DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: JUL 01 2010

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

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 405-10-I01

To: Director (405/00), VA Medical Center, White River Junction, Vermont

1. Paul L. Yurko, VHA National Health Physics Program, inspected the radiation safety program at the VA Medical Center, White River Junction, Vermont, on June 9, 2010. In addition to a routine core inspection, this inspection evaluated circumstances related to failure to have continuous coverage by a Radiation Safety Officer for permitted use of radioactive materials.

2. Attachment A has the inspection report narrative with the inspection findings, root causes, and corrective actions. Attachment B is a Notice of Violation (NOV) that cites two violations, which together represent a Severity Level III problem. One violation was characterized as being willful based on a careless disregard for regulatory compliance.

3. Willful violations are a very serious concern to us since we rely, in part, on the integrity of permittees and their staff to comply with applicable regulations. A willful violation represents unacceptable actions by a permittee.

4. You must respond to the NOV within 30 days of the date of this memorandum and use the instructions in the NOV to prepare the response.

5. If you have any questions, please contact Mr. Yurko at 410-642-2411, extension 6288.

G E Williams

Gary E. Williams

Attachments

cc: Chair, National Radiation Safety Committee, and members
Network Director, VISN 1 (10N1)
Nuclear Regulatory Commission

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Attachment A

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 405-10-I01
VA Medical Center, White River Junction, Vermont
June 9, 2010

1. Introduction

a. Paul L. Yurko, VHA National Health Physics Program (NHPP) completed an announced inspection at the VA Medical Center, White River Junction, Vermont, on June 9, 2010.

b. The inspector presented preliminary findings at meetings with key staff on June 9, 2010, and closed the inspection.

2. Scope of inspection

a. The inspection focus was risk-informed and performance-based.

b. The inspection consisted of an examination of rooms and equipment of Nuclear Medicine Service and research laboratories, review of radiation safety practices and records, observations of, and interviews with, key facility staff and executive management, and review of corrective actions in a facility issue brief dated May 4, 2010.

c. The inspector completed spot-check radiation measurements in the Nuclear Medicine Service hot laboratory. Radioactive materials were not in possession in areas authorized for research use of radioactive materials. All the research radioactive materials were stored in a refrigerator that was locked and only the temporary Radiation Safety Officer (RSO) had a key.

3. Findings and impressions (background information and inspection results)

a. The Nuclear Regulatory Commission (NRC) inspected the facility on February 16, 2005, and did not cite any violations. NHPP previously inspected the facility on June 20, 2007, and did not cite any violations.

b. Selected records and procedures in the following areas were reviewed with no violations or deficiencies identified.

(1) Written directives

(2) Dosimetry

(3) Sealed source inventories and leak test results

(4) Spills and incidents

(5) Radiation Safety Committee (RSC) meetings

c. On May 4, 2010, NHPP received via e-mail, a permit notification of a temporary RSO per 10 CFR 35.24(c). The notification was to approve and name Dr. James E. Lenz, an authorized user on the permit, as the temporary RSO.

d. On May 4, 2010, NHPP began review of the permit notification request. NHPP identified the following.

(1) The notification did not include sufficient information demonstrating adequate training and experience consistent with NRC and VHA requirements to approve Dr. Lenz as an RSO on their permit for research use of radioactive materials.

(2) The e-mail identified the current RSO named on the permit was no longer employed by the facility and had permanently discontinued duties as of April 30, 2010.

e. On May 4, 2010, NHPP contacted the facility by telephone to review the notification. The following issues were discussed.

(1) NHPP confirmed the named RSO on the permit was no longer employed at the facility.

(2) NHPP reported that the notification did not include adequate information to approve Dr. Lenz as RSO for research use of radioactive materials.

(3) Lacking additional information to demonstrate Dr. Lenz met NRC training and experience requirements to qualify as RSO for research use of radioactive materials, the research radioactive material program was suspended. Corrective actions were specified in a facility issue brief dated May 4, 2010.

f. On June 9, 2010, the facility submitted a new amendment request to approve and name F. X. Masse, the current consultant physicist, as RSO. NHPP issued Amendment No. 35, approving the new RSO on the permit with an effective date of June 17, 2010.

g. On June 9, 2010, NHPP initiated an on-site inspection to evaluate the continuous coverage by the RSO named on the permit during the period from April 30 until May 4, 2010.

h. Interviews conducted by the inspector along with a review of RSC minutes and e-mails between executive management, the RSO, and NHPP demonstrated the following information.

(1) The previous RSO retired on April 30, 2010.

(2) Executive management was not made aware that the RSO was retiring April 30, 2010, until May 3, 2010.

(3) The previous RSO only notified his immediate supervisor that he intended to retire on April 30, 2010. The notification was on April 12, 2010, and then the supervisor went on leave until April 26, 2010.

(4) On May 3, 2010, executive management was notified that the previous RSO had retired effective April 30, 2010, and began to identify an individual who would be qualified to serve as temporary RSO.

i. The inspector confirmed that executive management was aware of the requirement to have continuous RSO coverage.

(1) Executive management had copies of relevant documents including VHA Directive 1105.01, dated October 7, 2009, "Management of Radioactive Materials," and Deputy Under Secretary for Health for Operations and Management (10N) memorandum dated June 30, 2009, "Radiation Safety Officer."

(2) Executive management confirmed their understanding that the ultimate responsibility for regulatory compliance lies with the director as the named permitted official but concluded failure to submit a proper and timely amendment request was a direct result from a lack of information provided by the former RSO.

4. Findings and impressions (violations, root causes, and corrective actions)

a. NHPP identified two violations of regulatory requirements.

(1) The first violation was for failure to appoint, and have approved, a new RSO after the RSO named on the permit permanently discontinued duties. Contrary to 10 CFR 35.24(b) and VHA Directive 1105.01, paragraph 4(d)(3), from April 30, 2010 through May 4, 2010, a period of five days, the facility failed to ensure approval and continuous coverage by an approved RSO.

(2) The second violation was for failure to perform routine linearity checks on the Capintec dose calibrator as specified in the Capintec dose calibrator operating manual.

b. For the first violation, NHPP concluded the former RSO had shown careless disregard of regulatory requirements by failing to provide to executive management complete information for amending the permit for a new RSO before retiring. Such careless disregard is categorized under NRC Enforcement Policy as a willful violation.

c. NHPP identified a root cause for the first violation of "Management System - Standards, Policies, or Administrative Controls Need Improvement," in that facility written policies did not specifically address the requirement for continuous coverage by an RSO if permitted activities are allowed to continue without restriction after the RSO on the permit permanently discontinues performance of duties.

d. NHPP identified a root cause for the second violation as "Procedures - Procedures not used/ Procedures not followed," in that the previous RSO failed to follow procedures for quality assurance for the dose calibrator from January 2009 until April 30, 2010.

e. The corrective actions taken by the facility include the following.

(1) Permit amendment requested and approved: On June 9, 2010, the facility requested an amendment to its permit to change the named RSO. On June 17, 2010, NHPP issued a revised permit changing the named RSO. The facility had taken compensatory measures effective May 4, 2010, to ensure regulatory compliance while a new RSO was being identified and approved.

(2) Review of policies and procedures: The temporary RSO and executive management had reviewed the policies and procedures related to the conduct of the radiation safety program and continuous RSO coverage. They committed to revising, as necessary, radiation safety program policies and procedures including the requirement of continuous RSO coverage and updating the references to VHA Directive 1105.01.

(3) Perform linearity checks: A linearity check of the dose calibrator was performed in April 2010. Based on results, the dose calibrator appears to have been functioning properly in the interval during which checks were not performed.

f. The inspector noted the facility had qualified staff including a contracted medical physics consultant to respond to emergencies, evaluate possible incidents, be available for advice and assistance, and respond to any time-urgent health and safety issues, or provide help with worker concerns.

g. NHPP did not identify any circumstances that had resulted in a medical event, spill of radioactive materials, removable contamination above a limit, loss of radioactive material, or exposure to ionizing radiation that exceeded a limit during the time period the facility did not have continuous coverage by an approved RSO. Administrations of radiopharmaceuticals requiring a written directive did not occur during the time without RSO coverage.

h. The violations did not result in loss of radioactive material and prompt and comprehensive corrective action was taken. The lack of an RSO did not result in a health and safety issue

5. Notice of Violation: The inspection identified two violations of NRC regulations, which are cited in the Notice of Violation (Attachment B) and are categorized together as a Severity Level III problem. One of the violations represented a willful violation.

6. Persons Contacted

Robert M. Walton, Director [1,2,3]
Thomas A. Parrino, M.D., Chief of Staff [1,2]
James E. Lenz, M.D., Temporary RSO, and RSC Chair [1,2,3]
Brooks Robey, M.D., ACOS Research [3]

1. Individual(s) present at entrance meetings
2. Individual(s) present at exit meetings
3. Individual(s) present or participating in inspection discussions

Attachment B

Notice of Violation (NOV)
Inspection Report Number 405-10-I01

VA Medical Center, White River Junction, Vermont **VHA Permit Number 44-05123-01**

1. Violation(s)

a. Radiation Safety Officer (RSO): 10 CFR 35.24(b) requires facility management to appoint an RSO, who agrees to be responsible for implementing the radiation protection program. VHA Directive 1105.01, Item 4(d)(3), requires medical facility directors to establish a Radiation Safety Committee and ensure approval and continuous coverage by an RSO.

Violation: Contrary to the above, from April 30 through May 4, 2010, a period of five days, facility management failed to ensure approval and continuous coverage by an RSO. The failure to have continuous coverage resulted, in part, from a careless disregard for regulatory compliance by the former RSO by not providing accurate information to identify and approve a new RSO.

b. Failure to perform dose calibrator linearity: 10 CFR 35.60(a) requires a facility that performs direct measurements per 10 CFR 35.63 to possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient. 10 CFR 35.60(b) requires the facility to calibrate the instrumentation required in paragraph (a) of this section per nationally recognized standards or manufacturer's instructions.

Violation: Contrary to the above, from January 2009 to April 2010, the facility did not calibrate the instrumentation required in paragraph (a) of the section per nationally recognized standards or manufacturer's instructions. Specifically, the facility failed to perform the linearity check on their Capintec CRC®-15R dose calibrator at a quarterly frequency as specified by the manufacturer's operating manual.

These two violations represent a Severity Level III problem.

2. Required action

a. The facility must take prompt actions to correct the violations in this NOV and ensure the violations do not recur.

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

(1) Basic cause for the violation or agreement with the NHPP root causes and contributing factors, and, if contested, the basis for disputing the violation or severity level.

(2) Corrective steps already taken and/or concurrence with description of corrective actions outlined in the inspection report narrative, or, if needed, clarification of corrective steps outlined in the inspection report.

(3) Corrective steps which will be taken. Corrective actions must include, but not be limited to the corrective actions outlined in the inspection report and any other actions by the facility deemed necessary to prevent recurrence of the violations.

(4) Date full compliance was or will be achieved.

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