August 27, 2013

Ms. Gwen Sandefur, Senior Vice-President
St. Mary's Medical Center
3700 Washington Avenue
Evansville, IN 47750

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03020812/2013001 (DNMS) AND NOTICE OF VIOLATION – ST. MARY'S MEDICAL CENTER.

Dear Ms. Sandefur:

On July 31, 2013 , an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Evansville, Indiana facility. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. An exit meeting was held at the completion of on-site activities between Mr. Bill C. Lin of my staff; the Management Team at St. Mary's Medical Center; Dr. Saiyid M. Shah, your facility's Radiation Safety Officer (RSO); and Pam Duncan of your staff to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as 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 one 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 website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the licensee's failure to prepare a written directive for an administration of iodinie-131 (I-131) in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 35.40(b)(1). Specifically, the prescribed dosage was not included on the written directive. Despite the failure to include the prescribed dosage on the written directive, the administration was in accordance with the prescribing physician's intended order; therefore, no medical event, as defined in 10 CFR 35.2, occurred. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspector identified the violation.

The root cause of the violation was lack of attention to detail due to the amount of work performed by the licensee's nuclear medicine technologists. During the inspection, the inspector noticed that all technologists were extremely busy performing numerous procedures and duties in a short time frame. The technologists could be performing approximately 20 to 25 procedures on a given day. The inspector also reviewed training provided by the RSO that had discussed the merit of slowing down and taking the necessary time to evaluate the task before proceeding. As corrective action for the violation, the RSO and the Chief Nuclear Medicine Technologist provided refresher training to all the authorized users and nuclear medicine technologists on staff regarding how to properly prepare written directives and to

ensure that the written directives are complete and correct prior to administering radiotherapy to patients. The corrective action was completed on August 5, 2013. As such, you are now in compliance with NRC requirements.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Bill C. Lin of my staff if you have any questions regarding this inspection. Mr. Lin can be reached at (630) 829-9829.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-20812
License No. 13-03226-04

Enclosure:
Notice of Violation

cc w/encl: Saiyid M. Shah, PhD, RSO
State of Indiana

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Aaron T. McCraw, Chief
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cc w/encl: Saiyid M. Shah, PhD, RSO
State of Indiana

DISTRIBUTION:
See next page

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OFFICE	RIII DNMS		RIII DNMS		RIII		RIII	
NAME	Bill C. Lin*ATM for		Aaron T. McCraw*ATM					
DATE	8/27/2013		8/27/2013					

OFFICIAL RECORD COPY

Letter to G. Sandefur from Aaron T. McGraw dated August 27, 2013

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03020812/2013001 (DNMS) AND NOTICE OF VIOLATION – ST. MARY'S MEDICAL CENTER.

DISTRIBUTION:

Cynthia Pederson	Steven Orth	Patricia Buckley
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AnnMarie Stone	Paul Pelke	MIB Inspectors

NOTICE OF VIOLATION

St. Mary's Medical Center
Evansville, IN

Docket No. 030-20812
License No. 13-03226-04

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 31, 2013, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) 35.40(b)(1) states, in part, the written directive must contain the patient or human research subject's name and for any administration of quantities greater than 1.11 megabecquerel (30 microcuries) I-131: the dosage.
>
> Contrary to the above, on March 27, 2013, the licensee failed to prepare a written directive in accordance with Title 10 CFR 35.40(b)(1). Specifically, the licensee failed to include the prescribed dosage (4 milicuries I-131) on the written directive that was dated March 27, 2013.

This is a Severity Level IV violation (Section 6.3.d.1).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03020812/2013001(DNMS)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response may be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 27th day of August 2013.

Enclosure