UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 23, 2018

A. Joel Feldman, M.D., President
St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46260

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001579/2018001(DNMS) – ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Dr. Feldman:

On January 29, 2018, through February 1, 2018, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at several of your licensed facilities in Indiana, with continued in-office review through February 14, 2018. 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. The in-office review included receipt and review of information that was unavailable during the onsite inspection. Mr. Dennis O'Dowd of my staff conducted a final exit meeting by telephone with Mr. Ed Wroblewski of your staff on February 14, 2018 to discuss the inspection findings. This letter presents the results of the inspection.

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 use a dosage that was within the prescribed dosage range or to a dosage within 20 percent of the prescribed dosage, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.63(d).

Specifically, on March 31, 2017, a nuclear medicine technologist (NMT) at one of the authorized hospital locations specified on the license, administered a 10-millicurie (mCi) dosage of technetium-99m (Tc-99m) sestamibi to a patient for a myocardial perfusion stress test, when the prescribed dosage was 30 mCi of Tc-99m sestamibi. This violation was identified by your Radiation Safety Officer (RSO) on March 31, 2017. Your corrective actions included re-training the NMT, as well as the NMT staff throughout the licensee's organization, on the importance of ensuring that the proper dose is administered. In addition, the NMT involved was directed to: (1) read and verify each radiopharmaceutical dosage prior to each administration of radioactive material to ensure all dosages are accurately and appropriately administered; (2) assay each radiopharmaceutical dosage prior to each administration of radioactive materials to ensure all

dosages are accurately and appropriately administered; and (3) be monitored for a period of three months by another NMT to verify each radiopharmaceutical assay and that the radiopharmaceutical dosage was correct prior to patient administration. In addition, the institution implemented disciplinary action to the NMT as a reminder. Full-compliance was achieved by the licensee on April 1, 2017. The RSO wrote a "self-identified" violation to the hospital site, and discussed this audit finding during the Radiation Safety Committee (RSC) meeting held on June 13, 2017. This non-repetitive, licensee-identified, non-willful, and corrected violation is being treated as a non-cited violation, consistent with Section 2.3.2 of the Enforcement Policy.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was 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, please submit the information in accordance with the methods described in 10 CFR 30.6(a) and (b)(2).

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, any 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 Mr. O'Dowd if you have any questions regarding this inspection. Mr. O'Dowd can be reached at 630-829-9573.

Sincerely,

/RA/

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

Docket No. 030-01579
License No. 13-00133-02

cc: Edward E. Wroblewski,
RSO and Medical Physicist
Erica Wehrmeister, R.N., BSN, MBA,
Chief Operating Officer
State of Indiana

Letter to A. Feldman, M.D., from Aaron T. McCraw, dated February 23, 2018

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