

U.S. Nuclear Regulatory Commission
Region III, Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532 -4352
November 19, 2012

Radiation Oncology
Oakwood Hospital & Medical Center
18101 Oakwood Blvd.,
Dearborn, MI 48123-2500
Tel: (313) 593- 7335

Report and notification of a Medical Event

(Medical Event #48520)

Name of the prescribing physician: Dr. Choon K. Lee, MD

Description of the event:

██████████ underwent a Brachytherapy Prostate Radioactive (I-125) seeds implant on 9/18/12 at Oakwood Hospital & Medical Center. Patient then had a Post seed implant CT performed on 10/22/12 at Oakwood Hospital & Medical Center. The authorized user (Dr. Lee) wanted an independent verification of the dosimetry with contours drawn by him. After completion and final review of the Post seed implant study on 11/15/12 (Thursday), it was ascertained that the patient received an inadequate Prostate - D₉₀ dose ≈ 69%. NRC was informed on 11/19/12 (Monday).

Why the event occurred: The primary reason for an inadequate D₉₀ dose to the prostate was due to the radioactive seeds not adequately covering the prostate volume (as per the pre-plan), particularly at the base of the prostate.

The effect, if any, on the individual who received the administration: The organs at Risk (Bladder and Rectum) received negligible dose. Patient will discuss other treatment options after consultation with the Prescribing Physician.

What actions, if any, have been taken or are planned to prevent recurrence: Radiation Oncologist will verify the needle positioning with the Urologist. Both should make certain that the tip of each needle is at the base of the prostate using the longitudinal view of the ultrasound image.

We will also institute an in service for authorized users in our Quality Management Program (QMP) which will include the definition of Medical Event and the time line to notify NRC.

Certification that the licensee notified the individual: The referring physician was not available due to illness until 11/26/12 at which time he was notified. The Radiation Oncologist notified (11/28/12) the patient after discussing the case with the referring physician.