

January 7, 2008

EA-07-313
NMED No. 070641

Dan Goodwin
Administrator, Division of Medical Specialties
Oncology Institute of Greater Lafayette
420 North 26th Street
Lafayette, IN 47904

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-34812/2007-001(DNMS) AND
NOTICE OF VIOLATION - ONCOLOGY INSTITUTE OF GREATER LAFAYETTE

Dear Mr. Goodwin:

This refers to the routine inspection conducted on October 16, 2007 at the Lafayette, Indiana facility, with continued in-office review through November 20, 2007. The in-office review included the review of your report dated October 31, 2007, and the review of the NRC Medical Consultant's report dated November 8, 2007. The enclosed report presents the results of this inspection.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspection also included a review of the circumstances, root and contributing causes, and proposed corrective actions for a medical event that was identified by the inspector and reported to the NRC by a member of your staff on October 17, 2007.

The enclosed copy of our inspection report identifies areas examined during the inspection. The NRC obtained a Medical Consultant, Subir Nag, M.D., to review the medical significance of this incident. A copy of the results of Dr. Nag's evaluation is included as an enclosure to this letter.

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 www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations pertain to your staff's failure to instruct a supervised individual in your written directive procedures; and to develop, implement, and maintain written directive procedures to provide high confidence that each administration is in accordance with the written directive. The preliminary inspection findings were discussed with you and members of your staff during the onsite inspection exit meeting on October 16, 2007. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with a member of your staff during a telephone exit meeting on December 13, 2007. As a result, it may not be necessary to conduct a predecisional

enforcement conference in order to enable the NRC to make an enforcement decision. In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

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. 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 John Madera at (630) 829-9834 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in Inspection Report 030-34812/2007-001(DNMS); EA-07-313" 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 excerpt from 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 or schedule a predecisional enforcement conference. Your written response should be addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555. At the same time, a copy should be sent to the Regional Administrator and the Enforcement Officer at NRC Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4351.

In addition, please be advised that the characterization of the 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.

Based on the results of this inspection, the NRC has also determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they were identified by the inspector.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in Inspection Report 030-34812/2007-001(DNMS). Therefore, you are not required to respond to this letter unless the description in the inspection report 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.

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 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 K. O'Brien Acting for/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

License No.: 13-32087-01

Docket No.: 030-34812

Enclosures:

1. Notice of Violation
2. Inspection Report 030-34812/2007-001(DNMS)
3. NRC Medical Consultant's report
4. Excerpt from NRC Information Notice 96-28

cc w/encls: Phil Dittmer, Ph.D., Radiation Safety Officer
Leon McNealy, M.D.
State of Indiana

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

Sincerely,
/RA/
Steven A. Reynolds, Director
Division of Nuclear Materials Safety

License No.: 13-32087-01
Docket No.: 030-34812

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cc w/encls: Phil Dittmer, Ph.D., Radiation Safety Officer
State of Indiana
Leon McNealy, M.D.

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See next page

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Letter to Dan Goodwin from Steven A. Reynolds dated January 7, 2008

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-34812/2007-001(DNMS) -
ONCOLOGY INSTITUTE OF GREATER LAFAYETTE

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NOTICE OF VIOLATION

Oncology Institute of Greater Lafayette
Lafayette, Indiana

Docket No. 030-34812
License No. 13-32087-01

During an NRC inspection conducted on October 16, 2007, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. Title 10 CFR 35.633(a) requires, in part, that licensees authorized to use a remote afterloader unit for medical use perform full calibration measurements on each unit before medical use following replacement of the source. Title 10 CFR 35.633(b)(3) requires that the full calibration measurements include determination of source retraction with backup battery upon power failure.

Contrary to the above, following replacement of the source and before medical use, the licensee conducted full calibration measurements on its remote afterloader unit on June 15, 2007, and the full calibration measurements did not include determination of source retraction with backup battery upon power failure.

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

2. Item 9 of Amendment No. 10 of NRC License No. 13-32087-01 authorized possession and storage only of iridium-192 sealed sources and byproduct material permitted by 10 CFR 35.300 from February 26, 2007, through July 13, 2007.

Contrary to the above, on March 28, 2007, and June 15, 2007, the licensee used iridium-192 sealed sources to conduct full calibration measurements on its remote afterloader unit.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in Inspection Report 030-34812/2007-001(DNMS). 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," EA-07-313, and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator and the Enforcement Officer, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice)."

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 NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Notice of Violation

-2-

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 7th day of January 2008

Enclosure 1

NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-34812

License No.: 13-32087-01

Report No.: 030-34812/2007-001(DNMS)

Licensee: Oncology Institute of Greater Lafayette

Location: 420 North 26th Street
Lafayette, IN 47904

Date of Inspection: October 16, 2007

Exit Meeting: December 13, 2007

Inspector: Robert G. Gattone, Jr., Senior Health Physicist

Reviewed By: John R. Madera, Chief
Materials Inspection Branch

NMED No. 070641

Enclosure 2

EXECUTIVE SUMMARY

**Oncology Institute of Greater Lafayette
Lafayette, Indiana
Inspection Report 030-34812/2007-001(DNMS)**

During a routine inspection, the inspector identified a high dose rate (HDR) remote afterloader unit brachytherapy medical event that occurred during the licensee's administration of three treatment fractions administered to a patient on August 14, 2007, August 28, 2007, and September 11, 2007. As a result, portions of the treatment site received a dose that differed from the prescribed dose by more than 50 rem to tissue and a total dose that differed from the prescribed dose by more than 20 percent. The licensee did not identify any adverse effects to the patient as a result of the medical event. The licensee plans to follow-up on the patient and, based on information obtained during patient follow-up, determine if it will administer additional HDR treatments to the patient. An NRC Medical Consultant concluded that the medical event resulted in: (1) an overdose to the vaginal vault that is unlikely to cause vaginal necrosis; and (2) an underdosage to the inferior-posterior vaginal wall (which contained cancer) that increases the risk of cancer recurrence.

The root cause of the medical event was an error in entering the step size into the HDR unit. Contributing factors to the medical event included: (1) the licensee's failure to instruct an Authorized Medical Physicist (AMP) in its written directive (WD) procedures; (2) the AMP's failure to read the licensee's WD procedures until the inspection; (3) inability to transfer the treatment data electronically to the HDR unit for the treatment; (4) the AMP's perceived sense of urgency to complete the treatment because of the patient's discomfort; (5) the licensee staff's failure to check that the step size data was properly transferred to the HDR unit prior to the treatment; and (6) the licensee staff's failure to check that the step size that was actually used for the treatment was in agreement with the treatment plan after administration of the treatment.

The inspector identified apparent violations involving licensee failure to instruct a supervised individual in its WD procedures; and to develop, implement, and maintain WD procedures to provide high confidence that each administration is in accordance with the WD. Specifically, the licensee provided the AMP with its WD procedures when he was first employed by the licensee; however, the licensee did not instruct the AMP in its WD procedures. In addition, the licensee's WD procedures did not require that the treatment plan data be checked prior to treatment after it was transferred to the high dose rate remote afterloader unit by a means other than a program card, and other means of transferring the treatment plan data were used. Also, the licensee's WD procedures required that, after treatment, printouts of the actual treatment parameters be checked for agreement with the treatment plan; however, licensee staff did not verify, after treatment, that the step size (a treatment parameter) that was used for the treatments of four patients was in agreement with the treatment plan.

The inspector identified two other violations involving: (1) failure to include checks of HDR source retraction with backup battery upon power failure during full calibration measurements of the HDR unit; and (2) use of the HDR source to conduct full calibration measurements when the license authorization was limited to storage only.

The licensee implemented corrective actions to prevent a similar event and similar violations. The licensee changed the HDR unit's default step size setting from 2.5 millimeters to 5 millimeters because 5 millimeters is normally used by the licensee. In addition, the licensee: (1) had the AMP/Radiation Safety Officer (RSO) discuss the licensee's WD procedures with all applicable licensee staff and licensee management to ensure that they are aware of the WD procedures and that they will review them with new staff and ensure that the new staff understands the WD procedures prior to participation in licensed activities; (2) had the AMP review and implement its WD procedures and subsequently revise them to include dual verification that the parameters in the treatment console used for patient treatments are the same as those developed in the treatment planning computer, including step size, dwell times, and number of dwell positions; regardless of the means of transferring the treatment parameters from the treatment planning computer to the HDR; (3) worked with the HDR unit manufacturer to resolve the difficulty it had transferring the data electronically to the HDR unit; (4) made changes in patient handling methods to reduce the time patients must wait for treatments after applicators are inserted into the patients; (5) planned to expand physics staff coverage from three to five days per week to permit more thorough preparation work on procedures and equipment prior to treatments and periodic, independent review of the work; (6) planned to prohibit any use of byproduct material whenever its NRC license prohibited use of byproduct material; (7) planned to contact the NRC if there is any question about whether or not any use of byproduct material is authorized on its NRC license; (8) checked HDR source retraction with backup battery upon power failure to verify it was operable before the next medical use of the source; and (9) revised the Quality Assurance and New Source Calibration form to include a check of HDR source retraction with backup battery upon power failure.

Report Details

1 Program Scope and Inspection History

The NRC License Number 13-32087-01 authorized the Oncology Institute of Greater Lafayette (licensee) to use byproduct materials for therapeutic nuclear medicine and sealed source therapy using a high dose rate (HDR) remote afterloading brachytherapy unit (unit). On June 15, 2006, the license was amended to limit authorization to storage of licensed material exclusively. On July 13, 2007, the license was amended to re-authorize use of byproduct materials for therapeutic nuclear medicine and sealed source therapy using an HDR unit. On August 14, 2007, the licensee used its HDR unit to treat its first patient since its license was amended to re-authorize byproduct material use. The licensee treated four patients with the HDR unit between August 14, 2007, and October 16, 2007, with new principal staff, including a new physician authorized user, Authorized Medical Physicist (AMP), and Radiation Safety Officer (RSO).

No violations of NRC requirements were identified during the two previous NRC inspections conducted on November 1, 2004, and September 6, 2002.

2 Sequence of Events

2.1 Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical event. The inspector interviewed selected licensee personnel, reviewed patient treatment information, inspected equipment associated with the medical event, and toured selected facilities. In addition, the inspector reviewed the NRC Medical Consultant's report dated November 8, 2007.

2.2 Observations and Findings

On August 14, 2007, a physician authorized user signed and dated a written directive (WD) prescribing three fractions of 700 centigray each, to be administered on August 14, August 28, and September 11, 2007, totaling 2,100 centigray to the vagina at a distance of 0.5 centimeters from the surface of a vaginal applicator using the iridium-192 source in the HDR unit. On August 14, 2007, an AMP developed a treatment plan to achieve the dose prescribed by the WD.

The treatment plan included consideration of three-dimensional patient anatomical information obtained from x-rays and dose calculations to points of interest with a treatment planning computer. The treatment plan was reviewed, approved, signed, and dated by the physician authorized user on August 14, 2007. The treatment plan included, among other things, 13 source dwell positions with a step size of 5 millimeters to deliver prescribed doses to ten anatomical points representing the treatment site in accordance with the WD.

When initially employed by the licensee, the AMP was very experienced with HDR treatments because he participated in HDR treatments as the AMP for a broad scope licensee (Licensee 2) for several years. The licensee provided the AMP with its WD procedures when he was first employed by the licensee; however, the licensee did not

instruct the AMP in its WD procedures. The licensee's failure to instruct the AMP in its WD procedures is a contributing factor to the medical event.

Title 10 CFR 35.27(a)(1) requires, in part, a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, instruct the supervised individual in the licensee's WD procedures with respect to the use of byproduct material. The licensee's failure to instruct the AMP, an individual under the supervision of an authorized user, in its WD procedures with respect to the use of byproduct material is an apparent violation of 10 CFR 35.27(a)(1).

The AMP planned to review the WD procedures; however, he did not do so because he perceived other work as higher priority and he was confident that he could implement actions that he considered consistent with Licensee 2's WD procedures. The other work that the AMP considered higher priority included quality assurance on linear accelerator equipment and linear accelerator treatments. As a result, the AMP had not read the licensee's WD procedures until the inspection. Therefore, the AMP used the HDR knowledge and experience he received from Licensee 2 to perform his duties as the AMP for the licensee, including implementation of actions that he considered consistent with Licensee 2's WD procedures. The AMP's failure to read the licensee's WD procedures until the inspection is a contributing factor to the medical event.

Based on his HDR experience with Licensee 2, the AMP was accustomed to transferring treatment plan data (e.g., step size [i.e., distance that the iridium-192 source should be moved between each dwell position], number of dwell positions, and dwell times) electronically from the treatment planning computer to the HDR unit. However, the AMP was unable to transfer the data electronically to the HDR unit for the treatment on August 14, 2007. The AMP's inability to transfer the data electronically to the HDR unit for the treatment is a contributing factor to the medical event. In addition to the electronic data transfer problem, the AMP perceived a sense of urgency to complete the treatment because the patient was uncomfortable due to other delays, the large size of the HDR applicator, and the use of a rectal shield. The AMP's perception of a sense of urgency to complete the treatment because of the patient's discomfort is a contributing factor to the medical event. Therefore, the AMP transferred the treatment plan data from the treatment planning computer to the HDR unit by typing it in. The AMP erroneously entered a 2.5 millimeter step size into the HDR unit rather than the intended 5 millimeters. The AMP's error in entering the step size into the HDR unit was the root cause of the medical event.

The physician authorized user and the AMP conducted checks to verify that treatment planning data was properly transferred into the HDR unit, including verification of the source activity, number of dwell positions, and dwell times. However, the AMP did not check that the step size data was properly transferred to the HDR unit prior to the treatment because he assumed that the HDR unit included the typically prescribed 5 millimeter step size. In addition, the physician authorized user did not check that the step size data was properly transferred to the HDR unit prior to the treatment. Therefore, neither the AMP nor the physician authorized user noted that the HDR unit was set for a 2.5 millimeter step size rather than the intended 5 millimeters before the patient was treated on August 14, 2007, August 28, 2007, and September 11, 2007. The licensee staff's failure to check that the step size data was properly transferred to the HDR unit prior to the treatment was a contributing factor to the medical event.

The licensee staff did not verify, after the patient was treated on August 14, 2007, August 28, 2007, and September 11, 2007, that the step size (a treatment parameter) that was used for the treatments was in agreement with the treatment plan because they forgot that the step size could be changed and they did not focus on it during the post-treatment checks. The licensee staff's failure to verify, after the treatments, that the step size that was used for the treatments was in agreement with the treatment plan was a contributing factor to the medical event.

The patient was treated on August 14, 2007, August 28, 2007, and September 11, 2007, with the incorrect step size. The HDR treatment fractions administered on August 14, August 28, and September 11, 2007, resulted in a medical event because eight of the ten anatomical points representing the treatment site on the treatment plan received a dose that differed from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent or more. The difference of prescribed versus administered doses to areas of the treatment site varied from as much as about 31 percent more than what was prescribed to as much as about 49 percent less than what was prescribed. The licensee did not identify any adverse effects to the patient. The licensee plans to follow-up on the patient and, based on information obtained during patient follow-up, determine if it will administer additional HDR treatments to the patient. An NRC Medical Consultant concluded that the medical event resulted in: (1) an overdose to the vaginal vault that is unlikely to cause vaginal necrosis; and (2) an underdosage to the inferior-posterior vaginal wall (which contained cancer) that increases the risk of cancer recurrence.

The inspector determined that the licensee's staff failed to: (1) check that the step size data was properly transferred to the HDR unit prior to the HDR treatments of three subsequent patients; and (2) verify, after the treatments of three subsequent patients, that the step size that was used for the treatments was in agreement with the treatment plan.

The licensee developed and maintained WD procedures that required checks to ensure that the treatment plan data is properly transferred by program card to the HDR before treatment, including a check of the step size. However, the licensee's WD procedure did not require that the treatment plan data be checked after it is transferred to the HDR by a means other than a program card, such as direct electronic transfer or typing, and the licensee typed the treatment plan data into the HDR or used a direct electronic link to transfer the data to the HDR. In addition, the licensee's WD procedures required that, after treatment, printouts of the actual treatment parameters be checked for agreement with the treatment plan; however, licensee staff did not verify, after treatment, that the step size that was used for the treatments of four patients was in agreement with the treatment plan.

Title 10 CFR 35.41(a) states, in part, that for any administration requiring a WD, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the WD. The licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the WD is an apparent violation of 10 CFR 35.41(a).

The inspector identified the step size error during the inspection. The inspector and the AMP reviewed the HDR treatment records for the three subsequent patients and determined that the correct step size was used for those treatments.

2.3 Conclusions

An HDR medical event occurred during the licensee's administration of three treatment fractions administered to a patient on August 14, 2007, August 28, 2007, and September 11, 2007. The inspector identified apparent violations involving licensee failure to instruct a supervised individual in its WD procedures; and to develop, implement, and maintain WD procedures to provide high confidence that each administration is in accordance with the WD. The root cause of the medical event was an error in entering the step size into the HDR unit. Contributing factors to the medical event included: (1) the licensee's failure to instruct an AMP in its WD procedures; (2) the AMP's failure to read the licensee's WD procedures until the inspection; (3) inability to transfer the treatment data electronically to the HDR unit for the treatment; (4) the AMP's perceived sense of urgency to complete the treatment because of the patient's discomfort; (5) the licensee staff's failure to check that the step size data was properly transferred to the HDR unit prior to the treatment; and (6) the licensee staff's failure to check that the step size that was actually used for the treatment was in agreement with the treatment plan after administration of the treatment.

3 **Licensee Corrective Actions**

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to prevent similar events and similar violations. The inspector interviewed selected licensee personnel and reviewed information about the medical event and corrective actions described in the licensee's letters dated October 18 and October 31, 2007.

3.2 Observations and Findings

During the onsite inspection, the AMP noted that the HDR unit's default step size setting was 2.5 millimeters; therefore, failure to enter a step size into the HDR unit for any given treatment would result in a 2.5 millimeter step size being used. In response, the AMP changed the HDR unit's default step size setting from 2.5 millimeters to 5 millimeters because 5 millimeters is normally used by the licensee.

The licensee also: (1) had the AMP/RSO discuss the licensee's WD procedures with all applicable licensee staff and licensee management to ensure that they are aware of the WD procedures and that they will review them with new staff and ensure that the new staff understands the WD procedures prior to participation in licensed activities; (2) had the AMP review and implement its WD procedures and subsequently revise them to include dual verification that the parameters in the treatment console used for patient treatments are the same as those developed in the treatment planning computer, including step size, dwell times, and number of dwell positions; regardless of the means of transferring the treatment parameters from the treatment planning computer to the HDR; (3) worked with the HDR unit manufacturer to resolve the difficulty it had transferring the data electronically to the HDR unit; (4) made changes in patient handling methods to reduce the time patients must wait for treatments after applicators are

inserted into the patients; and (5) planned to expand physics staff coverage from three to five days per week to permit more thorough preparation work on procedures and equipment prior to treatments and periodic, independent review of the work.

3.3 Conclusions

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

4 Notifications and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notification of the medical event to the NRC Operations Center dated October 17, 2007, and the associated written report to verify compliance with reporting requirements.

4.2 Observations and Findings

During the inspection on October 16, 2007, the inspector identified the step size error associated with the HDR treatment fractions administered on August 14, August 28, and September 11, 2007. The licensee's RSO determined that a medical event may have resulted from the step size error; therefore, he notified the NRC's Operations Center of the event on October 17, 2007, in accordance with 10 CFR 35.3045(c). The licensee notified the patient's referring physician and the patient of the event on October 17, 2007. The licensee provided its written report of the event in a letter dated October 31, 2007. The inspector determined that the written report was submitted within 15 days of discovery of the event and it included the information required by 10 CFR 35.3045(d).

4.3 Conclusions

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

5 Full Calibrations

5.1 Inspection Scope

The inspector reviewed the licensee's HDR unit full calibration measurements by interviewing the AMP and reviewing selected records.

5.2 Observations and Findings

Item 9 of Amendment No. 10 of NRC License No. 13-32087-01 authorized possession and storage only of iridium-192 sealed sources and byproduct material permitted by 10 CFR 35.300 from February 26, 2007, through July 13, 2007. However, the AMP misinterpreted that the license prohibited medical use of the HDR iridium-192 sealed sources and authorized non-medical use of the sources. Therefore, the AMP used iridium-192 sealed sources to conduct full calibration measurements (non-medical use) on the licensee's HDR unit on March 28, 2007, and June 15, 2007, to enable the licensee to begin medical use of the HDR unit in the future on short notice. The

licensee's use of iridium-192 sources to conduct full calibration measurements on its HDR unit on March 28, 2007, and June 15, 2007, is a violation of Item 9 of Amendment No. 10 of its NRC license.

As discussed in Section 1 of this report, the licensee's NRC license was amended to re-authorize use of byproduct materials for therapeutic nuclear medicine and sealed source therapy using the HDR unit. Therefore, the licensee is now authorized to conduct full calibration measurements and medical use with its HDR unit.

The AMP conducted full calibration measurements on the HDR unit before medical use following replacement of the iridium-192 source on June 15, 2007, and October 9, 2007. The licensee used its HDR unit to treat patients with the source that was calibrated on June 15, 2007. The licensee's full calibration measurements included the source output within plus or minus 5 percent, source position accuracy to within plus or minus 1 millimeter, timer accuracy, and other required measurements. However, the full calibration measurement on June 15, 2007, did not include determination of source retraction with backup battery upon power failure.

Title 10 CFR 35.633(a) requires, in part, that licensees authorized to use a remote afterloader unit for medical use perform full calibration measurements on each unit before medical use following replacement of the source. Title 10 CFR 35.633(b)(3) requires that the full calibration measurements include determination of source retraction with backup battery upon power failure. The licensee's failure to include determination of source retraction with backup battery upon power failure during its HDR unit full calibration measurements on June 15, 2007, is a violation of 10 CFR 35.633(b)(3). The violation occurred because the licensee's AMP was unaware of the requirement.

The licensee implemented corrective actions to prevent similar violations that included: (1) planning to prohibit any use of byproduct material whenever its NRC license prohibited use of byproduct material; (2) planning to contact the NRC if there is any question about whether or not any use of byproduct material is authorized on its NRC license; (3) checking HDR source retraction with backup battery upon power failure to verify it was operable before medical use of the source that was used for the full calibration measurements on October 9, 2007; and (4) revising the Quality Assurance and New Source Calibration form to include a check of HDR source retraction with backup battery upon power failure.

5.3 Conclusions

The inspector identified two violations of NRC regulatory requirements involving: (1) use of the HDR unit to conduct full calibration measurements when the license authorization was limited to storage only; and (2) failure to include checks of HDR source retraction with backup battery upon power failure during full calibration measurements. The licensee implemented corrective actions to prevent similar violations.

6 Other Areas Inspected

6.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspector, and reviewing selected records. Areas reviewed included periodic spot checks of the HDR unit, HDR treatment emergency response, personnel dosimetry, equipment and instrumentation, and radiation surveys.

6.2 Observations and Findings

Licensee staff conducted periodic spot checks of the HDR unit each day before it was used to treat patients. The spot checks included all of the required checks, including, but not limited to, operation of electrical interlocks at each entrance of the HDR treatment room, viewing and intercom systems, and source exposure indicator lights. The staff knew how to recognize abnormal operational check results, and what to do in response to them.

Selected licensee staff understood how to respond to HDR treatments emergencies based on scenarios posed by the inspector. In addition, the licensee had appropriate equipment available for use to mitigate the consequences of an emergency.

Licensee staff wore personal radiation dosimeter badges as required. The doses received by licensee personnel were well below regulatory dose limits.

Licensee staff used calibrated instrumentation to perform required radiation surveys. Selected staff knew the survey trigger levels and what to do when trigger levels are exceeded. In addition, the staff performed daily operational checks on radiation survey instruments. The staff knew how to recognize abnormal operational check results, and what to do in response to them.

6.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program.

7 Exit Meeting

At the completion of the onsite inspection, the inspector discussed the preliminary inspection 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. A final telephone exit meeting was conducted on December 13, 2007.

Partial List of Persons Contacted

#*Phil Dittmer, Ph.D., Radiation Safety Officer

* Dan Goodwin, Administrator, Division of Medical Specialties

* Loubna Scally, M.D., Radiation Oncologist

* Attended the onsite exit meeting

Participated in the telephone exit meeting on December 13, 2007