November 25, 2005

EA-04-087
EA-05-173

NMED Nos:
050504
050591
050592
050593
050642

Michael Wiemann, M.D.
Senior Vice-President/Chief Medical Officer
St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46240

SUBJECT: EXERCISE OF ENFORCEMENT DISCRETION
NRC SPECIAL INSPECTION REPORT NO. 030-01579/05-002(DNMS) -
ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Dr. Wiemann:

This refers to the special inspection conducted on August 2, and October 5 and 6, 2005, at St. Vincent Hospital & Health Care Center, Indianapolis, Indiana, with continued in-office review through October 28, 2005. The purpose of the August 2nd inspection was to review the circumstances surrounding a medical event, identified by an independent medical physicist, that occurred on July 21, 2003. Based on the identification of this event, your staff conducted a retrospective (extent of condition) review of previous high-dose-rate (HDR) fractional treatments for the period of March 2002 through September 2005. As a result of your staff's review, six additional medical events were identified. On October 5 and 6, 2005, a follow-up inspection was conducted to review the results of your staff's retrospective review. The inspectors also conducted a review of additional treatments performed at your facility for the period of November 1998 through October 2004. The in-office review included the review of your written reports and correspondence, dated August 10, September 6, September 15, September 29, and October 12, 2005. 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 a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the information developed during the inspection, the NRC has determined that a violation of NRC requirements occurred. The violation involves the failure to adequately develop written procedures to ensure that seven HDR brachytherapy patient administrations were performed in accordance with the physician/authorized user's written directive. Specifically, your procedures for the use of the HDR brachytherapy treatment unit did not include appropriate steps or guidance to verify that the manually entered source step size length and dwell position in the treatment system were in accordance with the treatment plan.

The failure to develop adequate procedures is a significant safety concern since the failure resulted in seven medical events and a process was not in place to perform independent reviews of the treatment plans prior to initiating the brachytherapy treatments. Based on Supplement VI.C.5 of the Enforcement Policy, the failure of your brachytherapy procedure to address one or more of the elements in 10 CFR 35.41 is an example of a Severity Level III violation.

The NRC issued a Severity Level III violation on August 2, 2004, for the failure to have adequate procedures for brachytherapy administrations (EA-04-087). As a result of inadequate procedures, a medical event occurred involving three fractionated HDR brachytherapy treatments administered on March 15, 22, and 29, 2004. The NRC, in accordance with the Enforcement Policy, characterized this violation at Severity Level III since the failure was not isolated to a single treatment. Corrective actions for this violation included revising the brachytherapy treatment procedure to require: (1) an independent check of treatment plans prior to each treatment; (2) a second medical physicist to verify the treatment parameters are correct; and (3) the medical physicist to manually calculate the treatment dose and compare it to the dose developed in the treatment plan and written directive prior to administering the treatment to the patient. Additional corrective action included disseminating the results of the investigation, including root cause and corrective actions, to all members of the medical physics staff and authorized user physicians involved in HDR treatments. Finally, your staff upgraded the HDR treatment planning/delivery software in August 2004, allowing the electronic transfer of data between the treatment planning program and the HDR delivery program.

A Severity Level IV violation was issued November 29, 2004, for the failure to have adequate procedures for brachytherapy administrations. As a result of the inadequate procedures, a medical event occurred involving an incorrect indexer position for an HDR brachytherapy treatment administered on October 11, 2004. For this administration, a medical physicist planned the treatment with a 995 millimeter (mm) indexer position rather than the normally used 1500 mm indexer position. However, the treatment was delivered using a 1500 mm transfer tube resulting in the source not reaching the intended treatment site. The NRC characterized this violation at Severity Level IV since the failure was isolated and did not indicate a programmatic weakness in implementing the procedure. Corrective actions for this violation included revising the brachytherapy treatment procedure to only allow the use of the 1500 mm transfer tube for all HDR treatments, and contracting with an independent medical physicist to perform monthly onsite quality assurance reviews of the radiation oncology department, including treatment planning, for 12 months (through December 2005).

Based on the seven medical events, your staff indicated that the monthly reviews of brachytherapy treatments would continue indefinitely. Your staff also indicated that the reviews would be conducted “in-house” by the medical physicists who were not involved in the treatment planning and administration. The NRC may refrain from issuing a Notice of Violation for a violation that is identified after the NRC has taken enforcement action if the violation was licensee identified as part of corrective action for previous enforcement action, has a similar root cause as the previous violation, does not substantially change the safety significance or the character of the regulatory concern, and was corrected. We have determined that had we been aware of the additional medical events at the time we took enforcement action in August 2004 the resulting action would not have been different because: (1) the safety significance would not have changed since your staff indicated that no clinical complications were anticipated or expected from the unintended doses that resulted in the medical events; (2) the root cause of the additional examples is the same as that which formed the basis for our original enforcement action; and (3) the immediate and long term corrective actions were timely and comprehensive, and appeared to have corrected the issue since no medical events have been identified to have occurred after the corrective actions were implemented. Therefore, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion in accordance with Section VII.B.4 of the Enforcement Policy, and not issue a Notice of Violation for a Severity Level III violation associated with the additional examples of the failure to have adequate procedures that resulted in seven medical events.

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

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

Sincerely,

/RA by Geoffrey E. Grant Acting for/

James L. Caldwell
Regional Administrator

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

Enclosure: Inspection Report No. 030-01579/05-002(DNMS)

cc w/encl: Edward Wroblewski, Radiation Safety Officer

See Attached Distribution:

Distribution w/encl:
Docket File
OE:EA File
M. Johnson, OE
C. Nolan, OE Section Chief
A. Hayes, OE Specialist
J. Moore, OGC
P. Holahan, NMSS
G. Morell, NMSS
D. Holody, RI
C. Evans, RII
K. O'Brien, RIII
C. Weil, RIII
K. Fuller, RIV
G. Grant, RIII
S. Reynolds, RIII
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OE:EA(2)

*See prior concurrence
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OFFICE	RIII	E	RIII	E	RIII		RIII		OE[1]		RIII	
NAME	Mulay:mb*		Madera*		Reynolds*		Heller for O'Brien		Nolan for Johnson		Caldwell	
DATE	11/03/05		11/03/05		11/16/05		11/23/05		11/ 23/05		11/23 /05	

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[1] OE concurrence received via telephone from C. Nolan, OE, on November 23, 2005

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-01579
License No.:	13-00133-02
Report No.:	030-01579/05-002(DNMS)
Licensee:	St. Vincent Hospital & Health Care Center
Location:	2001 West 86th Street Indianapolis, IN 46240
Dates of Inspection:	August 2, 2005, through October 28, 2005 Onsite on August 2, and October 5 and 6, 2005
Final Exit Meeting:	October 28, 2005
Inspectors:	Samuel J. Mulay, Health Physicist Tony Go, Health Physicist
Reviewed By:	John R. Madera, Chief Materials Inspection Branch

EXECUTIVE SUMMARY

St. Vincent Hospital & Health Care Center
Indianapolis, Indiana
Inspection Report No. 030-01579/05-002(DNMS)

This was a special inspection at St. Vincent Hospital & Health Care Center (licensee), Indianapolis, Indiana, to review the circumstances, root and contributing causes, and the licensee's proposed corrective actions for seven high dose rate (HDR) remote afterloader brachytherapy medical events that occurred between December 18, 2002, and March 11, 2004.

During a routine, monthly, independent audit conducted on July 28, 2005, the licensee identified the medical event which occurred on July 21, 2003. The written directive called for a 500-centigray (cGy) dose to be delivered 0.5 centimeters (cm) from the surface of the naso-gastric (NG) tube. The event involved administration of a radiation dose to the distal (lower) end of the patient's esophagus that exceeded the prescribed dose by approximately 74 percent (870 cGy) and a radiation dose to the proximal (upper) end of the patient's esophagus that was approximately 92 percent (38.3 cGy) less than prescribed.

The treatment plan called for 12 step positions at 5.0 mm step length each for an active treatment length of 60 mm to be delivered over a treatment time of 155.6 seconds. The medical physicist correctly entered the 12 step positions in the HDR treatment program, but failed to adjust the HDR system default from a standard 2.5 mm step length to the necessary 5.0 mm step length, which resulted in a 30-mm treatment area, rather than the 60-mm treatment area required by the treatment plan. The licensee does not expect the patient to experience any adverse medical effects.

On August 2, 2005, a special inspection was conducted to review the circumstances surrounding the July 21, 2003 event, which included a review of the written directive, the licensee's simulated treatment plans, and interviews with available staff members. This review verified the licensee's aforementioned conclusions regarding this event. In addition, the possibility for an expanded licensee review of previous patient treatments was discussed with licensee management during the August 2, 2005, preliminary exit meeting.

As a result of the identification of this event, the licensee conducted an expanded retrospective (extent of condition) review of previous HDR treatments delivered for the period of March 2002 through September 2005, and included an overall review of 518 administrations representing 54 percent of all fractions performed within that time-frame. Based on this review, the licensee identified six medical events in addition to the July 21, 2003 event. These events occurred on December 18, 2002, December 19 and 26, 2002, January 2, 2003, August 7, 2003, and March 11, 2004. With the exception of the March 11, 2004 event (incorrect entry of source dwell positions), all other events involved a similar, incorrect manual entry of source step size length.

On October 5 and 6, 2005, a special, follow-up inspection was conducted to review the scope of the licensee's retrospective (extent of condition) reviews and evaluation of the additional medical events identified. The review period encompassed November 1998, when the licensee began HDR treatments, through October 2004. For this time period, the licensee performed a total of 659 fractionated HDR treatments. The inspection

included a representative sample of 127 fractions out of the total 659 treatment fractions, or approximately 19 percent. Based on this review, no additional medical events were identified. In addition, a systematic review of the six additional medical events was completed and indicated the licensee's findings were adequately evaluated and reported.

The licensee implemented corrective action in response to a Severity Level III violation issued on August 2, 2004, involving a medical event that occurred on March 15, 22, and 29, 2004. The corrective actions included revising the brachytherapy procedure to require: (1) the staff to independently check treatment plans prior to each treatment; (2) a second medical physicist to verify the treatment parameters are correct; and (3) the medical physicist to manually calculate the treatment dose and compare it to the dose developed in the treatment plan and written directive prior to administering the treatment to the patient. The licensee disseminated the results of the investigation, including root cause and corrective actions, to all members of the medical physics staff and authorized user physicians involved in HDR treatments. In addition, the licensee updated the system software in August 2004, to allow electronic data transfer from the treatment planning program directly to the HDR delivery system, thereby eliminating the necessity for manual data entry. Finally, as corrective action for a SL IV violation, issued November 29, 2004, the licensee contracted with a medical physicist to perform independent monthly audits of brachytherapy treatments through December 2005. Based on the seven medical events recently identified, the licensee staff indicated that monthly audits of brachytherapy treatments will continue to be performed. The audits would be performed by the medical physicists who were not involved with the treatment planning and administration.

Report Details

1 Program Scope and Inspection History

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, conventional brachytherapy and sealed source therapy using a HDR brachytherapy device. The licensee is authorized to conduct activities at authorized medical facilities located throughout the State of Indiana as specified in License Condition 10. Activities involving HDR are currently only performed at the licensee's main campus in Indianapolis, Indiana.

The NRC inspected the licensee at the main campus on April 7, 2004, to review the circumstances surrounding a reported medical event associated with fractionated HDR treatments that occurred on March 15, 22, and 29, 2004 (reference Inspection Report (IR) 030-01579/04-001(DMNS)). The inspection findings resulted in a Severity Level III violation of 10 CFR 35.41(a) for failure to develop written procedures to ensure that the final treatment plans and related calculations for HDR brachytherapy are in accordance with the written directive. Specifically, the written procedures did not include steps to verify that the administration was in accordance with the treatment plan and written directive, and to check both manual and computer-generated dose calculations.

During a routine, follow-up inspection conducted on May 25 and 26, 2004, the inspector identified that the corrective actions taken by the licensee regarding the March 2004 event were adequate and no similar events or violations were identified.

The NRC last inspected the licensee on October 27 and 28, 2004, to review the circumstances surrounding an HDR medical event that occurred on October 11, 2004 (reference IR 030-01579/04-007(DNMS)). The NRC cited a Severity Level IV violation of 10 CFR 35.41(a) for failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's procedures did not require a check of the treatment plan parameters against "typical" operating parameters for gynecological procedures.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspection included a review of the sequence of events that resulted in the July 21, 2003 medical event, as well as the subsequent identification of six additional medical events. The inspector also interviewed selected licensee personnel and reviewed patient treatment information.

2.2 Observations and Findings

On July 28, 2005, an independent auditor informed the licensee that a medical event occurred on July 21, 2003, involving the first of two HDR brachytherapy treatments on a patient (Patient A) diagnosed with esophageal cancer. The event was identified during an independent monthly audit of the licensee's HDR program. The authorized user prepared a written directive prescribing 500 centigray (cGy) to the patient's esophagus at 0.5 centimeters (cm) from the surface of a naso-gastric (NG) tube. The treatment plan called for 12 step positions of 5.0 mm each for an active treatment length of

60 millimeters (mm) and a total treatment time of 155.6 seconds. A licensee staff member entered the correct 12 step positions in the HDR treatment program; however, failed to adjust the HDR system default from the standard 2.5 mm step length to the 5.0 mm step length required by the treatment plan.

The licensee prepared a simulated treatment plan on July 29, 2005, based on the 2.5 mm step length error. The simulation reproduced the initial treatment plan and the actual treatment delivered. From this simulation, the licensee determined that the 2.5 mm error resulted in a treatment length of 30 mm, rather than the prescribed 60 mm treatment length. Based on that information, the licensee calculated that the patient received a radiation dose to the distal (lower) end of the esophagus that exceeded the prescribed dose by approximately 74 percent (870 cGy) and a radiation dose to the proximal (upper) end of the esophagus that was approximately 92 percent (38.3 cGy) less than prescribed. At the time of the event, the HDR unit required a manual adjustment of the 2.5 mm default step length setting to the prescribed 5.0 mm length.

On August 14, 2003, a written directive was prepared for the second fractional treatment, which called for a 300-cGy treatment to the same area of the esophagus. All treatment parameters were entered correctly and the treatment was delivered without incident. The licensee does not expect the patient to experience any adverse medical effects from the medical event that occurred on July 21, 2003.

As a result of the identification of this event, the licensee conducted an expanded retrospective (extent of condition) review of previous HDR treatments delivered for the period of March 2002 through September 2005. This review included an overall review of 518 administrations representing 54 percent of all fractions performed within that time-frame. The reviews included verification of correct treatment parameters such as treatment site, fractional dose, source strength, dwell positions, step size, number of dwell positions, and total treatment time. Based on this review, the licensee identified six medical events in addition to the July 21, 2003 event as follows:

- On December 18, 2002, a medical event occurred when the medical physicist entered an incorrect step length setting into the treatment system for a patient (Patient B) diagnosed with cervical cancer. The authorized user prepared a written directive prescribing three fractional doses of 500 cGy each at 0.5 cm from the surface of a 2.50 cm diameter vaginal cylinder for an active length of 4.0 cm. The treatment plan called for 17 indexer step positions at 2.5 mm spacing. The first two fractions were delivered without incident. However, the medical physicist entered 17 index step positions at 10.0 mm spacing for the final fraction. According to the licensee's simulated recreation of the treatment plan, this error resulted in an approximate 200 cGy exposure to an unintended site and an approximate 60 percent under dose to the intended treatment site. For the overall treatment, the calculated dose indicates that 1200 cGy rather then 1500 cGy was delivered to the intended site representing a 20 percent under dose for the overall treatment.

- On December 19 and 26, 2002, and January 2, 2003, three medical events occurred when the medical physicist entered an incorrect step length setting into the treatment system for a single patient (Patient C) diagnosed with endometrial

cancer. The authorized user prepared a written directive prescribing three treatments of 500 cGy each to be delivered at 0.5 centimeters (cm) from the surface of a 3.0 cm diameter vaginal cylinder for an active treatment length of 6.0 cm. The treatment plan called for 25 indexer step positions at a spacing of 2.5 mm. The medical physicist, however, entered 25 indexer step positions at 5.0 mm spacing, which resulted in a total dose to an unintended site of 1,080 cGy and an approximate 28 percent under dose to the intended site. According to the licensee's simulated recreation of the treatment plan, the patient may have received as much as 360 cGy to an unintended site for each of the three fractions representing a total of 1,080 cGy for the overall treatment and a 28 percent under dose overall to the intended treatment site.

- On August 7, 2003, a medical event occurred when the medical physicist entered an incorrect step length setting into the treatment system for the first of three fractional treatments delivered to a patient (Patient D) diagnosed with cervical cancer. The authorized user prepared a written directive prescribing a dose of 500 cGy at 0.5 cm from the surface of a 2.0 cm diameter vaginal cylinder for an active length of 6.0 cm. The treatment plan required 13 indexer step positions at 5.0 mm step length. The medical physicist involved with the first fractional delivery, entered 13 indexer step positions with 2.5 mm step length positions. According to the licensee's simulated recreation of the treatment plan, the patient may have received 60 percent (800cGy) over dose to the proximal portion of the intended site and approximately 44 per cent (280 cGy) under dose to the distal portion of the intended site. The remaining two fractions were delivered in accordance with the treatment plan and written directive.

- On March 11, 2004, a medical event occurred when the medical physicist entered incorrect source dwell positions into the treatment system for a single treatment delivered to a patient (Patient E) diagnosed with esophageal cancer. The authorized user prepared a written directive prescribing a dose of 500 cGy at 0.5 cm from the surface of an NG tube for an active length of 8.0 cm. The treatment plan required 17 indexer step positions at 5.0 mm step length to begin at dwell position 23 and terminate at dwell position 39. The medical physicist involved entered 17 indexer step positions at 5.0 mm step length. However, the medical physicist entered dwell positions 1 through 17, rather than 23 through 39, and treatment was delivered. The intended site was, therefore, not treated while an unintended site received 500 cGy.

The licensee reviewed patient radiation oncology treatment records to determine whether any adverse effects resulted from the medical events. The review of the records for Patient B identified that the patient initially, after treatment, reported some excoriation (abrasion/soreness) of the unintended site, but this had healed prior to a February 6, 2003 follow-up examination. The patient was last examined on January 3, 2004, with no evidence of clinical complications or abnormalities. The licensee concluded that no further clinical complications were anticipated or expected.

The licensee's review of patient treatment records for Patients A, C, and D, did not identify any abnormal findings during followup examinations. The licensee's radiation oncology physicians verified that the treatments parameters were within acceptable therapeutic dosages. The licensee concluded that no further clinical complications were

anticipated or expected.

The licensee's October 12, 2005 report indicated that Patient E had died in September 2004. The licensee's report also indicated that the medical event was not a contributing factor in the cause of death considering the prognosis of the disease.

On August 2, 2005, a special inspection was conducted to review the circumstances surrounding the July 21, 2003 medical event, which included an examination of the written directive, simulated treatment plans, and interviews with available staff members. Based on this review, the results of the licensee's evaluation were verified and a subsequent retrospective (extent of condition) review of previous patient treatments was initiated by the licensee.

On October 5 and 6, 2005, a follow-up inspection was conducted to review the scope of the licensee's retrospective (extent of condition) reviews and evaluation of the additional medical events identified. The review period encompassed November 1998, when the licensee began HDR treatments, through October 2004. For this time period, the licensee performed a total of 659 fractionated HDR treatments. The inspection included a representative sample of 127 fractions out of the total 659 treatment fractions, or approximately 19 percent, and included verification of correct treatment parameters to include: patient name, administered dose, step size length, dwell positions, treatment time, source activity and catheter length. Based on this review, no additional medical events were identified. In addition, a systematic review of the six additional medical events was completed and indicated the licensee's findings were adequately evaluated and reported.

Title 10 Code of Federal Regulations (CFR) Part 35.41(a) requires, in part, that for any administration requiring a written directive, licensees develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the treatment plan and the written directive. The written procedures must meet the requirements described in 10 CFR 35.41(b). At the time of the July 21, 2003 medical event, as well as the subsequently identified events, the licensee did not have written procedures to ensure that the administration was in accordance with the treatment plan and the written directive. Specifically, the licensee's written procedures for the use of its HDR brachytherapy treatment unit did not include appropriate steps or guidance to verify that the HDR delivery/treatment system manually entered source step size length and dwell positions were in accordance with the treatment plan. These seven medical events represent additional examples of the Severity Level III violation of 10 CFR Part 35.41(a), issued on August 2, 2004 (EA-04-087) for the failure to have adequate procedures.

2.3 Conclusions

The inspectors determined that seven medical events as a result of the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The medical events that occurred on December 18, 19, and 26, 2002, January 2, 2003, July 21, 2003, August 7, 2003, and March 11, 2004, are additional examples of the Severity Level III violation of 10 CFR 35.41(a) issued on August 2, 2004 (EA-04-087).

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspection included a review of the licensee's proposed corrective actions regarding the medical events of December 2002, January 2003, July 2003, August 2003, and March 2004. The inspector also reviewed the licensee's written reports of the medical events, dated August 10, September 6, and October 12, 2005, and interviewed selected licensee personnel.

3.2 Observations and Findings

The licensee implemented corrective actions following the March 15, 22, and 29, 2004 events and the issuance of the Severity Level III violation that included the development and implementation of written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the corrective actions included revising the brachytherapy treatment procedure to require:
(1) the staff to independently check treatment plans prior to each treatment;
(2) a second medical physicist to verify the treatment parameters are correct; and
(3) the medical physicist to manually calculate the treatment dose and compare it to the dose developed in the treatment plan and written directive prior to administering the treatment to the patient. In addition, the licensee disseminated the results of the investigation, including root cause and corrective actions, to all members of the medical physics staff and authorized user physicians involved in HDR treatments.

In addition to the above corrective action, the licensee upgraded the HDR treatment planning/delivery software in August 2004, allowing the electronic transfer of data between the treatment planning program and the HDR delivery program, eliminating the necessity for manual data entry. The two medical physicists involved with the medical events were no longer employed by the licensee.

The licensee also implemented corrective action for a Severity Level IV violation, issued November 29, 2004, for an inadequate procedure involving the use of a 995 mm indexer position rather than the standard 1500 mm indexer position. Specifically, the corrective actions included revising the procedure to allow only the use of the 1500 mm transfer tube and contracting with an independent medical physicist to perform monthly onsite quality assurance reviews of the radiation oncology department, including treatment planning, for 12 months (through December 2005).

Based on the seven medical events that were the subject of this inspection report, the licensee staff indicated that the monthly audits of the brachytherapy treatments would continue indefinitely. The licensee staff indicated that the audits will be performed “in-house” by medical physicists who were not involved in developing the treatment plan.

The inspectors observed two HDR patient treatments during the onsite inspections conducted on August 2, 2005, and October 5 and 6, 2005, and verified that the licensee’s current procedures, developed as a result of the aforementioned medical events, were well implemented and maintained.

3.3 Conclusions

The licensee implemented corrective actions following the March 15, 22, and 29, 2004, and the October 11, 2004 medical events. In addition, the licensee indicated that monthly audits of brachytherapy treatments would continue indefinitely.

4 Notifications and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notifications of the medical events and the associated written reports dated August 10, September 6, and October 12, 2005, to ensure compliance with reporting requirements.

4.2 Observations and Findings

During an audit of the HDR brachytherapy program on July 28, 2005, an independent medical physicist informed the licensee that a medical event occurred involving the first of two planned treatments for esophageal cancer on July 21, 2003. On July 29, 2005, at 3:55 p.m. (EDT) (within 24 hours of discovery), the licensee notified the NRC's Operations Center of the medical event. The licensee provided its written report of the medical event in a letter, dated August 10, 2005.

The referring physician was on vacation through July 29, 2005, and therefore, was unavailable for notification of the July 21, 2003 medical event. Upon his return on August 1, 2005, the referring physician was notified of the medical event and subsequently notified the patient later that same day.

On September 7, 2005, at 4:34 p.m. (EDT) (within 24 hours of discovery), the licensee notified the NRC Operations Center regarding five medical events that occurred on December 19 and 26, 2002, and January 2, 2003 (three fractional events involving one patient), December 18, 2002, and August 7, 2003. The licensee provided the written report to the NRC involving the five events on the day they were identified, September 6, 2005. According to licensee staff, in each of the above cases, the referring physician and the patient (or the patient's representative) were notified of the respective medical events.

On September 28, 2005, at 5:16 p.m. (EDT) (within 24 hours of discovery), the licensee notified the NRC Operations Center of a medical event that occurred on March 11, 2004. The licensee provided the written report of this event dated October 12, 2005. The patient died in September 2004. According to the licensee's written report, the referring physician was unavailable for notification until
October 3, 2005. Upon notification, the referring physician informed the physician/authorized user that based on medical judgement, informing the patient's responsible relative would be of no benefit and did not believe this event was a contributing factor when considering the overall patient prognosis.

4.3 Conclusions

The licensee provided the notifications and written reports as required by 10 CFR 35.3045. The notifications and written reports were provided within the specified time periods and included the required information.

5 Exit Meeting

At the completion of the onsite inspections on August 2 and October 6, 2005, the inspectors discussed the preliminary inspection findings with licensee management. A final exit meeting was conducted by telephone on October 28, 2005. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Partial List of Persons Contacted

Attended the August 2, 2005, Preliminary On-Site Exit Meeting:

Edward Wroblewski, Radiation Safety Officer, Senior Medical Physicist-
Jeff Heffelfinger MSA, CHE, Executive Director Oncology

Attended the October 6, 2005, Preliminary On-Site Exit Meeting:

Michael C. Wiemann, M.D., Senior Vice President, Chief Medical Officer
Jean M. Meyer, R.N., Senior Vice President, Chief Nursing Officer
Edward Wroblewski, Radiation Safety Officer, Senior Medical Physicist
Susann Stephenson, R.N., Risk Management
Ben Wen Ni, Ph.D., Chief Radiation Therapy Physicist
Louisa Hayenga, Director, Oncology Center

Attended the October 28, 2005, Final Exit Meeting via Telephone:

Edward Wroblewski, Radiation Safety Officer, Senior Medical Physicist
Jeff Heffelfinger MSA, CHE, Executive Director Oncology
Louisa Hayenga, Director, Oncology Center