

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: **JAN 03 2011**

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

Subj: Radiation Safety Program Inspection - Inspection Report 586-10-I01

To: Director (586/00), G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi

1. We initiated a reactive inspection of the radiation safety program at your medical center during September 8-9, 2010. This inspection focused on 11 medical events, discovered and reported by your staff to VHA National Health Physics Program (NHPP) on September 8, 2010, involving permanent implant prostate brachytherapy. As a follow-up to the escalated enforcement cited earlier this year, we initiated a routine inspection of your radiation safety program on December 7-8, 2010. Both inspections were closed during an exit meeting with you on December 8, 2010, and inspection results are being combined in this inspection report.
2. Thomas E. Huston, Ph.D., NHPP, performed both on-site visits. Darrel Wiedeman and Patricia Pelke, Nuclear Regulatory Commission, Region III, accompanied Dr. Huston during the December 7-8, 2010, on-site visit.
3. The inspection report is attached to this memorandum and consists of a narrative report and a Radiation Safety Committee audit worksheet completed during this inspection. No violations were identified for either the reactive or routine inspection.
4. You are not required to respond to this memorandum.
5. Thank you for the courtesy and cooperation extended during the inspection. Please contact Dr. Huston at 501-257-1578 if you have any questions about the inspection.



Gary E. Williams

Attachment

cc: Chair, National Radiation Safety Committee  
Director, VHA National Radiation Oncology Program  
Network Director, VISN 16 (10N16)

**RADIATION SAFETY PROGRAM INSPECTION**  
**Inspection Report Number 586-10-I01**  
**G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi**  
**September 8, 2010, through December 8, 2010**

**1. Introduction**

a. The VHA National Health Physics Program (NHPP) performed a reactive inspection of the radiation safety program at the G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi (JVAMC), on September 8-9, 2010. Thomas E. Huston, Ph.D., performed the inspection, which was initiated in response to the September 8, 2010, discovery of 11 medical events involving permanent implant prostate brachytherapy (hereafter referred to as prostate brachytherapy). Dr. Huston presented preliminary findings at a meeting with key staff on September 9, 2010. At that time, the inspection was left open to monitor additional reporting and actions related to the events.

b. NHPP (Dr. Huston) returned to the JVAMC on December 7-8, 2010, to complete the reactive inspection and perform a routine core inspection (6-month follow-up to earlier escalated enforcement action) by NHPP. Darrel Wiedeman and Patricia Pelke of the Nuclear Regulatory Commission (NRC) Region III accompanied the NHPP inspector. Dr. Huston presented findings for both the open reactive inspection and the routine core inspection at an exit meeting with key medical center staff on December 8, 2010. Both inspections were closed on that date, and it was noted the inspection results would be combined into a single report.

**2. Scope of inspection**

a. The reactive inspection focus was to examine circumstances, actions, and records related to the 11 medical events discovered on September 8, 2010. The inspection was initiated immediately after discovery of the medical events and consisted of a review of patient dose information for the prostate brachytherapy program, a review of root or basic causes and corrective actions for the events, and a review of compliance with event reporting requirements.

b. For the 6-month follow-up inspection, the inspector reviewed all items contained in a pre-approved inspection plan. The inspection focus was risk-informed and performance-based. The evaluation consisted of interviews with individuals to elicit their specific attitudes, perceptions and values to establish that, as an overriding priority safety issues receive the attention warranted by their significance. The inspector utilized information collection methods that assessed medical center attitudes and behaviors for safety culture, identifying consistencies in organizational attitudes and behavior through the use of interviews, structured behavioral observations, document review and analysis, and case studies. The inspection consisted of an examination of the rooms and equipment in the Nuclear Medicine Service and several research laboratories, review of radiation safety practices and selected records, and observations of and interviews with medical center staff. The inspector completed spot-check radiation measurements in the Nuclear Medicine Service hot laboratory, research radioactive materials waste storage area, iodination laboratory, and in two research laboratories. The inspector also reviewed effectiveness of corrective actions outlined in the JVAMC response of August 6, 2010, to NHPP Notice of Violation (NOV) issued July 15, 2010. NRC inspection procedures 87134 and 87126 were used for this inspection.

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**3. Findings and impressions (background information)**

a. Previous NHPP inspections

(1) NHPP performed a reactive inspection on October 8-10, 2008, and June 28-29, 2010, with continuing review through July 12, 2010, for reported medical events. The inspection report, issued July 15, 2010, cited a Severity Level III violation for not implementing adequate procedures for prostate brachytherapy, and a Severity Level IV violation for not including adequate membership of the Radiation Safety Committee (RSC). JVAMC described corrective actions, taken and planned, in a memorandum dated August 6, 2010.

(2) NHPP performed a routine inspection of the radiation safety program on February 18-23, 2009. No violations of NRC requirements were identified.

b. Previous NRC inspections

(1) NRC performed a reactive inspection on October 8-9, 2008, with continuing review through April 22, 2010, for reported medical events. The inspection report, issued August 23, 2010, cited a Severity Level III violation for not developing, implementing, and maintaining written procedures that addressed methods to verify that administrations were in accordance with the written directive. The citation was similar to that cited by NHPP on July 15, 2010. NHPP provided a response to NRC for the NOV on August 30, 2010. The response and corrective actions pertinent to JVAMC were consistent with those provided by JVAMC to NHPP on August 6, 2010.

(2) NRC performed a routine inspection of the radiation safety program on June 14-17, 2010, with continuing review through August 25, 2010. No violations of NRC requirements were identified.

c. Incident/Event History

(1) Since completion of the last NHPP inspection, JVAMC discovered 11 medical events in response to receipt of revised dose information on September 8, 2010, from the Director, National Radiation Oncology Program (DRO). The revised dose information was generated during a DRO-coordinated review involving individuals external to JVAMC. The review encompassed all 92 patients of JVAMC since inception of the prostate brachytherapy program.

(2) Ten of the 11 medical events were based on a post-implant D90 (defined as the dose that covers 90% of the volume of the estimated treatment site) being less than 80% of the prescribed dose. The remaining 11<sup>th</sup> medical event was based on the dose to the hottest 1 cm<sup>3</sup> the rectum being slightly greater than 150% of the expected dose (where the expected dose equals the prescribed dose).

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(3) NHPP was present at JVAMC when the data was received from the DRO, and assisted the facility staff during the medical event discovery process. The facility reached discovery of the 11 medical events on September 8, 2010, and immediately notified the NHPP on-site representative. NHPP notified the NRC Operations Center of the events by telephone on September 9, 2010. JVAMC submitted a 15-day written report to NHPP on September 20, 2010. NHPP submitted the written report to NRC on September 22, 2010.

(4) With these most recent 11 medical events, 21 medical events have been reported to NRC for the JVAMC prostate brachytherapy program. Ten events were reported during calendar years 2008 and 2009. Four of the 10 earlier events are candidates for retraction as medical events because final D90 values were deemed as adequate (i.e., greater than 80% of prescribed dose) by the DRO review; however, as of this date, a proposal to retract these four events has not been made to NRC.

**4. Findings and impressions (reactive inspection)**

a. The overall conclusion for the reactive inspection is that no violations of NRC requirements were identified. The inspector concluded that violations cited by NHPP in Inspection Report 586-08-I01 (issued July 15, 2010) and NRC Inspection Report 030-34235/2008-030 for the prostate seed implant program adequately addressed historical circumstances associated with the 11 additional medical events that were discovered on September 8, 2010.

b. For the 11 medical events, the inspector reviewed Radiation Safety Officer (RSO) records related to telephone and written reports made to the referring physicians and patients. These reports appeared to comply with NRC regulatory requirements in 10 CFR 35.3040.

c. Based on the on-site review during December 7-8, 2010, including an examination of post-implant imaging information for a limited number of treatments, the inspector agreed with the causes and corrective actions for the medical events, as stated in the 15-day written report submitted by JVAMC to NHPP on September 20, 2010 (NHPP submitted to NRC on September 22, 2010) with one clarification. Based on additional information provided by the DRO<sup>1</sup> for the medical event involving the elevated dose to the rectum, the specific anatomy of the patient was likely a contributing factor for that event in that an unusually thin tissue layer between the treatment volume and the rectum resulted in an increased dose to the rectum, as compared to what would normally be delivered.

d. Subsequent to closing the inspection, the inspector worked with the RSO and DRO to compile a spreadsheet of final dose information for all 92 patients treated by JVAMC with prostate brachytherapy. This spreadsheet was transmitted to the NRC on December 21, 2010.

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<sup>1</sup> Based on statements by the DRO during a telephone discussion on December 7, 2010, with the NHPP inspector, RSO, and NRC staff who accompanied NHPP.

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**5. Findings and impressions (routine inspection)**

a. The overall conclusion is that no violations of NRC requirements were identified for the routine inspection. In addition, corrective actions taken in response to violations in previous NHPP and NRC inspections (i.e., paragraphs 3a and 3b above) were completed and appeared to be effective.

b. Organization and scope of program

(1) JVAMC conducts a radiation safety program under a VHA broad-scope permit. The permit authorizes radioactive material for medical diagnostic and therapeutic uses with biomedical research. A tour of both nuclear medicine and research use areas was conducted during this inspection.

(2) Nuclear Medicine Service utilizes unit doses received from a commercial radiopharmacy. The service performs about 10 diagnostic procedures per day. Since February 2009, they performed about 1900 diagnostic procedures and about 41 therapeutic procedures. Studies involving positron emission tomography (PET) are not conducted on site.

(3) The RSC has seven authorized users approved to use radioactive materials for non-human research. No research on human subjects using radioactive materials was being performed. Research involving radioactive materials was not actively performed during the on-site visit; however, recent use was evident. Research areas involving permitted materials appeared to be properly posted and controlled, and radioactive materials appeared to be properly labeled and controlled/secured.

(4) The RSO is a full-time VA employee and reports to the Assistant to the Chief of Staff. The RSO has sufficient autonomy for radiation safety program implementation and stop-work authority. The RSO had direct access to the medical center director.

(5) An authorized user in research serves as Chairperson of the RSC. The RSC reports to the Environment of Care Committee.

c. Discussion of key records reviewed

(1) Incidents and spills: Other than historical medical events associated with prostate brachytherapy, there were no other incidents or major spills since the last NHPP routine inspection. Medical event records were examined as part of the reactive inspection (see Section 4 above).

(2) Personnel dosimetry: Worker doses since the last NHPP routine inspection were reviewed. Maximum worker doses were well below limits or levels of concern. Maximum dose for workers for 2009 were around 355 mrem for the whole body and 2990 mrem for extremities. Doses for 2010 were consistent with 2009 levels.

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(3) RSC meetings: RSC meetings have been held quarterly since the last routine inspection and meeting minutes were prepared. Minutes for the most recent meeting (September 29, 2010) were found to conform to the memorandum dated April 12, 2010, from the Deputy Under Secretary for Health for Operations and Management (DUSHOM) and to NHPP FAQ 08-04 with only one minor discrepancy. The minor discrepancy was that the most recent minutes for a meeting held September 29, 2010, did not include an item for “status of security” of radioactive materials (required by paragraph 3d of the DUSHOM memorandum). The discrepancy was minor and not being cited as a violation because the inspector concluded the permittee had made a good faith effort in implementing the DUSHOM requirements. An annual security review had been conducted in March 2010 by the Police Service and no issues were identified for radioactive materials; the previous RSC meeting minutes for July 7, 2010, formally addressed status of security with no issues identified; and tours of areas of use by the inspector confirmed that materials were being properly secured. The RSO agreed to include the “status of security” for radioactive materials as a standing agenda item for future committee meetings.

(4) Written directives: All written directives prepared since the last routine inspection were reviewed and appeared to comply with regulatory requirements.

(5) Annual program reviews: An annual radiation safety program review was performed and documented for 2009 and was presented to the RSC during a quarterly meeting.

(6) Decommissioning files: The decommissioning files were reviewed and appeared to meet NRC regulatory requirements. Based on a tour of areas of use in both research and medicine, locations of use were consistent with the decommissioning file and authorizations as a broad-scope permittee. The permittee had performed closeout surveys in several rooms (R307, R307A, R307B, R309, R309C, R311, R312, R315, R316, R317, and R318) since the last routine inspection and was preparing to approve for unrestricted use at their next RSC meeting. The permittee had adequate closeout surveys on file for the rooms. The pending action to release the rooms is under the authority of the RSC per the broad-scope permit.

d. Independent and confirmatory surveys

The inspector completed spot-check radiation surveys in the Nuclear Medicine Service hot lab and imaging rooms, select current and former research use areas, and research waste storage area. The instrument used was a Health Physics Instruments, Inc., Shadow Model 4020 GM Contamination Monitor, Serial Number 4259, with next calibration due on August 6, 2011. No contamination or dose rates inconsistent with use or above regulatory limits were observed.

e. Review of current generic issues identified by National Radiation Safety Committee

(1) NARM implementation: The inspector confirmed the permittee had implemented adequate controls for NARM. The permittee does not possess radium sources or perform PET studies.

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(2) Sealed sources on-site as compared to those listed on NHPP Web-based inventory: The inspector visually identified sealed sources listed in the NHPP inventory with the exception that one source had been transferred for disposal on October 20, 2010. The RSO agreed to update the inventory during the annual reconciliation due for completion by March 31, 2011.

(3) Oversight for use of radioactive materials

(a) Reporting structure for the RSC/RSO and the committee minutes for meetings held on or after July 15, 2010, for compliance with FAQ 08-04: This item is addressed in paragraphs 5b(3), 5b(4), 5b(5), and 5c(3). An RSC audit worksheet is included with this report.

(b) Possible undue reliance on affiliate universities or consultants: The inspector identified no concerns for this item.

(c) Reporting concerns or allegations: The inspector interviewed several individuals, including the RSO, nuclear medicine technologists, and laboratory staff. All individuals appeared knowledgeable of the ways to report concerns, both internally and externally, and willing to raise such concerns if necessary.

(d) Safety culture and focus for compliance with regulatory requirements and best practices: Based on staff interviews and interactions, the inspector concluded the medical center has a positive safety culture and a focus for compliance. The RSO was well recognized by all radiation workers and management and appeared to be well respected within the medical center.

(e) Requirements in VHA Directive 1105.01 and executive management role as the named permitted official: The medical center director was aware of the directive and appeared to understand her role as the named permitted official.

(f) Security for radioactive materials: Based on discussions with staff and tours of areas of use, the inspector confirmed security of radioactive materials was a priority and materials were being secured.

f. Follow-up on corrective actions for previous violations

(1) The inspector reviewed corrective actions related to the Severity Level III violations cited by NRC (August 23, 2010) and NHPP (July 15, 2010). The violations, related to the former prostate brachytherapy program, involved a failure to develop, implement, and maintain written procedures that addressed methods to verify administrations were in accordance with the written directive. The permittee prostate brachytherapy program remains suspended with no plans for restart. The permittee RSO demonstrated knowledge that restart of the program requires a pre-start inspection by NHPP, implementation of VHA standard procedures for prostate seed implant brachytherapy, as well as prior approval by VHA leadership. The inspector confirmed that corrective actions taken (and included as tied-down in permit Amendment Number 81) were effective.

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(2) The inspector reviewed corrective actions related to a Severity Level IV violation cited by NHPP (July 15, 2010) for not including adequate membership of the RSC. The inspector reviewed documents prepared August 31, 2010, appointing four new members (and alternates) to the committee, including a radiation oncologist, cardiologist, radiologist, and nuclear medicine physician. The inspector confirmed that the corrective actions for this violation were taken as described in the permittee's NOV response of August 6, 2010, and were effective.

**6. Key Persons Contacted**

Linda F. Watson, Medical Center Director <sup>4</sup>  
Kent Kirchner, M.D., Chief of Staff <sup>1,2,3,4,5</sup>  
Michael J. Smith, Radiation Safety Officer <sup>1,2,3,4,5</sup>  
Elise Gomez-Sanchez, DVM, Ph.D., Chairperson, Radiation Safety Committee <sup>5</sup>  
Robin Jordan, RT(T), CMD, Dosimetrist <sup>5</sup>  
Carmen Lamas, CNMT, Chief Nuclear Medicine Technologist <sup>5</sup>  
Robert Huddleston, CNMT, Nuclear Medicine Technologist <sup>5</sup>

1. Individual(s) present at entrance meeting on September 8, 2010 (reactive inspection)
2. Individual(s) present at exit meeting on September 9, 2010 (reactive inspection)
3. Individual(s) present at entrance meeting on December 7, 2010 (reactive and routine inspection)
4. Individual(s) present at exit meeting on December 8, 2010 (reactive and routine inspection)
5. Individual(s) present or participating in inspection discussions (reactive and routine inspection)

RADIATION SAFETY COMMITTEE AUDIT

Permittee: Jackson, Mississippi (December 7-8, 2010)

<b>Radiation Safety Committee Requirements (effective for meeting on or after July 15, 2010)</b>	<b>Yes</b>	<b>No</b>
<b>Timeliness</b>		
1. Are the minutes prepared and submitted to an internal oversight committee within 30 days after the committee meeting? <i>(One meeting was held on September 29, 2010. Submitted to Environment of Care Committee on October 5, 2010.)</i>	X	
2. Are the minutes signed and approved by the director within 45 days after the committee meeting? <i>(Signed October 8, 2010)</i>	X	
3. Are the meetings held at appropriate frequencies based on the scope of use of radioactive materials? <i>(Held quarterly.)</i>	X	
<b>Format for minutes and specific items within the minutes</b>		
4. Is the format for the minutes consistent with standard formats in FAQ 08-04 or have equivalent information?	X	
5. Does the agenda include old business, new business, and standing agenda items for dosimetry, status of all procedures requiring a written directive, status of footprint management, and status for security? <i>(All items were included in meeting agenda/minutes with the exception of standing item for security. The inspector discussed the item with the RSO, who agreed to include it in future meetings. Area tours provided evidence that no security issues existed. Also, the RSO provided a copy of a recent annual security audit that indicated security was a priority; no problems were identified. This deficiency is considered very minor.)</i>		X
6. Do committee discussions include, as needed, new business items for reports of spills, incidents, self-identified radiation safety program deficiencies, results for external audits or inspections, and notation of committee votes?	X	
7. Does the tracking matrix include assigned tracking numbers and a statement of the status for items being tracked?	X	
8. Does the attendance matrix include a list of attendees for each meeting and document a quorum?	X	
9. Do the minutes include, at least annually, the annual review and audit report under 10 CFR 20?	X	
<b>Committee files</b>		
10. Does the facility have a single file (hard copy or electronic) with committee minutes and supporting documents?	X	
11. Are the committee files readily available for external review?	X	

Additional Comments: The deficiency noted for Item 5 is considered to be minor and isolated. An earlier version of the minutes included a security agenda item. In addition, on August 31, 2010, several new members (and alternates) were added to the committee for radiation oncology, cardiology, diagnostic radiology, and nuclear medicine. All uses of radioactive material and radiation-generating machines appeared to be covered by the changes.