Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Diagnostic Radiopharmaceutical Management
VA North Texas Health Care System
Dallas, Texas

Report No. 07-01876-80 **February 20, 2008**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Executive Summary

The VA Office of Inspector General reviewed allegations that diagnostic radiopharmaceutical dosages are deliberately sabotaged or administered incorrectly and that internal problems within the Nuclear Medicine Service contributed to a poor work environment. The purpose of this inspection was to determine the validity of the allegations.

We found that the occurrence of administration errors was unusually high in relation to published data used for comparison. These errors resulted in rescheduling of diagnostic studies causing potential delays in diagnosis and treatment. We could not substantiate or refute that radiopharmaceutical administration errors were a result of sabotage. We did identify the lack of oversight in the service as a contributing factor. We substantiated that there is tension among staff. Finally, we determined the Radiation Safety Committee (RSC) and Radiation Safety Officer were not consistently in compliance with the local Radiation Safety Manual requirements.

We recommended that management: (1) conduct a comprehensive review of its Nuclear Medicine Service and take appropriate measures to reduce radiopharmaceutical administration errors; (2) require the Service Chief to exercise appropriate oversight and to address issues related to radiopharmaceutical administration errors and staff concerns; (3) require all personnel to report elevated radiation levels in accordance with the Radiation Safety Manual and VA policy; (4) ensure that the RSC conducts quarterly reviews of radioactive dosimeter records and radioactive material incidents as required by the local Radiation Safety Manual; and (5) review the cited cases of radiopharmaceutical administration errors with regional counsel to determine patient notification requirements.

The VISN and System Directors agreed with our findings and recommendations and submitted acceptable improvement plans.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Veterans Integrated Service Network (10N17)

SUBJECT: Healthcare Inspection – Diagnostic Radiopharmaceutical Management, VA North Texas Health Care System, Dallas, Texas

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections, reviewed allegations that diagnostic radiopharmaceuticals were administered incorrectly and that employee relations contributed to a poor work environment in the Nuclear Medicine Service (the service) at the VA North Texas Health Care System (the system), Dallas, TX. The purpose of the inspection was to determine the validity of the allegations.

Background

The complainant alleged that once diagnostic radiopharmaceuticals are prepared, dosages are administered incorrectly, preventing accurate scans of selected organs, bones, and/or tissues. Patients must then be rescheduled, causing possible delays in their diagnosis and/or treatment. The complainant also alleged internal strife brought on by a fellow employee contributed to a poor work environment. Finally, the complainant alleged possible sabotage of prepared radiopharmaceutical dosages.

The service is staffed by a chief, a staff nuclear medicine physician, a contract nuclear medicine physician, four nuclear medicine technologists (one is the interim supervisor), two appointment scheduler/clerks, a secretary, and the administrative officer (AO). The proper handling and disposal of radiopharmaceuticals is the responsibility of the nuclear medicine technologists.

The system is granted a license by the Veterans Health Administration (VHA) National Health Physics Program (NHPP), with their approval for the use of specific radioactive materials. The radiopharmaceutical most frequently used for patient scans is Technetium Tc99m;[1] therefore, we focused on this radioactive material for the purpose of our review.

[1] Technetium Tc99m is the principal component of the radiopharmaceutical preparation utilized for certain bone, heart, liver, and lung studies.

In addition, the system has a local Radiation Safety Manual that serves as the policy for the handling, administration, storage, inventory, and disposal of the radioactive materials. This policy describes the Radiation Safety Program (RSP), the responsibilities of the Radiation Safety Officer (RSO), and the role of the Radiation Safety Committee (RSC). The radiation safety policies and procedures in this manual are based on the Nuclear Regulatory Commission, Department of Transportation, Department of Labor, and Food and Drug Administration regulations, as well as, recommendations from the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, and applicable VHA Directives.

Scope and Methodology

We conducted a telephone interview with the complainant. We then contacted the system to procure pertinent documents prior to our site visit. We obtained and reviewed policies and procedures pertaining to Technetium Tc99m management, to include inventory, handling, storage, and disposal. In addition, we reviewed policies and procedures regarding the radiopharmaceutical administration process within the service. We also reviewed three incident reports related to radiopharmaceutical administration errors in 2007, RSC meeting minutes for the last year, Technetium Tc99m inventories and disposal records, a 2005 Administrative Investigation Board (AIB) Report, a Root Cause Analysis for a 2004 incident, quality management data related to diagnostic radiopharmaceutical administration errors, VHA NHPP inspection reports for the last 5 years, and the local Radiation Safety Manual.

After reviewing these documents, we scheduled a site visit to the system. During our site visit, we conducted interviews with the service staff, including two ex-employees and the former RSO. We also evaluated the current process in place for management of radiopharmaceuticals. We received a step-by-step briefing of the process of receiving, preparing, storing, documenting, administering, and disposing of the Technetium Tc99m used in the different studies.

Inspection Results

Issue 1: Radiopharmaceutical Administration Errors

We substantiated that radiopharmaceutical administration errors occurred. We reviewed the following incidents of radiopharmaceutical administration errors that occurred in 2007: February 9, a patient scheduled for a bone scan received a radiopharmaceutical for a lung scan; February 27, a patient scheduled for a cardiac stress test received a radiopharmaceutical for a bone scan; and April 4, a patient scheduled for a bone scan received a radiopharmaceutical for a heart study. Although the patients suffered no harm, the studies required rescheduling due to the 6 hour timeframe for the Technetium Tc99m to be excreted in the urine.

The preparation and storage area known as the "hot lab" is the area where the radioactive materials are handled prior to patient administration. The vials of testing agent for scheduled studies such as heart, lung, bone, and liver are mixed with the Technetium Tc99m and stored in lead lined drawers. The mixed vials for the studies are clearly marked for each specific study and multiple doses may be drawn from each vial for patient administration. However, the syringes with the drawn dosages, as well as the lead tubes they are carried in, all look the same.

The patients are called into the administration area, the study is explained, and an intravenous line is established. The technologist uses a syringe to draw the patient's dose from the mixed vial marked for the specific test the patient is to receive, enters the patient information in the computer, places the syringe in a lead tube, and carries it into the administration area to inject the patient. Once the radiopharmaceutical administration is completed, the study is conducted 3 hours later. The physician viewing the scan during the study can determine the organs or tissues marked by the Technetium Tc99m.

This occurrence rate of administration errors in the service was unusually high, as indicated by published data used for comparison. The Society of Nuclear Medicine described national nuclear medicine error rates in a news release dated January 18, 2006.[2] Referencing United States Pharmacopeia's[3] findings[4] regarding medication error and adverse event rates, this release suggested an error rate of less than .01 percent (about 40 errors per 20 million nuclear medicine procedures).

We found, however, that the error rate at the VA North Texas Health Care System was considerably higher. From June 2006 through May 2007 the system completed 5,780 nuclear medicine procedures (including PET scans) with 3 (.05 percent) radiopharmaceutical administration errors reported. This would be more than 5 times the error rate described by the Society of Nuclear Medicine.

While a complete evaluation of the reasons for this error rate is beyond the scope of this report, we did identify deficiencies in managerial oversight within the service as a possible contributing factor.

We reviewed the labor mapping of the current service chief, who is a full time VA employee. The labor mapping describes 25 percent for patient care, 50 percent for administrative duties, 15 percent for research, and 10 percent for educational activities. During our interview, the service chief stated she spends at least 2 half-days a week at the

[2] U.S. Pharmacopeia Report Demonstrates Safety of Nuclear Medicine Procedures, Society of Nuclear Medicine, January 18, 2006. http://interactive.snm.org/index.cfm?PageID=4786&RPID=627&Archive=1
[3] U.S. Pharmacopeia is the official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured and sold in the United States.
[4] MEDMARX®Data Report, *A Chartbook of 2000-2004 Findings from Intensive Care Units and Radiological Services*, U.S. Pharmacopeia, 2004.

medical school conducting research. She also stated she spends many hours in meetings and other administrative duties as well as 1 complete day viewing scans.

We concluded that oversight of the service is lacking and needs to be improved. The staff consistently expressed their concerns regarding the frequent physical absence of the service chief. They also expressed the need for more involvement with the daily operation of the service, including being accessible to staff when issues arise. They stated they relied upon the interim supervisory technologist for oversight of the service.

Issue 2: Work Environment Tension

We substantiated that there is significant tension among staff in the radiopharmaceutical laboratory. We conducted interviews with the service staff, two ex-employees, and the former RSO. Sixteen of 17 staff interviewed described an unpleasant work environment, making it difficult to put patients first. This appeared to result from poor interactions among the staff. Service staff also expressed a lack of leadership support when trying to address daily issues and concerns.

Issue 3: Sabotage of Radiopharmaceutical Doses

We could not substantiate or refute the allegation that diagnostic radiopharmaceutical doses were being sabotaged. Although various staff verbalized their suspicions of possible tampering and an AIB was conducted to address this issue, staff denied observing or manipulating dosages in both cases.

On February 1, 2005, the Acting Director of the system established an AIB to review concerns regarding patient safety submitted to the RSO by the service AO on November 18, 2004.

The AIB report, dated April 5, 2005, stated that the investigation was convened to review allegations of radiation and patient safety issues that occurred in the service from September 30–October 8, 2004. The allegations centered on intentional tampering of several radiation dose preparations, radiation contamination, and loosening of a component used in a diagnostic camera device that could have resulted in harm to a patient. The AIB concluded there was no evidence to substantiate the allegations; however, they made three recommendations upon which the system took action.

We inspected the service area and determined that tampering with prepared radiopharmaceuticals would be difficult to prove unless directly observed or captured by a surveillance device. At the time of our visit there were no surveillance devices installed in the area.

Issue 4: Radiation Safety

During our inspection, we also identified management issues related to documentation of quarterly RSO reviews and reporting of radioactive material incidents. The radiation safety policies indicate the exposure of all individuals on station (employees, patients, and visitors) to ionizing radiation should be kept as low as reasonably achievable. Barring an accident, all exposures will remain within the current regulatory limits.

The laboratory area should be monitored by measuring and evaluating radioactive contamination and radiation exposure levels. This is accomplished by survey meter readings, and wipe tests taken on personnel, bench tops, refrigerators, waste storage areas, and hoods. Based on the results, steps are taken to decontaminate and determine better handling and storage methods.

We reviewed documents of weekly wipe tests and radiation measurements for the nuclear medicine laboratory specific sites and found documentation was not always completed as mandated by policy. We identified various dates where wipe test results indicated elevated levels of radiation in the hot lab, yet the RSO was not notified as required. The reason for these elevated levels was not apparent on review of the documentation available at the time of our inspection. Failure to report these incidents to the RSO prevented a timely evaluation of potential causes. In addition, the RSC met quarterly; however, they did not consistently conduct quarterly reviews of radioactive dosimeter records and radioactive material incidents as required by the local Radiation Safety Manual. During our interview, the RSO admitted he was not always notified when levels of radiation were elevated.

Conclusion

We concluded that the service's radiopharmaceutical administration error rate was unusually high in relation to published data. The administration errors that occurred resulted in rescheduling of diagnostic studies causing potential delays in diagnosis and treatment. We did not substantiate that radiopharmaceutical administration errors were the result of sabotage.

Employees told us that there is significant tension among staff in the radiopharmaceutical laboratory. Employees also reported a lack of leadership support in addressing this issue and other employee concerns.

The RSO was not notified when wipe test results indicated elevated levels of radiation in the hot lab. This prevented a timely evaluation of potential causes. While the RSC met quarterly, committee members did not consistently conduct quarterly reviews of radioactive dosimeter records and radioactive material incidents as required.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the System Director requires the system to conduct a comprehensive review of its Nuclear Medicine Service and to take appropriate measures to reduce radiopharmaceutical administration errors.

Recommendation 2. We recommended that the VISN Director ensure that the System Director requires the Service Chief to exercise appropriate oversight and to address issues related to radiopharmaceutical administration errors and staff concerns.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires all personnel to report elevated radiation levels in accordance with the Radiation Safety Manual and VHA policy.

Recommendation 4. We recommended the VISN Director ensure that the System Director requires that the RSC conduct quarterly reviews of radioactive dosimeter records and radioactive material incidents as required by the local Radiation Safety Manual.

Recommendation 5. We recommended the VISN Director ensure that the System Director reviews the cited cases of radiopharmaceutical administration errors with regional counsel to determine patient notification requirements.

Comments

The VISN and System Directors agreed with the findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 8–15, for the full text of comments.) We will follow up on the planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: December 18, 2007

From: VISN Director

Subject: **Healthcare Inspection, Diagnostic Radiopharmaceutical Management, VA North Texas Health Care System, Dallas, Texas**

To: Assistant Inspector General for Healthcare Inspections

1. Thank you for the opportunity to submit this report. I concur with the findings and recommendations of this inspection.

2. I have reviewed the attached response from the Director of the VANTHCS for the areas of Improvement recommended by the Office of Inspector General Hotline report and concur with all recommended improvement actions.

(original signed by:)

Timothy P. Shea, FACHE

VISN Director's Comments to Office of Inspector General's Report

The following VISN Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the System Director requires the system to conduct a comprehensive review of its Nuclear Medicine Service and to take appropriate measures to reduce radiopharmaceutical administration errors.

Concur **Target Completion Date:** July 24, 2007

A comprehensive review of the Nuclear Medicine Services was conducted July 24, 2007 by the Radiation Safety Officer at the San Antonio VA and Chief of Nuclear Medicine at Temple VA. The HCS implemented a process of verification by a second technologist along with a Patient Safety Checklist that was disseminated to all Nuclear Medicine staff detailing preparation, identification and administration. During their exit briefing the consultative team concluded that the actions taken by VANTHCS were appropriate to reduce radiopharmaceutical errors. The HCS will continue to track and monitor radiopharmaceutical errors as a recurring agenda item and document their findings in the Radiation Safety Committee meeting minutes.

Recommendation 2. We recommended that the VISN Director ensure that the System Director requires the Service Chief to exercise appropriate oversight and to address issues related to radiopharmaceutical administration errors and staff concerns.

Concur **Target Completion Date:** August 30, 2007

The VANTHCS realigned the administrative duties of the previous and current Acting Chief of Nuclear Medicine to ensure that appropriate allocation of time for staff interaction, education and supervision. In addition, a Chief Technologist has been hired and the new Chief, Nuclear Medicine Service has been selected and is scheduled to report to duty February 2008.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires all personnel to report elevated radiation levels in accordance with the Radiation Safety Manual and VHA policy.

Concur **Target Completion Date:** August 30, 2007

The VANTHCS has implemented a process that requires all personnel to report elevated radiation levels in accordance with the Radiation Safety Manual and VHA policy. A memorandum was disseminated to all Nuclear Medicine staff Dated August 2, 2007 entitled "Report and Notification of a Medical Event", which is defined as “any abnormal wipe test results or daily hot lab survey results by GM counter. A report of an event will be reported to the Chief Technologist, Service Chief and RSO within an hour of occurrence. ” In addition, a report of these events will be tracked and monitored by the Radiation Safety Committee. The Chief of Staff is a member of the Radiation Safety Committee.

The VISN leadership will be notified if the radiation level is significantly above background. The need to notify the network leadership is at the discretion of the Radiation Safety Officer.

Recommendation 4. We recommended the VISN Director ensure that the System Director requires that the RSC conduct quarterly reviews of radioactive dosimeter records and radioactive material incidents as required by the local Radiation Safety Manual.

Concur **Target Completion Date:** August 2, 2007

The Radiation Safety Officer conducts quarterly reports in accordance with the local Radiation Safety Manual. The quarterly report is a recurring agenda item that is recorded in the Radiation Safety Committee minutes. The next report is due December 20, 2007.

Recommendation 5. We recommended the VISN Director ensure that the System Director reviews the cited cases of radiopharmaceutical administration errors with regional counsel to determine patient notification requirements.

Concur **Target Completion Date:** August 30, 2007

VANTHCS has consulted Regional Counsel about these incidents and all patients involved in the three incidents have been notified as documented in the CPRS "Disclosure of Adverse Event."

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: December 7, 2007

From: System Director

Subject: **Healthcare Inspection, Diagnostic Radiopharmaceutical Management, VA North Texas Health Care System, Dallas, Texas**

To: Acting Network Director, Heart of Texas Health Care Network (VISN 17)

1. I want to express my appreciation to the Office of the Inspector General (OIG) Review Team for their professionalism and comprehensive review. I have reviewed the draft report for VA North Texas Health Care System. I concur with the findings and recommendations.

2. I appreciate the opportunity for this review as a continuing process to improve care for our veterans.

(original signed by:)

Joseph M. Dalpiaz

System Director's Comments to Office of Inspector General's Report

The following System Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the System Director requires the system to conduct a comprehensive review of its Nuclear Medicine Service and to take appropriate measures to reduce radiopharmaceutical administration errors.

Concur **Target Completion Date:** July 24, 2007

VA North Texas Health Care System (VANTHCS) implemented a process of verification by a second technologist was implemented on July 2, 2007. Also on July 2, 2007, a Patient Safety Checklist was distributed to all Nuclear Medicine staff by Nuclear Medicine leadership detailing preparation, identification and administration precautions.

VA North Texas Health Care System (VANTHCS) requested a site visit by an external Nuclear Medicine physician and Radiation Safety Officer. This site visit occurred on July 24, 2007 and was focused specifically on reviewing actions taken prior to the OIG review and advising senior leadership on the strength of actions taken, and to determine if additional improvements were advisable. It was concluded that the actions taken by VA North Texas Health Care System were appropriate to reduce radiopharmaceutical errors. This report was shared with the OIG team on August 15, 2007.

Recommendation 2. We recommended that the VISN Director ensure that the System Director requires the Service Chief to exercise appropriate oversight and to address issues related to radiopharmaceutical administration errors and staff concerns.

Concur **Target Completion Date:** August 30, 2007

Following the OIG visit, the Chief of Nuclear Medicine's administrative duties were realigned to allow additional time for staff interaction, education and supervision. VANTHCS currently has an acting Nuclear Medicine Service Chief who continues to allocate additional time to staff education, supervision and training. As additional support, following the OIG visit, a Chief Technologist was hired in Nuclear Medicine Service. A new Chief, Nuclear Medicine Service has been selected and will report in February 2008.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires all personnel to report elevated radiation levels in accordance with the Radiation Safety Manual and VHA policy.

Concur **Target Completion Date:** August 30, 2007

A memorandum was delivered to all Nuclear Medicine staff dated August 2, 2007 titled "Report and Notification of a Medical Event" which indicated "any abnormal wipe test results or daily hot lab survey results by GM counter should be reported within one hour to the Chief Technologist, Service Chief, and RSO." The Radiation Safety Program policy, EC-10 is being modified to accommodate this memorandum. The policy will also recommend notification to the Chair of the Radiation Safety Committee, the Chief of Staff, and the Chief of Safety, with notification to the NHPP (VA National Health Physics Program) and NRC if applicable.

Recommendation 4. We recommended the VISN Director ensure that the System Director requires that the RSC conduct quarterly reviews of radioactive dosimeter records and radioactive material incidents as required by the local Radiation Safety Manual.

Concur **Target Completion Date:** August 2, 2007

Quarterly dosimeter reports have been completed by the Radiation Safety Officer and reported to the Radiation Safety Committee. The reports are included as a matter of record in the committee minutes. In addition the Radiation Safety Officer report includes a section on incidents and violations. The most recent quarterly report was September 19, 2007. The next report will be December 20, 2007. The reports are in electronic format, making them conducive to trending.

Recommendation 5. We recommended the VISN Director ensure that the System Director reviews the cited cases of radiopharmaceutical administration errors with regional counsel to determine patient notification requirements.

Concur **Target Completion Date:** April 4, 2007

Regional Counsel was consulted. Patients have been notified in all three incidents cited, as documented in CPRS as a "Disclosure of Adverse Event". The patient in the February 9 incident was notified by telephone by the service chief on March 1, 2007; the February 27 patient was notified by telephone by the service chief on March 1, 2007; and the patient in the April 4 incident was notified by the Acting Service Chief of Nuclear Medicine Service at the time of the incident.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Wilma Reyes, Healthcare Inspector, Office of Inspector General Office of Healthcare Inspections (214)253-3334
Acknowledgments	Andrea Buck, M.D, J.D., Medical Consultant Linda DeLong, Director Roxanna Osegueda, Program Analyst Marilyn Walls, Healthcare Inspector George Wesley, M.D., Medical Consultant

Appendix D

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