August 21, 2008

EA-08-221

Rob Thames
Executive Vice President
St. Anthony's Medical Center
10010 Kennerly Road
St. Louis, MO 63128

SUBJECT: NRC INSPECTION REPORT NO. 030-10108/2008-001(DNMS) – ST. ANTHONY'S MEDICAL CENTER

Dear Mr. Thames:

This refers to the inspection conducted on July 28 and 29, 2008, at St. Anthony's Medical Center, St. Louis, Missouri. This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

The preliminary inspection findings were discussed with you and members of your staff at the conclusion of the inspection on July 29, 2008. The enclosed report presents the results of the inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html. The apparent violation involved the failure to secure stored licensed material from unauthorized removal or access (see Section 2 of the enclosed report). The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit meeting on July 29, 2008. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two years, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming, on the license docket, that the corrective actions previously described to the NRC staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter, or (2) request a Pre-decisional Enforcement Conference (PEC), If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. Please contact Patrick L. Louden of my staff at 630-829-9627 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violation in Inspection Report No. 030-10108/2008-001; EA-08-221" and should include for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your corrective actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), 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 document 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, proprietary, or safeguards information so that it can be made available to the Public without redaction

If you have any questions concerning this matter, please contact Patrick L. Louden of my staff at 630-829-9627.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Inspection Report 030-10108/2008-001
2. Excerpt from NRC Information Notice 96-28

cc w/encls: State of Missouri

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DATE	08/20/08		08/20/08		08/21/08		08/21/08	

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Letter to Rob Thames from Steven A. Reynolds dated August 21, 2008

SUBJECT: NRC INSPECTION REPORT NO. 030-10108/2008-001(DNMS) – ST. ANTHONY'S MEDICAL CENTER

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REGION III

Docket No.:	030-10108
License No.:	24-01041-04
Report No.:	030-10108/2008-001(DNMS)
Licensee:	St. Anthony's Medical Center
Locations Inspected:	10010 Kennerly Road, St. Louis, Missouri, and 12700 Southfork Road, St. Louis, Missouri
Dates of Inspection:	July 28 and 29, 2008
Exit Meeting:	July 29, 2008
Inspector:	Robert G. Gattone, Jr., Senior Health Physicist
Reviewed By:	Patrick L. Louden, Chief Materials Inspection Branch

Enclosure 1

EXECUTIVE SUMMARY

St. Anthony's Medical Center
St. Louis, Missouri
Inspection Report 030-10108/2008-001(DNMS)

During a routine inspection, the inspector identified an apparent violation involving licensee failure to secure from unauthorized removal or access licensed material that was stored in a room. The quantity of licensed material in the room was greater than 1000 times the quantity specified in Appendix C to Title 10 Code of Federal Regulations Part 20. Most of the material was contained in a High Dose Rate remote afterloader brachytherapy unit (HDR unit). The violation occurred because a technician became distracted by a patient and left the room containing the licensed material unattended with the room door open.

The licensee implemented corrective actions to prevent a similar violation. The licensee: (1) re-instructed applicable staff to close and lock the room door every time they exit the room; (2) planned to install an automatic door closer device to the room; and (3) secured the HDR unit by chain locking it to heavy equipment in the room.

Report Details

1 Program Scope and Inspection History

The NRC License Number 24-01041-04 authorized the St. Anthony's Medical Center (licensee) to use byproduct materials for diagnostic and therapeutic nuclear medicine, and sealed source therapy, including use of a High Dose Rate remote afterloading brachytherapy unit (HDR unit). The licensee used an HDR unit to treat approximately six patients per year, most of which involved breast treatments. The licensee's low dose rate manual brachytherapy activities were limited to approximately 55 prostate implants per year. The licensee's therapeutic nuclear medicine activities included approximately 8 thyroid carcinoma treatments per year, and approximately 16 hyperthyroid treatments per year. Diagnostic nuclear medicine included approximately 750 studies per year, and about half were myocardial perfusion imaging studies.

No violations of NRC requirements were identified during the two previous NRC inspections conducted on January 19, 2006, and January 27- 30, 2004.

2 Security of Licensed Material

2.1 Inspection Scope

The inspector reviewed security of licensed material by touring selected facilities where licensed material was used and/or stored, and interviewing selected staff.

2.2 Observations and Findings

A Positron Emission Tomography technician (technician) was near an open door of a room that contained a quantity of licensed material that was greater than 1000 times the quantity specified in Appendix C to Title 10 Code of Federal Regulations (CFR) Part 20. Most of the licensed material was contained in an HDR unit. The technician became distracted by a patient and left the area near the room to tend to the patient, resulting in the room door being open and the licensed material being unattended.

Shortly after the technician left the area near the room, the inspector, accompanied by a licensee medical physicist during a tour of the facility, noted that the door to the room containing the licensed material was open and no direct surveillance was being maintained to prevent unauthorized access. The inspector and the medical physicist entered the unoccupied room and remained there until the technician returned to the room approximately one minute later and questioned the inspector.

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.
The licensee's failure to secure from unauthorized removal or limit access to licensed material in the room, a controlled area, is an apparent violation of 10 CFR 20.1801.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 20.1801 involving licensee failure to secure licensed material from unauthorized removal or access.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to prevent recurrence taken in response to the event discussed in Section 2 of this report. This review included interviewing selected licensee personnel, and the licensee's Radiation Safety Officer.

3.2 Observations and Findings

Within a week of the inspection, the licensee re-instructed applicable staff to close the door of the room containing licensed material every time they exit it. The door was already equipped with a combination lock that automatically locked upon door closure.

In addition, within a week of the inspection, the licensee secured the HDR unit from unauthorized removal by chain locking it to heavy equipment located in the room.

The licensee plans to take further corrective action by installing an automatic door closer device to the door of the room containing licensed material by August 19, 2008.

3.3 Conclusions

The inspector determined that the licensee developed corrective actions to prevent a similar violation.

4 Other Areas Inspected

4.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspector, observing licensed activities in progress, and reviewing selected records. Areas reviewed included implementation of procedures for administrations requiring a written directive, preparation and administration of diagnostic nuclear medicine dosages, preparation and administration of a therapeutic nuclear medicine dosage, response to radioactive spills, operational checks of equipment and instrumentation, use of personnel dosimetry, and performance of radiation surveys.

4.2 Observations and Findings

The licensee implemented procedures to ensure that brachytherapy and nuclear medicine administrations requiring a written directive were in accordance with the written directives. The written directives included the required information. The licensee conducted dual, independent checks to ensure that treatment plans were in accordance with the written directives. Patient identity was verified by at least two methods.

A medical physicist prepared and administered an iodine-131 dosage for therapy. The medical physicist wore gloves and protective clothing while handling the dosage. The medical physicist used time, distance, and shielding to reduce her radiation exposure. Prior to administration, the dosage was measured and the radioactivity was compared with that prescribed on the written directive. The patient was provided with instructions to keep radiation doses to members of the public as low as is reasonably acceptable.

Nuclear Medicine Technologists (NMT) prepared and administered diagnostic unit dosages. The NMTs wore protective clothing, used remote handling tools, and used shielding to reduce their radiation exposure. The NMTs measured each dosage to ensure that the radioactivity was as prescribed prior to administration. Dual means of verifying patients' identification were used.

An NMT demonstrated how to respond to a radiation spill based on a scenario posed by the inspector. The NMT knew where the spill response equipment was and how to use it to decontaminate the area. The NMT understood how to conduct appropriate radiation surveys to identify radioactive contamination on facility surfaces and on her person. In addition, the NMT understood how to conduct radiation surveys to monitor the effectiveness of decontamination activities and to determine if the facility could be released for unrestricted use.

The licensee conducted operational checks of equipment and instrumentation. Members of the medical physics staff conducted HDR unit spot checks as required. In addition, they checked to ensure that the HDR unit operated correctly if an applicator is not connected to the unit. The NMTs conducted dose calibrator constancy checks as required, and they knew how to identify abnormal results and what to do in response to them.

Applicable licensee staff properly wore personnel dosimeter badges when handling licensed material. Monitored individuals were informed of the radiation doses they received based on processing of their personnel dosimeter badges. No individual received a radiation dose in excess of regulatory limits.

Licensee staff used calibrated instrumentation to perform required radiation surveys. Selected staff knew the survey trigger levels and what to do when trigger levels are exceeded.

4.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program. No violations of NRC regulatory requirements were identified.

5 Exit Meeting

At the completion of the onsite inspection, the inspector discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

*Elizabeth Caspari, MS, Medical Physicist
*Sandy Evans, Radiation Oncology Manager
*Jeff Judd, M.D., Radiologist
#David Keys, Radiation Safety Officer
*Tim Keys, MS, Medical Physicist
*Toni Mignerone, CNMT, Section Chief, Nuclear Medicine
*Mickey Montero, Director of Radiology
*Rob Thames, Executive Vice President

* Attended the onsite exit meeting
# Participated in the onsite exit meeting via telephone