



U.S. OFFICE OF SPECIAL COUNSEL

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The Special Counsel

January 15, 2015

The President  
The White House  
Washington, D.C. 20510

Re: OSC File Nos. DI-12-0927 and DI-12-1933

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veterans Affairs' (VA) investigative reports, based on disclosures of wrongdoing at the South Texas Veterans Health Care System (STVHCS), Audie L. Murphy Memorial VA Hospital (Hospital), San Antonio, Texas, made to the Office of Special Counsel (OSC). OSC has reviewed the reports and, in accordance with 5 U.S.C. § 1213(e), provides the following summary of the allegations and our findings.

The whistleblowers, Dr. Tuhin Chaudhuri, a former staff physician, and Mr. Joe Jimenez, a former radiological technologist, assigned to the Hospital's Nuclear Medicine Service (Nuclear Medicine), disclosed that employees engaged in conduct that constituted a violation of law, rule, or regulation; gross mismanagement; and a substantial and specific danger to public health and safety. They alleged that Nuclear Medicine managers: implemented a new clinical procedure without obtaining approval from the Hospital's Radiation Safety Committee or providing training to staff; engaged in other unsafe clinical practices that resulted in unnecessary radiation exposure to patients and staff; and failed to report incidents of radiopharmaceutical dosing errors as required by VA rules.

**The investigation substantiated a radiopharmaceutical dosing error in violation of Nuclear Regulatory Commission (NRC) regulations and the failure to report the error as required by VA rules. The investigation also confirmed that in June 2011, Nuclear Medicine management implemented a new clinical procedure for lung ventilation studies without providing adequate training and orientation to staff, and that there was a lack of effective communication between Nuclear Medicine and the Radiation Safety Office. Nevertheless, the agency did not find a violation of regulations, VA policy or rules, a substantial and specific danger to public health or safety, or gross mismanagement in the implementation of the procedure or subsequent contamination incident. The investigation did not substantiate the allegation of wrongdoing relating to the modification of certain**

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**imaging study protocols. In response to the findings, the agency took corrective action, including providing training to staff and revision of the Hospital's spill procedures.**

**I have determined that the VA's reports meet all of the statutory requirements. I have also determined that the findings relating to the dosing error, reporting failure, and modification of imaging study protocols appear to be reasonable. Based on the information presented in the reports, however, I do not find reasonable the agency's conclusions concerning the implementation of the aerosol procedure and subsequent contamination incident.**

On May 2, 2012, OSC referred the whistleblowers' allegations to then-Secretary of Veterans Affairs Eric K. Shinseki to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). Secretary Shinseki tasked then-Under Secretary for Health Robert A. Petzel with the investigation in this matter, who requested that the Veterans Health Administration's (VHA) National Health Physics Program (NHPP) conduct the investigation. In addition, Dr. Milton Gross, then-chair, National Radiation Safety Committee and national director, Nuclear Medicine and Radiation Safety Services, reviewed information relating to the Nuclear Medicine clinical practices and conducted an expert panel review of patient ventilation studies. On October 19, 2012, Secretary Shinseki submitted the agency's report to OSC. In response to OSC's request, the agency provided a supplemental report on April 10, 2013, which included NHPP's investigation and inspection reports and related documents. Pursuant to 5 U.S.C. § 1213(e)(1), the whistleblowers submitted comments on the agency report and supplemental report. As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the agency reports and whistleblowers' comments to you.<sup>1</sup>

### ***I. The Whistleblowers' Disclosures***

The whistleblowers explained that pursuant to NRC regulations, VA facilities are required to use procedures based upon sound radiation protection principles to limit

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<sup>1</sup> The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c) and (g). Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

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exposure to radiation at levels that are “as low as reasonably achievable” (ALARA). See 10 C.F.R. part 20. Under VA rules, the chief of Nuclear Medicine is responsible for working with the facility’s Radiation Safety officer and Radiation Safety Committee to monitor activities to ensure safe radiation environments. The Radiation Safety Committee is responsible for reviewing and approving all proposed uses of radioactive material for clinical use. See Veterans Health Administration (VHA) Handbook 1105.02, *Nuclear Medicine and Radiation Safety Service*.

The whistleblowers disclosed that in May 2011, Dr. Daniel Duffy, chief, Nuclear Medicine Service, implemented a new clinical procedure for lung ventilation studies without obtaining approval from the Hospital’s Radiation Safety Committee or providing training to staff. The new procedure involved an aerosol radiopharmaceutical, technetium (Tc)-99m DTPA Aerosol (aerosol procedure). The ventilation study is one phase of a two-part ventilation/perfusion lung scan that studies inhalation and blood flow in the lungs. In the past, Nuclear Medicine used Xe-133 (xenon gas) for the ventilation phase of the study. However, Dr. Duffy directed Nuclear Medicine staff to use Tc-99m DTPA Aerosol, which requires the use of a particular nebulizer device and related equipment. The whistleblowers contended that the use of the new aerosol procedure and equipment required approval by the Radiation Safety Committee pursuant to VHA Handbook 1105.02.

The whistleblowers explained that Nuclear Medicine staff encountered problems with this new aerosol procedure, and the studies produced were not accurate or useful for diagnostic purposes. Mr. Jimenez stated that he and other technologists were not trained on the aerosol procedure or equipment. In addition, the whistleblowers reported that the nebulizer leaked, possibly as a result of a defect in the device, improper use, or both. Whatever the cause, they contended that the leakage adversely affected the accuracy of the studies and resulted in unnecessary radiation exposure to staff and patients.

Dr. Chaudhuri observed approximately 30 cases between May and December 2011 in which the aerosol procedure failed to yield accurate results. He noted that, in many cases, the studies revealed the presence of radiopharmaceutical material outside of the lungs, which was indicative of leakage. The whistleblowers raised their concerns to Dr. Duffy and Chief Nuclear Medicine Technologist Chea W. Kim, and requested to use the xenon gas protocol until the aerosol procedure was approved and the staff had been trained for its use. Nevertheless, Dr. Duffy insisted they continue using the aerosol procedure.

The whistleblowers described an incident on September 21, 2011, involving radioactive contamination of the hallway adjacent to the Nuclear Medicine laboratory (hot lab). The spill occurred when Mr. Jimenez transported the nebulizer and related equipment with residual radiopharmaceutical material to the hot lab after performing an aerosol procedure. Mr. Kim instructed Mr. Jimenez and another technologist to

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decontaminate the area by cleaning the floor for more than four hours. Dr. Chaudhuri recommended to Mr. Kim that the contaminated area should be covered, isolated, and monitored to allow the radioactive material to decay before cleaning. Nevertheless, Mr. Kim insisted that the clean-up efforts continue. Although Mr. Kim contacted Radiation Safety Officer John White, who was located in Dallas, on-site Radiation Safety staff were not notified of the contamination until several hours later that evening.

Radiation Safety Officer Eric Wittenbach subsequently investigated this incident and prepared a report identifying the root cause of the spill as “inadequate preparation and planning prior to initiating a new clinical procedure.” The report indicated that the clean-up was “an extraordinary exposure event” for the employees involved. It identified a lack of supervisory experience, training, and understanding of ALARA principles, and included recommendations for training and revision of the facility’s spill procedures. The report also recommended that the Radiation Safety Committee revise the aerosol procedure to provide adequate controls. However, the whistleblowers reported that Dr. Duffy continued to require staff to use the aerosol procedure without implementing Mr. Wittenbach’s recommendations. Dr. Chaudhuri continued to raise his concerns regarding clinical safety issues to Dr. Duffy and Chief of Staff Julianne Flynn, with no meaningful response. The whistleblowers noted that Dr. Duffy may have ceased using the aerosol procedure sometime in February or March 2012. They could not confirm this information because they were no longer working in the Clinic.

According to the whistleblowers, there were other instances of improper clinical practices that resulted in unnecessary exposure to radiation. Mr. Jimenez described an incident that occurred between February 25 and March 4, 2011, where Mr. Kim gave an incorrect dose of radiopharmaceutical to a patient during a heart imaging study. The first dose that Mr. Kim gave the patient was three times the amount prescribed for the rest phase of the study. When Mr. Jimenez pointed out this error, Mr. Kim waited two additional days to administer the second dose and conduct the stress phase of the study. Mr. Jimenez explained that in addition to receiving an excessive dose of radiopharmaceutical, this patient was required to undergo a three-day, rather than a one-day, study. Mr. Jimenez also asserted that this incident was not reported to the facility's Radiation Safety Officer as required by VA rules.

Additionally, the whistleblowers stated that in early 2011, Dr. Duffy and Mr. Kim began instructing staff to omit the dynamic portion of certain studies, including liver, bone, and gallbladder scans. Mr. Jimenez explained that Dr. Duffy and Mr. Kim did not provide any explanation for the elimination of the dynamic portion, which is typically a key component of these studies.

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## *II. The Agency's Reports*

The investigation conducted by NHPP confirmed that in June 2011, Dr. Duffy directed Nuclear Medicine staff to begin using the aerosol procedure with Tc-99m in lieu of the xenon gas protocol for all lung ventilation studies. The report noted that the Hospital's permit for radioactive materials provides for the use of any physical or chemical forms of radioactive material for imaging studies under 10 C.F.R. 35.200 when supervised by a physician authorized user. Dr. Duffy, as chief of Nuclear Medicine and a physician authorized user on the facility's permit, has the authority to determine the methods for imaging studies. The report concluded that approval of the aerosol procedure and related equipment by the Radiation Safety Committee was not explicitly required by NRC regulations. The agency's supplemental report further clarified that VA policy and rules likewise do not require approval to initiate the use of a new clinical imaging protocol if the use does not change the radiation safety program. NHPP concluded that the implementation of the aerosol procedure would not have been expected to involve such a change, particularly as a similar protocol for Tc-99m was already included in the Nuclear Medicine procedural manual.

Nevertheless, the report acknowledged that, while not required, "it is a good practice" to inform the Radiation Safety staff of protocol changes. NHPP found that there was a lack of effective communication between Nuclear Medicine and the Radiation Safety Office. The report explained that the decision to implement this new procedure was based on an external audit of Nuclear Medicine in June 2011 and the auditor's suggestion of a possible regulatory deficiency related to the use of xenon gas. The final audit report clarified that there was no regulatory deficiency, but recommended discussing the issue in detail with the Radiation Safety officer. NHPP found that the Radiation Safety officer was never consulted. Rather, Dr. Duffy took immediate steps following the audit to implement the aerosol procedure without communicating with the Radiation Safety officer. NHPP concluded that more effective communication and collaboration between Nuclear Medicine and the Radiation Safety Office might have precluded a perceived need for an abrupt change in protocols and, as stated in the supplemental report, may have helped provide additional radiation safety perspectives to Nuclear Medicine staff on the procedure.

The investigation further substantiated that the implementation of the aerosol procedure did not effectively involve training and orientation for applicable staff. According to the agency report, Mr. Kim provided training to the technologists on the use of the aerosol procedure, however this training was not documented or coordinated with the Radiation Safety Office, and some of the staff did not consider the training to be adequate. Following reports of leakage of radiopharmaceutical material from the aerosol equipment in mid-June 2011, the Radiation Safety Office was notified. Radiation Safety staff inspected the equipment and determined that there were issues with securing the

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equipment during use, and that the technologists were unclear about the location of a written protocol for the aerosol procedure. Radiation Safety staff determined that the training that had been provided to the technologists “was not adequate and sufficient for radiation safety purposes,” and they provided additional training to the technologists on June 29, 2011. NHPP concluded that the reports of radiation safety issues with the aerosol procedure were addressed by the Radiation Safety Office. Further, NHPP concluded that a regulatory violation was not warranted, because “the lack of training did not lead to a regulatory violation or radiation safety outcomes that exceeded a regulatory limit and since the supervised technologists were following instructions of the physician authorized user for the clinical use of the imaging agent.”

With respect to the written protocol for the aerosol procedure, the report confirmed that pursuant to VHA Handbook 1105.02, Nuclear Medicine is required to publish its policies, procedures, and protocols. The report also explained that NRC regulations require written protocols for each nuclear medicine exam. NHPP found that the Nuclear Medicine procedural manual included a procedure, dated January 25, 2003, for a Tc-99m DTPA lung aerosol study. A cover sheet was signed by Dr. Chaudhuri on November 24, 2004, and by Dr. Duffy on June 2, 2011. NHPP determined, however, that the written procedure had not been reviewed or re-validated by Nuclear Medicine prior to initiating the new aerosol procedure in June 2011. In response to OSC’s request for clarification, the agency’s supplemental report explained that the January 25, 2003 procedure found in the procedural manual was not the protocol for the aerosol procedure implemented by Dr. Duffy in June 2011. Rather, Nuclear Medicine staff were directed verbally and by e-mail to use the instructions and suggested protocols provided by the manufacturer of the equipment for the new aerosol procedure. NHPP determined that the written procedure was not revised to reflect the new protocol until April 1, 2012, and was then added to the procedural manual sometime before May 23, 2012. The supplemental report noted that Nuclear Medicine ceased using the aerosol procedure in December 2011, reverting to the use of the xenon gas protocol, but resumed use of the aerosol procedure on May 23, 2012, due to a shortage of xenon gas. The Hospital currently has the option to use either procedure. Most often, the xenon gas procedure is used, with the aerosol procedure used only when there is a shortage of xenon gas.

According to the report, the expert panel review of the lung ventilation studies alleged to involve contamination did not substantiate those allegations.<sup>2</sup> The expert panel found that the doses of aerosol administered in those cases were within protocol limits. Further, the review did not reveal evidence of contamination. The expert panel found that the quality of the images was sufficient for diagnostic purposes and comparable to the

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<sup>2</sup> Dr. Milton Gross, then-chair, National Radiation Safety Committee and national director, Nuclear Medicine and Radiation Safety Services, along with Dr. K-K Wong, a board certified senior member of the nuclear medical staff at the Ann Arbor VA Medical Center, performed the expert panel review.

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quality of images obtained in other nuclear medicine labs. The report noted that the protocols for lung ventilation studies require technical expertise and patient cooperation to limit leakage of the gas or aerosol, and that the escape of aerosol in the course of an examination results in very low levels of radioactivity that pose no significant additional radiation exposure risk to the patient beyond that of the examination itself, or to the involved technologist.

NHPP did not find a regulatory violation, significant deviation from best health physics practices or VA policy, or a substantial and specific danger to public health or safety in relation to the implementation of the aerosol procedure. The report did not consider or make any finding concerning gross mismanagement. NHPP recommended that the Hospital continue efforts for increased communication between Nuclear Medicine and the Radiation Safety staff. It also recommended that the Hospital continue efforts to effectively communicate with all staff and finalize changes to the procedural manual.

Further, the investigation did not substantiate the whistleblowers' allegations of improper clean-up procedures resulting in excessive radiation exposure following the spill and contamination incident in September 2011. NHPP concluded that the immediate response to the spill was appropriate based on the information available to the Nuclear Medicine staff and Radiation Safety Officer at the time. NHPP found that the two technologists wore proper protective equipment and used appropriate radiation survey methods and equipment to determine the extent of the contamination. According to NHPP, there are two options for reducing surface exposure rates to below trigger levels or a predetermined rate: (1) clean the area using routine surface cleaning techniques; or (2) cover the contaminated area to minimize spreading and allow the radioactive material to decay. NHPP found either method was viable in this instance, and that Mr. Kim took appropriate measures to minimize further spread of the contamination. NHPP noted that then-Radiation Safety Officer John White, who was not on-site, concurred in the plan to clean the area based on the information he was given and that the spill did not warrant tasking the on-site Radiation Safety staff with the clean-up. Mr. White was not aware that the cleaning continued for four hours. Mr. Kim eventually decided to cover the locations to provide additional time to decay. After review of the radiation survey results, NHPP found that the exposure rates did not preclude efforts to clean the area.

The report indicated that following this incident, a training session on spill response procedures was held with the technologists. Several weeks later, the Radiation Safety Office received a report from the dosimetry vendor indicating that the dosimeters for Mr. Jimenez and the other technologist involved in the clean-up had recorded radiation doses that required an investigation. The results were 1.7 rem for Mr. Jimenez and 3.7 and 3.8 rem for the other technologist, compared to an annual limit of 5 rem. Mr. Wittenbach attributed these doses to the spill clean-up effort. The report explained that, as the radiation safety officer, Mr. Wittenbach prepared a draft report of root causes

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and recommendations; however, the draft report was not formally accepted by the Radiation Safety Committee. Rather, Hospital leadership determined that a root cause analysis team should be convened to conduct a formal investigation of the incident, which was completed in mid-January 2012.

According to the report, the root cause analysis team concluded that the dosimeters worn by the two technologists might have been contaminated and, thus, the dose results were not reflective of actual individual exposures. Further, the team concluded that the root causes for the contamination event and elevated radiation doses were: (1) the complex mechanism for the aerosol procedure increases the risk of human error resulting in potential radioactive spills; and (2) disassembly and transport of the equipment within the patient care area increased the likelihood of a spill and contamination of that area, hot lab, and hallway. The team recommended that Nuclear Medicine: (1) standardize and reinstitute the use of the xenon gas protocol, minimizing the use of the aerosol procedure; (2) develop standard procedures for disassembly of aerosol equipment; and (3) if using the aerosol procedure, designate specific patient care rooms to minimize the risk of contamination of other areas. In response, Nuclear Medicine discontinued the use of the aerosol procedure in January 2012 until May 2012, when it was necessary to use the procedure due to a shortage of xenon gas. In April 2012, Nuclear Medicine developed a standard procedure for the use and disassembly of equipment for the aerosol procedure, which limited the use of the procedure to a specific room, as recommended. NHPP concurred with the root cause analysis team's determination of root causes and recommendations and the corrective actions taken.

NHPP found that while the validity of the dose results reported by the vendor could not be ruled out, those results were highly inconsistent with the exposure levels that were measured during the clean-up of the contaminated area. NHPP explained that the reported dose results would have required exposure levels significantly higher than those recorded during the clean-up, which were reportedly within the range typically encountered in a nuclear medicine environment. NHPP further concluded that the elevated doses could not be specifically attributed to the spill clean-up and determined that the annual doses for the two affected technologists were well below NRC regulatory limits or any external reporting requirements. NHPP did not find that the clean-up efforts were outside of acceptable best health physics practices or caused a violation of the ALARA provisions under 10 C.F.R. part 20. Further, NHPP did not conclude that any radiation workers exceeded a regulatory dose limit, or that the spill event represented a substantial and specific danger to public health or safety.

Nevertheless, NHPP concluded that the coordination and communication between Nuclear Medicine and the Radiation Safety Office required improvement to address possible future spills. NHPP recommended that the Hospital implement a more detailed spill procedure to provide clarification and improve coordination. The report recommended that the physician authorized user should continue to determine the

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imaging procedures appropriate for individual patients and the facility should ensure continued implementation of the recommendations by the root cause analysis team and the revised spill procedure. In response to NHPP's recommendation, the Radiation Safety Committee developed and provided training to staff on a facility-level, detailed spill procedure in May 2012.

The investigation substantiated the allegations that an incorrect dose of radiopharmaceutical was administered to a patient during a heart scan, and that this error was not reported to the Radiation Safety officer as required by VA rules. Generally, the report explained that NHPP does not interpret the ALARA provisions in NRC regulation 10 C.F.R. 20.1101(b) to apply to patients administered radiopharmaceuticals under the direction of a physician authorized user. NRC regulations require facilities to have written protocols for each nuclear medicine exam that include the specific dose of radioactivity for each test. Deviations that exceed twenty percent of the dose prescription represent a potential medical event with reporting requirements based on the dose given to the patient.

The report confirmed that a patient was injected with a cardiac stress dosage of approximately 30 millicuries instead of the prescribed dose of 10 millicuries for the rest-phase of the test. NHPP determined that the dosing error did not require external reporting to NHPP or NRC pursuant to 10 C.F.R. 35.3045; however, the error was contrary to 10 C.F.R. 35.63(d) because the administered dose exceeded the prescribed dose by more than twenty percent. NHPP concluded that in light of this regulatory violation, the error should have been reported to the Radiation Safety Officer, Radiation Safety Committee, and Patient Safety officer, pursuant to VA Handbook 1050.01, to ensure that timely and adequate corrective actions could be taken to address the matter and prevent recurrence. The report explained that the dosage of radiopharmaceutical erroneously administered to the patient for the rest phase of the exam is routinely used for the stress phase of a one-day exam. Thus, NHPP found that there was not a substantial increase in the risk of harm to the patient. NHPP did not identify any other dosing errors through its investigation.

The report further confirmed that Nuclear Medicine completed training in dosing errors and incident reporting requirements in June 2012. NHPP recommended that the Hospital comply with VHA Handbook 1050.01 for the identification and reporting of incidents such as dosing errors. NHPP further recommended that the Hospital monitor future effectiveness of the training and reporting of dosing errors during routine audits by the Radiation Safety Office. The agency confirmed with OSC that a follow-up inspection by NHPP did not identify any regulatory violations.

With respect to the allegations concerning Dr. Duffy's instruction to change the imaging protocol for certain studies, the investigation confirmed that Dr. Duffy did instruct staff to omit the dynamic portion of certain studies. NHPP determined, however,

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that the specification of imaging protocols is within the purview of a nuclear medicine physician. Physician authorized users, such as Dr. Duffy, have the authority to modify imaging protocols as needed to facilitate care and provide diagnostic information. The report notes that this is an integral part of the supervising nuclear medicine physician's responsibilities. Thus, the agency did not substantiate the alleged wrongdoing.

### *III. The Whistleblowers' Comments*

The whistleblowers provided comments on the report and supplemental report pursuant to § 1213(e)(1). In his initial comments, Dr. Chaudhuri noted that the report confirmed that his allegations were legitimate. He contended, however, that the report attempted to undermine and/or conceal violations of law, regulations, and rules; minimize the severity of the wrongdoing; and avoid disciplinary action against STVHCS managers. Dr. Chaudhuri asserted that the draft report prepared by Mr. Wittenbach in response to the spill incident was suppressed, and contended that it should have been considered, as it contained information regarding the negligence and violations committed by management. He further commented on managers' failure to review and renew the procedural manual in accordance with VA rules, and emphasized that VA rules require that each procedure performed by the laboratory must be written and updated, even if infrequent or newly implemented. Further, protocols must be specific for the particular laboratory and equipment inventory. Dr. Chaudhuri expressed his concern regarding the confirmed lack of training provided for the aerosol procedure, asserting that this was a clear violation of NRC requirements, as well as VA and Joint Commission rules. He also refuted the findings of the expert panel review of the lung ventilation studies and challenged NHPP's position that ALARA principles do not apply to patients. He provided several citations and excerpts demonstrating that the concept of ALARA is a well accepted principle applied to patient care and maintained that the ALARA principles were violated.

In his supplemental comments, Dr. Chaudhuri disagreed with the agency's finding that the implementation of a new procedure does not require approval by the Radiation Safety Committee or Radiation Safety Office. He further disputed NHPP's findings concerning the procedural manual that was in effect at the time the aerosol procedure was implemented in June 2011 and maintained that there was not a current manual in use at that time. Dr. Chaudhuri also refuted the evidence pertaining to the training provided to staff. Noting NHPP's acknowledgement that NRC regulations require Nuclear Medicine staff to have adequate and sufficient training, he asserted that NHPP's conclusion that there was no violation of those requirements was baseless. He contended that the violations committed by Nuclear Medicine supervisors endangered both patients and employees.

Mr. Jimenez noted in his comments that communication between Nuclear Medicine and the Radiation Safety Office was almost nonexistent. He further asserted

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that Nuclear Medicine leadership failed to comply with NRC requirements by not ascertaining that a radiation protection program, including a program manual, was in place. He noted that management's failure to effectively implement changes in the program resulted in confusion among the technologists. Employees who suggested updating the manual to reflect changes were chastised by management. He further contended that Mr. Kim did not provide the level of training that was required, which contributed to several radiation spills.

Regarding the September 2011 spill incident, Mr. Jimenez expressed his disagreement with management's response to the spill, noting that they panicked. He asserted that the unavailability of a radiation protection program manual contributed to the panic. He contended that the spill was not properly controlled, and that the general public walking in the hallway adjacent to Nuclear Medicine was exposed to the contamination as the area was not blocked off immediately. He further asserted that the lack of containment, as well as the clean-up he was instructed to perform, violated ALARA principles. Mr. Jimenez also challenged NHPP's position that ALARA principles are not applicable to patients. He noted that there were numerous other radiation spills that occurred in Nuclear Medicine, resulting in a substantial and specific danger to public health, specifically to veterans. Regarding the dosing error, Mr. Jimenez noted there were issues that were not addressed. He asserted that Hospital management should have requested a root cause analysis, but instead covered up the incident by failing to report the error. He believes that managers should be held accountable for these actions. Mr. Jimenez concluded that the agency investigation demonstrated that there were numerous leadership and management problems at the Hospital and that the veterans were not receiving the level of care they had earned.

#### *IV. The Special Counsel's Findings*

I have reviewed the original disclosure, the agency reports, and the whistleblowers' comments. Based on that review, I have determined that the reports contain all of the information required by statute. I have also determined that the findings of a violation of NRC regulation and VA rules with respect to the dosing error and reporting failure appear to be reasonable. However, I have determined that the VA's findings with respect to the implementation of the aerosol procedure and subsequent spill incident do not appear reasonable. The evidence and findings in the reports establish that the aerosol procedure was hastily implemented without both the recommended consultation or effective communication with the Radiation Safety Office. Nor was the new protocol for the procedure published in the procedural manual as required by VA rules and NRC regulations. Finally, it was implemented without providing adequate training to Nuclear Medicine staff as required by NRC regulations. The report further concluded that during the subsequent spill incident and clean-up, which resulted in the exposure of two technologists to elevated levels of radiation, there was again a lack of communication and coordination between Nuclear Medicine and the Radiation Safety

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Office. Despite these findings, the agency report nevertheless concluded there was no regulatory violation, non-compliance with VA policies or rules, or a substantial and specific danger to public health or safety. Nor did the agency consider or make a finding of gross mismanagement. These conclusions do not appear to be supported by the evidence and findings presented. While I am encouraged that the Hospital took the recommended corrective actions and resolved the problems associated with the use of the aerosol procedure, it is critical that close oversight and monitoring continue to ensure that there is effective communication and coordination between Nuclear Medicine and the Radiation Safety Office.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the unredacted agency reports and the whistleblowers' comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed copies of the redacted agency reports and whistleblower's comments in OSC's public file, which is available online at [www.osc.gov](http://www.osc.gov).<sup>3</sup> This matter is now closed.

Respectfully,



Carolyn N. Lerner

Enclosures

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<sup>3</sup> The VA provided OSC with reports containing employee names (enclosed), and redacted reports in which employees' names were removed. The VA has cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the reports produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the reports in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version of the reports as an accommodation.