

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

February 22, 2011

David J. Keys, Ph.D. Radiation Safety Officer St. Anthony's Medical Center 10010 Kennerly Road St. Louis, MO 63128

SUBJECT:

NRC ROUTINE INSPECTION REPORT NO. 030-10108/11-01(DNMS)

ST. ANTHONY'S MEDICAL CENTER, ST. LOUIS, MISSOURI

Dear Dr. Keys:

On January 26, 2011, the U. S. Nuclear Regulatory Commission (NRC) conducted an on-site inspection at St. Anthony's Medical Center. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with the NRC requirements and to follow up on your report dated November 9, 2010, addressing receipt of Ocura Model 6711 iodine-125 seeds without being authorized by your license. The results of the inspection were discussed with Mr. Brian Pence, Director of the Cancer Center, and you.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety to confirm compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <a href="http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html">http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html</a>. The violation involves the failure to have a valid license authorizing the receipt and possession of iodine-125 as Ocura Model 6711 seeds for prostate implants. Specifically, on October 22, 2010 and November 5, 2010, St. Anthony's Medical Center received 38.42 millicuries (mCi) and 32.68 mCi, respectively, of iodine-125 as Oncura Model 6711 seeds which were not authorized by License No. 24-01041-04. This violation was identified during an audit of the radiation safety program on November 9, 2010. Corrective actions for the violation included notifying NRC of the violation and requesting an amendment to St. Anthony's license for the Model 6711 Oncura seeds. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the NRC Enforcement Policy.

If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Regional Administrator, Region III, and the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be 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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. 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.

Sincerely,

Tamara E. Bloomer, Chief
Materials Inspection Branch

Division of Nuclear Material Safety

Docket No. 030-10108 License No. 24-01041-04

cc: State of Missouri

D. Keys -2-

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Sincerely,

/RA/

Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Material Safety

Docket No. 030-10108 License No. 24-01041-04

cc: State of Missouri

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