May 22, 2007

EA-07-065

E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
Little Rock, AR 72114

SUBJECT: EXERCISE OF ENFORCEMENT DISCRETION (NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2006-021) DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, WEST PALM BEACH, FLORIDA

Dear Mr. McGuire:

This refers to an investigation conducted by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI) at the Department of Veterans Affairs (DVA) facility in West Palm Beach, Florida. The OI investigation was completed on September 7, 2006, and concluded that one DVA Nuclear Medicine Technologist (NMT) willfully failed to monitor the external surfaces of labeled packages for radioactive contamination upon receipt of packages containing licensed material during the period from April 2 to June 11, 2006. This is a violation of 10 CFR 20.1906, "Procedures for Receiving and Opening Packages." A copy of the OI Report Synopsis is enclosed with this letter. Additionally, the DVA National Health Physics Program (NHPP) conducted inspections at the West Palm Beach facility from June 13, 2006, to January 4, 2007. The NHPP inspections concluded that two NMTs failed to monitor the external surfaces of labeled packages for radioactive contamination delivered to the facility during the period from April 1 to June 13, 2006.

Based on the information developed during the OI investigation and the DVA inspections, the NRC has determined that a violation of NRC requirements occurred. The circumstances surrounding the violation are described in detail in the OI and NHPP reports. In summary, NMTs at the West Palm Beach facility were required to monitor the external surfaces of labeled packages for radioactive contamination upon receipt of packages containing licensed material. However, on at least 15 occasions from April 1 through June 13, 2006, two NMTs failed to monitor incoming packages for radioactive contamination, as required by 10 CFR 20.1906. The NMTs indicated that when a large volume of patients were scheduled for testing and when the NMTs were working alone, such as on weekends, they did not always monitor incoming packages for radioactive contamination. Based on the NMT's knowledge, training, and prior experience in monitoring incoming packages for radioactive contamination, OI concluded that one NMT willfully failed to comply with 10 CFR 20.1906.

Willful violations of NRC requirements are a significant regulatory concern because the NRC's regulatory program is based on licensees and the employees of licensees acting with integrity and communicating with candor. Therefore, it is essential that the NRC has confidence in those individuals working with licensed material and that managers closely monitor their program to ensure that individuals entrusted to use licensed material adhere to regulatory and/or license requirements. That was not the case at the West Palm Beach facility since facility management failed to provide adequate oversight of staff in the nuclear medicine department. As a result, managers at the West Palm Beach facility responsible for implementing the radiation safety program at the facility were not aware that NMTs in the nuclear medicine department were not following the requirements of 10 CFR 20.1906.

As a licensee of the NRC, the DVA is responsible for the acts of its employees and for ensuring that licensed activities are conducted in accordance with applicable regulatory and/or license requirements. The willful failure to monitor incoming packages for radioactive contamination is a violation of 10 CFR 20.1906. In accordance with the NRC Enforcement Policy,[1] the violation is categorized at Severity Level III.

A base civil penalty in the amount of $3,250 is considered for a willful violation categorized at Severity Level III. The civil penalty assessment factors of *Identification* and *Corrective Action* were evaluated in accordance with Section VI.C of the Enforcement Policy. Credit was warranted for both the *Identification* and *Corrective Action* adjustment factors since the DVA NHPP identified the violation and took corrective actions. The corrective actions consisted of: (1) taking disciplinary actions; (2) implementing a comprehensive training program regarding package receipt and survey procedures for labeled packages containing radioactive material; (3) conducting daily audits of all radiation surveys for labeled packages containing radioactive material; and (4) posting information about this issue in a "Frequently Asked Question" article on the NHPP Web site. Furthermore, the DVA NHPP processed the violation in accordance with the enforcement procedures described in the NRC Master Materials License and issued a Severity Level III violation to the West Palm Beach facility on January 31, 2007, in accordance with DVA NHPP Standard Operating Procedure (SOP-03), "NRSC Enforcement Procedures."

Therefore, to encourage prompt identification, comprehensive correction of violations and in recognition of the enforcement action taken under your NRC Master Materials License, and in consultation with the Director, Office of Enforcement, the NRC is exercising enforcement discretion in accordance with Section VII.B.6 of the NRC Enforcement Policy and is not issuing a Notice of Violation or proposing a civil penalty in this matter. However, significant violations in the future could result in the issuance of a Notice or civil penalty.

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[1] The current edition of the NRC Enforcement Policy can be found at the NRC Web site www.nrc.gov.

Additionally, the NHPP inspections determined that the two NMTs willfully entered false survey data into a DVA computer database and included this issue in the Notice the NHPP issued to the West Palm Beach facility on January 31, 2007. However, the OI investigation did not reach a similar conclusion. Therefore, the NRC staff is not pursuing enforcement action related to this finding.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed in OI Report No. 3-2006-021, in the January 30 and 31, 2007, DVA NHPP inspection reports, and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to An Exercise of Enforcement Discretion, EA-07-065," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator and the Enforcement Officer, Region III, and a copy to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, the enclosure to this letter, and your response, should you choose to respond, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at www.nrc.gov. To the extent possible, if you choose to respond, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov.

Please feel free to contact Patricia J. Pelke, Chief, Nuclear Materials Licensing Branch, with questions. Ms. Pelke can be reached at telephone number (630) 829-9868.

Sincerely,

/RA/

James L. Caldwell
Regional Administrator

Docket No. 030-34325
License No. 03-23853-01VA

Enclosure:
Synopsis of OI Report No. 3-2006-021

cc w/encl: M. Kussman, M.D.,M.S., MACP
Acting Under Secretary for Health
Department of Veterans Affairs

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The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed in OI Report No. 3-2006-021, in the January 30 and 31, 2007, DVA NHPP inspection reports, and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to An Exercise of Enforcement Discretion, EA-07-065," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator and the Enforcement Officer, Region III, and a copy to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this letter.

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Docket No. 030-34325
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Enclosure: Synopsis of OI Report No. 3-2006-021
cc w/encl: M. Kussman, M.D.,M.S., MACP
Acting Under Secretary for Health
Department of Veterans Affairs

FILE NAME: C:\FileNet\ML071490115.wpd ***See previous concurrence**
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[1] OI concurrence limited to approving release of OI report synopsis

[2] OE concurrence by D. Solorio, OE on 5/10/07

[3] FSME concurrence by G. Morell, FSME on 4/23/07

[4] OGC concurrence by M. Bupp, OGC on 4/27/07

SYNOPSIS

This investigation was initiated on April 24, 2006, by the U.S. Nuclear Regulatory Commission, Office of Investigations, Region III, to determine whether nuclear medicine technologists for the U.S. Department of Veterans Affairs' West Palm Beach facility willfully failed to conduct wipe tests on packages containing radioactive material and whether they willfully falsified wipe test data for those tests.

Based on the evidence developed, this investigation did substantiate the allegation that one nuclear medicine technologist for the U.S. Department of Veterans Affairs' West Palm Beach hospital facility deliberately failed to conduct wipe tests on packages containing radioactive material. This investigation did not substantiate the allegation that nuclear medicine technologists for the West Palm Beach facility willfully falsified wipe test data.

Letter from J. Caldwell to E. McGuire dated May 22, 2007

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