



# **Department of Veterans Affairs Office of Inspector General**

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## **Healthcare Inspection**

### **Radiation Safety in Veterans Health Administration Facilities**

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# Contents

	Page
<b>Executive Summary</b> .....	i
<b>Introduction</b> .....	1
Purpose.....	1
Background .....	1
Scope and Methodology .....	3
<b>Radiation Modalities and Review Results</b> .....	4
Radiation Therapy.....	4
Computed Tomography .....	6
Fluoroscopy .....	8
Nuclear Medicine.....	10
<b>Conclusions</b> .....	12
<b>Recommendations</b> .....	12
<b>Comments</b> .....	13
<b>References</b> .....	14
<b>Appendixes</b>	
A. Sites Visited for Radiation Safety Review .....	16
B. Under Secretary for Health Comments.....	17
C. OIG Contact and Staff Acknowledgments.....	22
D. Report Distribution .....	23

## Executive Summary

As requested by the U.S. House of Representatives Committee on Veterans' Affairs, we evaluated program oversight and quality assurance (QA) processes for diagnostic and therapeutic radiation procedures at Veterans Health Administration (VHA) facilities. The review focused on four areas associated with the greatest potential for harm—radiation therapy (RT), computed tomography (CT), fluoroscopy, and nuclear medicine. We excluded brachytherapy as this has been examined in detail in a recent OIG report.

To evaluate RT care, we queried 32 VHA facilities about processes pertaining to physician peer review (PPR) and conducted onsite inspections at 26 facilities. Site visits focused on compliance with American College of Radiology QA requirements for RT. For the 41 linear accelerators at the 26 facilities we inspected, there were 1,092 treatment days during April–May 2010. We found a day for one linear accelerator on which a daily machine check was not documented. All but 1 of the 771 treatment records reviewed for patient-specific QA demonstrated full compliance. For PPR, we found that the 32 RT programs varied widely with respect to the frequency of peer reviews.

VHA has disseminated information to hospital radiology departments in an effort to reduce CT dose variability, but we found no oversight of actual doses being delivered. In our review of patients with the highest cumulative radiation doses from CT scans, we found that neither patients nor providers had data about cumulative radiation exposure available to them at the time of clinical decision making. We also found that patients were not informed that CT scans may cause cancer. To explore the issue of radiation exposures which may confer a particularly high risk of cancer, we identified patients who had undergone multiple CT scans. Based on published estimates of radiation levels associated with each type of CT study, we enumerated those patients with the greatest cumulative radiation exposure.

For nearly 2 years, VHA has been developing, but has yet to publish, guidance regarding the use of fluoroscopy. In nuclear medicine, VHA monitors data provided by all facilities and proficiency assessments are accomplished annually.

We recommended that the Under Secretary for Health: (1) clarify the current expectations for frequency of PPR in RT, (2) develop a process for monitoring delivered radiation dose to ensure that patients do not receive excessive doses from CT scans, (3) develop risk-based criteria for informed consent prior to CT scans, (4) plan for the development of a mechanism by which patients and providers have information about prior radiation exposure available to them at the time of clinical decision making, and (5) ensure that the fluoroscopy handbook is implemented.

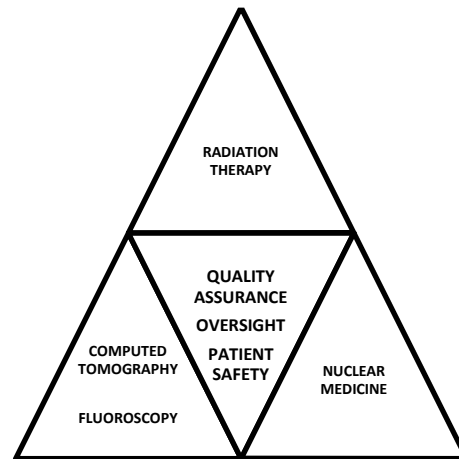
The Under Secretary for Health agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

# Introduction

## Purpose

On January 28, 2010, the U.S. House of Representatives Committee on Veterans' Affairs requested that the VA Office of Inspector General (OIG) investigate “quality assurance and program management of all nuclear medical care, patient safety, and oversight at the Department of Veterans Affairs.”

This review evaluated program oversight and quality assurance (QA) processes for diagnostic and therapeutic radiation procedures at Veterans Health Administration (VHA) facilities, with a focus on areas with the greatest potential for harm to patients—computed tomography (CT), fluoroscopy, nuclear medicine, and radiation therapy (RT).



## Background

Radiation has been used for more than a century to diagnose diseases and conditions, contributing greatly to advances in medical care. While any exposure to radiation entails the possibility of harm, the benefits from more accurate diagnosis are generally considered to exceed the risks inherent in radiation exposure. However, with the increased application of sophisticated technologies involving radiation, concerns have arisen about whether radiation is being used appropriately.

Many imaging procedures are employed in current medical practices, but most radiation exposure associated with diagnosis occurs with CT, fluoroscopy, and nuclear medicine studies. Because these procedures involve repeated or extended exposure to radiation, they are associated with a higher radiation dose. Although CT, fluoroscopy, and nuclear medicine studies account for only 26 percent of imaging performed annually in the U.S., together they comprise 89 percent of the total yearly exposure of patients to radiation.<sup>1</sup>

While the magnitude of increased cancer risk from exposure to diagnostic radiation is debated, some degree of increased risk is implicit.<sup>2</sup> Patient safety is optimized when clinical practice guidelines are followed, equipment is functioning properly, staff adhere to standardized procedures, shielding and engineered safety features are employed, and radiation doses are as low as reasonably achievable.<sup>3,4</sup>

In October 2009, officials at Cedars-Sinai Medical Center in Los Angeles notified the Food and Drug Administration (FDA) that more than 200 patients had received excessive radiation while undergoing CT perfusion scans. Because these studies require multiple scans during intravenous injection of a contrast agent, they entail substantially more radiation exposure than more typical CT scans. The FDA subsequently identified additional patients at other hospitals who were exposed to excessive levels of radiation and in February 2010 issued interim recommendations to address ongoing concerns about CT perfusion imaging.<sup>5</sup>

In December 2009, a VHA survey found that 12 facilities performed CT brain perfusion scans.<sup>6</sup> None of the 984 brain scans reported by these 12 facilities were described as exceeding the maximum recommended radiation dose. Subsequently, VHA instructed radiology service chiefs and chief technologists on calculation of CT radiation dose, methods to control dose, target dose levels, and levels that would require disclosure to the patient.

In contrast to diagnostic radiology, such as CT and fluoroscopy, which uses x-rays from outside the body, nuclear medicine makes use of radioactive materials which are ingested, inhaled, or injected into the body. The use of radioactive materials in nuclear medicine provides an assessment of metabolic function and may be diagnostic or therapeutic in nature.

According to the American Nuclear Society, an estimated 10 to 12 million diagnostic and therapeutic nuclear medicine procedures are performed each year in the U.S. In fiscal year (FY) 2008, VHA's Nuclear Medicine and Radiation Service (NMRS) program reported that VHA facilities performed 602,895 procedures. Cardiac procedures comprised about 75 percent of the workload while positron emission tomography/CT (PET/CT) studies grew at the fastest rate (an average of 25 percent in each of the previous 3 FYs).<sup>7</sup>

Radiation can also be used therapeutically to treat cancers and other abnormal cell growth while protecting normal cells as much as possible. In the most common form of RT, conventional or external beam RT, intense radiation from linear accelerators is directed at tumors. With intensity modulated RT (IMRT), higher doses can be delivered to abnormal tissue while reducing exposure of adjacent non-target structures.<sup>8</sup>

With higher doses and better targeted delivery of radiation, IMRT offers the possibility of more effective treatment with fewer side effects. However, its use also carries an increased risk of harm to patients when practice guidelines and patient safety systems are not in place or are not followed. On January 27, 2010, the New York Times reported that 36 cancer patients at the East Orange campus of the VA New Jersey Health Care System had been over-radiated and that 20 more had received inappropriately low doses of radiation.

## Scope and Methodology

For this evaluation, we considered all diagnostic and therapeutic uses of radiation but excluded brachytherapy because this form of treatment has been examined in detail in a recent OIG report.<sup>9</sup> We explored issues pertinent to radiation safety with VHA and private sector experts and focused this review on four areas of medical imaging modalities considered to involve the greatest potential for harm to veterans—RT, CT, fluoroscopy, and nuclear medicine.

To evaluate RT care, we queried 32 VHA facilities about processes pertaining to physician peer review and conducted onsite inspections at 26 facilities from August 10 through September 3, 2010. Prior to site visits, we developed and pilot-tested our inspection measurements at an academically affiliated VHA facility. Site visits focused on compliance with key elements of American College of Radiology (ACR) machine- and patient-specific QA requirements for RT<sup>9,10</sup> as well as compliance with required physician peer review activities.<sup>10,11</sup>

We inspected all 23 RT programs that performed IMRT as of May 2010. In addition, we visited a probability-based random sample of three of the nine facilities that provided conventional RT only. Appendix A lists the facilities inspected.

For onsite inspections of patient-specific QA documentation, we statistically and randomly selected 30 patients who had undergone treatment during October 2009–May 2010 from each of the 26 VHA facilities. For the 23 IMRT sites, we selected IMRT patients for onsite QA documentation inspection because the documentation to be reviewed for conventional patients was included in the documentation to be reviewed for IMRT patients.

All IMRT patients were included in our review if the facility had 30 such patients or fewer. For the IMRT sites with fewer than 30 patients, we sampled additional conventional RT patients.

For onsite machine-specific QA documentation inspection, we verified the existence of each machine's QA documentation for the daily and monthly checks for April and May 2010, annual machine calibration during July 2009–August 2010, and biennial dosimetry system check during July 2008–August 2010.

To evaluate CT, fluoroscopy, and nuclear medicine procedures, we reviewed VHA documents and interviewed VHA radiology and nuclear medicine leaders. We also reviewed requirements and guidelines published by various regulatory and professional organizations, including the Nuclear Regulatory Commission (NRC), the FDA, the ACR, and the American Association of Physicists in Medicine (AAPM).

To explore the issue of radiation exposures which may confer a particularly high risk of cancer, we identified VHA patients who underwent CT scans of the chest, abdomen, or pelvis during 2009. We excluded CT scans of the head because, except for perfusion studies, these scans entail lower levels of radiation exposure. Adverse effects of low-dose radiation exposure are believed to manifest over many years; therefore, we excluded patients older than 40 and for this analysis considered only patients who were ages 39–40 at the time of their most recent scan. Based on published estimates of radiation levels associated with each type of CT study,<sup>12</sup> we enumerated those patients with the greatest cumulative radiation exposure from the selected CT scans performed during 2005–2009, excluding patients for whom scans were associated with a cancer diagnosis.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## **Radiation Modalities and Review Results**

### **Radiation Therapy**

**Overview.** ACR practice guidelines and standards for RT, in place since 1990, were revised in 2009.<sup>10</sup> RT delivers radiation to targeted tissue while limiting the radiation dose to surrounding healthy tissue to an acceptable level.

Because of the higher doses of radiation typically delivered, IMRT entails a higher risk of complications and therefore requires specific QA processes to ensure accurate and reproducible radiation delivery. An effective QA program for IMRT includes systematic testing of hardware and software as well as reviews of each patient’s treatment plan and of the actual implementation of that plan.

Peer review is an organizational function designed to maintain and improve the quality of care through assessments of individual professionals by other peer professionals or a committee of professionals. Peer review encompasses various activities, including evaluations in response to specific clinical incidents and ongoing professional practice evaluation.<sup>11</sup> With respect to IMRT, ACR practice guidelines specify that radiation oncologists must “participate in the peer review of contours and IMRT treatment plans in conjunction with other members of the team.”<sup>13</sup>

### **Review Results**

**Machine-Specific QA.** Inspectors examined documentation of the following:

- Daily machine output checks performed on each linear accelerator prior to the performance of any RT procedure during April and May 2010.
- Monthly verifications by a medical physicist during April and May 2010.



- Annual calibration analyses performed by a medical physicist during July 2009–August 2010.
- Biennial dosimetry system check by a certified laboratory during July 2008–August 2010.

The 41 linear accelerators at the 26 VHA facilities visited provided 1,092 treatment days during April and May 2010. We found 1 day for one linear accelerator on which a daily machine check was not documented.

**Patient-Specific QA.** For this component of the review, we reviewed the treatment records of randomly selected patients. Review elements included verification that a treatment plan was in place and that a second, independent verification of plan calculations had been performed. For conventional (non-IMRT) treatments, inspectors also sought documentation that the treatment plan had been compared with a phantom\* prior to treatment.

We reviewed a total of 771 patient treatment records (649 IMRT and 123 conventional RT).† With the exception of one conventional RT patient who was undergoing palliative treatment, we found that every treatment record at the 26 VHA facilities demonstrated compliance with patient-specific QA requirements.

**Physician Peer Review.** For this component of the review, we assessed all 32 VHA RT programs and found wide variation in the nature and frequency of physician peer review.

All 32 facilities had physician peer review processes in place for RT. Four facilities within one Veterans Integrated Service Network (VISN) (3) accomplished reviews collaboratively. We observed paperless systems for peer review documentation at two facilities—the East Orange campus of the VA New Jersey Health Care System and the Louis Stokes VA Medical Center in Cleveland, OH. Nine facilities (28 percent) described substantial dependence on locum tenens contractors, fee basis, and university- and military-affiliated physicians.

We noted variation in the frequency of peer reviews conducted at the 32 facilities, ranging from weekly in 18 facilities (56 percent) to bi-annually at 1 facility (3 percent). Six facilities (19 percent) reported that peer reviews occurred at least monthly, and seven (22 percent) reported that peer reviews occurred at least quarterly.

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\* A phantom is an object with mass, composition, and dimensions resembling a body or body part used to measure absorption of radiation.

† Information was received on 4,308 patients who had undergone external beam RT at 26 facilities; 266 cases (6 percent) were excluded because therapy type was not specified or therapy was initiated outside of the review period.

## **Summary**

We found compliance with standards of practice for machine- and patient-specific QA processes in VHA RT programs. However, we found inconsistent physician peer review practices, which could be improved by clarifying national expectations for frequency of physician peer review practices in RT.

## **Computed Tomography**

**Overview.** CT is a radiographic technique that constructs three-dimensional images from a series of cross-sectional images or “slices.” CT typically requires repeated or extended radiation exposures with radiation doses higher than other frequently performed x-ray tests. For example, the radiation dose for an abdominal CT scan is more than 10 times the dose for a mammogram and more than 150 times the dose for a chest x-ray.<sup>12</sup>

The number of CT scans performed per year has increased dramatically in recent decades from 3 million in 1980 to 70 million in 2007. More than 1.5 million CT scans are performed annually in VHA facilities.<sup>14</sup>

Two recent studies highlighted the potential consequences of radiation exposure from commonly performed CT scans, indicating that radiation doses are probably higher than previously believed and may cause tens of thousands of future cancer cases.<sup>15,16</sup> One publication found a surprising degree of dose variability among CT scanners at four hospitals in the San Francisco area, with doses generally higher than expected. Within each type of CT scan, doses varied significantly within and across institutions, with a mean 13-fold variation between the highest and lowest dose for each study type.<sup>16</sup> In response to those studies, the ACR issued a statement pointing out the established benefits of diagnostic imaging, the uncertainty regarding associated cancer risk, and the continuing need to evaluate the appropriate use of imaging in clinical practice.<sup>17</sup>

Older CT scanners lack displays of dose metrics. Newer CT scanners either display dose metrics at the operator’s console, or dose metrics are embedded with the image itself. These displays provide parameter settings that optimize both the radiation dose and the alert system when the radiation dose in a given scan exceeds a particular reference level. Older scanners also lack the ability to calculate cumulative dose and report standardized dose. This is a concern because cumulative radiation dose information can be used by the physician to order the most appropriate diagnostic exam.

## **Review Results**

**Dose Variability.** VHA has disseminated program standards which specify methods of measuring delivered dose and upper limits of acceptable dose.<sup>14</sup> However, we found an absence of oversight to ensure that delivered doses of radiation are not excessive.

**Cumulative Dose.** Experts have estimated that as many as 800 malignancies will be caused by the 1.5 million CT scans performed in VHA facilities annually.<sup>14</sup> Although the magnitude of cancer risk from diagnostic imaging is debated, professional consensus is that the induced risk of cancer from CT scans is substantial. For relatively young people undergoing multiple scans, the risk probably exceeds 1:500, and disclosure of risk is warranted.<sup>18</sup>

In our review of 40-year-old patients who had CT scans of the chest, abdomen, or pelvis over a period of 5 years, we identified those individuals with the highest cumulative radiation dose from these procedures. After excluding patients with cancer diagnoses, who often require multiple imaging procedures, we determined the reason for the most recent scan in the treatment of 10 individuals. See the table on the next page.

Notably, only four of the requesting providers indicated awareness that their patients had had multiple prior CT scans, and VHA has no mechanism to inform patients and providers of cumulative radiation exposure prior to further medical imaging. Additionally, there was no documentation that any of the patients had been informed about the risk of or alternatives to CT scans.

We also noted that in 5 of the 10 cases, a provisional diagnosis describing the need for a scan was not specified by the requesting provider. In our interviews with VHA leaders, we found that VHA has no mechanism to ensure that CT scans are requested appropriately. Although appropriateness criteria have been promulgated,<sup>19</sup> they are not readily available to providers at the time of order entry in VHA's electronic medical record.

	Reason for Most Recent CT	Other Clinical Condition(s)	Estimated 5-year cumulative dose, mSv
1	Chronic inguinal pain	Irritable bowel syndrome, history of kidney stones	140
2	Abdominal pain with UTI	PTSD, irritable bowel syndrome	130
3	Abdominal pain	Adjustment disorder	128
4	Abdominal pain	Recurrent diverticulitis	120
5	Chronic abdominal pain	History of gastric bypass, lumbar pain, menorrhagia	120
6	Follow-up after bowel resection for IBD		120
7	Flank pain	PTSD, depression	120
8	Kidney cyst	HIV infection	114
9	Flank pain	Diabetes, hypertension, recent stroke	108
10	Flank pain	Chronic back pain, anxiety	108

**Table. Clinical conditions and radiation cumulative dose for chest, abdomen, and pelvis CT scans among patients ages 39-40 (eight male, two female) with non-cancer diagnoses and multiple prior CT scans.**

A single CT scan of the abdomen is associated with an effective radiation dose of approximately 10 mSv. The effective dose for a single chest x-ray is 0.04 mSv.<sup>12</sup>

mSv = millisievert, a measure of the biological effect of absorbed radiation on specific tissues;  
 IBD = inflammatory bowel disease; PTSD = post-traumatic stress disorder; UTI = urinary tract infection; HIV = human immunodeficiency virus.

## **Summary**

VHA needs to ensure that patients undergoing testing with CT scans receive non-excessive doses of radiation. Better clinical decisions could result if patients and clinicians were aware of past radiation exposures.

## **Fluoroscopy**

**Overview.** Fluoroscopy is a technique for generating x-ray images and presenting them continuously during a diagnostic or interventional procedure. An x-ray beam is transmitted through the patient and onto a fluorescent screen coupled with an “image intensifier” that produces real-time or “live” images on a television monitor.

Fluoroscopic imaging devices are widely utilized throughout VHA facilities both within and outside of radiology departments. The benefit of utilizing fluoroscopy over other modalities is its ability to transmit live images during the course of a procedure. With fluoroscopy, the passage of contrast material can be tracked through the gastrointestinal

system. Fluoroscopy also permits visualization of blood flow to organs and controlled manipulation of devices.

Common procedures that utilize fluoroscopy are upper and lower gastrointestinal studies, cardiac catheterization, intravenous catheter placement, orthopedic surgery, angiography of the leg and cerebral vessels, and urological surgery. Services within a medical facility that utilize fluoroscopes include but are not limited to radiology, cardiology, RT, orthopedic surgery, gastroenterology, vascular surgery, and urology.

Many patients benefit from fluoroscopic procedures, but this use of radiation constitutes a potential hazard if administered incorrectly.<sup>20</sup> Fluoroscopes can deliver large doses of radiation, increasing the long-term risk of cancer and subjecting patients to the possibility of immediate harm from skin injury.<sup>21,22</sup>

The National Health Physics Program (NHPP) provides oversight for radiation safety throughout VHA. The NHPP's mission is to assist Radiation Safety Officers (RSOs) and other personnel working with radiation by making relevant information easily and readily accessible.<sup>23</sup>

The Radiology Program Office recommends courses of action to VHA headquarters, VISNs, and facility staff regarding trends in imaging in order to facilitate timely, cost effective, and high quality diagnostic care for patients. It also provides guidance for VHA radiology programs through the Radiology Field Advisory Group.<sup>24</sup>

## **Review Results**

Since early 2009, VHA has been developing a fluoroscopy handbook which incorporates guidance from the AAPM, the ACR, the FDA, and the National Council on Radiation Protection and Measurements. The VA Online Radiology Guide also provides guidelines on radiation safety relative to fluoroscopy.<sup>25</sup>

According to the National Radiation Safety Group, a team of radiation safety experts within VHA, policies addressing fluoroscopy safety practices have been developed by each facility.

The Joint Commission considers prolonged fluoroscopy time as a reviewable sentinel event. Therefore, facilities are required to maintain a log book to record the duration of fluoroscopy procedures and to have a process to follow if the facility-established threshold for allowable fluoroscopy time is exceeded.<sup>26</sup> In addition, various regulatory agencies have developed practice guidelines and standards for QA and quality control (QC).<sup>‡</sup>

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<sup>‡</sup> QC is a set of procedures intended to ensure adherence to a defined set of performance criteria.

## **Summary**

Patient safety during fluoroscopy procedures could be enhanced by the completion and implementation of VHA's fluoroscopy handbook so that specific standards are established for fluoroscopy care in all VHA facilities.

## **Nuclear Medicine**

**Overview.** Nuclear medicine diagnostic procedures involve the use of small amounts of radiopharmaceuticals (also referred to as tracers) to examine organ function and structure. For these procedures, a tracer is injected into a vein, swallowed, or inhaled as a gas. After accumulating in the area of the body being examined, the tracer emits energy in the form of gamma rays. This energy is detected and used for computer-generated images showing both structure and function of the tissues being examined.

Therapeutic procedures entail the use of radioactive materials to deliver therapeutic doses of radiation to specific tissues. In a typical procedure for the treatment of thyroid cancer, radioactive iodine ( $^{131}\text{I}$ ) is swallowed, absorbed from the gastrointestinal tract, and concentrated from the blood into the thyroid gland.

Because of their potentially hazardous properties, the use of radioactive materials is closely regulated by the NRC. The Code of Federal Regulations sets forth requirements pertaining to the use of radioactive by-product materials for medical use.<sup>§</sup> The NRC ensures that users of radioactive materials keep radiation exposure within the agency's specified dose limits and as low as reasonably achievable. Users are required to be licensed and must undergo inspections by the NRC to ensure safe practices with radioactive materials and compliance with regulations.

In 2003, the NRC issued a Master Materials License (MML) to the VA. The VA NHPP manages the MML and issues each VHA facility a Materials Permit for all use of radioactive materials. Under the guidance of the VA National Radiation Safety Committee (NRSC), the NHPP provides regulatory oversight for the NRC's MML, which entails permitting the use of radioactive materials, conducting onsite inspections, and investigating allegations and incidents.

As with other imaging modalities, patients undergoing nuclear medicine procedures are exposed to ionizing radiation. Minimizing the risk of medical radiation requires reducing unnecessary use of radiation in diagnosis and treatment and ensuring that equipment and practices meet regulatory standards.

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<sup>§</sup> Title 10 of the Code of Federal Regulations, Part 35 (10 CFR Part 35).

## **Review Results**

In 1991, VHA established the NMRS to advise the Under Secretary for Health on all matters related to nuclear medicine and radiation safety. The NMRS has issued guidance to promote and monitor quality of care and safety practices in nuclear Medicine.<sup>27</sup> Additionally, the NMRS has instituted annual reporting of nuclear medicine services' resource utilization and performance with respect to quality and safety. Also, the NMRS has developed guidelines for screening procedure requests for appropriateness based on published criteria.<sup>28</sup>

As authorized under the NRC's MML, the NRSC has primary oversight responsibility for all uses of ionizing radiation at all VHA facilities.<sup>29</sup> The NRSC maintains and implements the MML through NHPP. In turn, NHPP directs the day-to-day implementation of the MML and coordinates NRSC activities. In addition, NHPP provides consultations and performs reactive and proactive inspections to investigate incidents and evaluate regulatory compliance.

At the facility level, the Director is the individual responsible for ensuring regulatory compliance and safe use of radioactive materials. Generally, this responsibility is delegated to the facility Radiation Safety Committee (RSC) and the RSO. The RSC develops local policies for the control of the administration of radio-labeled blood products.<sup>30</sup> The RSO completes day-to-day activities and performs an annual review of the Radiation Safety Program.

Nuclear Medicine Services are required to develop a comprehensive program that includes daily QC procedures for gamma cameras and other equipment, protocols for each nuclear medicine procedure, review of scan requests for appropriateness, and imaging proficiency and radio-bioassay laboratory testing.

To assess proficiency, NMRS contracts with the Society for Nuclear Medicine to provide VHA facilities with phantom testing materials annually. These exercises are designed to test each facility's ability to display images, identify abnormalities, and formulate a clinical diagnosis.

Clinical laboratories oversee radio-bioassay testing or the measurement of radioactivity in body fluids, and the College of American Pathologists conducts regular onsite inspections to ensure compliance with regulatory requirements.

## **Summary**

Overall, we determined that VHA has appropriate oversight and QA activities to minimize radiation risks to nuclear medicine patients at VHA facilities.

## Conclusions

We found compliance with standards of practice for machine- and patient-specific QA processes in RT. However, we found inconsistent performance of physician peer review, which could be improved by clarifying national expectations for frequency of physician peer review practices in RT.

Regarding CT scans, we found an absence of oversight to ensure that delivered doses of radiation are not excessive. We also found that patients are not routinely informed prior to imaging procedures which carry a significant risk of induced cancer. Further, we identified a need for patients and providers to have information about prior radiation exposure available to them at the time of clinical decision making.

Patient safety during fluoroscopy procedures could be enhanced system wide with expedited implementation of the VHA fluoroscopy handbook.

We found that VHA has appropriate oversight and QA activities in place to minimize radiation risks to nuclear medicine patients.

## Recommendations

We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers:

**Recommendation 1:** Clarify the current expectations for frequency of physician peer review practices in RT.

**Recommendation 2:** Develop a process for monitoring delivered radiation dose to ensure that patients do not receive excessive doses during CT procedures.

**Recommendation 3:** Develop criteria for patient informed consent requirements prior to CT testing.

**Recommendation 4:** Include in strategic planning a mechanism by which patients and providers have information about prior radiation exposure available to them at the time of clinical decision making.

**Recommendation 5:** Ensure that the fluoroscopy handbook is implemented.



## Comments

The Under Secretary for Health agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up until all actions are completed.

*(original signed by:)*

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- <sup>28</sup> Department of Veteran Affairs. Nuclear Medicine Radiation Safety Services Appropriateness Criteria for Commonly Performed Nuclear Medicine Imaging Procedures, February, 2007.
- <sup>29</sup> VHA Memorandum Delegation of Authority, Under Secretary for Health, September 21, 1998.
- <sup>30</sup> VHA Directive 2010-037, *Administrative Practices for Ensuring Safe Injection of Radio-Labeled Blood Products*, August 17, 2010.

## Sites Visited for Radiation Safety Review

Name	Location	VISN
Samuel S. Stratton VA Medical Center	Albany, NY	2
James J. Peters VA Medical Center	Bronx, NY	3
VA NY Harbor Healthcare System, Brooklyn Campus	Brooklyn, NY	3
VA New Jersey Health Care System, East Orange Campus	East Orange, NJ	3
Northport VA Medical Center	Northport, NY	3
Philadelphia VA Medical Center	Philadelphia, PA	4
VA Pittsburgh Healthcare System	Pittsburg, PA	4
Washington DC VA Medical Center	Washington, DC	5
Hunter Holmes McGuire VA Medical Center	Richmond, VA	6
Durham VA Medical Center	Durham, NC	6
Atlanta VA Medical Center	Decatur, GA	7
Miami VA Healthcare System	Miami, FL	8
James A. Haley Veterans' Hospital	Tampa, FL	8
Mountain Home VA Medical Center	Mountain Home, TN	9
Memphis VA Medical Center	Memphis, TN	9
Louis Stokes VA Medical Center	Cleveland, OH	10
Dayton VA Medical Center	Dayton, OH	10
VA Ann Harbor Healthcare System	Ann Harbor, MI	11
Richard L. Roudebush VA Medical Center	Indianapolis, IN	11
Edward Hines Jr. VA Hospital	Hines, IL	12
Clement J. Zablocki VA Medical Center	Milwaukee, WI	12
St. Louis VA Medical Center	St. Louis, MO	15
Michael E. DeBakey VA Medical Center *	Houston, TX	16
VA North Texas Health Care System – Dallas VA Medical Center	Dallas, TX	17
VA Greater Los Angeles Healthcare System	Los Angeles, CA	22
VA Long Beach Healthcare System	Long Beach, CA	22
Minneapolis VA Health Care System	Minneapolis, MN	23

\* pilot site

## Under Secretary for Health Comments

**Department of  
Veterans Affairs**

### Memorandum

**Date:** Feb 17, 2011

**From:** Under Secretary for Health (10)

**Subject:** OIG Healthcare Inspection Draft Report, Radiation Safety in Veterans Health Administration Facilities (VAIQ 7013978)

**To:** Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with all five of the of the report's recommendations. Attached is VHA's corrective action plan for the report's recommendations.
2. Thank you for the opportunity to review the draft report. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10B5) at (202) 461-7014.



Robert A. Petzel, M.D.

Attachment

## VETERANS HEALTH ADMINISTRATION (VHA) Action Plan

### OIG Draft Report, Radiation Safety in Veterans Health Administration Facilities (VAIQ 7013978)

**Date of Draft Report: December 9, 2010**

Recommendations/ Actions	Status	Completion Date
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We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers:

**Recommendation 1:** Clarify the current expectations for frequency of physician peer review practices in RT.

#### VHA Comments

Concur

VHA concurs about the need for a robust physician peer review process related to all RT programs; however, VHA also notes that the variation in the types of practices throughout the country requires that VHA evaluate what works best in an individual practice depending on its unique characteristics. This is in the context of the broad expectations included in the physician peer requirements used in the American College of Radiology (ACR) accreditation process, and the 2007 Joint Commission medical call standards that placed a renewed emphasis on measurement of practitioner competency.

The current nationally defined expectation regarding the frequency of physician peer review practice for RT is that they are to be done either through weekly case conference reviews, or through periodic peer reviews of each physician. The selection of one system over the other depends upon available physician staffing, or the association with a university affiliate. In some cases, facilities do both types of physician peer review. While periodic physician peer review in RT by a second physician must occur on at least a semi-annual basis, new case peer reviews occur weekly. Either of these processes meets the ACR requirement for physician peer review.

The 2007 Joint Commission medical call standards do not specifically quantify a timeframe for ongoing evaluations, but the suggestion has been that, at a minimum, clinical leadership must be able to demonstrate that it examines relevant provider data every 6 months and is able to demonstrate continuous monitoring of important aspects of care on a frequent basis.

In recognition of the OIG concern and to ensure that satisfactory peer review processes are in place for each RT practice, the National Director for the Radiation Oncology Program will review and verify by March 1, 2011, that the frequency for each practice is appropriate. Also, two methods for providing weekly case conference reviews to every VHA radiation oncology practice are under consideration. Technical issues preclude implementation in the near future, but evaluation of these possibilities will be ongoing.

Completed

**Recommendation 2:** Develop a process for monitoring delivered radiation dose to ensure that patients do not receive excessive doses during CT procedures.

#### VHA Comments

Concur

VHA's Radiology Program Office and the National Health Physics Program will develop guidelines for monitoring computed tomography (CT) exposures. Statements from professional societies will be utilized in formulating this guide. The guideline will define the following parameters:

- What radiation dose measurements should be monitored and in what units the measurements should be recorded.
- Reference and alert values for common CT procedures.
- Resource materials to assist radiology services in reviewing protocols and choosing acquisition parameters.
- Reporting procedure for doses that exceed reference values.

VHA's Radiology Program Office and the National Health Physics Program will collaborate with the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to test the guidelines at select field locations. The guidelines will be composed by May 2011. Once testing has been completed, the guidelines will be converted into Directives for all facilities to utilize.

In process

May 31, 2011

**Recommendation 3:** Develop criteria for patient informed consent requirements prior to CT testing.

VHA Comments

Concur

VHA's Radiology Program Office, the National Center for Ethics in Healthcare, and the National Health Physics Program, will develop a patient information sheet to educate patients on stochastic and deterministic risk. They will also establish criteria for obtaining signature informed consent for high-risk CT scans. This criteria will be based on parameters such as age, life expectancy, and predicted dose. VHA Handbook 1004.01 "Informed Consent for Clinical Treatments and Procedures," will be appropriately updated.

In process

June 30, 2011

**Recommendation 4:** Include in strategic planning a mechanism by which patients and providers have information about prior radiation exposure available to them at the time of clinical decision making.

VHA Comments

Concur

VHA's Radiology Program Office has entered a New Service Request for an information system that will automatically collect procedure radiation dose from imaging equipment, save the data in a registry, and display the information at the time of order entry or ad hoc. Patients will be counseled about the availability of this information and may request a list of procedures and approximate radiation doses. Completion of this project will depend on funding. The Veterans Health Information Systems and Technology Architecture (VistA) Imaging development team has begun analysis of data extraction from image files which will be completed in July 2011.

In process

July 31, 2011

**Recommendation 5:** Ensure that the fluoroscopy handbook is implemented.

VHA Comments

Concur



VHA's Radiology Program Office, the National Health Physics Program Office, and the Office of Medical Staff Affairs within VHA's Chief Quality and Performance Office will finalize the Fluoroscopy Handbook. The remaining task is to define what personnel can operate fluoroscopes. State laws differ on operation and supervision requirements for such individuals as nurses, nurse practitioners, and physician assistants.

In process

May 31, 2011

Veterans Health administration  
February 2011

## OIG Contact and Staff Acknowledgments

OIG Contact	Daisy Arugay, MT Los Angeles Office of Healthcare Inspections
Acknowledgments	Limin X. Clegg, PhD Matthew Frazier, MBA Douglas Henao, RD Jerome E. Herbers, MD Simonette Reyes, RN Kathi Shimoda, RN Mary Toy, RN Julie Watrous, RN Elizabeth Bullock, Program Support

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