waste control were provided to the interventional radiology members. The interventional radiologist discarded the g-tube into the waste container, contaminating the floor in the process.

Your investigation of this event determined that the majority of the I-131 (approximately 160 mCi) was mistakenly injected into the "balloon" port rather then the intended "medication" port of the feeding tube. Therefore, the I-131 remained in the "balloon" mimicking a sealed source within the patient. This event was initially reported as a medical event because you estimated that the patient received less then half of the intended dose. Further investigation showed that this event also involved a dose to an organ or tissue (the stomach) other than the treatment site that exceeded 50 rem to an organ or tissue and 50 percent or more of a dose expected from the administration as defined in the written directive.

Violation A.1 of the Notice involved the failure to develop, implement, and maintain written procedures for administering byproduct material through a g-tube in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a)(2), and to instruct the supervised individuals in the permittee's written radiation protection procedures, and written directive procedures with respect to the use of byproduct material. The root cause of the violation appeared to be a lack of detailed policies and procedures for the administration of byproduct material through an unfamiliar medical apparatus, and a lack of recognition of the importance of

providing clear guidance and direction for infrequently performed administrations of I-131 doses through g-tubes with inexperienced staff. The violation represents a programmatic weakness in the implementation of procedures for administrations requiring a written directive, and a failure to provide adequate training on those procedures. Additionally, the violation resulted in the patient receiving a significant unintended dose to the stomach, an organ other than the treatment site. Therefore, Violation A.1 has been categorized at Severity Level III.

Violation A.2 of the Notice involved the failure to report by telephone to the NRC Operations Center no later than the next calendar day when you had information on September 23, 2009, that a medical event had occurred, as required by 10 CFR 35.3045(c). The root cause of the violation appears to have been the permittee's "wait and see" approach for assessing the I-131 treatment. The failure to inform the NRC of a medical event no later than the next calendar day impacted the NRC's ability to promptly assess the event circumstances and respond to ensure that public health and safety was not at risk. Therefore, Violation A.2 has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In your response to Violation A.2 dated March 29, 2010, you stated that the facility offers a logical argument that the clinical care of the patient was an overriding consideration in the decision-making process such that discovery of the medical event could not have been established until September 25, 2009.

Your response to Violation A.2 was reviewed by an independent member of our inspection staff. We concluded that on September 23, 2009, the permittee had sufficient information to discover that a medical event occurred prior to removing the g-tube from the patient on September 25, 2009. As stated in Section 2.2 of our inspection report, for patients administered therapeutic doses of I-131 orally, with normal renal function, 90 to 95 percent of the administered dose, which is not taken up by the residual and metastatic thyroid tissues, is rapidly metabolized and excreted in the urine. There is a rapid reduction in the external radiation profile commensurate with the biological elimination of unbound I-131. Following this initial rapid decline in external radiation levels, the measurements would normally diminish according to an effective half-life of about three days.

During each day the patient was hospitalized, a health physicist measured radiation levels at the patient's bedside and at one meter from the patient. The survey results indicated that the I-131 was not being eliminated by the patient. On September 23, 2009, the patient was transported to the nuclear medicine (NM) department for imaging. During review of the NM image, the physician AU noted some I-131 uptake in the patient's head and neck regions and a significant amount of I-131 in the abdominal area. Because the NM image showed some I-131 passed out of the g-tube and was absorbed by the patient's body, the AU suspected that there was adherence of I-131 to the lumen of the g-tube or a kink within the tube which prevented the I-131 from being absorbed by the patient. The NM image indicated that a significant amount of I-131 remained in the stomach approximately 48 hours post administration.

On September 23, 2009, the permittee had results of the patient's surveys and an NM image indicating that a significant amount of the I-131 was still in the patient's stomach and was not eliminated by the patient two days after administration. In addition, the permittee missed an opportunity to conduct a quantitative assessment of the amount of I-131 in the patient's stomach relative to other areas of the patient's body by processing the NM image data with available equipment. The patient surveys and NM image were obtained non-invasively and provided sufficient information on September 23, 2009, for the permittee to discover that a medical event occurred and to notify the NRC as required prior to removing the tube from the patient on September 25, 2009.

Additionally, your response stated that you disagreed with the apparent violation regarding reporting of the medical event. However, the NRC staff concluded that on September 23, 2009, you had sufficient information based on patient survey data and imaging data from the nuclear medicine department to report the medical event.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $7,000 is considered for each Severity Level III violation. Because the DVA has been the subject of escalated enforcement actions within the last two years,[1] 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. Credit was not warranted for identification. The procedural aspect of Violation A.1 was identified in response to an event and the training aspect was identified by the NRC. Violation A.2 was identified by the NRC.

Credit was warranted for your corrective actions. Your corrective actions for Violation A.1 included: (1) developing a detailed step-by-step procedure for g-tube administrations, including checklists, established trigger levels for patient surveys and an action requirement if trigger levels are exceeded; (2) improving communication between the radiation safety office and the nuclear medicine department; (3) implementing a "time-out" process when using unfamiliar medical devices; (4) ensuring a member of radiation safety would be physically present during g-tube administrations; and (5) providing formal training by the Radiation Safety Officer to the nuclear medical technologists and the authorized users on g-tube administrations. Your corrective actions for Violation A.2 included providing formal training by the Radiation Safety Officer to the nuclear medical technologists and the authorized users on the NRC's reporting requirements for medical events and the new policies and procedures for g-tube administrations. The new policies and procedures include established trigger levels for patient surveys and action requirements if trigger levels are exceeded, which would prompt personnel to identify medical events.

Therefore, to emphasize the importance of implementing detailed policies and procedures for the administration of byproduct material through an unfamiliar medical apparatus, providing adequate training on those procedures, and promptly identifying and reporting medical events, and in recognition of your previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the base amount of $14,000 for the Severity Level III violations. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

Additionally, Violation B was identified for the failure to instruct four members of the interventional radiology staff the on the proper handling of the patient's contaminated g-tube in order to ensure that contamination of the interventional suite and individuals did not occur. The violation was categorized at Severity Level IV and is being cited in the enclosed Notice because it was identified by the NRC.

---

[1] The NRC issued a SL III violation with proposed civil penalty of $6,500 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.

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. 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. 40-15030-01

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

cc w/Enclosure 1:
1. State of California
2. Stan Johnson, Medical Center Director, VASDHS
3. Rene Michel, M.S., Radiation Safety Officer, VASDHS

Letter to Gary Williams from Mark A. Satorius dated June 2, 2010

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES – $14,000; NRC INSPECTION REPORT NO. 030-34325/2009-002 DEPARTMENT OF VETERANS AFFAIRS SAN DIEGO HEALTHCARE SYSTEM, SAN DIEGO, CALIFORNIA

DISTRIBUTION:

Docket File
RidsSecyMailCenter.Resource
OCADistribution
Bill Borchardt
Martin Virgilio
Michael Weber
Roy Zimmerman
Nick Hilton
Kerstun Day
Mark Satorius
Cynthia Pederson
Marvin Itzkowitz
Catherine Scott
Charles Miller
Robert Lewis
Cynthia Carpenter
Michele Burgess
Glenda Villamar
Duane White
Shirley Xu
Daniel Holody
Carolyn Evans
William Jones
Holly Harrington
Hubert Bell
Cheryl McCrary
Cynthia Rheaume
Mona Williams
Steven Reynolds
Patrick Louden
Patricia Pelke
Cassandra Frazier
Darrel Wiedeman
Deborah Piskura
Steven Orth
Jared Heck
Allan Barker
Harral Logaras
James Lynch
Viktoria Mitlyng
Prema Chandrathil
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Sarah Bakhsh
Patricia Buckley
Tammy Tomczak
OEMAIL.Resource
OEWEB Resource

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-10-023

During a U.S. Nuclear Regulatory Commission (NRC) reactive inspection at the Department of Veterans Affairs (licensee), San Diego Healthcare System, conducted on November 2 and 3, 2009, with continued NRC in-office review through February 3, 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 Title10 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 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. 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, as of September 21, 2009, 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, Veteran Affairs San Diego Healthcare System, "Quality Management Procedure for the Administrations of I-131 Sodium Iodide Greater Than 30 uCi, Any Therapeutic Dosage of Unsealed Byproduct or Any Therapeutic Dose of Radiation from Byproduct Material," revised January 15, 2003, did not include written procedures for administering byproduct material through a gastrostomy tube to ensure that the administered dose was in accordance with the written directive. Additionally, as of September 21, 2009, two nuclear medicine technologists, who were supervised individuals, had not been instructed on procedures for administering byproduct material through a gastrostomy tube prior to performing the administration in order to ensure that the administered dose was in accordance with the written directive. This resulted in an administration of a dose of 187 millicuries of sodium iodide iodine-131 (I-131) on September 21, 2009, through a patient's gastrostomy tube, where the administered dose was not in accordance with the written directive. Specifically, the patient received a dose of

approximately 21 millicuries rather than the prescribed 200 millicuries because the dose was inadvertently administered through the wrong component of the patient's gastrostomy tube.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $7,000

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 sufficient information was available on September 23, 2009, to determine that a medical event had occurred. Specifically, the licensee had sufficient information, based on the patient survey data and the image from the nuclear medicine department, to make a determination on September 23, 2009, that the administration of a 200 millicurie dose of sodium iodide I-131 was not in accordance with the authorized user's written directive and constituted a medical event. The licensee notified the NRC of the medical event on September 26, 2009, a period greater than one calendar day after September 23, 2009.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $7,000

B. Violation Not Assessed a Civil Penalty

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, as of September 25, 2009, four members of the interventional radiology staff had not been instructed on the proper handling of the patient's contaminated gastrostomy tube in order to ensure that contamination of the interventional suite and individuals did not occur.

This is a Severity IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Department of Veteran Affairs 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-10-023)" 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. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time provided for the response required under 10 CFR 2.201, the licensee 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 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 response 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, and to the extent possible, it 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 2nd day of June 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. 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. 40-15030-01

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

cc w/Enclosure 1:
1. State of California
2. Stan Johnson, Medical Center Director, VASDHS
3. Rene Michel, M.S., Radiation Safety Officer, VASDHS

DISTRIBUTION: See next page
FILE NAME: G:\EICS\ENFORCEMENT\Enforcement Cases 2010\EA-10-023 VA San Diego\EA-10-023 Draftl Letter & NOV w CP.doc
☑ Publicly Available ☐Non-Publicly Available ☐Sensitive ☑ Non-Sensitive

OFFICE	RIII	RIII	D:OE	D: FSME	D:OGC
NAME	PRPelke	PJ Pelke	Day for Zimmerman[1]	White for Miller[2]	[3]Safford
DATE	5/28/10	6/01/10	5/25/10	5/24/10	5/24/10
OFFICE	RIII	RIII	RIII	RIII	
NAME	Reynolds	Heck	Orth	Satorius	
DATE	6/01/10	6/02/10	6/01/10	6/02/10	

OFFICIAL RECORD COPY

1 OE concurrence received via E-mail from K. Day on May 25, 2010.
2 FSME concurrence received via E-mail from D. White on May 24, 2010.
3 OGC No Legal Objection received via E-mail from C. Safford on May 24, 2010.