UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 28, 1998

Ms. Ann Lovell
313 North Woodland Avenue
Glenolden, PA 19036

Dear Ms. Lovell:

I am responding to your Petition dated January 28, 1998, filed with the U.S. Nuclear Regulatory Commission (NRC), Region I, requesting immediate action to suspend or revoke the NRC license issued to the Department of Veterans Administration Medical Center, Philadelphia, Pennsylvania. By letter dated February 27, 1998, I acknowledged receipt of your Petition and informed you that, pursuant to 10 CFR § 2.206, the Petition was referred to me for action and would be acted on within a reasonable time. You were also informed that the information you presented did not warrant the immediate action that you requested. For the reasons set forth in the enclosed Director's Decision, under 10 CFR § 2.206 (DD-98-07) (Enclosure 1), your Petition has been denied.

A copy of the Director's Decision will be filed with the Secretary of the Commission, for its review, in accordance with 10 CFR § 2.206(c) of the Commission's regulations. As provided by this regulation, the Director's Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision, unless the Commission, on its own motion, institutes a review of the decision within that time.

A copy of the Notice of "Issuance of Final Director's Decision under 10 CFR § 2.206, (DD-98-07)," which is being filed with the Office of the Federal Register for publication, is enclosed as Enclosure 2.

Sincerely,

Carl J. Paperiello

Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-14526

Enclosures: 1. Director's Decision DD-98-07
2. Federal Register Notice

cc: Margaret O'Shay, Chief Operating Officer
Mary Moore, Radiation Safety Officer
Department of Veterans Administration
Medical Center, Philadelphia, Pennsylvania

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SECY-EHD - 001

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August 28, 1998

LETTER TO: Ms. Ann Lovell

FROM: Carl J. Paperiello

SUBJECT: PETITION DATED JANUARY 28, 1998 (G980069) (DD-98-07)

NRC Central File
IMNS r/f
NMSS Dir. Off. r/f
ASLBP (**letterhead copy)**
Rulemaking & Adjudication, SECY **[handcarry 5 copies of Director's Decision (DD), 2 copies of DD, FRN, and Letter to Lovell, 2 copies of incoming Petition]**
NRCWEB (**by e-mail)**
JGoldberg, OGC
VYanez, OCIO
CPoland
PTressler, EDO
GPangburn, RI
TDarden, RI
RBlough, RI
BFewell, RI
MShanbaky, RI
JDelMedico, OE
FCombs,IMNS
GKenna, RI/OI
WStryker, OIG
SChidakel, OGC
JLieberman, OE
PGoldberg, IMNS
SGagner, OPA
EDO r/f
LJCallan, EDO
BTravers, DEDO
HThompson, DEDO
PNorry, DEDO
JBlaha
SBurns, OGC
HMiller, RI
KCyr, OGC
RSubbaratnam, NRR
OCA
OCAA
Public Document Room
Public Document Room, RI, c/o SVillar

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
Carl J. Paperiello, Director

In the Matter of	)	
	)	
The Department of Veterans	)	
Administration Medical Center	)	Docket No. 030-14526
Philadelphia, Pennsylvania	)	License No. 37-00062-07
	)	
	)	(10 CFR § 2.206)

DIRECTOR'S DECISION UNDER 10 CFR § 2.206

I. INTRODUCTION

By a Petition addressed to the Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC), Region I, dated January 28, 1998, Ann Lovell (Petitioner), requested that NRC take immediate action to suspend or revoke the NRC license issued to the Department of Veterans Administration Medical Center, Philadelphia, Pennsylvania (PVAMC or licensee). As grounds for her request, the Petitioner asserts that executive management is operating in a manner that has the potential to present a significant danger to PVAMC patients, staff, and the general public. Specifically, the Petitioner asserts that: (1) there has been a consistent pattern of NRC violations occurring within the medical center for which PVAMC has failed to take corrective action; (2) PVAMC has a history of supplying false information to NRC; (3) individuals, including the Petitioner, became contaminated with radioactive material in the nuclear medicine department as a result of what the Petitioner believes was an intentional incident; and (4) PVAMC employees are fearful of bringing safety concerns to the licensee, for fear of retaliation, and to NRC, because of NRC's "history of inaction" regarding the PVAMC.

Additionally, the Petitioner claims that NRC withdrew a civil penalty after a change in NRC Region I management, which may have been withdrawn because it was not "cost-effective" to pursue the issue against the Department of Veterans Affairs.

On February 27, 1998, the receipt of the Petition was acknowledged and the Petitioner was informed that the Petition had been referred to the Office of Nuclear Material Safety and Safeguards pursuant to 10 CFR § 2.206 of the Commission's regulations. The Petitioner was also informed that her request that NRC immediately suspend or revoke the PVAMC's license was denied, and that other action on her request would be completed within a reasonable time, as provided by 10 CFR § 2.206.

II. BACKGROUND

The circumstances surrounding the issues raised in the Petition can be summarized as follows. From 1994 until Spring 1998, the Petitioner was employed by PVAMC as the Radiation Safety Officer (RSO). In November 1995, the Petitioner raised concerns to NRC regarding the safety of the licensee's operations in connection with a potential furlough of Federal government employees. As a result, NRC conducted a special inspection of the licensee's facility on November 17, 1995 (Inspection Report No. 030-14526/95-002). During the inspection, the inspector discovered that the licensee had replaced the RSO before NRC approval and had held a Radiation Safety Committee (RSC) meeting without a quorum, in that the RSO and half of the RSC membership were not present. Based on these violations, a Notice of Violation (NOV) was issued to PVAMC on January 4, 1996.

The licensee responded to the NOV by letter dated February 23, 1996. In its response, the licensee stated that it replaced the RSO with a nuclear physician, to ensure continuous coverage of the radiation safety program during a Federal government furlough, and that the full complement of the RSC could not be assembled to formalize the decision, because of the furlough of personnel, including the RSO.

On February 5, 1996, the Petitioner filed a discrimination complaint with the United States Department of Labor (DOL), asserting that she had been discriminated against for contacting NRC. In a decision issued on March 6, 1996, the Acting District Director of the DOL Wage and Hour Division determined that discrimination was a factor in the actions that comprised the complaint, in violation of Section 211 of the Energy Reorganization Act of 1974, as amended, 42 U.S.C. § 5851 (1988 and Supp. V. 1993). The licensee did not appeal the findings of the Acting District Director, so that the decision of the Acting District Director became the final DOL decision.

NRC held an Enforcement Conference with PVAMC on August 26, 1996, regarding this matter. On September 18, 1996, NRC issued a NOV and Proposed Imposition of Civil Penalty to PVAMC based on the DOL Acting District Director's decision and information provided by PVAMC during the conference, for a violation of the Commission's Employee Protection regulations, 10 CFR § 30.7 (EA 96-182). Specifically, the licensee was cited for discriminating against the Petitioner in that her supervisor had chastised her for contacting NRC. The

violation was categorized, in accordance with the Commission's Enforcement Policy, NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions" (hereafter, Enforcement Policy), as a Severity Level II violation, and a civil penalty of $8000 was proposed.

On November 15, 1996, PVAMC submitted a "Response to Notice of Violation and Proposed Imposition of Civil Penalty" and "Answer to a Notice of Violation." In these documents, it admitted the violation, but requested reconsideration of the determination that the violation constituted a Severity Level II violation warranting a civil penalty of $8000. In support of its request, PVAMC stated that the supervisor had chastised the Petitioner not just for contacting NRC, but for failing to notify him of certain information of which she was aware; that the chastisement was an isolated occurrence; that other employees were not "chilled" from raising safety concerns as a result of this event; and that a Severity Level II violation was for the most severe violations involving actual or high potential impact on the public, which had not been the case here. Following a review of the licensee's response and the findings of an investigation conducted by NRC's Office of Investigations (OI) that there had been no continued discrimination against the Petitioner, NRC informed the licensee, by letter dated September 25, 1997, that it had concluded that the violation would be more appropriately classified as a Severity Level III violation and that enforcement discretion should be exercised to not issue a civil penalty, in accordance with Section VII.B.6. of the Enforcement Policy.[1]

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[1]Section VII.B.6 of the Enforcement Policy (63 FR 26630, May 13, 1998) provides that NRC may refrain from issuing a civil penalty if the outcome of the normal process described in the Enforcement Policy does not result in a sanction consistent with an appropriate regulatory message. The Enforcement Policy further provides that NRC may reduce, or refrain from issuing, a civil penalty, for a Severity Level II, III, or IV violation based on the merits of the case.

NRC conducted an inspection of the licensee's facility from July 9 through October 20,1997, (Inspection Report 030-14526/97-001). On approximately July 24, 1997, a contamination incident occurred in the licensee's Nuclear Medicine Department, in which the hands of the RSO and the Chief Nuclear Medicine Technologist (CNMT) became contaminated. The inspector determined that a radiation survey instrument may have become contaminated during surveys of the Nuclear Medicine Department, and that the two individuals' hands became contaminated as a result of handling the instrument. The inspection results indicated that the incident may have been caused by a weakness in the licensee's contamination control techniques, including not using contamination control precautions during the use of radioactive material, and, in some cases, failing to wear gloves. In addition, NRC determined that significant weaknesses existed in the licensee's program in such areas as the functioning and effectiveness of the RSC, training, teamwork, communications, leadership, and conflict resolution. NRC issued a Confirmatory Action Letter (CAL) to PVAMC on December 19, 1997, (with corrected copy issued December 31, 1997), confirming the licensee's commitments to conduct a comprehensive review and assessment of its radiation safety program; to provide training to staff, including among other things, instruction regarding employees' rights to raise safety concerns to management and NRC; and to develop a formal program audit system to continuously identify and correct program deficiencies.

III. DISCUSSION

As stated above, the Petitioner has raised numerous issues in support of her assertion that executive management of PVAMC is operating in a manner that has the potential to present

a significant danger to medical center patients, staff, and the general public. These issues, and NRC's evaluation of these issues, are set forth below.

A. Petitioner's Assertion of Consistent Pattern of Violations for Which PVAMC Failed to Take Corrective Action

Among other things, the Petitioner maintains that there has been a consistent pattern of NRC violations occurring within the medical center for which PVAMC has failed to take corrective action. In support of this assertion, the Petitioner has submitted an attachment to her Petition, entitled "Chronology of PVAMC/NRC Interaction Since Whistle Blower Incident of November 17, 1995," that she purports "attests" to such a consistent pattern of violations within the facility.

NRC inspections conducted at PVAMC's facilities from 1995 through 1997 identified several violations. However, none of these violations was of high safety significance, and, with the exception of the enforcement action discussed above, involving discrimination against the Petitioner for raising safety concerns (EA 96-182), all the violations were categorized as Severity Level IV violations in accordance with the Commission's Enforcement Policy.[2] The Severity Level IV violations are described in Inspection Reports 030-14526/96-002 and 030-14526/97-001, issued on September 11, 1997, and December 10, 1997, respectively. The licensee responded to the violations identified in Inspection Report 030-14526/96-002 by

[2]As described in the Enforcement Policy, Severity Level IV violations are less serious violations, but of more than minor safety concerns, in that, if left uncorrected, they could lead to a more serious concern.

letter dated November 4, 1997, and to the violations identified in Inspection Report 030-14526-001, by letter dated January 9, 1998. In its responses, the licensee described its corrective actions for the violations.

In addition, as noted above, during these inspections, certain programmatic weaknesses were identified by NRC, including conflicts between management, the RSO, the RSC, and the licensee's staff. NRC determined that weaknesses existed in such areas as the functioning and effectiveness of the RSC, training, teamwork, communications, leadership, and conflict resolution. NRC also was concerned that PVAMC employees may have been reluctant to raise safety concerns because of these communication problems. As a result of these findings, NRC management toured the facilities on December 15, 1997, and met with representatives of the licensee on December 18, 1997, to discuss these program weaknesses. Subsequently, on December 19, 1997 (with corrected copy issued December 31, 1997), a CAL was issued to PVAMC, documenting the licensee's commitment to: (1) have the RSO and the RSC Chairman conduct a comprehensive review and assessment of the radiation safety program; (2) provide training, conducted by the RSO and the RSC Chairman, to all nuclear medicine staff, researchers using radioactive material, RSC members, and the facility management, on all applicable NRC regulatory requirements, on management expectations, and on the policy on bringing forth identified program deficiencies; and (3) establish a formal program audit system to identify, report, and correct program deficiencies. The licensee completed these actions by May 30, 1998. Additionally, the CAL provided that the licensee was to notify NRC, after completing all items in the CAL, so as to arrange for a meeting between NRC and PVAMC senior management, to discuss the program status and achievements. This meeting was held as part of the exit meeting on June 3, 1998, at the conclusion of the inspection conducted by

NRC at the licensee's facilities from June 1-3, 1998 (Inspection Report 030-14526/98-001, issued July 23, 1998).[3]

By letters dated February 20, April 6 (with revisions to audit report dated April 10), April 13, and May 28, 1998, PVAMC responded to the CAL, and submitted the results of its audit. In its responses, it stated that it had made numerous improvements to its program. Among these were the implementation of an "Open-Door Policy" of encouraging staff to identify and report program deficiencies. A notice from executive management, the RSC, and the RSO was sent to employees and posted in numerous, visible locations. The notice encouraged all staff to report apparent radiation safety problems, violations, and potential misadministrations. It explained that management, the RSC, and the RSO encouraged all staff to report problems without fear of reprisal, indicating that it was management's responsibility to assure a safe working environment. The notice stated that the goal was to create a secure, friendly environment that fosters self-identification of problems. A list of whom to contact, including the RSO, executive management, and the members of the RSC, and their phone numbers, was included in the notice. PVAMC staff has received training in this policy. PVAMC hired an Interim RSO while the previous RSO (the Petitioner) was out on medical leave,[4] and also informed NRC of the new Interim Director of the PVAMC. The Interim RSO was mandated to evaluate the radiation safety program and to recommend any needed changes. PVAMC provided NRC with a copy of its assessment and audit of the radiation safety program, in which it evaluated its program, identified certain program deficiencies, and specified its corrective

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[3]This inspection is discussed later in Section D of this Decision.

[4]The Petitioner has subsequently resigned from PVAMC.

actions. PVAMC also indicated that training would be provided, by March 15, 1998, to staff who use radioactive material. The training would include, as a minimum, instruction regarding all applicable NRC regulatory requirements, management expectations, and the policy on bringing forth identified program deficiencies. PVAMC also submitted its formal radiation safety audit program.

NRC has verified that the licensee has taken the actions required by the CAL. NRC has reviewed PVAMC's audit report and found that the licensee's audit demonstrated that PVAMC had taken corrective actions and implemented its commitments in the CAL to improve its oversight of the radiation safety program and to improve its problems related to communication, teamwork, and conflict resolution. PVAMC has conducted a comprehensive review and assessment of the radiation safety program. NRC has determined that PVAMC's audit was thorough in its assessment of the problems with communication, teamwork, and conflict resolution, as well as its evaluation of program deficiencies. In the audit report, PVAMC recognized the problems, and indicated that it had made progress in those areas. PVAMC noted that it had been concentrating on re-focusing attention on issues rather than past interpersonal conflicts, and is working on re-establishing trust and team work. PVAMC also stated that staff was beginning to feel more comfortable with admitting mistakes and initiating corrective actions. To clarify responsibilities, and to prevent the RSO from auditing its own activity, the Interim RSO recommended that the authorized users and their staff perform their own routine monitoring duties, with radiation safety staff auditing these duties. Staff has received training on all applicable NRC regulatory requirements, on management expectations, and on the policy on bringing forth identified program deficiencies. Additionally, PVAMC has established a formal system for conducting radiation safety program audits.

NRC conducted an inspection from June 1-3, 1998, at the licensee's facility (Inspection Report 030-14526/98-001, issued July 23, 1998). The inspection focused on the licensee's responses, dated November 4, 1997, and January 8, 1998, to the violations identified in Inspection Reports 030-14526/96-002 and 030-14526/97-001, respectively; licensee actions to assess and improve the radiation safety program; and implementation of management commitments addressed in the CAL. Within the scope of this inspection, no violations were identified. The inspectors verified that PVAMC's submitted corrective actions, as described previously, had been implemented for the violations identified in Inspection Reports 030-14526/96-002 and 030-14526/97-001.

The NRC inspectors, through a review of records, discussions with the licensee's staff, and observation of onsite activities, noted that major staff changes have occurred in areas that affect radiation safety and communication of management's message to staff concerning the significance of bringing forth any safety concerns. A new chairman of the RSC was appointed in September 1997, and a new RSO was appointed in December 1997. The Chief Operating Officer currently has direct oversight of the radiation safety program, and the RSO is reporting to this individual. When the new Chief of Staff (COS) is appointed, the RSO will report directly to the COS. The inspectors noted that these staff changes, and their initiatives, significantly improved personnel's understanding of the importance of radiation safety and the importance of a work environment in which staff is encouraged to bring forth issues relating to radiation safety without fear of retaliation. The licensee's Interim Director (appointed March 1998), the new RSC chairman, and the new RSO, in cooperation with the facility staff, have initiated and implemented specific actions that enhanced and improved management oversight of the radiation safety program. These actions included establishing a formal audit program and

providing training to staff on all applicable NRC regulatory requirements and the importance of reporting any program deficiencies. Additionally, management has worked to build teamwork and improve communication, and has made a commitment to increase program oversight.

In summary, although the Petitioner is correct that certain violations and programmatic weaknesses have been identified in the past at PVAMC, as discussed above, the violations were not of major safety significance, and the licensee has undertaken extensive corrective actions for such deficiencies. In addition, NRC will continue to inspect the licensee's radiation safety program on an accelerated inspection schedule, in accordance with NRC's Inspection Manual Chapter 2800, so as to closely monitor the licensee's progress in improving its radiation safety program and communication among its RSO, RSC, management, and staff. In sum, the NRC has not substantiated the Petitioner's assertion that there has been a consistent pattern of violations occurring at the licensee's facilities for which the licensee has failed to take corrective action, and has found no basis for taking the action requested by the Petitioner.

B. Petitioner's Assertions of Altered Records and Licensee's "History" of Providing Inaccurate Information

The Petitioner also asserts that the inspector to whom she had provided information concerning problems at PVAMC had "copies of records which appeared to have been deliberately altered by medical center personnel." In addition, she asserts that PVAMC has a "history of supplying information inconsistent with reality to the NRC." Finally, in her attachment to the Petition, the Petitioner refers to a letter from PVAMC to NRC, dated February 23, 1996, which she asserts contained inaccurate information.

The Petitioner has not specified the records that were allegedly altered by PVAMC personnel, and NRC has not identified any alterations of records required to be provided or maintained by NRC requirements. Therefore, this portion of the Petitioner's assertion has not been substantiated.

The Petitioner also asserts that her attached "chronological summary" of correspondence between PVAMC and NRC will "attest" to the fact that there had been a "consistent pattern of NRC violations occurring within the medical center" and that the licensee has a "history of supplying information inconsistent with reality to the NRC, and taking minimal, if any effort to correct cited violations." The attachment to the Petition references, among other documents: (a) an NOV issued to the licensee dated January 4, 1996; (b) a letter from PVAMC responding to the NOV, dated February 23, 1996, in which PVAMC allegedly supplied NRC with inaccurate information; (c) a letter from NRC to the licensee dated April 19, 1996, which noted "inconsistencies" in the licensee's letter, dated February 23, 1996; (d) a letter from the licensee dated May 6, 1996, in which the licensee acknowledged that there were inconsistencies in its letter dated February 23, 1996; and (e) a letter from NRC, dated June 27, 1996, accepting the licensee's statements in its letter, dated May 6, 1996, and approving the licensee's corrective actions to the violations cited in the NOV dated January 4, 1996.

The licensee's letter, dated February 23, 1996, responded to the NOV issued on January 4, 1996, citing it, among other things, for violating 10 CFR 35.13(c) by replacing the RSO without receiving a license amendment, and for violating 10 CFR 35.21(a) and 35.22(a)(3) by conducting a meeting of the RSC without half of the RSC membership or the RSO being present. In its response to the violations, by letter dated February 23, 1996, the licensee stated

that an amendment request had been filed during the government-wide furlough, as the RSO was furloughed but, in order to ensure uninterrupted coverage of the radiation safety program, a nuclear physician was assigned as RSO until the shutdown terminated. The licensee also stated that the full RSC could not be assembled because its members, including the RSO, had been furloughed.

This information initially appeared to the NRC staff to be inconsistent with its understanding of the events surrounding the furlough. Among other things, the NRC determined that, contrary to the licensee's statement, the RSO had never been furloughed. By letter dated April 19, 1996, the licensee was requested to provide clarification of the facts surrounding its understanding of these events. By letter dated May 6, 1996, the licensee submitted its response to this letter. In its response, it apologized for any inconsistency. The licensee stated that the RSO had been scheduled to be furloughed and the redesignation request filed with the NRC was to ensure radiation safety compliance in preparation for the contingency of the furlough. The licensee admitted, however, that the RSO was never officially furloughed and had not been contacted to attend the meeting.

NRC evaluated the information submitted by the licensee and determined that the information it had submitted in its letter dated February 23, 1996, was inaccurate. Nonetheless, the NRC concluded that the inaccuracy was not a deliberate attempt by the licensee to deceive the NRC, and that the licensee admitted to, and clarified, its error. The Petitioner's "chronological summary" that she submits as an attachment to her Petition does not provide any additional examples of the licensee's failure to submit accurate information. Therefore, this single incident of supplying inaccurate information does not support the Petitioner's assertion that PVAMC has

a "history of supplying information inconsistent with reality to the NRC and taking minimal, if any, effort to correct cited violations." In addition, as described above, the licensee has taken considerable corrective action with regard to other identified violations and problems. Therefore, this matter does not provide a sufficient basis for taking the action the Petitioner has requested.

C. Petitioner's Assertion Regarding Contamination Incident

The Petitioner also asserts that individuals at PVAMC have become contaminated in what the Petitioner believes was an intentional incident. As noted above, NRC conducted an inspection of PVAMC during the period of July 9 through October 20, 1997, during which the inspectors examined the circumstances surrounding a contamination incident that occurred in the Nuclear Medicine Department around July 24, 1997 (Inspection Report 030-14526/97-001, dated December 5, 1997). The incident involved the contamination of the hands of the RSO and the CNMT and contamination of a survey instrument.

The cause of the contamination was not definitively identified; however, NRC staff believes that the instrument may have been contaminated during routine surveys of the Nuclear Medicine Department. The licensee later determined that the survey instrument was contaminated with indium-111, a radionuclide that is not regulated by NRC. However, during the course of NRC's investigation of the contamination incident, NRC found violations of procedures related to the use of byproduct material. The inspector noted that the incident may have been caused by a weakness in the licensee's contamination control techniques, including not using contamination control precautions during the use of radioactive material, and, in some cases, failing to wear

gloves. The inspector determined that the RSO and CNMT hand contamination was most likely caused by handling the contaminated instrument. The PVAMC was cited for four violations, three of which were related to NRC program deficiencies found as a result of NRC's review of the contamination incident, in an NOV dated December 10, 1997 (Inspection Report 030-14526/97-001): (1) failure to provide training to personnel who work in or frequent an area where radioactive materials are used or stored; (2) performing inadequate surveys in an area where radiopharmaceuticals were prepared for use and administered, in that an instrument with a faulty cable that rendered the instrument inoperable was used; and (3) failure to use an extremity monitor by a nuclear medicine technologist.[5]

Notwithstanding the above, the results of urinalyses performed on the licensee personnel involved in the incident indicated that there had been no intake of radioactive material by any of these individuals, including the Petitioner. In addition, the results of thyroid counts taken of these individuals indicated that the Petitioner did not exhibit any counts above background in any of the radioactive iodine channels.[6]

The Petitioner also asserted in her Petition that she was fearful for her personal safety as well as that of her then unborn child, that certain NRC staff shared these concerns, and that she

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[5]The licensee committed, in its response to the NOV by letter dated January 9, 1998, to providing training to staff, to ensure that appropriate techniques will be used by its personnel so as to minimize contamination and avoid such incidents in the future. It also committed to provide training in the requirement to use personnel monitors and proper survey techniques.

[6]The CNMT did have an uptake of 1.5 $X10^{-3}$ Bq (40 nanocuries) of iodine-123, which is indicative of a minor intake of iodine-123 (a radionuclide not regulated by NRC, but regulated by the State of Pennsylvania). The licensee indicated that training will be given to this individual to ensure that appropriate techniques are used to minimize contamination in the future.

believed that the contamination was intentional. In support of her claim, she stated that "two senior NRC physicists telephoned, and cautioned me to remove all consumable items from my office and not to eat or drink anything over which I did not have positive control." Although the NRC inspector did caution the Petitioner as she stated, this was advice given following the contamination incident as a reasonable precautionary health physics recommendation, based on the circumstances of the individual situation and the Petitioner's expressed concern for her personal safety.

Additionally, the Petitioner stated that "I received a visit in my office by two NRC inspectors, one of whom came to caution me that he believed my physical safety was in jeopardy due to the allegations I had made regarding violations involving human uses of radioactive materials." The Petitioner has not provided specific information as to who the inspector was who made this statement, and NRC has been unable to identify any individual as having made this statement. Nonetheless, NRC is aware that the Petitioner had raised a concern about her personal safety during 1997 following her raising allegations to NRC. However, NRC also was aware that the PVAMC security force was contacted by the parties involved. Therefore, the Petitioner has not raised any new information of which the NRC was not aware. As discussed above, NRC investigated the contamination incident, and did not find any evidence that the contamination incident was intentional and that the Petitioner was in any physical danger as a result of this incident.

Furthermore, as explained above, the licensee has since made numerous changes to its program and organizational structure, and has developed a program to encourage employees to raise nuclear safety concerns without fear of retaliation. In addition, as is also explained

above, NRC will continue to closely monitor the licensee's program on an accelerated inspection schedule to assure that PVAMC's corrective actions for past problems continue to be effective. Therefore, notwithstanding the seriousness of the situation that occurred during 1997, the Petitioner has not provided any information that would provide a basis for the NRC to take additional action such as she requested at this time.

D. Petitioner's Assertion of Employees' Fear of Raising Safety Concerns

The Petitioner also asserts that PVAMC employees are fearful of bringing safety concerns to the licensee for fear of retaliation, and to NRC due to NRC's "history of inaction" regarding the medical center.[7] With regard to the Petitioner's assertion that PVAMC employees are fearful of bringing forth safety concerns, as described above, during NRC inspections conducted at the licensee's facility from 1995 through 1997, certain programmatic weaknesses were identified, including communication problems among PVAMC staff, management, the prior RSO, and the previous RSC chairman. Furthermore, NRC became aware that, as a result of these problems, some PVAMC employees may have been reluctant to inform management or NRC about safety concerns. However, as described above, NRC Region I and Headquarters management met with the licensee on December 18, 1997, to discuss these program deficiencies, and subsequently issued a CAL, in which the licensee made several commitments to improve its oversight of the radiation safety program and to provide training to all nuclear medicine staff, researchers using radioactive material, RSC members and the facility management, on all applicable NRC regulatory requirements, on management expectations, and on the policy on

[7]The Petitioner's assertion of NRC's history of inaction regarding the PVAMC was referred to the Office of the Inspector General on February 12, 1998.

encouraging employees to bring identified program deficiencies to management's attention. The licensee committed to complete these items by May 30, 1998. As discussed above, NRC inspected the facility June 1-3, 1998, and confirmed that the licensee completed these items. Additionally, the licensee is on an accelerated inspection schedule so that NRC can closely monitor PVAMC's progress in improving communication among the facility staff and program performance.

The licensee has conducted a comprehensive review and assessment of its radiation safety program and provided a copy of the report to NRC by letters dated April 6 (with revised copy of report dated April 10) and April 13, 1998. NRC has determined that the assessment was of an adequate depth and breadth and covered not only technical radiation safety program issues but was expanded to include interpersonal communications, cooperation, and conflict resolution among the facility staff, as well. An audit was also performed by the Department of Veteran's Affairs' National Health Physics office manager.

NRC has found, through a review of the audit report and during its inspection performed June 1-3, 1998, that PVAMC has provided comprehensive training to all nuclear medicine staff, researchers using radioactive materials, RSC members, and facility management. The training focused on, among other things, the right and duty of employees to raise any nuclear safety concerns to management, or directly to NRC.

The inspectors also reviewed the implementation of PVAMC's actions documented in its responses to the CAL. The inspectors, through a review of records, discussions with the licensee's staff, and observation of onsite activities, noted that major staff changes have

occurred in areas that affect communication of management's message to staff concerning the improved communications at all levels and the significance of bringing forth any safety concerns. The inspectors noted that these staff changes, as well as the implementations of their directives, significantly improved personnel's understanding of the importance of radiation safety and the importance of a work environment in which staff is encouraged to bring forth issues relating to radiation safety without fear of retaliation. The licensee's new senior management, the new RSC chairman, and the new RSO, in cooperation with the facility staff, have initiated and implemented specific actions, including providing training to staff on the importance of reporting any program deficiencies and safety concerns. Additionally, management has worked to build teamwork and improve communication, and has made a commitment to increase program oversight. During the June 1998 inspection, the inspectors found that the licensee's corrective actions to date have been effective. The new RSO and management team are making a concerted effort to create a favorable work environment which fosters an open flow of communication. The inspectors interviewed staff and found that individuals appear to be "more comfortable" raising safety concerns without fear of retaliation.

In sum, although, as a result of a general weakness in communications at the licensee's facility, there may have been, in the past, a reluctance among employees to raise safety concerns, NRC has found that the licensee has taken numerous effective corrective actions to ensure that employees are encouraged to raise nuclear safety concerns. Additionally, as stated earlier, PVAMC is on an accelerated inspection schedule, and this issue will be reviewed during future inspections. Therefore, the Petitioner's assertions regarding this issue do not provide a basis that would warrant the action she has requested.

The Petitioner also asserts that NRC withdrew a civil penalty after a change in NRC Region I management, possibly because it was not "cost-effective" to pursue the issue. She states that NRC's withdrawal of a civil penalty involving a violation of protected activities sent a "chilling" effect to individuals both within and external to the PVAMC who may have thought of raising a safety concern.

NRC staff assumes that the Petitioner is referring to the NOV dated September 18, 1996 (EA 96-182). As discussed earlier, NRC issued a NOV and Proposed Imposition of Civil Penalty of $8000 to PVAMC as a result of concluding that PVAMC had discriminated against the Petitioner for raising safety concerns in November 1995, related to then-impending Federal government furloughs. NRC had identified this violation based on the determination of the DOL Acting District Director of the Wage and Hour Division that the Petitioner had been chastised by her immediate supervisor, the Chief of Engineering, for raising safety concerns. However, as explained previously, after its review of all of the available information, including the results of the OI investigation and PVAMC's responses to the NOV, NRC concluded, in a letter dated September 27, 1997, that the violation would be more appropriately classified as a Severity Level III violation and that enforcement discretion would be exercised to withdraw the civil penalty, pursuant to Section VII.B.6 of the Enforcement Policy. In this case, the determination to withdraw the civil penalty was made based on the fact that the chastisement of the Petitioner did not substantially affect the conditions of her employment; an apology was issued; she remained the RSO; DOL had concluded that it found that PVAMC had met the terms and conditions of remedies it had outlined concerning the violation; and investigations conducted by DOL and OI failed to substantiate that there had been any continued discrimination against the Petitioner. Nonetheless, while NRC believes that there is no merit to the Petitioner's assertion

that the decision to withdraw the civil penalty resulted from the fact that it was not "cost-effective" to pursue the issue against PVAMC, the Petition was forwarded to the Office of the Inspector General for its review on February 12, 1998.

IV. CONCLUSION

NRC has determined that, for the reasons discussed above, the Petitioner has not provided a sufficient basis for taking any action to suspend or revoke PVAMC's license, as requested in the Petition. Accordingly, the Petition is denied.

As provided by 10 CFR § 2.206(c), a copy of this Decision will be filed with the Secretary of the Commission, for the Commission's review. The Decision will become the final action of the Commission 25 days after issuance unless the Commission, on its own motion, institutes review of the Decision within that time.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello

Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

Dated at Rockville, Maryland, this 28 day of August, 1998.

7590-01-P

U.S. NUCLEAR REGULATORY COMMISSION

Docket Number: 030-14526

License Number: 37-00062-07

Department of Veterans Administration Medical Center

Philadelphia, Pennsylvania

ISSUANCE OF DIRECTOR'S DECISION UNDER 10 CFR § 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (Commission or NRC), has taken action with regard to a Petition dated January 28, 1998, submitted by Ann Lovell (Petitioner), regarding the Department of Veterans Administration Medical Center, Philadelphia, Pennsylvania (PVAMC). The Petitioner has requested that NRC take immediate action to suspend or revoke the NRC license issued to PVAMC. As grounds for her request, the Petitioner asserts that executive management is operating in a manner that has the potential to present a significant danger to medical center patients, staff, and the general public. Specifically, the Petitioner asserts that: (1) there has been a consistent pattern of NRC violations occurring within the medical center for which PVAMC has failed to take corrective action; (2) PVAMC has a history of supplying false information to NRC; (3) individuals, including the Petitioner, became contaminated with radioactive material in the nuclear medicine department as a result of what the Petitioner believes was an intentional incident; and (4) PVAMC employees are fearful of bringing safety concerns to the licensee for fear of retaliation, and to NRC because of NRC's "history of

inaction" regarding the medical center. Additionally, the Petitioner claims that NRC withdrew a civil penalty after a change in NRC Region I management, which may have been withdrawn as it was not "cost-effective" to pursue the issue.

The Director of the Office of Nuclear Material Safety and Safeguards has denied the Petition. The reasons for this denial are explained in the "Director's Decision Under 10 CFR § 2.206," (DD-98-07) the complete text of which follows this notice. The Director's Decision is available for public inspection at NRC's Public Document Room, the Gelman Building, 2120 L Street, N.W., Washington, D.C.

A copy of this Decision will be filed with the Secretary of the Commission, for the Commission's review, in accordance with 10 CFR § 2.206(c) of the Commission's regulations. As provided by this regulation, the Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision, unless the Commission, on its own motion, institutes a review of the Decision within that time.

Dated at Rockville, Maryland, this 28 day of August 1998.

FOR THE NUCLEAR REGULATORY COMMISSION.

Carl J. Paperiello

Carl J. Paperiello, Director,
Office of Nuclear Material Safety and Safeguards.

313 North Woodland Avenue
Glenolden, PA 19036
January 28, 1998

Director, Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Request to Suspend or Revoke the NRC Operating License issued to the Philadelphia VA Medical Center, License No. 37-00062-07

To Whom It May Concern:

I am writing to you pursuant to section §2.200 of Subpart B in 10 CFR Part 2, ***"Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"*** to request that the NRC issued operating license granted to the Department of Veterans Affairs-Philadelphia VA Medical Center, be immediately suspended or revoked. The reasons for this request are that despite ***repeated*** actions or the threat of actions by the Region I US NRC staff, the executive management of the Philadelphia Veterans Affairs Medical Center has continued to operate in a manner which has the potential to present a significant danger to medical center patients, staff, and the general public.

I can speak with some authority on the subject as I was the Radiation Safety Officer on the above noted NRC license until I was medically unable to continue working in October, 1997. As an employee, and the individual who formerly was held responsible for safe radiological operations consistent with 10 CFR §35.21, I am sure the request to suspend or terminate the license of my employer is unique as it would leave me without a job, but I am deeply concerned about the health and safety of the patients, radioactive research subjects, and my former colleagues.

I believe immediate suspension of the NRC license is ***imperative*** to ensure a safe radiological environment as well as safe working environment in general. When working at the medical center, I for one was fearful for my personal safety as well as that of my then unborn child and clearly, senior US NRC Region I health physicist shared these concerns. For example, I received a telephone conference call from two senior NRC physicists who **cautioned me to remove all consumable items from my office and not to eat or drink anything which I did not have positive control over.** As one of these inspectors was involved in investigating the National Institute of Health incident where a pregnant worker ingested radioactive material, I believe the concern was that I might fall prey to a similar event. While I followed this guidance and immediately removed all edible items from my office, less than 2 weeks later I, and two other members of the staff, became contaminated with radioactive material in the nuclear medicine department. I have come to believe that the contamination incident was intentional.

As if that incident were not enough, I also received a visit in my office by two NRC inspectors, one of whom came to caution me that he believed my physical safety was in jeopardy due to the allegations I made regarding significant violations involving human uses of radioactive materials

occurring within the medical center which he and other inspectors were able to independently substantiate. I understand that this inspector returned to the NRC Region I office and informed all members of management at the NRC of the extreme problems I had informed him of (and which he substantiated) and demanded immediate action. To date, no action has been taken, and inspection reports received by the medical center make no mention whatsoever of these incidents. I also know that the inspector had copies of records which appeared to have been deliberately altered by medical center personnel.

For more than a year, the NRC was aware and has even espoused, verbally and in writing, on multiple occasions that medical center staff, including members of the Radiation Safety Committee, are fearful of raising safety concerns regarding radioactive materials uses (or misuses) for fear of retaliation by VA management. I have also learned that NRC Region I and Headquarters personnel were informed by Philadelphia VAMC staff during an inspection conducted 12/97 that **the staff are fearful of bringing safety concerns not only to VA management, but also to the NRC due to NRC's history of inaction within the medical center.** With that knowledge, permitting the PVAMC to continue to use radioactive materials for the past two years is nothing short of reprehensible and permitting the use of radioactive materials to date defies both the spirit of radiation protection philosophy as well as the law as described in the Atomic Energy Act and the Energy Reorganization Act.

As the attached chronological summary of PVAMC/NRC correspondence will attest, there has been a consistent pattern of NRC violations occurring within the medical center . The PVAMC has a history of supplying information inconsistent with reality to the NRC, and taking minimal, if any, effort to correct cited violations. In the single instance where the NRC issued a base Civil Penalty which was doubled based on VA harassment of a whistleblower, the penalty was later completely withdrawn following a change in NRC Region I management. This was despite the fact that the former NRC Region I Director of the Division of Nuclear Material Safety was apparently so appalled by both the local and national VA response to this important safety issue that he stated during a transcribed Enforcement Conference (where VA local and national representatives spent two hours trying to justify their treatment of whistleblowers):

"Okay, you know, I guess I would normally apologize for preaching, but I would--the perception here is that you haven't gotten the message with regards to your roles and responsibilities even at this late date, many months after the issues began."

What is absolutely appalling is that a year and a half after this statement was made, in my opinion, VA management had not made one single attempt to improve the working environment, has not investigated the incident, nor have they provided a safe working environment where employees are able to raise safety concerns without fear of retaliation.

Apparently, the "new" NRC Region I management did not perceive a significant problem worthy of a civil penalty even though the VA ***admitted*** harassing the employee for engaging in a "protected activity". In this single action, the NRC sent a "chilling effect" to individuals both within and external to the PVAMC who may have thought of raising a safety concern. I had later been informed that the fine may have been withdrawn as it was not "cost effective" to pursue the issue in court against the economically powerful Department of Veterans Affairs.

In summary, I have resorted to requesting the NRC license 37-00062-7 be immediately suspended or revoked as it is apparent that the NRC has not effectively ensured a safe working environment exists where employees are free to raise safety concerns. This is despite a repeated NRC presence at the PVAMC and issuance of several violations for more than two years. When reviewing Enforcement Sanctions as described in 10 CFR 2, Appendix C, I am dumbfounded that violations directly impacting human health and safety occurring in the PVAMC are overlooked, numerous and repeat violations occur and continue to occur with alarming regularity, radioactive materials "control" is out-of-control. I do understand that the NRC has discretionary authority, but I cannot help but wonder if these events occurred at a non-federal facility if the same Enforcement Actions (or lack of them) would have occurred. I therefore implore the Commission to issue an order to suspend or revoke the PVAMC operating license because of the clear radiological danger it presents in its current state.

Ann Lovell

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

cc US NRC Headquarters, Director-Enforcement
Commonwealth of Pennsylvania
Honorable Senator Rockefeller (W. Virginia)

Attachment 1
Chronology of Philadelphia VA/NRC interaction since whistleblower incident of 11/17/95

11/17/95: NRC inspectors on station following removal of RSO following her contact with the NRC.
12/5/95: Radiation worker submits claim to DOL regarding harassment for engaging in a protected activity.
1/4/96: NRC issues NOV (030-14526/95-002) as VA management identified conducting NRC license business in violation of regulations.
2/23/96: VA responds to NRC letter of 1/4/96 and supplies the NRC with inaccurate information.
3/6/96: DOL finds that the VA was discriminated against the RSO for her contact with the NRC to discuss a safety issue.
4/12/96: NRC responds to DOL finding of discrimination and requests information under oath from the VA. Specifically, the NRC wants to know what actions the agency has taken to discourage a "chilling effect".
4/19/96: NRC responds to VA letter dated 2/23/96 and writes "...upon review of your letter, we find your characterization of events surrounding the violations to be inconsistent with our understanding. The following inconsistencies were noted...."
5/6/96: VA responds to NRC letter dated 4/19/96 and notes that the VA was wrong and the NRC understanding of the events was correct.
5/21/96: VA responds to NRC letter of 4/12/96 indicating that there is no chilling effect. Hence, the VA felt secure that employees felt free to raise safety concerns.
6/27/96: NRC issues a letter to the VA accepting the statements in the VA's 5/6/96 letter and approves corrective actions to the violations noted in the 1/4/96 NOV.
7/23/96: NRC schedules a predecisional enforcement conference with the VA regarding the harassment of the whistleblower.
8/26/96: Multiple representatives from local and national VA organizations report to Region I to meet with the NRC regarding the harassment issues. Several VA representatives have undergone "rehearsals" with the VA national attorney and have prepared, typewritten statements to read to the commission. After several hours of presentations, the Region I NRC Director makes the statement quoted in page 2 of this letter.
9/18/96: NRC proposes $8,000 civil penalty based on VA actions from 11/95 through 8/96 as well as statements made during the 8/26/96 Enforcement Conference. The maximum penalty was issued, and then doubled due to the level of management involved in the discrimination as well as the failure of the VA to take any corrective action whatsoever. A Level II violation is also issued.
11/15/96: VA admits the violation of 9/18/96 but states that no civil penalty should be assessed.
9/11/97: NRC issues 9 violations against the VA (03-14526/96-002) based on the results of inspections conducted within the medical center from 1/97-5/97. Issues are safety related and poor communications are cited as a major causative factor for the violations.
9/25/97: NRC withdraws penalty for worker discrimination and reduces the severity level of the violation to a Level III.
11/4/97: VA admits the violations identified in the 9/11/97 correspondence.
12/10/97: NRC issues results of inspection conducted from 7/97 through 10/97 and identifies four additional safety violations.
12/19/97: NRC issues a CAL to the VA for its communications problems and the chilling effect among its employees and overall degradation of the radiation protection program.