



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

Office of Healthcare Inspections

Report No. 16-03920-197

Evaluation of Computed Tomography Radiation Monitoring in Veterans Health Administration Facilities

April 11, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General completed a healthcare evaluation of computed tomography (CT) radiation monitoring in Veterans Health Administration facilities. The evaluation determined whether facilities complied with selected Veterans Health Administration radiation safety requirements.

CT combines a series of x-ray images to create cross-sectional images of the body. Sophisticated computers process the data to generate three-dimensional CT images of the inside of the body that can reveal the presence of disease or injury. CT scans are extremely helpful in diagnosing serious injuries to the head, chest, abdomen, spine, and pelvis. CT scans can also pinpoint the size and location of tumors. However, CT scans also contribute significantly to the amount of total patient radiation exposure and could result in the development of future cancers. For this reason, clinicians should eliminate avoidable exposure.

We performed this evaluation in conjunction with 56 Combined Assessment Program reviews conducted from April 1, 2015 through March 31, 2016.

We noted high compliance with VHA requirements in multiple areas. For example, facilities had designated Radiation Safety Officers; clinicians documented radiation doses as required by facility policy; CT technologists were certified, received selected training, and had dosimetry monitoring.

We identified a system weakness and recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure a medical physicist inspects CT scanners after repairs or modifications that affect the dose or image quality prior to returning the scanners to clinical service.

Comments

The Under Secretary for Health concurred with the report. (See Appendix A, pages 8–10, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) completed a healthcare evaluation of computed tomography (CT) radiation monitoring in Veterans Health Administration (VHA) facilities. The evaluation determined whether facilities complied with selected VHA radiation safety requirements.

Background

CT combines a series of x-ray images to create cross-sectional images of the body. The x-ray tube spins rapidly around the patient, and the x-rays strike numerous detectors after passing through the body. Sophisticated computers process the data to generate three-dimensional CT images of the inside of the body that can reveal the presence of disease or injury. CT scans are extremely helpful in diagnosing serious injuries to the head, chest, abdomen, spine, and pelvis. CT scans can also pinpoint the size and location of tumors.

According to the National Council on Radiation Protection and Measurements,¹ in 2006, medical exposure constituted nearly half of the total radiation exposure of the United States population from all sources. CT and nuclear medicine alone contributed 36 percent of the total radiation exposure and 75 percent of the medical radiation exposure of the United States population. Another report² estimated that approximately 29,000 future cancers and 14,500 future deaths could develop due to radiation exposure related to CT scans performed in the United States in 2007 based on a cancer incidence rate of 0.04 percent. Experts have estimated that as many as 800 malignancies will be caused by the 1.5 million CT scans performed in VHA facilities annually.³

While experts disagree on the risks of cancer from diagnostic imaging, clinicians should consider a risk-benefit analysis to eliminate avoidable exposure.^{4,5} Methods to eliminate avoidable exposure include establishing safety policies and procedures, reviewing CT protocols to reduce possible radiation doses, inspecting CT equipment

¹ National Council on Radiation Protection and Measurements. Report No. 160 – Ionizing Radiation Exposure of the Population of the United States. National Council on Radiation Protection and Measurements website. <http://ncrponline.org/publications/reports/ncrp-report-160/>. 2009. Accessed July 11, 2016.

² Berrington de Gonzalez A, Mahesh M, Kim K, et al. Projected Cancer Risks From Computed Tomographic Scans Performed in the United States in 2007. *Arch Intern Med*. 2009;169(22):2071–7.

³ Anderson CM. *Controlling CT Radiation Dose*. March 2010.

⁴ U.S. Food and Drug Administration, Center for Devices and Radiological Health. *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*. February 16, 2010.

⁵ National Institutes of Health, National Cancer Institute. Computed Tomography (CT) Scans and Cancer. National Cancer Institute website, <https://www.cancer.gov/about-cancer/diagnosis-staging/ct-scans-fact-sheet>. Accessed October 17, 2016.

annually and after repairs that may affect patient doses, and ensuring CT technologists are certified and appropriately trained.^{6, 7, 8}

In 2011,⁹ we published the findings from our evaluation of program oversight and quality assurance processes for diagnostic and therapeutic radiation procedures at VHA facilities. That review focused on radiation therapy, CT, fluoroscopy, and nuclear medicine. We made five recommendations, one of which was specific to CT imaging. We recommended that VHA develop a process for monitoring delivered radiation doses to ensure patients do not receive excessive radiation during CT procedures. In this current report, we note high compliance for facilities with CT quality control programs, including methods for identifying and reporting excessive patient doses.

Scope and Methodology

We performed this review in conjunction with 56 Combined Assessment Program reviews of VHA medical facilities conducted from April 1, 2015 through March 31, 2016. We excluded four facilities from the review because they did not offer onsite CT services. The facilities we visited were a stratified random sample of all VHA facilities and represented a mix of facility size, affiliation, geographic location, and Veterans Integrated Service Networks. OIG generated an individual Combined Assessment Program report for each facility. For this report, we analyzed the data from the individual OIG Combined Assessment Program CT reviews to identify system-wide trends.

Based on the sampled facilities, we analyzed compliance with selected requirements to estimate results for the entire VHA system. We presented a 95 percent confidence interval (CI) for the true VHA value (parameter).¹⁰ To take into account the complexity of our multistage sample design, we used the Taylor expansion method to obtain the sampling errors for the estimates. We used Horvitz-Thompson sampling weights, which are the reciprocal of sampling probabilities, to account for our unequal probability sampling. All data analyses were performed using SAS statistical software, version 9.4 (TS1M0), SAS Institute, Inc. (Cary, NC).

We reviewed facilities' policies and other relevant documents; 111 CT scanner inspection documents, qualification and training records of 447 technologists, and dosimetry monitoring records. We also randomly selected 50 patients from each facility

⁶ VHA Directive 1129, *Radiation Protection for Machine Sources of Ionizing Radiation*, February 5 2015.

⁷ ACR-AAPM *Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment*. Revised 2012.

⁸ VHA Handbook 5005/77, *Staffing*, June 26, 2014

⁹ OIG report, *Healthcare Inspection – Radiation Safety in Veterans Health Administration Facilities*, (Report No. 10-02178-120, March 10, 2011).

¹⁰ A CI gives an estimated range of values (calculated from a given set of sample data) that is likely to include an unknown parameter. The 95 percent CI indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

for review. Our initial electronic health records sample consisted of 2,572 patients¹¹ who had a CT scan performed January 1, 2014 through December 31, 2014.

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

¹¹ Twenty-eight patients were excluded because of reasons including CT not performed, CT performed by an outside facility, the CT was for a guided biopsy, and the CT was for research purposes.

Inspection Results

We noted high compliance with VHA requirements in multiple areas. For example, facilities designated Radiation Safety Officers (95 percent CI: 85.99–99.53); clinicians documented radiation doses as required by facility policy (95 percent CI: 94.44–98.01); and CT technologists were certified (95 percent CI: 96.83–99.51), received selected training (95 percent CI: 95.46–98.79), and had dosimetry monitoring (95 percent CI: 98.61–99.85).

CT Scanner Inspections

VHA requires the inspection of CT scanners following repairs or modifications that may affect patient dose or image quality.¹² Further, a medical physicist must perform and document testing after these repairs or modifications before the CT scanner is returned to clinical service. This testing is necessary to ensure that repaired or modified CT scanners do not expose patients to radiation doses that exceed national standards.

We estimated that 29.1 percent (95 percent CI: 16.92–45.33) of CT scanners that underwent repairs or modifications affecting image quality were not inspected by a medical physicist at VHA facilities prior to the return of the scanner to clinical service. Reasons for noncompliance with required inspections included lack of documentation and failure to notify the Radiation Safety Officer of scanner repairs.

We recommended that a medical physicist inspect CT scanners after completion of repairs or modifications that affect the dose or image quality prior to returning the scanners to clinical service.

Conclusions

We noted high compliance with VHA requirements in multiple areas. For example, facilities had designated Radiation Safety Officers; clinicians documented radiation doses as required by facility policy; CT technologists were certified, received selected training, and had dosimetry monitoring.

We identified a system weakness and recommended that a medical physicist inspect CT scanners after completion of repairs or modifications that affect the dose or image quality prior to returning the scanners to clinical service.

¹² VHA Handbook 1105.04, *Fluoroscopy Safety*, July 6, 2012.

Recommendation

1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure a medical physicist inspects computed tomography scanners after completion of repairs or modifications that affect the dose or image quality prior to returning the scanners to clinical service.

Project Questions and Data¹³

Table 1. Validated Facility Self-Assessment Responses

Question	Number No	Percent No	Total Number Yes and No	Lower 95 Percent CI	Upper 95 Percent CI
Does the facility have a designated Radiation Safety Officer?	1	2.7	52	0.47	14.01
Does the facility CT/imaging/radiation safety policy/procedure include a CT quality control program?	6	10.7	52	5.81	18.98
If yes, does the policy specify that a medical physicist monitor the quality control program at least annually?	2	3.9	46	1.29	11.07
If yes, does the quality control program monitor the quality of CT images produced?	2	3.9	46	1.29	11.07
If yes, does the quality control program include maintenance of the CT scanner?	2	3.9	46	1.29	11.07
Does the facility CT/imaging/radiation safety policy/procedure include monitoring CT protocols to ensure they are as low as reasonably achievable?	4	7.1	52	3.2	14.86
Does the facility CT/imaging/radiation safety policy/procedure include a method for identifying and reporting excessive patient doses for CT to the Radiation Safety Officer?	4	7.1	52	3.2	14.86
Does the facility CT/imaging/radiation safety policy/procedure include a process for managing/reviewing CT protocols?	6	11.1	52	5.7	20.52
Does the facility CT/imaging/radiation safety policy/procedure include radiologist review of appropriateness of the CT order?	5	9.1	52	4.68	17.01
Does the facility CT/imaging/radiation safety policy/procedure include protocol specification by the radiologist before the patient is scanned?	3	5.5	52	2.19	13.19
If the facility revised any CT protocols during the past 12 months, was a radiologist expert in CT part of the work group that reviewed the revised protocols?	0	0	42		
If the facility revised any CT protocols during the past 12 months, was a technologist expert in CT part of the work group that reviewed the revised protocols?	0	0	40		
Does the medical physicist test a sample of CT protocols at least annually?	0	0	52		

Source: VA OIG Review Guide

¹³ Tables 1–4 present estimated percentages of noncompliance and the 95 percent CIs for selected elements of the review. Using a 10 percent noncompliance threshold, we only made recommendations when the entire 95 percent CI for noncompliance was greater than the 10 percent threshold. If the lower limit of the CI was below 10 percent, we could not be certain that facilities missed the threshold and were noncompliant. For example, although 10.7 percent of facilities did not have CT policies/procedures that included a CT quality control program, the CI for noncompliance was 5.81–18.98 percent. In this example, the lower limit of the CI did not exceed 10 percent noncompliance; therefore, we did not make a recommendation.

Table 2. CT Scanner Inspection Review

Question	Number No	Percent No	Total Number Yes and No	Lower 95 Percent CI	Upper 95 Percent CI
Is there documentation that a medical physicist performed an annual inspection of the CT scanner?	2	1.7	111	0.71	4.07
Did a medical physicist complete an inspection of scanners after all repairs or modifications?	11	29.1	39	16.92	45.33

Source: VA OIG Review Guide

Table 3. Electronic Health Records Review

Question	Number No	Percent No	Total Number Yes and No	Lower 95 Percent CI	Upper 95 Percent CI
Was the radiation dose for the exam documented as required? (NA if not required)	68	3.3	2,028	1.99	5.56

Source: VA OIG Review Guide

Table 4. Technologist Qualifications, Training, and Dosimetry Monitoring Review

Question	Number No	Percent No	Total Number Yes and No	Lower 95 Percent CI	Upper 95 Percent CI
Is the technologist currently certified by the American Registry of Radiologic Technologists® in radiography, or did the technologist meet requirements related to documented competence?	6	1.3	447	0.49	3.17
Is there documentation that the technologist received annual radiation safety training?	12	2.4	447	1.21	4.54
Is there documentation that the technologist received training in dose reduction/optimization techniques? (NA if not required by the facility)	1	0.3	375	0.05	1.17
Is there documentation that the technologist received training on safe procedures for operating the types of CT equipment the technologist uses? (NA if not required by the facility)	14	4.1	322	1.8	9.14
Was dosimetry monitoring completed for the technologist?	2	0.05	447	0.15	1.39

Source: VA OIG Review Guide

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: February 10, 2017

From: Under Secretary for Health (10)

Subject: Office of Inspector General (OIG) Draft Report, Combined Assessment Program (CAP) Summary Report – Evaluation of Computed Tomography Radiation Monitoring in Veterans Health Administration Facilities (Project No. 2016-03920-HI-0683) (VAIQ 7769260)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report, Evaluation of Computed Tomography Radiation Monitoring in Veterans Health Administration Facilities. The Veterans Health Administration (VHA) is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality and safety of the Department of Veterans Affairs (VA) health care system. VHA is using the input from VA's Office of Inspector General, and other advisory groups to identify root causes and to develop critical actions. As VHA implements corrective measures, we will ensure our actions are meeting the intent of the recommendations. VHA is dedicated to sustained improvement in the high risk areas.
2. The recommendations in this report apply to GAO high risk areas 1 and 4. VHA's actions will serve to address ambiguous policies and inconsistent processes, and inadequate training for VA staff.
3. I have reviewed the draft report, and provide the attached action plan to address the report's single recommendations.
4. If you have any questions, please email Karen M. Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRService@va.gov.



David J. Shulkin, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, Evaluation of Computed Tomography Radiation Monitoring in VHA Facilities

Date of Draft Report: January 18, 2017

Recommendations/ Actions	Status	Completion Date
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OIG Recommendation

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure a medical physicist inspects computed tomography scanners after completion of repairs or modifications that affect the dose or image quality prior to returning the scanners to clinical service.

VHA Comments: Concur

VHA Response:

The Office of the Deputy Under Secretary for Health for Operations and Management (DUSH-OM) and Office of Healthcare Technology Management, in cooperation with the Office of the Deputy Under Secretary for Health for Policy and Services (DUSH-PS) and Office of Diagnostic Radiology and the National Health Physics Program, will work collaboratively to ensure a medical physicist inspects computed tomography scanners after completion of repairs or modifications that may affect the dose or image quality prior to returning the Scanners to clinical service.

The DUSH-OM in cooperation with the DUSH-PS, will clarify the national policy that addresses physicist inspections following repair services or modifications of Computed Tomography (CT) scanners. Policy will be communicated from the DUSH-OM to all VHA facilities. Quarterly VHA facilities will report the number of CT Scanner repairs or modifications that require medical physicist inspection and the number of physicist inspections that were completed. VHA's Office of Healthcare Technology Management will aggregate submitted data and analyze for compliance with requirements. Quarterly reporting will continue for four quarters (through FY2018, Quarter 2) or until compliance with VA requirements is consistently met.

At completion of this action, VHA will provide the following documentation:

- A memorandum clarifying policy for physicist inspection of CT Scanners following repair services or modifications
- Evidence of compliance with the physicist inspection requirements

Status:
In Process

Target Completion Date:
March 2018

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	<p>Margie Chapin, RT, JD, Project Coordinator Daisy Arugay-Rittenberg, MT Bruce Barnes Michael Bishop, MSW Craig Byer, MS Darlene Conde-Nadeau, MSN, ARNP Stacy DePriest, LCSW Laura Dulcie, BSEE Donna Giroux, RN Wachita Haywood, RN Terri Julian, PhD Gayle Karamanos, MS, PA-C Martha Kearns, MSN, FNP Francis Keslof, EMT, MHA Jennifer Kubiak, BSN, MPH, CPHQ Laura Snow, LCSW, MHCL Carol Torczon, MSN, ACNP Laura Tovar, MSW, LSCSW Glen Trupp, RN, MHSM Jovie Yabes, RN, BSN Katrina Young, RN, MSHL</p>
Other Contributors	<p>Elizabeth Bullock Paula Chapman, CTRS Lin Clegg, PhD Chip Harvey, MS Nathan McClafferty, MS Larry Ross, Jr., MS Robert Wallace, MPH, ScD Julie Watrous, RN, MS Jarvis Yu, MS</p>

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