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U.S. Nuclear Regulatory Commission
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Washington, D.C.

March 24, 2008

Reply to a Notice of Violation

Docket Number 03011672
NRC RAM License Number 45-16806-01

In response to correspondence from NRC dated March 5, 2008 and the enclosed Notice of Violation for a Severity Level IV violation, the following reply is submitted for consideration of the NRC.

Statement of Violation. During an inspection dated December 5, 2007 the following violation was identified:

“10CFR 20.1802 requires, in part, that a licensee maintain control and constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.”

“Contrary to the above, the licensee did not maintain control of licensed material that was in a controlled or unrestricted area and that was not in storage. Specifically, on July 25, 2007 in preparation for a prostate implant, the licensee lost a 0.34 millicurie iodine-125 seed. The seed has not been found.”

“This is a Severity Level IV violation (Supplement IV).”

Description of the Event. For each prostate implant case, seeds are assayed prior to the implant, to assure proper source strength. These seeds are placed in a shielded container and taken to the operating room (OR). The Nuclear Medicine (NM) technologist assays the seeds and places them into the container. These seeds are placed in a shielded container by Nuclear Medicine. The Medical Physicist retrieves the container from Nuclear Medicine and takes them to the OR, and after the case is completed, returns unused seeds to Nuclear Medicine for ultimate storage/disposal. In this particular case, the container held 12 seeds as indicated by Nuclear Medicine. At the end of the case, the Medical Physicist confirmed the presence of 11 seeds in the container, which were not used for the case. Subsequent radiation and visual surveys from OR back to the NM department failed to reveal the presence of the unaccounted seed. Accordingly, the NRC Operations Center was notified of the event.

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Reason for Violation. On review of the procedures for seed handling, it was determined that the accountability process was unsatisfactory in the exchange of custody between Nuclear Medicine personnel and the Medical Physicist. The exchange failed to maintain the control of licensed material as required in 10 CFR 20.1802.

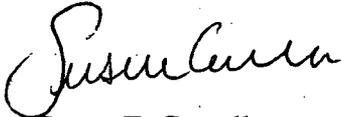
Corrective Steps and Results Achieved. The NRC Operations center was notified in accordance with regulations to permit any actions by the NRC in regard to the event. The facility RSO was notified immediately. In response to these notifications, there were repeat surveys and visual inspections by individuals not involved with the event. There were no radiation levels detected and the seed was not located. Commencing with the next available case, the exchange of seed custody in Nuclear Medicine required a verification of the accuracy of seed count. *This practice has continued, and to date, there have been no adverse accountability occurrences.*

Corrective Actions to Avoid Further Violations. The procedures for seed accountability were revised immediately and reviewed by the Radiation Safety Committee and Radiation Safety Officer. The revised procedures include a written document for the exchange of seed custody. The Medical Physicist conducted training for all involved staff (from Nuclear Medicine and the Cancer Center) to assure the procedures were understood. Management has committed to staff compliance to these procedures, with oversight through the Radiation Safety Committee.

Date of Full Compliance. Implementation of revised procedures and training were considered essential to full compliance. This occurred as of August 1st, 2007

Inova Loudoun Hospital Center is committed to full compliance with all NRC regulations, and acknowledges the assistance and oversight of the NRC in the correction process related to this event.

Sincerely,



Susan T. Carroll
Chief Operating Officer

Cc: Regional Administrator Region I
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P. Dutt Radiation Oncology Center
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