November 29, 2004

Jean Meyer, Senior Vice-President
St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46240

SUBJECT: NRC INSPECTION REPORT 030-01579/2004-007(DNMS) AND NOTICE OF VIOLATION - ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Ms. Meyer:

This refers to the special inspection conducted on October 27 and 28, 2004, at St. Vincent Hospital & Health Care Center, Indianapolis, Indiana, with continued in-office review through November 9, 2004. The in-office review included the review of your report dated November 1, 2004, associated with a medical event. In addition, we reviewed your letter dated November 22, 2004, amending your corrective actions. The inspection was conducted to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event reported to the NRC on October 19, 2004. The enclosed report presents the results of this inspection.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a violation of NRC requirements occurred. The violation pertains to your staff's failure to ensure that a fractionated high dose rate (HDR) remote afterloading brachytherapy treatment was administered as prescribed by the authorized user. Specifically, your staff administered a dose of 1.4 to 4.3 rads to the patient's skin (thigh), rather than the prescribed 350 rads to the intended treatment site. The circumstances surrounding the violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with members of your staff at the inspection exit meeting conducted on October 28, 2004, and during a subsequent teleconference on November 24, 2004, between John Madera and George Parker of my staff and Edward Wroblewski and Jeff Heffelfinger of your staff.

This violation, which is cited in the enclosed Notice of Violation (Notice), and the previous enforcement action taken in April of this year, as a result of a similar medical event, are of concern to the NRC because they indicate continued ineffective management oversight of your radiation safety program. Effective management of the radiation safety program is vital to licensees achieving safe and compliant operations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. Because the violation indicates a weakness in

the management oversight of your radiation safety program, you are requested, in your response, to describe: 1) how you plan to improve the oversight of your radiation safety program; 2) how you plan to monitor the effectiveness of your actions to improve the management oversight of your radiation safety program; and 3) why you believe your corrective actions will be more successful in preventing similar violations and issues in the future.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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.

Please note that on October 25, 2004, the NRC terminated public access to ADAMS and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Documents Room is located at NRC Headquarters in Rockville, MD, and can be contacted at (800) 397-4209 or (301) 415-4737 or pdr@nrc.gov.

We appreciate your cooperation and will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA by T. Bergman Acting for/

Marc L. Dapas, Director
Division of Nuclear Materials Safety

License No.: 13-00133-02
Docket No.: 030-01579

Enclosures: 1) Notice of Violation
2) Inspection Report No. 030-01579/2004-007(DNMS)

cc w/encls: Edward Wroblewski, Radiation Safety Officer

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NOTICE OF VIOLATION

St. Vincent Hospital
Indianapolis, IN

Docket No. 030-01579
License No. 13-00133-02

During an NRC inspection conducted on October 27 and 28, 2004, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

10 CFR 35.41(a) requires that, for any administrations requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Contrary to the above, the licensee's written procedures did not provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for the implementation of treatment plans with its high dose rate (HDR) remote afterloader brachytherapy unit did not require a check of the treatment plan parameters against "typical" operating parameters for gynecological treatments. As a result, the licensee failed to deliver the prescribed dose to the treatment site by using a "non-typical" indexer position of 995 millimeters (mm) instead of the "typical" 1500 mm indexer position used in treatment plans for the delivery of prescribed HDR gynecological therapy treatments.

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 was achieved is already adequately addressed on the docket in Inspection Report No. 03001579/2004-007(DNMS), and the November 1, 2004, letter from the licensee. However, you are required to submit a written response to the questions raised in the NRC's concerns over management oversight of the radiation safety program. Additionally, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description in your November 1, 2004, letter does not accurately reflect your corrective actions or your position. 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, DC 20555 with a copy to the Regional Administrator, Region III, 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, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond your response 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 Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

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

Dated this 29th day of November 2004

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-01579
License No.:	13-00133-02
Report No.:	030-01579/2004-007(DNMS)
Licensee:	St. Vincent Hospital & Health Care Center
Location:	2001 West 86th Street Indianapolis, IN 46240
Dates of Inspection:	October 27-28, 2004
Exit Meeting:	October 28, 2004
Inspector:	George Parker, Health Physicist
Reviewed By:	John R. Madera, Chief Materials Inspection Branch

NMED No. 41133

EXECUTIVE SUMMARY

St. Vincent Hospital & Health Care Center
Indianapolis, Indiana
Inspection Report No. 030-01579/2004-007(DNMS)

The inspector conducted a special inspection to review the circumstances, root and contributing causes, and proposed corrective actions for a high dose rate (HDR) remote afterloader brachytherapy medical event that resulted in a failure to deliver the prescribed dose, and the delivery of an unintended dose to the patient's skin (thigh) of 1.4 to 4.3 rads. Based on a review of the medical event, the licensee does not expect the patient to experience any adverse medical effects.

The inspector identified one violation of NRC requirements involving the licensee's failure to ensure each administration is in accordance with the written directive prior to patient treatment. Specifically, the licensee's procedures for the implementation of treatment plans with its HDR unit did not require a check of the treatment plan parameters against "typical" operating parameters for gynecological therapy treatments. As a result, the medical event was caused by the licensee's failure to identify that the treatment plan required the use of a "non-typical" indexer position of 995 millimeters (mm) instead of the "typical" 1500 mm indexer position.

To reduce the likelihood of similar events, the licensee initiated several immediate and long-term corrective actions to prevent recurrence of a similar event. The corrective actions included: (1) using a single catheter (transfer tube) delivery length of 1500 mm for all gynecological, bronchogenic, and esophageal HDR treatment procedures, excluding mammosite treatment procedures; (2) conducting a formal "time-out" before HDR treatment is implemented, which includes active participation of the prescribing physician and the physicist to verify the procedure being performed; and (3) initiating a formal independent review by physicists currently working with the Novalis intra-vascular brachytherapy modality procedures to improve the written procedure for preparing and verifying HDR treatment plans.

Report Details

1.0 Program Scope and Inspection History

The NRC License Number 13-00133-02 authorizes St. Vincent Hospital & Health Care Center (licensee) to use a variety of byproduct materials for medical purposes, including diagnostic and therapeutic nuclear medicine, and sealed source therapy using a high dose rate (HDR) remote afterloading brachytherapy device. The licensee was authorized to conduct activities at five medical facilities located in Carmel, Elwood, Frankford, and two facilities in Indianapolis, Indiana.

The last NRC inspection of the licensee at the Indianapolis, Indiana facility was on April 4, 2004. That inspection resulted in escalated enforcement for failure to develop written procedures for use of its HDR treatment planning software.

2.0 Sequence of Events and Licensee Investigation

a. Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical event and the licensee's investigation of the event. In addition, the inspector interviewed selected licensee personnel, reviewed patient treatment information, and inspected equipment associated with the medical event, and toured related facilities.

b. Observations and Findings

On October 11, 2004, the licensee delivered the first of two planned high dose rate (HDR) remote afterloading brachytherapy treatments to a patient. Prior to the first treatment, a licensee authorized user physician completed a written directive that prescribed the fractionated treatment of 700 centigray (cGy) to a point 0.5 centimeters (cm) from the surface of a 2.0 cm in diameter gynecological cylinder using a 7.031 curie iridium-192 source. The authorized user physician planned to administer two fractionated doses, 350 cGy each, for a total dose of 700 cGy to the endometrium. However, the authorized user physician also requested, prior to the treatment, semi-orthogonal films of the treatment site, which are routinely requested for esophageal or bronchial treatments with a 995 mm transfer tube, not for HDR gynecological therapy treatments.

Prior to the HDR treatment, a medical physicist prepared a treatment plan which required a 995 mm indexer position to be programmed into the HDR unit. Following the preparation of the treatment plan, a second medical physicist and the authorized user physician reviewed and approved the plan. However, no one recognized that the plan called for the treatment to be delivered using a 995 mm indexer position, rather than the intended 1500 mm indexer position normally used in conjunction with the 1500 mm source transfer tube, that was connected to the HDR unit, for typical gynecological treatments. This resulted in the source not entering the patient. The source remained positioned in the transfer tube for the treatment duration at an estimated distance of 35 to 50 cm from the patient’s skin (thigh).

Title 10 CFR 35.41(a) requires that, for any administrations requiring a written directive, licensees develop, implement, and maintain written procedures to provide high

confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. The written procedures must meet the requirements described in 10 CFR 35.41(b). The licensee's written procedures for implementation of treatment plans with its HDR unit did not require a check of the treatment plan parameters against "typical" operating parameters for HDR gynecological treatments. As a result, the licensee failed to identify that the treatment plan required the use of a "non-typical" indexer position of 995 mm instead of the "typical" 1500 mm indexer position for HDR gynecological treatments. Therefore, the licensee's failure to develop, implement, and maintain adequate written procedures to provide high confidence that each administration is in accordance with the written directive, constitutes a violation of 10 CFR 35.41(a).

As a result of the error in the treatment plan, no dose was delivered to the treatment site, and 1.4 to 4.3 rads was delivered to the patient's skin (thigh). The authorized user physician did not expect any adverse medical effects to the patient as a result of the medical event.

The licensee immediately initiated an investigation of the medical event and determined that the root cause and contributing factors included: (1) the medical physicist's confusion when the authorized physician user requested semi-orthogonal films, which are routinely requested for esophageal or bronchial treatments with the 995 mm transfer tube not for HDR gynecological therapy treatments. The medical physicist did not recognize or compensate for the correct transfer tube length in the preparation of the treatment plan for the gynecological treatment; (2) the second medical physicists and the physician authorized user's failure to recognize that the treatment plan was different from the "typical" HDR treatment plan for gynecological treatments while performing the second verification; and (3) failure to verify the reference length of the transfer tube that was connected to the HDR unit prior to treatment.

c. Conclusions

A medical event occurred on October 11, 2004, when the licensee failed to administer an HDR brachytherapy treatment dose of 350 cGy to a point 0.5 cm from the surface of a 2.0 cm in diameter gynecological cylinder. There was no dose actually delivered to the treatment site, and subsequently a dose of 1.4 to 4.3 rads was delivered to the patient's skin (thigh). The physician did not expect the dose to the patient's thigh to result in any adverse medical effects.

The medical event was caused by the medical physicist's failure to recognize or compensate for the transfer tube length in the preparation of the treatment plan for the HDR brachytherapy gynecological treatment. In addition, the licensee's written procedures for implementation of HDR treatment plans did not require a check of the treatment plan parameters against the "typical" operating parameters for gynecological therapy treatments. The inspector identified a violation of NRC requirements associated with the failure of the licensee's written procedures to provide high confidence that each administration is in accordance with the written directive.

3.0 Licensee Corrective Actions

a. Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's November 1, 2004, written report regarding the medical event, and interviews of selected licensee personnel.

b. Observations and Findings

The inspector determined that the licensee initiated several immediate and long-term corrective actions to prevent recurrence of a similar event. The corrective actions included: (1) using a single catheter (transfer tube) delivery length of 1500 mm for gynocological, bronchogenic, and esophageal HDR treatment procedures, excluding mammosite treatment procedures; (2) conducting a formal “time-out” before HDR treatment is implemented, which includes active participation of the prescribing physician and the physicist to verify the procedure being performed; and (3) initiating a formal independent review by physicists currently working with the Novalis intra-vascular brachytherapy modality procedures to improve the written procedure for preparing and verifying HDR treatment plans.

c. Conclusions

The inspector determined that the licensee developed appropriate corrective actions to address the violation and prevent similar events.

4.0 Notifications and Reports

a. Inspection Scope

The inspector reviewed the licensee's notification to the NRC Operations Center and the associated written report to ensure compliance with reporting requirements.

b. Observations and Findings

On October 18, 2004, the licensee’s Radiation Safety Officer determined that the first of two planned fractionated treatments using an HDR unit resulted in a medical event and notified the NRC's Operations Center of the event within 24 hours. The licensee provided its written report of the event in a letter dated November 1, 2004. The inspector determined that the written report included the information required by 10 CFR 35.3045(d).

The licensee notified the patient's referring physician immediately after the event. The authorized user physician then immediately informed the patient’s representative.

c. Conclusions

The inspector determined that the licensee provided the notification and written report as required by 10 CFR 35.3045.

5.0 Exit Meeting

At the completion of the onsite inspection, the inspector discussed the findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

List of Persons Contacted

*Michael Wiemann, M.D. Senior Vice-President, Chief Medical Officer
*Edward Wroblewski, Radiation Safety Officer, Senior Medical Physicist
*Awat Aliyar, Ph.D., Chief Radiation Therapy Physicist
*Jeff Hefflefinger MSA, CHE, Executive Director Oncology
*Suzanne Stevenson, R.N., Director, Risk Management
*Robert Liebross, M.D.

* Attended the October 28, 2004, exit meeting