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**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

August 4, 2017

EA-17-092

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

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

Dear Mr. Lewis:

On May 1, 2017, through May 3, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Ann Arbor, Michigan, with continued in-office review through July 5, 2017. 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 a review of security-related items. The enclosed inspection report (Enclosure 2) and its non-public Security Addendum (Enclosure 3) present 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, two apparent violations of NRC requirements were identified and are being considered for escalated enforcement action 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 apparent violations were of a security-related nature and are discussed in detail in Enclosure 3.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for these inspection findings at this time. Mr. Luis Nieves of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with Mr. Lieto of your staff on July 5, 2017.

**Enclosures 1 and 3 contain Sensitive Unclassified
Non-Safeguards Information. When separated from
Enclosures 1 and 3, this transmittal letter and
Enclosure 2 are decontrolled.**

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A. Lewis

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Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Mr. Aaron T. McCraw at 630-829-9650 within 10 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 “Response to the Apparent Violations in Inspection Report No. 03001997/2017001(DNMS); EA-17-092,” and should include, for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (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 was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be useful in preparing your response. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. In addition, if you choose to provide a written response, please mark your entire response, “Security-Related Information – Withhold from Public Disclosure under Title 10 of the *Code of Federal Regulations* (CFR) 2.390.” In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements for your response to this letter. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information. 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 PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violations 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 the following: 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. If a PEC is held, the NRC will issue a press release to announce the time and date of the PEC. The PEC will be closed to public observation due to the security-related nature of the findings.

Please be advised that the number and characterization of the 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 addition, based on the results of this inspection, the NRC has also determined that two Severity Level IV violations of NRC requirements occurred. These violations were also evaluated in accordance with the NRC Enforcement Policy. The violations are of a security-related nature also and are being cited in the enclosed, non-public Notice of Violation (Notice) (Enclosure 1). The NRC is citing the violations in the Notice because the violations were identified by the inspector.

A. Lewis

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 2 will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agency wide Documents Access Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. However, Enclosures 1 and 3 and your written response, if you choose to provide one, will not be made available electronically for public inspection because of the security-related information that is or would be contained in each.

Please feel free to contact Mr. Nieves of my staff if you have any questions regarding this inspection. Mr. Nieves can be reached at 630-829-9571.

Sincerely,

/RA Christine Lipa Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosures:

1. Notice of Violation (non-public)
2. IR 03001997/2017001(DNMS) (public)
3. Security Addendum to IR (non-public)

cc w/encl: Mr. Ralph Lieto,
Radiation Safety Officer
cc w/o encl: State of Michigan

A. Lewis

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Letter to Alonzo Lewis from John Giessner, dated August 4, 2017

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

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**U.S. NUCLEAR REGULATORY COMMISSION
REGION III**

Docket No. 030-01997

License No. 21-00943-03

Report No. 03001997/2017001

EA No. EA-17-092

Licensee: St. Joseph Mercy Health System

Facility: 5301 East Huron River Drive
Ann Arbor, Michigan

Inspection Dates: May 1-3, 2017, with continued in-office review
through July 5, 2017

Exit Meeting Date: July 5, 2017

Inspector: Luis Nieves, Health Physicist

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

**Enclosures 1 and 3 contain Sensitive Unclassified
Non-Safeguards Information. When separated from
Enclosures 1 and 3, this transmittal letter and
Enclosure 2 are decontrolled.**

Enclosure 2

EXECUTIVE SUMMARY

**St. Joseph Mercy Health System
NRC Inspection Report 03001997/2017001(DNMS)**

On May 1-3, 2017, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of St. Joseph Mercy Health System. The purpose of the inspection was to review activities performed under the NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of security-related items.

As a result of this inspection, the agency identified two apparent violations and two Severity Level IV violations of a security-related nature that are discussed in the non-public Security Addendum to this inspection report.

REPORT DETAILS

1.0 Program Overview and Inspection History

St. Joseph Mercy Health System (the licensee) was authorized to use byproduct material for medical purposes at its main hospital in Ann Arbor, Michigan, and at its community hospitals in Howell and Chelsea, Michigan. At the time of the inspection, the licensee performed a full spectrum of diagnostic procedures – about 20 per day – at the primary nuclear medicine department in Ann Arbor. This department also performed approximately 25 therapeutic administrations of iodine-131 per year, four Xofigo radium-223 dichloride administrations per year, and one Zevalin yttrium-90 administration per year. The licensee also maintained a second nuclear medicine department in Ann Arbor, exclusively for diagnostic cardiac imaging. This lab performed 5-10 stress tests per day. In addition, an authorized mobile service provider performed positron emission tomography (PET) scans at the main hospital every Tuesday, Thursday, and Sunday.

The licensee's radiation oncology department in Ann Arbor delivered 10 fractionated treatments monthly using a high dose-rate remote (HDR) afterloader containing iridium-192. The majority of these were gynecological treatments, though the licensee did also use the HDR unit once per week on average for prostate treatments. The licensee was authorized for manual brachytherapy, but it had not performed any implants since before the last inspection.

The licensee maintained a Radiation Safety Committee (RSC), which met quarterly, and retained the services of a medical physics consultant to periodically audit its nuclear medicine departments.

The licensee was previously cited in IR 03001997/2015001(DNMS) for one Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 35.643(d)(6) for the licensee's failure to assure the proper operation of timer accuracy in periodic spot-checks of its HDR unit. The inspectors reviewed the licensee's corrective actions on the docket, which appeared to be adequate. The inspectors also reviewed the HDR spot checks to verify the licensee was performing time accuracy spot-checks. This violation is closed.

2.0 Radiation Safety Program

2.1 Inspection Scope

The inspector interviewed licensee personnel, reviewed select records, toured the nuclear medicine and oncology department, and performed independent radiation measurements.

2.2 Observations and Findings

The inspector reviewed the written directives and the treatment plans. The inspector also interviewed the RSO, the authorized medical physicist, and the authorized user.

The inspector toured the licensee's nuclear medicine departments in Ann Arbor to evaluate the measures in place for materials security, hazard communication, and

exposure control. The inspector observed the licensee perform one bone scan and two stress test administrations. The inspector also observed the implementation of licensee procedures for package receipt, waste handling, area surveys, and spill response. Through these observations, demonstrations and various discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and licensee procedures for the safe use of radioactive material.

The inspector toured the licensee's radiation oncology department in Ann Arbor to evaluate the measures in place for materials security, hazard communication, and exposure control. The inspector observed the licensee demonstrate HDR spot checks and performed independent surveys in the treatment room and adjacent areas.

The inspector reviewed a selection of the licensee's safety-related records, including written directives and patient release calculations for therapeutic administrations, written directives and treatment plans for a variety of HDR treatments, daily and monthly HDR quality control checks, quarterly nuclear medicine audits, dosimetry, semiannual irradiator audits, irradiator use logs and RSC meeting minutes.

2.3 Conclusions

No violations of NRC safety requirements were identified.

3.0 **Exit Meeting Summary**

The inspector presented preliminary inspection findings following the onsite inspection on May 3, 2017. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The inspector conducted a final exit meeting by telephone on July 5, 2017. The licensee acknowledged the findings presented.

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

- # Angela Grunn, Nuclear Medicine Manager
- # Anne Mercer, Human Resources Bus. Partner
- # Carey-Marie Watts, Human Resources Talent Acquisition
- # Tonia Schemer, Executive Director HR
- # Alonzo T. Lewis, SVP Operations
- #*Ralph Lieto, Radiation Safety Officer
- # Aurelian Belecciu, Physicist
- *Alice Pichan, Director, Dept. of Radiology
- *David Fugenshuh, MD, Chair, Dept. of Radiology
- *Daniel Lawson, Director, Dept. of Radiation Oncology

#Attended preliminary exit meeting on May 3, 2017.

*Attended final exit meeting on July 5, 2017.

LIST OF PROCEDURES USED

- | | |
|-----------------------------|---|
| Inspection Procedure 87131: | Nuclear Medicine Program – Written Directive Required |
| Inspection Procedure 87132: | Brachytherapy Program |