



THE SECRETARY OF VETERANS AFFAIRS  
WASHINGTON  
October 12, 2012

The Honorable Carolyn Lerner  
Special Counsel  
U.S. Office of Special Counsel  
1730 M Street, NW, Suite 300  
Washington, DC 20036

RE: OSC File Nos. DI-12-0927 & DI-12-1933

Dear Ms. Lerner:

I am responding to your letter regarding allegations of misconduct made by two whistleblowers at the Department of Veterans Affairs (VA) South Texas Veterans Health Care System, Audie L. Murphy Memorial VA Hospital, in San Antonio, Texas. You asked me to investigate the whistleblower's allegations and identify any conduct that constituted a violation of law, rule or regulation, gross management or a substantial and specific danger to public health.

I asked the Under Secretary for Health to review this matter and conduct an investigation for purposes of providing your office a report as required under 5 U.S.C. § 1213(c) and (d). He, in turn, referred the matter to the Veterans Health Administration's National Health Physics Program for investigation.

The investigation did find one violation of rules related to failure to report a dosing error. Based on the findings, a number of recommendations were also made. The enclosed final report is submitted for your review.

I have reviewed the report and concur with the findings, conclusions, and recommendations. Thank you for the opportunity to respond to this issue.

Sincerely,

A handwritten signature in black ink, which appears to read "Eric K. Shinseki".

Eric K. Shinseki

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS**

**Report to the  
Office of Special Counsel  
OSC File Numbers DI-12-0927 and DI-12-1933**

**Department of Veterans Affairs  
South Texas Veterans Health Care System  
San Antonio, Texas, USA**



**Veterans Health Administration  
Washington, DC**

**Report Date: September 18, 2012**

Any information in this report that is the subject of the Privacy Act of 1974 and/or the Health Insurance Portability and Accountability Act of 1996 may only be disclosed as authorized by those statutes. Any unauthorized disclosure of confidential information is subject to the criminal penalty provisions of those statutes.

## Executive Summary

The Under Secretary for Health at the Department of Veterans Affairs (VA) requested that the National Health Physics Program (NHPP) investigate the allegations that took place at the South Texas Veterans Health Care System (STVHCS), Audie L. Murphy Division, San Antonio, Texas described in the U.S. Office of Special Counsel (OSC) letter dated May 2, 2012. NHPP's investigation included an on-site inspection at the facility, interviews with facility staff and the whistleblowers named in the letter, and a review of available documents related to the facility. The NHPP investigation was primarily limited to issues under Nuclear Regulatory Commission (NRC) regulatory purview and best health physics practices. However, NHPP also collected information related to clinical nuclear medicine practices at STVHCS for review by the National Director, Nuclear Medicine & Radiation Safety Services. The National Director completed additional clinical reviews for patient studies. This Veterans Health Administration (VHA) response for OSC is based on NHPP inspection and investigation reports, additional clinical reviews, and internal VA reviews.

### Summary of Allegations, Findings, Conclusions and Recommendations

#### Allegation #1

(b) (6), Chief, Nuclear Medicine, implemented a new clinical procedure for lung ventilation studies without obtaining approval from the hospital's Radiation Safety Committee or providing training to clinic staff, in violation of VA rules and Federal regulations.

#### Findings

The facility began technetium (Tc-99m) diethylene triamine pentaacetic acid (DTPA) aerosol for ventilation studies in June 2011, after an external audit indicated the previously used Xenon (Xe-133) ventilation studies might not be within regulatory requirements based on air flow (i.e., lack of negative pressure) in the imaging rooms.

The orientation or training in the methods for the procedure was not coordinated with the Radiation Safety Office and some staff did not consider the training to be adequate. In response, the Radiation Safety Office later provided additional training.

(b) (6), as a physician authorized user on the facility permit for radioactive materials and Chief of Nuclear Medicine Service, had the discretion to determine the methods to complete imaging studies. Neither VHA nor Federal regulations require the Radiation Safety Committee to approve the study. The extant procedures manual for the Nuclear Medicine Service included Tc-99m DTPA aerosol for ventilation studies even though the procedure had not been used recently.

Some staff disagreed with the clinical parameters used for the Tc-99m DTPA aerosol procedure and more generally with using this method for ventilation studies. However, the aerosol imaging procedure has historically been accepted for clinical uses, as approved by a physician authorized user, with adjustments to imaging parameters and methods depending on patient circumstances.

The method of ventilation studies employed by the facility for the performance of Tc-99m DTPA aerosol lung ventilation studies are those used routinely in Nuclear Medicine Laboratories in VHA and elsewhere to perform these diagnostic examinations that are the most commonly performed nuclear medicine lung ventilation examinations.

### **Conclusion**

A regulatory violation or significant deviation from best health physics practices was not identified. Additionally, no substantial or specific danger to public health and safety was found.

A lack of effective communication existed between the nuclear medicine service and the Radiation Safety Office at the time of the external audit, and the change to the Tc-99m DTPA aerosol procedure did not effectively involve coordination with all staff.

### **Recommendations**

The facility should continue with efforts for increased communication between nuclear medicine service and the Radiation Safety Office. The facility should continue with efforts to effectively communicate with all staff and finalize any needed changes to the procedures manual.

### **Allegation #2**

In September 2011, an incident of radioactive contamination of the hallway adjacent to the Nuclear Medicine Laboratory, and improper clean-up of the area, resulted from the use of this unapproved procedure and caused excessive radiation exposure to two clinic staff members, including (b) (6). (b) (6) continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed.

### **Findings**

A contamination event occurred on September 20, 2011, which resulted in extensive clean-up efforts. Two staff involved in the clean-up had higher dose results for that time period, though the dose results were not clearly related to the clean-up.

The facility convened a root cause analysis team that identified corrective actions that were implemented. The spill procedure was also revised. One area for emphasis, in the training of the revised spill procedure was to consider the option to restrict access to areas that were contaminated, rather than to complete extensive clean-up.

The facility procedures for aerosol imaging are normally in a clinical procedures manual while the procedures for spill response are in a radiation safety manual. The lack of a recently updated imaging procedure does not specifically impact spill procedures, or the possibility of a spill for an individual patient procedure. The aerosol imaging procedure has historically been used safely at medical facilities.

## **Conclusions**

A regulatory violation or significant deviation from best health physics practices was not identified nor was there a substantial or specific danger to public health or safety based on this allegation. Corrective actions from the root cause analysis and the revised spill procedure should mitigate consequences for any future contamination events.

## **Recommendations**

The facility should ensure continued implementation of the corrective actions from the root cause analysis and the revised spill procedure.

## **Allegation #3**

Nuclear Medicine Clinic management has failed to report incidents involving errors in the administration of radiopharmaceuticals to patients resulting in unnecessary radiation exposure, as required by VA rules.

## **Findings**

In January 2011, a patient was injected with a cardiac stress dosage that was around 30 millicuries instead of the prescribed dosage of 10 millicuries for a rest-phase cardiac test. The dosing error did not require external reporting as a medical event under 10 Code of Federal Regulations (CFR) 35.3045, but was a dosing error per 10 CFR 35.63(d). Since a regulatory deficiency occurred, the dosing error should have been reported to the Radiation Safety Officer, Radiation Safety Committee, and Patient Safety Officer to ensure timely and adequate corrective actions were taken.

## **Conclusions**

NHPP cited a regulatory violation for the dosing error. However, no substantial or specific danger to public health and safety were found to result from this violation.

On June 5, 2012, the facility completed training for Nuclear Medicine Service in dosing errors. The requirement stated in this training, to report such errors as a patient incident, which should result in any future errors being identified and corrective action completed.

## **Recommendations**

The facility should monitor future effectiveness of the training and reporting of dosing errors during routine audits by the Radiation Safety Office.

## Report to the Office of Special Counsel

### I. Summary of Allegations

VHA's Under Secretary for Health requested NHPP investigate allegations made by two whistleblowers (b) (6), a Staff Physician, and (b) (6), a former Radiology Technologist, at the STVHCS, Audie L. Murphy Division, San Antonio, Texas listed in the OSC letter dated May 2, 2012. NHPP is the organizational entity within VHA with regulatory oversight for uses of radioactive materials. The investigation included an on-site inspection at the facility, interviews with facility staff and the whistleblowers named in the letter, and a review of available documents related to the facility. NHPP's investigation was primarily limited to issues under NRC regulatory purview and best health physics practices. Best health physics practices are those generally consensus methods and practices that result in regulatory compliance, reduced radiation dose to workers, and provide overall protection for the public health and safety. During the investigation NHPP did not collect patient names or records since such information was not required for the scope of the issues under NHPP purview and neither the whistleblower or radiation workers identified specific patient names to NHPP. NHPP collected information related to clinical nuclear medicine practices at STVHCS for review by the National Director, Nuclear Medicine & Radiation Safety Services. The Director, Nuclear Medicine Service, also conducted an expert panel evaluation of the lung ventilation studies of the patients alleged to have been harmed.

The NHPP inspector was (b) (6), who is a board certified health physicist approved by the VHA National Radiation Safety Committee to conduct independent inspections at VHA facilities. (b) (6), NHPP's Director, accompanied the inspector and assisted with radiation worker interviews.

The allegations were the following:

- 1) (b) (6), Chief, Nuclear Medicine, implemented a new clinical procedure for lung ventilation studies without obtaining approval from the Hospital's Radiation Safety Committee or providing training to clinic staff, in violation of VA rules and Federal regulations.
- 2) In September 2011, an incident of radioactive contamination of the hallway adjacent to the Nuclear Medicine Laboratory, and improper clean-up of the area, resulted from the use of this unapproved procedure, and caused excessive radiation exposure to two clinic staff members, including (b) (6). (b) (6) continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed.
- 3) Nuclear Medicine Clinic management has failed to report incidents involving errors in the administration of radiopharmaceuticals to patients resulting in unnecessary radiation exposure, as required by VA rules.

## II. Facility Profile

STVHCS holds a permit to use radioactive materials for medical and research purposes. STVHCS is referred to as a permittee. NHPP issued the STVHCS permit under authority of a NRC master materials license issued to VHA. The Under Secretary for Health is the named licensed official for the license and exercises oversight through a National Radiation Safety Committee (NRSC). NHPP functions under the NRSC and performs inspections at permittee facilities to confirm regulatory compliance with radiation safety practices.

Before May 2012, the last routine NHPP inspection at STVHCS was completed during May 14-15, 2009. NHPP reviewed both medical and research uses and did not cite any regulatory violations of NRC requirements.

On May 15, 2012, NRC performed a routine inspection at STVHCS as part of the NRC independent oversight for uses of radioactive materials under the VHA master materials license. NRC reviewed both medical and research uses and did not cite any regulatory violations of NRC requirements. NHPP (b) (6), Program Manager) observed most of the NRC inspection.

On May 15, 2012, (b) (6) Chair, NRSC, provided NHPP the letter from OSC with the whistleblowers' allegations. In consultation with (b) (6), NHPP immediately began planning for a special inspection at STVHCS to evaluate the allegations and statements.

During May 23-24, 2012, (b) (6) and (b) (6) (Director, NHPP) inspected STVHCS to evaluate the allegations and statements in the OSC letter. Due to the recent favorable inspection by NRC, NHPP defined the inspection scope to be focused to allegations and statements related to regulatory compliance and radiation safety issues, and any associated observations and interviews during the on-site portion of the inspection. The inspection scope and findings were limited to issues under NHPP purview (i.e., regulatory compliance and best health physics practices). However, NHPP also collected information for (b) (6) in his role as National Director for nuclear medicine. (b) (6) independently convened an expert panel review of lung ventilation studies on patients alleged to have been harmed (the findings of the expert panel are discussed on page 23 of this report).

A facility using radioactive materials under an NRC license (or permit issued by a master materials licensee such as VHA) must comply with NRC regulations. The primary regulatory compliance requirements for receipt, possession, use, and disposal of radioactive materials at a permittee facility are established in title 10 of the CFR, including but not limited to 10 CFR 19, 20, 30, and 35. Other Federal agencies also regulate various aspects of radioactive materials uses including the Environmental Protection Agency, Food and Drug Administration, and Department of Transportation; however, NRC regulations are the primary regulatory compliance regulations for workers and the public that are applicable to a permittee. Some specific requirements related to the focused NHPP inspection are described below.

- (1) 10 CFR 20.1101(a) requires a permittee to develop, document, and implement a radiation protection program commensurate with the scope and extent of permitted activities and sufficient to ensure compliance with 10 CFR 20.
- (2) 10 CFR 20.1101(b) requires a permittee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA). NHPP does not interpret this regulation to apply to patients administered radiopharmaceuticals under the direction of a physician authorized user. NRC regulations requires facilities to have written protocols for each nuclear medicine exam and that each nuclear medicine protocol include the specific dose of radioactivity, for each nuclear medicine test and that deviations that exceed  $\pm 20$  percent of the written dose prescription represent a potential "medical event" with specific NRC and local facility quality management reporting requirements based upon the radiation dose to the patient. NHPP is not aware of any other regulations or policies related to patient doses and the concept of ALARA.
- (3) 10 CFR 35.27(a) requires a permittee to instruct supervised individuals (i.e., nuclear medicine technologists working under direction of a physician authorized user) in the permittee written radiation protection procedures. Also this NRC regulation requires supervised individuals to follow instructions of the physician authorized user.
- (4) 10 CFR 35.63(d) stipulates that a permittee may not use a radiopharmaceutical dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent, unless otherwise directed by the physician authorized user.

The primary VHA policy documents of interest for this inspection were VHA Directive 1105.01 (Management of Radioactive Materials) and VHA Handbook 1105.02 (Nuclear Medicine and Radiation Safety Service). Copies of both policies are available on VHA's publication Web site.

- (1) VHA Directive 1105.01, paragraph 4e, requires, inter alia, the facility Radiation Safety Committee to provide oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA, and a safety conscious work environment is achieved. The Committee is tasked to review and approve proposed changes to training, equipment, facilities, and radiation safety procedures or practices.
- (2) VHA Handbook 1105.02, paragraph 12b, requires, inter alia, the Nuclear Medicine Service at a facility to publish policies, procedures, and protocols that describe operations, which provide the highest quality of nuclear imaging and radiobioassay testing. The Handbook does not specifically require approval of those nuclear medicine policies, procedures, and protocols by the Radiation Safety Officer or the Radiation Safety Committee.

### III. Conduct of the Investigation

During its investigation, the NHPP contacted the following individuals at the facility:

- (b) (6) [REDACTED], Director
- (b) (6) [REDACTED], Associate Director and Chair, Radiation Safety Committee
- (b) (6) [REDACTED], Chief of Staff
- (b) (6) [REDACTED], current Radiation Safety Officer (since December 28, 2011)
- (b) (6) [REDACTED], former Radiation Safety Officer (May 1, 2011, through December 27, 2011)
- (b) (6) [REDACTED], Physician, Chief, Nuclear Medicine Service
- (b) (6) [REDACTED], Chief Nuclear Medicine Technologist
- (b) (6) [REDACTED], Physician, Authorized User
- (b) (6) [REDACTED], Nuclear Medicine Technologist, retired
- (b) (6) [REDACTED], Accreditation Coordinator
- (b) (6) [REDACTED], Nuclear Medicine Technologist, VA North Texas Health Care System, Dallas, Texas

NHPP sent an inspection report to the facility to document inspection findings. The inspection documents, as a routine practice, were posted on the NHPP Intranet Web site for information for other VHA facilities. NHPP also sent an investigation report to the Chair of the National Radiation Safety Committee, who is also at this time the National Director of Nuclear Medicine & Radiation Safety Services. NHPP provided the inspection documents and investigation report to NRC. The National Director completed additional clinical reviews for patient procedures. This response to OSC is based on NHPP inspection and investigation reports, the additional clinical reviews by the National Director, and internal VA reviews.

### IV. Allegations, Findings, Conclusions and Recommendations Based on the Investigation

#### Allegation #1

(b) (6) [REDACTED], Chief, Nuclear Medicine, implemented a new clinical procedure for lung ventilation studies without obtaining approval from the hospital's Radiation Safety Committee or providing training to clinic staff in violation of VA rules and Federal regulations.

#### Findings

During June 1-2, 2011, VHA staff completed an audit of the STVHCS Nuclear Medicine Service. Due to a lack of effective communication between the Nuclear Medicine Service and the Radiation Safety Office during the time of the audit, the auditor perceived a possible regulatory deficiency related to lung ventilation studies with Xe-133, a radioactive noble gas,

because negative air pressure was not demonstrated to the auditor for some areas being used for these studies.<sup>1</sup>

During interviews with NHPP, the Chief of Staff (b) (6) and the Nuclear Medicine Service Chief (b) (6) noted efforts were undertaken immediately after the exit briefing on June 2, 2011, to identify and implement a different imaging procedure for lung ventilation studies to preclude curtailing other clinical care at STVHCS that required the capability for ventilation studies. (b) (6) identified the use of Tc-99m labeled DTPA aerosol as the alternative imaging procedure for the Xe-133 gas studies. (b) (6) is listed on the STVHCS permit as a physician authorized user. In his role as the service chief and a physician authorized user, (b) (6) has the prerogative, from the regulatory compliance perspective, to determine imaging procedures to be used at STVHCS.

(b) (6) tasked the Chief Nuclear Medicine Technologist (b) (6) to obtain equipment to support the DTPA aerosol imaging procedure. The equipment associated with the aerosol administration is the Ultravent™ Ventilation Kit and Ultravent™ Shield. The ventilation kit is single-use equipment obtained from the radiopharmacy along with the Tc-99m radiopharmaceutical. The kit contains an aerosol generator (nebulizer), a manifold fitted with aerosol trap (bacterial filter), mouthpiece, plastic tubing, nose clip, air/oxygen interconnector, and plastic disposal bag. The Ultravent™ Shield is reusable equipment, about the size of a shoebox, and serves as a retaining mechanism for the single-use ventilation kit, and as shielding for radiation emitted by the Tc-99m DTPA. Affixed inside the top lid of the shield box are detailed instructions for assembly and disposal of the ventilation kit, as well as suggested protocols for administration.

(b) (6) stated he became aware of availability of a shield box at a non-VA Federal facility in the geographical area and retrieved the shield box himself. Both (b) (6) and (b) (6) noted that they inspected the shield box and found it favorable prior to first use. Both individuals stated that they had previous experience performing Tc-99m aerosol studies. In addition, (b) (6) stated that he had a STVHCS biomedical equipment technician check the shield box prior to first use. (b) (6) noted that since the shield box has no electrical components or moving parts, the biomedical equipment technician did not identify any specific testing or preventative maintenance prior to placing the box into use for the imaging procedure. The NHPP inspector examined the shield box being used at STVHCS and concluded the box was essentially a device for stabilizing or securing the various components of the imaging kit and for minimizing radiation exposure to the radioactive materials.

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<sup>1</sup> Based on NHPP interviews with the former Radiation Safety Officer (at the time of audit), the Radiation Safety Officer was not consulted about the audit results or the negative pressure issue. The current Radiation Safety Officer (who was a radiation safety technician at STVHCS at the time of the audit) indicated the rooms in question were actually under negative pressure at the time of the audit; however, this information was not specifically requested by the auditor, or Nuclear Medicine Service.

The NHPP inspector observed that a procedure titled "Lung Aerosol Study (Tc-99m-DTPA Aerosol)" was included in a procedure binder located in the Nuclear Medicine Service. Specific markings on the procedure indicated a review/revision was completed on January 25, 2003. Also, the cover page of the procedure binder was signed by (b) (6) on November 24, 2004, and later by (b) (6) on June 2, 2011. Based on this information, NHPP concluded that a written procedure for Tc-99m DTPA aerosol studies predated use of Tc-99m DTPA aerosol in June 2011. However, based on NHPP interviews, the procedure was not revalidated or reviewed by Nuclear Medicine Service prior to initiating the Tc-99m DTPA aerosol procedure in June 2011, nor was a specific review required by regulation or policy.

Prior to first use of the Tc-99m DTPA aerosol procedure in June 2011 (b) (6) provided orientation training to the nuclear medicine technologists on the use of the Ultravent™ Ventilation Kit and Ultravent™ Shield. This training was not documented. The training was not specifically required to be documented by regulation or policy.

Based on NHPP interviews with the staff, some of the nuclear medicine technologists did not consider the orientation training to be adequate and sufficient. Based on NHPP interviews with the former and current Radiation Safety Officers, NHPP concluded that the radiation safety office was not involved in the initial training effort or implementation of the Tc-99m DTPA aerosol procedure, and that a lack of effective communication existed between the Nuclear Medicine Service and the Radiation Safety Office. The lack of involvement by the Radiation Safety Office was not a violation of law, rule, or regulation.

Beginning June 6, 2011 through December 2011, under the supervision of (b) (6) (a physician authorized user listed on the STVHCS permit since January 26, 2011), the Nuclear Medicine Service used solely Tc-99m DTPA aerosol to perform lung ventilation studies. Approximately 76 aerosol lung studies were conducted in this time period with activities ranging between 17 and 42 millicuries. Beginning in January 2012 through May 22, 2012, STVHCS reverted back to solely using Xe-133 gas for ventilation studies. Since May 23, 2012, STVHCS resumed DTPA aerosol studies in response to a shortage of Xe-133 gas. Under the regulations and permit approvals, the facility has the option to use either imaging method currently and in the future. The selection of the imaging procedure for an individual patient is under purview of the physician authorized user.

Sometime after initiating aerosol studies and prior to June 29, 2011, (b) (6) received a report of leakage of radioactive materials from the shield box.

(b) (6) stated that the Radiation Safety Office was asked to review the use of the aerosol equipment. On-site radiation safety staff (b) (6) and another radiation safety staff member) inspected the equipment and had a technologist perform a dry run. The radiation safety staff concluded the nebulizer was not seating completely to the breathing tube, the radiation shield was not being closed during use, and nuclear medicine technologists were unclear about the location of a written nuclear medicine protocol for the aerosol lung studies. The radiation safety staff also concluded that the earlier training provided to nuclear medicine technologists on

the use of the device was not adequate and sufficient for radiation safety purposes. NHPP did not identify a specific non-conformance to a regulation or policy.

On June 29, 2011, (b) (6), the on-site radiation safety technician (who is currently the Radiation Safety Officer on the permit) stated to the then Radiation Safety Officer that a training session was held with all available nuclear medicine technologists on use of equipment for the Tc-99m DTPA aerosol procedure. The nuclear medicine staff was requested to notify the Radiation Safety Office upon the next use of the device and to locate the protocols for the procedure. The radiation safety staff noted that they considered the issue resolved, and that the Nuclear Medicine Service "should be allowed to proceed with DTPA studies." Based on NHPP interviews with nuclear medicine staff, specific instances of contamination by a worker have not been identified for the Tc-99m DTPA aerosol procedure. Additionally, the expert panel under (b) (6) to which was convened to evaluate ventilation lung scans did not confirm contamination or quality issues that would have resulted in harm to patients. It is important to understand that both gas phase-based lung scans done with Xe-133 or Tc-99m labeled DTPA ventilation lung scans require technical expertise to perform, and patient cooperation to limit leakage of Xenon gas or DTPA aerosol that can occur as part of the inhalation of either tracer. Escape of aerosol in the normal course of these examinations results in very small levels of radioactivity that pose no significant additional radiation exposure risk to the patient over that of the examination itself, or significant radiation dose to nuclear medicine technologists or members of the public.

The additional value of the ventilation study is the ability to compare the pattern of lung ventilation to the other component of the examination, the lung perfusion scan that is usually done sequentially after ventilation. The patterns of ventilation vs. perfusion form the basis for the diagnosis of pulmonary embolism where arterial blockages by pulmonary emboli will produce characteristic patterns on perfusion lung scans that are confirmed by their absence on ventilation lung scans. Multi-projection lung scans have become a routine part of Tc-99m-DTPA aerosol lung ventilation that provide improved diagnostic images with projection to projection comparisons of lung ventilation to lung perfusion in the nuclear medicine approach to the diagnosis of pulmonary embolism.

NHPP concluded that reports of radiation safety issues with the Tc-99m DTPA aerosol procedure were addressed by the Radiation Safety Office to include a review of the procedure and training in use of the equipment.

With respect to the allegation and statements in the OSC letter related to the approval of the Tc-99m DTPA aerosol procedure by the STVHCS Radiation Safety Committee, NHPP concludes that Committee approval is not explicitly required by NRC regulations for use of the procedure or the associated equipment such as the nebulizer device. The STVHCS permit, as related to medical uses, provides for use of any physical or chemical forms of radioactive material for imaging studies under 10 CFR 35.200 when the use is supervised by a physician authorized user. During NHPP interviews, (b) (6), who serves as the Chief of Nuclear Medicine Service and is listed on the STVHCS permit as a physician authorized user, assumed

accountability and responsibility for approving and supervising patient administrations using the Tc-99m DTPA aerosol procedure.

While VHA Handbook 1105.02 requires the Nuclear Medicine Service to publish policies, procedures, and protocols that describe operations, the Handbook does not specifically require approval of these items by the Radiation Safety Committee. NHPP observed that STVHCS had a published procedure dated January 25, 2003, for the Tc-99m DTPA aerosol procedure in its procedure binder, and the binder was approved in writing by (b) (6) on June 2, 2011. Furthermore, at the time of the NHPP inspection, STVHCS had developed an updated and more detailed standard operating procedure dated April 1, 2012, for the Tc-99m DTPA aerosol procedure.

An independent expert review convened by (b) (6) of lung ventilation scans noted that the doses of aerosol administered were within protocol limits, the ventilation images did not disclose contamination, and in the opinion of the reviewers, the quality of the images was sufficient for diagnostic purposes and comparable to ventilation images obtained in the reviewer's laboratory and other nuclear medicine laboratories.

### **Conclusions**

A new clinical procedure was introduced and a written protocol was available. There is no requirement for radiation safety approval of new protocols or modifications to existing nuclear medicine procedures. Ventilation lung scans with DTPA aerosol are commonly performed throughout VHA facilities, and are most often combined with lung perfusion scans as an urgent or emergency diagnostic examination to identify the presence of pulmonary emboli, a potential life threatening condition. The protocol described the equipment used to perform aerosol lung scans using a single use aerosol nebulizer and tubing that conveys airflow to the aerosol nebulizer and the DTPA aerosol to the patient. The nebulizer is filled with Tc-99m DTPA and placed into a lead shield. The patient's nostrils are gently closed with a padded clamp and the patient inhales the aerosol through a mouthpiece. The aerosol then flows into the patient's lungs depicting the pattern of lung ventilation. The allegation that the lead shield of the equipment used, was defective was not confirmed. An issue with proper seating of the single use nebulizer into the shield and assembly of the tubing was identified and addressed with additional training. An independent review of lung ventilation scans alleged to be inaccurate was not confirmed, there was no evidence on the scans of surface contamination and the overall quality of the images was in the opinion of the content experts, comparable to those obtained in the panel member's laboratory and other nuclear medicine laboratories. Furthermore, a regulatory violation or significant deviation from best health physics practices or VA policy was not identified nor was there found to be a substantial or specific danger to public health and safety based on these allegations.

A lack of effective communication existed between the Nuclear Medicine Service and the Radiation Safety Office at the time of the external audit. The change to the Tc-99m DTPA aerosol procedure did not effectively involve training and orientation for all applicable staff. It is

a good practice to inform the radiation safety staff of protocol changes, but not a regulatory requirement that the radiation safety staff approve nuclear medicine protocol changes.

### **Recommendations**

The facility should continue with efforts for increased communication between Nuclear Medicine Service and the Radiation Safety Office. The facility should continue with efforts to effectively communicate with all staff and finalize changes to the procedures manual.

### **Allegation #2**

In September 2011, an incident of radioactive contamination of the hallway adjacent to the Nuclear Medicine Laboratory, and improper clean-up of the area, resulted from the use of this unapproved procedure and caused excessive radiation exposure to two clinic staff members, including (b) (6). (b) (6) continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed.

### **Findings**

NHPP confirmed that near the end of the work day on September 20, 2011, a contamination event occurred involving waste material from a patient administration using the Tc-99m DTPA aerosol procedure. The event involved the nuclear medicine hot laboratory (Room J204) hallway adjacent to the hot laboratory, and an adjacent area (Room J206) where the patient administration was performed. The event appeared to have occurred when a nuclear medicine technologist transferred a leaking ventilation kit disposal bag from Room J206 to Room J204. The administration involved about 21 millicuries of Tc-99m, so any residual material involved in the spill event would have been much less than 21 millicuries.

While always undesirable, spills and contamination events occur periodically in use of radioactive materials, especially in medical use circumstances. Of importance and interest from a regulatory compliance perspective is the response to control and remediate the spill and prevent recurrence. NHPP reviewed the immediate actions to respond to the contamination event, as well as subsequent follow-up actions and did not identify any specific regulatory or internal policy violations related to the event or event response.

Based on NHPP interviews with Nuclear Medicine Service staff and the former and current Radiation Safety Officers, NHPP concluded the following:

- The immediate response to the spill was appropriate based on the information available to the Nuclear Medicine Service staff and Radiation Safety Officer at the time of the event.
- The nuclear medicine technologists used appropriate radiation survey methods and equipment to locate and characterize the extent of the contamination.

- The Nuclear Medicine Service supervisor took appropriate steps to minimize any further spread of the contamination. Appropriate personal protective equipment and radiation dosimeters (whole body and finger rings) were used during clean-up activities.
- NHPP identified an area for improvement for closer interaction between Nuclear Medicine Service and the Radiation Safety Office to determine if locations with radioactive contamination might be restricted from access to the public and left to decay rather than requiring the nuclear medicine staff to complete extensive surface cleaning.

The radiation levels measured by nuclear medicine technologists during the spill clean-up were reportedly within the range typically encountered in a nuclear medicine environment. The maximum exposure rate was around 30 mR/hour at surface contact prior to cleaning. Exposure rates a few feet away from the surface were reported to be even lower at less than about 1 mR/hour. The values or ranges noted above were measured during the clean-up efforts for the spill by trained staff using survey instruments.

Based on NHPP interviews, the Chief Nuclear Medicine Technologist, who was supervising the response to the spill, understood that exposure levels above 1 mR/hour required intensive cleaning efforts to reduce the levels, and that cleaning efforts should continue until the efforts are no longer effective in reducing the exposure rates.

NHPP identified two options for reducing surface exposure rates to below trigger levels or a predetermined rate. Trigger levels are levels that, if reached or exceeded, require a designated action to be taken or performed. These levels are normally listed in local facility procedures. VHA does not have specific policies that are applicable to trigger levels or options for response to a spill.

One option is to perform cleaning using routine surface cleaning techniques. The other is to cover contaminated locations to minimize possible spreading of the contamination and allow the radioactive material to decay. For this spill with Tc-99m and its 6-hour half-life, the decay option is viable. A decision to clean a contaminated location rather than to allow for radioactive decay is a facility-level decision and involves many factors including potential dose to workers, and the need to have the location available for possibly urgent patient care.

The Chief Nuclear Medicine Technologist contacted the Radiation Safety Officer by telephone within about 30 minutes of becoming aware of the contamination event to discuss the extent of the appropriate actions and seek advice for cleaning or decay. The Radiation Safety Officer concurred with the plan to clean surfaces in an effort to reduce exposure rates to below the trigger level. The Radiation Safety Officer noted his impression of the spill based on the initial information provided was that the spill was small, controlled from public access, and did not warrant tasking the on-site radiation safety staff to assist in the cleanup. At this time, the Radiation Safety Officer was not on-site; however, the Radiation Safety Officer is not required by regulation or policy to be on-site. The lack of an on-site Radiation Safety Officer did not contribute to any specific impact to a radiation worker that was identified during the NHPP inspection. After cleaning efforts were concluded, exposure rates in the highest locations

continued to be around 2 mR/hour on contact. The Chief Nuclear Medicine Technologist eventually decided to cover locations with large absorbent pads and provide additional time for decay.

After review of radiation survey results for the contamination event, NHPP concluded that exposure rates did not necessarily preclude efforts to clean the locations below a trigger level. That is, the facility had the option either to allow the radioactive material to decay or to clean the areas.

As a follow-up to the contamination event, a special training session was held with nuclear medicine technologists on September 23, 2011, to retrain the staff in the spill response methods. The training was stated to include DTPA aerosol kit disposal, spill procedures, and provided the opportunity for questions and answers from nuclear medicine technologists. This training is documented in an e-mail dated September 23, 2011, from (b) (6) to (b) (6).

Several weeks after the contamination event, on about November 1, 2011, via a report dated October 20, 2011, by the dosimetry vendor (Landauer, Inc.), the Radiation Safety Officer became aware that the September 2011, dosimeters for the two nuclear medicine technologists who participated in the clean-up had recorded doses above the STVHCS action levels that required an investigation into the results. The Radiation Safety Officer began a timely investigation into the dose results. While the Radiation Safety Officer used the wording "an extraordinary exposure event" it was used in the context of comparing the higher dosimetry results to what is normally received by workers on a day-by-day basis.

Results for deep dose equivalent were 1.7 rem and 3.7 rem, respectively, for two nuclear medicine technologists, as compared to an annual limit of 5 rem. The lenses of eye dose equivalent and shallow dose equivalent were comparable to the deep dose equivalent, indicating that the dosimeters were exposed to penetrating radiations typical of materials used in nuclear medicine. Also, the finger rings that were worn by the two individuals indicated doses of about 1.7 rem and 3.8 rem, respectively, for the two individuals. The doses were less than the annual limit. The facility maintains cumulative exposure records for radiation workers to ensure the annual limit is not exceeded. Since 3.7 rem is less than 5 rem, NHPP concluded the annual limit was not exceeded.

Since the same two individuals were involved in the September 20, 2011, cleaning efforts and no other work circumstances or actions were specifically attributable to the doses, the Radiation Safety Officer presumed that the exposures came from the cleaning efforts. An independent investigation by the Radiation Safety Officer resulted in the doses being accepted since the doses could not be otherwise rejected as having occurred.

A formal investigation by a STVHCS root cause analysis team concluded that the dosimeters might have been contaminated and the dose results were not reflective of actual individual exposures. The root cause analysis report was not provided for NHPP to retain; however, the content was reviewed with NHPP to assist with the inspection. This is the usual practice followed for a root cause analysis report that has restricted distribution. NHPP had an

opportunity to review the report to the extent needed to complete the NHPP inspection and investigation. That report has the conclusion noted above. The root cause analysis report reaches a different conclusion than the conclusion made by the Radiation Safety Officer in a draft report that was not accepted by the facility Radiation Safety Committee.

According to statements made by the nuclear medicine technologists to NHPP, the finger rings were worn under gloves during cleaning efforts which would minimize the likelihood of finger ring contamination, and the dosimeters were stored in personal lockers when not being worn. NHPP notes that, during surface contamination cleaning, finger ring results are expected to be much higher than whole body results as the hands would be closer to the contaminated surface. NHPP concludes that while the dose results cannot be ruled out as being valid, the dose results are highly inconsistent with the exposure levels reported as being measured while cleaning on September 20, 2011. For example, an average exposure rate of about 700 mR/hr would be required over a 5-hour period to result in a dose of 3.5 mrem on a dosimeter. The exposure levels that were reported were generally below 30 mR/hr.

Based on information reviewed, NHPP did not find that efforts to clean the spill on September 20, 2011, caused a violation of worker ALARA provisions in 10 CFR 20. NHPP concluded the elevated doses, while reported for a dosimeter worn within the same timeframe, could not be specifically attributed to the spill cleanup efforts. NHPP determined that the annual doses for the two workers with higher dose results were well below NRC regulatory limits or any external reporting requirements. The annual doses to the workers included the dose results recorded during the time period for the spill circumstances and were less than a regulatory limit. The doses are listed in a paragraph above. NHPP did not specifically determine doses were inaccurate for the spill circumstances. Rather, NHPP noted the dose results were problematic.

NHPP concluded that the coordination and communication between the Nuclear Medicine Service and Radiation Safety Office needed improvement to address possible future spills. While spill response is generally covered under the STVHCS radiation safety manual, NHPP discussed with the Chair of the Radiation Safety Committee that a more detailed spill procedure should be implemented to provide additional clarification and to facilitate improved coordination between the two areas. However, the facility was not required by regulation or policy to have a more detailed spill procedure.

A draft procedure had been previously discussed during Radiation Safety Committee meetings. NHPP was informed by e-mail on June 5, 2012, that a detailed facility-level spill procedure was endorsed by the Radiation Safety Committee on May 25, 2012, and that staff was trained in the procedure on May 30, 2012.

The OSC letter notes "the whistleblowers further explained that (b) (6) subsequently investigated this incident and prepared a report outlining root causes and recommendations." NHPP determined that (b) (6), in his role as the Radiation Safety Officer, had prepared a draft report on the causes of the elevated doses around November 10, 2011. (b) (6) provided the draft report to various individuals for comment; however, STVHCS determined that a root cause analysis team should be convened to review the overall contamination event and

higher dose results to the two workers. NHPP reviewed the outcomes from the root cause analysis effort which was concluded around January 16, 2012.

The root cause analysis report was not released to NHPP and a comparison to the draft report by the Radiation Safety Officer was not specifically completed. The differences between the two reports were conclusions related to the evaluation of the dosimeter results. That draft report by the Radiation Safety Officer was not accepted by the facility Radiation Safety Committee.

For purposes of individual dose records, the readings on the dosimeters were maintained as the official dose record for the individual workers.

The following root causes for the contamination event and subsequent elevated doses were identified in the root cause analysis report.

- The complex mechanism for the delivery of DTPA increases the likelihood of human error resulting in potential radioactive spill.
- Disassembly and transport of the nebulizer housing kit within the patient care area increased the likelihood of a spill, spreading radioactive contaminants and exposure in the nuclear medicine patient care area, hallway, and hot lab.

The following corrective actions were recommended in the root cause analysis report and approved by executive management.

- Standardize and reinstitute the use of Xe-133 gas for ventilation studies, minimizing the use of DTPA. (Implementation: NHPP noted that Xe-133 use was reinstated by STVHCS on January 3, 2012, and that Tc-99m DTPA was not used again until May 23, 2012, due to a shortage of Xe-133 gas.)
- A standardized process for disassembly of aerosol kits in the hot lab to prevent spills and contamination in the patient care rooms will be implemented by all nuclear medicine technologists. All nebulizer kits will be placed in plastic bags that are provided in each kit after nebulizer treatment; all used kits will be transported on a rolling cart and taken to the hot lab. All disassembly procedures and pre-disposal scanning will be conducted in the hot lab. (Implementation: NHPP noted that a standard operating procedure dated April 1, 2012, was issued to provide additional detail on the Tc-99m DTPA lung scans and to address disassembly of the kits in the hot lab.)
- In the event that administration of DTPA is required, specific patient care room designation to perform DTPA aerosol nebulizer treatments will be implemented to limit spreading of contamination to multiple areas. Designation of rooms will prevent possible contamination in the main hospital hallway and the main treatment area. (Implementation: NHPP observed that the new standard operating procedure issued April 1, 2012, limited use of DTPA to a specified room, Room J205.)

NHPP concurred with the root causes and actions. NHPP was provided information indicating that exclusive use of Xe-133 resumed for ventilation studies from January 2012 until May 22, 2012. On May 23, 2012, due to a reported shortage of Xe-133 gas, the Tc-99m DTPA aerosol procedure was reinstated to ensure continuity of patient care.

NHPP discussed separately with (b) (6) and (b) (6) their understanding of a safety conscience work environment and the opportunity for workers to raise issues without fear of retaliation. Both of these physicians stated that they encouraged staff to raise safety issues, that they considered such issues raised by staff very seriously, and to their understanding they had been responsive to issues that were raised.

NHPP determined that clinical and radiation safety issues were raised about the Tc-99m DTPA aerosol procedure by (b) (6), the radiation safety office, and other staff. NHPP determined STVHCS convened a root cause analysis team to evaluate the September 2011 contamination event and higher dosimetry results for the two workers. STVHCS promptly implemented corrective actions based on the report and later issued a more detailed spill procedure. NHPP concluded STVHCS adequately addressed the radiation safety issues for the Tc-99m DTPA aerosol procedure.

### **Conclusions**

A regulatory violation or significant deviation from best health physics practices was not identified nor was there a substantial and specific danger to public health and safety based on these allegations. Corrective actions from the root cause analysis and the revised spill procedure should mitigate consequences for any future contamination events.

NHPP did not determine that the clean-up procedures were outside of acceptable best health physics practices, that any radiation workers exceeded a regulatory dose limit, or that the spill event represented a substantial or specific danger to public health or safety.

### **Recommendations**

The physician authorized user should continue to determine the imaging procedure that is most appropriate for individual patients and the facility should ensure continued implementation of the corrective actions from the root cause analysis and the revised spill procedure.

### **Allegation #3**

Nuclear Medicine Clinic management has failed to report incidents involving errors in the administration of radiopharmaceuticals to patients resulting in unnecessary radiation exposure, as required by the facility's patient safety policy and NHPP regulations should the incident meet the NRC definition of a "medical event."

## **Findings**

Based on an interview with the Chief Nuclear Medicine Technologist, NHPP determined that on or around January 25, 2011, a patient was injected with a cardiac stress dosage that was around 30 millicuries instead of the prescribed dosage of 10 millicuries for a rest-phase cardiac test.

NHPP determined that the dosing error did not require external reporting as a medical event to NHPP or NRC under 10 CFR 35.3045; however, the dosing error was contrary to 10 CFR 35.63(d) because the administered dosage exceeded 20 percent of the prescribed dosage. Since a regulatory deficiency occurred, the dosing error should have been reported to the Radiation Safety Officer, Radiation Safety Committee, and Patient Safety Officer (using the facility incident reporting system) to ensure that timely and adequate corrective actions could be taken to address the circumstance and prevent recurrence. NHPP refers facilities to VHA Handbook 1050.01, that require facilities to identify, report, and complete follow-up for circumstances such as a dosing error.

NHPP cited the dosing error as a violation of NRC requirements since STVHCS did not identify the error before the NHPP inspection. Corrective actions are detailed in the NHPP inspection report and included retraining of all nuclear medicine staff by the Patient Safety Office and Radiation Safety Officer to require reporting of dosing errors.

NHPP did not identify any other dosing errors where the wrong dosage was involved nor did staff interviews identify any other specific instances of such errors and expert panel review of the lung ventilation studies did not disclose dosing errors or contamination in the patient cases.

## **Conclusions**

NHPP cited a regulatory violation for the dosing error. The dose involved is one routinely used for the stress portion of the exam where a smaller rest dose and a larger stress dose are given on the same day for a one day myocardial perfusion scan or as a rest-phase dose in 2-day rest/stress myocardial perfusion imaging protocol. There would not be any expected harm to the patient or danger to public safety.

The facility completed training for Nuclear Medicine Service in dosing errors on June 5, 2012. The requirement stated in this training, to report such errors as a patient incident, should result in any future errors being identified and corrective action completed.

## **Recommendations**

Although the dose of the radiopharmaceutical exceeded the dose prescribed by the protocol, the dose at this level is routinely administered as part of the stress portion of the examination that this patient would subsequently have received, and would not represent a substantial increased risk or harm to the patient, and a disclosure would not be required. However, the facility should monitor future effectiveness of the training and reporting of dosing errors during routine audits by the radiation safety office. Additionally, facilities should comply with VHA

Handbook 1050.01 and identify, report, and complete follow-up for circumstances such as a dosing error in the future.

### **Additional Allegations**

#### **Allegation #4**

In the letter from the OSC one of the whistleblowers stated that since early 2011, (b) (6) and (b) (6) have instructed staff to omit some portions of the examination in which images are obtained immediately after radiopharmaceutical injection, which are referred to as the “dynamic portion” of certain studies.

#### **Findings**

NHPP interviews with nuclear medicine staff did confirm that (b) (6), who is a physician authorized user on the STVHCS permit, did instruct staff to omit the dynamic portion of certain studies. This is an important component of the clinical decision-making process and within the scope and purview of an authorized nuclear medicine supervising physician.

Nuclear medicine imaging takes advantage of the distribution of radioactivity to create a functional map to facilitate diagnosis. The imaging process is individualized for a given patient and may require modification during scanning to take advantage of or to better image areas of interest or to further investigate unusual or unexpected findings. This process also includes omitting some aspects of the imaging procedure given the particular aspects of a case. The decision to add or omit images or to change an imaging protocol is within the purview of a nuclear medicine physician and represents an important aspect of how nuclear medicine approaches patients, their medical problems and answers questions posed by referring physicians.

#### **Conclusion**

The specification of imaging protocols is within purview of the physician authorized user and does not represent a deviation from acceptable clinical practices. Authorized user physicians have the purview to modify imaging protocols as needed to facilitate care that might omit an unnecessary part of an exam or add additional projections or images as deemed necessary to provide diagnostic information. This is an integral part of the supervising nuclear medicine physician’s responsibilities.

#### **Allegation #5**

In letters dated May 28, 2012 and June 3, 2012 (b) (6) stated that he was denied access to the NRC inspector during the recent NRC on-site inspection.

10 CFR 19.15 states:

“During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control.”

### **Findings**

NHPP observed the NRC inspection on May 15, 2012. Prior to exiting the site, the NRC inspector did privately inform the NHPP observer that she was aware that an undisclosed off-site individual wanted to speak to her; however, the NRC inspector noted that the off-site individual could contact an NRC office to discuss any issues.

During the NRC inspection, (b) (6) was on administrative leave and not working on-site at STVHCS. The on-site inspection occurred from about 6:30 a.m. until 2:00 p.m., at which time an exit meeting was held with executive management. While a worker has a right to bring issues privately to the inspector's attention during the course of the inspection, NHPP did not conclude in this case that STVHCS had a specific regulatory obligation to set up a meeting between the NRC inspector and an off-site individual who was on administrative leave and not actively engaged in on-site work activities during the inspection.

NHPP met with (b) (6) on May 22, 2012, and discussed this circumstance with (b) (6). (b) (6) reviewed options to contact NRC either by telephone or in writing to raise concerns without fear of retaliation.

In a facsimile to NHPP, received June 1, 2012, (b) (6) provided copies of two e-mails related to this item. One e-mail was apparently sent to the Radiation Safety Officer late in the morning at around 9:55 a.m., on May 15, 2012, asking the Radiation Safety Officer to transmit information to the NRC inspector about a desire to speak to the inspector that day. The other e-mail was an “official” request apparently sent to the Radiation Safety Officer with a copy to the STVHCS Director and Chief of Staff at 2:13 p.m. (after the exit meeting had begun).

Based on a telephone discussion with the Radiation Safety Officer on June 4, 2012, NHPP was informed the Radiation Safety Officer did inform the NRC inspector while the inspector remained on-site that an undisclosed off-site individual expressed a desire to meet with her during the NRC inspection; however, the inspector noted to the Radiation Safety Officer that the individual could contact NRC at its regional office at any time to discuss any issues.

### **Conclusion**

NHPP did not identify a specific regulatory violation related to providing access for a worker to meet privately with the NRC inspector.

## **Allegation #6**

Patients were contaminated during aerosol ventilation studies.

### **Findings**

A subsequent discussion with the whistleblower disclosed that the actual number of cases with alleged contamination was an estimate that was less than 30 cases, however, the whistleblower has not responded to requests for a list of cases in which ventilation scans resulted in alleged "contamination." In response to this allegation an expert review of ventilation lungs scans was performed by the Program Director, Nuclear Medicine Service, (b) (6) and (b) (6) a nuclear medicine board certified, senior member of the nuclear medicine staff at the Ann Arbor VA Medical Center. The expert panel reviewed 21 individual cases which were identified as the ones performed by the whistleblower during the interval June to December 2011. The ventilation studies were evaluated with respect to the dose of aerosol prescribed, the clinical quality of the images and for the presence of contamination. The doses of aerosol administered were within stated protocol limits, and the images as judged by the expert reviewers demonstrated Tc-99m aerosol ventilation scan quality that would not be unexpected in the population of patients referred for suspected pulmonary thromboembolic disease. Findings of central airway trapping and gastrointestinal tracer uptake of aerosol that were seen in a majority of the cases submitted for review may have been assumed to be contamination. These findings are very common and relate to the presence of chronic obstructive pulmonary disease and the level of cooperation by the patient in inhaling the radioactive aerosol. There were no cases where, in the opinion of the reviewers, the images depicted contamination. In addition, the whistleblower is correct that lung ventilation studies are optimally performed before lung perfusion studies, and although this is the sequence of imaging that is most often followed, there are some laboratories that perform a perfusion study first, and if there is a normal finding that would preclude pulmonary embolism, a subsequent ventilation study would be omitted.

### **Conclusion**

Expert review of ventilation images did not confirm the allegation of contamination, the doses of aerosol were within protocol and the images were of acceptable clinical quality.

## **Allegation #7**

The nebulization equipment utilized for the ventilation study was second hand and flawed.

### **Findings**

The nebulizer, reservoir, and all of the associated tubing and mouthpiece that convey aerosol to the patient is a single use/per patient disposable apparatus. The lead shield serves as a platform to hold the apparatus while in use. The only explanation for leakage would be improper assembly and seating of the nebulizer in the shield.

**Conclusion**

There is no evidence that lead shield was defective and the additional nebulization equipment is single use.

**Allegation #8**

ALARA principles were violated.

**Findings**

The clinical interpretation of ALARA, which is not a regulatory requirement but often used as a clinical best practice, is to limit radiation exposure to patients. In this context written protocols are required by NRC regulations to specify the doses of radioactivity administered to patients as low as possible to obtain the highest quality images with regulatory compliance defined as doses within 20 percent of the specified doses. Radiation doses that deviate by  $\pm 20$  percent of the written dose prescription represent a potential "medical event" with specific NRC and local facility quality management reporting requirements based upon the radiation dose to the patient. There is no evidence that appropriate steps were not taken in the performance of the lung ventilation studies to limit radiation dose to the patients and staff performing these examinations.

**Conclusion**

There is no evidence to support the allegation that ALARA concepts were violated.

## Attachment A

### Documents Reviewed

The following documents were evaluated for the report. In addition, verbal statements by facility staff and the whistleblowers identified in the OSC letter were evaluated.

- The OSC letter dated May 2, 2012, to VA Secretary and identified as OSC File Nos. DI-12-0927 and DI-12-1933. NHPP received the letter on May 15, 2012.
- A single page which listed four issues that (b) (6) a whistleblower identified in the OSC letter, handed to NHPP during an interview on May 22, 2012. (b) (6) noted the issues were previously reported to OSC and did not request to remain anonymous.
- (b) (6) letter addressed to NHPP ((b) (6) Program Manager) dated May 28, 2012, and received by facsimile on May 30, 2012.
- (b) (6) facsimile to NHPP (b) (6) undated and received on June 1, 2012.
- (b) (6) letter addressed to NHPP (b) (6) dated June 3, 2012, and received by facsimile on June 4, 2012.
- (b) (6) letter addressed to NRSC (b) (6) dated July 8, 2012, and received by facsimile on August 2, 2012.