INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY - INDIANAPOLIS

March 15, 2012

US Nuclear Regulatory Commission
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Potential Medical Event – NRC License No. 13-02752-03

Dear Sir/Madam:

In accordance with 10 CFR 35.3045(d), attached please find a written report for a potential medical event that was reported to the NRC Operations Center on March 7, 2012. Please do not hesitate to contact me should there be any questions related to the attached report.

Sincerely,

Mack L. Richard, MS, CHP
Radiation Safety Officer

Attachment: 1

Cc: E. Swank, JD
R. Payne, MD
S. Ko, MD
T. Gardner, MD
H. Fosmire, MD
J. Kent, MS

RECEIVED MAR 2 2 2012

541 Clinical Drive – Room 159 Indianapolis, IN 46202-5111 (317) 274-4797 Fax (317) 274-2332

REPORT OF POTENTIAL MEDICAL EVENT

This report is being submitted in accordance with 10 CFR 35.3045(d). It should be noted that the licensee is not certain the event described below meets the definition of a medical event; however, in the interest of being pro-active and conservative, the licensee notified the NRC Operations Center on March 7, 2012 that a potential medical event had occurred.

Name of Licensee: Indiana University Medical Center – NRC License No. 13-02752-03

Name of Prescribing Physician: Song-Chu Ko, MD

Brief Description of the Event: A pre-implant CT scan was obtained on April 27, 2011 on a patient referred for a ^{125}I prostate seed implant. The prostate contoured on these images was 27.6cc. On July 5, 2011, a patient was implanted by the Authorized User for prostate cancer with 52 ^{125}I seeds. The implant was performed under ultrasound guidance and an intra-operative plan was generated. The prostate contoured was 16.7cc and the dose which covered 90% of the prostate volume (D90) was 129.7%.

The target volume on a post-operative CT scan performed on August 9, 2011 was contoured by another radiation oncologist who is also an Authorized User and the Medical Director for the Methodist Hospital (MH) Radiation Oncology Department which also operates under the IUMC license. This was done due to the fact that the prescribing Authorized User while still authorized at IUMC, had relocated his primary practice location to the IU Health-Arnett in Lafayette, IN and was not immediately available to evaluate the post-operative CT scan.

The prostate contoured on the post-implant CT was 39.9 cc and all 52 seeds were implanted within the target volume. The follow-up dosimetry calculations indicated the D90 was 52%. This low D90 value was attributed to the fact that the evaluation of the post-operative CT scan indicated a significant increase in the size of the prostate. Due to the fact that the D90 has been shown to be a poor indicator for defining a medical event, the licensee considers any prostate implant where the number of seeds outside the target volume is greater than 20% to be the indicator that a medical event has occurred. Based upon the post-operative CT scan contour of the target volume, this implant did not constitute a medical event.

The patient had originally been referred to the IU Health Urology Department by a radiation oncologist from the Richard A. Roudebush VA Medical Center located on the IUMC campus. On December 21, 2011, the VA radiation oncologist saw the patient in follow-up and was concerned with the sub-optimal dosimetric paremeters. The radiation oncologist attempted to obtain MR images to better visualize the prostate and the ^{125}I seed positions; however, the VA refused to approve an MR scan as this was not the Standard of Care for these patients. As a result, the radiation oncologist forwarded the post-operative CT scan to a physician outside the IU Health/IUMC system who she considers to be an expert in ^{125}I seed implants. That physician contoured what he considered to be the prostate volume, and that information was forwarded to the medical physicist who had generated the pre-implant, inter-operative, and post-implant treatment plans. A revised post-implant treatment plan from that information was generated and indicated that 21 of the 52 seeds implanted were outside the prostate volume and as such, met the

definition of a medical event using the existing criteria (i.e. >20% of the seeds outside the target volume). The medical physicist discussed the circumstances described above with the radiation oncologist who had initially contoured the target volume on the post-operative CT scan and following that discussion, the medical physicist notified the Radiation Safety Officer (RSO) on the morning of March 7, 2012 that a medical event had potentially occurred. The RSO notified the NRC Operations Center via telephone on the afternoon of March 7, 2012.

In the days since the telephone notification, the Authorized User who performed the implant has reviewed the intra-operative ultrasound and the post-operative CT scans and does not agree with the target volume contoured by the outside expert. One of the primary reasons for that disagreement relates to the fact that while most prostate glands are relatively symmetrical in shape, this particular patient's prostate was asymmetrical. As of this date, an inspector from the Nuclear Regulatory Commission (NRC) is scheduled to review the circumstances described above on March 19, 2012 to help determine if a medical event has occurred.

Why the Event Occurred: Whether or not a medical event has occurred has not been finally determined. Until such time that is determined, causation cannot be established.

The Effect on the Patient: The VA radiation oncologist saw the patient on March 8, 2012. The patient appears to be doing well and decided against additional treatment at this time to supplement the supposed lower D90 dose to his prostate. Patient is not experiencing any rectal or bladder complications to date and his PSA is not rising.

Actions Taken and/or Planned to Prevent Recurrence: As noted above, since it is uncertain whether or not a medical event has occurred, specific actions have yet to be developed. Regardless of that determination, one action that will be implemented is that the Authorized User who performs the implant will contour the target volume on the post-operative CT scan and compare that contour to pre-treatment and intra-operative images to assure all seeds were implanted in accordance with the written directive.

Certification that the Patient Has Been Notified: The patient was notified by the referring VA radiation oncologist about this potential medical event when she saw the patient on March 8, 2012.

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RADIATION
SAFETY OFFICE

7000 0600 0027 2878 9222

CERTIFIED MAIL

PLACE STICKER AT TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS.
FOLD AT DOTTED LINE

MAR 19 2012

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