DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: DEC 07 2009

From: Interim Director, VHA National Health Physics Program (115HP/NLR)

Subj: Radiation Safety Program Inspection - Inspection Report 561-09-I01

To: Director (561/00), VA New Jersey Health Care System, East Orange, New Jersey

1. We completed an on-site reactive inspection of the radiation safety program at the VA New Jersey Health Care System, East Orange, on September 16-17, 2009, and November 5, 2009, with continuing review through December 4, 2009. The inspection evaluated circumstances related to the temporary suspension of nuclear medicine procedures. The inspection was closed December 4, 2009.

2. Attachment A to this memorandum is the inspection report narrative with inspection findings, root causes, and corrective actions. Attachment B is a Notice of Violation (NOV) that cites two regulatory violations.

3. We determined a willful violation occurred when a technologist knowingly failed to monitor radioactive material packages received at the facility and deliberately recorded false data as radiation survey results. We categorized this violation at Severity Level III under the Nuclear Regulatory Commission Enforcement Policy. This represents escalated enforcement.

4. We also cited a violation related to record keeping for patient doses at Severity Level IV.

5. You must respond to the NOV within 30 days of the date of this memorandum and follow the instructions in the NOV in preparing the response.

6. Please contact Joseph R. Wissing, National Health Physics Program, at 734-845-3083, if you have any questions about the inspection.

GE Williams

Gary E. Williams

Attachments

cc: Chair, National Radiation Safety Committee
Network Director, VISN 3 (10N3)
Nuclear Regulatory Commission

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Attachment A

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 561-09-I01
VA New Jersey Health Care System, East Orange, New Jersey
September 16 through December 4, 2009

1. Introduction

a. Joseph R. Wissing, VHA National Health Physics Program (NHPP), completed a reactive inspection at the VA New Jersey Health Care System, East Orange, New Jersey, to evaluate the circumstances related to temporary suspension of diagnostic nuclear medicine procedures. The on-site inspections were on September 16-17, and November 5, with continuing review through December 4, 2009. The inspector presented preliminary findings at meetings with key staff on September 18, and November 5, 2009.

b. For continuity of patient care, therapy procedures requiring a written directive were not suspended but performed under the direct supervision of the Radiation Safety Officer (RSO) and Chief, Nuclear Medicine Service.

c. NHPP determined the suspension of nuclear medicine procedures did not require a report to the Nuclear Regulatory Commission (NRC). NHPP provided details of inspection findings to NRC by telephone during the initial on-site visit time frame, and informed NRC about a possible willful violation.

d. The health care system self-identified and self-corrected the circumstances for the reported items of non-compliance.

2. Scope of inspection

The inspection was risk-informed and performance-based and included, but was not limited to, the following.

a. Interviews with health care system staff.

b. Review of records related to health and safety and regulatory compliance.

c. A tour of facilities.

d. A review of the health care system initial actions, including evaluation of the effectiveness and comprehensiveness of actions to prevent a recurrence.

e. Review of radiation safety practices.

f. Evaluation of root or basic causes for the circumstances that resulted in the temporary suspension of nuclear medicine procedures.

3. Findings and impressions (background information)

a. NHPP previously inspected the health care system on February 21-26, 2007, and cited one violation. The violation was for failing to receive a permit amendment releasing an area of use before demolition. NHPP inspected the health care system on July 19, 2007, and did not cite any violations.

b. NRC inspected the health care system on February 21-22, 2001, and did not identify any violations.

c. The health care system has a full-time RSO who is delegated complete autonomy for radiation safety program implementation and stop-work authority. The RSO was named on the health care system permit on November 9, 2007.

d. Executive management provides oversight for the Radiation Safety Committee (RSC) and RSO by having the committee report quarterly to the Environment of Care Committee.

4. Findings and impressions (suspension of nuclear medicine procedures)

a. The inspection focus was to evaluate the circumstances related to temporary suspension of diagnostic nuclear medicine procedures. NHPP became aware of this suspension after a media inquiry was received by a National Radiation Safety Committee member. The inquiry also noted possible regulatory violations including a purported contamination incident.

b. The RSO had identified deviations from regulatory requirements during audits that were completed over an 18-month period and summarized in the 2008 annual review of the radiation safety program. The audits continued into 2009.

c. Monthly audits performed by the RSO identified nuclear medicine technologists had not completed the following tasks as required.

(1) Record all required information for patient dose records.

(2) Record end-of-day radiation surveys in the Nuclear Medicine Service areas.

(3) Perform and/or record dose calibrator constancy checks.

(4) Perform and record package receipt surveys and maintain proper inventory of radioactive material received.

(5) Perform and record weekly wipe test surveys of areas.

(6) Maintain constant surveillance of radioactive materials in use.

(7) Wear personal dosimetry devices.

(8) Avoid drinking coffee in stress laboratory room.

d. On at least one occasion, a technologist, Technologist A, had recorded false data as radiation survey results for receipt of a package with radioactive materials.

(1) The RSO discussed this willful violation with Technologist A, who confirmed the package receipt survey was not completed and the data entry was based on false data.

(2) The RSO reported the willful violation to executive management who initiated a personnel action under VHA policy. Technologist A later resigned from the health care system.

e. For other items of non-compliance identified during audits, the RSO provided documentation in the format of four separate memoranda (March 2, March 11, April 3, and July 15, 2009), and in several face-to-face meetings with the technologist responsible for the non-compliance and the Chief, Nuclear Medicine Service. The interactions and documentation identified items of non-compliance and reminded the technologist and service chief of required policies and procedures.

f. The RSC had a meeting on July 30, 2009, to discuss the items of non-compliance. The RSC concluded that one technologist, Technologist B, was primarily responsible for the numerous items of noncompliance, and recommended to the health care system director that Technologist B be suspended.

g. On August 4, 2009, executive management reassigned Technologist B to duties not involving nuclear medicine procedures pending further review. This action resulted in the Nuclear Medicine Service being staffed with only one full-time technologist, Technologist C, who was new and still in the initial probationary period of employment.

h. The Radiology Service and Nuclear Medicine Service managers recommended to executive management that, based on Nuclear Medicine Service being staffed with only a single technologist with limited experience and the Service's historical challenges for regulatory compliance, a prudent response was to temporarily suspend nuclear medicine procedures until staff retraining was performed.

i. On August 7, 2009, executive management approved a temporary suspension for diagnostic nuclear medicine procedures.

(1) For continuity of patient care, the therapy procedures requiring a written directive were not suspended but allowed to be performed under the direct supervision of the RSO and Chief, Nuclear Medicine Service.

(2) Executive management did not identify any patient care deficiencies or issues as a basis for the temporary suspension of nuclear medicine procedures.

j. On September 15, 2009, NHPP became aware that clinical use of radioactive materials in the Nuclear Medicine Service had been suspended. NHPP contacted the facility and confirmed the suspension had occurred effective August 7, 2009.

k. On September 16-18, 2009, NHPP completed an on-site reactive inspection at the health care system to evaluate circumstances related to the temporary suspension.

l. On October 5, 2009, diagnostic nuclear medicine procedures resumed on a limited basis consistent with staffing the Nuclear Medicine Service with Technologist C. Procedures were resumed based on training provided by the RSO and oversight of clinical procedures performed under the direct supervision of the RSO and Chief, Nuclear Medicine Service.

m. On November 5, 2009, NHPP performed a second on-site review of the radiation safety program to confirm corrective actions were implemented and review regulatory compliance after the resumption of nuclear medicine procedures.

n. The reassigned technologist, Technologist B, has been tasked with completing comprehensive retraining of all radiation safety program policies and procedures including those regulatory requirements for use of the dose calibrator and recording patient doses. After successful completion of retraining, the health care system executive management plans to reinstate Technologist B with approval for participation in nuclear medical procedures.

5. Findings and impressions (violations, root or basic causes, and corrective actions)

a. The inspector agreed with the health care system finding that Technologist A had engaged in deliberate misconduct on March 11, 2009, and other occasions by intentionally failing to perform radiation surveys of incoming packages with radioactive materials and deliberately recording false data as radiation survey results. This is a willful violation of regulatory requirements.

(1) 10 CFR 20.1906 requires the health care system to survey the external surfaces of labeled packages for radioactive contamination within 3 hours after receipt, if received during the normal workday.

(2) 10 CFR 30.10 requires the health care system not to engage in any deliberate misconduct that causes the health care system to be in violation of NRC regulations and defines misconduct as an intentional act or omission that a person knows would cause the health care system to be in such a regulatory violation.

(3) For the willful violation, the inspector did not identify a root or basic cause for the deliberate nature of the violation. The deliberate act is addressed as a personnel issue and not under NHPP guidelines. As a result of personnel actions taken by the health care system, Technologist A resigned and is no longer employed by the health care system.

b. The inspector determined that on April 2, 9, 24, 28, and June 5, 2009, patient dose records for nuclear medicine procedures did not contain the date and time of the dosage determination, and the name of the individual who determined the dosage.

(1) 10 CFR 35.2063(b) requires records of dosage determinations required by § 35.63 contain the radiopharmaceutical; patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); date and time of the dosage determination; and name of the individual who determined the dosage.

(2) The inspector identified a root or basic cause as "Procedures Followed Incorrectly," in that the technologists failed to follow procedures for recording all required information on patient dose records. A contributing factor was written policies and procedures lacked detail prescribing all requirements for patient dose records.

c. The inspector concluded that other items of non-compliance noted by the RSO in monthly audit reports were deviations from internal procedures (personal and area surveys, dose calibrator, personal dosimeters, drinking in area, and inventory). NHPP recognizes all items identified by the RSO as important practices to be followed by Nuclear Medicine Service staff for the safe use of radioactive materials. The inspector exercised discretion for the security of radioactive materials incident due to the time frame of the material not under direct surveillance being 1 minute or less.

d. Corrective actions taken by the health care system were the temporary suspension of nuclear medicine procedures and staff retraining on all procedures and policies for use of radioactive materials in Nuclear Medicine Service. The health care system committed to performing a review of current policies, procedures, and revisions, as necessary.

e. The inspector determined the temporary suspension of nuclear medicine procedures did not constitute regulatory non-compliance.

f. The inspector noted the health care system self-identified the regulatory deficiencies and initiated prompt and comprehensive corrective action to prevent recurrence. All staff interviewed stated their commitment to compliance with all radiation safety program requirements including internal procedures, and ensuring a safety culture consist with NRC and NHPP requirements.

g. The inspector noted that medical event(s), worker or public overexposures, spills of radioactive material, and incidents did not occur as a result of the self-identified deficiencies or the violations identified in paragraphs 5a and 5b.

h. Selected records and procedures reviewed with no deficiencies or violations noted included written directives, dosimetry results, sealed source inventories and leak test results, spill and incident reports, and radioactive material security.

i. No regulatory violations were identified during this inspection for circumstances since resuming diagnostic nuclear medicine procedures on October 5, 2009.

j. The inspector did examine details of a contamination event involving Tc-99m which occurred in the treadmill stress test laboratory on April 16, 2009. The contamination event did not appear to involve bulk material (i.e., there was no indication of a spill involving bulk liquid, such as a dropped or broken syringe). The RSO identified the contamination during a routine

survey, noting surface contamination on the floor and treadmill. In response, the areas were cleaned until background was measured. One technologist's shoe measured approximately 10 mR/hr at the surface. Another employee's shoe measured around 1 mR/hr. These shoes were confiscated and secured for decay to background levels. No individual skin contamination was identified. The inspector did not identify any regulatory violations with respect to the permittee's response to this contamination event.

6. Notice of Violation: The inspection identified two violations. One violation is at Severity Level III. One violation is cited at Severity Level IV. Attachment B is the Notice of Violation citing the two violations.

7. Personnel Contacted

K. Mizrach, Director [1,2,3]
S. Lieberman, M.D, Chief of Staff [1,2,3]
C. Mele, M.D., Chief, Radiology Service [1,2,3]
M. Cook, M.D., Chief, Nuclear Medicine Service [1,2,3]
J. Shah, M.D., Chair, Radiation Safety Committee [2]
V. Havrilko, AO, Radiology Service [1,2]
V. Lanka, Radiation Safety Officer [1,2,3]
P. Selikowitz, CNMT, Chief, Nuclear Medicine Technologist [3]
M. Beltran, CNMT, Nuclear Medicine Technologist [3]

1. Present at entrance meeting
2. Present at exit meeting
3. Present in inspection discussions

Attachment B

Notice of Violation (NOV)
Inspection Report Number 561-09-I01

VA New Jersey Health Care System,
East Orange, New Jersey

VHA Permit Number 29-04481-01

1. Violation(s)

a. Radiation surveys and staff conduct: 10 CFR 20.1906 requires permittees to survey any incoming packages with radioactive materials. 10 CFR 30.10 requires permittees not to engage in any deliberate misconduct that causes the permittee to be in violation of Nuclear Regulatory Commission regulations.

Violation: Contrary to the above, a technologist engaged in deliberate misconduct causing the permittee to be in violation of 10 CFR 20.1906, in that on numerous occasions during the months of February and March of 2009, the technologist intentionally failed to perform radiation surveys of incoming packages with radioactive materials and deliberately recorded false data as radiation survey results. This is a willful violation of regulatory requirements.

This is a Severity Level III violation.

b. Patient dose records: 10 CFR 35.2063(b) requires the dosage records include specific information including date and time of dosage determination and the name of the individual who determined the dosage.

Violation: Contrary to the above, on April 2, 9, 24, 28, and June 5, 2009, the dosage records for the nuclear medicine procedures did not contain the date and time of the dosage determination, and the name of the individual who determined the dose.

This is a Severity Level IV violation.

2. Required action

a. The health care system must take prompt actions to correct the violations listed in this NOV and ensure the violations do not recur.

b. For each violation, the health care system must submit a written statement to the National Health Physics Program (NHPP) within 30 days of the date of the memorandum transmitting this NOV. The response must describe the following.

(1) Basic cause or causes for the violation or agreement with the basic causes identified in the inspection report narrative, or, if contested, the basis for disputing the violation or severity level.

(2) Corrective steps already taken and/or confirmation that the corrective actions outlined in the inspection report were taken.

(3) Corrective steps which will be taken.

(4) Date full compliance will be achieved for the corrective steps that will be taken.

c. Where good cause is shown, NHPP will consider extending the response time.