April 4, 2007

EA-07-071
NMED No. 070024

Charla Higbee, Director of Cancer Services
Hackley Hospital
1700 Clinton St.
Muskegon, MI 49443-3302

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002044/2007-001(DNMS)

Dear Ms. Higbee:

This refers to the special inspection conducted on January 11 and 12, 2007, with continued in-office review through March 16, 2007. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a medical event that occurred on January 8, 2007. The in-office review included the review of your original written report dated January 18, 2007, and its subsequent revisions, and the NRC medical consultant's report dated March 15, 2007.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel. The NRC contracted 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, one apparent violation was identified and is 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. The apparent violation pertains to the failure to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the authorized user physician's written directive, as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive." Specifically, the "Prostate Seed Implant Procedure" did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan. A contributing factor to the event was the lack of communication with the anesthesiologist regarding the length and invasiveness of the procedure.

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 the corrective actions you have taken, a civil penalty may not be warranted in accordance with Section VI.C.2 of the NRC Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the NRC 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 violation 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 Jamnes Cameron at (630) 829-9833 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 instead of requesting a predecisional enforcement conference, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 03002044/2007-001(DNMS); EA-07-071." 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. The written response should include for the 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.

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

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. 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 T. Reis Acting for/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-02044
License No. 21-04125-01

Enclosures:
1. Inspection Report 03002044/2007-001
2. NRC Medical Consultant's Report
3. Excerpt from NRC Information Notice 96-28

cc w/encls: David Waid, Radiation Safety Officer
Carlo Santa Ana, Physicist
State of Michigan

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Letter to Charla Higbee from Steven A. Reynolds dated April 4, 2007

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002044/2007-001(DNMS)

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REGION III

Docket No.:	030-02044
License No.:	21-04125-01
Report No.:	03002044/2007-001(DNMS)
Licensee:	Hackley Hospital
Facility:	1700 Clinton Street Muskegon, MI 49443
Inspection Dates:	January 11 and 12, 2007, with continued in-office review through March 16, 2007
Preliminary Exit Teleconference:	January 29, 2007
Final Exit Teleconference:	March 20, 2007
Inspector:	Sarah Bakhsh, Health Physicist
Approved By:	Jamnes Cameron, Chief Decommissioning Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Hackley Hospital
NRC Inspection Report 03002044/2007-001(DNMS)

The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a medical event that occurred on January 8, 2007, involving a brachytherapy iodine-125 (I-125) prostate seed implant.

The authorized user physician's written directive prescribed a total dose of 120 Gray (Gy) to the patient's prostate using I-125 seeds as permanent implants. However, 34 out of 41 I-125 seeds were inadvertently deposited 4 centimeters inferior to the prostate, resulting in a medical event. The licensee discovered the medical event after performing radiographs of the patient's prostate upon completion of the implant procedure. As a result, the prostate received a dose of approximately 13 Gy rather than the prescribed dose of 120 Gy, a difference that is more than 20 percent of the prescribed dose (10 CFR 35.3045(a)(1)(i)). In addition, the penile bulb, an unintended site, received a dose of approximately 110 Gy. This is considered a medical event since the unintended site received a dose that was greater than 0.5 Gy, and was greater than 50 percent of the dose expected from the administration defined in the written directive (10 CFR 35.3045(a)(3)). Additionally, the patient's skin received a dose of approximately 2.4 Gy, which was greater than 0.5 Gy and was greater than 50 percent of the dose expected from the administration defined in the written directive. The authorized user physician expected the effect to the patient, as a result of the 2.4 Gy overdose, to include skin discomfort and irritation. The physician also expected, as a result of the 110 Gy overdose to the penile bulb, possible scarring, fibrosis, and erectile dysfunction.

The NRC contracted a medical consultant to review the event and determine if any health consequences were expected. The consultant agreed with the licensee's dose estimate, and the consultant's report indicated that the risk for impotency is somewhat increased by the additional radiation dose to the penile bulb. The consultant also indicated that there may be some risk of perineal tissue fibrosis and skin irritation as a result of the event, although the risk may not be significant enough to cause clinical concerns.

The licensee's long term corrective actions to prevent recurrence included revising their written procedure for brachytherapy procedures and ensuring that the revisions were implemented by staff. The revisions to the written procedure included: (1) imaging of treatment area using film or fluoroscopy at the beginning, middle, and end of implant procedure; (2) placing a marker around the ultrasound probe to verify probe insertion distance into the rectum; (3) alerting the anesthesiologist prior to beginning needle insertion; (4) loading base plane of the prostate with needles first; and (5) performing specific steps of the "Prostate Seed Implant Procedure" prior to resuming treatment incident to patient movement.

The inspector identified one apparent violation of 10 CFR 35.41, *Procedures for Administrations Requiring a Written Directive,* Section 35.41(a) involving the licensee's failure to develop adequate written procedures, which would ensure a high confidence that each brachytherapy administration was in accordance with the authorized user physician's written directive. Specifically, the "Prostate Seed Implant Procedure" did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan.

Report Details

1 Program Scope and Inspection History

Hackley Hospital (licensee) is a 181 bed facility with an independent building for cancer care services. The licensee is authorized by NRC License No. 21-04125-01 to use a variety of byproduct materials for diagnostic and therapeutic nuclear medicine and sealed source brachytherapy using cesium-137 (gynecological treatments), strontium-90 (eye applicator), and iodine-125 (I-125) (prostate treatments). The licensee had performed ten brachytherapy treatments since June 2006.

Routine inspections were last conducted at the licensee's facility in Muskegon, Michigan, in March 2002 and September 2005, during which no violations of NRC requirements were identified.

2 Event Chronology

2.1 Inspection Scope

The inspector evaluated the events leading up to the January 8, 2007 medical event, and the licensee's subsequent event investigation. The inspector toured the facility, examined equipment used for the treatment, verified the licensee's process for I-125 seed accountability, interviewed selected staff, reviewed patient treatment information, and reviewed select records (written directive, histogram, licensee's written seed implant procedure, patient's x-ray, computer images of patient's anatomy and seed placement therein).

2.2 Observations and Findings

The authorized user physician developed a written directive that prescribed the administration of 120 Gray (Gy) to the patient's prostate using 41 I-125 seeds in 14 needles as permanent implants. On January 8, 2007, approximately two weeks after the patient's initial volume studies, the patient was admitted to Hackley Hospital's Cancer Care Center and underwent treatment.

As part of the preparation for the implant procedure, a Foley balloon catheter was inserted into the patient and used as a marker to assist in imaging the contour of the prostate. In addition, a transrectal ultrasound probe was used to locate and image the patient's prostate. These images were compared to the original volume studies of the patient's prostate to ensure that they matched. Then two stabilizing needles were inserted to hold the template in the patient's prostate. The physician and urologist inserted two of the fourteen needles, deposited the seeds and retracted the needles from the patient's prostate successfully. One of those two needles contained three I-125 seeds and the other contained four I-125 seeds. After retraction of the second needle, the patient "bucked" (sudden reflexive movement by the patient in response to surgical stimulation). The physician and the urologist discontinued the procedure while the anesthesiologist stabilized the patient. The anesthesiologist was not familiar with the length of this implant procedure and the effects of the invasive nature of the needles on the patient. The anesthesiologist monitored the patient's vital signs and administered the amount of anesthesia consistent with the duration of the procedure, which was

prolonged due to the patient's initial movement. The anesthesiologist indicated that the combination of surgical stimulation by the insertion of the needles and the low level of anesthesia (the patient had been under anesthesia for over an hour at this point) caused the sudden response by the patient. After stabilizing the patient, approximately two minutes after the patient "bucked," the urologist re-imaged the prostate, urethra, and rectum to match the original volume studies and resumed the treatment.

Throughout the procedure, the licensee used a software program which was part of the ultrasound probe, to observe the needles as they were inserted into the prostate. Due to the patient's movement, the stabilizing needles caused internal bleeding in the patient's prostate, blurring the ultrasonic images, which was expected by the urologist. The treatment was resumed despite the blurry images, with the third needle being inserted. The physicist, physician, and urologist continued with the treatment inserting the remaining 14 needles.

A radiograph of the area was taken at the end of the procedure to verify seed placement within the prostate. The radiograph revealed that the 34 seeds deposited by needles 3 through 14 were located approximately 4 centimeters inferior to the prostate. Based on the licensee's histogram of the treatment plan, the patient's prostate received a dose of approximately 13 Gy rather than the prescribed dose of 120 Gy, a difference that was more than 20 percent of the prescribed dose. In addition, the penile bulb, an unintended site, received a dose of approximately 110 Gy. This was considered a medical event since the penile bulb received a dose that was greater than 0.5 Gy and was greater than 50 percent of the dose defined in the written directive. Additionally, the patient's skin received a dose of approximately 2.4 Gy, which was greater than 0.5 Gy and was greater than 50 percent of the dose expected from the administration defined in the written directive.

As a result of the 2.4 Gy overdose to the skin, the authorized user physician expected the patient effects to include discomfort and irritation, with a possibility of scarring. As a result of the 110 Gy overdose to the penile bulb, the physician expected possible fibrosis or scarring of the tissue and possible erectile dysfunction.

Title 10 Code of Federal Regulations (CFR) 35.41(a) requires, in part, for any administration requiring a written directive, the licensee 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). One of the requirements the procedure must address includes verification that the administration is in accordance with the written directive and treatment plan.

The licensee failed to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the physician's written directive, as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive." Specifically, the "Prostate Seed Implant Procedure" did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan. A contributing factor to the event was the lack of communication with the anesthesiologist regarding the length and invasiveness of the procedure. Although the licensee implemented their

original version of the “Prostate Seed Implant Procedure” without error, the procedure was deficient in that it did not address actions necessary to ensure that sources were positioned in the patient in accordance with the written directive.

The licensee initiated an investigation and determined that the root cause of the event was the failure to identify a second movement by the patient prior to insertion of the third needle. None of the individuals present in the operating room observed any movement by the patient after the first occurrence during the procedure.

The licensee’s failure to develop adequate procedures to ensure that the brachytherapy administration was performed in accordance with the physician’s written directive constitutes an apparent violation of 10 CFR 35.41(a).

2.3 Conclusions

The inspector identified one apparent violation of 10 CFR 35.41(a) involving the licensee’s failure to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the written directive.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector interviewed select licensee personnel and reviewed the licensee’s proposed corrective actions to preclude similar events. The review included the licensee’s January 18, 2007, written report regarding the medical event, and subsequent revisions on January 19, 22, and 29, 2007.

3.2 Observations and Findings

To reduce the likelihood of similar events, the licensee initiated several immediate and long term corrective actions. Upon discovery of the event, all scheduled prostate seed implants were cancelled. The patient was brought back in that afternoon for a CT scan. The patient, referring physician, and the NRC were notified of the event within 24 hours. Prior to resuming brachytherapy treatments, the licensee planned to have the manufacturer calibrate the ultrasound equipment and review the treatment planning system.

The licensee’s long term corrective actions to prevent recurrence included revising their written procedure and ensuring that the revisions were implemented by staff. The revisions to their written procedure included: (1) imaging of treatment area using film or fluoroscopy at the beginning, middle, and end of implant procedure; (2) placing a marker around the ultrasound probe to verify probe insertion distance into the rectum; (3) alerting the anesthesiologist prior to beginning needle insertion; (4) loading base plane of the prostate with needles first; and (5) performing specific steps of the "Prostate Seed Implant Procedure" prior to resuming treatment incident to patient movement.

The licensee requested that the patient return for treatment using external beam after a few months to correct for the underdose to the prostate.

3.3 Conclusions

The inspector concluded that the licensee had implemented corrective actions to address the apparent violation and prevent similar events.

4 Notifications and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notification to the NRC Operations Center and the written 15 day report to ensure compliance with reporting requirements.

4.2 Observations and Findings

On January 8, 2007, the licensee determined that a medical event had occurred. Within 24 hours, the licensee notified the NRC regarding the medical event. An initial written report was submitted on January 18, 2007. The licensee also notified licensee management, the patient's referring physician and the patient within 24 hours.

4.3 Conclusions

The inspector determined that the licensee's notification and written report were submitted within the specified time periods as required by 10 CFR 35.3045(a).

5 NRC Medical Consultant's Review

The NRC staff contracted a medical consultant, Subir Nag, M.D., to review the event and determine any health consequences to the patient. Dr. Nag concluded that there were no acute or subacute effects noted in the patient, but did not eliminate the possibility of long term consequences including an increased risk of impotency from this medical event.

According to the medical consultant, the medical event could have occurred because of two reasons (or a combination thereof): (1) The patient may have moved further without being noticed after the second needle insertion and prior to the third needle deposition. Or, it is more likely that (2) the bleeding and blurring of the image caused confusion and the penile bulb was mistaken to be the prostate (target). The medical consultant concluded that this error could have been prevented by taking an AP fluoroscopic image to see the relationship of the previously deposited seeds, the foley bulb, bony anatomy and the tips of the new needles before proceeding further with the case.

6 Exit Meeting Summary

The inspector met with licensee representatives during the onsite inspection on January 12, 2007, and a conducted a preliminary exit teleconference on January 29, 2007. The inspector discussed the preliminary conclusions described in this report with the licensee during a final exit teleconference on March 20, 2007. The inspector summarized her understanding of the sequence of events that led to the medical event, the root and contributing causes of the event, and the licensee's proposed corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Jeff Alexander, Chief Operating Officer
Larry Carpenter, Director, Risk Management
Charla Higbee, Director of Cancer Services
* Carlo Santa Ana, Medical Physicist
\# Mary Tobin, Chief Nursing Officer
* David Waid, Medical Physicist

* Attended the Preliminary Exit Meeting
\# Attended the March 20, 2007 final exit meeting teleconference

Attachment