May 11, 2012

NMED No. 120166 (closed)

Mack L. Richard, M.S.
Radiation Safety Officer
IUPUI/Indiana University Medical Center
541 Clinical Drive
Indianapolis, IN 46202-5111

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001609/12-001(DNMS) – IUPUI/INDIANA UNIVERSITY MEDICAL CENTER

Dear Mr. Richard:

On March 19, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection at Methodist Hospital in Indianapolis, Indiana, with continuing in-office review through April 18, 2012. The purpose of the inspection was to follow up on the potential medical event you initially reported on March 7, 2012. The in-office review included review of your letter dated April 16, 2012, containing additional information on the potential medical event. The enclosed report presents the results of this inspection. A preliminary exit meeting was held by telephone on March 26, 2012, and a final exit meeting was held by telephone between you and Geoffrey Warren of my staff on April 19, 2012.

Based on the results of this inspection, no violations were identified. You are not required to respond to this letter unless the description herein does not accurately reflect your position. In that case, or if you choose to provide additional information, clearly mark your response as a "Reply to NRC Inspection Report No. 030-01609/12-001(DNMS)“ 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, Region III, within 30 days of the date of this letter.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 Agencywide Documents Access and Management 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 or proprietary, information so that it can be made available to the public without redaction.

Please feel free to contact Geoffrey Warren if you have any questions regarding this inspection. You can reach Mr. Warren at 630-829-9742.

Sincerely,

***/RA Jack R. Giessner Acting For/***

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-01609
License No. 13-02752-03

Enclosure:
Inspection Report No. 03001609/12-001(DNMS)

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Division of Nuclear Materials Safety

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REGION III

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| Docket No. | 030-01609 |
| License No. | 13-02752-03 |
| Report No. | 03001609/12-001(DNMS) |
| Licensee: | IUPUI/Indiana University Medical Center |
| Location: | Methodist Hospital<br>Indianapolis, Indiana |
| Date: | March 19, 2012, with continuing in-office review until April 18, 2012 |
| Exit Meeting: | April 19, 2012 |
| Inspector: | Geoffrey M. Warren, Health Physicist |
| Approved by: | Tamara E. Bloomer, Chief<br>Materials Inspection Branch<br>Division of Nuclear Materials Safety |

Enclosure

## EXECUTIVE SUMMARY

### IUPUI/Indiana University Medical Center (Methodist Hospital)
### Indianapolis, Indiana
### NRC Inspection Report No. 03001609/12-001(DNMS)

The purpose of this reactive inspection was to review the circumstances associated with a potential medical event that occurred on July 7, 2011, involving a permanent iodine-125 (I-125) seed prostate implant. The licensee reported a potential medical event to the U.S. Nuclear Regulatory Commission (NRC) on March 7, 2012.

The inspector evaluated the events leading up to the potential medical event that occurred on July 5, 2011, and the licensee's subsequent activities evaluating the potential event and did not identify any violations.

As a result of the on-site NRC inspection, licensee personnel met and determined that that the post implant CT contour was accurate and that only one seed of 52 was placed outside the prostate volume. The licensee determined that a medical event did not occur. The licensee provided sufficient information for the NRC to determine that the procedure did not meet the regulatory criteria to qualify as a medical event. On April 19, 2012, the licensee has withdrawn the event notification of a medical event.

Report Details

## 1 Program Scope and Inspection History

IUPUI/Indiana University Medical Center (licensee) was authorized by NRC License No. 13-02752-03 to perform medical and research operations at a number of facilities in Indianapolis, Indiana. Among these facilities was Methodist Hospital, a 1,500-bed hospital. At this hospital, licensee personnel performed a variety of medical procedures including permanent prostate implants using iodine-125 (I-125) seeds.

No escalated enforcement action has been taken as a result of the previous routine or security inspections in April 2009 and October 2011 or the previous reactive inspection in May 2009 in response to a medical event. The NRC cited four Severity Level IV violations resulting from these inspections.

## 2 Sequence of Events and Licensee Investigation

### 2.1 Inspection Scope

The inspector evaluated the events leading up to the potential medical event that occurred on July 5, 2011, and the licensee's subsequent activities evaluating the potential event. The inspector toured the facility, interviewed selected staff, and reviewed selected patient treatment records and procedures.

### 2.2 Observations and Findings

On April 27, 2011, the licensee performed a CT scan of a patient in preparation for a permanent iodine-125 seed implant to treat prostate cancer. The referring physician had sent the patient to Methodist Hospital for this implant because the referring hospital did not perform such implants. Based on this scan, the physician authorized user (Dr. A) contoured the prostate and identified a prostate volume of 27.6 cubic centimeters (cc). Based on this information, Dr. A prepared a written directive prescribing a dose of 145 Gray (Gy) using 67 seeds, each seed containing 0.405 millicuries (mCi) of I-125.

On July 5, 2011, Dr. A performed the implant for the patient with the assistance of a urologist and a medical physicist in accordance with the hospital's written procedure. Ultrasound imaging of the patient's prostate indicated that the prostate gland had an asymmetric shape and a smaller volume of 16.7 cc. Based on this information, Dr. A revised the written directive prior to treatment to indicate that 52 seeds would be implanted to meet the intended dose. All seeds were accounted for following the implant. Soon after this, Dr. A left Methodist Hospital for a position in Lafayette, Indiana, though he maintained privileges at Methodist Hospital.

On August 9, 2011, the patient returned to Methodist Hospital for a post-implant CT scan to verify the placement of the seeds. Because Dr. A was not available to contour the prostate in this scan, another physician authorized user (Dr. B) contoured the prostate. No issues were identified at this time; all seeds were inside the contour Dr. B identified for the prostate. This contour indicated that the prostate had increased in size to 39.9 cc. While the dose to 90 percent of the treatment volume (D90) was only 52 percent of the prescribed dose, Dr. B was satisfied with the result. In September 2011, the procedure was reviewed through the hospital's peer review program and no issues were raised.

In October 2011, an NRC inspector conducted a routine inspection of the licensee and identified a violation concerning the licensee's written procedure for permanent prostate implants. Specifically, the licensee's written procedure did not adequately provide criteria to evaluate such procedures. As corrective action, the licensee revised the written procedure to provide such criteria, defining a medical event to have occurred if more than 20 percent of the seeds were placed outside the treatment volume. As further action, licensee personnel reviewed each prostate implant procedure performed in the previous two years against these criteria to determine whether any medical events had occurred.

As part of this review, the licensee determined that this procedure did not meet the definition of a medical event based upon these criteria. However, Dr. B recontoured the prostate because of concerns about the low D90 value. This second contour indicated only one seed of 52 outside the prostate volume, so no medical event was identified.

The referring physician reviewed the case in December 2011 when the patient returned for a follow-up visit. This physician was concerned with the low D90 value, and attempted to have a second CT scan performed to confirm the information. The referring physician was unable to arrange for such a scan, and contacted Methodist Hospital to request that an outside physician perform a review of the CT scan. Methodist Hospital sent the post-treatment scan electronically to the outside physician, who drew a third contour of the prostate and provided this information to Methodist Hospital. The medical physicist entered this contour into the planning computer and identified that 21 of the 52 seeds were outside the prostate volume. The physicist identified that this contour indicated that a medical event had occurred according to the licensee's criteria and reported this information to the licensee's radiation safety officer (RSO). Based on this information, the RSO notified NRC of a potential medical event on March 7, 2012. The patient and referring physician were also notified in accordance with regulatory requirements.

After the RSO had reported this potential medical event to NRC, Dr. A returned to Methodist Hospital and drew a fourth contour of the prostate based on the same scan. This fourth contour indicated that only one of the 52 seeds had been placed outside the prostate volume, and that no medical event had occurred.

On March 15, 2012, the RSO provided the 15-day report to NRC as required. This report contained all information required by NRC regulations.

On March 19, 2012, an NRC inspector conducted an inspection to review the potential medical event reported by the licensee. The referring physician stated during this inspection that the patient was doing well, and that the referring hospital continued to follow up with the patient.

As a result of the NRC's onsite inspection, the licensee assembled a group of personnel including authorized users, medical physicists, the urologist, and other individuals to determine which contour was most appropriate and, based on this determination, whether a medical event occurred. On April 12, 2012, this group met and determined that the first contour that was performed was the most appropriate and thus no medical event had occurred. They based this on the observation that this contour had been reviewed during the peer review process and was considered to be clinically acceptable. In addition, two of the three other contours drawn were consistent with this result. The group also observed that the outside physician did not have access to the ultrasound scan, so was not aware of the asymmetry of the prostate and could not use that information in contouring the prostate. Based on this determination, the licensee retracted the report of a potential medical event on April 19, 2012.

The RSO stated during the telephonic exit meeting on April 19, 2012, that, as a result of this situation, the licensee intended to have the same authorized user contour the post-implant CT scan as performed the procedure whenever possible.

2.3 Conclusions

The inspector identified no violations of NRC requirements and accepts the licensee's determination that no medical event occurred in this case.

## 3 Exit Meeting Summary

The inspector discussed the conclusions, as described in this report, with the licensee during the exit meeting conducted by telephone with the licensee's RSO on April 19, 2012. The inspector discussed the activities reviewed and the inspection findings. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

## LIST OF PERSONS CONTACTED

* Helen Fosmire, M.D., Radiation Oncologist, Richard A. Roudebush VA Medical Center
* Katherine Haldeman, B.S., Assistant Radiation Safety Officer
Mark Henderson, M.D., Radiation Oncologist
* John Kent, Medical Physicist
* Song-Chu Ko, M.D., Radiation Oncologist
*# Mack Richard, M.S., Radiation Safety Officer
* Eric Swank, J.D., Executive Director of Research Compliance
* James Terwilliger, IU Health Administration

* attended the preliminary telephonic exit meeting on March 26, 2012
\# attended the final telephonic exit meeting on April 19, 2012