



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 7, 2007

Docket No. 03003296
NMED No. 070074

License No. 45-00034-26

Leonard W. Sandridge, Jr.
Executive Vice President and Chief Operating Officer
University of Virginia
P.O. Box 400228
Charlottesville, VA 22904-4228

SUBJECT: INSPECTION 03003296/2007001, UNIVERSITY OF VIRGINIA,
CHARLOTTESVILLE, VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Mr. Sandridge:

On February 12, 2007, Sandy Gabriel of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of a medical event reported by your staff to the NRC Operations Center on February 5, 2007, as well as a review of your followup actions in response to the Notice of Violation dated October 5, 2004. This inspection was continued in the Region I office to review: (1) followup information provided by your staff in a report dated February 20, 2007, and in electronic mail communications on February 27, April 30, and May 4, 2007; and (2) a report by a medical consultant retained by the NRC to review this event. Preliminary findings of the inspection were discussed with James Amato, Medical Center Administrator, and other members of your organization at the conclusion of the onsite portion of the inspection. A final exit meeting was held with Peg Van Bree, Medical Center Chief Operations Officer and other members of your organization by telephone on May 7, 2007, at the conclusion of the inspection. The enclosed report presents the results of this inspection. Also enclosed is a copy of the medical consultant's report.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in your report dated February 19, 2007, and in NRC Inspection Report 03003296/2007001. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement**; then **Enforcement Policy**. You may also obtain these

L. Sandridge
University of Virginia

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documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact me at 610-337-6952 if you have any questions regarding this matter.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:

1. Inspection Report No. 03003296/2007001
2. Notice of Violation
3. Medical Consultant's Report [not released to public]

cc:

Ralph Allen, Ph.D., Radiation Safety Officer
Bernard F. Schneider, M.D., Associate Professor of Radiation Oncology
Commonwealth of Virginia

L. Sandridge
University of Virginia

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Ralph Allen, Ph.D., Radiation Safety Officer
Bernard F. Schneider, M.D., Associate Professor of Radiation Oncology
Commonwealth of Virginia

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NOTICE OF VIOLATION

University of Virginia
Charlottesville, VA

Docket No. 03003296
License No. 45-00034-26

During an NRC inspection conducted on February 12, 2007, with continued in-office review through May 4, 2007, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(1) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b)(2) requires, in part, that the licensee's procedures for administration of licensed material requiring a written directive include verification that the administration is in accordance with the treatment plan and written directive.

Contrary to the above, the licensee did not develop, implement, and maintain written procedures to verify that brachytherapy sources were positioned in accordance with the treatment plan. Specifically, on February 2-4, 2007, a manual brachytherapy treatment was performed and the licensee's procedures did not require personnel to verify that tandem sources were placed within an insert of the correct length. As a result, the tandem sources were displaced from the intended position, resulting in a delivered dose to Point A of approximately 7.7 Gy (770 rads) instead of the intended 30 Gy (3000 rads).

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the

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specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 7 day of May 2007

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03003296/2007001
Docket No. 03003296
License No. 45-00034-26
NMED No. 070074
Licensee: University of Virginia
Location: Office of Environmental Health and Safety
515 Edgemont Road
P.O. Box 400322
Charlottesville, VA 22904-4322
Inspection Dates: February 12, 2007; by telephone May 7, 2007
Date Followup
Information Received: February 20 and 27, April 30, and May 4, 2007

Inspector: **Original Signed by:** 05/07/07
Sandra Gabriel date
Senior Health Physicist

Approved By: **Original Signed by:** 05/08/07
Pamela J. Henderson, Chief date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

University of Virginia
NRC Inspection Report No. 03003296/2007001

An announced, special inspection was conducted to review the circumstances surrounding a medical event that was identified on February 4, 2007 and reported to the NRC on the following day. The medical event involved a temporary, manual brachytherapy implant of cesium-137 initiated on February 2, 2007. Upon removal of the implant on February 4, 2007, the licensee identified that the tandem applicator had been loaded with a plastic radioactive source carrier insert (tandem insert) that was approximately 4 cm shorter than the required 24 cm. This caused the sources in the tandem applicator to be displaced from the intended positions, resulting in a delivered dose to Point A of approximately 7.7 Gy (770 rads) instead of the intended 30 Gy (3000 rads).

An NRC medical consultant concluded that “no significant adverse effect is expected.”

Within the scope of this inspection, one apparent violation of NRC regulations was identified. The licensee’s procedures did not meet the requirements described in 10 CFR 35.41(b)(2) in that the procedures did not require licensee personnel to verify that manual brachytherapy sources were positioned in accordance with the treatment plan. Specifically, procedures did not require licensee personnel to verify that the correct length tandem insert was used in order to assure that tandem sources were positioned in accordance with the treatment plan.

REPORT DETAILS

I. Event Description

a. Inspection Scope

This inspection was limited to a review of the circumstances surrounding the brachytherapy medical event that was occurred on February 2-4, 2007 and was identified at the time of source removal on February 4. The inspection of the event consisted of observations of the inspector, interviews with physicists, physicians, and Radiation Safety Office staff members, and a selected examination of records describing the event and followup actions.

b. Observations and Findings

Brachytherapy Program

The licensee's brachytherapy program for treatment of gynecological cancers includes both manual brachytherapy and high dose rate remote afterloading brachytherapy (HDR). All gynecological manual brachytherapy treatments are performed using Fletcher-Suit applicators, with an average of approximately 40 implants per year. The licensee also performs approximately 130 gynecological HDR cases per year primarily using vaginal cylinder applicators.

Event Chronology

February 2, 2007	The patient was taken to the operating room for surgical insertion of the Fletcher-Suit applicator by Authorized User 1 (AU1) and Resident 1. Later in the day, simulation films were taken using "dummy" sources to simulate the intended position of the active sources. A treatment plan to deliver 30 Gy (3000 rads) to Point A was designed by AU1, Physicist 1, and Dosimetrist 1. AU1 signed the written directive. Physicist 2 then preloaded cesium-137 sources into the tandem insert and ovoid buckets, with Dosimetrist 1 witnessing to confirm source activity and arrangement. The preloaded tandem insert and ovoid buckets were placed in a shielded transport container and taken to the patient's room, where Resident 1 afterloaded them into the patient's Fletcher-Suit applicator. Physicist 2 and Dosimetrist 1 performed radiation surveys and posted the patient's room.
February 4, 2007	At the conclusion of the 48.5 hour planned implant duration, Resident 2 attempted to remove the tandem insert from the patient's Fletcher-Suit applicator. Resident 2 unscrewed the tandem cap and found that the end of the tandem insert did not project out beyond the edge of the metal tandem. As a result, Resident 2 was unable to grasp the end of the tandem insert to remove it. She contacted AU1 and Physicist 3, who advised her

to remove the entire tandem and place it in the shielded transport container for return to the source storage room. Working behind the shielded L-block, Physicist 3 examined the tandem and removed the insert. He determined that the tandem insert was approximately 4 cm shorter than intended; it was about 20 cm long instead of the intended 24 cm length. Physicist 1, the Director of Physics, AU1, and Resident 1 were notified.

February 5, 2007 AU1, Physicist 1, and the Director of Physics met to discuss the event. Physicist 1 revised the implant dose calculations to reflect the estimated actual source positions in the tandem. The revised calculations showed a delivered dose to Point A of approximately 7.7 Gy (770 rads) instead of the intended 30 Gy (3000 rads). The Radiation Safety Officer and licensee Administration were notified. AU1, Physicist 1, and the Director of Physics reviewed the dose calculations and confirmed that a medical event had occurred. The patient and referring physician were notified.

Notification of the Event

As noted above, the licensee made a telephone report to the NRC Operations Center on February 5, 2007, within 24 hours of identification of the medical event, and notified the patient and referring physician. The licensee also submitted a 15-day written report, which was received in Region I on February 20, 2007.

Written Directive Procedures

10 CFR 35.41 requires, in part, that the licensee develop, implement, and maintain written procedures to provide high confidence that licensed material or radiation from licensed material will be administered as directed by the Authorized User. 10 CFR 35.41(b)(2) requires the licensee to verify that the administration is in accordance with the treatment plan, if applicable, and the written directive.

In response to the inspector's request, the licensee provided a copy of its detailed (105 step) procedures for performance of Fletcher-Suit implants in effect at the time of the medical event. The procedures included a series of steps to verify that the administration is in accordance with the treatment plan and written directive, including verification of the patient's identity prior to treatment, double-check of the computer-generated treatment plan and dose calculation, and confirmation by a second staff member of the accuracy of the activity and sequence of the preloaded sources. Steps to assure correct positioning of sources in the tandem applicator included verification that dummy sources are fully inserted into the applicator during simulation and measurement of the space in the tandem insert to determine the length of the required spacers. However the detailed procedures did not require licensee personnel to verify that the correct length tandem insert is used in order to assure that tandem sources are positioned in accordance with the treatment plan.

Licensee's Corrective and Preventive Actions

During the inspection conducted on February 12, 2007 and in subsequent correspondence, the licensee indicated that it took the following corrective and preventive actions:

- (1) Additional, external beam radiation treatment was administered to the patient.
- (2) The licensee held an in-service training session for Radiation Oncology dosimetrists, physicists, and physicians, including discussion of the event and specific procedures to avoid recurrence.
- (3) A plastic sheet with a 24 cm black stripe was affixed to the source preparation table, to allow licensee personnel to check the length of the tandem insert when preloading sources. A 24 cm black stripe was also affixed to the handle of the source transport container to allow personnel to confirm the length of the tandem insert before loading sources into the patient.
- (4) Two steps were added to the licensee's detailed procedures for Fletcher-Suit implants. The first new step requires the individual preloading sources into the tandem insert to measure the length of the insert to confirm that it is correct. The second new step requires the physician loading sources into the patient to confirm that the tandem insert is fully inserted and to visually observe that the white plastic spacer cap extends out about 0.3 cm from the metal tandem tube (before affixing the screw-on metal tandem cap into which extended plastic spacer cap fits).
- (5) The supply of tandem inserts in the source loading room was limited to new inserts of the correct length. In the future, if the length of a tandem insert is modified to less than 24 cm (e.g., for use in a Syed-Neblett implant), the shorter insert will be discarded after use.

c. Conclusions

The inspector concluded the following:

- (1) The licensee performed a temporary, manual brachytherapy implant of cesium-137 in which the tandem insert was approximately 4 cm shorter than intended. This resulted in a dose to Point A of approximately 7.7 Gy (770 rads) instead of the intended 30 Gy (3000 rads). Because the administered dose differed from the prescribed dose by more than 50 rem to an organ or tissue and by more than 20 percent, this administration met the medical event reporting definition in 10 CFR 35.3045(a)(1)(i).

In addition, several calculation points received doses that exceeded the dose that would have been delivered in a correctly administered treatment by more than 50 rem to an organ or tissue and by more than 50 percent. As a result, this

administration also met the medical event reporting definition in 10 CFR 35.3045(a)(3).

- (2) The licensee's notification to the NRC, referring physician, and patient, and 15-day report to the NRC were in compliance with the requirements of 10 CFR 35.3045.
- (3) The root cause of the event was failure to assure that the tandem insert was of the correct length prior to preloading of cesium-137 sources. Contributing factors were Physicist 2's inexperience in preloading of cesium-137 sources and the storage of short tandem inserts together with inserts of the correct length.
- (4) The licensee's procedures to ensure compliance with 10 CFR 35.41(b)(2) for Fletcher-Suit implants were inadequate in that they did not require licensee personnel to verify that the correct length tandem insert was used in order to assure that tandem sources were positioned in accordance with the treatment plan. This is an apparent violation of NRC requirements.
- (5) The licensee's corrective actions directly address the cause of the medical event and appear to be adequate to prevent recurrence of this type of medical event.

II. Medical Consultant's Report

The NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant's report was received on March 15, 2007. The consultant concluded that "no significant adverse effect is expected."

III. Closeout of Violations from 2004 Inspection

a. Inspection Scope

The inspector interviewed licensee personnel and examined documents to review the licensee's followup actions to the four violations identified as a result of inspection 2004001 and described in the Notice of Violation dated October 5, 2004.

b. Observations and Findings

- (1) 10 CFR 35.404(b): inadequate survey of a patient after removing the last temporary implant source. The inspector confirmed that the licensee replaced the malfunctioning survey meter, provided additional physician training in survey meter use, assigned physicists to supervise surveys performed by physicians during loading of brachytherapy sources during normal working hours, and performed operational checks of survey meters using a source in Radiological Physics.

- (2) 10 CFR 20.1802: loss of control for two hours of a nylon ribbon of iridium-192. The inspector confirmed that the licensee performed source inventories before removing radiation postings from the patient's room, developed a new emergency response procedure for missing sources, and provided an annual radiation safety inservice for Radiation Oncology physicians and physicists.
- (3) 10 CFR 20.2201(a)(1)(i): failure to immediately report to the NRC the temporary loss of a nylon ribbon of iridium-192 containing an aggregate quantity greater than 1000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appeared an exposure could result to persons in unrestricted areas. The inspector confirmed that the licensee provided additional training on NRC reporting requirements and also provided wallet cards with lists of emergency phone contacts and NRC reporting requirements to all individuals who could discover or report a missing brachytherapy source.
- (4) 10 CFR 35.27(a)(2): administration to a patient of a dosage of iodine-131 greater than 30 microcuries without a signed and dated written directive. The inspector confirmed that the licensee's written directive forms for iodine-131 now include two locations requiring an authorized user's signature: (a) an initial prescription authorizing the technologist to order the dosage, followed by (b) an order to administer the dosage.

c. Conclusions

The inspector closed out the violations from inspection 2004001.

IV. Exit Meeting

A preliminary exit meeting was conducted on February 12, 2007 to discuss the scope of the inspection and the inspector's initial observations. On May 7, 2007, at the conclusion of the inspection, an exit meeting was held by telephone to discuss the inspector's observations and the medical consultant's report.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

- *+ Deborah Steva, Assistant Radiation Safety Officer
 - *+ Ralph Allen, Ph.D., Radiation Safety Officer
 - *+ Catherine S. Perham, Assistant Radiation Safety Officer
 - *+ Michael Cohen, Radiation Safety Specialist
 - * Robert Mulder, Ph.D., Medical Physicist
 - * Stanley H. Benedict, Ph.D., Director of Radiological Physics
 - Paul W. Read, M.D., Assistant Professor of Radiation Oncology
 - Bernard F. Schneider, M.D., Associate Professor of Radiation Oncology
 - Alyson McIntosh, M.D., Radiation Oncology Resident
 - * Denise Mathew, Director, Radiation Oncology
 - *+ James Amato, Medical Center Administration
 - * Karen Forsman, Medical Center Administration
 - * Thomas Buckley, Performance Improvement
 - + Trevor Thomas, Senior Radiation Safety Technician
 - + Peg Van Bree, Medical Center Chief Operations Officer
- * Present at preliminary exit meeting conducted on February 12, 2007
- + Present at telephonic exit meeting conducted on May 7, 2007