



**DEPARTMENT OF VETERANS AFFAIRS**  
**Veterans Health Administration**  
**National Health Physics Program**  
**2200 Fort Roots Drive**  
**North Little Rock, AR 72114**

In Reply Refer To: 598/115HP/NLR

March 25, 2013

The Honorable (b) (6)  
Special Counsel  
U.S. Office of Special Counsel (OSC)  
1730 M Street, NW, Suite 300  
Washington, DC 20036-4505

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

Dear Ms. Lerner:

I am responding to the additional questions sent to Department of Veterans Affairs in an e-mail from (b) (6), OSC, to (b) (6) on January 24, 2013.

I am enclosing a response to the questions to provide additional details and clarification related to the referenced OSC files. I reviewed this response with the impacted facility to ensure factual accuracy and to provide additional details about facility training.

As the supporting documents for the response, I am enclosing our investigation report that was sent to the Chair, National Radiation Safety Committee. This report includes our inspection report and record. I am also enclosing a copy of the Nuclear Regulatory Commission medical policy statement.

If you have any questions, please contact (b) (6), Ph.D., at 501-257-1578, or you may reach me at 501-257-1571.

Sincerely,

(b) (6)

(b) (6)

Director, National Health Physics Program

Enclosures: as stated

Enclosure 1

Enclosure to National Health Physics Program (NHPP) letter dated March 25, 2013, to Office of Special Counsel (OSC)

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

The NHPP prepared this response in coordination with the Chair, National Radiation Safety Committee. The facility provided training details to include in this response. The response is to comments and questions raised by the OSC regarding the previously submitted subject report. The eight OSC questions are listed below with a response below the question. The acronyms used for the response sections are noted below.

ALARA	As low as is reasonably achievable
NHPP	National Health Physics Program
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer

1. The report provided to OSC references the investigation and inspection reports prepared by the NHPP, which was tasked to conduct the investigation in this matter. We request copies of the NHPP investigation and inspection reports.

Response:

The investigation report (dated June 7, 2012) is provided as a separate enclosure to this response to OSC. The inspection documents (with report and record dated June 6, 2012) are included as an attachment to the investigation report.

2. Regarding implementation of the Tc-99m DTPA aerosol procedure, the report concludes that a regulatory violation or significant deviation from best health physics practices was not identified. It states that approval of procedures and protocols by the Radiation Safety Committee (RSC) or Radiation Safety Officer (RSO) is not required. VHA Directive 1105.01 states that the RSC is tasked to review and approve proposed changes to training, equipment, facilities, and radiation safety procedures or practices. We request clarification regarding whether this or any other VA directive, policy, or procedure requires or recommends notification or approval of the RSC or RSO for new or modified procedures or equipment used by the Nuclear Medicine Service. We also request information regarding the "best health physics practices" referenced in the report.

Response:

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, especially a protocol that is in the current procedural manual, if such use does not change the radiation protection program. In the case of Tc-99m DTPA aerosol studies, NHPP concluded that implementation of this diagnostic procedure would not have been expected to involve a change to the radiation protection program given that a similar protocol was already in the current procedural manual and could have

been implemented by the Nuclear Medicine Service under supervision of the physician authorized user.

Nuclear medicine imaging protocols are considered to be a component of the practice of medicine and not specifically subject to committee or RSO approval, unless the new protocol will result in a change to the radiation safety program.

NHPP did comment in the investigation report that lack of effective communications did exist between Nuclear Medicine Service and Radiation Safety Office such that better communications may have helped provide additional radiation safety perspectives to the nuclear medicine staff on the procedure.

A best practice is a method or technique that has consistently shown results superior to those achieved with other means and that is used as a benchmark, especially for review of practices by a subject matter expert. Best practices are used in nearly every industry and professional discipline. Best practices are used to maintain quality as an alternative to mandatory legislated standards. Best practices are not specifically codified or listed in a specific document but rather represent informed and collected judgments by subject matter experts as to practices or procedures that should be followed.

Health physics is the science concerned with the recognition, evaluation, and control of health hazards to permit the safe use and application of ionizing radiation such as in a medical facility. Health physics professionals such as embodied in NHPP staff have the training and experience to evaluate radiation safety practices to identify if the practices are reasonable, adequate, and sufficient to protect public health and safety. Thus, a NHPP health physics inspector as a subject matter expert not only confirms regulatory compliance but also reviews radiation safety practices to determine if the practices are consistent with "best" practices.

3. The report states that NHPP observed there was a published protocol for the Tc-99m DTPA aerosol procedure, dated January 25, 2003, in a procedure binder, but also found that this procedure was not revalidated or reviewed by the Nuclear Medicine Service prior to implementation in June 2011. The report further states that technologists were unclear about the location of a written protocol for the procedure. We request information regarding the operative Nuclear Medicine Service procedural manual in use in June 2011, and when the protocol for the procedure implemented in June 2011 was published and included in that manual.

Response:

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 (b) (6) on November 24, 2004, and by (b) (6) on June 2, 2011. NHPP does not have an objective method to confirm what, if any, specific procedures or protocols were in the procedure binder during June 2011.

Based on discussions with (b) (6) (physician authorized user and Chief of Nuclear Medicine Service) and (b) (6) (Chief Technologist, Nuclear Medicine Service) during the NHPP on-site inspection, the procedure dated January 25, 2003, and observed in the binder by NHPP during the inspection, was not the procedure followed by the Nuclear Medicine Service when imaging with Tc-99m-DTPA aerosol was initiated in June 2011.

Rather, Nuclear Medicine Service, working under (b) (6) supervision as a physician authorized user, used procedures and suggested protocols from the manufacturer of the Ultravent Radioaerosol Delivery System.

Use of this protocol was documented in an e-mail dated July 7, 2011, from (b) (6) to the staff technologists and copied to (b) (6), RSO, and others. The manufacturer procedure, was last revised in May 2011, and is normally added as a hard copy document with each shipment sent to a facility with the aerosol imaging kit.

Based on information provided to and observed by NHPP during the inspection, the facility-specific procedure in the procedure manual was revised April 1, 2012, and then added to the manual sometime before May 23, 2012. Due to a shortage of Xenon-133 gas for lung ventilation studies, the facility resumed the Tc-99m DTPA aerosol studies on May 23, 2012, after not performing the procedures for a period of nearly 6 months.

4. According to the 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. We request confirmation that there is no requirement under NRC regulations or VA directives, policies, or procedures that Nuclear Medicine Service staff be adequately trained on the procedures and equipment used with radiopharmaceuticals.

Response:

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.

The on-site Health Physics Technician, who later became the RSO, did conclude additional training was needed in response to questions raised by Nuclear Medicine Service staff and to ensure common understanding by the staff on how to use the equipment safely and efficiently. This is a usual, and expected, role for an RSO when providing oversight for radiation safety programs.

NHPP did not conclude that a regulatory violation was warranted for the lack of effective training since the lack of training did not lead to a regulatory violation or radiation safety outcomes that exceeded a regulatory limit and since the supervised technologists were following instructions of the physician authorized user for the clinical use of the imaging agent.

5. The report concludes that the RSO provided training on the use of the Tc-99m DTPA aerosol procedure after safety concerns were raised. We request 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.

Response:

Based on discussions between NHPP and (b) (6) (Chief Nuclear Medicine Technologist), (b) (6) 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, prior to first patient use on that same date. (b) (6) indicated that he provided the manufacturer operating instructions for the Ultravent Radioaerosol Delivery System to all technologists on that day. These instructions include a step-by-step procedure for use of the device and are normally included as a hardcopy with each single-use patient kit received for the radioaerosol delivery system. While a specific training roster was not generated for this training session, (b) (6) recollection was that all nuclear medicine technologists employed at that time were present for the "dry run" training session, which included (b) (6) (b) (6) and (b) (6)

During the NHPP on-site inspection of May 23-24, 2012, (b) (6) (RSO at the time of the inspection; Health Physics Technician at time of referenced training) provided NHPP a copy of an e-mail dated June 29, 2011, indicating that himself and (b) (6) (Assistant RSO at time of referenced training) provided training to all available Nuclear Medicine Service staff on use of the DTPA aerosol nebulizer device. While a specific training roster was not generated for this training session, (b) (6) recollection was that the training occurred on June 29, 2011, and all nuclear medicine technologists working that day were present for the training session. This included (b) (6) (b) (6), and (b) (6)

During the NHPP on-site inspection of May 23-24, 2012, (b) (6) (physician authorized user) provided NHPP a copy of an e-mail dated July 7, 2011, that was sent by (b) (6) to all nuclear medicine technologists (viz., (b) (6)

(b) (6) and (b) (6) ) and copied to ancillary staff (viz., (b) (6) | RSO at that time; (b) (6), Assistant RSO at that time; (b) (6), physician authorized user; (b) (6), physician authorized user; (b) (6); and (b) (6). The e-mail included, among other protocol and guideline documents, the Ultravent Radioaerosol Delivery System instructions as an attachment. The e-mail requested that staff review the documents and contact (b) (6) or (b) (6) with any questions.

During the NHPP on-site inspection of May 23-24, 2012, (b) (6) (physician authorized user) provided NHPP a copy of an e-mail dated September 23, 2011, that was sent by (b) (6) to (b) (6) to document additional training that was provided to nuclear medicine technologists that same date to emphasize Tc-99m DTPA ventilation kit disposal and spill procedures. While a specific training roster was not generated for this training session, (b) (6) recollection was that the training occurred on September 23, 2011, and all nuclear medicine technologists employed at that time were present for the training session, which included (b) (6), (b) (6), and (b) (6).

6. Regarding the September 2011 contamination event, the report states that the STVHCS root cause analysis team reached a different conclusion than that of the RSO in his draft root cause analysis. We request a copy of the STVHCS root cause analysis team's report. We also request clarification concerning why the Radiation Safety Officer's report was not accepted by the RSC.

Response:

VA is not authorized to provide the root cause analysis report as it is a protected 5705 quality assurance document.

NHPP determined that the facility decided to form a root cause analysis team to review the circumstances in order to benefit from other perspectives about the spill incident. NHPP concluded the RSO report was not adopted or accepted by the full committee in a formal sense. The committee accepted recommendations for corrective actions in the report by the root cause analysis team.

NHPP determined that the dosimetry results from the vendor for the two individuals who helped with spill clean-up were assigned for the individuals and not impacted by either the report by the RSO or root cause analysis team. NHPP concluded using dosimetry results from the vendor, without change, to be the most conservative approach to resolve any questions about the results.

7. The report cites 10 CFR 20.1101(b), requiring the use of procedures and controls to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA). It also cites VHA Directive 1105.01, which incorporates ALARA requirements. The report states, however, that NHPP does not interpret 10 CFR 20.1101(b) to apply to patients administered radiopharmaceuticals under the direction of a physician authorized user. We request clarification regarding

the VA's policy concerning the application of ALARA requirements with respect to VA patients.

Response:

For a regulatory perspective, NHPP follows the NRC medical policy statements for the use of radioactive materials. In this perspective, NHPP minimizes intrusion into medical judgments affecting patients and other areas traditionally considered to be the practice of medicine. NHPP does not evaluate or review the medical decisions by a physician authorized user as to what would constitute appropriate care (i.e., if a patient procedure was consistent with an ALARA concept). Rather, the NHPP role is to determine if procedures are completed as intended by the physician authorized user.

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.

VHA policy does not specifically address an ALARA concept for patients. The standard of care in nuclear medicine practice is for doses of radiopharmaceuticals to be as low as possible while not comprising or sacrificing the quality of the diagnostic images.

8. Finally, we request information regarding the status of 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.

Response:

Corrective actions taken by the facility in response to the inspection report are in the inspection report. The report is provided in a separate enclosure to this response to OSC as an attachment to the enclosure with the NHPP investigation report.

Specifically, as stated in Item 4 of NHPP Form 591, "the permittee completed training in incident reporting and regulatory requirements on June 5, 2012, to nuclear medicine staff to promote future compliance and ensure that prompt internal reporting of any future dosing errors is undertaken. Full compliance was achieved on June 5, 2012."

As the usual follow-up for violations cited during an inspection, NHPP will review the corrective action at the next routine inspection, which is unannounced to the facility. The target time for the next inspection is in the window of May 2013 to February 2014, unless some non-routine item causes a change in the routine inspection schedule.

Currently, the facility has the option to use the Tc-99m DTPA aerosol procedure or the Xenon-133 gas for lung ventilation studies as determined by the physician authorized user for individual patients. Most often, the Xenon-133 procedure is used with aerosol imaging only used if Xenon-133 gas is not available.

Enclosure 2

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: **JUN 07 2012**

From: Director, National Health Physics Program (NHPP)

Subj: Investigation for Allegation Circumstances at the South Texas Veterans Health Care System, Audie L. Murphy Division

To: Chair, National Radiation Safety Committee, and National Director, Nuclear Medicine & Radiation Safety Services

1. NHPP investigated the allegation circumstances listed in the U.S. Office of Special Counsel (OSC) letter dated May 2, 2012. The investigation included an on-site inspection at the facility, interviews with facility staff and the alleged named in the letter, and review of available documents related to the facility. Our investigation was primarily limited to issues under Nuclear Regulatory Commission (NRC) regulatory purview and best health physics practices. Under your guidance, NHPP collected information related to clinical nuclear medicine practices at the facility.

2. For your consideration, I am providing the following attachments.

a. Attachment A is a summary for each allegation in the OSC letter with a statement of findings, conclusions, and recommendations.

b. Attachment B is an investigation report to address allegations and statements in the OSC letter. This report also provides background details for the facility use of radioactive materials, results for the on-site NHPP inspection, and NHPP summary of conclusions related to regulatory compliance and best health physics practices.

c. Attachment C is NHPP inspection documents to include the inspection plan, inspection record, and transmittal memorandum to the facility with attached NHPP Form 591. For the inspection, NHPP cited one Severity Level IV violation for a dosing error in the administration of a diagnostic dose to a patient. When the violation was identified to the facility, a plan for corrective action was promptly established.

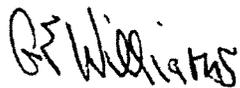
d. Attachment D is results for an independent NRC inspection at the facility. The inspection did not identify any requirements for corrective action or cite a violation.

e. Attachment E is a documents provided to NHPP by one of the alleged.

Investigation for Allegation Circumstances at the South Texas Veterans Health Care System, Audie L. Murphy Division

3. In sum, NHPP did not identify significant regulatory violations, significant deviations from best health physics practices, or restrictions on, or retaliation for, worker protected activities. NHPP concluded the ongoing facility transition to a new Nuclear Medicine Service Chief and Radiation Safety Officer has been fraught with difficult challenges for communication and coordination to the extent that some staff stated they are unclear about clinical procedures and whether issues might be raised to supervisory staff.

4. Please let me know if you have any questions or comments.

A handwritten signature in black ink that reads "G. Williams". The signature is written in a cursive, somewhat stylized font.

Gary E. Williams

Attachments: 5

## Attachment A

### Summary for allegations

#### Allegation #1

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

#### Findings

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

The orientation or training in the methods for the procedure were not coordinated with the radiation safety office and some staff did not consider the training to be adequate. The radiation safety office later provided additional training.

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

Some staff disagreed with the clinical parameters used for the Tc-99m DTPA aerosol procedure and more generally with using this method for ventilation studies.

#### Conclusions

A regulatory violation or significant deviation from best health physics practices was not identified.

A lack of effective communication existed between the Nuclear Medicine Service and the radiation safety office at the time of the external audit. The change to the Tc-99m DTPA aerosol procedure did not effectively involve all staff.

#### Recommendations

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

## Summary for allegations

### 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 [REDACTED] (b) (6) [REDACTED] (b) (6) continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed;

### Findings

(b) (6) [REDACTED], as a physician authorized user on the facility permit for radioactive materials and Chief of Nuclear Medicine Service, had the prerogative to determine the methods to complete imaging studies. The Tc-99m DTPA aerosol procedure is a well-recognized procedure which can be completed safely within regulatory compliance.

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

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

### Conclusions

A regulatory violation or significant deviation from best health physics practices was not identified. Corrective actions from the root cause analysis and the revised spill procedure should mitigate consequences for any future contamination events.

The physician authorized user should continue to determine the imaging procedure that is most appropriate for individual patients.

### Recommendations

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

## **Summary for allegations**

### **Allegation #3**

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

### **Findings**

On or around January 25, 2011, a patient was injected with a cardiac stress dosage that was around 30 millicuries instead of the prescribed dosage of 10 millicuries for a rest-phase cardiac test.

The dosing error did not require external reporting as a medical event under 10 CFR 35.3045 but was a dosing error per 10 CFR 35.63(d). Since a regulatory deficiency occurred, the dosing error should have been reported to the Radiation Safety Officer, Radiation Safety Committee, and Patient Safety Officer to ensure timely and adequate corrective actions were taken.

### **Conclusions**

The National Health Physics Program cited a regulatory violation for the dosing error.

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

### **Recommendations**

The facility should monitor future effectiveness of the training and reporting of dosing errors during routine audits by the radiation safety office.

## Attachment B

### Investigation report

1. This attachment is an investigation report to address allegations and statements in a U.S. Office of Special Counsel (OSC) letter dated May 2, 2012. This report also provides background details for uses of radioactive materials at the South Texas Veterans Health Care System, Audie L. Murphy Division, San Antonio, Texas (hereafter referred to as STVHCS), results for an on-site National Health Physics Program (NHPP) inspection, and NHPP findings related to regulatory compliance and best health physics practices. NHPP collected information related to clinical nuclear medicine practices at STVHCS for review by the National Director, Nuclear Medicine & Radiation Safety Services.

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

a. The OSC letter dated May 2, 2012, to VA Secretary and identified as OSC File Nos. DI-12-0927 and DI-12-1933. NHPP received the letter on May 15, 2012. The letter identified whistleblower allegations and had statements related to the use of radioactive materials at the STVHCS Nuclear Medicine Service.

b. A single page which listed four issues that (b) (6) [REDACTED], M.D., an allegeder identified in the OSC letter, handed to NHPP during an interview on May 22, 2012. Dr. (b) (6) [REDACTED] noted the issues were previously reported to OSC and did not request to remain anonymous.

c. (b) (6) [REDACTED] letter addressed to NHPP ((b) (6) [REDACTED], Ph.D., Program Manager) dated May 28, 2012, and received by facsimile on May 30, 2012.

d. (b) (6) [REDACTED] facsimile to NHPP ((b) (6) [REDACTED]) undated and received on June 1, 2012.

e. (b) (6) [REDACTED] letter addressed to NHPP ((b) (6) [REDACTED]) dated June 3, 2012, and received by facsimile on June 4, 2012.

3. Background information for STVHCS uses of radioactive materials and regulatory inspections.

a. STVHCS holds a permit to use radioactive materials for medical and research purposes. STVHCS is referred to as a permittee. NHPP issued the STVHCS permit under authority of a Nuclear Regulatory Commission (NRC) master materials license issued to the Veterans Health Administration (VHA). The Under Secretary for Health is the named licensed official for the license and exercises oversight through a National Radiation Safety Committee (NRSC). NHPP functions under the NRSC and performs

inspections at permittees to confirm regulatory compliance with radiation safety practices.

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

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

d. (b) (6) [REDACTED] M.D., Chair, NRSC, provided NHPP the OSC letter on May 15, 2012. In consultation with (b) (6) [REDACTED], NHPP immediately began planning for a special inspection at STVHCS to evaluate allegations and statements in the OSC letter.

e. During May 23-24, 2012, (b) (6) [REDACTED] and (b) (6) [REDACTED] (Director, NHPP) inspected STVHCS to evaluate allegations and statements in the OSC letter. Due to the recent favorable inspection by NRC, NHPP defined the inspection scope to be focused to allegations and statements in the OSC letter, related regulatory compliance and radiation safety issues, and any associated observations and interviews during the on-site portion of the inspection.

f. The inspection scope and findings were limited to issues under NHPP purview (i.e., regulatory compliance and best health physics practices). However, NHPP also collected information for (b) (6) [REDACTED] in his role as National Director, Nuclear Medicine & Radiation Safety Service.

g. The inspection was based on a pre-approved inspection plan. The inspection documents are provided as a separate attachment and include the inspection plan, inspection record, and transmittal memorandum to the facility with attached NHPP Form 591. A list of individuals contacted during the investigation is provided in a paragraph below.

h. On May 28, 2012, (b) (6) [REDACTED] had a conference call with two STVHCS staff who requested the call to provide additional information to NHPP. The issues they raised are identified in paragraph 5b below.

i. On May 30, 2012, (b) (6) [REDACTED] received a faxed letter dated May 28, 2012, from (b) (6) [REDACTED] with additional information related to the allegations. (b) (6) [REDACTED] also raised a new issue related to his opportunity to meet with the NRC inspector who had inspected STVHCS on May 15, 2012. This letter is included as a separate attachment.

j. A facility using radioactive materials under an NRC license (or permit issued by a master materials licensee such as the VHA) must comply with NRC regulations. The

primary regulatory compliance requirements for receipt, possession, use, and disposal of radioactive materials at a permittee are established in Title 10 of the Code of Federal Regulations (CFR), including but not limited to 10 CFR 19, 20, 30, and 35. Other Federal agencies also regulate various aspects of radioactive materials uses including Environmental Protection Agency, Food and Drug Administration, and Department of Transportation; however, NRC regulations are the primary regulatory compliance regulations for workers and public that are applicable to a permittee. Other conditions or requirements are listed on the specific permit issued by NHPP to a facility. Some specific requirements related to the focused NHPP inspection are described below.

(1) 10 CFR 20.1101(a) requires a permittee to develop, document, and implement a radiation protection program commensurate with the scope and extent of permitted activities and sufficient to ensure compliance with 10 CFR 20.

(2) 10 CFR 20.1101(b) requires a permittee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA). NHPP does not interpret this regulation to apply to patients administered radiopharmaceuticals under the direction of an authorized user physician.

(3) 10 CFR 35.27(a) requires a permittee to instruct supervised individuals (i.e., nuclear medicine technologists working under direction of a physician authorized user) in the permittee written radiation protection procedures. Also this NRC regulation requires supervised individuals to follow instructions of the physician authorized user.

(4) 10 CFR 35.63(d) stipulates that a permittee may not use a radiopharmaceutical dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent, unless otherwise directed by the physician authorized user.

k. The primary VHA policy documents of interest for this inspection were VHA Directive 1105.01 (Management of Radioactive Materials) and VHA Handbook 1105.02 (Nuclear Medicine and Radiation Safety Service).

(1) VHA Directive 1105.01, paragraph 4e, requires, *inter alia*, the facility Radiation Safety Committee to provide oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA and a safety conscious work environment is achieved. The committee is tasked to review and approve proposed changes to training, equipment, facilities, and radiation safety procedures or practices.

(2) VHA Handbook 1105.02, paragraph 12b, requires, *inter alia*, the Nuclear Medicine Service at a facility to publish policies, procedures, and protocols that describe operations, which provide the highest quality of nuclear imaging and radiobioassay testing. The handbook does not specifically require approval of those nuclear medicine

policies, procedures, and protocols by the Radiation Safety Officer or the Radiation Safety Committee.

4. NHPP evaluation for allegations in OSC letter.

a. Allegation related to implementation of new clinical procedure for lung ventilation studies.

(1) During June 1-2, 2011, staff from a different VHA permittee completed an audit of the STVHCS Nuclear Medicine Service. During the exit briefing on June 2, 2011, the auditor discussed with attendees, including the Chief of Staff, a possible regulatory deficiency related to lung ventilation studies with Xenon (Xe-133), a radioactive noble gas, because negative air pressure was not demonstrated to the auditor for some areas being used for these studies.

(a) On or about June 24, 2011, a final audit report was issued. The report clarified the exit meeting comments about negative pressure and stated,

“Although still considered a best practice policy, upon further detailed research and discussion with NHPP it has been determined that there are no licensing regulations governing this fact. There may be internal/local policy requirements, study procedure requirements, RSO directives, or licensing directives that may determine otherwise, but from a national directive there are no regulations that state negative pressure is a requirement for Xe-133 studies. The only stipulation would be exposure limits and ALARA and this should be discussed in detail with the Radiation Safety Officer.”

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

(c) NHPP concluded a lack of effective communication existed between the Nuclear Medicine Service and the radiation safety office at the time of the audit. More effective communication and collaboration might have precluded a perceived need for an abrupt change from Xe-133 studies to a different imaging procedure; however, ultimately a change might have been necessary because radiopharmacies have been experiencing shortages of Xe-133 gas. NHPP also notes a decision to change to a different imaging procedure is within the scope of clinical discretion by the physician authorized user.

(2) During interviews with NHPP, the Chief of Staff ((b) (6) ██████████, M.D.) and the Nuclear Medicine Service Chief ((b) (6) ██████████, M.D.) noted efforts were undertaken immediately after the exit briefing on June 2, 2011, to identify and implement a different

imaging procedure for lung ventilation studies to preclude curtailing other clinical care at STVHCS that required the capability for ventilation studies. (b) (6) identified use of technetium (Tc-99m) labeled diethylene triamine pentaacetic acid (DTPA) aerosol as the alternative imaging procedure for the Xenon gas studies. (b) (6) is listed on the STVHCS permit as a physician authorized user. In his role as the service chief and a physician authorized user, (b) (6) has the prerogative, from the regulatory compliance perspective, to determine imaging procedures to be used at STVHCS.

(3) (b) (6) tasked the Chief Nuclear Medicine Technologist ((b) (6)) to obtain equipment to support the DTPA aerosol imaging procedure.

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

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

(4) The NHPP inspector observed that a procedure titled "Lung Aerosol Study (Tc-99m-DTPA Aerosol)" was included in a procedure binder located in the Nuclear Medicine Service. Specific markings on the procedure indicated a review/revision was completed on January 25, 2003. Also, the cover page of procedure binder was signed by (b) (6) on November 24, 2004, and later by (b) (6) on June 2, 2011. Based on this information, NHPP concluded that a written procedure for Tc-99m DTPA aerosol studies predated use of Tc-99m DTPA aerosol in June 2011. However, based on NHPP interviews, the procedure was not revalidated or reviewed by Nuclear Medicine Service prior to initiating the Tc-99m DTPA aerosol procedure in June 2011.

(5) Prior to first use of the Tc-99m DTPA aerosol procedure in June 2011, (b) (6) provided orientation training to the nuclear medicine technologists on the use of the Ultravent™ Ventilation Kit and Ultravent™ Shield. This training was not documented. Based on NHPP interviews with the staff, some of the nuclear medicine technologists did not consider the orientation training to be adequate and sufficient. Based on NHPP interviews with the former and current Radiation Safety Officers, NHPP concluded that the radiation safety office was not involved in the initial training effort or implementation of the Tc-99m DTPA aerosol procedure and a lack of effective communication existed between the Nuclear Medicine Service and the radiation safety office.

(6) Beginning on June 6, 2011, and through December 2011, under supervision of (b) (6) (a physician authorized user listed on the STVHCS permit since January 26, 2011), the Nuclear Medicine Service used solely Tc-99m DTPA aerosol to perform lung ventilation studies. Approximately 76 aerosol lung studies were conducted in this time period with activities ranging between about 17 and 42 millicuries. Beginning in January 2012 through about May 22, 2012, STVHCS reverted back to using solely Xe-133 gas for ventilation studies. On May 23, 2012, STVHCS resumed DTPA aerosol studies in response to a shortage of Xe-133 gas.

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

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

(b) On June 29, 2011, (b) (6), the on-site radiation safety technician (who is currently the Radiation Safety Officer on the permit) stated to the then Radiation Safety Officer that a training session was held with all available nuclear medicine technologists on use of equipment for the Tc-99m DTPA aerosol procedure. The nuclear medicine staff was requested to notify the radiation safety office upon the next use of the device and to locate the protocols for the procedure. The radiation safety staff noted that they considered the issue resolved and that the Nuclear Medicine Service "should be allowed to proceed with DTPA studies." Based on NHPP interviews with nuclear medicine staff, specific instances of contamination by a worker have not been identified for the Tc-99m DTPA aerosol procedure.

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

(8) With respect to the allegation and statements in the OSC letter related to the approval of the Tc-99m DTPA aerosol procedure by the STVHCS Radiation Safety Committee, NHPP concludes that committee approval is not explicitly required by NRC regulations for use of the procedure or the associated equipment such as the nebulizer device.

(a) NHPP notes that the STVHCS permit, as related to medical uses, provides for use of any physical or chemical forms of radioactive material for imaging studies under 10 CFR 35.200 when the use is supervised by a physician authorized user. During NHPP interviews, (b) (6), who serves as the Chief of Nuclear Medicine Service and is listed on the STVHCS permit as a physician authorized user, assumed accountability and responsibility for approving and supervising patient administrations using the Tc-99m DTPA aerosol procedure.

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

(9) With respect to statements in the OSC letter related to accuracy and diagnostic usefulness of the Tc-99m DTPA aerosol procedure as compared to other possible imaging modalities or protocols, NHPP concludes the efficacy of imaging procedures is subject to varying clinical opinions and is a practice of medicine issue, not a regulatory compliance issue under NHPP purview.

(a) NHPP concludes that the clinical decision by a physician authorized user to perform a specific procedure on a specific patient is a practice of medicine decision outside of NHPP regulatory compliance purview.

(b) NHPP concludes that the dosage prescribed and administered for a patient is a practice of medicine decision by the physician authorized user. NHPP has regulatory purview only to ensure that the dose intended by the physician authorized user was actually administered to the patient. NHPP recognizes and supports the accepted clinical practice to reduce radiation doses to patients when reasonable to do so as determined by the physician authorized user. However, NHPP interprets the regulatory provisions for ALARA in 10 CFR 20 only to apply to workers and members of the public and not to patients undergoing medical diagnosis.

b. Allegation related to a radioactive contamination event and elevated dosimetry readings for two technologists.

(1) NHPP confirmed that near the end of the work day on September 20, 2011 (vice September 21 in OSC letter), a contamination event occurred involving waste material from a patient administration using the Tc-99m DTPA aerosol procedure. The event involved the nuclear medicine hot laboratory (Room J204), hallway adjacent to the hot laboratory, and an adjacent area (Room J206) where the patient administration was performed.

(a) The event appeared to have occurred when a nuclear medicine technologist transferred a leaking ventilation kit disposal bag from Room J206 to Room J204. The administration involved about 21 millicuries of Tc-99m, so any residual material involved in the event would have been some lesser amount of activity.

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

(2) Based on NHPP interviews with Nuclear Medicine Service staff and the former and current Radiation Safety Officers, NHPP concluded the following.

(a) The immediate response to the spill was appropriate based on the information available to the Nuclear Medicine Service staff and Radiation Safety Officer at the time of the event.

(b) The nuclear medicine technologists used appropriate radiation survey methods and equipment to locate and characterize the extent of the contamination.

(c) The Nuclear Medicine Service supervisor took appropriate steps to minimize any further spread of the contamination. Appropriate personal protective equipment and radiation dosimeters (whole body and finger rings) were used during cleanup activities.

(d) NHPP identified an area for improvement for closer interaction between Nuclear Medicine Service and the radiation safety office to determine if locations with radioactive contamination might be restricted from access to the public and left to decay rather than requiring the nuclear medicine staff to complete extensive surface cleaning.

(3) The radiation levels measured by nuclear medicine technologists during spill cleanup were reportedly within the range typically encountered in a nuclear medicine environment.

(a) The maximum exposure rate was around 30 mR/hour at surface contact prior to cleaning. Exposure rates a few feet away from the surface were reported to be even lower at less than about 1 mR/hour.

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

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

(d) The Chief Nuclear Medicine Technologist contacted the Radiation Safety Officer by telephone within about 30 minutes of becoming aware of the contamination event to discuss the extent of the appropriate actions and seek advice for cleaning or decay. The Radiation Safety Officer concurred with the plan to clean surfaces in an effort to reduce exposure rates to below the trigger level. The Radiation Safety Officer noted his impression of the spill based on initial information provided was that the spill was small, controlled from public access, and did not warrant tasking the on-site radiation safety staff to assist in the cleanup. At this time, the Radiation Safety Officer was not on-site. The Radiation Safety Officer was not aware the cleaning efforts continued for about 4 hours.

(e) After cleaning efforts were concluded, exposure rates in the highest locations continued to be around 2 mR/hour on contact. The Chief Nuclear Medicine Technologist eventually decided to cover locations with large absorbent pads and provide additional time for decay.

(f) NHPP concluded, after review of radiation survey results for the contamination event, that exposure rates did not necessarily preclude efforts to clean the locations to below a trigger level.

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

(5) Several weeks after the contamination event, on about November 1, 2011, via a report dated October 20, 2011, by the dosimetry vendor (Landauer, Inc.), the Radiation Safety Officer became aware that the September 2011 dosimeters for the two nuclear medicine technologists who participated in the cleanup had recorded doses above the

STVHCS action levels that required an investigation into the results. The Radiation Safety Officer began a timely investigation into the dose results.

(a) Results for deep dose equivalent were 1.7 rem and 3.7 rem, respectively, for two nuclear medicine technologists, as compared to an annual limit of 5 rem. The lenses of eye dose equivalent and shallow dose equivalent were comparable to the deep dose equivalent, indicating that the dosimeters were exposed to penetrating radiations typical of materials used in nuclear medicine. Also, the finger rings that were worn by the two individuals indicated doses of about 1.7 rem and 3.8 rem, respectively, for the two individuals.

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

(c) A formal investigation by a STVHCS root cause analysis team concluded that the dosimeters might have been contaminated and the dose results were not reflective of actual individual exposures.

(d) According to statements made by the nuclear medicine technologists to NHPP, the finger rings were worn under gloves during cleaning efforts which would minimize the likelihood of finger ring contamination, and the dosimeters were stored in personal lockers when not being worn. NHPP notes that, during surface contamination cleaning, finger ring results are expected to be much higher than whole body results as the hands would be closer to the contaminated surface. NHPP concludes that while the dose results cannot be ruled out as being valid, the dose results are highly inconsistent with the exposure levels reported as being measured while cleaning on September 20, 2011. For example, an average exposure rate of about 700 mR/hr would be required over a 5-hour period to result in a dose of 3500 mrem on a dosimeter. The exposure levels that were reported were generally below 30 mR/hr.

(6) Based on information reviewed, NHPP did not find that efforts to clean the spill on September 20, 2011, caused a violation of worker ALARA provisions in 10 CFR 20. NHPP concluded the elevated doses, while reported for a dosimeter worn within the same timeframe, could not be specifically attributed to the spill cleanup efforts. NHPP determined that the annual doses for the two workers with higher dose results were well below NRC regulatory limits or any external reporting requirements.

(7) NHPP concluded that the coordination and communication between the Nuclear Medicine Service and radiation safety office needed improvement to address possible future spills. While spill response is generally covered under the STVHCS radiation safety manual, NHPP discussed with the Chair of the Radiation Safety Committee that a more detailed spill procedure should be implemented to provide additional clarification

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

(8) The OSC letter notes “the whistleblowers further explained that (b) (6) subsequently investigated this incident and prepared a report outlining root causes and recommendations.” NHPP determined that (b) (6), in his role as the Radiation Safety Officer, had prepared a draft report on the causes of the elevated doses around November 10, 2011. (b) (6) provided the draft report to various individuals for comment; however, STVHCS determined that a root cause analysis team should be convened to review the overall contamination event and higher dose results to the two workers. NHPP reviewed the outcomes from the root cause analysis effort which was concluded around January 16, 2012.

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

(i) *The complex mechanism for the delivery of DTPA increases the likelihood of human error resulting in potential radioactive spill.*

(ii) *Disassembly and transport of the nebulizer housing kit within the patient care area increased the likelihood of a spill, spreading radioactive contaminants and exposure in the nuclear medicine patient care area, hallway, and hot lab.*

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

(i) *Standardize and reinstitute the use of Xenon gas for ventilation studies, minimizing the use of DTPA.* (Implementation: NHPP noted that Xe-133 use was re-instituted by STVHCS on January 3, 2012, and that Tc-99m DTPA was not used again until May 23, 2012, due to a shortage of Xe-133 gas.)

(ii) *A standardized process for disassembly of aerosol kits in the hot lab to prevent spills and contamination in the patient care rooms will be implemented by all Nuclear Medicine Technologists. All nebulizer kits will be placed in plastic bags that are provided in each kit after nebulizer treatment; all used kits will be transported on a rolling cart and taken to the hot lab. All dis-assembly procedures and pre-disposal scanning will be conducted on the hot lab.* (Implementation: NHPP noted that a standard operating procedure dated April 1, 2012, was issued to provide additional detail on the Tc-99m DTPA lung scans and to address disassembly of the kits in the hot lab.)

(iii) *In the event that administration of DTPA is required, specific patient care room designation to perform DTPA aerosol nebulizer treatments will be implemented to limit*

*spreading of contamination to multiple areas. Designation of rooms will prevent possible contamination in the main hospital hallway and the main treatment area.*  
(Implementation: NHPP observed that the new standard operating procedure issued April 1, 2012, limited use of DTPA to a specified room, Room J205.)

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

(9) The OSC letter included a statement that (b) (6) raised issues in early November 2011.

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

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

(c) NHPP did not evaluate or address the apparent differences in clinical opinions between physician authorized users about the efficacy of the Tc-99m DTPA aerosol procedure as compared to a different imaging modality. This issue is not within the NHPP regulatory purview.

c. Allegation related to errors in administration of radiopharmaceuticals to patients.

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

(2) NHPP determined that the dosing error did not require external reporting as a medical event to NHPP or NRC under 10 CFR 35.3045; however, the dosing error was contrary to 10 CFR 35.63(d) because the administered dosage exceeded 20 percent of the prescribed dosage. Since a regulatory deficiency occurred, the dosing error should have been reported to the Radiation Safety Officer, Radiation Safety Committee, and Patient Safety Officer (using the facility incident reporting system) to ensure that timely

and adequate corrective actions could be taken to address the circumstance and prevent recurrence.

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

(4) NHPP did not identify any other dosing errors where the wrong dosage was involved nor did staff interviews identify any other specific instances of such errors.

d. Statements in OSC letter related to omitting dynamic portion of studies.

(1) NHPP interviews with nuclear medicine staff did confirm that (b) (6), who is a physician authorized user on the STVHCS permit, did instruct staff to omit the dynamic portion of certain studies.

(2) NHPP notes that the decision about what studies to perform on a given patient is a clinical decision subject to varying physician opinions. NHPP concluded the decision by an authorized user physician to perform a specific procedure on a specific patient falls under the practice of medicine and is not under NHPP regulatory purview.

5. NHPP evaluation for other statements made during course of investigation.

a. Other statements, not addressed above, by (b) (6) in letters dated May 28, 2012 (received by NHPP on May 30, 2012), and June 3, 2012 (received by NHPP on June 4, 2012).

(1) In both letters, (b) (6) stated that he was denied access to the NRC inspector during the recent NRC on-site inspection.

(a) 10 CFR 19.15 states:

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

(b) NHPP (b) (6) observed the NRC inspection on May 15, 2012. Prior to exiting the site, the NRC inspector did privately inform the NHPP observer that she was aware that an undisclosed offsite individual wanted to speak to her; however, the NRC inspector noted that the offsite individual could contact an NRC office to discuss any issues.

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

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

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

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

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

(2) (b) (6) stated "during the cleaning procedure on September, 2011, all three cardinal rules of radiation protection were violated: time...distance...and shielding."

(a) NHPP considers time, distance, and shielding to represent cardinal principles of radiation protection and ALARA, but not to be specific regulatory requirements.

(b) NHPP reviewed the circumstances associated with the cleaning efforts and did not identify a specific regulatory requirement that was violated. NHPP concluded that better coordination was needed between the Nuclear Medicine Service and radiation safety office. Subsequently, a more detailed spill response procedure was endorsed by the STVHCS Radiation Safety Committee and implemented on May 30, 2012.

(3) (b) (6) stated that, "there had been no written procedure book recently generated locally by the Nuclear Medicine department."

(a) NHPP observed that a procedure binder was located in the Nuclear Medicine Service during the on-site inspection during May 23-24, 2012. The binder was initiated by (b) (6) on June 2, 2011.

(b) Some individuals interviewed opined that the procedure binder contained only guidelines and lacked the level of detail needed for protocols and that the binder had not always been present and available to all staff.

(c) NHPP identified no specific NRC regulatory requirement for written protocols for all diagnostic studies other than administrations requiring a written directive, which were observed to be present. Rather regulations in 10 CFR 35.27 require that supervised individuals (e.g., nuclear medicine technologists) must follow the instructions, whether verbal or written, of the supervising physician authorized user.

(d) VHA Handbook 1105.02, paragraph 12(b)(2), requires published policies, procedures, and protocols that describe operations, provide the highest quality of nuclear imaging and radiobioassay testing. NHPP concludes that the quality and completeness of the procedures binder is a clinical issue not under NHPP regulatory purview.

(4) (b) (6) states that "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."

(a) NHPP agrees that an investigation and internal reporting should be performed whenever an unintended contamination event above facility trigger levels occurs on any surface. The investigation should identify the cause and undertake corrective actions to remediate and prevent recurrence.

(b) However, NHPP concludes that NRC regulations do not specifically require skin dose to patients undergoing diagnostic studies to be determined unless medical event reporting requirements in 10 CFR 35.3045 might be triggered. For diagnostic studies, these reporting requirements would not be triggered for unsealed sources unless the administered dose was 20 percent or more of the prescribed dose or exceeded the dose range established by the authorized user or the study involved the wrong patient, wrong radiopharmaceutical, or wrong route of administration.

(c) During the NHPP inspection, some staff did state that skin contamination of some patients from the Tc-99m DTPA aerosol procedure was suspected (based primarily on imaging); however, they further stated that the issues were raised to their supervisor and the radiation safety office was involved in reviewing the procedure and

providing additional training on June 29, 2011. Subsequent to the training, the possible skin contamination issue was apparently resolved.

(5) (b) (6) states that "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."

(a) NHPP observed that STVHCS was quite forthcoming with information about worker doses and did not identify any efforts to be less than forthcoming with NHPP request for information.

(b) NHPP observed that the two workers involved in the September 20, 2011, spill cleanup did have elevated dosimetry results for the month of September 2011. NHPP review comments and conclusions about the spill cleanup and the doses are provided in paragraphs above.

(c) STVHCS convened a root cause analysis to identify the causes and corrective actions for the elevated doses.

(6) (b) (6) stated that he disagreed with the NHPP assertion that the ALARA concept did not strictly apply to patients.

(a) NHPP interprets the NRC regulatory requirement for ALARA in 10 CFR 20 as not specifically applying to a patient who is administered radiopharmaceuticals by or under the supervision of a physician authorized user since specific decisions about how to administer radiopharmaceuticals to a patient is a matter of medical practice and not specifically regulated by NRC.

(b) NHPP agrees with the concept that from the clinical perspective, the physician authorized user should exercise ALARA principles to reduce, when possible, the radiation dose to the patient by assuring the right test is done for the right reasons (appropriateness screening) and that the dose of the radiopharmaceutical used is appropriate for that test (by written protocol supported by medical literature).

b. Other statements and issues raised by others during the NHPP inspection effort and not otherwise identified in written correspondence that was provided to NHPP.

(1) Some individuals stated that radioactive iodine was administered to a patient who had recently taken amiodarone, which was stated to be a drug that can negatively impact the quality of iodine uptake studies. Though requested to provide specific details during the interview, the individuals did not provide any specific patient names or dates for follow up evaluation. NHPP concluded that the statement is about a clinical issue not under NHPP regulatory purview.

(2) Some individuals stated that on May 1, 2012, a patient was injected with 25 millicuries of Tc-99m methylene diphosphonate (MDP) for a bone scan, but was not imaged. The patient had apparently left the hospital building and was late in returning to Nuclear Medicine Service for the imaging portion of the procedure. Purportedly, non-physician staff decided not to image the patient and did not involve the physician authorized user in the decision. The individual stated a nuclear medicine technologist might have been scheduled overtime to complete the scan. Based on discussions with the Chief Nuclear Medicine Technologist, the physician authorized user was informed of the circumstance so that medical judgment could be rendered. NHPP concluded that this statement represents a clinical management issue and does not represent a violation of a specific NRC regulatory requirement.

(3) One individual stated that some radiation survey meters and other equipment important to radiation safety practices (e.g., dose calibrators) had been obtained outside of normal procedures but did not offer any specific details. Equipment acquisition is not an item under NHPP regulatory purview as long as the equipment is properly calibrated and operating to meet its intended function under the regulations. NHPP discussed the acquisition of equipment with the Radiation Safety Officer and Chief Nuclear Medicine Technologist and both stated such equipment would not have been placed in service without appropriate checks and calibrations as required by regulations. NHPP did not identify violations with equipment calibrations or use. Also, the May 15, 2012, NRC inspection reviewed radiation safety equipment and did not identify any violations.

(4) One individual stated that a cobalt-57 sealed source used for quality control testing was improperly transported from another address to the Nuclear Medicine Service by a VHA employee using his personal vehicle. The Radiation Safety Officer did note that sealed sources had been brought from the formerly permitted Kerrville, Texas, location and were received at the San Antonio address; however, he noted that Department of Transportation requirements were followed. NHPP did not identify a violation of regulatory requirements as 49 CFR 171.1(d)(5) provides for transport by Federal employees.

(5) One individual stated that some of the nuclear medicine technologists were not appropriately certified to operate or use the 64 slice PET/CT unit. NHPP discussed this item with the Chief Nuclear Medicine Technologist who noted that those individuals operating PET/CT equipment had undergone training by the vendor and on-the-job training to ensure safe operation of equipment. Specific certification for PET/CT by an accrediting body is not an issue under NHPP regulatory purview.

(6) One individual stated that sometime in January 2012, a patient's clothing was contaminated in the PET/CT area and had to be retained. The individual stated that radiations safety was not involved in the response. NHPP interviewed the Chief Nuclear Medicine Technologist and the Radiation Safety Officer and did substantiate that a patient's personal items were inadvertently contaminated on about February 16, 2012. The permittee temporarily confiscated the contaminated items from the patient and bagged and stored the items for decay. The Radiation Safety Officer indicated that

he was not immediately made aware of the issue but did become aware later that same day. Contamination of surfaces and individuals is an inherent risk associated with use of unsealed radioactive materials in medicine. NHPP concluded that the permittee took appropriate steps to control the possible spread of contamination by confiscating and retaining contaminated items. NHPP did not identify a violation associated with the permittee's response to this issue. The spill response procedure implemented May 30, 2012, should provide for improved coordination and communication between the Nuclear Medicine Service and radiation safety office.

#### Persons contacted

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

## Attachment C

### South Texas VA Health Care System, San Antonio, Texas Inspection Plan, May 23-24, 2012

1. Conduct an entrance meeting with executive management and note the following information. This VHA National Health Physics Program (NHPP) inspection is a special, focused inspection to examine radiation safety details about nuclear medicine uses of radioactive materials. The focus of the inspection is regulatory compliance to ensure health and safety. NHPP may also collect specific clinical information as requested by Director, VHA National Nuclear Medicine & Radiation Safety Services. NHPP's role in performing the inspection is separate from any actions of the Nuclear Regulatory Commission.
2. Conduct private interviews with key staff depending on availability. Key staff to interview include: Chief of Staff, Chief of Imaging (Nuclear Medicine Service), Radiation Safety Officer, Chief Technologist (Nuclear Medicine Service), and nuclear medicine technologists.
3. Tour the Nuclear Medicine Service to examine equipment and observe practices related to health and safety. We are specifically interested in examining equipment and practices used to perform lung ventilation studies with Tc-99m DTPA.
4. Review documents and records related to safety and oversight for use of radioactive materials in nuclear medicine (for timeframe since around January 2011) to include clinical protocol manual, radiation safety manual and policies, staff training outlines and records, patient dosage assessment, dosing errors, and follow-up actions, worker dosimetry, radiological surveys, incidents, spills, and Radiation Safety Committee meeting minutes. Determine the type and extent of other records to review based on performance-based inspection results.
5. Conduct an exit meeting with representatives of executive management.

Submitted by: (b) (6) M.D.

Date: May 17, 2012

Approved by: (b) (6)  
Director, NHPP

Date: 18 May 12

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: JUN 06 2012

From: Director, VHA National Health Physics Program (NHPP)

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 671-12-I01

To: Director (671/00), South Texas Veterans Health Care System, San Antonio, Texas

1. NHPP inspected the radiation safety program at the South Texas VA Health Care System, San Antonio, Texas, on May 23-24, 2012, with continuing review through June 6, 2012. This was a focused, announced inspection.
2. In sum for the inspection scope, NHPP did not identify significant regulatory violations or deviations from best health physics practices. NHPP concluded ongoing facility transition to a new Chief, Nuclear Medicine Service and Radiation Safety Officer has been fraught with difficult challenges for communication and coordination to the extent that some staff stated to the NHPP inspectors they are unclear about clinical procedures and whether issues might be raised to the supervisory staff. However, NHPP did not identify any specific restrictions on, or retaliation for, protected activities. NHPP does not opine on the apparent clinical differences of opinion related to the efficacy of ventilation studies since these are not under regulatory purview.
3. The inspection report is attached and consists of an NHPP Form 591 citing one violation that is a deviation from Nuclear Regulatory Commission requirements. You should note the NHPP Form 591 summarizes the violation, corrective actions, and full-compliance date. You must sign and return the form within 30 days of the date of this memorandum.
4. I encourage you to continue ongoing efforts to establish and maintain a safety conscious work environment where all staff is free to raise issues or concerns without fear of retaliation. I note that the corrective actions for the root cause analysis report and recently updated spill procedure should enhance safe use of radioactive materials for ventilation studies and provide for response to any future contamination events.
5. Please contact (b) (6), Ph.D., at 501-257-1578, if you have questions about the inspection.

(b) (6)

(b) (6)

Attachment

cc: Chair, National Radiation Safety Committee  
Network Director, VISN 17 (10N17)

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. PERMITTEE/PERMIT NUMBER:</p> <p>South Texas Veterans Health Care System San Antonio, Texas 42-15881-01</p>	<p>2. LOCATION(S) INSPECTED:</p> <p>Audie L. Murphy Division 7400 Merton Minter Boulevard San Antonio, Texas 78229-4404</p>
<p>3. INSPECTION DATES: May 23 -June 6, 2012</p>	<p>4. INSPECTION REPORT NUMBER: 671-12-101</p>

**PERMITTEE:**

The inspection was an examination of activities under your permit as they relate to radiation safety and compliance with Nuclear Regulatory Commission (NRC) rules and regulations and your permit conditions. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and performance-based observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting per 10 CFR 19.11. The violations and corrective actions are as follows:

Contrary to 10 CFR 35.63(d), on or around February 25, 2011, the permittee administered a radiopharmaceutical dosage to a patient that differed from the prescribed dosage by more than 20 percent and did not obtain prior approval by a physician authorized user. The dosage was for a rest-phase cardiac stress test and contained approximately 30 millicuries of Tc-99m rather than the prescribed 10 millicuries. As corrective action, the permittee completed training in incident reporting and regulatory requirements on June 5, 2012, to nuclear medicine staff to promote future compliance and ensure that prompt internal reporting of any future dosing errors is undertaken. Full compliance was achieved on June 5, 2012.

**STATEMENT OF CORRECTIVE ACTIONS**

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made per 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand no further written response to the VHA National Health Physics Program will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
PERMITTEE			
NHPP INSPECTOR	(b) (6)	(b) (6)	June 6, 2012

**VHA National Health Physics Program Inspection Record**

Inspection report number: 671-12-I01

Permit number: 42-15881-01

Permittee (name and address): South Texas Veterans Health Care System  
Audie L. Murphy Division  
7400 Merton Minter Boulevard  
San Antonio, Texas 78229-4404

Locations of use being inspected: same as above

Permittee contact: (b) (6), Radiation Safety Officer (RSO), 210-617-5300, x14003

Permit priority: 3

Permit program code: 2120/3610

Date of last NHPP inspection: May 14-15, 2009

Date of last NRC inspection: May 15, 2012

Date of this inspection: May 23-24, 2012, with continuing review through June 6, 2012

Type of inspection:  Announced       Unannounced  
 Initial                       Routine                       Special

Next inspection date: May 2013 for core inspection

Normal schedule for NHPP core inspection was May 2012; 12-month delay after NRC core inspection in May 2012, so new NHPP inspection target date is May 2013.

**Summary of findings/actions**

- No violations (inspection report or NHPP Form 591 issued)
- Severity Level IV and/or non-cited violations (NHPP Form 591 issued)
- Severity Level IV and/or non-cited violations (inspection report and NHPP Form 591 issued)
- Severity Level I, II, or III violations (inspection report and NOV issued)
- Follow-up on previous violations

Inspector(s): (b) (6)  
(b) (6)

Date: June 6, 2012

Approved: (b) (6)  
(b) (6), NHPP Director

Date: 6 June 12

## VHA National Health Physics Program Inspection Record

### PART I - PERMIT, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

#### 1. AMENDMENTS AND PROGRAM CHANGES

Amendment No. 50, January 6, 2010, added authorized user (AU)  
Amendment No. 51, March 1, 2010, added and deleted AUs, deleted nuclear pharmacist  
Amendment No. 52, June 21, 2010, added AU  
Amendment No. 53, July 9, 2010, added use under 10 CFR 35.400  
Amendment No. 54, January 26, 2011, added AU  
Amendment No. 55, April 28, 2011, changed RSO  
Amendment No. 56, December 28, 2011, changed RSO  
Amendment No. 57, February 6, 2012, deleted AU

#### 2. INSPECTION AND ENFORCEMENT HISTORY

No violations identified for NRC core inspection of May 15, 2012. No violations identified for NHPP core inspection of May 14-15, 2009.

#### 3. INCIDENT/EVENT HISTORY

None in NMED since the last NHPP core inspection. Two reports of landfill alarms were in the NHPP permit files. The reports appeared to have been resolved based on the details in the permit files. The special focus of this inspection did not include follow-up on these items, which should be reviewed at the next core inspection.

### PART II - INSPECTION DOCUMENTATION

#### 1. ORGANIZATION AND SCOPE OF PROGRAM

The program is approved for both limited-scope medical and broad-scope research uses of radioactive materials. Approved medical uses include those under 10 CFR 35.100, 35.200, 35.300, and 35.400.

The RSO is a full-time VHA employee who reports to the Chief of Safety. The RSO has stop-work authority and direct access to the Director, as needed. The RSO is assisted by one technician. The Associate Director functions as the Chair, Radiation Safety Committee (RSC), which meets routinely on a quarterly basis.

Nuclear Medicine Service is currently budgeted for eight nuclear medicine technologists; however, currently the Service has only five nuclear medicine technologists on staff, including one who serves in a supervisory capacity as the chief technologist.

#### 2. INSPECTION SCOPE AND NRC INSPECTION PROCEDURES USED

The inspection followed a pre-approved inspection plan. The focus was to specific issues in nuclear medicine as described in the inspection plan. The inspection approach was risk-informed

## VHA National Health Physics Program Inspection Record

and performance-based. The inspection included examination of certain rooms and equipment in the Nuclear Medicine Service, review of selected radiation safety practices, review of selected records, and observations of, and interviews with, facility staff. All items on the inspection plan were completed.

NRC inspection procedure used for this focused inspection was IP 87131, "Nuclear Medicine Programs, Written Directive Required." The inspector used the focus areas in NRC procedures (i.e., security and control of radioactive materials, shielding, comprehensive safety measures, dosimeter, instrumentation and surveys, training and practices, and management oversight) as applicable to the issues under review and determined the adequacy of radiation safety practices following a performance-based approach.

The radiation safety program records reviewed were selected from:

- Personnel dosimetry results for 2011
- Staff training information
- Spill report information for 2011 and 2012
- RSC minutes for 2011 and 2012
- Clinical protocol manual
- Radiation safety manual and policies

### 3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

Independent measurements were not performed as part of this focused inspection. The inspector notes that NRC performed a routine core inspection on May 15, 2012.

### 4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES

The inspector identified a violation of 10 CFR 35.63(d) in that on about February 25, 2011, the permittee administered Tc-99m for a stress test that was more than 20% of the prescribed dosage. The amount administered was around 30 millicuries. The amount prescribed was 10 millicuries. Since physician AU approval was not obtained prior to administration, a violation of the regulation occurred. Furthermore, the dosing error was not reported to the RSO, RSC, or Patient Safety Officer. As corrective actions a training session was held with nuclear medicine staff on May 30, 2012, with all training completed on June 5, 2012, to outline reporting expectations for dosing errors. NHPP did not identify other dosing errors involving diagnostic studies and did not receive a specific report during staff interviews of other dosing errors.

NHPP reviewed circumstances related to implementation of a Tc-99m DTPA aerosol procedure for ventilation studies in June 2011. NHPP concluded that the studies were implemented by and performed under supervision of a physician AU who was named on the permit. NHPP determined that initial training was conducted with nuclear medicine technologists prior to use of the equipment for the ventilation study. NHPP determined some leakage of radioactive materials had occurred within the first few weeks after implementation of the procedure and that the radiation safety office was engaged to examine the equipment and provide additional training to nuclear medicine technologists. While challenges did occur with the use of the equipment and

## VHA National Health Physics Program Inspection Record

varying opinions were stated about the training, NHPP did not identify a specific violation of NRC requirements related to implementation and use of the DTPA aerosol procedure. Clinical efficacy of the procedure as compared to other possible imaging methods for ventilation studies is not an issue under NHPP purview.

NHPP reviewed circumstances related to a contamination event that occurred September 20, 2011, involving the Tc-99m DTPA procedure. Apparently, a plastic bag containing disposable equipment with residual radioactivity from an aerosol administration leaked while the bag was being transported from the room where the dose was administered to the hot laboratory for decay in storage.

The leak of material, which impacted two rooms and part of a hallway, apparently occurred near the end of the day and was immediately identified during a routine end-of-day survey. NHPP discussed the event response with Nuclear Medicine Service staff, current and former RSOs, and executive management. NHPP observed that additional training in use and disposal of the DTPA aerosol equipment was undertaken by Nuclear Medicine Service staff a few days after the event.

As discussed in a paragraph below, NHPP also reviewed actions and outcomes associated with a formal facility-level root cause analysis undertaken for the event after higher dosimetry results were identified for two nuclear medicine technologists involved in the cleanup efforts. While NHPP notes, with benefit of a retrospective review, that response to the event might have been better coordinated between the Nuclear Medicine Service and radiation safety office, NHPP did not identify specific violations of NRC requirements related to the response.

As an a means of improving coordination and communication between the Nuclear Medicine Service and radiation safety office, NHPP recommended to the Associate Director, who is the Chair, RSC, that the more detailed spill procedure which was currently under review be finalized and implemented. On June 5, 2012, NHPP was informed that the more detailed spill procedure was implemented, with training of appropriate staff, on May 30, 2012.

NHPP reviewed dosimetry results for Nuclear Medicine Service staff for calendar year 2011. Annual doses for most individuals were well below NRC monitoring thresholds in 10 CFR 20 (i.e., < 500 mrem deep dose equivalent, < 1500 mrem lens of eye, and < 5000 mrem for skin and extremities).

However, annual doses for two individuals were around 1700 mrem and 3700 mrem for deep dose equivalent, lens of eye, and skin and extremities, respectively. These doses were well below regulatory limits but were elevated above normal levels for Nuclear Medicine Service staff and triggered the permittee's internal investigation criteria. NHPP observed that the permittee undertook a thorough investigation, through a formal root cause analysis process, to attempt to determine the validity and cause of the doses and to determine corrective actions to prevent recurrence. This review included evaluation of the methods for safe use of the Tc-99m DTPA procedure. Although inconsistencies were apparent when comparing the two higher dosimetry results to the measured exposure rates for the contamination event, the permittee attributed the doses to the cleaning efforts on September 20, 2011. Corrective actions were identified and implemented related to the DTPA aerosol procedure to minimize likelihood of any

## VHA National Health Physics Program Inspection Record

significant leakage and cleanup efforts for future DTPA aerosol studies. NHPP did not identify a specific violation of NRC requirements related to the contamination event or investigation undertaken for elevated doses.

NHPP inspectors discussed RSC oversight for safe uses of radioactive materials and regulatory compliance with the Chair, RSC, and RSO. Specific items emphasized included compliance with VHA prescriptive requirements for committee meetings and documentation such as tracking of unresolved compliance issues and events (i.e., spill events and elevated doses) to completion as timely as possible. The Chair indicated an understanding of the committee requirements and a commitment to ensuring implementation and involvement, as needed, by executive management.

During interviews and discussions, some staff noted a general reluctance to raise radiation safety issues to supervisors and other management. Nuclear Medicine Service has experienced a recent reduction in staff that some staff attributed to individuals having raised clinical or safety issues.

However, when questioned about their awareness of any specific retaliation for raising issues or any restrictions on raising issues, NHPP was not provided any examples or circumstances where raising issues was related to retaliation or resulted in an outcome adverse to the worker who had raised the issue. During discussions with supervisors and other management, NHPP emphasized that a safety conscience work environment where individuals feel free to raise issues requires continual encouragement and effort, especially during periods of significant staffing transitions.

NHPP encouraged use of informal training sessions such as "standup or tailgate" meetings to provide updated information to workers and solicit feedback for health and safety or regulatory compliance issues. These sessions should support the overall permittee efforts to foster a safety culture and have a safety conscious work environment.

### 5. KEY PERSONNEL CONTACTED

(b) (6), Director <sup>1,2</sup>  
(b) (6), Associate Director and Chair, Radiation Safety Committee <sup>1,2,3</sup>  
(b) (6), M.D., Chief of Staff <sup>1,2,3</sup>  
(b) (6), current Radiation Safety Officer (since December 28, 2011) <sup>2,3</sup>  
(b) (6), former Radiation Safety Officer (May 1, 2011, through December 27, 2011) <sup>3</sup>  
(b) (6) M.D., Physician, Chief, Nuclear Medicine Service, STVHCS <sup>3</sup>  
(b) (6) Chief Nuclear Medicine Technologist <sup>3</sup>  
(b) (6), Accreditation Coordinator <sup>1,2,3</sup>

1. Individual(s) present at entrance meeting
2. Individual(s) present at exit meeting
3. Individual(s) present or participating in inspection discussions



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352  
May 25, 2012

██████████ (b) (6) ██████████, Director  
National Health Physics Program (115 HP/NLR)  
Department of Veterans Affairs  
Veterans Health Administration  
2200 Fort Roots Drive  
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 030-34325/12-016(DNMS) — SOUTH TEXAS VA  
HEALTH CARE SYSTEM, SAN ANTONIO, TEXAS

Dear (b) (6) ██████████:

On May 15, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the South Texas VA Health Care System, San Antonio, Texas. The inspection was limited to a review of activities authorized under Permit Number 42-15881-01. The inspector conducted an exit briefing with the staff at the facility at the completion of the inspection.

The inspection was an examination of activities conducted under the Permit as they relate to radiation safety and to compliance with the Commission's rules and regulations. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of the inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

■ (b) (6)

-2-

Should you have any questions concerning this inspection or the enclosed report, please contact (b) (6) of my staff at (630) 829-9854.

Sincerely,

(b) (6)

Materials Licensing Branch

Docket No.: 030-34325  
License No.: 03-23853-01VA  
Permit No.: 42-15881-01

Enclosure:  
Inspection Report 030-34325/12-016(DNMS)

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Department of Veterans Affairs Under Secretary for Health Washington, D.C. Location: South Texas VA System, San Antonio, TX</p> <p>REPORT NUMBER(S) 2012-016</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-34325</p>	<p>4. LICENSE NUMBER(S)</p> <p>03-23853-01VA</p>	<p>5. DATE(S) OF INSPECTION</p> <p>May 15, 2012</p>
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**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE		<i>[Signature]</i>	
NRC INSPECTOR	(b) (6)	(b) (6)	5/25/12
BRANCH CHIEF	(b) (6)	(b) (6)	5/25/2012

**Docket File Information**  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

*PJP*

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Department of Veterans Affairs Under Secretary for Health Washington, D.C. Location: South Texas VA System, San Antonio, TX</p> <p>REPORT NUMBER(S) 2012-016</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-34325</p>	<p>4. LICENSE NUMBER(S)</p> <p>03-23853-01VA</p>	<p>5. DATE(S) OF INSPECTION</p> <p>May 15, 2012</p>
<p>6. INSPECTION PROCEDURES USED</p> <p>87131</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01 - 03.07</p>	

**SUPPLEMENTAL INSPECTION INFORMATION**

<p>1. PROGRAM CODE(S)</p> <p>2120/3610</p>	<p>2. PRIORITY</p> <p>3</p>	<p>3. LICENSEE CONTACT</p> <p>(b) (6)</p>	<p>4. TELEPHONE NUMBER</p> <p>(501) 257-1572</p>
--------------------------------------------	-----------------------------	-------------------------------------------	--------------------------------------------------

Main Office Inspection                      Next Inspection Date: \_\_\_\_\_

Field Office Inspection    South Texas VA, San Antonio, TX

Temporary Job Site Inspection                      \_\_\_\_\_

**PROGRAM SCOPE**

The radiation safety program oversees active nuclear medicine and nuclear cardiology programs, and limited research activities. The facility does approximately 12-13 patients per day and uses approximately 700 mCi of Tc-99m/month. All doses are single unit doses. Per the RSO, no brachytherapy has been conducted on site since his appointment (approximately 8 months ago). The radiation safety staff consists of the RSO and two assistant RSO's. The RSO reports to the Director of Radiology, and also has the ability to report directly to the Director of the facility. The program is overseen by a Radiation Safety Committee (RSC). Active research at the facility currently only consists of the use of tritiated glucose by (b) (6) for research related to diabetes.

The nuclear medicine program uses Tc-99m for standard nuclear medicine modalities (e.g., bone, liver, and cardiac studies), I-131 for thyroid therapies, Xe-133 for lung imaging, and F-18 (FDG) for PET/CT imaging. The department is budgeted for eight nuclear medicine technologists (NMT's) but staffing losses has the current level at four NMT's and one lead NMT. Of these only two are currently cross certified in PET/CT. Both of these individuals were not available on the day of the inspection, so all PET/CT imaging had to be cancelled. The PET/CT program was reviewed and found to be adequate. The radiation safety staff contracts with Cardinal Health pharmacy for maintenance of the five (5) dose calibrators at the facility.

**Performance Observations**

Radiation controls associated with the research area were reviewed and found to be adequate. The hospital is currently undergoing significant changes associated with remodeling and upgrading of facilities. Discussions with the radiation safety staff indicated they are actively involved in the planning and remodeling processes to ensure that shielding, negative air balance, and other radiological concerns are addressed during the construction. The nuclear medicine and nuclear cardiology areas were reviewed and found to be adequate and personnel found to be informed and appropriately trained.

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Under Secretary for Health Washington, D.C. Location: South Texas VA System, San Antonio, TX REPORT NUMBER(S) 2012-016		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-34325	4. LICENSE NUMBER(S) 03-23853-01VA	5. DATE(S) OF INSPECTION May 15, 2012	

(Continued)

Radiation Survey instruments are sent to a vendor for calibration. Personnel are badged using a NVLAP approved vendor. Staff dosimetry results ranged between 20-35 mrem whole body and extremity dose ranged between 14-113 mrem. All other functions are performed by the radiation safety staff. Records for staff training, leak tests, physical inventory, dose calibrator linearity & accuracy, instrument calibration, monthly RSO audits and personnel exposure were reviewed and no issues identified. The inspector observed the check-in of material and the administration of a dose to a patient. No issues were identified.

No violations were identified.

Received from [redacted] (b) (6) (He noted this provided to OSG)  
on 5/22/24 [redacted] (b) (6)

**Attachment E**

**Please identify the type of agency wrong doing that you are alleging**  
Substantial and specific danger to public safety:

**Please describe the agency wrong doing that you are disclosing**

I am concerned with radioactive safety procedures in the Nuclear Medicine, Imaging Service, Audie Murphy Medical Center. I am alleging that radiation exposures are not maintained as low as reasonably achievable. Rather, exposures are a safety hazard. Therefore, I am reporting specific safety nuclear medicine issues at Audie Murphy VA Medical Hospital, Nuclear Medicine.

Specific items:

1. Late this year, there was a recent incident involving radioactive contamination of the hallway floor adjacent to the hot laboratory in Nuclear Medicine. The hallway is on the second floor of the Audie Murphy VA Hospital where employees, patients and visitors have access.
2. There were three recent incidents involving the administrations of a diagnostic quantity of a radiopharmaceutical that was performed incorrectly, or in error, resulting in unnecessary patient exposure leading to serious safety hazards.
3. Several clinical procedures altered or new to the Nuclear Medicine clinic have been implemented without the approval of the Radiation Safety Committee. These new procedures are not scientifically sound and may cause unnecessary radiation exposure to patients and VA employees leading to safety hazards.
4. The Chief of Nuclear Medicine has been provided with repeated explanations with scientific data on these inadequate nuclear medicine procedures regarding unnecessary radiation exposures. These concerns have been ignored and staff have been actually ordered to follow these alleged practices. Our nuclear medicine technologists are not pleased with the new implemented procedures.

I am alleging that the following statutes and VHA Handbook may have been violated: 10 CFR Chapter 1; 21 CFR 361.1; 40 CFR Part 261; 10 CFR Part 61, Subpart I; EPA 520/1-89-003; 29 CFR 1910.1096; and 42 CFR Part 493. VHA Handbook 1100.19. And VHA facilities, based on Pub. L. 93-438.

**Other Actions You Are Taking On Your Disclosure: Inspector General of department / agency involved**

**Other Actions You Are Taking On Your Disclosure: Inspector General of department / agency involved Date**

**Other Actions You Are Taking On Your Disclosure: Other office of department / agency involved**

**Other Actions You Are Taking On Your Disclosure: Other office of department / agency involved Date**

**Other Actions You Are Taking On Your Disclosure: Other office of department / agency involved Text**

**Other Actions You Are Taking On Your Disclosure: Department of Justice**

To: [REDACTED] (b) (6) [REDACTED], Ph.D.  
FAX # 501-257-1570  
Tel # 501-454-7264

From: (b) (6) [REDACTED] M.D.  
Tel # 210-867-6264

As per conversation —

Please acknowledge —

Regards —

(b) (6)

6 pages including this page.

Rec'd 1/20/2012  
(b) (6)

May 28, 2012

(b) (6) [REDACTED], 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 (b) (6) [REDACTED],

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 radiolotopes. 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. (b) (6) 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 (b) (6) 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 (b) (6) as Chief of Nuclear Medicine Service) and the RSO (b) (6), 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 [REDACTED] (b) (6)' 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.

[REDACTED] (b) (6), 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: [REDACTED] (b) (6)

E-mail: [REDACTED]

Cell phone: [REDACTED] (b) (6)

CC: Mr. (b) (6), Director, NHPP  
The Employment Law Group (TELG)

FAX TO: 501-257-1570

To : [REDACTED] (b) (6) [REDACTED]  
 NHPP.  
 Tel # (501)-257-1578 (office)

From : [REDACTED] (b) (6) [REDACTED]  
 Tel # 210-867-6264

[REDACTED] (b) (6)  
 Some more documents to enhance your investigation.  
 Referring all 13 pages, I will send you the captions.  
 Have to run for a doctor's appointment now.  
 Thank you. (b) (6)

13 pages + this page



(b) (6)

To:  
Cc:

(b) (6)

Subject:

Use of 99mTc-Aerosol

(b) (6)

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.

(b) (6), M.D., FACNP, FACNM

(b) (6)

From: (b) (6)  
To: (b) (6)  
Sent: Tuesday, November 22, 2011 5:57 PM  
Subject: Read: Use of 99mTc-Aerosol

Your message

To: (b) (6)  
(b) (6)

Use of 99mTc-Aerosol  
Sent: 11/22/2011 10:25 AM

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



(b) (6)

From: (b) (6)  
 Sent: Monday, November 21, 2011 7:39 AM  
 To: (b) (6)  
 Cc: (b) (6)  
 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. (b) (6) 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 (b) (6) and myself.

r/esw

(b) (6), MSED, USN, RET  
 Radiation Safety Officer/Laser Safety Officer  
 VA Radiation Safety Office (007R)  
 Room H-214  
 Phone 14003; Page 203-5427

NOTE: In spite of the recommendation of the RSO, Dr. (b) (6) 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, (b) (6), and RSO (b) (6) I was told by (b) (6) the situation was under control and I need not come in. The circumstances of the accident are as follows in a verbatim statement by (b) (6)

"Ms. (b) (6) was checking in a package of radiopharmaceutical from Cardinal Health in room J204 for an emergent Lung scan from ED. As she was surveying the package from one meter away, Mr. (b) (6) walked in with a bag of radioactive waste from prior lung scan performed in room J206. (b) (6) 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.

(b) (6) 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. (b) (6) to her credit realized that there was something amiss and at this time Ms. (b) (6) entered J204.

All three individuals decided to survey themselves and realized that their feet were contaminated. (b) (6) 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 (b) (6) and (b) (6) 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 (b) (6) Chief Nuclear Medicine of the contamination. I then called and notified (b) (6) 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. (b) (6) 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

(b) (6)  
c/o (b) (6), 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 (b) (6)

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:

- (b) (6) Chief, Nuclear Medicine, implemented a new clinical procedure for lung ventilation studies without obtaining approval from the Hospital's Radiation Safety Committee or providing training to Clinic staff, in violation of VA rules and federal regulations;
- 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. (b) (6) continued to require the staff to use this unapproved procedure, even after he was advised of the safety hazards it posed; and

(b) (6)

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 (b) (6)

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,

(b) (6)

Attorney, Disclosure Unit

(b) (6)

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

013

**Subject:** Appointment  
**From:** (b) (6)  
**To:** (b) (6);  
**Cc:** (b) (6);  
**Bcc:** (b) (6);  
**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.

12

My cell phone # is (b) (6)

Thank you.

(b) (6), MD, FACNP, FACNM

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

01/22/2010 18:08 FAX  
 of 1



FAX TO : 501-257-1570

To : [redacted] (b) (6)

NHPP

Tel # 501-257-1578

From : [redacted] (b) (6) M.D.

Tel # 210-867-6264

[redacted] (b) (6)

This is the continuation of my last fax of 13 pages of documents.  
Thank you. [redacted] (b) (6)

(Now → 4 pages including this page.)

6-3-12

(b) (6), 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 (b) (6),

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. (b) (6) or Chief of the Imaging Service, Dr (b) (6) 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. (b) (6) and (b) (6) 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, (b) (6) 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, (b) (6) has promised to send me a copy of your report upon completion of your investigation. Please send it to my following address.

Thank you.

(b) (6)

CNP, FACNM

(b) (6)

(b) (6)

cc: (b) (6)  
The Employment Law Group

## 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.

Enclosure 3

UNITED STATES NUCLEAR REGULATORY COMMISSION  
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

COMMISSION NOTICES  
POLICY STATEMENTS

MEDICAL USES

65 FR 47654  
Published 8/3/00  
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10 CFR CH. I

**Medical Use of Byproduct Material;  
Policy Statement, Revision**

AGENCY: Nuclear Regulatory  
Commission.

ACTION: Final policy statement; revision.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is revising its 1979 policy statement on the medical use of byproduct material. These revisions are one component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the

highest risk and to structure its regulations to be risk-informed and more performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997-Fiscal Year 2002." The policy informs NRC licensees, other Federal and State agencies, and the public of the Commission's general intentions in regulating the medical use of byproduct material.

EFFECTIVE DATE: August 3, 2000.

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SUPPLEMENTARY INFORMATION:

I. Background

In 1979, the NRC published a policy statement, "Regulation of the Medical Uses of Radioisotopes," (44 FR 8242, February 9, 1979) in which it informed NRC licensees, other Federal and State agencies, and the public of the Commission's general intention in regulating the medical use of byproduct material. Specifically,

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal agencies, have been guided by this policy.

On August 6, 1997 (62 FR 42219-42220), NRC published a document in the Federal Register, "Medical Use of Byproduct Material: Issues and Request for Public Input," describing NRC's detailed, four-year examination of the issues surrounding its medical use program. This process started with a 1993 internal senior management review; continued with a 1996 independent external review by the National Academy of Sciences' (NAS) Institute of Medicine (IOM); and culminated in NRC's Strategic

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Assessment and Rebaselining Project (SA). Since that Federal Register document was issued, NRC conducted an exhaustive and public review of the medical use program. Specifically, in 1997 and 1998, NRC's current and future role in regulating the medical use of byproduct material was discussed at meetings of the Advisory Committee on Medical Uses of Radioisotopes<sup>1</sup> (ACMUI) and the Organization of Agreement States (OAS), and with various professional societies and government agencies. During this period, the NRC staff also presented four alternative proposed revised versions of the 1979 Medical Policy Statement (MPS) to participants at NRC sponsored workshops and public meetings. These workshops and public meetings also included discussions on the major areas that were being considered for revision in 10 CFR Part 35, "Medical Use of Byproduct Material."

On August 13, 1998 (63 FR 43560), a proposed revision to the MPS was published in the Federal Register for a 90 day public comment period. This comment period was later extended 30 days, to December 16, 1998, (63 FR 64829; November 23, 1998) to allow additional time for public, stakeholder, and State comments. In addition, to allow for wide participation in the process, NRC discussed the proposed revision of the MPS with interested individuals and organizations at 3 public meetings during the comment period (San Francisco, California, on August 19 and 20, 1998; Kansas City, Missouri, on September 16 and 17, 1998; and Rockville, Maryland, on October 21 and 22, 1998).

NRC received 42 specific comments on the proposed MPS from various organizations and individuals. These comments were extracted from the transcripts of the 3 public meetings and the 10 written comment letters submitted in response to the Federal Register document. Additional details about the comments are provided in Section IV, "Discussion of Public Comments." These comments were similar to the comments that were discussed in the August 13, 1998 (63 FR 43582-43583), Federal Register. Based on NRC's consideration of all the comments, no changes to the proposed MPS are being made. (See the final statements that appear in Section II, below.)

<sup>1</sup> The ACMUI advises the Commission on regulating and licensing uses of radionuclides in medicine.

### II. Statement of General Policy

This NRC policy statement informs NRC licensees, other Federal and State agencies, and the public of the Commission's general intentions regarding the regulation of the medical use of byproduct material. The current revision of 10 CFR part 35 is based on this statement of NRC policy. The Commission expects that future NRC rulemaking activities in the medical area and future NRC involvement with other Federal and State agencies will follow this statement of policy. This NRC policy promotes a more risk-informed approach to regulation of byproduct material.

The following is the final Medical Use Policy Statement to guide NRC's future regulation of the medical use of byproduct material.

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

### III. Rationale

NRC's principal statutory authority for regulating medical use of byproduct material is at sections 81, 161, 182, and 183 of the Atomic Energy Act of 1954, as amended (AEA). See 42 U.S.C. 2111, 2201, 2232, and 2233. Section 81 of the Act prohibits, without NRC authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material (42 U.S.C. 2111). Specifically, section 81 of the AEA provides in pertinent part that:

The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission. *Id.* (emphasis added).

By virtue of section 161 of the Act, the Commission is authorized to undertake a variety of measures "(in) the performance of its functions" (42 U.S.C. 2201). As stated in subsection b, the Commission may "establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable \* \* \* to protect health or to minimize danger to life or property" (42 U.S.C. 2201(b) (emphasis added)). Similarly, section 161.i. authorizes the Commission to "prescribe such regulations or orders as it may deem necessary" to "(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property" (42 U.S.C. 2201(i) (emphasis added)).

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to "protect health and minimize danger to life." This statutory standard applies to the myriad of uses of byproduct material, including not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104.a. of the AEA, which is often mistakenly cited for the proposition that, in regulating the medical use of byproduct material, the AEA requires that the Commission "impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public" (42 U.S.C. 2134(a)). This "minimum regulation" limitation does not apply to the medical use of byproduct material which falls within NRC's broad standard-setting authority in sections 81 and 161. Section 104.a., on its face, applies only to medical therapy licenses for "utilization facilities" (e.g., reactors) and "special nuclear material." This "minimum regulation" directive does not govern the Commission's regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR parts 30 through 39. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 as stated in

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§ 20.1002 is that, "[t]he limits in this part do not apply to doses due \* \* \* to any medical administration the individual has received or due to voluntary participation in medical research programs." The Commission has clarified that "the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in part 35" (60 FR 48623).

The provisions of part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to \* \* \* other requirements in this chapter" (§ 30.2). This section requires that "any conflict between the general requirements in part 30 and the specific requirements in another part" are governed by those specific requirements (§ 30.2). The regulations in part 35 are designed "to provide for the protection of the public health and safety" and reflect the broad statutory standard in the AEA, discussed above (§ 35.1). The Commission has determined that, as a matter of policy, "the patient \* \* \* as well as the general public \* \* \* are all members of the public to be protected by NRC" (44 FR 8242, at 8244).

### IV. Discussion of Public Comments

As previously noted, NRC received 42 comments on the proposed revision to the MPS, taken from 10 letters that were submitted and from the transcripts of the 3 public meetings. NRC received verbal comments on the proposed MPS (63 FR 43580; August 13, 1998) from stakeholders (e.g., physicians, medical physicists, nuclear medicine technologists, and radiation safety professionals) during the public meetings that were held in August, September, and October 1998. Stakeholders also submitted written comments to NRC in response to that Federal Register document.

NRC has reviewed all comments, identified the issues raised by the commenters, and combined comments where appropriate. The following discussion includes these issues, the combined comments, and the NRC responses to these combined comments.

### General Comments

#### Issue 1: Absent Harm, What Is the Purpose of NRC Regulation?

*Comment.* A commenter stated that only physicians can determine what is unnecessary radiation exposure to patients. This commenter cited the "Rationale" portion of the August 13, 1998 (63 FR 43584) document about the responsibility of NRC to regulate actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures. According to the commenter, "If the patient exposure is unnecessary and harm is done, then the physician 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?"

*Response.* The purpose of NRC regulation of the medical use of byproduct material is to reduce unnecessary radiation exposure to patients, workers, and the public. Protection of patient radiation safety is an overall goal in regulating the medical use of byproduct material. The focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radiation or radionuclide, rather than to other, non-radiation related aspects of the administration. 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 patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their 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.

#### Issue 2: Should the MPS Be Revised More Frequently?

*Comment.* A commenter noted that the proposed revision is an improvement over the 1979 MPS; however, the commenter recommended that the NRC review the MPS more frequently (e.g., every 10 years).

*Response.* How often the Commission reviews and/or revises the MPS depends on a variety of factors. These factors may be internal, such as the need for a change in the focus of NRC's regulations, or external, such as technological developments. NRC believes that a set interval to review the MPS would not provide the flexibility needed to respond to the many factors which may influence a decision to revise this policy. For example, this revision of the MPS coincides with the NRC's detailed examination of its medical use program which started in 1993 and includes issuances of the Commission's 1997 Strategic Plan (NUREG-1614, Vol. 1).

#### Issue 3: Is the MPS Being Revised To Justify the New Part 35?

*Comment.* Several commenters noted that the current MPS was adequate for effective regulation in safeguarding public health and safety in radiation protection and should not be revised, but simply understood and implemented as originally intended. Several other opinions were stated more strongly. Specifically, one commenter stated that NRC has never paid meaningful attention to the MPS because most existing provisions of Part 35 do not "pass muster" under the MPS, particularly as they apply to physicians conducting nuclear medicine procedures. Another commenter's opinion was that the proposed MPS was a step backward and the MPS is being revised to justify the proposed rule.

*Response.* The Commission agrees that the 1979 MPS was adequate. However, based on the Commission's recent review of its regulatory framework for medical use of byproduct material, these revisions are being made to emphasize a risk-informed regulatory approach. The Commission strongly disagrees with the commenters' opinions that the medical use regulations in part 35 were promulgated without considering the 1979 MPS. In point of fact, all part 35 rulemaking activities have been issued after ensuring compatibility with the 1979 MPS.

After the Commission initiated the review process in 1993, the policy and the rule were revised in parallel in order to achieve a consistent regulatory framework for medical use of byproduct material. As stated before in response to other comments and explanations of the background for this matter, the Commission's Strategic Assessment in 1997 included a decision to consider developing a more risk-informed, performance-based approach. In the process, the three-part 1979 MPS was

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revised into a four-part MPS with rearranged statements to clarify NRC's policy.

The revised MPS was published for public comment in the Federal Register (63 FR 43580-43586; August 13, 1998) and was discussed at meetings with stakeholders and Agreement States. Discussions with stakeholders were meaningful and beneficial, and addressed substantive issues from the medical community (e.g., patient safety, perceived NRC intrusion into the practice of medicine, and regulatory relief for diagnostic nuclear medicine). No new issues were identified during the public comment period and NRC has not revised the MPS any further.

**Issue 4: Should NRC Regulation of the Medical Use of Byproduct Material Be Based on Section 104 of the Atomic Energy Act?**

*Comment.* A commenter disagreed with NRC's interpretation that section 104 of the AEA applies only to special nuclear material. In the commenter's opinion, NRC's medical use regulations should be based on section 104 of the AEA.

*Response.* NRC's principal authority for regulating medical use of byproduct material is at Sections 81, 161, 162, and 163 of the AEA. As previously discussed under Section III, "Rationale", NRC regulation of byproduct material is not bound by the limitation in section 104.a. of the AEA, that refers to minimal regulation of reactor facilities or special nuclear material used for medical therapy.

*Comments on Statements 1, 2, 3, and 4 of the MPS*

*Statement 1:* NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.

**Issue 1: Should the MPS Refer to "Radionuclides" or to "Byproduct Materials?"**

*Comment.* Several commenters noted that Statement 1 made reference to uses of radionuclides in medicine. They indicated that NRC only has the statutory authority to regulate byproduct material.

*Response.* The Commission believes that the general term "radionuclide" is appropriate for a general statement of policy such as the MPS. The latter is intended to inform the public, NRC licensees, and other Federal and State agencies of the Commission's general intentions regarding the regulation of medical use. The 1979 MPS referred to "medical uses of radioisotopes" and the term is now being changed to "uses of

radionuclides in medicine" (see 63 FR 43584; August 13, 1998). As rephrased, the term "radionuclide" is a more accurate technical statement of the scope of NRC regulation in this area.

**Issue 2: Is Statement 1 Needed if Individuals Handling Radioactive Material Are Properly Trained?**

*Comment.* According to one commenter, the goal of this statement is adequately served by assuring qualification of professionals involved in nuclear medicine. In the commenter's opinion, NRC has no evidence that these individuals do not already adequately provide for the radiation safety of workers and the public, and nuclear medicine is of low risk to workers and members of the public.

*Response.* The Commission agrees that one way of meeting the goal is to ensure that individuals are adequately trained in radiation safety practices and are placed in key positions within a licensee's organization to maintain radiation exposures as low as are reasonably achievable. Statement 1 sets forth this position. As previously stated, the Commission is bound by statute to regulate byproduct material (and source and special nuclear materials) to "protect health and minimize danger to life." Statement 1 of the MPS continues to provide a regulatory approach to maintain an adequate level of safety. The Commission expects all medical licensees to provide radiation safety for workers and the general public.

*Statement 2:* NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

**Issue 1: Does This Statement Provide Justification for NRC To Interfere in the Treatment of Patients?**

*Comment.* One commenter was concerned that Statement 2 continues to justify NRC interference in the treatment of patients. According to the comment, there is no supporting data that clearly demonstrates that unsealed byproduct material, when used by qualified authorized users to treat patients, has harmed workers or the public.

*Response.* Statement 2 does not provide justification for NRC to "interfere" in the medical treatment of patients. The modifications to this statement express the Commission's policy not to intrude (rather than "minimizing" intrusion as set forth in the 1979 MPS) into judgments affecting patients except to provide for the radiation safety of workers and the general public. Providing for the radiation safety of the public and workers is essential for the Commission

to carry out its statutory mandate. When this protection involves a degree of regulation of medical judgments affecting patients, the NRC may find it necessary to intrude, to a certain extent, into medical judgments affecting patients.

For example, the release from a hospital of a patient to whom radioactive materials have been administered has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment ("Criteria for the Release of Individuals Administered Radioactive Material," 62 FR 4120; January 29, 1997). From a medical point of view, it may be appropriate for a physician to release from a hospital a patient to whom radioactive materials have been administered. However, the patient release criteria in NRC regulations may require hospital confinement of that patient if his or her release could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA (44 FR 8242; February 9, 1979). Commission regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration that are not listed in the FDA-approved package insert. In addition, Commission regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. The recent amendment of 10 CFR 35.75, cited above, substitutes a dose-based limit for patient release (rather than an activity-based limit) that may provide medical use licensees greater flexibility in determining when patients may be released from their control.

Finally, Statement 2 of the MPS is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." (There are certain exceptions to this

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mandate, which do not change any-existing prohibition on the promotion of unapproved uses of legally marketed devices.) "Food and Drug Administration Modernization Act of 1997," Public Law 105-115, sec. 906, 111 Stat. 2298 (1997).

### Issue 2: Is the NRC the Appropriate Body To Be Involved in Medical Judgments Affecting Patients?

*Comment.* According to one commenter, the NRC is not the right body to intrude into medical judgments affecting patients because NRC's experience in this area is extremely limited.

*Response.* As discussed above and noted in Statement 2, the Commission's policy is not to intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

This comment does not account for the principle that "[t]he substantive area in which an agency is deemed to be expert is determined by statute." *Massachusetts v. United States*, 856 F.2d 378, 382 (1st Cir. 1988). See also, *Commonwealth of Massachusetts v. NRC*, 924 F.2d 311, 324 (D.C. Cir.), cert. denied, 112 S. Ct. 275 (1991). The AEA commits to the NRC the duty of regulating the use of radioactive byproduct materials, including radiopharmaceuticals, to protect public health and safety.

### Issue 3: Should This Statement Include Reference To Providing for the Radiation Safety of Workers and the General Public?

*Comment.* Several commenters requested that Statement 2 be revised to read, as follows, "NRC will not intrude into medical judgments." They believed that the last phrase, "... except as necessary to provide for the radiation safety of workers and the general public," should be deleted.

*Response.* The Commission does not agree that this statement should be revised as indicated by the commenters because providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. The final MPS explicitly states that the Commission's intention is not to intrude into medical judgments affecting patients except to provide for the radiation safety of workers and the general public. When this protection necessitates a degree of regulation of medical judgments affecting patients, the NRC may find it necessary, as previously explained, to intrude, to a certain extent, into medical judgments to protect the public and workers.

*Statement 3:* NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

### Issue 1: Does This Statement Conflict With Statement 2?

*Comment.* One commenter believed that, as written, Statement 3 conflicted with Statement 2, unless the word "primarily" was deleted from Statement 3. Without this change, the commenter believed NRC would intrude into medical judgments affecting patients.

*Response.* The Commission does not agree that, as written, Statement 3 conflicts with Statement 2. Statement 3 makes clear that the focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the authorized user physician's directions are followed. Statement 2 emphasizes the intent of NRC to avoid intrusion into medical judgments affecting patients, except where necessary to provide for the radiation safety of workers and the public. NRC's goal in this aspect of medical use regulation is focused on the physician's directions as they pertain to the administration of radiation or a radionuclide, rather than to other, non-radiation-related aspects of the administration. Consistent with its statutory authority, if a situation should arise in the future that identifies an additional risk to a patient's health and safety, the Commission will consider adopting an additional limitation or control on a particular radiation or radionuclide modality, as necessary.

### Issue 2: Does the Commission Have Any Useful Role in Assuring the Accurate Delivery of Byproduct Material to Patients? Should References to Patient Radiation Safety Be Deleted?

*Comment.* Several commenters indicated that NRC has no useful role in assuring the accurate delivery of byproduct material to patients. They believe that all references to patient radiation safety should be removed, and that NRC should simply state that it will make regulatory efforts to ensure the physician's orders are followed.

*Response.* The Commission has a role in assuring accurate delivery of radiation doses and dosages to patients and has rejected the notion that NRC should not regulate patient radiation safety (44 FR 8243, February 9, 1979). NRC will continue to regulate the radiation safety of patients when justified by the risk to patients, primarily to ensure that the authorized user physician's directions are followed. The Commission recognizes that

physicians have primary responsibility for the protection of their patients. However, NRC's role is also necessary to ensure radiation safety of patients.

### Issue 3: Does NRC Regulation of the Medical Use of Byproduct Material Duplicate FDA Regulation?

*Comment.* One commenter noted that any attempt by NRC to regulate the radiation safety of patients would duplicate the efforts of the FDA and state boards of pharmacy and medicine and, as such, would be an unwarranted intrusion into the practice of medicine.

*Response.* The Commission disagrees with this comment. NRC is responsible for regulating the actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures to the public, patients, and occupational workers. In general, the FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products (i.e., drugs, devices, and biologics). NRC routinely relies on prior FDA approval of medical devices as an essential component of NRC's sealed source and device safety evaluations. In a "Memorandum of Understanding" (MOU), effective August 26, 1993, NRC and FDA coordinated existing NRC and FDA regulatory programs for these devices, drugs, and products (58 FR 47300, September 8, 1993).

NRC regulation of the medical use of byproduct material does not duplicate licensing by State boards of pharmacy and medicine or pharmacists and physicians, respectively, to practice pharmacy or medicine within their borders. NRC regulations rely on the licensure of these professionals by a State (or Territory of the U.S., the District of Columbia, or Puerto Rico) to practice their respective professions as a prerequisite to NRC authorizing them to use byproduct material in pharmacy or medicine.

### Issue 4: Should NRC Regulation Be Risk-Based and, If So, Should NRC Share Such an Approach With the Medical Community?

*Comment.* A commenter insisted that NRC regulation should be "risk-based" (i.e., justified by risk analysis), and if NRC adopts such an approach, the risk analysis should be shared with the medical community.

*Response.* The Commission believes the regulations for use of byproduct material in medicine should be "risk-informed" rather than "risk-based." In March 1997, the Commission directed the revision and restructuring of part 35 into a risk-informed and, where appropriate, more performance-based

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regulation. The Commission is attempting to make its medical use regulatory framework more "risk-informed" and agreeable with its regulatory strategy of regulating "material uses consistent with the level of risk involved, by decreasing oversight of those materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities."<sup>2</sup> In addition, this portion of the MPS reflects the Commission's strategy of identifying those regulations and processes that are now or can be made risk-informed.<sup>3</sup>

The Commission's efforts to make the regulations more risk-informed are evidenced in its recent actions to revise part 35. Before initiating the rulemaking and the associated revision of the MPS, the Commission thoroughly reviewed several extensive assessments, as previously noted. In developing the overall revision of part 35 and the MPS, the Commission considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased. The Commission also examined whether continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated MPS, NRC held public workshops with early opportunities for comment from potentially affected parties. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

Although a formal risk assessment was not performed, the Commission believes that the risks associated with use of byproduct material in medicine have been adequately evaluated and considered. Based on these considerations, the revised regulatory approach is more risk-informed and more performance-based and significantly reduces regulatory burden in many areas. The Commission has retained prescriptive regulatory requirements (e.g., in part 35) only where it believes they are necessary to ensure adequate protection of workers, patients, and the public. However, there is nothing in the NRC's regulations that prohibits the medical community or other stakeholders from conducting an independent formal risk assessment of the medical use of byproduct material

<sup>2</sup> Page 11, NUREG-1814, Vol. 1, "Strategic Plan, Fiscal Year 1997-Fiscal Year 2002".

<sup>3</sup> Id., and SRM dated March 20, 1997, COMSECY-96-057, "Materials/Medical Oversight (DSI 7) at 2.

and forwarding its analysis and recommendations for Commission consideration.

**Issue 5: Should NRC Be Involved With Prescriptions for the Medical Use of Byproduct Material?**

*Comment.* A commenter pointed out that NRC should not be involved with prescriptions because the requirements for accurate delivery of prescriptions are covered under state medical and pharmacy law. The commenter believes that written directives are not necessary to ensure high confidence that the actual administration of radiation to the patient was intended by the authorized user.

*Response.* The Commission's statutory authority to regulate the medical use of byproduct material provides for NRC to have a role with respect to patient radiation safety. Statement 3 narrows the primary focus of NRC regulation of the radiation safety of patients to whether the physician's directions for the administration of byproduct material are followed. This regulatory role is in contrast to the broad regulation by a State board of pharmacy or medicine of the general practice of those disciplines within its borders.

The Commission is not using the term "prescription" because it might typically include aspects of the administration that are outside NRC's purview. Instead, the term "written directive" (as defined in part 35) is used to specify the physician's directions (i.e., the procedure to be performed and the dose or dosage). This regulatory objective is currently reflected in provisions of part 35 requiring "high confidence" that byproduct material will be administered as directed by an authorized user physician.

*Statement 4:* NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

**Issue 1: How Should Industry Standards Be Used in Regulating the Medical Use of Byproduct Material?**

*Comment.* According to several commenters, the NRC ignores professional standards and regulates as it pleases. In the commenters' opinions, NRC should accord industry and professional standards the respect they deserve. They believe that if NRC in fact endorses standards developed by private, consensus organizations, the revised MPS would be improved.

*Response.* The Commission believes that Statement 4 commits NRC to an

approach for regulation of medical use that considers both industry and professional standards that define acceptable levels of achieving radiation safety. NRC reviewed industry and professional standards in developing and implementing part 35 and the guidance document (NUREG 1556, Volume 9). For example, some provisions in 10 CFR part 35 allow medical licensees the flexibility to use standards from nationally recognized organizations to meet the performance standards reflected in the rule.

Consideration of industry and professional standards as part of NRC's policy to achieve radiation safety in medical use of byproduct material conforms to the Commission's Strategic Plan<sup>4</sup> that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." The NRC's intention is to consider industry and professional standards in developing regulations and guidance for the medical use program, consistent with the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTAA), Public Law 104-113, 110 Stat. 775 (1995). Section 12(d) of the NTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies \* \* \* as a means to carry out policy objectives or activities, 'except when use of such standards,' is inconsistent with applicable law or otherwise impractical."

Not all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTAA ("performance-based or design-specific technical specifications and related management systems practices"). Nevertheless, as indicated above, in regulating medical use of byproduct material, the Commission endorses the concept in section 12 (a) of the NTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations."

**Issue 2: Should NRC Consider Task Group Reports of the American Association of Physicians in Medicine (AAPM) for Developing Approaches for Achieving Radiation Safety?**

*Comment.* A commenter pointed out that, in defining acceptable approaches for achieving radiation safety, NRC should consider the task group reports of the AAPM, which are the latest

<sup>4</sup> Page 10, NUREG-1814, Vol. 1, "Strategic Plan, Fiscal Year 1997-Fiscal Year 2002".

## POLICY STATEMENTS

standards of practice for medical physicists.

*Response.* The Commission agrees that AAPM standards of practice for professionals involved in the use of certain byproduct material modalities and for radiation safety equipment should be considered as part of NRC's risk-informed and performance-based approaches to regulating the medical use of byproduct material. The Commission acknowledges that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. Therefore, where appropriate, the NRC focused part 35 on performance objectives to be achieved by licensees and is allowing licensees to select among the various performance standards to meet the objective of the regulation. This provides a licensee significant flexibility in designing its radiation protection program.

For example, in developing the final rule for the therapeutic uses of sealed sources, the NRC consulted several AAPM Radiation Therapy Committee Reports, including: Task Group 40 (Comprehensive QA for Radiation Oncology, 1994); Task Group 56 (Code of Practice for Brachytherapy Physics, 1998); Task Group 59 (HDR Treatment Delivery Safety, 1997 Draft); and AAPM Report No. 54 (Stereotactic Radiosurgery, 1995).

In addition to the AAPM, other groups and societies set professional radiation safety and practice standards for medical use. NRC plans to review such standards for possible use in developing regulatory positions (e.g., National Council on Radiation Protection and Measurements, Health Physics Society, and Society of Nuclear Medicine).

**Issue 3: Does the Existence of Professional Standards Mean That NRC Regulation Is Unnecessary?**

*Comment.* Several commenters expressed the opinion that NRC regulations were unnecessary. They believe that NRC should not make regulations or license conditions out of industry or professional standards, because that reduces flexibility (i.e., regulations cannot evolve as quickly and easily as professional standards). In their opinion, NRC should recognize that these standards are implemented by other appropriate oversight bodies and that the existence of professional standards should signal to the NRC that regulation is unnecessary. Finally, these commenters indicated that a mechanism is needed to require the NRC to justify why an implemented industry standard is not acceptable.

*Response.* The Commission disagrees with the comment about professional standards necessarily replacing NRC's radiation safety requirements. Many of the professional standards are voluntary in nature, do not have the force of law, and may not meet the definition of a consensus standard under the NTTAA. As such, not all professional standards are adequate to meet the Commission's objectives for the regulation of medical use of byproduct material.

The Commission must consider industry consensus standards before a "government-unique standard" is promulgated. The process is described in NRC Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards." Further information on this topic is available on the NRC's web site, [www.nrc.gov/reference\\_library/standards\\_program/reference\\_documents](http://www.nrc.gov/reference_library/standards_program/reference_documents), e.g., Public Law 104-113, "National Technology Transfer Advancement Act of 1995" (NTTAA), OMB Circular on implementation of the NTTAA, NRC Annual Standards Reports (listings of consensus standards endorsed by NRC).

For example, NRC reviewed the technical literature to identify consensus standards and protocols that could be used or referenced in the rule and guidance document, thereby avoiding promulgation of "government-unique standards" when revising the MPS, 10 CFR part 35, and NUREG 1556 (Volume 9). Part 35, subparts C, F, and H, describe various performance objectives to be achieved (e.g., calibration of survey instruments, calibration of radiation sources used for manual brachytherapy and used in radiation therapy devices, and acceptance testing of treatment planning computers): A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the AAPM. Alternatively, a licensee may select and implement an appropriate voluntary performance standard from a published protocol that was accepted by a nationally recognized body in order to meet the performance objectives of these regulations. This approach is consistent with the Commission's goal to develop regulations that are more performance-based. The Commission believes this approach provides significant flexibility for medical use licensees to design radiation protection programs that, when fully implemented, maintain radiation exposures to workers, patients, and the public to levels that are as low as are reasonably achievable.

Dated at Rockville, Maryland, this 27th day of July, 2000.

For the Nuclear Regulatory Commission,  
Annette L. Vietti-Cook,  
Secretary of the Commission.