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

May 22, 2007

Docket No. 03002512 License No. 29-08285-01
EA-07-102

Maureen P. Barnes
Vice President, Risk Management
The Cooper Health System
Robert Wood Johnson Medical School at Camden
One Cooper Plaza
Camden, NJ 08103

SUBJECT: INSPECTION 03002512/2006001, THE COOPER HEALTH SYSTEM, ROBERT WOOD JOHNSON MEDICAL SCHOOL AT CAMDEN, CAMDEN, NEW JERSEY

Dear Ms. Barnes:

On December 18 and 20, 2006, and January 5, 2007, Sandy Gabriel of this office conducted a safety inspection at the above address and at your other sites in Camden, Voorhees, Cherry Hill, and Willingboro, New Jersey, of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the conditions in your license. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your correspondence dated December 28, 2006, February 16 and March 16, 2007; electronic mail dated April 3, 2007; and updated procedures provided on May 11, 2007 were also examined as part of the inspection. The findings of the inspection were discussed with you, Carolyn Bekes, M.D. and Edward Goldschmidt, M.S. of your organization at the conclusion of the inspection on May 11, 2007. The enclosed report presents the results of this inspection.

Based on the results of this inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current enforcement policy is included on the NRC's Web site at http//www.nrc.gov; select **About NRC, Organization and Functions, Office of Enforcement, About Enforcement,** then **Enforcement Policy.** The first apparent violation involves the failure to assure that a high dose rate remote afterloader treatment on November 9, 2006, was administered in accordance with the treatment plan and written directive, as required by 10 CFR 35.41(b)(2), resulting in a medical event. The second apparent violation involves the failure to report the medical event that occurred on November 9, 2006, as required by 10 CFR 35.3045. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you and members of your staff at the inspection exit meeting on May 11, 2007.

The NRC notes that because your facility has not been the subject of escalated enforcement actions within the last two inspections and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. However, before the NRC makes its enforcement decision, we are providing you an opportunity to either (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter, or (2) request a predecisional enforcement conference (PEC). If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Pamela J. Henderson at (610) 337-6952 within seven days of the date of this letter to notify the NRC of your intended response.

You may also choose not to provide a written response or attend a conference since the NRC has concluded that the information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in your correspondence dated December 28, 2006, February 16 and March 16, 2007; electronic mail dated April 3, 2007; and updated procedures provided on May 11, 2007. Therefore, you are not required to provide a written response or attend a conference unless the description of the corrective actions, as described in your correspondence and in the enclosed inspection report, does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional written information, you should follow the instructions below.

If you choose to provide a written response, it should be clearly marked as a “Response to Apparent Violations in Inspection Report No. 03002512/2006001" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

***Original signed by Mark Thaggard***

Brian Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03002512/2006001
2. NUREG 1600 (Enforcement Policy)
3. NRC Information Notice 96-28

cc:
Edward Goldschmidt, M.S., Radiation Safety Officer
State of New Jersey

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

***Original signed by Mark Thaggard***

Brian Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03002512/2006001
2. NUREG 1600 (Enforcement Policy)
3. NRC Information Notice 96-28

cc:
Edward Goldschmidt, M.S., Radiation Safety Officer
State of New Jersey

DISTRIBUTION w/encl:
ADAMS (PARS)
SECY
CA
OEMAIL
OEWEB
L Reyes, EDO
M Virgilio, DEDMRT
C Carpenter, OE
S Merchant, OE
L Sreenivas, OE
B Jones, OGC (Bradley)
L Chandler, OGC
C Miller, FSME
G Pangburn, FSME
J Schlueter, FSME
D Rathbun, FSME
J. Lamb, OEDO
Enforcement Coordinators
RII, RIII, RIV
T Fredericks, OE
L Lopez, OE
O Samuel, OE
R Taylor, OE
G Veneziano, OGC
E Hayden, OPA
H Bell, OIG
G Caputo, OI
L Tremper, OCFO
D Screnci, PAO-RI
N Sheehan, PAO-RI
B Holian, RI
P Henderson, RI
K Farrar, RI
D Holody, RI
A. DeFrancisco,RI
R Summers, RI
C O'Daniell, RI
S. Villar, RI
Region I OE Files (with concurrences)

DOCUMENT NAME: C:\FileNet\ML071420244.wpd

SUNSI Review Complete: SGabriel
After declaring this document "An Official Agency Record" it **will** be released to the Public.

**To receive a copy of this document, indicate in the box:** "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

| OFFICE | DNMS/RI | N | DNMS/RI | | DNMS/RI | | RI/ORA | |
|---|---|---|---|---|---|---|---|---|
| NAME | SGabriel * slg2 | | PHenderson* pjh1 | | B Holian mxt for | | D Holody rjs for | |
| DATE | 5/17/07 | | 5/17/07 | | 5/18/07 | | 5/18/07 | |

| DNMS/RI | |
|---|---|
| B Holian mxt for | |
| 5/21/07 | |

*See Previous Concurrence

OFFICIAL RECORD COPY ADAMS ACCESSION # ML071420244

# U.S. NUCLEAR REGULATORY COMMISSION
# REGION I

## INSPECTION REPORT

| | |
|---|---|
| EA No. | 07-102 |
| Inspection No. | 03002512/2006001 |
| Docket No. | 03002512 |
| License No. | 29-08285-01 |
| NMED No. | 060760 |
| Licensee: | The Cooper Health System, Robert Wood Johnson Medical School at Camden |
| Address: | One Cooper Plaza<br>Camden, New Jersey |
| Other Locations Inspected: | 401 Haddon Avenue, Camden, New Jersey<br>3 Cooper Plaza, Suite 318, Camden, New Jersey<br>900 Centennial Boulevard, Voorhees, New Jersey<br>1210 Brace Road, Suite 106, Cherry Hill, New Jersey<br>218C Sunset Road, Willingboro, New Jersey |
| Inspection Dates: | December 18 and 20, 2006; January 5, 2007 |
| Dates Followup Information Received: | December 28, 2006 through May 11, 2007 |
| Exit Meeting Date: | May 11, 2007 |

Inspector:

**/RA/** **5/17/07**

Sandra Gabriel — date
Senior Health Physicist

Approved By:

**/RA/** **5/17/07**

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

Document Name: C:\FileNet\ML071420244.wpd

## EXECUTIVE SUMMARY

The Cooper Health System, Robert Wood Johnson Medical School at Camden
NRC Inspection Report No. 03002512/2006001

A routine, unannounced onsite inspection was performed on December 18 and 20, 2006, and January 5, 2007, to review the licensee's broad scope medical program. The inspection revealed that for a fractionated high dose rate remote afterloader (HDR) treatment on November 9, 2006, the reference source position for one of the two applicators was incorrectly entered into the treatment console. Consequently, the source was displaced by 18 centimeters from the intended dwell positions and was outside the patient's body during this portion of the treatment. The patient received 1.67 Gy (167 rads) of the prescribed 6 Gy (600 rads) for this treatment fraction, which was the second of five planned fractions. An additional fraction was added to the course of treatment to ensure that the patient received a sufficient dose. Radiation Oncology personnel directly involved in this event did not recognize that the treatment error met the NRC definition of a medical event and failed to report it to the Radiation Oncology Department's Quality Assurance Committee and to the Radiation Safety Officer.

Within the scope of this inspection, two apparent violations of NRC regulations were identified:

(1) failure to verify that an HDR treatment was administered in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2); and

(2) failure to report to the NRC a medical event, as required by 10 CFR 35.3045.

## REPORT DETAILS

### I. Organization and Scope of the Program

a. Inspection Scope

The inspector interviewed licensee personnel and toured the licensee's facilities including the Nuclear Medicine Department, Radiation Oncology Department, self-shielded irradiator area, radioactive waste storage area, research labs, and four outpatient satellite locations. The inspector observed an iodine-131 thyroid carcinoma treatment in Nuclear Medicine and an HDR treatment in Radiation Oncology.

b. Observations and Findings

The licensee operates a university-affiliated hospital, as well as satellite outpatient facilities, and a small non-human research program. The broad scope license is administered by a full-time Radiation Safety Officer (RSO) with one assistant. The RSO reports to a Senior Vice President who also serves as the licensee's Chief Compliance Officer. There is an active Radiation Safety Committee (RSC) which approves Authorized Users (AUs), Authorized Medical Physicists (AMPs), authorized uses, and facilities. The Chief of Radiology serves as RSC chairman.

Nuclear Medicine provides the full range of diagnostic studies at two locations: the main hospital and the outpatient facility in Voorhees. At the main hospital, approximately 4500 diagnostic examinations are performed annually with three imaging cameras. At the Voorhees facility, approximately 400 diagnostic examinations are performed annually with 1 imaging camera. Seven nuclear medicine technologists staff the two locations. All dosages are assayed in a dose calibrator prior to administration. Radiopharmaceutical therapy is also performed at the main hospital, with an estimated annual workload of 70 outpatient iodine-131 treatments for hyperthyroidism, 45 outpatient iodine-131 treatments for thyroid carcinoma, 18 administrations of samarium-153 Quadramet, and 1 Zevalin treatment.

Nuclear Cardiology operates five outpatient sites. The facilities at 3 Cooper Plaza and Voorhees are open Monday through Friday, Cherry Hill is closed on Fridays, Willingboro is closed on Thursdays, and Salem is open only on Mondays and Wednesdays. There are two imaging cameras at Voorhees and one imaging camera at each of the other facilities. Approximately 3400 examinations are performed annually, primarily myocardial perfusion studies. A total of eight technologists staff the five sites. Only unit dosages are used and all dosages are assayed in a dose calibrator prior to administration.

In 2006, Radiation Oncology performed 17 iodine-125 prostate implants, primarily at the Voorhees outpatient facility. HDR treatments are conducted at the main hospital. In 2006, approximately 225 treatment fractions were administered to 47 patients. Two outpatient iodine-125 GliaSite treatments were performed in 2005, however the program is currently inactive.

The self-shielded irradiator is used to irradiate blood products.

The current research program was initiated in October 2006. There is one AU supervising one researcher who performs cell labeling in two laboratories using microcurie quantities of carbon-14 and hydrogen-3. The licensee has requested authorization from the county to release effluents (within NRC limits) into the sanitary sewer system. There are no active human use research protocols.

c. Conclusions

No safety concerns were identified

## II. Management Oversight of the Program

a. Inspection Scope

The inspector reviewed minutes of the RSC meetings; records of approvals of new AUs, AMPs, authorized uses, and facilities; program audits; and annual program reviews. The inspector also interviewed licensee personnel.

b. Observations and Findings

The inspector noted that the licensee has an active RSC that was overseeing implementation of the program, as evidenced by e-mail communication, discussions held during the meetings and the results of interviews with personnel. The RSC membership includes representatives of all types of AUs for both human and non-human use, as well as the RSO and representatives of Administration and Nursing. Approvals of new AUs and AMPs were performed in accordance with the regulatory requirements in effect at the time of the approvals. The RSO performed audits of all program components and facilities and discussed safety issues with members of senior management.

c. Conclusions

No safety concerns were identified.

## III. Facilities and Equipment

a. Inspection Scope

The inspector toured the licensee's facilities and evaluated the adequacy of the facilities and equipment to ensure that radioactive material could be used safely and radiation exposures to workers and members of the public could be maintained ALARA.

b. Observations and Findings

The inspector toured all facilities, except the Salem Nuclear Cardiology site, and observed that facilities and equipment were as described in the license and adequate to ensure safety. Posting and labeling were found to be adequate. Based on its remote location and limited operating hours, the inspector was unable to tour the Salem Nuclear Cardiology site,

however the inspector reviewed the RSO's audit report dated September 13, 2006, and the State of New Jersey clear inspection report dated October 17, 2005.

c. Conclusions

No safety concerns were identified.

## IV. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspector interviewed licensee personnel and reviewed a sampling of records of material inventories and periodic checks of dose calibrators, survey instruments, and the HDR unit.

b. Observations and Findings

The inspector reviewed the licensee's procedures for maintaining accountability and security of licensed material, instrument calibration, and material use. The inspector found the licensee's procedures to be in conformance with the regulatory requirements. An AMP conducts all full calibrations of the HDR unit and either conducts or reviews HDR spotchecks. Following an update of HDR full calibration procedures to extend timer checks over the full range of use and to maintain documentation of all required tests, the inspector confirmed that HDR full calibrations and spotchecks were performed in accordance with the licensee's procedures and the regulatory requirements. The inspector recommended relocation of the HDR keys from a secretarial area to a location accessible only to Physics staff. The licensee did this immediately.

c. Conclusions

No safety concerns were identified.

## V. Training of Workers

a. Inspection Scope

The inspector interviewed licensee personnel, observed use of licensed material, and reviewed training records.

b. Observations and Findings

The licensee conducted initial and annual radiation safety training for staff members who may receive occupational exposure. Formal, written tests of radiation safety knowledge were on file for Nuclear Medicine technologists and irradiator operators. For other users of licensed material, the RSO carried out performance-based evaluations of radiation safety knowledge during audits and walk-throughs. The RSO developed a radiation safety intranet computer site which includes training materials and is planned to include computer-based

testing of radiation safety knowledge. The inspector observed staff in various departments using proper procedures for handling radioactive material and found them to be knowledgeable of methods to minimize radiation exposure and of emergency response procedures.

The licensee did not have a routine program to provide training about the medical event reporting requirements in 10 CFR 35.3045.

c. Conclusions

Licensee staff received radiation safety training and appeared knowledgeable about radiation safety practices, however the licensee did not have a routine program to provide training about the requirements in 10 CFR 35.3045.

## VI. Closeout of Violation from 2005 Inspection

a. Inspection Scope

The inspector interviewed licensee personnel and examined documents to review the licensee's followup actions to the violation identified as a result of inspection 2005001 and described in the Notice of Violation dated December 16, 2005. The violation involved the licensee's failure to keep a record of the transfer of depleted uranium shielding in two linear accelerators.

b. Observations and Findings

The inspector confirmed that the licensee updated its procedures to require (a) RSO approval of all transfers of radioactive material, (b) confirmation prior to transfer that the recipient is authorized to receive the material, and (c) maintenance of records of both the transfer and the confirmation that the recipient is authorized to receive the material.

c. Conclusions

The inspector closed out the violation from inspection 2005001.

## VII. Medical Administration on November 9, 2006

a. Inspection Scope

The inspector reviewed records and interviewed licensee personnel concerning an HDR treatment on November 9, 2006, during which the reference source position for one of the two applicators was incorrectly entered into the treatment console.

b. Observations and Findings

Event Chronology

10/30/06 The patient received the first of an intended series of five HDR treatment fractions for cervical carcinoma. The AU prescribed 6 Gy (600 rads) to be delivered to Point A for each fraction, for a total treatment of 30 Gy (3000 rads). This was prescribed as a ring and tandem treatment to be performed using a 4 cm tandem. CT treatment planning was performed and the treatment fraction was delivered without incident.

11/9/06 The patient returned for the second HDR treatment fraction. The AU was able to insert a 6 cm tandem applicator, however after reviewing the configuration of applicators and patient anatomy on simulation films, the AU asked the AMP to modify the effective tandem length to 4 cm (e.g., refrain from treating the deepest 2 cm) to spare excess dose to normal structures. CT imaging was not performed on this date. Instead of running a new treatment plan, the AMP used the treatment plan from the first treatment fraction and made the positional change at the HDR treatment console. He intended to offset the reference source position or "source length" by 2 cm from the tip of the tandem. This HDR device uses units of millimeters for "source length", with a default length of 1500. The AMP changed the "source length" at the treatment console to 1300. Because a new treatment plan was not run, there was no opportunity to confirm the accuracy of the "source length" at the treatment console by doublechecking it against the reference source position in the treatment plan. Immediately following delivery of this treatment fraction, the AMP reviewed the post-treatment display on the console monitor and realized that the "source length" had been offset by 20 cm (200 mm) from the tip of the tandem rather than by the intended 2 cm (20 mm). As a result, the source dwell positions were displaced 18 cm from the intended positions and the source was outside the patient's body for the tandem portion of the treatment. The AMP informed the AU. The AMP determined that a dose of 1.37 Gy (137 rads) was delivered rather than the intended 6 Gy (600 rads). To correct for the treatment error, the AU modified the written directive, adding a $6^{th}$ treatment fraction of 6 Gy (600 rads). This resulted in a change of the total prescribed dose for the course of treatment to 31.37 Gy (3137 rads).

The AMP informed the chief AMP of the treatment error. Neither the AMP, AU, or chief AMP realized that it might be necessary to report a single fraction, underdose treatment error to anyone else, including the Chief of Radiation Oncology, the Radiation Oncology Quality Assurance Committee, or the Radiation Safety Officer.

11/13-27/06 The remainder of the patient's HDR treatment course was completed without incident, with a total delivered dose of 31.37 Gy (3137 rads) in 6 treatment fractions.

12/12/06 The RSO performed an audit of written directives for HDR treatments performed from September 1 to December 4, 2006. He noted that the AU had modified the original written directive for the course of HDR treatment that included the treatment fraction on November 9, 2006. [This authorized

user was known to use a dynamic treatment planning approach involving changes in the written directive as the course of treatment progressed.] The RSO noted that the modified total dose prescription of 31.37 Gy (3137 rads) was not consistent with the prescription of 6 Gy (600 rads) for each of 6 fractions. The RSO e-mailed a copy of the audit report to the AU and asked her to respond regarding steps she will take to (a) ensure that dose per fraction and number of fractions are consistent with the prescribed total dose, and (b) provide clear documentation of changes in written directives. The AU agreed to review the issue with the chief AMP, then respond. [No response had been provided by the time of the routine inspection on December 18, 2006.]

12/18/06 During the routine inspection, the inspector reviewed the written directive for the course of HDR treatment that included the treatment fraction on November 9, 2006. She asked to see the patient's treatment chart, recognizing that the reason for the change in the written directive might have been a treatment error.

The RSO obtained the patient's treatment chart, conferred with Radiation Oncology staff members involved with the patient's treatment, and learned that an error had occurred during the HDR treatment fraction on November 9, 2006. He informed the inspector.

The inspector informed the RSO that the HDR treatment error on November 9, 2006 met the NRC medical event reporting criteria.

12/28/06 The licensee informed the inspector that the maximum dose to unintended tissue from this medical event was approximately 47 rads.

Notification of the Event

As noted above, the AMP, AU, and chief AMP were aware of the HDR treatment error on November 6, 2006, however they did not report this to the RSO for consideration of whether a medical event report was necessary. After the inspector informed the RSO on December 18, 2006 that the treatment error met the NRC medical event reporting criteria, the licensee made a telephone report to the NRC Operations Center on December 19, 2006. The licensee also submitted a 15-day written report, which was received in Region I on December 28, 2006. On December 21, 2006, the licensee notified the patient's referring physician of the medical event. The patient had previously been informed that an additional HDR treatment fraction was required and had received the additional treatment. The licensee's written report stated that, after learning that this treatment error constituted a reportable medical event, the AU concluded that it would be harmful to explain to the patient the details of the treatment error.

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 AU. 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.

The inspector asked the RSO to evaluate the licensee's compliance with its internal procedures with regard to this medical event. The RSO responded that the following portions of the licensee's procedures for compliance with 10 CFR 35.41 were not followed:

a) "Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices."

b) "Dose calculations will be checked before administering the prescribed therapy dose. An AU or qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following: .....2. For computer-generated dose calculations entered into the therapy console, verifying the correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)."

The inspector noted that the licensee used an "HDR Patient Check List" for each treatment fraction, including a detailed series of steps to be followed. Despite the licensee's stated procedure in the last sentence of b), above, the "HDR Patient Check List" in use at the time of the medical event did not specifically require checks of any parameters at the treatment console.

Licensee's Corrective and Preventive Actions

a) Radiation Oncology instituted a policy that HDR plans are never to be modified at the treatment console, only at the treatment planning workstation. In addition, the "HDR Patient Check List" was updated to include a check of several parameters at the treatment console, including "source length", indexer length, dwell positions, dwell time, and source activity.

b) The RSO instituted a program of in-service training for AUs and AMPs regarding NRC medical event reporting requirements.

c) Radiation Oncology adopted written criteria to identify treatment errors to be reviewed by the Quality Assurance Committee.

d) The Radiation Safety Committee adopted a policy on event reporting per the requirements of multiple agencies, including reporting of medical events to the NRC.

e) The Clinical Director of Radiation Oncology conducted an AU peer review of the medical event case and found no additional issues of concern.

f) The Director of Physics (AMP), Clinical Director of Radiation Oncology (AU), and Chief of Radiation Oncology (AU) conducted a peer review of 2006 HDR cases which identified no additional medical events.

g) The licensee extended its program of HDR written directive audits to include quarterly audits by the RSO, an AMP, and an AU.

h) The licensee contracted with the Chief Clinical Physicist (AMP) from another broad scope medical program to perform a review of the brachytherapy program and make recommendations. The consultant also reviewed 2006 HDR cases and identified no additional medical events and no other alterations of treatment plans at the treatment console.

i) The licensee agreed to increase staffing by one physicist and one dosimetrist, and began a search for a new Director of Physics.

c. Conclusions

The inspector concluded the following:

a) The licensee performed a fractionated high dose rate remote afterloader (HDR) treatment in which the tandem source was displaced by 18 centimeters from the intended dwell positions and was outside the patient's body during this portion of the treatment. This resulted in a dose to Point A of 1.67 Gy (167 rads) instead of the intended 6 Gy (600 rads). Because the administered dose differed from the prescribed dose by more than 50 rem to an organ or tissue and the fractionated dose differed from the prescribed dose by more than 50%, this administration met the medical event reporting definition in 10 CFR 35.3045(a)(1)(iii).

b) The root cause for the occurrence of the medical event was the licensee's failure to run a new treatment plan to reflect the actual treatment geometry. As a result, there was no opportunity to confirm the accuracy of the "source length" setting at the treatment console by doublechecking it against the source position in the treatment plan.

c) The licensee failed to follow its written procedures for compliance with 10 CFR 35.41(b)(2), as discussed above under "Written Directive Procedures." In addition, the licensee's "HDR Patient Check List" did not require checks of any parameters at the treatment console. The failure to verify that the HDR treatment fraction was delivered in accordance with the treatment plan and written directive is an apparent violation of 10 CFR 35.41(b)(2).

d) Results of audits conducted by both the licensee and a consultant identified no other treatment errors and no other alterations of HDR treatment plans at the treatment console.

e) There was no adverse affect on the patient in that the treatment error was immediately identified and an additional HDR treatment fraction was prescribed to assure that the patient received an adequate therapeutic dose.

f) Although three Radiation Oncology staff members were aware of the treatment error, they did not report it to the RSO for consideration of whether a reportable medical event had occurred. The inspector, rather than the licensee, identified that a medical event had occurred. As a result the medical event that occurred on November 9, 2006 was not reported to the NRC Operations Center until December 19, 2006. This is an apparent violation of 10 CFR 35.3045 for failure to report a medical event.

g) The root cause for the failure to report the medical event was the lack of specific criteria and procedures for reporting of treatment errors.

h) The licensee's corrective actions directly address the cause of both the medical event and the failure to report the medical event. The corrective actions appear to be adequate to prevent recurrence of both this type of medical event and of failure to report a medical event.

## VIII. Exit Meeting

A preliminary exit meeting was conducted on January 5, 2007, to discuss the scope of the inspection and the inspector's initial findings. On May 11, 2007, at the conclusion of the inspection, the inspector met with the licensee's staff members identified at the end of this report to discuss the apparent violations of 10 CFR 35.41(b)(2) and 35.3045.

## PARTIAL LIST OF PERSONS CONTACTED

Licensee

*+ Edward Goldschmidt, M.S., Radiation Safety Officer
* Robert Mounce, Radiation Safety/Medical Physics Assistant
*+ Maureen Barnes, Vice President, Risk Management
*+ Carolyn Bekes, M.D., Senior Vice President and Chief Compliance Officer
* Raymond Baraldi, M.D., Chairman, Radiation Safety Committee
* Alex Khariton, Administrative Director, Radiation Oncology
Clarissa Henson, M.D., Radiation Oncologist/HDR AU
Yun-Ping Zhu, Ph.D., Director of Physics/Chief AMP
Inwhan Yeo, Ph.D., AMP
* Donna Handy, R.T., Nuclear Medicine Manager
Louis Zeiger, M.D., Chief of Nuclear Medicine/AU
Lisa Monzo, Nuclear Medicine Technologist
Elaine Matarano, Nuclear Medicine Technologist
Sherry Truxell, Nuclear Medicine Technologist
Sherry Wilkinson, Manager, Outpatient Nuclear Cardiology
Misty Price, Nuclear Medicine Technologist (Voorhees Cardiology)
Sally Farkas, Nuclear Medicine Technologist (Cherry Hill Cardiology)
Michelle Vitucci, Nuclear Medicine Technologist (Cardiology floater)
Tammy Deloskey, Nuclear Medicine Technologist (Willingboro Cardiology)
Robin Dolan, Nuclear Medicine Technologist (3 Cooper Plaza Cardiology)
Artressia Urquhart, Blood Bank Supervisor
Sonia Cevallos, Blood Bank
Kemi Obajimi, Ph.D., Researcher

* Present at preliminary exit meeting conducted on January 5, 2007
+ Present at exit meeting conducted on May 11, 2007