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1730 M Street, N.W., Suite 218  
Washington, D.C. 20036-4505  
Re: OSC File No. DI-12-0927

Dear Ms. Pennington:

On November 27, 2012, by regular US mail, I received your letter dated November 20, 2012 and a copy of the report of investigation (ROI) from Honorable Eric K. Shinseki, Secretary of Veterans Affairs.

Pursuant to 5 U.S.C. § 1213(e)(1), I would like to submit my following comments regarding the report to the agency head, the President, and the appropriate congressional oversight committees in accordance with 5 U.S.C. § 1213(e)(3). I am in compliance with the deadline set by you.

**It is very important to note from Mr. Shinseki's report that all my allegations were found by their own investigators to be legitimate and true as noted in their "Conclusion" and "Recommendations" as follows:**

**Allegation #1**

"Dr. Duffy, 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 the clinical staff, in violation of VA rules and Federal regulations".

**Conclusion (Inter Alia):**

"A lack of effective communication existed between the nuclear medicine and 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 of all staff".

**Recommendations:**

"The facility should continue with efforts of 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 procedure 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 Mr. Jimenez. Dr. Duffy continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed".

**Conclusion (Inter Alia):**

"Corrective action 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 radio-pharmaceuticals to patients resulting in unnecessary radiation exposure, as required by VA rules".

**Conclusion (Inter Alia):**

"NHPP cited a regulatory violation for the dosing error. 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".

**Disagreement with the Report:**

The major problem in this report is an obvious attempt to undermine and/or conceal the violations of rules, regulations and laws by the current supervisors of the STVHCS. This is evident in statements such as "However, no substantial or specific danger to public health and safety were found to result from this violation". Of course, from these incidents, one would not expect to see any immediate danger like it was in "Three Mile Island" or "Chernobyl". However, I

sincerely believe that this statement implies an attempt to escape any disciplinary actions against the STVHCS supervisors, which they deserve for the sake of societal safety. The ALARA principle is to keep any and each member of our society protected from any unnecessary radiation exposure. But, at STVHCS the ALARA principle was thoroughly violated. Plenty of proofs and arguments were provided to the investigators. But, these documents were recklessly suppressed and none of these documents have been forwarded with the investigative reports to the O.S.C.. We don't know whether the honorable Secretary or Under Secretary has ever seen these documents either. I am now resubmitting these very important documents to O.S.C. with my comments for their review and transmittal to the proper authorities pursuant to 5 U.S.C. 1213 (e) (1)&(3).

In addition, there are now concrete evidences that at the STVHCS level, attempts by the supervisors are progressively being made to hide the facts by not admitting their faults, obstructing the appearance of the real documents and supplying the investigators with artificially created wrong or doctored documents. I will now provide evidences for my preceding statement.

#### **1. Suppression of Draft Report from the Radiation Safety Office of the STVHCS :**

This report was honestly prepared by a qualified person who has been recently promoted to the position of Radiation Safety Officer of the STVHCS. The report does not contain any PHI and it was never mandated/ intended to be kept away from the investigators. This document provides important information regarding the negligence and violations caused by the STVHCS supervisors. As such, it should be considered most relevant and I am compelled to provide a copy of this document as an attachment herewith (Attach pp: 5 - 9).

Among other things, this report noted:

- \* "The radiation levels are not reported correctly and do not reflect the distance from the source making accurate reconstruction of this event unlikely".
- \* "Personnel were working in an uncharacterized radiation area for an extended period without monitoring indicating a lack of familiarity with the principles of ALARA".
- \* "Of the two workers involved in the clean-up effort, one received an exposure

of approximately 3500 mR and the other approximately 1500 mR of exposure. The average annual exposure for nuclear medicine worker is less than 100 mR. This was an extraordinary exposure event".

\* "The radiation safety office found areas of the spill that was not covered until the next day".

\* "Liquid radioactive material should not have been transported through hallways in a non-secure container risking a spill of this nature".

\* "Improper use of the equipment indicates a lack of operator training and supervisory experience".

\* "Personnel unnecessarily exposed by working in an undefined radiation area indicate a lack of understanding of ALARA principles and a lack of supervisory training".

\* "Undiscovered areas of contamination after declaring the scene under control indicate a lack of thorough radiological control and inadequate supervisory experience and training".

\* "Radiation Safety Handbook does not adequately address spill recovery procedures to reflect attention to ALARA principles in the spill response section".

\* "Inadequate preparation and planning prior to initiating a new clinical procedure".

The recommendations were:

\* Supervisory staff should be trained on the proper uses of radiation detection equipment.

\* "Supervisory staff should be trained on proper application of ALARA principles."

\* "Supervisory staff should be trained in proper radiological control procedures with regard to spills and handling of radioactive materials."

\* "The lung scan procedure central to this event should be reviewed by Radiation Safety and Nuclear Medicine staff and supervisors with the intent to properly plan the implementation of this procedure with a revised protocol that provides adequate process and functional controls for protection of the public, patient, and worker."

\* "Nuclear Medicine policies should be amended to provide Radiation Safety with notification any time new procedures or protocols are initiated to include changes in route of administration, isotopes used, sites of use, chemical form of isotope, or any other substantial change in the routine procedures used at

the facility. Radiation Safety is not to approve or disapprove the bona fide use of radioactive material but evaluate the safe handling of the material during and after its use.”

[NOTE: None of the above violations happened during the last 3 decades of my tenure as Chief of Nuclear Medicine Service. All rules, regulations and laws had been followed correctly during that time period. None of the experienced staff technologists have been at fault then or now. All recent violations resulted from the actions of the current supervisors during their last 2-3 years of tenure. Yet, attempts have been made by the supervisors to scapegoat other physicians and the staff technologists].

## **2. Prohibited Practices Bordering Fraud:**

**A. Procedure Manual:** Contrary to the VACO directive/rule, there had been no Procedure Manual for the department reviewed or newly written after 2008. Such a review or a rewrite was supposed to have taken place in 2010 and/or 2011 by the new Nuclear Medicine Chiefs (Dr. Leuschen in 2010 and/or Dr. Duffy in 2011). Last two Procedure Manuals had been reviewed, renewed and published in 2006 and 2008 by me with the help from Ms. Nancy Burton, Administrative Support Assistant and was subjected to joint review by all staff members and signed by Radiation Safety Officer, Radiopharmacist, Chief Technologist and me as Chief of Nuclear Medicine Service (A requirement). This had been our policy. Each manual was valid only for 2-3 years. In 2010/2011 the latest 2008 manual disappeared from the department and one copy was last seen in mid-2010 in what appeared to be a waste-bin. As a local and VACO policy, in these procedure manuals, every reviewed and approved ongoing procedure had to be signed by the RSO and the Service Chief. Ventilation study with Radio-aerosol has never been a part of it. In the history of STVHCS, this procedure had never been implemented until May or June of 2011.

It is interesting to note in Honorable Secretary's report (p-10, 1st para and p-12, para-2) that the NHPP investigators were provided with an obsolete copy of a Procedure Manual from 2003-4 with Dr. Duffy's signature dated June of 2012. In this manual, if every procedure had not been signed by the RSO and me, then, it must be a purchased book for my personal teaching and research reference. The RI also noted that this binder had my signature dated November

24, 2004 on the cover page. The Procedure Manual always had to be current. No radio-aerosol study has ever been done at the STVHCS until 2011. I was not fond of any aerosol study either, when we had very successful results with Xe-133 for ventilation study. So, what was the reason of having a protocol signed nine (9) years pre-dated? This was not our protocol or Procedure Manual. It shows that the supervisors did not have any either. I do not have any access to my office since January 12, 2012. The supervisors took away my keys. All my clinical, teaching, research and administrative documents are still in those two rooms of my office. The supervisors assumed their power of authority to do anything they pleased to do with my binders, books and other documents.

**Please look at VACO's own publication (copy attached), which says:**

"Procedure must be written for each procedure performed by the laboratory, even if infrequent or newly implemented. Procedure must be updated, as needed, to conform to current practice standards".

"Protocols must be specific for the particular laboratory and equipment inventory i.e. specifically written for each gamma camera. Copied "textbook" and/or generic protocols are not acceptable." (Attach page-14).

**B. Training:** The NHPP was told by the Nuclear Medicine supervisors that the Radio-aerosol ventilation study training of the technical staff happened sometime in June, 2011. But, the investigative report noted that the RSO was not involved in the training and no official record was kept of the training. Every staff technologist denied being trained until one year later in 2012, which was one year after the beginning of this new procedure with aerosol and months after my complaints to the C.O.S. and the O.S.C.(Attach page - 26-27).

To have a training, it requires trainer/s and trainees. Usually, the trainers are volunteers from the manufacturing companies or the RSO or other knowledgeable professionals. Dr. Duffy or Mr. Kim could not possibly be the trainers. They are the ones who committed the violations. They could be the two of the trainees. Possible trainees in the department at that time would have been all technologists (Mr. Arellano, Mr. Jimenez, Mr. Kim, Ms. Valdez, Ms. Melendez, Ms. Leo, Ms. Cardenas and Ms. Norine) and all physicians (Drs. Latoni, Chaudhuri and Duffy). It is very simple to ask the supposedly trained

persons if there had been any training on radio-aerosol in 2011. In fact on page 12 of the investigative report, the bottom lines noted, "The change to the Tc-99m DTPA aerosol procedure did not effectively involve training and orientation for all applicable staff". This is a clear violation of local rule, VACO rule, NRC rule and JCHA rule. I have been the main clinic physician present all the time within the clinical area carrying out more than 80% of clinical load excluding P.E.T. studies (only 1 to 2 per day) and avoiding prescribing radio-aerosol studies except when ordered by Dr. Duffy by telephone to sign for his verbal order during his physical absence from the nuclear medicine department. I can categorically say that no such training happened within the department in 2011. During that time period, according to the report (p 24), at least 76 patients underwent this procedure and I strongly believe and can prove that all of them received useless radiation from the procedure.

### **3. Understanding of the Science of Radio-Aerosol Lung Ventilation Study and the Violations:**

The report of Honorable Secretary says, "An independent expert review convened by Dr. Gross 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 reviewer's laboratory and other nuclear medicine laboratories."

The statement above would be embarrassing to Drs. Gross and Wong unless they would now recognize that they had been deceived/fooled by the STVHCS supervisors by providing the images with intentionally created wrong or doctored data. I will now prove my points.

Regarding radio-aerosol, "The first technical consideration is particle size. In order to accurately image the entire lung, sufficient radioactive material must be deposited at the alveolar level throughout the lungs. Knowing that particles increase in size (hygroscopic growth) as they travel through the warm and humidified airways, it is important to start with very small particles. Although smaller particles will not grow too large, and will therefore be able to reach the

alveoli, individually they will not carry as much radioactivity as larger particles. So it is imperative to use a radio-aerosol delivery system that will provide a very large amount of small particles.

Secondly, if the aerosol stream contains an excess of medium to large particles, they will cause more radioactivity to deposit in the central airways ("clumping" or "hot spots") thereby making the visualization of the alveolar regions more difficult".

Package Inserts:

Suggested Protocol for Pre-Perfusion and Post-Perfusion Studies for the Medi/  
Nuclear Radio-aerosol Delivery System

**Pre-Perfusion** 1. Follow package insert instructions.

2. Use 99mTc-DTPA in a 15-20mCi/mL concentration.

3. Inject a 2mL volume in to the nebulizer.

4. Have the patient inhale until approximately 1mCi 99mTc-DTPA is deposited in the patient's lungs. (Depending on the model unit and using a 2 mL volume with a concentration of 20 mCi/mL the dosing time should be within 1.5 to 4 minutes). The approximate dosing time for each unit is: Insta/Vent™ Plus 1-1.5 minutes, Insta/Vent™ 2-3 minutes, Aero/Vent™ Plus 3-4 minutes, Aero/Vent™ MAX 1.5-2.5 minutes, and Aero/Vent™ Jr 1.5-2.5 minutes."

**Post-Perfusion** 1. Use a reduced perfusion dose of approximately 1mCi 99mTc-MAA.

2. Ensure that the 99m Tc-DTPA is in a 30-40 mCi/mL concentration.

3. Inject a volume of 2 mL into the nebulizer.

4. Inhale patient until count rate in the patient's lungs has increased to 2-3 times the residual from the perfusion study. (When using a concentration of 30 mCi/mL, approximately 3.5 minutes of patient breathing time should deposit approximately 3 mCi 99mTc - DTPA in the lungs.)

Note: Always check your NRC or agreement state license to see if special licensing is required for inhalation lung studies or for the increased dosage required for post-perfusion inhalation lung studies. As with the use of any radioactive material always observe proper radiation safety precautions".

In spite of my respectful objection, the STVHCS supervisors adopted "**Post-Perfusion**" technique and ordered all staff (physician and technical) to follow the same but with their own unscientific way. The scientific way is to perform the 1st study (in this case he chose Perfusion study) with as low dose as possible. The literature suggests only 1mCi of MAA (see above). Dr. Duffy kept on prescribing 2 to 5 mCi. Then for the second study, he prescribed only 17 to 42 mCi of Aerosol (see page 10, para - 4 of the ROI) as a starting dose in the nebulizer in all or most of the 76 patients, which relative to the first dose, deposited a very low "homeopathic dose" of 0.2 to 0.5 mCi of Aerosol within the peripheral lung alveoli in most cases. On top of this, there were severe artifacts from the bronchial and tracheal clumps of activity due to ineffective nebulization by a defective machine. As can be seen from the above mentioned package inserts that the starting dose for the Aerosol (2nd study) should have been 60 to 80 mCi per mCi of MAA used in the first study. So, in the cases where he used 5 mCi of MAA (not recommended by any of the three societies) as the first study, the over powering Aerosol dose in the second study should have required a minimum of 600 to 800 mCi of Aerosol to get any meaningful ventilation image. Please see below my table of data obtained from images of nine patients of STVHCS that I had analyzed previously for teaching purpose.

The ROI notes (page 22, para-2), "A subsequent discussion with 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 request for a list of cases in which ventilation scans resulted in alleged "contamination"." **\*\*[Please see bottom of the last page 18].**

Since January 12, 2012, I have no access to any documents in my office or other places within the STVHCS. In writing I was directed not to enter the facility. Dr. Gross attempted to negotiate with Dr. Flynn, C.O.S. for my access to the case list. But, due to a total noncooperation from the C.O.S. this did not materialize and I could not provide Dr. Gross with the list. Please see my communications with Dr. Gross and Dr. Flynn (Attach pp 22-25).

The TABLE 1 below is from the data I had from 9 teaching cases analyzed during my physical presence in the department in November-December of 2011.

TABLE 1. Decay corrected count rate (CPM) from the region of interest (ROI) of the posterior view of lung field of nine (9) randomly available patients' images from the STVHCS. Counts from the trachea, bronchi and oesophagus in the mediastinal and hilar areas were excluded from the ROI.

<b>Patient</b>	<b>(A) 1st Study Perfusion Actual CPM from MAA</b>	<b>(B) 2nd Study MAA plus Aerosol</b>	<b>(C) Actual CPM from Aerosol (B) - (A)</b>	<b>(D) Desired CPM from Aerosol (minimum)</b>	<b>(E) Is Ventilation (Aerosol) Study Readable</b>
1	180	220	40	540	No
2	137	293	156	411	No
3	84	120	36	252	No
4	360	403	43	1080	No
5	309	326	17	927	No
6	362	393	31	1086	No
7	240	327	87	720	No
8	479	505	26	1437	No
9	420	549	129	1260	No

These data completely agree with the non-interpretability of the images. I don't know how Drs. Gross and Wong felt comfortable reading those images. Most likely they were led to erroneously compare the images from wrong data provided by the STVHCS supervisors. If Dr. Gross and Wong are still inclined to support the STVHCS supervisors, I can only challenge them and request to provide me with PHI data redacted version discs of all 76 cases. It is easy to prove my point. Numbers do not lie.

In fact, STVHCS did not follow a set protocol, because, they did not have one. For those eight months they had been trying their ignorance by changing the sequence, altering the doses blindly and not achieving the clinical diagnostic goals. They were probably involved in medical malpractice and definitely they had violated ALARA principles, local policy (if there is one anymore) and the VACO policy.

#### ACR-SNM-SPR PRACTICE GUIDELINE FOR THE PERFORMANCE OF PULMONARY SCINTIGRAPHY IN ADULTS AND CHILDREN

Revised 2009 (Res. 13)

Aerosol a. Radiopharmaceutical

“Thirty to 50 millicuries (1,110 to 1,850 MBq) of technetium-99m diethylene-triamine pentacetic acid (DTPA) or other approved radiopharmaceutical is placed in a nebulizer and agitated with oxygen. If the aerosol study is performed first, the patient should inhale enough radioaerosol to deposit about 1 millicurie (37 MBq) in the lungs (approximately 100,000 counts per minute). If the ventilation study is performed after a perfusion study, the patient should inhale enough aerosol to triple or quadruple the perfusion count rate.”

Note: The above guidelines were adopted by the American College of Radiology (ACR), Society of Nuclear Medicine (SNM) and Society for Pediatric Radiology (SPR). Dr. Lorraine Fig, Deputy Director of Nuclear Medicine, VACO, has been a member of the Guidelines and Standard Committee – Nuclear Medicine.

The same guidelines were also recommended by the V.A. Nuclear Medicine Procedure Guideline Committee, Chaired by Dr. Tuhin Chaudhuri and adopted by the office of Dr. Milton Gross and Dr. Lorraine Fig.

#### 4. Violation of ALARA Principle:

On page 7 paragraph 2 of the "Report of Investigation", it says,  
" 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). The NHPP does not interpret this regulation to apply to patients ....." .

This statement above defies all sorts of current concepts and concerns within different professional societies and the general public at large. The investigators probably forgot that the patients are also members of the public. They are the major victims of unnecessary diagnostic radiation. Unfortunately, some of the offenders are some of my colleagues, the physicians who hold themselves as untouchable, even if they demonstrate recklessness in exposing unsuspecting patients to danger and wanton disregard of other person's rights.

**Now, I will cite below some acclaimed professional scientific publications to support my point:**

**(1) A complimentary publication of The Joint Commission (Issue 47, August 24, 2011) : Radiation risks of diagnostic imaging**

"Diagnostic radiation is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.<sup>1,2,3</sup> Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.<sup>4</sup> The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.<sup>1,5,6,7</sup> X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.<sup>1</sup>

Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.<sup>8</sup> Diagnostic imaging can occur in hospitals, imaging centers, physician and dental offices, and any physician can order tests involving exposure to radiation at any frequency, with no knowledge of when the patient was last irradiated or how much radiation the patient

received. From the 72 million CT (computerized tomography) scans performed in the U.S. during 2007, one study estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).<sup>9</sup> Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.<sup>10</sup> While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information. While experts disagree on the extent of the risks of cancer from diagnostic imaging, there is agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation.<sup>7</sup> Patients most prone to harm from diagnostic radiation are children and young adults;<sup>11</sup> pregnant women;<sup>12</sup> individuals with medical conditions sensitive to radiation, such as diabetes mellitus and hyperthyroidism;<sup>6</sup> and individuals receiving multiple doses over time.<sup>2</sup> The diagnostic procedures most commonly associated with avoidable radiation doses are CT, nuclear medicine and fluoroscopy.<sup>13</sup> This Alert focuses on diagnostic radiation and does not cover therapeutic radiation or fluoroscopy. While fluoroscopy is used diagnostically, there are special issues associated with its use that make it inappropriate to be included here".

"Right dose" (1 & 2 omitted)

“3. Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for “as low as reasonably achievable” – making sure doses are as low as possible while achieving the purposes of the study.<sup>18</sup>

4. Adhere to the Society for Pediatric Radiology’s Image Gently guidelines when providing imaging radiation (or fluoroscopy) to children<sup>11,19,20</sup> and, for adults, adhere to the Image Wisely guidelines (developed by the American College of Radiology and the Radiological Society of North America in collaboration with the American Association of Physicists in Medicine and the American Society of Radiologic Technologists).<sup>22</sup>

5. Provide physicians and technologists with reference doses based on anatomy, purpose of the study, and patient size. Establish appropriate dose ranges for high-volume and high-dose diagnostic imaging studies.

6. Radiologists should assure that the proper dosing protocol is in place for

the patient being treated.

7. Institute a process for the review of all dosing protocols either annually or every two years to ensure that protocols adhere to the latest evidence.

8. Investigate patterns outside the range of appropriate doses. Track radiation doses from exams repeated due to insufficient image quality or lack of availability of previous studies to identify the causes. Address and resolve these problems through education and other measures.<sup>4</sup>

9. Record the dosage or exposure as part of the study's summary report of findings."

(Note: Numbered references could be found in the main publication noted above).

**(2) JAMA. 2012 Jun 13;307(22):2400–9. doi: 10.1001/jama.2012.5960. Use of diagnostic imaging studies and associated radiation exposure for patients enrolled in large integrated health care systems, 1996–2010. Smith–Bindman R, Miglioretti DL, Johnson E, Lee C, Feigelson HS, Flynn M, Greenlee RT, Kruger RL, Hornbrook MC, Roblin D, Solberg LI, Vanneman N, Weinmann S, Williams AE.**

**Abstract:**

"During the 15-year study period, enrollees underwent a total of 30.9 million imaging examinations (25.8 million person-years), reflecting 1.18 tests (95% CI, 1.17–1.19) per person per year, of which 35% were for advanced diagnostic imaging (computed tomography [CT], magnetic resonance imaging [MRI], nuclear medicine, and ultrasound). Use of advanced diagnostic imaging increased from 1996 to 2010; CT examinations increased from 52 per 1000 enrollees in 1996 to 149 per 1000 in 2010, 7.8% annual increase (95% CI, 5.8%–9.8%); MRI use increased from 17 to 65 per 1000 enrollees, 10% annual growth (95% CI, 3.3%–16.5%); and ultrasound rates increased from 134 to 230 per 1000 enrollees, 3.9% annual growth (95% CI, 3.0%–4.9%). Although nuclear medicine use decreased from 32 to 21 per 1000 enrollees, 3% annual decline (95% CI, 7.7% decline to 1.3% increase), PET imaging rates increased after 2004 from 0.24 to 3.6 per 1000 enrollees, 57% annual growth. Although imaging use increased within all health systems, the adoption of different modalities for anatomic area assessment varied. Increased use of CT between 1996 and 2010 resulted in increased radiation exposure for enrollees, with a doubling in the mean per capita

effective dose (1.2 mSv vs 2.3 mSv) and the proportion of enrollees who received high (>20–50 mSv) exposure (1.2% vs 2.5%) and very high (>50 mSv) annual radiation exposure (0.6% vs 1.4%). By 2010, 6.8% of enrollees who underwent imaging received high annual radiation exposure (>20–50 mSv) and 3.9% received very high annual exposure (>50 mSv)".

"Within integrated health care systems, there was a large increase in the rate of advanced diagnostic imaging and associated radiation exposure between 1996 and 2010".

**(3). The ALARA (as low as reasonably achievable) concept in pediatric interventional and fluoroscopic imaging: striving to keep radiation doses as low as possible during fluoroscopy of pediatric patients—a white paper executive summary**

Keith J. Strauss<sup>1</sup> and Sue C. Kaste corresponding author<sup>2</sup>

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"ALARA represents a practice mandate adhering to the principle of keeping radiation doses to patients and personnel As Low As Reasonably Achievable. This concept is strongly endorsed by the Society for Pediatric Radiology, particularly in the use of procedures and modalities involving higher radiation doses such as CT and fluoroscopic examinations of pediatric patients. There is no doubt that medical imaging, which has undergone tremendous technological advances in recent decades, is integral to patient care. However, these technological advances generally precede the knowledge of end-users concerning the optimal use and correct operation of the resulting imaging equipment, and such knowledge is essential to minimizing potential risks to the patients".

**(4) Concept and federal regulation of ALARA: by Nicholas Joseph Jr, RT (R) & Jeffery Phalem, M.D.**

"The concept of ALARA is not new to radiology. It began when the Nuclear Regulatory Commission in December 1977 began pushing for radiation standards that lowered the dose to patients and occupational workers. As a result, The Office of Standards of the Nuclear Regulatory Commission published NUREG-0267, a follow up document to their attempts to reduce radiation exposure. This document was called, Principles and Practices for

keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable. The acronym ALARA remained as the documents impact on the radiology community to include patient and occupational exposure mandate for minimum necessary exposure. In 1994 the ALARA document became a part of title 10 of the Code of Federal Regulations (10CFR35.20) which is binding on all institutions as a NRC regulation. Therefore, it must be practiced as a matter of mandate of federal code. So when the radiographer stresses the practice of ALARA it should be understood by all that it is because it is required and respectful to the patient."

**As one can see from the above references, the ALARA principle is mainly devoted these days for the interest of the patients.** The workers in the field of radiation and the public have not been excluded from the ALARA principle.

## CONCLUSION

In his 24 page ROI, Honorable Secretary Shinseki has corroborated multiple times with the whistle-blowers' allegations.

The report documented (page 10, para 4), "Beginning June 6, 2011 through December 2011, under the supervision of Dr Duffy (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". Literature data showed that this technic with 2 -5 minutes of breathing through the nebulizer is expected to deposit a maximum of only one millicurie of radioactivity within the peripheral alveolar system of the lungs. At the STVHCS, with the defective equipment and wrong procedure, the computer generated data showed even lesser degree of deposit (0.2 to 0.8 millicuries). It is also a fact that for the first performed perfusion portion of the studies, between 2 to 5 millicuries of Tc-99m-MAA were used, all of which was expected to be deposited within the lung capillaries and at the STVHCS, it did (proven data).

Now, with as high a dose of 2 to 5 mCi in the 1st study (perfusion) and as low a dose of 0.2 to 0.8mCi in the 2nd (ventilation) study, under the then followed technics at the STVHCS, nobody in the world at this time should be able to interpret the 2nd study (ventilation scan). All published literature suggest the 2nd deposited dose must be at least 3 to 5 times more than the first. So, the question is how could the ROI note (page 12, line 11 – 15), “ An independent expert review convened by Dr. Gross 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”? Knowing Dr. Gross’s credentials for all these year, I can not believe that he and his colleague, Dr. Wong would make such naive and ignorant comments, unless they have been deceived by providing with wrong data by the STVHCS supervisors. This part definitely needs further investigation, If the STVHCS supervisors had generated 76 uninterpretable ventilation scans, then each study has caused unnecessary radiation to our unsuspecting veterans. This is clearly an ALARA violation and attempted cover-ups.

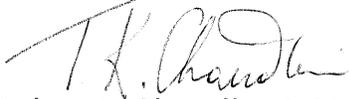
Although, the R.O.I. virtually agrees with all the allegations, there appears to be obvious attempts to minimize the severity of the guilt. In that process, the agency has engaged itself to several “cover ups” that belittles the organization (V.A.) in the eyes of the public. The “cover ups” are in the main areas of (a) Clinical Protocol, (b) Radiation Safety Training (c) Final Appearance of the Images/Studies and (d) ALARA violations. As it is said, “Cover ups are more punishable than the offense itself”. There are proofs after proofs showing the absence of protocol and lack of training during the time period in question. Yet, the local supervisors at the STVHCS are trying to present with wrong, deceiving and/or doctored documents to conceal the facts or violations.

It is sad that, even after I pointed out in my letter of May 28, 2012 to the NHPP the gravity of ALARA concept and consequence of its violation as imposed by our highest court of law, the investigators decided to overlook the violations. On the subject of violation of ALARA philosophy and radiation safety, Honorable Justice wrote, **"Exemplary damages are not limited to cases where there is direct evidence of fraud, malice or gross negligence. They may be allowed when there is evidence of such recklessness and wanton disregard of another's rights that malice and evil intent will be inferred. If a defendant**

**is grossly and wantonly reckless in exposing others to dangers, the law holds him to have intended the natural consequences of the acts, and treats him as guilty of a willful wrong” –Silkwood v. Kerr-McGee Corp. 464 U.S. 238, (1984).**

And the jury returned the verdict, **"The defendant is guilty"**.

Respectfully submitted,



Tuhin K. Chaudhuri, M.D., FACNP, FACNM  
6514 Pemview  
San Antonio, TX 78240

E-mail:

Tel:

Enclosure/Attachment : One page INDEX plus 27 Pages

\*\* [Contd from page 9]: **SKIN CONTAMINATION:** External skin contaminations were not any focal spots. These were uniformly deposited radioactivity on the anterior chest wall and abdomen of the patients caused by radioactive aerosol spray from the leakage of the delivery system. This type of contamination can be easily detected by flagging the region of interest (ROI) outside the lung field of the computerized image. I can demonstrate that ant time. After every aerosol procedure, with Geiger Counter unusual amount of radioactivity could be detected on the scanning table, camera head, floor and on the shoes of the staff. For this reason, lately the aerosol studies were being scheduled in a separate room and towards the end of the day, so that the other studies were not interfered by the background radio-activity.

\*\***Internal artifacts** due to the accumulation of radio-activity in the trachea, bronchi, oesophagus and stomach were focal spots easily identifiable in the image. At STVHCS, these spots had been extensive due to the formation of many larger particles than usual in the defective delivery system (nebulizer).

## INDEX OF ATTACHMENTS (by hand written page number at the bottom)

	Page Number
1. Requests to STHCS supervisors to stop the Radio-Aerosol studies until proper training, authorization and protocol set-up (Nov. 2011)	1 - 3
2. Continuing spillage of radioactive Aerosol (Jan. 4, 2012)	4
3. Original Violation Report and Recommendation by the RSO (Nov 21, 2011)	5 - 9
4. Initial Review Report by the OSC (May 2, 2012)	10 - 11
5. Denied requests from Dr. Chaudhuri to meet with the NRC investigator (May 15, 2012)	12 - 13
6. VACO Directive for mandatory Clinical Protocol Review and Publication by every local V.A. facility (2011)	14
7. Dr. Chaudhuri's letter to NHPP dated May 28, 2012 mentioned in the VA-ROI, but not included ... (May 28, 2012)	15 - 19
8. Dr. Chaudhuri's letter to NHPP dated June 3, 2012 mentioned in the VA-ROI, but not included (June 3, 2012)	20 - 21
9. Dr. Chaudhuri's letter to Dr. Gross Re: C.O.S.'s denial to enter the facility & STVHCS's attempted cover ups of violations (Oct 10, 2012)	22 - 25
10. Documents of the first Radiation Safety training after one year of its continuous use with violations of rules, regulations and laws	26 - 27

**Subject:** Patient Care  
**From:** Chaudhuri, Tuhin K (Tuhin.Chaudhuri@va.gov)  
**To:** Julianne.Flynn@va.gov;  
**Cc:** tuhin.chaudhuri@yahoo.com;  
**Date:** Tuesday, November 1, 2011 3:30 PM

Dear Dr. Flynn,

As you recall, a few days back you kindly gave me an appointment to meet with you to discuss certain patient care related issues. However, at the last moment, due to other unavoidable business, you had to postpone our appointment. Since then, I have been waiting to hear from you regarding a rescheduled appointment.

One of the issues has now become so urgent, that, for appropriate patient care I need to discuss the matter with you. I am very familiar with the "Chain of Commands" and respectfully try to abide by the principle. Between you and me there are three other links in this chain. I have exhausted my several attempts to resolve the issue through these respective administrative links but without any positive result.

As a senior and experienced member of your physicians team, may I have an appointment to meet with you as soon as possible for about 15 minutes, to bring the matter to your notice for advice? As I have said earlier, the subject is patient care related. If you wish to know the exact subject, please do not hesitate to call me any time at 867-6264.

Thank you in anticipation.

Tuhin K. Chaudhuri, M.D., FACNP, FACNM

NOTE:  
*Of course, Dr. Flynn knew, the subject matter of our discussion was, "Illegal use of radio-aerosol and violation of radiation safety codes." Needless to say that, I can never given any appointment on this issue.*  
 T.K.C.

①

## Chaudhuri, Tuhin K

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To: Duffy, Daniel  
Cc: Arellano, Jose (STX); Cardenas, Monique C.; Kim, Chea; Jimenez, Joe M; Leuschen, Calvin T.; Melendez, Nelly; Valdes, Martha P; Wittenbach, Eric S.; Flynn, Julianne  
Subject: Use of 99mTc-Aerosol

Dr. Duffy,

As you know, in our clinic, the use of 99mTc-Aerosol has become a problem. The way we perform the studies, its use in lung ventilation study in our clinic does not help us clinically. It confuses the reader and radiates people within the department unnecessarily. For example, when you use 30 – 35 mCi for the patient, the patient gets less than 1 mCi and potentially the atmosphere and we receive much more than that. The scan becomes simply unreadable and our environment becomes unsafe. The technologists and I have brought this matter to your attention several times but without any result. On several occasions, I had to read the perfusion scans simply by ignoring the ventilation scan. It is not a good clinical practice.

I hereby request you to stop the Aerosol procedure in our department until its safe use is established. Also, from now on, it may be unwise for me to prescribe and/or read any Aerosol study, until its safe use is established within our clinic.

Thank you for your attention in this matter.

T. K. Chaudhuri, M.D., FACNP, FACNM

Chaudhuri, Tuhin K

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From: Flynn, Julianne  
To: Chaudhuri, Tuhin K  
Sent: Tuesday, November 22, 2011 5:57 PM  
Subject: Read: Use of 99mTc-Aerosol

Your message

To: Duffy, Daniel  
Cc: Arellano, Jose (STX); Cardenas, Monique C.; Kim, Chea; Jimenez, Joe M; Leuschen, Calvin T.; Melendez, Nelly; Valdes, Martha P; Wittenbach, Eric S.; Flynn, Julianne  
Subject: Use of 99mTc-Aerosol  
Sent: 11/22/2011 10:25 AM

was read on 11/22/2011 5:57 PM.



Chaudhuri, Tuhin K

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From: Wittenbach, Eric S.  
Sent: Monday, November 21, 2011 7:39 AM  
To: Flynn, Julianne; Duffy, Daniel; Leuschen, Calvin T.; White, John C.  
Cc: Vlosich, Kristopher W.; Lambert, Agapito; Smith, Billie Von; Chaudhuri, Tuhin K  
Subject: RE: Spill Exposure NM Input  
Attachments: September 2011 spill and recovery draft 3.doc

I believe the latest draft is what has been discussed. I will attach it here to be certain it is the current one. Dr. Chaudhuri should be at the meeting as well as the three other technologists involved due to his presence during the event and his expert observations.

If there is more data available, especially data that defines the spill more completely, please forward it to Mr. White and myself.

r/esw

Eric Wittenbach, MSED, USN, RET  
Radiation Safety Officer/Laser Safety Officer  
VA Radiation Safety Office (007R)  
Room H-214  
Phone 14003; Page 203-5427

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NOTE: In spite of the recommendation of the RSO, Dr. Chaudhuri was carefully excluded from all meetings regarding spill and radiation safety issue.

ORIGINAL REPORT DRAFTED BY THE RSO

Nov 18, 2011

My first knowledge of this event was from a phone call I received from a VA staff member around eight o'clock the evening of 20 September. This staff member notified me of a significant spill in the Nuclear Medicine Clinic. Since the phone was not answered in the Nuclear Medicine Clinic, I called the VA Police shortly after and asked them to go to the Nuclear Medicine Clinic and investigate. After speaking to the police, Dr. Chaudhuri, and RSO John White I was told by Mr. White the situation was under control and I need not come in. The circumstances of the accident are as follows in a verbatim statement by Mr. Kim:

"Ms. Monique Cardenas was checking in a package of radiopharmaceutical from Cardinal Health in room J204 for a emergent Lung scan from ED. As she was surveying the package from one meter away, Mr. Joe Jimenez walked in with a bag of radioactive waste from prior lung scan performed in room J206. Mr. Jimenez was bringing in the radioactive waste to survey (and log in) the decay in storage binder for decay in room J204. The items included were a nebulizer, tubing, mouthpiece and other accessories utilized for the lung scan.

Ms. Cardenas then moved the package to the other end of the room on the counter next to the Hot Sink due in part as the survey meter was detecting high levels of radiation thought to be due to the radioactive waste. As she proceeded to perform the survey again, she was still detecting high levels on the survey meter from one meter away. Ms. Cardenas to her credit realized that there were something amiss and at this time Ms. Martha Valdes entered J204.

All three individuals decided to survey themselves and realized that their feet were contaminated. Ms. Cardenas began a quick survey of the floor and noticed that the floor in the hot lab was contaminated.

About this time I went to the hot lab room J204 to check on the status of the dose for the ED patient. This was around 1630 hrs on 20 Sept 2011. As I entered the hot lab, I was informed that there was radioactive contamination detected on the floor of the hot lab. After donning shoe covers, I surveyed using the survey meter to check the floor of the door to room J204. I found it to be contaminated. As I continued my survey, the contamination trail led from the room J204 to room J206. I informed everyone inside the hot lab that we had radioactive contamination in the hallway and needed to be careful so as not to track it throughout the section.

I informed Ms. Valdes and Mr. Jimenez that we would need to survey room J206 to detect for radioactive contamination and I proceeded to the hot lab check for contamination as well. To our dismay, both rooms were found to be contaminated. This was around 1700 hours.

I informed Dr. Dan Duffy, Chief Nuclear Medicine of the contamination. I then called and notified Mr. John White, Radiation Safety Officer at approximately 1703 hours. I informed him of the radioactive contamination and gave him a brief synopsis of what had transpired.

I surmised that the plastic bag that comes with the aerosol ventilation kit might have been ripped and or punctured and could have leaked the remaining Technetium 99m DTPA in the nebulizer causing the contamination. I informed him that we would document the results of the initial survey and swipe for contamination. We would then proceed to clean up the spill as best we could, take a post clean up survey and swipe, cover up the contaminated area and inform him in the morning. He agreed with my assessment and will plan to follow up in the morning of 21 Sept 2011.

Ms. Valdez, Mr. Jimenez and myself began a through survey and swipe of the areas in question and covered up the contaminated areas with absorbent pads to minimize further contamination and annotated the readings of the areas. In total, we identified 30

areas of contamination with readings as high as 30mr/hr and swipe results as high as 2 Million counts.

We began a meticulous clean up of the radioactive spill utilizing the materials contained in the spill kit. Finally after almost 5 hours of clean up we once again surveyed and swiped the areas of contamination. The highest reading were about 2mr/hr and we covered up the hallway and rooms J204 and J206 utilizing the large absorbent pads. The cleaning materials, such as paper towels, absorbent pads, sani-wipes and gloves were disposed of as radioactive waste and logged into the decay in storage binder. The hallway was cordoned off by VA Police."

Further investigation the next several days did not reveal any new or different interpretations of the events as they occurred. The only other item of significance discovered was an apparent concerted effort to discover the identity of the person that called me the evening in question. Reviewing this statement, the spill area, and dosimetry records reveals some areas of concern:

- The radiation levels are not reported correctly and do not reflect the distance from the source making accurate reconstruction of this event unlikely.
- Personnel were working in an uncharacterized radiation area for an extended period without monitoring indicating a lack of familiarity with the principles of ALARA. Neither the workers nor supervisor appeared to be aware of the ambient radiation levels in the spill area.
- Of the two workers involved in the clean-up effort, one received an exposure of approximately 3500 mR and the other approximately 1500 mR of exposure. The average annual exposure for a nuclear medicine worker is less than 100 mR. This was an extraordinary exposure event.
- The radiation safety office found areas of the spill that were not covered until the next day.
- Liquid radioactive material should not have been transported through hallways in a non-secure container risking a spill of this nature.

Root Causes of the high exposure to two employees:

- Improper use of the radiation detection equipment indicates a lack of operator training and supervisory experience.
- Personnel unnecessarily exposed by working in an undefined radiation area indicate a lack of understanding of ALARA principles and a lack of supervisory training.
- Undiscovered areas of contamination after declaring the scene under control indicate a lack of thorough radiological control and inadequate supervisory experience and training.
- Radiation Safety Handbook does not adequately address spill recovery procedures to reflect attention to ALARA principles in the spill response section.

Root Cause of the spill:

- Inadequate preparation and planning prior to initiating a new clinical procedure.

Recommended actions:

1. Supervisory staff should be trained on the proper uses of radiation detection equipment.
2. Supervisory staff should be trained on proper application of ALARA principles.
3. Supervisory staff should be trained in proper radiological control procedures with regard to spills and the handling of radioactive materials.
4. Radiation Safety should revise spill procedures in the Radiation Safety Handbook to reflect ALARA principles and graded spill response.
- ✓ 5. The lung scan procedure central to this event should be reviewed by Radiation Safety, Nuclear Medicine staff and supervisors with the intention to properly plan the implementation of this procedure with a revised protocol that provides adequate process and functional controls for protection of the public, patient, and worker.
6. Waste handling in Nuclear Medicine should be reviewed by Radiation Safety and Nuclear Medicine to establish process and functional controls designed prevent further loss of control events and spread of contamination.
- ✓ 7. Nuclear Medicine policies should be amended to provide Radiation Safety with notification any time new procedures or protocols are initiated to include changes in route of administration, isotopes used, sites of use, chemical form of isotope, or any other substantial change in the routine procedures used at this facility. Radiation Safety is not to approve or disapprove the bona fide use of radioactive material but evaluate the safe handling of the material during and after its use.

Proposed Plan of Action and Milestones:

A Draft addendum to the Radiation Safety Handbook will be written by the RSO and circulated for approval and comment through the membership of the MRRCC specifically including Nuclear Medicine supervisors and staff. The addendum will be immediately issued upon approval by electronic vote and incorporated in the new issue of the handbook on its anniversary. Suspense date will be 25 November, 2011.

A working group of Nuclear Medicine Technologists and Radiation Safety Staff will be assembled with the charge of producing a protocol for safe operations during and after the lung study at issue (DTPA aerosol ventilation). The Chief Nuclear Medicine Technologist will generate the protocol for review and comment by the Nuclear Medicine Technologists and the RSO staff. Suspense date will be 25 November, 2011.

The Chief Nuclear Medicine Technologist will make himself available for refresher training in the principles of ALARA, spill recovery, use of detection equipment and reporting of results. This training can be conducted in concert with the Nuclear Medicine Staff under the auspices of the Radiation Safety Office during a general training session. Suspense date will be 25 November, 2011.

Waste handling in Nuclear Medicine should be reviewed by Radiation Safety and Nuclear Medicine staff within the same working group established to create the lung study to establish process and functional controls designed prevent further loss of control events and spread of contamination through inappropriate waste handling. A working document has been created by the RSO to serve as a point of reference for the discussion. A waste handling policy will be generated by the RSO for review and comment by 25 November, 2011.

- ✓ Nuclear Medicine policies should be amended to provide Radiation Safety with notification any time new procedures or protocols are initiated to include changes in route of administration, isotopes used, sites of use, chemical form of isotope, or any other substantial change in the routine procedures used at this facility. This may be presented as an SOP from either the RSO or Nuclear Medicine. Suspense date will be 25 November, 2011.



U.S. OFFICE OF SPECIAL COUNSEL  
1730 M Street, N.W., Suite 218  
Washington, D.C. 20036-4505  
202-254-3600

May 2, 2012

Dr. Tuhin K. Chaudhuri  
c/o David Scher, Esq.  
The Employment Law Group  
888 17<sup>th</sup> Street, NW, Suite 900  
Washington, DC 20006-3307

Re: OSC File No. DI-12-0927

Dear Dr. Chaudhuri:

The Office of Special Counsel (OSC) has completed its review of the information you referred to the Disclosure Unit. You alleged that employees at the Department of Veterans Affairs (VA), South Texas Veterans Health Care System (STVHCS), Audie L. Murphy Memorial VA Hospital (Hospital), San Antonio, Texas, have engaged in conduct that may constitute a violation of law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health and safety.

OSC is authorized by law to refer protected disclosures to the involved agency for an investigation and report. Disclosures OSC may refer for investigation must include information that establishes a substantial likelihood of a violation 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 or safety. OSC does not have the authority to investigate disclosures and, therefore, does not conduct its own investigations.

You disclosed that Nuclear Medicine Clinic managers have failed to follow required radiation safety procedures and implemented unapproved and unsafe clinical procedures that have resulted in unnecessary radiation exposure to patients and staff. Specifically, you alleged that:

- Dr. Daniel Duffy, 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;
- 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. Dr. Duffy continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed; and

Dr. Tuhin K. Chaudhuri

Page 2

- 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.

Based on this information, OSC has concluded that there is a substantial likelihood that the information you provided discloses a violation of law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health and safety. Accordingly, we are referring this information to the Secretary of Veterans Affairs for an investigation and report under 5 U.S.C. §1213. With your consent, we identified you as the source of the information so that agency officials may contact you. Also, with your consent, we transmitted your allegations with disclosures made by Mr. Joe Jimenez.

We have provided the Secretary 60 days to conduct an investigation of your allegations and to report back to OSC. You should be aware, however, that these matters may take somewhat longer and agencies may request an extension of the reporting date. After we have reviewed the report, unless it is classified or otherwise not releasable by law, we will send you a copy and give you an opportunity to comment, if you wish. The report and your comments will be transmitted to the President and the appropriate congressional oversight committees, and will be maintained by OSC in a public file. We emphasize that until the agency's final report is forwarded to the President and Congress, this remains an open matter under investigation. Thus, we request that all information and correspondence related to this matter be kept confidential until you receive notification that the matter has been closed.

If you wish to discuss this matter, please contact me at (202) 254-3646.

Sincerely,



Jennifer B. Pennington  
Attorney, Disclosure Unit

CAM:JBP/jbp

*Copies sent to NHPP investigators as per their requests.*

11

**Subject:** Appointment  
**From:** tuhin.chaudhuri (tuhin.chaudhuri@yahoo.com)  
**To:** eric.wittenbach@va.gov;  
**Cc:** elizabeth.garces@va.gov;  
**Bcc:** tuhin.chaudhuri@yahoo.com;  
**Date:** Tuesday, May 15, 2012 9:55 AM

Dear Radiation Safety Personnels,

I understand that the inspectors are there at the STVHCS facility. For public safety, it is very important that I speak to them today. Please transmit this information to them as soon as possible and let me know when would they wish to meet with me. I can be there in your office with one hour notice.

My cell phone # is 210-867-6264.

Thank you.

Tuhin K. Chaudhuri, MD, FACNP, FACNM

Formerly, Chief of Nuclear Medicine  
 STVHCS, San Antonio, TX.

12



## II. CLINICAL PROTOCOLS (NRC/TJC REQUIREMENT)

Deficiencies in clinical protocols were frequently encountered. Among problems identified were outdated protocols, protocols containing insufficient detail to perform or process studies and/or generic protocols not written specifically for the laboratory in question. Frequently, protocols showed no evidence of periodic review.

### Recommendations:

- Protocols must be written for each procedure performed by the laboratory, even if infrequent or newly implemented. Protocols must be updated, as needed, to conform to current practice standards.
- Protocols must be specific for the particular laboratory and equipment inventory i.e. specifically written for each gamma camera. Copied "textbook" and/or generic protocols are not acceptable.
- Revisions should include step-by-step detail ("cookbook" style) to include both image acquisition and processing specific for the equipment in that laboratory.
- At a minimum, protocols should include the following sections:
  - Indications/contraindications for the study
  - Patient preparation
  - Radiopharmaceutical, desired dose (or range) and route of administration
  - Dosimetry
  - Acquisition parameters, including collimator/s
  - Processing parameters and display
- Protocols must be reviewed at least every 3 years and this "approval" should be documented by the signature/date of the Nuclear Medicine Chief or designee on each protocol.
- Appropriateness criteria need to be clearly written for each study and an appropriateness screen must be performed on all studies before they are performed.

Note: The above document came from the office of VACO Nuclear Medicine Director in 2010-11. In STVHCS, it has been also a requirement for each new procedure to meet the R.S.O. approval. No such document was available. If any such document was produced during recent investigation, its authenticity should be challenged.

May 28, 2012

Thomas E. Houston, Ph.D.  
Program Manager  
VHA National Health Physics Program (115HP/NLR)  
2200 Fort Roots Dr  
North Little Rock, AR 72114

[SUBJECT : NHPP INVESTIGATION ON RADIATION SAFETY VIOLATION]

Dear Dr. Huston,

Thank you very much for your prompt and serious investigation into the matter of alleged continuous multiple Radiation Safety Violations by the supervisors and leaders of the South Texas Veterans Health Care System (STVHCS).

Let me first clarify two items as I understand to be correct: A. Relation between clinical aspects of Nuclear Medicine and Radiation Safety and B. Relation of ALARA philosophy in regard to patients, general public and the employees (workers dealing with radiation).

A. Nuclear Medicine within the VA is a clinical department and practically all of its clinical applications involve use of radioisotopes or radiation. So, any wrong clinical procedures are prone to affect the radiation safety. Multiple violation of rules, regulations and laws of clinical procedures are directly related to radiation safety violation of rules, regulations and laws set by the VA, NHPP, NRC or other regulatory bodies. Hence, it is generally difficult to separate Clinical Violation (malpractice) in Nuclear Medicine from Radiation Safety Violations. For example, if a Nuclear Medicine Physician uses a wrong radiopharmaceutical or a wrong dose (high or low) or a wrong procedure leading to no useful images, it becomes a clinical malpractice. By doing so, he might have given unnecessary radiation to the patient and his surrounding people without any benefits. Then it becomes a violation of ALARA philosophy and Radiation Safety. Legal use of radioisotope must fulfill three rules: intent benefits, maximum dose limit and ALARA. One or two inadvertent human errors within the prescribed dose limits may be acceptable; but, continuous negligence, with reckless and wanton disregard of another's rights and safety for months of malpractice (May, 2011 to December, 2011) on multiple patients and workers and violations of rules, regulations and laws should be punishable by law.

In 1984, in the case of *Silkwood v Kerr-McGee*, the U.S. Supreme Court Justice wrote, "Exemplary damages are not limited to cases where there is direct evidence of fraud, malice or gross negligence. They may be allowed when there is evidence of such recklessness and wanton disregard of another's rights that malice and evil intent will be inferred. If a defendant is grossly and wantonly reckless in exposing others to dangers, the law holds him to have intended the natural consequences of his acts, and treats him as guilty of a willful wrong." The jury returned a verdict in favor of Mr. Silkwood, finding

actual damages of \$505,000 and punitive damages of \$10 million. The trial court entered judgement against Kerr-McGee in that amount. ALL THESE OUTCOMES WERE MAINLY DUE TO RECKLESS VIOLATION OF ALARA PRINCIPLE.

B. As Low As Reasonably Achievable (ALARA) philosophy was not developed only for the workers with radiation or radioisotopes. The entire society has been kept in mind. So, the general public was included in every consideration related to ALARA. Of course, the patients are the primary members of the general public in Clinical Nuclear Medicine. However, the public and patients can not control the use of radioactive materials. The radioactive materials are used on them by the approved users (Nuclear Medicine Physician, Physicists, Technologists, Nurses etc). So, the burden of following the ALARA principle falls on the workers; and not on unsuspecting public or the patients.

With my 37 years of clean Radiation Safety practice and service to our veterans, I am now concerned with the current and continuous Radiation Safety violations at the STVHCS by its supervisors and the leaders. On 5-22-12, during my meeting with Mr. Gary E. Williams and you, I have submitted to you a copy of my four (4) written allegations for which you are now investigating. To enumerate, these are: 1) spillage and improper cleaning procedure with excessive radiation to the technologists, 2) several incidents of misadministration of radiopharmaceuticals and the attempted cover up by not informing the Radiation Safety Office (RSO) or Medical Radioisotope and Radiation Control Committee (MRRCC); 3) without the approval of the RSO and/or MRRCC, implementation of new procedures like lung ventilation study with RADIO-AEROSOL or altered diagnostic procedures that give no valuable clinical information but radiation; and 4) in spite of repeated expression of concerns and warnings, the supervisors continued to recklessly violate ALARA principles and thereby the VACO, NHPP, NRC and other regulatory bodies' rules, regulations and the laws of the land.

I am sure, during your visit of last week, from several documents and personal interviews you have confirmed some of the validities of these concerns. At your request, now I am sending some more as following:

1. I was appalled that I was denied access to the NRC inspector during the recent inspection, despite my request while the inspector was still on site. It is my understanding that this violates the requirement of 10 CFR 19. The inspectors probably did not know that the STVHCS was acting wrongfully behind their back.

[Proof: Copies of my e-mail communication with the agency requesting for a meeting with the inspectors that went without any response.]

2. During the cleaning procedure on September, 2011, all three (3) cardinal rules of radiation protection were violated: Time: the technologists could have finished the initial containment of radioactivity in 10 to 20 minutes. They were forced to spent five (5) hours. Distance: They were compelled against their will to kneel down on the floor to rub & scrub the floor for hours to clean the floor. I witnessed and requested the

Chief Technologist to stop it. He ignored by saying, "I have my Chief's (Dr. Duffy) order; let me do my job". Shielding: There was no special shielding.

[Proof: You have seen several documents including the report from the RSO. The testimonies of the affected employees should have confirmed my allegation also.]

3. There had been no written procedure book recently generated locally by the Nuclear Medicine department. The VACO directive clearly says that, copies of a book or other published document will not be considered as a written local document. In fact, the written last document was a thick white cover paged book signed by me (Dr. Chaudhuri as Chief of Nuclear Medicine Service) and the RSO (Dr. Wiatrowski), about two years back, when every procedure written new and/or reviewed were signed separately with dates. The ventilation study with radio-aerosol was not one of them. In fact, aerosol study had never been performed before, in STVHCS Nuclear Medicine department.

[Proof: A copy of VACO directive will show the requirement of locally developed "Procedure Manual". No recent locally developed Nuclear Medicine Procedure Manual approved by the RSO or MRRCC is available. Testimony from technologists and myself should have confirmed this allegation.]

4. The very first statement of the ALARA program of the STVHCS states: "The management of the South Texas Veterans Health Care System are committed to ensuring that: a. The radiation exposure of employees, patients, visitors and members of the public is as low as reasonably achievable (ALARA)." The NRC, and consequently the NHPP, have specific regulatory requirement for patient radiation safety. 10 CFR 35 contain prescriptive requirements for notification and investigation of a patient's radiation exposure when it was not consistent with the intent of the procedure or practitioner. The medical event reporting requirement concerns itself with patient radiation safety and not worker safety. An additional requirement in 10 CFR 35 requires a licensee to have written procedures to insure that the radiation dose received by a patient is consistent with the intent of the procedure or practitioner. In the alleged unapproved AEROSOL ventilation study, when a patient's skin became contaminated with radioactivity during a procedure in which there was no intent to contaminate the skin, there should have been a thorough investigation to include the assessment of dose to the patient's skin from the contamination.

[Proof: No investigation or assessment of skin dose was ever conducted so the extent of the unintended patient dose to the skin of veterans undergoing these faulty procedures remains unknown. There are multiple numbers of scan documents with aerosol ventilation studies showing extensive skin contaminations.]

5. It is my understanding that the personnel dosimetry records, presumably reviewed during the inspection, demonstrated doses in excess of 1500 mrem to the two Nuclear Medicine Technologists involved in the prolonged spill cleanup. Certainly, I would have expected even an inexperienced inspector to have questioned those exposures, unless the agency had tried to cover up the incident.

[Proof: Those exposures, if they were recorded, should have triggered an inquiry into the circumstances that caused the large doses. I would certainly hope that NHPP would determine whether the high doses were identified by the inspector and whether any investigation of high employee doses was conducted during the NRC inspection.]

6. I respectfully disagree with Mr. Williams' assertion that the ALARA concept is only for the employees or workers with radiation and radioactive material and not for the patients. ALARA concept applies to patients as well as workers and members of the public. Considerable effort has been expended to insure that dose to a patient is ALARA consistent with the intent of the imaging procedure.

[Proof: As I am sure you are aware that the American College of Radiology continues to expend considerable effort to educate the public and physicians of the importance of keeping patient dose ALARA during all medical procedures. Every institution's ALARA program includes patients as its benefactors; STVHCS is not an exception as it has been stated in their publication of January, 2012.]

7. Multiple misadministration without reporting to the RSO or MRRCC.

[Proof: I have testified to you that I have been informed by the technologists and the RSO about these events. You have probably heard from these directly involved people during your interviews with them. Patient's chart record will also confirm these events.]

As promised, I am sending this document directly to you by e-mail with copies to the individuals mentioned herein. Please do not hesitate to call me and e-mail me, if you have any further questions or instructions.

Thank you for giving me the opportunity to interact with you for the benefits of our veterans, coworkers and the society.

Tuhin K. Chaudhuri, MD, FACNP, FACNM  
Professor of Radiology  
University of Texas Health Science Center  
San Antonio, TX  
Formerly: Chief of Nuclear Medicine  
South Texas Veterans Health Care System  
San Antonio, TX

Contact Information:

Mailing address: 6514 Pemview  
San Antonio, TX 78240

E-mail: [tuhin\\_chaudhuri@yahoo.com](mailto:tuhin_chaudhuri@yahoo.com)

Cell phone: 210 - 867-6264

CC: Mr. Gary E. Williams, Director, NHPP  
The Employment Law Group (TELG)

6-3-12

Thomas E. Huston, Ph.D.  
Program Manager - VHA  
National Health Physics Program  
115HP/NLR  
2200 Fort Roots Drive  
North Little Rock, AR 72114

[The Facts of Unauthorized Use of Radio-Aerosol for Clinical Studies in STVHCS Nuclear Medicine Department and Violation of Radiation Safety & ALARA Principle]

Dear Dr. Huston,

Recently, I have faxed you 13 pages of documents as some added supporting evidence for your investigation. Due to an urgent piece of business, at that time, I requested you to allow me a couple of days to send you the captions for those pages. Beside this letter, I have added another page as P-14.

In or around May 2011, without meeting any required official approval, suddenly the clinical use of 99m-Tc-DTPA Aerosol was started within the STVHCS Nuclear Medicine department. I thought, the Chief of the Nuclear Medicine Section, Dr. Dan Duffy or Chief of the Imaging Service, Dr Calvin Leuschen had obtained the proper authorization before implementing the study for the first time within our department.

After seeing the procedure being done unscientifically and hearing complaints from the technologists that they were not trained on the procedure and there was no locally written approved procedure guidelines, I became very concerned. All of us noticed that there were considerable amount of leakage from the system and contamination with radioactivity all over the place. I also noticed signs of unusual amount of skin contamination in the scanned images.

We then confirmed from the Radiation Safety Office (RSO) that the procedure had not been approved by the RSO. The technologists and I protested to our respective supervisors repeatedly and asked to stop the procedure until every thing is done correctly and we go back to the procedure with Radio-Xenon, since this had been an approved procedure without any problem for a long time. Drs. Duffy and Leuschen continued to ignore us.

I sent several e-mails to the supervisors (see page 1 thru 3) without any result. Since, I would not prescribe any Radio-Aerosol, Dr. Duffy would adamantly prescribe it himself on every case, but as Chief of the Section he would order me to read the scans and report it in the CPRS. Since, these were uninterpretable, I would annotate so in the CPRS and report on the perfusion study only.

In the mean time several spillage and contaminations would continue. Besides the one in September, 2011, I remembered another major one on January 4, 2012 (see p - 4). Regarding the major contamination in September, we know attempts to downplay it or even to cover it up by the agency was evident. I was the only clinician who observed most of the event thoroughly. Yet, I was carefully excluded from all meetings and/or discussions about the event (see page-5). Following the event, a very credible draft report and recommendation were made by the Radiation Safety Office. There was a "Proposed Plan of Action and Milestone" (see page 6 thru 9). What happened to that report? This report gives lots of clue.

I waited months with false hope that the agency (STVHCS) would stop its continuing radiation safety violation and would take measures to save us (employees and patients) from unnecessary radiation, before finally I reported to the Office of Special Council. At your request, I am providing there report to you (see p 10-11). Please remember this is still confidential.

It is to be noted that the STVHCS continued to violate the regulation and probably the law, when they denied my access to the NRC inspector during her recent visit in mid-May, 2012 (see page 12 -13). The inspector was probably kept unaware of this.

Finally, regarding new use of any radiopharmaceutical or any device within the Nuclear Medicine department, there has been a clear Directive/Recommendation from the VA Central Office (see page 14, now included). I will be waiting to see from your report how much of this circular has also been violated.

During the first day of our meeting here in San Antonio, Mr. Williams has promised to send me a copy of your report upon completion of your investigation. Please send it to my following address.

Thank you.

Sincerely,

Tuhin K. Chaudhuri, MD, FACNP, FACNM

6514 Pemview  
San Antonio, TX 78240

Tel: (210) 867-6264  
Fax: tuhin.chaudhuri@yahoo.com

cc: Mr. Gary E. Williams  
The Employment Law Group

Oct 10, 2012

From

[rubin.chaudhuri](#)

To

[Milton \(SES EOY\) Gross](#)

BCC

[Bapi](#)

Dr. Gross,

My multiple e-mails and telephone calls to Dr. Flynn were non-productive. I have confirmed that she had received my e-mails and messages. But, she did not respond. I did not wish to be insulted any further. You may find many radiation safety violations data arisen from unapproved Radio-Aerosol studies from the computer in your office.

The NHPP has found at least one violation of mis-administration or wrong administration of radioactive drug to patient at the STVHCS. They have also detected the wrong practice of cleaning radioactive material spillage. At your request, I am now providing you with the data in support of my complaints on two other issues:

**(1). STVHCS Nuclear Medicine department did not have any legitimate protocol or approval for Radioactive Aerosol Lung Ventilation Study before or during the time span of May 2011 to January 12, 2012 :**

You told me that during their inspection, the NHPP inspectors were shown a procedure manual. I challenge this! I have heard from the technologists also that the current supervisors took an SNM published blue book from my office library (every book in my selves had my name on it) to present to the inspectors as our protocol list. This was not our protocol book. Before Dr. Leuschen took over the Nuclear Medicine department in 2010 and then Dr. Duffy in 2011, every protocol used to be reviewed and signed by me and the RSO and these were used to be kept in a thick bound white notebook. These white note books disappeared in 2010 - 2011. With repeated requests from the technologists, these were never replaced. In the mean time all procedures were being short changed by the Chief Physician (first Dr.

Leuschen, then Dr. Duffy) and the Chief Technologist (Shea Kim) by trial and error and deviations were being made on a daily basis in the injection room and/or on the imaging table. Of course, all other physicians and technologists were upset. As a protest, four technologists left the department. Dr. Latoni and I continued to protest. With the military mentality within the department, by now you know that we have met our fate. So was the fate of our Ex-Chief Techs and the Administrative Assistant.

Even if one perpetrates to follow the SNM guidelines (without local approval), how would the sequence of perfusion and ventilation studies be changing on a daily basis? How could the dose of the radiopharmaceuticals be varying by 500%? Why the intake from the nebulizer to lungs was so low? As an equipment, was the used defective nebulizer approved by the bio-medical engineering or the RSO? Why between May and December of 2011, almost all Aerosol studies were uninterpretable? Why as the clinicians of the day, I was getting so many legitimate complaints from the technologists and in some cases the patients? What I hear now is "cover ups" that are bordering to fraud. Showing wrong documents to the inspectors to hide the violations! As it has been known in the past, "cover ups are sometimes more serious than the violation itself". These are not new. Record shows two consecutive Radiation Safety Violations in 2008 and 2009 in their previous work place, resulting in warnings and fine by the NRC (Ref: NRC Special Inspection Report 030-28641/08-003 and Notice of Violation by United States N.R.C.; May 18, 2009).

Besides the alleged violators, you need to interview those people who had been directly involved with Nuclear Medicine at the STVHCS. They are Mr. Jose Arellano, Ms. Martha Valdez, Ms. Monique Cardenas - (current technologists) and Mr. Joe Jimenez, Ms. Nelly Melendez, Ms. Leo Huynh, Mr. Pete Medina - (past technologists), Ms. Nancy Burton (administrative assistant) and Dr. Dimitri Latoni and me (physicians).

In this connection, let me point out from your own "Directive", which came to my hand in 2011 through Dr. Duffy. It says: "Protocol must be written for each procedure performed by the laboratory, even if infrequent or newly implemented. Protocol must be updated, as needed to conform to current practice standard". It also says, "Protocols must be specific for the particular laboratory and equipment inventory. Copied "text book" and/or generic protocols **are not acceptable**".

**(2). No Radiation Safety Training Regarding the Use of the Nebulizer and the Aerosol Ventilation Study Procedure During the Entire 2011, when most of the violations occurred:**

Regarding the safety training , I can categorically state that no such training did take place within the department in 2011. This was one of the major complaints from the technologists. All and any of the above technologists, doctors and the administrative assistant can be interviewed on this subject. Who can be the more qualified person to testify than the supposedly trained trainees? I have no clue as to what could have been produced to the NHPP inspectors by the administrators to cover up this **inaction** also. If there was any, I would like to challenge the authenticity of that document. In fact, after a long two and half years of delay, following the pressure from the NHPP, on June 22, 2012, the first such training was offered within the department. (Please see below the attached e-mails to and from the Associate Director regarding the training).

**A BIG QUESTION: Where and how did the original report of the RSO disappear and how was it replaced by a new report? A copy of that original report carries the real truth and it will be sent to you soon.**

Finally, even if these deficiencies might have been corrected lately after about one to two and half years of continuous violations, who would be responsible for these violations for which employees and patients both

have suffered and are continuing to suffer. The violators must face disciplinary action and no less.

With regards!

T. K. Chaudhuri, MD. FACNM

----- Forwarded Message -----

**From:** tuhin chaudhuri <[tuhin\\_chaudhuri@yahoo.com](mailto:tuhin_chaudhuri@yahoo.com)>  
**To:** "Gross, Milton (SES EQV)" <[Milton\\_Gross2@va.gov](mailto:Milton_Gross2@va.gov)>  
**Sent:** Friday, September 28, 2012 10:46 AM  
**Subject:** Re: Case list

Thank you. I will contact Dr. Flynn soon.

Tuhin

**From:** "Gross, Milton (SES EQV)" <[Milton\\_Gross2@va.gov](mailto:Milton_Gross2@va.gov)>  
**To:** tuhin chaudhuri <[tuhin\\_chaudhuri@yahoo.com](mailto:tuhin_chaudhuri@yahoo.com)>  
**Cc:** "Flynn, Julianne" <[Julianne\\_Flynn@va.gov](mailto:Julianne_Flynn@va.gov)>  
**Sent:** Thursday, September 27, 2012 12:40 PM  
**Subject:** Case list

Tuhin,

I have spoken to Dr. Flynn, COS at the San Antonio VA about your need to access your office to provide us with a list of the patients who had lung ventilation scans that you mention in your letter to the SECVA. The facility will provide you access to your files for this purpose. Please contact Dr. Flynn at 210-617-5300 ext 15176 to make the necessary arrangements.

If there is anything that I can do to assist you please do not hesitate to contact me.

Re: Radiation Safety Mandatory Training

Hide Details

From

tuhin.chaudhuri

To

Vlosich, Kristopher W.

BCC

Bapi

Mr. Vlosich,

As you can see, the e-mail below has been sent to me at least 8 days late. As their long time physician, I have been contacted by many veterans regarding the radiation safety issue and credibilities of the current Nuclear Medicine Physicians at the STVHCS.

As a concerned citizen for our veterans, I would have liked very much to observe the training.

Please let me know next time. Thank you.

Regards,

Tuhin K. Chaudhuri, MD, FACNP, FACNM

**From:** "Vlosich, Kristopher W." <[Kristopher.Vlosich@va.gov](mailto:Kristopher.Vlosich@va.gov)>

**To:** [Tuhin.chaudhuri@vahco.com](mailto:Tuhin.chaudhuri@vahco.com)

**Sent:** Tuesday, June 26, 2012 10:02 AM

**Subject:** FW: Radiation Safety Mandatory Training

**When:** Friday, June 22, 2012 12:30 PM-3:30 PM (GMT-06:00) Central Time (US & Canada).

**Where:** Nuclear Medicine

**Note:** The GMT offset above does not reflect daylight saving time adjustments.

\*~\*~\*~\*~\*~\*~\*~\*~\*~\*

-----Original Appointment-----

**From:** Wittenbach, Eric S. **On Behalf Of** Vlosich, Kristopher W.

**Sent:** Monday, June 18, 2012 9:52 AM

**To:** Vlosich, Kristopher W.; Torres, Norine A; Arellano, Jose (STX); Weathers, Michelle F; Valdes, Martha P; Ramon, Sylvia M.; Cardenas, Monique C.; Padgett, Cheryl; Duffy, Daniel; Wittenbach, Eric S.; Lambert, Agapito; Flynn, Julianne; Leuschen, Calvin T.; Kim, Chea; Garces, Elizabeth

**Subject:** FW: Radiation Safety Mandatory Training

**When:** Friday, June 22, 2012 12:30 PM-3:30 PM (GMT-06:00) Central Time (US & Canada).

**Where:** Nuclear Medicine

-----Original Appointment-----

**From:** Vlosich, Kristopher W.

**Sent:** Monday, June 18, 2012 9:27 AM

**To:** Vlosich, Kristopher W.; Weathers, Michelle F; Ramon, Sylvia M.; Padgett, Cheryl; Duffy, Daniel; Wittenbach, Eric S.; Lambert, Agapito; Flynn, Julianne; Leuschen, Calvin T.; Kim, Chea; Garces, Elizabeth

**Subject:** Radiation Safety Mandatory Training

**When:** Friday, June 22, 2012 12:30 PM-3:30 PM (GMT-06:00) Central Time (US & Canada).

**Where:** Nuclear Medicine

Attendance is mandatory for Nuclear Medicine and Radiation Safety.  
Others on the invite, this informational if you would like to attend.

NOTE: The training date is June 22, 2012. There was no such training before this date on radio-aerosol. Safety violations we are talking about were in 2011 and early 2012.