

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: **SEP 03 2008**

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

Subj: Radiation Safety Program Inspection - Inspection Report 528A8-08-I01

To: Director (528A8/00), Samuel S. Stratton VA Medical Center, Albany, New York

1. Edwin M. Leidholdt, Ph.D., and Gary E. Williams, VHA National Health Physics Program, inspected the radiation safety program at Samuel S. Stratton VA Medical Center, Albany, New York, on August 27-28, 2008.
2. The inspection report is attached and consists of an NHPP Form 591 with no violations cited and a decommissioning worksheet completed during this inspection.
3. You are not required to respond to this memorandum or return a signed NHPP Form 591.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Williams at (501) 257-1572, if you have any questions about the inspection.


E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 2 (10N2)

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. PERMITTEE/PERMIT NUMBER:

Samuel S. Stratton VA Medical Center
Albany, New York
Permit Number 31-02755-05

2. LOCATION(S) INSPECTED:

113 Holland Avenue
Albany, New York 12208

3. INSPECTION DATES: August 27-28, 2008

4. INSPECTION REPORT NUMBER: 528A8-08-I01

PERMITTEE:

The inspection was an examination of activities under your permit as they relate to radiation safety and compliance with Nuclear Regulatory Commission rules and regulations and your permit conditions. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and performance-based observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of Nuclear Regulatory Commission requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting per 10 CFR 19.11. The violations and corrective actions are as follows:

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made per 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand no further written response to the VHA National Health Physics Program will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
PERMITTEE			
NHPP INSPECTOR	Gary E. Williams		August 28, 2008

Decommissioning Review

Permittee: Albany, New York (August 27-28, 2008)

Decommissioning Issue	Yes	No
General decommissioning files (per 10 CFR 30.35(g)(1) and (2))		
1. Does the permittee have records of spills, or other occurrences, where residual contamination remains or has spread to inaccessible areas?	NA	
2. Does the permittee have records of as-built diagrams/modifications of structures/equipment in locations of use?	X	
Specific decommissioning files and updated documents (per 10 CFR 30.35(g)(3))		
3. Does the permittee have locations of use where sealed sources leaked and residual contamination remains?	NA	
4. Does the permittee have locations of use and adjacent areas for radioactive material with $T^{1/2} = 65$ days?		X
5. Does the permittee have a document listing these locations of use and adjacent areas that require approval for unrestricted use?	X	
6. Is the permittee's document updated at least every two years? (updates during annual program review)	X	
Footprint management (for changes to locations of use since the last inspection, not involving a permit action)		
7. Has the permittee's footprint changed (i.e., added or deleted a location of use)?	X	
8. Have principal activities ceased in a location of use for a period approaching 24 months (10 CFR 30.36(d)(4))?	X	
9. Has the permittee begun decommissioning, or closeout surveys of, locations of use in which principal activities have ceased for a period greater than 24 months (10 CFR 30.36(d))?	X	
10. Has the permittee conducted closeout surveys to release locations of use for which a permit action is not required, but is subject to review during inspections (10 CFR 20.1501 and 30.36(j)(2))?	X	
11. Has the Radiation Safety Committee approved footprint changes, closeout surveys results, or a pending notification for 10 CFR 35.100 or 35.200 locations of use?	X	
12. Is a permit action required, but not yet submitted, for any footprint change?		X

Additional comments: RSO agreed to revise closeout surveys to have more historical information, list release criteria for fixed surveys, and provide survey results in DPM (vice CPM) for fixed surveys.

VHA National Health Physics Program Inspection Record

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

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No. 34, extended expiration date.

2. INSPECTION AND ENFORCEMENT HISTORY:

NRC inspection, February 24-25, 2004, with no violations

NHPP inspection, August 7, 2006, with no violations

The permittee does not have a significant enforcement history.

3. INCIDENT/EVENT HISTORY:

Results from a Nuclear Materials Events Database review did not identify any listings for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The Samuel S. Stratton VA Medical Center, Albany, New York, conducts a radiation safety program under a VHA broad-scope permit. The permittee is authorized for medical and research uses.

Nuclear Medicine Service utilizes a Mo-99/Tc-99m generator and unit dose radiopharmaceuticals received from a commercial radiopharmacy. Occasionally, radiopharmaceutical therapy requiring written directives are performed. Radiation Oncology Service performs permanent implant seed brachytherapy around twice per month. This seed implant program was a focus for the inspection.

Ten authorized users are approved by the Radiation Safety Committee (RSC) for non-human research but the program has been inactive for at least 40 months. Human research using radioactive materials is also inactive. A depleted uranium shield for a linear accelerator was disposed.

The radiation safety program staff consists of the Radiation Safety Officer (RSO). The RSO performs audits, radiation safety training, transportation duties of radioactive materials, and equipment calibrations. Other radiation safety program responsibilities are delegated to staff in research, nuclear medicine, and radiation oncology. The RSO reviews clinical and radiation safety practices periodically. RSO audits are reported to the RSC.

The RSO has complete autonomy with regard to radiation safety program implementation and stop-work authority.

2. INSPECTION SCOPE AND NRC INSPECTION PROCEDURES USED:

The inspectors reviewed all items in the inspection plan. The inspection was oriented to a risk-informed, performance-based evaluation of radiation safety program practices and staff interviews. The inspectors observed nuclear medicine staff work routines.

VHA National Health Physics Program Inspection Record

Specific written records reviewed included dosimetry, package receipt, RSC minutes with the annual radiation safety program review, and written directives.

For the NRC inspection procedures, the inspectors 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) to determine the radiation safety program adequacy following a performance-based approach. NRC inspection procedures used for this inspection were IP 87134, "Medical Broad Scope Programs," and IP 87132, "Brachytherapy Programs."

The inspectors reviewed footprint management issues with the RSO. The decommissioning review is attached to the inspection report. The closeout survey worksheet was not completed during the inspection since the permittee has not recently completed any surveys. The RSO agreed to add a survey grid, release criteria for fixed contamination, and results in DPM for fixed contamination surveys for future closeout surveys. The RSC is actively evaluating footprint issues.

Interviews with two technologists, two medical physicists, an authorized user for radiation oncology, and a warehouse foreman indicated adequate understanding for radiation safety program practices.

The RSC meets at least quarterly. The director is the management representative and signs the minutes. The minutes are routed to the QUAD, an executive management group.

The facility does not have any radium sources or PET materials. The sealed sources at the permittee were consistent with the sources listed on the NHPP Web-based inventory.

The inspection focused on the seed implant program using an audit checklist. The checklist is being completed separately from the inspection report and will be filed in the facility permit files. The inspectors did not identify any violations for the seed implant program.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors performed a survey of the locations of use as part of this inspection and did not find any contamination. Survey results were consistent with workload and types of procedures. All readings were within regulatory limits. The instrument used a Shadow Model 4020, serial number 4259; last calibrated July 7, 2008.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Within the scope of this inspection, the inspectors did not identify any violations.

5. PERSONNEL CONTACTED:

D. Erickson, Associate Director^{1,2}
K. Cipperley, Radiation Safety Officer^{1,2,3}

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

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

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The audit checklist should be used to determine overall status for the seed implant program and to ensure compliance with specific regulatory requirements and best clinical practices. The issues or categories to evaluate and review are in the five major sections below.

1. Handling and security for sealed sources

- a. Radioactive material package receipt surveys and records (10 CFR 20.1906).

Incoming packages received by warehouse and promptly transported to Nuclear Medicine Service by warehouse staff.

RSO performs receipt surveys. Surveys and records conform to NRC requirements.

- b. Security requirements (10 CFR 20.1801 and .1802) and two delay methods if stored.

Conform to NRC requirements and permit conditions. Seeds stored in locked cabinet in locked room in Radiation Oncology Service.

The inspectors asked the RSO to review security of keys to locked cabinet.

- c. Source accountability and inventories (10 CFR 35.406 and .67(g)).

Electronic recordkeeping does not appear to fully conform to 10 CFR 35.2406. Required information was available in patient charts or files. Previous hard copy records consistent with regulatory requirements.

The inspectors asked RSO to modify the electronic record format to conform to 35.2406 and ensure that these records are backed-up.

- d. Plans for source disposal (i.e., ship to vendor or decay on site).

Unused seeds are returned to the vendor. Biologically-contaminated seeds are stored for decay.

2. Preparations for seed implant procedures

- a. Written procedures and checklists (10 CFR 35.40 and .41).

Conform to NRC requirements.

- b. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and .41).

Conform to NRC requirements.

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- c. Preplan and transfer to written directive, including prescribed dose.

Conform to NRC requirements.

- d. Patient release procedures (10 CFR 35.75).

Conform to NRC requirements, with exception noted in Item 2.f. below.

- e. Surveys after source implantation with a survey meter capable of accurately measuring exposure rate, air kerma rate, or dose rate for photons of the energy emitted or a method to correct the measurements for the energy response of the meter (10 CFR 35.404).

Surveys for patient release are being performed mostly with a Fluke/Victoreen 451B ambient air ionization chamber survey meter. RSO stated that the survey measurements are performed with the window open.

A correction is not being made for the energy response of the survey meter. A review of the response curve in the operator's manual indicated that the indicated exposure rate is about 85% of the actual exposure rate.

The inspectors asked the RSO to modify the survey record to indicate survey measurements that are energy corrected.

- f. Calibration measurements of sources (10 CFR 35.432).

The facility purchases seeds from Bard. Documents from Bard attest that each seed is individually calibrated. In addition, the facility purchases two calibration seeds with each order. These seeds are assayed using a well-type ionization chamber and electrometer, which are calibrated by an ADCL every two years.

Conform to NRC requirements.

- g. Acceptance testing of treatment planning system (10 CFR 35.457).

The facility uses the CMS Interplant treatment planning system. The facility was not able to locate records of acceptance testing of the system.

The inspectors asked the facility either to locate the records or repeat the testing and to send a copy of the acceptance testing results to NHPP.

- h. Quality assurance checks for imaging (i.e., TRUS, CT, and accuracy of image transfer).

Testing of the geometric fidelity of the TRUS is being measured, but image quality is not.

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Testing of the CT and transfer of its images to the treatment planning system is not being performed.

The inspectors asked the facility to initiate testing of the CT and transfer of its images to the treatment planning system.

- i. Requirements for a medical event or other incident circumstances including after-hours recall or notifications (10 CFR 35.3045).

Interviews of an authorized user physician and two medical physicists indicated that they had an adequate understanding of NRC requirements for medical event reporting.

- j. Training (i.e., initial and periodic) for authorized user physicians, medical physicists, and other staff.

Interviews with an authorized user physician, two medical physicists, and the RSO indicated that they had adequate understanding about NRC requirements and facility procedures for prostate brachytherapy.

3. Performance-based interviews and observations

- a. Authorized user physicians.

Robert Belgam, M.D., interviewed
Ralf Kiehl, M.D., not available and not interviewed

- b. Medical physicists and dosimetrists.

John P. Balog, Ph.D., and Yani Stathokos, M.S., interviewed
Viola Heleba, CMD, not available and not interviewed

- c. Radiation Safety Officer.

Kris Cipperley, interviewed.

- d. Support staff.

None interviewed.

4. Performance-based tours and observations

- a. Radiation oncology areas.

Room in Radiation Oncology Service is used for seed storage and assays of calibration seeds.

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b. Package receipt areas.

Incoming packages received in warehouse and promptly transferred to Nuclear Medicine Service for package receipt surveys.

c. Seed implant preparation areas.

See 4.a. above.

d. Seed storage areas.

See 4.a. above.

5. Evaluation of patient treatment results

a. Methods and procedures to determine if all seeds implanted properly.

TRUS and fluoroscopy used during procedure. Spot film radiograph taken at end of procedure.

CT images obtained after procedure and post plan prepared around one week after CT images.

b. Written directive, part 2: when completed and how.

In operating room, after the implant is performed.

c. Post implant CT scans or images; when completed.

For Dr. Belgam's implants, CTs are typically performed on the day after each implant in most cases.

For Dr. Kiehl's implants, CTs are typically performed about three weeks after each implant.

d. Review of treatment result to dose criteria such as V100 and D90.

Dose indices, including the V100 and D90, are calculated for each patient.

D90s for the last 11 procedures were reviewed. All exceeded 80% of the prescribed dose of 144 Gy.

e. Post plans: how to verify complies with written directive.

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See 5.d. above.

f. Clinical quality assurance or oversight, including peer review.

Dr. Belgam stated that there is only limited peer review, but that more complete peer review is being instituted.