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Ref: OSC File No. DI-12-0927

Dear Ms. Pennington,

Pursuant to 5 U.S.C. #1213(e) (1), I would like to submit my comments on the responses of the Agency to the additional eight (8) questions raised by the O.S.C.

First, let me express my sincere appreciation to the O.S.C. for exploring the real problems with the V.A. Medical Center in San Antonio, also known as South Texas Veterans Health Care System (STVHCS). After review of their initial response, you have raised the eight very critical and legitimate questions that go to the heart of the radiation safety issue at the STVHCS.

If the agency's current responses to these eight questions were honest and factually correct, these responses would have clearly expose and identify some of the supervisors at the facility to be willfully negligent in violating the rules, regulations and laws of the land and our human society. These violations have endangered our unsuspecting veterans and dedicated technologists' health with unnecessary radiation exposure and potential health hazards. These violations require immediate remedies and disciplinary actions against those individuals who are responsible for these violations and the attempted cover ups.

Unfortunately, like the first set of responses, the current responses to the eight questions are factually inaccurate and the respondents have either avoided to respond to some questions or decided to stay away from the truth in an attempt to cover up the violations.

Please allow me to submit the attached/enclosed documents in support of my comments.

Please feel free to call me or e-mail me if you have any questions regarding this communication.

Sincerely,


Tuhin K. Chaudhuri, MD, FACNP, FACNM

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Attachments :

COMMENTS ON THE RESPONSES OF THE AGENCY TO OSC's QUESTIONS

Foreword:

"The Commission has determined that as a matter of policy, the patient as well as the general public are all member of the public to be protected by NRC (44 FR 8242 et 8244)".

Comments were made by the public:

"If the patient exposure is unnecessary and harm is done, then the physicians may be guilty of malpractice (monetary awards, civil penalties, possible loss of medical license etc.). NRC regulations won't prevent malpractice and NRC penalties are the least of the guilty physician's worries. If the patient exposure is unnecessary but no harm is done, then the physician may be still guilty of fraud (billing for unnecessary procedures). But if no harm is done, what is the purpose of NRC regulation?" (Ref: Title 10, Ch 1, CFR - ENERGY).

A clear response was made by the NRC:

"The purpose of NRC regulation of medical use of byproduct material is to reduce unnecessary radiation exposure patients, workers, and the public. Protection of patient radiation safety is an overall goal in regulating the medical use of byproduct material. Although the commission recognizes that physicians have primary responsibility for the protection of their patients, NRC also has a necessary role with respect to the radiation safety of the patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of the patients. Moreover, there is nothing in the commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material." (Ref: Title 10, Ch 1, CFR - ENERGY).

Comments:

Comments to Agency's Response to Question #1 (Asking for copies of the NHPP investigation and Inspection Report):

The NHPP has attached a copy now. I have seen this report before. Immediately protested to the NHPP and to the Nuclear Medicine Service Director at the VACO. The O.S.C. has copies of these documents on file. I have pointed out several omissions of truth and inclusions of statements that were not factually correct. Of these the most noticeable omissions were the testimonies of Dr. Chaudhuri and Mr. Jimenez. At the request of the NHPP investigators, Chaudhuri and Jimenez arrived at their (Mr. Gary William and Dr. Thomas Huston) hotel lobby in San Antonio on the eve of their investigative visit to the STVHCS. Dr. Chaudhuri and Mr. Jimenez were interviewed separately for more than an hour each. However, none of their testimonies critical of the STVHCS supervisors have been included in the report. Important portion of the following day's testimonies and follow up telephone calls to NHPP informing the concerns of at least three experienced technologists have not been included in the report either. (Note: After the technologists saw the NHPP investigative report that was circulated to them by the Agency, they voluntarily contacted me to express their dissatisfaction with the

report. Some of them then contacted the NHPP to express so). Their common complaints had been the NHPP's attempts to white wash the allegation of "not having a procedure manual", "lack of radiation safety training for a long period of time (April, 2010 through June, 2012)" and "unauthorized use of Aerosol without any approval and training". Detailed concerns and complaints about this report are on file with the NHPP and OSC.

Comments to Agency's Response to Question #2 (Approval of the RSC or RSO for new or modified procedures or equipment. What is meant by 'best health physics practice?'):

The agency's response is, "The Nuclear Medicine Service is not specifically required by policy or regulation to have approval by either the RSC or RSO to initiate use of a clinical imaging protocol....".

This statement by the agency (supported by the NHPP) is totally inaccurate. Any new procedure should get approval from the RSC/RSO before it can be started.

Please see the following two pages of "NRC Guidelines" from www.thewritingrad.com.

Page 4. [TheWritingRad.com](http://www.thewritingrad.com) Page 4 NRC Guidelines

Delegation of authority (The judicious delegation of Radiation Safety Committee authority is essential to the enforcement of an ALARA program): The Radiation Safety Committee will delegate authority to the RSO for enforcement of the ALARA concept. The Radiation Safety Committee will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's semi-annual meeting.

Review of ALARA program: The Radiation Safety Committee will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept. The Radiation Safety Committee will perform a semi-annual review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

The Radiation Safety Committee will evaluate the institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

Radiation Safety Officer (RSO) duties:

1. Annual and semi-annual review:

A. Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific procedures may be conducted on a more frequent basis.

B. Semi-annual review of occupational exposures. The RSO will review at least every six months external radiation exposures of authorized users and workers to determine that the exposures are ALARA.

C. Semi-annual review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous six months.

2. Education responsibilities for ALARA program:

A. The RSO will schedule briefings and educational sessions as needed to inform workers of ALARA program efforts.

B. The RSO will ensure that authorized users, works, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that the management, the Radiation Safety Committee, and the RSO are committed to implementing the ALARA concept.

3. Cooperative efforts for development of ALARA procedures:

A. Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

B. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

C. The RSO will establish procedures for receiving and evaluation the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

4. Reviewing instances of deviation from good ALARA practices:

A. The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

Authorized users:

1. **New procedures involving potential radiation exposures:**

A. **The authorized user will consult with, and receive the approval of, the RSO during the planning stage before using radioactive material for a new procedure.**

B. **The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures**

will be keep ALARA. This may be enhanced through the application of trial runs.

2. Responsibilities of authorized user to persons under his/her supervision:

A. The authorized user will explain the ALARA concept to his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

B. The authorized user will ensure that persons under his/her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintained exposure ALARA.

Persons who receive occupational radiation exposure:

1. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

2. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

Establishment of investigational levels in order to monitor individual occupational external radiation exposures:

1. This institution hereby establishes Investigational Levels for occupational external radiation exposure who, when exceeded, will initiate review or investigation by the RSO.

Comments to Agency's Response to Question #3 (Operative Nuclear Medicine Service procedural manual in use in June 2011 with its publication date):

The agency responded, "NHPP observed during the on-site inspection of May 23-24, 2012, a procedure entitled 'Lung Aerosol Study (Tc-99m-DTPA Aerosol),' and dated January 25, 2003, was in the Nuclear Medicine Service procedure binder. Furthermore, NHPP observed that a cover page in the procedure binder was signed by Dr. Chaudhuri on November 24, 2004, and by Dr. Duffy on June 2, 2011. NHPP does not have an ablative method to confirm what, if any, specific procedures or protocols were in the procedure binder during June 2011."

Very interesting! There are several things to note here. (A) At the STVHCS, there had been no Aerosol study ever done before, until Dr. Duffy suddenly started this in April of 2011. (B) So, for the STVHCS, there should not be any need for a protocol of 'Lung Aerosol Study' in 2003. (C) Every individual procedure used to be reviewed and renewed by retyping any addition or alteration every two years or just before its implementation for the first time. (D) Every single approved procedure was dated and signed by the RSO and the Service Chief. (E) The cover page of the procedure manual in a white binder (not blue) used to be signed by at least four people, Chief Technologist, Radiopharmacist, Chief Technologist and the Service Chief (a copy of the cover page of the last published procedure manual of 2009 at the STVHCS nuclear medicine department is attached - **Attachment - 1**). (F) The blue binder was a referenced educational material from 2003, signed and kept in Dr. Chaudhuri's personal office library and nobody else was supposed to sign on it. (G) By no means this should be called an "Operative Nuclear Medicine Service Procedure Manual" (please see the attached communication from the VACO Nuclear Medicine Director, Dr. Milton Gross - **Attachment -2**).

So, it is clear that there had been no "Operative Procedure Manual in use in June 2011, including 'lung Aerosol Study'. But, an attempt was made to cover up this deficiency and to replace with a faked one. Unfortunately, knowingly or unknowingly, the NHPP had participated in this attempted cover up.

Comments to Agency's Response to Question #4 (Was there adequate training requirement for Nuclear Medicine Service staff under NRC regulations or VA directives, policies or procedures for the procedures and equipment used with radiopharmaceuticals?)

This 'cover up' really gets interesting here. According to the initial report, the RSO concluded that the initial training provided to the technologists on the Tc-99m DTPA aerosol procedure was not adequate and sufficient for radiation safety purposes. The report concludes that the

change to the procedure did not effectively involve training and orientation for all applicable staff. The report concludes, however, that a regulatory violation or significant deviation from best health physics practices or VA policy was not identified.

Under pressure from the question from the OSC, the current response by the NHPP notes, "NRC regulations in 10 CFR 19.12 and 10 CFR 35.27 have requirements for providing training and instructions to workers on items important to radiation safety and for requiring supervised individuals to follow the instructions of the authorized user. For medical use of radioactive materials, nuclear medicine technologists are considered supervised individuals working under the direction of the physician authorized user, and the physician authorized user may provide instructions, in both written and verbal form, to the supervised technologists for clinical use of the radioactive materials. These NRC regulations do require Nuclear Medicine Service staff to have adequate and sufficient training. The issue for these circumstances is whether the lack of effective training was a basis to cite a regulatory violation."

There are definitely many identifiable radiation safety violations within the STVHCS. The responsible employees causing these violations are not the staff technologists. The violators are the supervisors, Chief of the Service and the Chief Technologist. Their lack of knowledge on the aerosol study and complete disregard to the radiation safety issues have caused unnecessary radiation exposure to our veterans and employees. The NHPP's lack of interest to go against any physician violators is baseless, as cited in the following paragraph obtained from the enclosure provided by the NHPP to the the OSC. The following were noted by the NRC:

"Comments were made by the public: If the patient exposure is unnecessary and harm is done, then the physicians may be guilty of malpractice (monetary awards, civil penalties, possible loss of medical license etc.). NRC regulations won't prevent malpractice and NRC penalties are the least of the guilty physician's worries. If the patient exposure is unnecessary but no harm is done, then the physician may be still guilty of fraud (billing for unnecessary procedures). But if no harm is done, what is the purpose of NRC regulation?" (Ref: Title 10, Ch 1, CFR - ENERGY).

"A clear response was made by the NRC: The purpose of NRC regulation of medical use of byproduct material is to reduce unnecessary radiation exposure patients, workers, and the public. Protection of patient radiation safety is an overall goal in regulating the medical use of byproduct material. Although the commission recognizes that physicians have primary responsibility for the protection of their patients, NRC also has a necessary role with respect to the radiation safety of the patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of the patients. Moreover, there is nothing in the commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material."
(Ref: Title 10, Ch 1, CFR - ENERGY).

Comments to Agency's Response to Question #5: (Information regarding the training provided, including the date(s), attendees, and individual(s) who conducted the training as well as information regarding any subsequent training provided on this procedure).

In their initial report, the agency denied having any record kept for the claimed training. Now, through NHPP, they are claiming to have provided verbal training that was reflected in their allegedly sent e-mails of June 9, June 29, July 7 and September 23 of 2011. In NHPP's word, this time again the report was "based on discussions between NHPP and Mr. Kim (Chief Nuclear Medicine Technologist). Mr. Kim noted to NHPP that he provided verbal training, including a "dry run" involving use of the device, to all nuclear medicine technologists on June 9, 2011". NHPP further noted this time again, "While a specific training roster was not generated for this training session, Mr. Kim's recollection was that all nuclear medicine technologists employed at that time were present for the "dry run" training session, which included Jose Arellano, Joe Jimenez, Norine Torres, Monique Cardenas, Nelly Melendez and Martha Valdes." Jose, Joe, Monique, Nelly and Martha denied such training to date. Readers may remember that at least three of these technologists complained on May 23-24, 2012 to the NHPP inspectors during their inspection, of not having any training at least up to that point in time. It should also be noted that during 2011, in nuclear medicine clinic, I had been put on duty as the main physician and Medical Officer on Duty (MOD) and compelled to serve 10-12 hr a day without any extra compensation. I had been continuously asking to stop the aerosol procedure and demanding training for the employees and approval of such procedure by the RSO; but in vain.

Regarding those alleged e-mails regarding training in four different dates, I have a copy of the one from July 7, 2011 only. This was a one liner with a package insert from a company regarding their aerosol kit. This can be reconsidered as a reading material. But, no way can it be considered as a training course or training session. It would have been great if the agency had followed the company's package inserted dose guidelines. Unfortunately, they did not. Dr. Duffy and Mr. Kim implemented their own dose guidelines, which was entirely opposite of the company's guideline.

To compare, the company was suggesting Aerosol first, with a dose of 20-30 mCi in the nebulizer, thereby delivering approximately less than one (1) mCi inside the lungs for ventilation study. Then, in the second study, flood the lungs with at least 5 mCi of MAA for the perfusion study thereby over powering the existing radioactivity in the lungs from the first study (ventilation study). This would have been a good procedure.

Unfortunately, Dr. Duffy and Mr. Kim were using 5 mCi of MAA first for perfusion study, then less than one (1) mCi of aerosol for ventilation study. This results in an appropriate perfusion study, but no image for interpretable ventilation study. I had 9 such cases on a table showing numerical data (please see **Attachment - 3**) from each PHI data redacted patients, who had been unfortunately exposed to extra radiation but without any clinical benefit - clearly a violation of ALARA principle. According to Dr. Gross's report, there had been at least 30 such unfortunate veterans within STVHCS receiving unnecessary radiation without their knowledge. In each instance, the supervisors had been the offenders and not the other technologists or other physicians in the clinic.

Comments to Agency's Response to Question #6 (Request for a copy of the STVHCS root cause analysis team's report and clarification concerning why the RSO's report was not accepted by the RSC):

Agency's response (or excuse) was, "VA is not authorized to provide the root cause analysis report as it is a protected 5705 quality assurance document".

It has been a known common practice of this agency to take protection under 5705 whenever they are in trouble for their mischievous acts. I believe, in the face of proven negligence and malpractice with the violations of rules, regulations and laws causing unnecessary radiation exposure to our veterans and to the government employees, it should be appropriate for the investigative body like OSC, OIG or FBI to ask for any PHI or other Personal Information (PI) data redacted document from the suspected supervisors of the agency.

In my mind, the response to the second portion of the question: it can be simply termed as "avoidance due to the lack of any reasonable answer".

Comments to Agency's Response to Question #7 (Clarification regarding VA's policy concerning the application of ALARA requirements with respect to VA patients):

The agency through their mouthpiece of NHPP responded, "The ALARA concept, as a regulatory perspective, is applicable to radiation workers and members of the public **but not to patients**. NRC medical policy statements are provided as a separate enclosure to this response to OSC."

Amazing! Let us examine the same NRC statements enclosure provided by the NHPP:

In the 3rd page (PS-MU-3) of the document the NRC (Commission) clearly states, "The Commission has determined that as a matter of policy, the patient as well as the general public are all member of the public to be protected by NRC (44 FR 8242 et 8244)".

Further on the same page the NRC cites the public comments which says:

"If the patient exposure is unnecessary and harm is done, then the physicians may be guilty of malpractice (monetary awards, civil penalties, possible loss of medical license etc.). NRC regulations won't prevent malpractice and NRC penalties are the least of the guilty physician's worries. If the patient exposure is unnecessary but no harm is done, then the physician may be still guilty of fraud (billing for unnecessary procedures). But if no harm is done, what is the purpose of NRC regulation?" (Ref: Title 10, Ch 1, CFR - ENERGY).

The NRC responds clearly again (PS-MU-3):

"The purpose of NRC regulation of medical use of byproduct material is to reduce unnecessary radiation exposure patients, workers, and the public. Protection of patient radiation safety is an overall goal in regulating the medical use of byproduct material. Although the commission recognizes that physicians have primary responsibility for the protection of their patients, NRC also has a necessary role with respect to the radiation safety of the patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of the patients. Moreover, there is nothing in the commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material." (Ref: Title 10, Ch 1, CFR - ENERGY).

Finally, the document ends with the notation on the last page (PS-MU-7):

".....radiation protection programs that, when fully implemented, maintain radiation exposures to workers, **patients**, and the public to levels that are **as low as reasonably achievable**."

Comments to Agency's Response to Question #8 (Any corrective actions taken by STVHCS in response to the recommendations by NHPP, as well as information regarding the current use of the Tc-99m DTPA aerosol procedure at STVHCS):

I can not comment on the response to question #8 by the NHPP who responded on behalf of the agency, other than what the unhappy and fearful employees tell me voluntarily. Two employees called me to tell that two weeks back in early June, 2013, the NHPP investigator (Dr. Huston) came to the facility and interacted mainly with the supervisors. Seeing him around, these employees wanted to talk to him regarding some matters of concern. Dr. Huston's response was that the STVHCS authorities did not schedule him (Dr. Huston) to meet with them (the technologists).

Attach-1

SOUTH TEXAS VETERANS HEALTH CARE SYSTEM

NUCLEAR MEDICINE SERVICE

POLICIES AND PROCEDURES

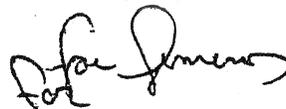
2009

Reviewed and Recommend Approval:



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Supervisory, Nuc Med Technologist

Reviewed and Recommend Approval:



JOHN STRAW, MS, BCNP
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Reviewed and Recommend Approval:



WAYNE A. WIATROWSKI, PhD
Radiation Safety Officer

Reviewed and ~~Recommend~~ Approval.



TUHIN K. CHAUDHURI, M.D.
Chief, Nuclear Medicine Service

Attach - 2

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.

(14)

Decay corrected Count-Rate from the Posterior Lung Field of Nine (9) randomly available patients' Perfusion / Ventilation Studies : Perfusion study 1st with 2 to 5 mCi of Tc-99m-MAA, followed by, Ventilation study 2nd with 20 to 30 mCi starting dose of Tc-99m-DTPA-Aerosol in the Nebulizer, ending with Lung concentration of less than 1 mCi in most cases. Activities from the Trachea, Bronchi and Stomach were excluded from the flagged Region of Interest (ROI).

Patient	Count Rate cpmX1000 1st Study (A) Perfusion	Count Rate cpmX1000 1st+2nd Study (B)	Count Rate cpmX1000 2nd Study (B-A=C) Ventilation	Desired Count Rate For Ventilation (3XA)	Is Ventilation Study Clinically Useful?
A	180	220	40	540	No
B	137	293	156	411	No
C	84	120	36	252	No
D	360	403	43	1080	No
E	309	326	17	927	No
F	362	393	31	1086	No
G	240	327	87	720	No
H	479	505	26	1437	No
I	420	549	129	1260	No

There have been 2 sets of images A and B supposedly Perfusion and Ventilation. But C was so negligible, that the readers were reading Perfusion and Perfusion. So, most pair resulted in erroneously observed "matched scan". Every patient received unnecessary radiation from radio-aerosol and some of them probably received wrong diagnoses.