



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352
October 26, 2017

EA-17-092

Mr. Alonzo Lewis
SVP Operations
St. Joseph Mercy Health System
5301 East Huron River Drive
Ann Arbor, MI 48106

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT
NO. 03001997/2017001 (DNMS) – ST. JOSEPH MERCY HEALTH SYSTEM

Dear Mr. Lewis:

This letter refers to the inspection conducted May 1 through 3, 2017, with continued in-office review through July 5, 2017, at your Ann Arbor, Michigan, facility. The purpose of the inspection was to review activities performed under your U.S. Nuclear Regulatory Commission (NRC) license to ensure that activities were being performed in accordance with NRC requirements. During this inspection, apparent security-related violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with your radiation safety officer (RSO), Ralph Lieto, during the exit meeting on July 5, 2017. Details regarding the apparent violation were provided in the non-publicly available NRC Inspection Report No. 03001997/2017001(DNMS), dated August 4, 2017.

On September 25, 2017, a predecisional enforcement conference (PEC) was conducted at the NRC's Region III office with you and members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions. A copy of the handout you provided at the PEC, titled Nuclear Regulatory Commission Pre-Decisional Enforcement Conference, dated September 25, 2017, was entered into the NRC's Agencywide Documents access and Management System (ADAMS) as a Non-Public document. During the PEC, you and your staff provided your perspective on the facts and corrective actions associated with the apparent violations.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1) (Non-Public) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are of concern to the NRC for the reasons stated in the Final Determination of Significance (Enclosure 2) (Non-Public). Therefore, in accordance with the NRC Enforcement

**Enclosures 1 and 2 contain Sensitive Unclassified
Non-Safeguards Information. When separated
from Enclosures 1 and 2, this transmittal letter is
decontrolled.**

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Policy, escalated violations of NRC requirements occurred. In accordance with the NRC Enforcement Policy, a base civil penalty is considered for escalated violations of NRC requirements.

Additionally, two violations have been categorized at Severity Level IV. One of those violations originally cited in the Notice, dated August 4, 2017, has been revised to reflect the correct time frame for the violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy for escalated violations. The NRC determined that credit for *Corrective Actions* was warranted based on the corrective actions described in Enclosure 2 (Non-Public).

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this violation constitutes escalated enforcement action that may subject you to increased inspection effort.

You are required to respond to this letter for one violation and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

The NRC has concluded, for the additional violations, that information regarding: (1) the reason for violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the handout, dated September 25, 2017, that you provided to the NRC at the PEC. Therefore, you are not required to respond to this letter, for those violations, unless the description therein 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 addition, Section labelled Clarifications of your handout provided clarifications and corrections to several items in the Program Overview section of our inspection report that did not accurately reflect the scope of your program. We acknowledge your clarifications that included: (1) performing approximately 73 therapeutic administrations of iodine-131 in the previous 12 months; (2) performing 20 Xofigo (radium-223 dichloride) administrations in the previous 12 months; (3) clarifying that the nuclear cardiac stress imaging lab is not a second nuclear medicine department, it is a separate suite of rooms attached to the same department and is also occasionally used for noncardiac imaging; (4) clarifying that the authorized mobile service provider is contracted to perform positron emission tomography scans at the hospital and is a separate licensee; and (5) clarifying that the radiation safety committee meets bimonthly not quarterly.

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In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, because of the Security-Related Information contained in the two enclosures, and in accordance with 10 CFR 2.390, copies of Enclosure 1 and 2 will not be available for public inspection.

Sincerely,

/RA by Kenneth G. O'Brien acting for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01997
License No. 21-00943-03

Enclosures:

1. Notice of Violation (Non-Public)
2. Final Determination of Significance (Non-Public)

cc w/encls: Mr. Ralph Lieto, RSO

cc w/o encls: State of Michigan

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Letter to Alonzo Lewis from Cynthia D. Pederson, dated October 26, 2017

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