

VHA National Health Physics Program Inspection Record

Inspection report number: 663-08-I01

Permit number: 46-00990-01

Permittee (name and address):

VA Puget Sound Health Care System
1660 S. Columbian Way
Seattle, Washington 98108

Locations of use being inspected:

Seattle Division
1660 S. Columbian Way
Seattle, Washington 98108

American Lake Division
9600 Veterans Drive
Tacoma, Washington 98493

Permittee contact (name and telephone number): David Dunn, (206) 277-1789

Permit priority: 2

Permit program code: 2110/3610

Date of last inspection: NHPP – June 29 and December 14-15, 2005

Date of this inspection: February 5-7, 2008

Type of inspection: () Announced (X) Unannounced
() Initial (X) Routine () Special

Next inspection date: February 2010 (normal, unless modified by NHPP inspection algorithm)

Summary of findings/actions:

- () No violations (NHPP Form 591 issued)
- (X) Severity Level IV and/or non-cited violations (NHPP Form 591 issued)
- () Severity Level IV and/or non-cited violations (NHPP inspection report and Form 591 issued)
- () Severity Level I, II, or III violations (NHPP inspection report and NOV issued)
- () Follow-up on previous violations

Inspector(s): Joseph R. Wissing
Joseph Wissing

Date: March 3, 2008

Approved: E. Lynn McGuire
E. Lynn McGuire, NHPP Director

Date: 3/13/08

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PART I - PERMIT, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

- a. Amendment No. 70, approved December 21, 2006, changed the RSO.
- b. Amendment No. 71, approved by NHPP on February 26, 2008, released Waste Storage Area 3 for unrestricted use based on permittee's amendment request dated April 17, 2007, and additional information in e-mails dated June 15 and December 11, 2007. Request was approved by Nuclear Regulatory Commission (NRC) in a February 15, 2008, letter.

2. INSPECTION AND ENFORCEMENT HISTORY:

- a. NRC inspection performed on February 10-11, 2004, cited one violation, considered closed in NHPP's inspection of December 2005.
- b. NHPP routine inspections performed on June 29, and December 14-15, 2005, did not cite violations.
- c. The permit does not have any significant regulatory enforcement history.

3. INCIDENT/EVENT HISTORY:

Over exposures or medical events have not been identified or reported since the last NHPP inspection. Results from the Nuclear Materials Events Database review identified no listings relevant to the authorized locations of use on the permit.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The VA Puget Sound Health Care System, Seattle, Washington, conducts a radiation use program under a VHA broad-scope permit for medical and research use. Permitted material may be used at the permittee's facilities located at 1660 South Columbian Way, Seattle, Washington; 4815 North Assembly Street, Spokane, Washington; and American Lake Division, 9600 Veterans Drive, Tacoma, Washington. The scope of program operations remains relatively unchanged since NHPP's last inspection. Permanent implant prostate brachytherapy is routinely performed in Seattle. The Spokane site of use was not reviewed during this inspection.

The Radiation Safety Officer (RSO) is listed on the permit. The RSO prepares and submits summaries of radiation safety program audits to the Radiation Safety Committee (RSC), prepares RSC agendas, trains staff, performs certain equipment calibrations, tracks radioactive material inventories, reviews administrations of radiopharmaceuticals requiring a written directive, and performs other duties as necessary to accomplish radiation safety program objectives. The permittee RSC meets quarterly. RSC membership and attendance was commensurate with the permit scope of operations. The RSC reviews RSO reports, authorized area and user changes, radioactive material uses, regulatory compliance, and employee exposures to ionizing radiation. The RSO reviews operations in Tacoma monthly and Spokane quarterly.

Nuclear Medicine Service (Seattle and Spokane) receive unit dose radiopharmaceuticals from a local radiopharmacy. At Seattle, administrations of radiopharmaceuticals requiring a written directive are routinely performed. For radiopharmaceutical therapy using encapsulated I^{131} sodium iodide, patients are

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treated and released according to 10 CFR 35.75, or hospitalized and released when permitted by regulation, depending on the patient's individual circumstances. Security of areas authorized for Nuclear Medicine Service includes door keys and card-coded door locks. Nuclear medicine technologists perform various radiation safety program duties such as area surveys, package check-in surveys, dose calibrator quality control, radioactive waste disposal, and other duties necessary to achieve radiation safety program objectives.

Manual loading permanent implant brachytherapy using I¹²⁵ and Pd¹⁰³ is authorized and routinely performed by the permittee at Seattle. Procedures are performed weekly.

Research radioactive materials are ordered through the RSO and delivered to the respective division warehouse. At the Seattle Division, packages are collected by the RSO or Radiation Safety Technician (RST) and transported to the radiation safety lab, for survey and logging into the computer. The RSO or RST then delivers the packages to the end user. At the American Lake Division, the packages are picked up from the warehouse by the user who performs package survey and logging. For both divisions, inventories are maintained using a computer program to ensure permit limits are not exceeded. Each research package is assigned a unique number and recorded on an inventory form. The research users maintain stock vial inventories and return the completed forms when the radioactive material is transferred to waste. The RST and RSO manage the radioactive waste pick-up and transfer program. The waste is segregated and either stored for decay in the radiation safety storage area or transferred to a licensed radioactive waste broker.

Research labs are located in buildings secured by card-reader systems or on dedicated floors accessible only by key system. Research staff must register with R&D Service to obtain a magnetic card or key. R&D Service performs background checks on all VA and non-VA employees (WOC). Security requirements and intruder alert training is emphasized during new employee orientation, which includes radiation safety information and procedures for reporting lost or stolen magnetic cards and ID.

At the time of the inspection, the Seattle Division had 24 principal investigators (PIs) authorized to conduct biomedical research not involving human subjects and 2 PIs at the American Lake Division. Approximately 50 areas are posted for radioactive material use for research and radioactive material storage. Authorized PIs are delegated certain radiation safety program operations within their authorized areas including waste management, area and removable contamination surveys, research worker training within their laboratory, and radioactive material inventories. Security of areas authorized for non-human research use of radioactive materials includes standard door keys and in some cases, electronic swipe cards, and numeric key-coded door locks. Research studies using radioactive materials in animals and radioiodinations are not routinely performed. The RSO reported that eventually all research activities will be transferred from the American Lake Division to the Seattle Division necessitating closeout surveys for two remaining research buildings and the radioactive waste storage shed.

The RSO has complete autonomy with regard to radiation safety program implementation and stop-work authority to manage the radiation safety program and achieve program goals and objectives as coordinated with the permittee's RSC and executive management. The permittee maintains a library with regulations contained in 10 CFR, NRC guidance documents including the recent security bulletin, VHA directives and handbooks, access to NHPP's Web site, and previous *NHPP Scatterings*.

2. INSPECTION SCOPE AND NRC INSPECTION PROCEDURES USED:

The inspector reviewed all items contained in the inspection plan approved by the NHPP Director. The inspection was oriented to a risk-informed, performance-based evaluation of the radiation safety program and interviews with staff, observations of radiopharmaceutical handling procedures, package survey and

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check-in procedures, shipping and receipt of byproduct material, inventories of radioactive material, and security. The inspector observed nuclear medicine and research staff work routines to determine how radiopharmaceutical doses were assigned, how dose information was recorded, and how staff followed their delegated radiation safety program responsibilities. Specific written records reviewed back to NHPP's last inspection included personal dosimetry records, annual radiation safety program reviews, RSC meeting minutes, and internal radiation safety program audits.

For the NRC inspection procedures, the inspector used the focus areas identified in the inspection procedures (i.e., security and control of radioactive materials, shielding, comprehensive safety measures, dosimetry, instrumentation and surveys, training and practices, and RSC/RSO/management oversight) and determined the adequacy of the radiation safety program following a performance-based approach. The NRC inspection procedure used for this inspection was IP 87134, "Medical Broad Scope Programs."

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Area survey measurements were taken with the permittee's calibrated survey meter, Biodex Model 14-C, serial number 051-014 with a GM detector, last calibrated on April 4, 2007. Spot-check radiation surveys were completed in the Nuclear Medicine Service hot laboratory, sealed source storage cabinet, central storage area for radioactive materials, and adjacent unrestricted areas. All area exposure readings in the hot laboratory area measured 0.3 mR/hr or lower. Areas with radiopharmaceutical waste and patient doses are adequately shielded. No radioactive contamination was found in areas where it would not be expected. No radiation exposure rates were found that would cause regulatory limits to be exceeded or were contrary to the ALARA philosophy.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

a. Within the scope of this inspection, three violations were identified.

(1) The permittee failed to receive approval releasing "Waste Storage Area 3" for unrestricted use prior to its demolition. The inspector reviewed actions taken by the permittee to prevent recurrence of releasing an authorized area of use without proper approval. VHA Permit Amendment No. 71, releasing the building for unrestricted use was approved by NHPP on February 26, 2008, based on permittee's amendment request dated April 17, 2007, and additional information in e-mails dated June 15 and December 11, 2007. The request was approved by NRC in a letter dated February 15, 2008. The permittee RSC adopted NHPP's footprint management and closeout survey procedures. Interviews with executive management and the RSO demonstrated their understanding of the decommissioning and closeout survey process as adequate to prevent recurrence.

(2) Containers of radioactive material stored in research freezers, containing at least 1 mCi of H^3 , were not labeled in accordance with 10 CFR 20.1904(a).

(3) The permittee failed to calibrate surveys meters in accordance with 10 CFR 35.61(a)(1), in that a survey meter used in Nuclear Medicine Service for quantitative surveys (removable contamination and area surveys) was not calibrated with a radiation source on all scales. The permittee was calibrating survey meters "in-house" with an electronic pulser. The permittee committed to having the survey meter taken out of service, replaced with a properly calibrated survey meter, and ensure all future survey meters are calibrated consistent with NRC regulations.

b. The inspector noted violation (1) cited for failing to receive approval releasing a building for unrestricted use prior to its demolition was self-identified, non-repetitive, corrective action was taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were

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satisfied. The inspector recommends that in accordance with the NRC Enforcement Policy, the violation is categorized as a non-cited violation (NCV).

c. The inspector noted violations (2) and (3) are categorized at a Severity Level IV in accordance with NRC Enforcement Manual. Due to actions committed to be taken by the permittee during the exit briefing to use survey meters calibrated with a radiation source on all scales appropriate for their use, immediately label all containers with radioactive material in accordance with the regulation, provide training for regarding the proper labeling of containers with radioactive materials, and complete all corrective actions within 30 days of the preliminary exit briefing on February 7, 2008, the inspector recommends that a written response to violations 2 and 3, be waived. The inspector confirmed on March 3, 2008, that all corrective actions were implemented. Corrective actions are to be reviewed during the next scheduled routine NHPP inspection.

d. In addition to the violations noted above, the inspector noted the following items.

(1) The RSO could not locate records demonstrating RSC approval of authorized users in Nuclear Medicine Service. It was noted that all authorized user physicians in Nuclear Medicine Service are contracted from the University of Washington, and are approved through the University's RSC (an agreement State broad-scope program). The inspector left the inspection open pending the permittee's submission of evidence that physicians performing duties for 10 CFR 35.100, 35.200, 35.300, and 35.500 uses, are approved by the permittee's RSC. The inspector recommended that historical RSC records be located to ensure proper authorizations of use and/or that the University be contacted to obtain records of their approval by the University's RSC and reapprove the physicians through the RSC. RSC records of authorized user approvals should be reviewed during the next NHPP inspection.

(2) The inspector noted RSC meeting minutes were not signed by the Chair or executive management. A formal oversight mechanism of the RSC meetings was not evident. The inspector reviewed options of RSC oversight including having copies of RSC meetings reviewed by the Environment of Care Committee and the Environment of Care Committee policy be revised to require such oversight. Executive management oversight of RSC operations should be reviewed during the next NHPP inspection.

(3) The inspector noted radioactive material use in Building 18 South at the American Lake Division has ceased for a period exceeding 12 months. The permittee RSC and RSO are taking steps and reviewing options to permanently close out the building. Contracting the closeout surveys to an outside vendor is an option being considered by the permittee. The inspector noted the Seattle Division has numerous inactive areas authorized for radioactive material use in Research Service. The RSC and RSO are reviewing these areas for possible close out. Current survey records demonstrated inactive authorized areas did not have radioactive material contamination and no inventories of radioactive materials in possession. The inspector confirmed with the RSO and executive management that action would be taken to close out inactive authorized areas at both Seattle and American Lake Divisions in accordance with the NRSC mandate. At the next RSC meeting, the RSO plans to recommend close out of certain research laboratories and locations of use that have permanently discontinued use of radioactive materials. The inspector discussed the requirements of the decommissioning rule, historical site assessment, and NRSC mandate for permittee footprint reduction with the RSO. Close out of inactive laboratories and compliance with the decommissioning rule should be reviewed during the next scheduled NHPP inspection.

(4) The inspector noted the permittee had previously possessed two radium sources. These sources were shipped to the Hanford disposal facility. The RSO had a copy of the letter from Hanford documenting their receipt of the sources. The permittee has no other radium sources in possession.

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(5) The inspector noted the permittee does possess approximately 30 kg of depleted uranium. The depleted uranium was used for shielding in their ADAC attenuation correction device. The RSO is pursuing options for disposal or transfer of the depleted uranium.

(6) The inspector noted the RSO is due to receive updated DOT/Hazmat employee training. This should be reviewed during the next scheduled NHPP inspection.

(7) Sealed sources in possession were consistent with the NHPP sealed source inventory database. Security of sealed sources was consistent with NRC and VA requirements. NARM materials were managed as required and consistent with byproduct material use regulations.

5. PERSONNEL CONTACTED:

S. Johnson, Director ²

D. R. Dietrich, Associate Director ²

J. Harley, M.D., Chief, Radiology Service, and Chair, Radiation Safety Committee ³

J. Rajendran, M.D., Physician, Authorized User, University of Washington ³

C. Bergsagel, Physicist, Radiation Oncology Service ³

D. Dunn, Radiation Safety Officer ^{2,3}

R. Miura, CNMT, Lead Nuclear Medicine Technologist ³

B. Marck, Research Scientist ³

E. Haines, Research Scientist ³

C. Davis, Research Scientist ³

K. Garg, VISN 20 Safety Officer ²

Note: Executive management waived an entrance meeting.

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