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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Patient and Radiation Safety Concerns at the John D. Dingell VA Medical Center

Detroit, Michigan

HEALTHCARE INSPECTION | REPORT #18-02210-19 | NOVEMBER 27, 2018

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a confidential complainant's allegations regarding patient safety concerns and non-compliance with radiation safety at the John D. Dingell VA Medical Center (Facility) in Detroit, Michigan. The complainant made 11 specific allegations:

- The X-ray machines were not inspected annually and were overdue for 2017.[1]
- Radiologists performed fluoroscopy procedures without current training or credentialing [privileging].[2, 3, 4]
- The Chief of Radiology changed the radiology privileging form to request and grant clinical Fluoroscopically Guided Interventional procedures and Authorized User (AU) status.[5]
- The Chief of Nuclear Medicine does not have U.S. Nuclear Regulatory Commission (NRC) approval to use radioactive materials and conducts AU functions without AU supervision.[6]
- The Chief of Nuclear Medicine lacked the required training for an AU license.

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[1] To ensure a comprehensive review, the OIG reviewed all ionizing emitting equipment including x-rays and fluoroscopes. The OIG used the term radiologic equipment to include all equipment requiring an annual qualified medical physicist inspection.

[2] Fluoroscopy involves a continuous x-ray image, which is used to display real-time images of a procedure or passage of a radioactive "dye" through the body on a monitor. Radiation Emitting Products, U.S. Food and Drug Administration, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm. (The website was accessed on February 15, 2018.)

[3] Credentialing refers to the systematic process of screening and evaluating qualifications and other credentials, including, but not limited to: licensure, required education, relevant training and experience, and current competence and health status. VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

[4] Clinical privileging is defined as the process by which a practitioner, licensed for independent practice, is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training and licensure. VHA Handbook 1100.19.

[5] An authorized user is a physician who meets U.S. Nuclear Regulatory Commission (NRC) requirements, and is identified as an AU on a license or permit for medical use of radioactive materials. U.S. Nuclear Regulatory Commission, 10 C.F.R. § 35.2– Definitions, Last Reviewed/Updated August 29, 2017. https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0002.html. (The website was accessed on July 13, 2018.)

[6] U. S Nuclear Regulatory Commission, 10 C.F.R. § 35.11– Medical Use of Byproduct Material, Last Reviewed/Updated August 29, 2017. https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0011.html. (The website was accessed on August 15, 2018.)

- The Facility was not permitted to perform nuclear medicine studies due to the Facility's Master Material License (MML) permit being revoked in 2009.[7]
- The Facility staff did not report two patients exposed to [high] radiation doses to the radiation safety officer (RSO).
- Radiology does not conform to radiation safety standards as outlined in Veterans Health Administration (VHA) Handbook 1105.04, *Fluoroscopy Safety,* and VHA Directive 1129, *Radiation Protection for Machine Sources of Ionizing Radiation*.[8, 9]
- The RSO lacked funding to ensure department compliance.
- The RSO does not have supervision over radiologic equipment.
- The Radiation Safety Committee (RSC) did not show documentation of work in meeting minutes; met without a quorum; did not have appropriate representation; and did not meet in quarter (Q) 4, fiscal year (FY) 2017.

The OIG substantiated that annual inspections did not occur on radiologic equipment and were overdue for 2017. Annual inspections should be completed by a qualified medical physicist (QMP). The Facility did not comply with the annual QMP inspections of radiologic equipment for FY 2015, FY 2016, and most of FY 2017. However, the OIG found that annual radiologic equipment inspections were current as of April 5, 2018.

Facility leaders identified deficiencies in other aspects of the radiation safety program including equipment testing, annual inspections of lead aprons and shields, and processing dosimeter badges.[10] The OIG determined that Facility leaders complied with the preventative maintenance schedule for radiologic equipment, and distribution and monitoring of dosimeters. The OIG noted that the Facility completed annual inspections of aprons and shields in 2015 and 2017, but not in 2016. The 2018 inspections were not due at the time of the OIG inspection. The OIG also reviewed the waiting room dosimeter reports from October 2015 through September 2017 and found the dosimeter was not replaced from September 2017 until May 2018. The available

[7] NRC issues an MML that authorizes VHA to issues permits to individual VA medical centers to approve the medical centers use of radioactive materials; VHA Directive 1105, *Management of Radioactive Materials*, February 5, 2015.

[8] VHA Handbook 1105.04, *Fluoroscopy Safety,* July 6, 2012. This handbook was replaced by VHA Directive 1105.04, *Fluoroscopy Safety*, June 21, 2018. The handbook and directive contain the same or similar language related to radiation safety standards.

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

[10] A dosimeter is a "radiation-sensitive device that is worn on the body to measure or evaluate the absorbed radiation dose to personnel." Facility Medical Center Memorandum 001S-48, *Radiation Safety Manual for Nurses*, Appendix A, July 18, 2012.

reports demonstrated that the exposure rates were consistently low with some reported rates below the minimum levels.

The OIG substantiated that radiologists were performing fluoroscopy procedures without having current training or credentialing (privileging). The OIG reviewed the initial and annual fluoroscopy training records for 38 radiology and non-radiology providers and found that all had completed the initial training. The OIG found that 21 of the 38 providers consistently completed the annual fluoroscopy training. The OIG also found that the urology privileging form contained fluoroscopy within the core privileges but did not contain the initial training requirements. The OIG also reviewed the training records of eight radiology technicians (RTs) and determined that none had completed the required initial training.

The OIG team reviewed the credentialing folders of the 38 radiology and non-radiology providers that completed the initial training and found that all 38 providers were credentialed. Of those, the OIG found that 14 providers requested and were granted fluoroscopy privileges. Although the remaining 24 providers completed the fluoroscopy training, the OIG did not find documentation that the providers' requested fluoroscopy privileges.

The OIG substantiated that the Chief of Radiology changed the Radiology privileging form; however, the OIG did not substantiate the form was changed to request and grant AU status. The Chief of Radiology stated that he modified the radiology privileging form to ensure that the providers requesting fluoroscopy privileges completed the required training prior to the granting of privileges. AU status is not part of the Facility's privileging process. The Acting Director for the National Health Physicist Program (NHPP) stated that NHPP separately reviews and grants AU status to providers.

The OIG did not substantiate that the Chief of Nuclear Medicine used radioactive materials or conducted AU functions without AU supervision. The OIG was informed that the Chief of Nuclear Medicine worked within a scope of practice, and an AU was available to handle doses over the protocol limit.

While the OIG substantiated that the Chief of Nuclear Medicine lacked the required training for an AU license, the Facility did not require the Chief of Nuclear Medicine to have an AU license. The Chief of Nuclear Medicine submitted the AU application; however, the then-RSO had not forwarded it on to NHPP for review.

Although the OIG substantiated that Facility staff were not permitted to perform nuclear medicine studies because the MML permit was revoked in 2009, the MML permit was reinstated in 2010.[11] NHPP revoked the Facility's MML permit in 2009 due to the lack of continuous

[11] NRC issues an MML, which authorizes VHA to issue permits to VA facilities to approve the use of radioactive materials; VHA Directive 1105, *Management of Radioactive Materials*, February 5, 2015

coverage of an RSO. NHPP reinstated the Facility's MML permit on December 29, 2010, upon confirmation of a new RSO.

The OIG did not substantiate that the RSO was not informed of two patients who were exposed to high radiation doses. The OIG found that the patients' exposure levels were below VHA and Facility requirements.[12,13] Patient A's electronic health record contained documentation of the RSO notification, and for Patient B, the OIG was informed that the RSO was waiting to speak with the provider following the procedure in Fall 2017.

The OIG substantiated that the radiology department did not conform to radiation safety standards as required by VHA.[14,15] NHPP reported no violation for the materials use audits in 2011 and 2015. In 2016, the then-RSO self-identified a violation regarding the failure to notify NHPP about the addition of an area of use prior to 2010. The Facility Director and RSO responded with the corrective actions in the submission of a renewal application with the addition of the identified area. Between February 21 and March 27, 2018, NHPP conducted a materials use audit in response to concerns from an anonymous source. NHPP inspectors did not substantiate the anonymous source's concerns but did notify the Facility of three Severity Level IV violations on April 10, 2018.[16] As of June 2018, the Facility Director had not provided information to the OIG regarding their response to NHPP.

In 2012, NHPP conducted a machine sources audit of the Facility, which resulted in 13 recommendations. The 2015 NHPP audit resulted in nine recommendations, including that "…some deficiencies noted [in 2012] had not been addressed by the time of [the 2015] site visit." The NHPP Interim Director report dated May 20, 2015, outlined the recommendations and a timeframe for completion of the corrective actions. The OIG reviewed the Facility's responses, and the RSC minutes from Q3 FY 2015 through Q2 FY 2018 and determined that the Facility did not comply with the nine NHPP recommendations.

The OIG did not substantiate that the RSO lacked funding to ensure department compliance. When appropriately requested, the RSO received funding for ordering equipment necessary to ensure radiation safety maintenance.

The OIG did not substantiate that the RSO did not have supervision over radiologic equipment safety. As of 2015, VHA and Facility policies granted the RSO oversight for radiologic equipment safety.

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[12] VHA Handbook 1105.04; VHA Directive 1105.04.

[13] Facility Medical Center Memorandum 001-5, *Safe Use of Fluoroscopic Equipment,* March 25, 2015.

[14] VHA Handbook 1105.04; VHA Directive 1105.04.

[15] VHA Directive 1129.

[16] NRC defines Severity Level IV violations as more than minor concerns.

The OIG did not substantiate that RSC minutes lacked documentation of work, the committee met without a quorum, and they did not have appropriate representation. The OIG reviewed RSC minutes from Q2 FY 2015 through Q2 FY 2018 and found that the RSC complied with VHA and Facility meeting requirements. In addition, RSC members confirmed that the minutes reflected the RSC meeting discussion.

While the OIG substantiated that the RSC did not have documentation of two meetings in Q1 FY 2016 and Q4 FY 2017, the OIG found that the RSC consistently met from Q2 FY 2015 through Q2 FY 2018.

During the inspection, the OIG determined that despite a recommendation during the 2015 NHPP audit and a VHA requirement, the RSO and RSC did not comply with the use of a required tracking matrix to track unresolved action items to closure.

Although the OIG found deficiencies in the Facility's radiation safety program and made recommendations, the OIG did not identify deficiencies that put patients and staff at immediate risk or warranted stopping patient care.

The OIG made six recommendations related to equipment testing, fluoroscopy training, clinical privileges, radiation safety, and tracking and monitoring corrective actions to completion.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans. (See Appendixes B and C, pages 20–24 for the Directors' comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.

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Assistant Inspector General
for Healthcare Inspections

Contents

Abbreviations

AU	Authorized User
CT	computed tomography
C&P	credentialing & privileging
EOCC	Environment of Care Committee
Facility	John D. Dingell VA Medical Center
FDA	Food and Drug Administration
FY	fiscal year
Gy	Gray
MML	Master Material License
NHPP	National Health Physics Program
NRC	Nuclear Regulatory Commission
OIG	Office of Inspector General
PM	preventative maintenance
Q	quarter
QMP	qualified medical physicist
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RT	radiology technician
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a confidential complainant's allegations regarding patient safety concerns and non-compliance with radiation safety at the John D. Dingell VA Medical Center (Facility), Detroit, Michigan.

Background

The Facility provides a broad range of inpatient and outpatient medical, surgical, geriatric, and mental health services. The Facility has 105 acute care beds, 109 nursing home/palliative care beds, a 50 bed Domiciliary Residential Rehabilitation Treatment Program, and a Veterans Community Resource and Referral Center. The Facility is part of Veterans Integrated Service Network (VISN) 10 and serves a veteran population of about 330,000 throughout four counties located in southeastern Michigan and has two community based outpatient clinics located in Pontiac and Yale, Michigan.

Medical Imaging

According to the U. S. Food and Drug Administration (FDA), medical imaging refers to several different technologies used to view the human body for diagnosis, monitoring, or treating medical conditions.[17] Medical imaging uses ionizing radiation[18] to generate images of the body. To create an image, x-ray beams pass through the body where some structures will absorb the radiation and others will scatter it. The resulting pattern is sent to a film or computer screen. Some examples of imaging are radiography,[19] computed tomography (CT),[20] and fluoroscopy.[21]

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[17] Radiation-Emitting Products, U. S. Food and Drug Administration website, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm2005914.htm. (The website was accessed on February 15, 2018.)

[18] Ionizing radiation has the potential to cause damage to deoxyribonucleic acid (DNA) and may increase a person's risk of developing cancer over a lifetime. Radiation-Emitting Products, U. S. Food and Drug Administration website, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/default.htm. (The website was accessed on February 15, 2018.)

[19] Radiography is the process of obtaining a single image for evaluation, such as a chest x-ray. Radiation-Emitting Products, U. S. Food and Drug Administration website, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/default.htm. (The website was accessed on February 15, 2018.)

Both CT and fluoroscopy imaging can result in higher radiation doses due to longer patient exposure to radiation.

Nuclear imaging involves the use of dye that contains a small amount of radioactive material. Patients receive the dye through injection or inhalation. Providers use nuclear imaging to detect coronary artery disease and cancer, as well as evaluate lung, liver, and kidney function.

Fluoroscopy Safety

Veterans Health Administration (VHA) identifies the integral role of imaging devices in health care and outlines the requirements VA facilities must follow to protect both patients and health care workers.[22] Staff can reduce the risk of unnecessary radiation exposure to patients and health care workers by ensuring equipment is operating properly, following appropriate procedures, using shielding and engineered safety features, and assuring radiation doses are as low as reasonably achievable.

Radiation Safety Officer and Committee

VHA Directive 1129 states that the Radiation Safety Officer (RSO) and Radiation Safety Committee (RSC) function together to support the medical center director and take necessary actions to ensure radiation safety for machine sources of ionizing radiation.[23] Usually, the RSO completes day-to-day actions, with support from radiation safety supervisors or points of contact, with overall compliance oversight by the RSC.

[20] CTs records many images as the detector moves around the patient's body and then reconstructs the individual images to create visual "slices" of internal organs and tissues. Radiation-Emitting Products, U. S. Food and Drug Administration website, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/default.htm. (The website was accessed on February 15, 2018.)

[21] Fluoroscopy involves a continuous x-ray image, which is used to display real-time images of a procedure or passage of a radioactive "dye" through the body on a monitor. Radiation-Emitting Products, U. S. Food and Drug Administration website, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/default.htm. (The website was accessed on February 15, 2018.)

[22] VHA Handbook 1105.04, *Fluoroscopy Safety*, July 6, 2012. This handbook was replaced by VHA Directive 1105.04, *Fluoroscopy Safety*, June 21, 2018. The handbook and directive contain the same or similar language related to radiation safety standards.

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

Credentialing and Privileging

VHA defines credentialing and privileging as follows:[24]

> Credentialing refers to the systematic process of screening and evaluating qualifications and other credentials, including, but not limited to: licensure, required education, relevant training and experience, and current competence and health status.
>
> Clinical privileging is defined as the process by which a practitioner, licensed for independent practice, is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure.

VHA requires that providers' clinical privileges are facility-specific, practitioner-specific, and within available resources.[25]

Prior OIG Reports

In a 2017 OIG report, *Comprehensive Healthcare Inspection Program Review of the John D. Dingell VA Medical Center, Detroit, Michigan* (Report No. 17-01849-42, December 21, 2017), the OIG identified deficiencies in the inspection and testing of radiation aprons and shields, and with annual inspections of radiology equipment.[26]

VHA requires aprons and shields to be used for the protection of radiology personnel and patients and that they are well maintained and periodically inspected and tested for integrity.[27] This ensures employees are not exposed to unnecessary doses of fluoroscopic radiation. The OIG found no evidence that the aprons and shields were inspected or tested. The OIG was informed that an electronic system used to record inspection and test results was non-functional.

VHA requires radiology equipment to be tested after installation before clinical use, annually, and after each repair or modification.[28] The OIG found that 2 of 10 pieces of radiology equipment did not have evidence of inspection by the medical physicist within the past

[24] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook expired October 31, 2017, and has not been recertified or replaced.

[25] VHA Handbook 1100.19.

[26] VA OIG *Comprehensive Healthcare Inspection Program Review of the John D. Dingell VA Medical Center, Detroit, Michigan*, Report No. 17-01849-42, December 21, 2017.

[27] VHA Handbook 1105.04; VHA Directive 1105.04.

[28] VHA Handbook 1105.04; VHA Directive 1105.04.

12 months. Managers were aware of noncompliance and failed to take follow-up actions to ensure compliance due to staffing issues and other priorities.

The Facility leaders provided acceptable action plans and sufficient evidence for OIG to close the recommendations on June 15, 2018.

Allegations

The OIG received allegations in December 2017 regarding patient safety concerns and non-compliance with radiation safety at the Facility. The complainant made 11 specific allegations:

- The X-ray machines were not inspected annually and were overdue for 2017.
- Radiologists performed fluoroscopy procedures without current training or credentialing [privileging].
- The Chief of Radiology changed the radiology privileging form to request and grant clinical Fluoroscopically Guided Interventional procedures and Authorized User (AU) status.[29]
- The Chief of Nuclear Medicine does not have U.S. Nuclear Regulatory Commission (NRC) approval to use radioactive materials and conducts AU functions without AU supervision.
- The Chief of Nuclear Medicine lacked the required training for an AU license.
- The Facility was not permitted to perform nuclear medicine studies due to the Facility's Master Material License (MML) permit being revoked in 2009.[30]
- The Facility staff did not report two patients exposed to [high] radiation doses to the RSO.
- Radiology does not conform to radiation safety standards as outlined in VHA Handbook 1105.04, *Fluoroscopy Safety,* and VHA Directive 1129, *Radiation Protection for Machine Sources of Ionizing Radiation*.[31,32]
- The RSO lacked funding to ensure department compliance.
- The RSO does not have supervision over radiologic equipment.

[29] U. S Nuclear Regulatory Commission, 10 C.F.R. § 35.11– Medical Use of Byproduct Material, Last Reviewed/Updated August 29, 2017. https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0011.html. (The website was accessed on August 15, 2018.)

[30] NRC issues an MML, which authorizes VHA to issue permits to VA facilities to approve the use of radioactive materials; VHA Directive 1105, *Management of Radioactive Materials*, February 5, 2015.

[31] VHA Handbook 1105.04; VHA Directive 1105.04.

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

- The RSC did not show documentation of work in meeting minutes; the committee met without a quorum; did not have appropriate representation; and did not meet in quarter (Q) 4, fiscal year (FY) 2017.

The OIG also received an allegation of retaliation, which was not reviewed as part of this healthcare inspection because it does not fall under the purview of the OIG. For this allegation, the OIG referred the complainant to the Office of Special Counsel, the Equal Employment Opportunity Commission, and the VA Office of Accountability and Whistleblower Protection.

During the inspection, Facility leaders identified some requirements of the radiation safety program that were not completed in a consistent and timely manner, including deficient equipment testing, lack of annual inspections of lead aprons and shields, and the processing of dosimeter badges. The OIG team also identified issues with the nuclear medicine waiting room dosimeter, radiology technicians' training records, and a tracking matrix.

Scope and Methodology

The OIG initiated a healthcare inspection in January 2018 and conducted a site visit April 2–5, 2018.

The OIG team interviewed the complainant, Facility leaders, relevant staff from radiology, vascular surgery, and quality management, and the credentialing and privileging (C&P) coordinator. The OIG team also interviewed the Acting Director of the National Health Physics Program (NHPP).

The OIG team reviewed applicable VHA and Facility policies and practices related to radiation safety, and C&P. The OIG team also reviewed NRC regulations, RSC and Environment of Care Committee (EOCC) meeting minutes from January 2015 through February 2018, NHPP audits from 2011 through 2018, a relevant Administrative Investigation Board (AIB), and staff training and privileging records from the staff hire date through 2018.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to substantiate or not substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

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

Inspection Results

Issue 1: Lack of Equipment Safety

Radiologic Equipment Inspections

The OIG substantiated that annual inspections did not occur on radiologic equipment and were overdue for 2017.[33] Annual inspections are to be completed by a qualified medical physicist (QMP). The Facility did not comply with the annual QMP inspections of radiologic equipment for FY 2015, FY 2016, and most of FY 2017. However, the OIG found that annual radiologic inspections were current as of April 5, 2018.

VHA and Facility policies require that a QMP test radiologic equipment prior to clinical use, after major repairs and modifications, and annually thereafter.[34,35]

Facility policy states that the RSO is responsible for the day-to-day operations of the radiation safety program including monitoring compliance with VHA requirements. The RSO is responsible to report to the RSC any known or suspected non-compliance with Facility and VHA requirements; and to notify the Facility Director of known significant violations of VHA requirements.[36]

As noted in the Facility's response to the OIG report, *Comprehensive Healthcare Inspection Program Review of the John D. Dingell VA Medical Center, Detroit, Michigan* (Report No. 17-01849-42, December 21, 2017) recommendations, the Facility began conducting annual inspections in September 2017, and concluded in March 2018, with all radiologic equipment passing.

Additional Concerns

In late 2016 and early 2017, Facility leaders identified that some requirements of the radiation safety program were not completed in a consistent and timely manner, including deficient equipment testing, lack of annual inspections of lead aprons and shields, and the processing of dosimeter badges. In December 2016, the Facility contracted a QMP to review the radiation safety program. The QMP identified that most of the problems could be attributed, either directly or indirectly, to the lack of organization within the radiation safety program. In response, Facility

[33] To ensure a comprehensive review, the OIG reviewed all ionizing emitting equipment including x-rays and fluoroscopes. The OIG used the term radiologic equipment in this report to show the inclusivity of all equipment requiring an annual QMP inspection.

[34] VHA Handbook 1105.04; VHA Directive 1105.04.

[35] Facility Medical Center Memorandum (MCM) 001-5, *Safe Use of Fluoroscopic Equipment*, March 25, 2015.

[36] Facility MCM 001-5; VHA Handbook 1105.04; VHA Directive 1105.04.

leaders worked with the RSO to develop and implement an action plan to address the identified deficiencies.

Preventative Maintenance

Facility policy requires service and maintenance of radiologic equipment.[37] The Facility's biomedical engineering department works directly with the vendors for preventative maintenance (PM) and general repairs of the equipment.

To ensure that the radiologic equipment received PM, the OIG reviewed the PM reports from FY 2015 through Q2 FY 2018 and determined that radiologic equipment complied with the PM schedule.[38]

Aprons and Shields

Facility policy states that aprons and shields are evaluated and inventoried annually, and copies of the inspection reports are maintained.[39] According to the Safety Manager, the inspections of the aprons and shields were "hit or miss." In 2017, a Facility leader found that inspections were not occurring and assigned the RSO to complete the necessary inspections.

The OIG reviewed the 2015 and 2017 inspection reports and noted that aprons and shields were in compliance. The OIG was informed that the facility could not provide the 2016 inspection report, and the 2018 inspection is not due until later this year.

Dosimeters

Facility policy requires staff to wear radiation dosimeters[40] to monitor their occupational exposure to radiation.[41] The RSO distributes and collects dosimeters from the section dosimetry coordinators throughout the Facility and maintains records of occupational radiation exposures for all Facility radiation workers. The policy also advises that staff should not relinquish their dosimeters until a replacement is in hand.

The OIG reviewed the dosimeter records from FY 2016 through Q2 FY 2018 and determined that the Facility's dosimeter processes complied with Facility policy.[42]

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[37] Facility MCM 001S-49, *Radiation Safety Program for X-ray and Imaging Machines*, November 13, 2014.

[38] The Facility provided reports on 46 pieces of equipment. The OIG found that 12 items were out of service, had no PM reports, or had one or less PM reports included for the item. Based on the information provided, the PMs reviewed do not completely match the number of QMP reports.

[39] Facility MCM 001S-49.

[40] A dosimeter is a "radiation-sensitive device that is worn on the body to measure or evaluate the absorbed radiation dose to personnel." Facility MCM 001S-48, *Radiation Safety Manual for Nurses*, July 18, 2012, Appendix A.

[41] Facility MCM 001S-45, *Maintenance of Radiation Dosimeters*, October 27, 2017.

[42] Facility MCM 001S-45.

Nuclear Medicine Waiting Room Dosimeter

During an interview, a Facility staff member expressed concern with the possible level of radiation exposure to staff, patients, and family members sitting in the nuclear medicine waiting room (waiting room). The OIG conducted a walking tour of the radiology and nuclear medicine area, and noted a dosimeter placed on the back wall of the waiting room. Because patients, staff, and family members utilize this space, the OIG requested the dosimeter reports for this area, and spoke with the vendor about the reports.

The OIG reviewed the waiting room reports from October 2015 through September 2017 and found the dosimeter was not replaced from September 2017 until May 2018. The available reports demonstrated that the exposure rates were consistently low with some reported rates below the minimum levels.[43]

Issue 2: Lack of Providers' Training and C&P

Training and C&P

The OIG substantiated that radiologists were performing fluoroscopy procedures without having current training or credentialing (privileging).

Provider's Fluoroscopy Training and Privileging[44]

VHA and Facility policies require that providers requesting fluoroscopy privileges complete an initial three-tiered training (initial training) prior to granting privileges.[45] The initial training includes a one-time only didactic with successful completion of a written test, hands-on, and preceptor training.[46] In addition, the Facility's privileging forms requires providers to complete an annual fluoroscopy training to maintain their privileges.[47]

The OIG reviewed the initial and annual fluoroscopy training records for 38 radiology and non-radiology providers. The OIG found that the 38 providers completed the initial training, with one provider stating that they performed fluoroscopy procedures prior to completing the initial

[43] The waiting room dosimeter was read monthly, but in April 2016, it was changed to a quarterly badge.

[44] The OIG reviewed fluoroscopy training for radiology and non-radiology providers. Providers are inclusive of physicians, nurse practitioners, and physician assistants.

[45] VHA Handbook 1105.04; VHA Directive 1105.04. The handbook and directive contain the same or similar language related to fluoroscopy training requirements; Facility MCM 001-5.

[46] On July 6, 2012, VHA published the Fluoroscopy Handbook, which considered any provider who regularly operated a fluoroscope prior to the handbook publication as having met the requirements for hands-on and preceptor training.

[47] Providers in Diagnostic Radiology/Nuclear Medicine, Cardiology, Pulmonary, Orthopedic Surgery, and Vascular Surgery required the annual refresher training.

training. The OIG found that only 21 providers consistently completed the annual fluoroscopy training.

Additionally, the OIG reviewed the most recent privileging forms for radiology and non-radiology services that contained fluoroscopy privileges approved in November 2017. The OIG found that although the urology privileging form contained fluoroscopy within the core privileges, it did not mention the initial training requirements.

Additional Concern

Radiology Technician Training

During the inspection, the OIG reviewed the training records of eight radiology technicians (RTs) and found that seven had American Registry of Radiologic Technologist certification and one RT was grandfathered. The OIG found no evidence that the eight RTs completed the hands on and preceptor trainings that are necessary to complete the required initial training.

VHA and Facility policies requires that non-physician personnel (such as RTs) who operate fluoroscopic equipment, complete the same initial training as providers.[48] The policies consider an RT to have met the didactic portion of the initial training if the RT received certification in radiography or radiation therapy by the American Registry of Radiologic Technologists. Facility policy states that non-physician practitioners, which include RTs, "…who regularly operated a fluoroscope at the time the [VHA] policy was issued (July 6, 2012) are considered to have met the requirements for preceptor training."[49]

C&P

VHA requires that a provider's clinical privileges must be practitioner-specific, facility-specific, and within available facility resources.[50] The OIG was told that providers must request core and any specialty privileges within their scope of practice. For example, a radiologist would request core privileges within radiology, and specialty (fluoroscopy) privileges as applicable. Providers must be fully credentialed and privileged prior to their initial appointment or reappointment.

OIG team reviewed the credentialing folders of the 38 radiology and non-radiology providers that completed the initial training and found that all 38 providers were credentialed. Of those, the OIG found that 14 providers requested and were granted fluoroscopy privileges. Although the remaining 24 providers completed the fluoroscopy training, the OIG could not confirm that they requested fluoroscopy privileges.

[48] VHA Handbook 1105.04; VHA Directive 1105.04; Facility MCM 001-5.

[49] Facility MCM 001-5.

[50] VHA Handbook 1100.19.

Privileging Forms and AU Status

The OIG substantiated that the Chief of Radiology changed the Radiology privileging form; however, the OIG did not substantiate the form was changed to request and grant AU status.

VHA requires providers who request fluoroscopy privileges to complete the initial training.[51] When the provider completes the training, the Medical Staff Office reviews the privileging request and then submits the request to the Clinical Executive Committee/Professional Standards Board for review and approval.

The Chief of Radiology stated that he modified the radiology privileging form to ensure that the providers requesting fluoroscopy privileges completed the required training prior to the granting of privileges. Additionally, the OIG found that the Chief of Radiology cannot grant AU status. The Acting Director for NHPP stated that they separately review and grant AU status to providers.

NRC Approval and AU Functions and Supervision

The OIG did not substantiate that the Chief of Nuclear Medicine used radioactive materials or conducted AU functions without AU supervision. According to the NRC, an individual does not need AU status to prepare, receive, possess, use, or transfer radioactive materials, provided this work is not prohibited by license conditions, and the individual conducts this work under the supervision of an AU.[52] The OIG was informed that the Chief of Nuclear Medicine worked within his or her scope of practice and an AU was available to handle doses over the protocol limit.[53]

AU Training

While the OIG substantiated that the Chief of Nuclear Medicine lacked the required training for an AU license, the Facility did not require the Chief of Nuclear Medicine to have an AU license. The OIG was informed that the Chief of Nuclear Medicine submitted the AU application to the then-RSO upon appointment to the VA; however, the then-RSO did not forward the application to NHPP for review.

MML Permit

Although the OIG substantiated that the Facility was not permitted to perform nuclear medicine studies because the MML permit was revoked in 2009, the Facility's MML permit was reinstated

[51] VHA Handbook 1105.04; VHA Directive 1105.04.

[52] U. S Nuclear Regulatory Commission, 10 C.F.R. § 35.11–Medical Use of Byproduct Material, Last Reviewed/Updated August 29, 2017. https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0011.html. (The website was accessed on August 15, 2018.)

[53] The protocol limits were set by the NHPP with the assistance of the Chief of Nuclear Medicine in June 2015.

in 2010. VHA requires that medical center directors with MML permits ensure continuous coverage by an RSO.[54] The Acting Director for NHPP stated that they have the authority to revoke a medical center's permit if coverage by an RSO lapses.

The OIG found that NHPP reinstated the Facility's MML permit on December 29, 2010, upon confirmation of a new RSO. In late 2017, to ensure continuous coverage, the Facility Director appointed the Chief of Radiology as the acting RSO. The Chief of Radiology remained the acting RSO until Facility leaders contracted the RSO position to an outside agency in March 2018. The Facility maintained their MML permit throughout this transition.

Issue 3: Lack of Patient Safety and Compliance

Reports to RSO

The OIG did not substantiate that the RSO was not informed of two patients who were exposed to high radiation doses. VHA and Facility policy requires that exposures of five gray (Gy)[55] or more must be reported to the RSO.[56] The OIG found that the patients' exposure levels were below VHA and Facility reporting requirements. Patient A's electronic health record contained documentation of the RSO notification, and for Patient B, the OIG was informed that the RSO was waiting to speak with the provider following the procedure in Fall 2017.

Radiation Safety Standards

The OIG substantiated that the radiology department did not conform to radiation safety standards as stated in VHA Directive 1105.04.[57] VHA Handbook 1105.04 describes the objective of the radiation safety program as the medical use of ionizing radiation "to obtain optimum diagnostic information or therapeutic effect with minimum exposure to staff and members of the public and to minimize unnecessary irradiation of the patient."[58]

VHA Directive 1129 "…establishes policies and actions to implement and maintain a radiation protection compliance program for machine sources of ionizing radiation used for medical

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[54] VHA Directive 1105, *Management of Radioactive Materials*, February 5, 2015.

[55] "Gy is one of the two units used to measure the amount of radiation absorbed by an object or person, which reflects the amount of energy that radioactive sources deposit in materials they pass through." Skin damage may occur to varying degrees, depending on skin dose exposure. A dose of 2–5 Gy may cause transient redness and possible hair loss; at 5–10 Gy, the hair loss may be permanent, and recovery take longer; at 10–15 Gy early onset skin loss leads to skin atrophy and weakness; doses greater than 15 Gy lead to acute ulceration likely to require surgical intervention. U.S. Nuclear Regulatory Commission, https://www.nrc.gov/reading-rm/basic-ref/glossary/gray-gy.html. (The website was accessed on July 30, 2018.); VHA Handbook 1105.04, Appendix B.

[56] VHA Handbook 1105.04; VHA Directive 1105.04; Facility MCM 001-5.

[57] VHA Handbook 1105.04; VHA Directive 1105.04; VHA Directive 1129.

[58] VHA Handbook 1105.04; VHA Directive 1105.04.

diagnosis and treatment."[59] Goals for compliance focus on protecting patients, staff, and the public. The National Radiation Safety Committee provides oversight of radiation protection policies for machine sources of ionizing radiation, with the day-to-day protection actions assigned to the NHPP.

NHPP conducts two types of routine tri-annual audits at VHA medical centers using radiation, one for materials use, and the other for machine sources of ionizing radiation.[60] The first type of audit examines radiation safety and compliance with NRC rules and regulations under the Facility's permitted materials use and is reported using form 591. To determine compliance with policy, NHPP utilizes a checklist for the machine sources audit (form 41a) that incorporates VHA requirements.[61]

Materials Use Audit

The OIG reviewed form 591 for the 2011 and 2015 audits and found no violations. However, in 2016, the Facility self-identified a violation regarding the failure to notify NHPP about the addition of an area of use prior to 2010.[62] The Facility Director and RSO responded with the corrective actions in the submission of a renewal application with the addition of the identified area.

The OIG found that from February 21 through March 27, 2018, NHPP conducted a materials use audit of the Facility's radiation safety program in response to concerns received from an anonymous source. NHPP inspectors did not substantiate the anonymous source's concerns, but they did discover other violations during a routine, unannounced materials use inspection conducted while on site. The Facility received notice of three Severity Level IV violations in a memorandum dated April 10, 2018.[63] As of June 2018, the Facility Director had not provided information to the OIG regarding their response to NHPP.

Machine Sources Audit

In 2012, NHPP conducted an audit of the Facility, which resulted in 13 recommendations. At the time of this audit, the Facility Director was not required to respond to NHPP. The 2015 NHPP audit resulted in nine recommendations, including that "…some deficiencies noted [in 2012] had not been addressed by the time of [the 2015] site visit." The NHPP Interim Director report, dated May 20, 2015, outlined the recommendations, and a timeframe of 45 days for the Facility Director to take corrective actions and provide a response to NHPP. The Facility provided a

[59] VHA Directive 1129.

[60] Due to staffing limitations, NHPP is unable to conduct routine, machine sources audits in 2018.

[61] Form 41a is the audit form used during the inspection of diagnostic and interventional x-ray imaging.

[62] NHPP sent a Notice of Violation letter in response to the self-identified violation.

[63] NRC defines Severity Level IV violations as more than minor concerns.

response to NHPP 82 days later on August 10. The OIG reviewed the Facility's response and the RSC minutes from Q3 FY 2015 through Q2 FY 2018, to verify compliance with the NHPP recommendations and found that the Facility did not comply.

AIB

In March 2016, Facility staff completed an AIB regarding deficiencies in radiation safety culture including patient safety issues. VA uses administrative investigations when significant incidents occur, and issues arise within VA facilities "to collect and analyze evidence to determine what actually happened and why it happened, so that individual and systemic deficiencies can be identified and effectively corrected."[64] On August 22, 2016, the Facility Director charged the Chief of Staff to address the AIB's recommendations. According to the Chief of Staff's interim report dated September 16, 2016, and a letter to the Chief of Radiology dated November 3, 2016, the AIB recommendations have been completed or were in the process of being completed. The OIG reviewed the actions taken by the Facility leaders and found them to be satisfactory.

Issue 4: Lack of Funding and Authority of the RSO and the RSC

RSO

Lack of Funding

The OIG did not substantiate that the RSO lacked funding to ensure department compliance. The RSO and RSC share responsibility for regulatory compliance. The RSO carries out daily functions with oversight from the RSC.[65] Although individual departments may present purchases during RSC meetings to record new medical radiation use, the purchases are made using their own departmental budgets. To purchase equipment, the RSO submits a request to the Radiology or Safety Departments, who authorize the expenditure.

Based on the information provided by the Facility and a review of the EOCC minutes from January 2015 through February 2018, the OIG found that, when appropriately requested, the RSO received funding for ordering equipment necessary to ensure radiation safety maintenance.[66]

[64] VA Directive 0700, *Administrative Investigations*, March 25, 2002.

[65] VHA Directive 1105.

[66] The RSC reports to the EOCC, a higher-level committee within the facility, which provides administrative oversight.

Lack of Authority

The OIG did not substantiate that the RSO did not have supervision over radiologic equipment safety.[67] VHA and Facility policies delineates the RSO's authority with respect to radiologic equipment.[68] The RSO monitors compliance as stated in VHA Directive 1105.04.[69] The OIG found that as of 2015, VHA and Facility policy granted the RSO oversight for radiologic equipment safety.[70]

RSC

The OIG did not substantiate that RSC minutes lacked documentation of work, that the committee met without a quorum, and did not have appropriate representation.[71] The OIG reviewed RSC minutes from Q2 FY 2015 through Q2 FY 2018 and found that the RSC complied with VHA and Facility requirements.[72] In addition, RSC members confirmed that the minutes reflected the RSC meeting discussion.

RSC Meetings

While the OIG substantiated that the RSC did not have documentation of two meetings in Q1 FY 2016 and Q4 FY 2017, the OIG found that the RSC consistently met from Q2 FY 2015 through Q2 FY 2018. Facility policy requires the RSC to hold quarterly meetings.[73] The OIG reviewed RSC meeting minutes from Q2 FY 2015 through Q2 FY 2018 and determined that the RSC complied with Facility policy, therefore the OIG did not make a recommendation.

Tracking Matrix

During the inspection, the OIG determined that despite a recommendation during the 2015 NHPP audit, the RSO and RSC did not comply with the use of a required tracking matrix. VHA requires that a tracking matrix is used to track unresolved action items to closure.[74]

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[67] The complainant explained that the RSO does not have x-ray delegation for electronic generated radiation, including x-rays, CT, and fluoroscopy. The OIG used the term radiologic equipment in this report to include all radiation producing machines.

[68] VHA Directive 1105; Facility MCM 001-5.

[69] VHA Handbook 1105.04; VHA Directive 1105.04.

[70] VHA Directive 1105; Facility MCM 001-5.

[71] A quorum as "at least one-half of committee membership for meetings, which must include the Radiation Safety Officer and management representative." Facility Policy, Bulletin No. 91, *Radiation Safety Committee,* December 11, 2017.

[72] VHA Directive 1105; Facility Policy, Bulletin No. 91.

[73] Facility Policy, Bulletin No. 91.

[74] VHA Directive 1105.

Conclusion

The OIG substantiated that annual inspections did not occur on radiologic equipment and were overdue for 2017. Annual inspections are to be completed by a QMP. The facility did not comply with the annual QMP inspections of radiologic equipment for FY 2015, FY 2016, and most of FY 2017. However, the OIG found that annual radiologic equipment inspections were current as of April 5, 2018.

The OIG substantiated that radiologists were performing fluoroscopy procedures without having current training or credentialing (privileging). The OIG reviewed the initial and annual fluoroscopy training records for 38 radiology and non-radiology providers and found that all had completed the initial training. The OIG found that 21 of the 38 providers consistently completed the annual fluoroscopy training. The OIG also found that the urology privileging form contained fluoroscopy within the core privileges but did not contain the initial training requirements.

The OIG team reviewed the credentialing folders of the 38 radiology and non-radiology providers that completed the initial training and found that all 38 providers were credentialed. Of those, the OIG found that 14 providers requested and were granted fluoroscopy privileges. Although the remaining 24 providers completed the fluoroscopy training, the OIG did not find documentation that the providers requested fluoroscopy privileges.

The OIG substantiated that the Chief of Radiology changed the Radiology privileging form; however, the OIG did not substantiate the form was changed to request and grant AU status. The Chief of Radiology stated that he modified the radiology privileging form to ensure that the providers requesting fluoroscopy privileges completed the required training prior to the granting of privileges. The Acting Director of NHPP stated that they separately review and grant AU status to providers.

The OIG did not substantiate that the Chief of Nuclear Medicine used radioactive materials or conducted AU functions without AU supervision. The OIG was informed that the Chief of Nuclear Medicine worked within his or her scope of practice and an AU was available to handle doses over the protocol limit.

While the OIG substantiated that the Chief of Nuclear Medicine lacked the required training for an AU license, the Facility did not require the Chief of Nuclear Medicine to have an AU license. The Chief of Nuclear Medicine submitted his or her AU application; however, the then-RSO had not forwarded it on to NHPP for review.

Although the OIG substantiated that the Facility was not permitted to perform nuclear medicine studies due to their MML permit revocation in 2009, the MML permit was reinstated in 2010. The OIG found that NHPP revoked the Facility's MML permit in 2009 due to the lack of continuous coverage of an RSO. NHPP reinstated the Facility's MML permit on December 29, 2010, with the confirmation of a new RSO.

The OIG did not substantiate that the RSO was not informed of two patients who were exposed to high radiation doses. The OIG found that both patients' exposure levels were below VHA and Facility requirements. Patient A's electronic health record contained documentation of the RSO notification, and for Patient B, the OIG was informed that the RSO was waiting to speak with the provider following the procedure in fall 2017.

The OIG substantiated that the radiology department did not conform to radiation safety standards as required by VHA. NHPP reported no violation for the materials use audits in 2011 and 2015. In 2016, the Facility self-identified a violation regarding the failure to notify NHPP about the addition of an area of use prior to 2010. The Facility Director and RSO responded with the corrective actions in the submission of a renewal application with the addition of the identified area. Between February 21 and March 27, 2018, NHPP conducted a materials use audit in response to concerns from an anonymous source. NHPP inspectors did not substantiate the anonymous source's concerns but did notify the Facility of three Severity Level IV violations on April 10, 2018. As of June 2018, the Facility Director had not provided information to the OIG regarding their response to NHPP.

In 2012, NHPP conducted a machine sources audit of the Facility, which resulted in 13 recommendations. The 2015 NHPP audit resulted in nine recommendations, including that "…some deficiencies noted [in 2012] had not been addressed by the time of [the 2015] site visit." The NHPP Interim Director report dated May 20, 2015, outlined the recommendations and a timeframe for completion of the corrective actions. The OIG reviewed the Facility's responses and the RSC minutes from Q3 FY 2015 through Q2 FY 2018 to verify compliance with the NHPP recommendations and found that the Facility did not comply.

The OIG did not substantiate that the RSO lacked funding to ensure department compliance. When appropriately requested, the RSO received funding for ordering equipment necessary to ensure radiation safety maintenance.

The OIG did not substantiate that the RSO did not have supervision over radiologic equipment safety. As of 2015, VHA and Facility policy granted the RSO oversight for radiologic equipment safety.

The OIG did not substantiate that RSC minutes lacked documentation of work, the committee met without a quorum, and they did not have appropriate representation. The OIG reviewed RSC minutes from Q2 FY 2015 through Q2 FY 2018 and found that the RSC complied with VHA and Facility quorum and representation meeting requirements. In addition, RSC members confirmed that the minutes reflected the RSC meeting discussion.

While the OIG substantiated that the RSC did not have documentation of two meetings in Q1 FY 2016 and Q4 FY 2017, the OIG found that the RSC consistently met from Q2 FY 2015 through Q2 FY 2018.

During the OIG inspection, Facility leaders identified some requirements of the radiation safety program that were not completed in a consistent and timely manner, including deficient

equipment testing, lack of annual inspections of lead aprons and shields, and the processing of dosimeter badges. In addition, the OIG team also identified issues with the nuclear medicine waiting room dosimeter, radiology technicians' training records, and a tracking matrix.

Although the OIG found deficiencies in the Facility's radiation safety program and made recommendations, the OIG did not identify deficiencies that put patients and staff at immediate risk or warranted stopping patient care.

The OIG made six recommendations.

Recommendations 1–6

1. The John D. Dingell VA Medical Center Director ensures that radiologic equipment receives the required inspection and testing by a qualified medical physicist, and monitors compliance.
2. The John D. Dingell VA Medical Center Director ensures providers and radiology technicians complete fluoroscopy training as required, and monitors for compliance.
3. The John D. Dingell VA Medical Center Director ensures clinical privileges are granted in accordance with policy, and monitors for compliance.
4. The John D. Dingell VA Medical Center Director ensures that the radiology department conform to radiation safety standards as outlined through the National Health Physics Program and fully address any recommendations and violations, and monitors to completion.
5. The John D. Dingell VA Medical Center Director ensures that the Radiation Safety Committee minutes reflect actions taken to address National Health Physics Program recommendations and violations, and monitors compliance.
6. The John D. Dingell VA Medical Center Director ensures that the Radiation Safety Officer and Radiation Safety Committee initiate and utilize the Veterans Health Administration required tracking matrix to track unresolved action items to completion, and monitors compliance.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: October 9, 2018

From: Acting Network Director, VISN 10 (10N10)

Subj: Healthcare Inspection—Patient and Radiation Safety Concerns at the John D. Dingell VA Medical Center, Detroit, Michigan

To: Director, Denver Office of Healthcare Inspections, (54DV)

Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the responses to each recommendation provided in the Healthcare Inspection -Patient and Radiation Safety Concerns at the John D. Dingell VA Medical Center (553), Detroit, Michigan.
2. The facility will ensure that the corrective action plans are implemented with continued oversight.

(*Original signed by*:)

T. Jane Johnson
for Denise M. Deitzen
VISN 10 Network Director

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: October 10, 2018

From: Director, John D. Dingell VA Medical Center (553/00)

Subj: Healthcare Inspection—Patient and Radiation Concerns at the John D. Dingell VA Medical Center, Detroit, Michigan

To: Director, Michigan VA Healthcare System (VISN10)

1. On behalf of the John D. Dingell VA Medical Center, we would like to thank the Office of Inspector General for their thorough hotline complaint review. We would also like to thank the survey team for providing recommendations to help improve our internal processes.
2. The Detroit VA Medical Center concurs with the findings listed in this report. Action statements and target dates established throughout the recommendation responses.

(*Original signed by*:)

Pamela J. Reeves, MD
Detroit VAMC Medical Center Director

Comments to OIG's Report

Recommendation 1

The John D. Dingell VA Medical Center Director ensures that radiologic equipment receives the required inspection and testing by a qualified medical physicist, and monitors compliance.

Concur.

Target date for completion: 03/30/2018

Director Comments

The facility remediated this recommendation in March of 2018, this included a new RSO contract awarded as a base plus four year contract to establish full RSO oversight at the Detroit VA Medical Center. Within the contract the standards for testing and inspection of required radiologic equipment are defined. This is overseen by the facilities Safety Manager. All equipment was inspected for FY18 and plans are in place to ensure ongoing compliance through FY19.

OIG Comment

The OIG considers this recommendation open in order to allow time for the Facility to provide supporting documentation.

Recommendation 2

The John D. Dingell VA Medical Center Director ensures providers and radiology technicians complete fluoroscopy training as required, and monitors for compliance.

Concur.

Target date for completion: 10/01/2018

Director Comments

100% of providers were educated including the three tiered education, this is currently tracked through credentialing and privileging. Radiology Technologists were all trained by 10/01/2018.

OIG Comment

The OIG considers this recommendation open to allow time for the Facility to provide supporting documentation.

Recommendation 3

The John D. Dingell VA Medical Center Director ensures clinical privileges are granted in accordance with policy, and monitors for compliance.

Concur.

Target date for completion: 06/30/2018

Director Comments

New processes for provider privileging, including 100% tracking of providers requiring education, training and privilege validation. This is completed prior to granting privileges, the process was put in place on 03/27/2018. As of June 2018, the providers were all noted as compliant.

OIG Comment

The OIG considers this recommendation open to allow time for the Facility to provide supporting documentation.

Recommendation 4

The John D. Dingell VA Medical Center Director ensures that the radiology department conform to radiation safety standards as outlined through the National Health Physics Program and fully address any recommendations and violations, and monitors to completion.

Concur.

Target date for completion: 12/01/2018

Director Comments

2018 survey: 3 recommendations all completed by April 1, 2018.

2015 and 2012 survey recommendations will be re-evaluated and presented through the quality leadership committee and Radiation Safety Committee along with an NHPP survey preparation plan to ensure ongoing compliance with standards. In addition, the new RSO contractor will lead the survey preparation efforts.

Recommendation 5

The John D. Dingell VA Medical Center Director ensures that the Radiation Safety Committee minutes reflect actions taken to address National Health Physics Program recommendations and violations, and monitors compliance.

Concur.

Target date for completion: 12/01/2018

Director Comments

Radiation safety committee ownership transitioned in January of 2018, including NHPP recommendation follow up. Beginning 10/16/2018, the RSC will begin active oversight of NHPP preparation and ongoing compliance efforts, in addition, as indicated through Recommendation 4, the NHPP survey follow up, and preparation efforts will also report to the quality leadership committee.

Recommendation 6

The John D. Dingell VA Medical Center Director ensures that the Radiation Safety Officer and Radiation Safety Committee initiate and utilize the Veterans Health Administration required tracking matrix to track unresolved action items to completion, and monitors compliance.

Concur.

Target date for completion: 10/16/2018

Director Comments

The Detroit VAMC has implemented a standard tracking matrix, all recommendations will be reviewed and placed on the matrix for tracking. This will report to the Radiation Safety Committee, and the Quality leadership committee. This tool will be utilized to track any outstanding recommendation and used for survey preparation.

OIG Contact and Staff Acknowledgments

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